id.DRIVE pilot study to assess the detection of RSV, hMPV and PIV when using multi-specimen collection compared to a single nasopharyngeal swab

First published: 17/10/2025

Last updated: 17/12/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000780

Study ID

1000000780

DARWIN EU® study

No

Study countries

☐ Spain

Study description

Pilot study to assess the detection of RSV, hMPV and PIV when using multi-specimen collection compared to a single nasopharyngeal swab.

Planned study recruitment period:

07 January 2026 – 30 June 2026

Last patient in on 30 June 2026, last sample taken by the 31 July 2026.

Study status

Planned

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

Networks

id.DRIVE (former COVIDRIVE)

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

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Last updated: 29/02/2024

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: 30/09/2025

Actual: 30/09/2025

Study start date

Planned: 07/01/2026

Data analysis start date

Planned: 01/04/2026

Date of interim report, if expected

Planned: 30/04/2026

Date of final study report
Planned: 17/12/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

Protocol_Multi-Specimen Pilot_ES_0901_V1.0_English_18 Nov 2025_Redacted Final.pdf (1002.8 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

id.DRIVE Webpage

Methodological aspects

Study type

Study topic:

Disease /health condition

Medical procedure

Study topic, other:

Diagnosis methods

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Method development or testing

Data collection methods:

Primary data collection

Study design:

Prospective cohort

Main study objective:

To assess the detection rates (%) of Respiratory Syncytial Virus (RSV), human Metapneumovirus (hMPV) and Parainfluenzavirus (PIV) in adult (S)ARI patients (≥18 years), when using multi-specimen collection (oropharyngeal swab, saliva, sputum and blood) compared to a single nasopharyngeal swab, overall and by additional specimen type.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Respiratory pathogen panel

Infection

Additional medical condition(s)

(Severe) Acute Respiratory Infection ((S)ARI), parainfluenza virus, respiratory syncytial virus, human metapneumovirus

Population studied

Short description of the study population

Hospitalised (S)ARI patients, (S)ARI patients at emergency departments, (S)ARI patients in general practitioner practices

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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)

Estimated number of subjects

Study design details

Setting

Multi-setting (450 hospitalised study participants + 624 study participants recruited from emergency departments and general practitioner practices).

Comparators

Detection rates in different specimen types

Outcomes

(S)ARI associated with RSV and/or PIV and/or hMPV

Data analysis plan

The analysis are mainly descriptive in nature. Demographic and clinical characteristics of the patients will be described both overall and by respiratory pathogen positivity or other stratifications. Euler diagrams will be used to visually represent the overlap in pathogen detection across specimen types. Positive laboratory results for each respiratory pathogen of interest will be reported by specimen type. This includes nasopharyngeal swabs, saliva, blood, and sputum. Serology is considered positive for recent infection if a fourfold or greater rise in virus-specific IgG antibodies is observed between paired samples. For each specimen type, the percentage of positive diagnoses will be calculated by dividing the number of patients in whom the pathogen was detected using that specimen (alone or in combination) by the total number of included patients.

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

Vaccination registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No