Surveillance of Respiratory Pathogens and Brand-Specific Vaccine Effectiveness in Adults Hospitalised with SARI: An Observational Study (former id.DRIVE surveillance study of respiratory pathogens in adults hospitalised for severe acute respiratory infection (SARI) across Europe)

First published: 28/02/2024

Last updated: 28/09/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000012

Study ID

1000000012

DARWIN EU® study

No

Study countries

Austria
Belgium
Canada
France
Germany
Italy
Spain
United Kingdom

Study description

id.DRIVE’s Study Network will be leveraged to continuously monitor severe acute respiratory infection (SARI)-causing pathogens (e.g., severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza, and respiratory syncytial virus [RSV]), including virological and clinical trends, as well as burden of disease (e.g., pathogen-specific morbidity; in-hospital mortality).
The surveillance of additional pathogens allows for study preparedness, with the potential to perform feasibility assessments for future impact and effectiveness studies within the id.DRIVE Study Network.

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). 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

Grand Hôpital de Charleroi

UZA University Hospital Antwerp

CHU Saint-Pierre Hospital Brussels

Klinik Favoriten Hospital

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

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

Ospedale Luigi Sacco

Universitätsklinikum Freiburg

Universitätsklinikum Frankfurt

Universitätsklinikum Ulm

Charité - Universitätsmedizin Berlin

Universitätsklinikum Düsseldorf

Universitätsklinikum Essen

Hôpitaux Universitaires Henri-Mondor

Centre Hospitalier Annecy Genevois and St Julien/Sallanches

Manchester University NHS Foundation Trust (MFT)

NHS Lothian

The Ottawa Hospital

Calgary Corridor Hospitals

The Toronto Invasive Bacterial Diseases Network (TIBDN)

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
Actual: 14/12/2023

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

Current and former partners of COVIDRIVE and id.DRIVE:

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

Study protocol

Surveillance study_Protocol_V1.0_21 Mar 2024.pdf (832.64 KB)

Master Protocol Surveillance + VE_V3.0_02 Mar 2026.pdf (830.1 KB)
Master Protocol Surveillance + VE_V3.0_02 Mar 2026.pdf (830.1 KB)
Surveillance Study protocol V2.0_23 Apr 2025.pdf (818.46 KB)
RSV Vaccine Effectiveness protocol v3.0_21 Feb 2025.pdf (856.05 KB)
Surveillance Study protocol V2.0_23 Apr 2025.pdf (818.46 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.eu

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study topic, other:

Surveillance of respiratory pathogens + vaccine effectiveness (COVID-19 and RSV)

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Feasibility analysis

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

Non-interventional multi-country, multi-centre, hospital-based surveillance and vaccine effectiveness study.

Main study objective:

Surveillance module:

This surveillance study aims to establish active surveillance for hospitalised SARI cases in adults in Europe.

Primary objectives:

1. To calculate the proportion of laboratory samples positive for each viral respiratory pathogen of interest among adult patients hospitalised with SARI
2. To characterise adult SARI patients (including age, gender, protective and risk factors, specific treatments, and healthcare utilisation outcomes) overall and by viral respiratory pathogen of interest

CVE module (paused):

Primary objective:

To estimate brand-specific CVE against hospitalisation due to laboratory-confirmed SARS-CoV-2 in SARI patients who have received the COVID-19 vaccine dose of interest, compared to the selected comparator group

RSV VE module:

Primary objective:

To estimate RSV VE for brand-specific RSV vaccine against hospitalisation due

to laboratory-confirmed RSV infection overall or within a specific timeframe from vaccination in adult patients with SARI, eligible to receive the vaccine

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Test-negative case control

Study drug and medical condition

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

Adults aged 18 years and older (patients), presenting at the participating hospitals during the study period, who are willing and able to provide informed consent (or alternatively, informed consent is obtained form the patient´s legally acceptable representatitve) AND who are hospitalised and meet the SARI patient definition.

A SARI patient is defined as a hospitalised person with a suspicion of a respiratory infection with at least one of the following symptoms:

• new or worsening cough

• fever (≥ 38 C°)

• new or worsening shortness of breath

• sudden onset of anosmia, ageusia or dysgeusia

with symptom onset within the last 14 days prior to hospital admission.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

Hospitals

Outcomes

Surveillance module (Sep 2024-ongoing):

The outcome of interest for the primary objectives will be laboratory-confirmed infection with one of the viral respiratory pathogens of interest in patients hospitalised with SARI symptoms, and laboratory-confirmed co-infection for the secondary objectives (prevalence of co-infection with the viral respiratory

pathogens of interest, in adult patients hospitalised with SARI, and the impact on healthcare utilisation outcomes [level of severity, hospital discharge destination, length of hospital stay]).
Pathogen-specific SARI incidences will be calculated to address the first exploratory objective (pathogen-specific SARI incidences and description of trends in hospitalised adults [time period, country, level of severity]).
The denominator will be based on the sum of the catchment populations covered by the Study Contributors.
For the second exploratory objective, feasibility assessments for future respiratory disease impact and effectiveness studies will be made.

CVE module (Sep 2021-Aug 2026; currently paused):
The primary endpoint is hospitalisation due to laboratory-confirmed SARS-CoV-2 infection in adult patients with SARI.
Genomic sequencing is an optional component of the study. Sites opting into this module will perform sequencing using commercially available molecular kits. For prospective data collection, participating sites aim to sequence all SARS-CoV-2–positive cases. For retrospective data, sequencing results will be used if present in medical records.

RSV VE module (Sep 2024-ongoing):
The primary endpoint is hospitalisation due to laboratory-confirmed RSV infection in adult patients with SARI who were eligible for vaccination in their country.
The secondary endpoints in patients hospitalised with SARI symptoms include the detection of RSV subtypes A and B.
Information on the RSV subtypes (A and B) will be collected to the extent possible, preferably on all confirmed RSV cases when sample quality allows.

Data analysis plan

A statistical analysis plan (SAP) is developed prior to the conduct of the analysis. The SAP specifies all statistical analyses, including sensitivity analyses, to be conducted and includes table shells and mock figures.

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

Medical records, laboratory records, vaccination registries etc.

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