

# Vaccine Effectiveness, Burden and Impact Studies (VEBIS), Vaccine effectiveness against COVID-19 and seasonal influenza among patients presenting to primary care physicians in EU/EEA

**First published:** 04/04/2024

**Last updated:** 03/04/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000095

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### Study ID

1000000095

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

-  Hungary
  -  Ireland
  -  Netherlands
  -  Portugal
  -  Romania
  -  Spain
  -  Sweden
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## **Study description**

Primary care systems offer the opportunity to conduct vaccine effectiveness studies; ECDC has since 2007 commissioned annual influenza vaccine effectiveness studies against seasonal influenza in primary care settings. Since February 2022, leveraging previous efforts and experience, the VEBIS primary care network has conducted studies for the vaccine effectiveness of both seasonal influenza and COVID-19 against moderate disease.

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## **Study status**

Ongoing

## Research institutions and networks

### Institutions

European Centre for Disease Prevention and Control

EpiConcept

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

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**Study contact**

[vpd.vpd@ecdc.europa.eu](mailto:vpd.vpd@ecdc.europa.eu)

### Primary lead investigator

Esther Kiessling

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 19/10/2021

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### Study start date

Actual: 01/02/2022

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### Date of final study report

Planned: 31/10/2025

## Sources of funding

- Other

## More details on funding

Funded by European Centre for Disease Prevention and Control

## Study protocol

[Core protocol for ECDC studies of vaccine effectiveness against symptomatic laboratory-confirmed influenza or SARS-CoV-2 infection at primary care level.pdf \(12.81 MB\)](#)

## 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

## Methodological aspects

Study type

Study type list

**Study topic:**

Human medicinal product

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**Study topic, other:**

Vaccine effectiveness

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

At study site/country level: test-negative, case-control study design in primary care setting.

At European level: test-negative, case-control study design in primary care setting using pooled data from several countries.

**Main study objective:**

The primary objective is to measure, for each EU/EEA primary care study site participating in IVE and CVE studies, and for pooled analyses, the direct effect of influenza and COVID-19 vaccines overall and by vaccine product against symptomatic laboratory-confirmed influenza or SARS-CoV-2

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Medicinal product name**

BIMERVAX

COMIRNATY

JCOVDEN

NUVAXOVID

SPIKEVAX

VAXZEVRIA

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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)

DAVESOMERAN

ELASOMERAN

IMELASOMERAN

RAXTOZINAMERAN

TOZINAMERAN

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BN) Covid-19 vaccines

Covid-19 vaccines

(J07BN01) covid-19, RNA-based vaccine

covid-19, RNA-based vaccine

(J07BN02) covid-19, viral vector, non-replicating

covid-19, viral vector, non-replicating

(J07BN04) covid-19, protein subunit

covid-19, protein subunit

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**Medical condition to be studied**

COVID-19

### **Additional medical condition(s)**

Influenza-like illness (ILI) or acute respiratory infection (ARI)

## Population studied

### **Short description of the study population**

The study population comprises of community-dwelling individuals with symptoms of influenza-like illness (ILI) or acute respiratory infection (ARI) and no contraindication for influenza/COVID-19 vaccination, who consult a participating study physician.

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### **Age groups**

- **Paediatric Population (< 18 years)**
  - Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **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**

The study population comprises community-dwelling individuals who present to participating physicians in the primary care setting, with symptoms meeting the case definition of their influenza or COVID-19 surveillance system, with no contraindications for influenza vaccination (for IVE) or COVID-19 vaccination (for CVE). The study period for seasonal IVE starts when the seasonal influenza vaccine of the corresponding season becomes available and the influenza season begins in the country/region, and will finish at the end of the influenza period. Cases and controls are included from the week of onset of the first influenza positive case presenting in each country-specific study.

The study period for CVE starts when the COVID-19 vaccine is available for the target group of interest in each of the participating countries and when SARS-CoV-2 is circulating. The study period is defined for each priority vaccination group, and begins for each vaccination group, when vaccination campaign in this group begins.

Physicians in participating primary care practices recruit patients and collect data throughout the year.

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## **Outcomes**

### IVE studies

The primary outcome of interest will be PCR laboratory-confirmed influenza in symptomatic patients of all ages consulting at primary care level. The specific outcomes of interest are:

- subtype-specific laboratory-confirmed influenza A;
- laboratory-confirmed influenza B overall and, if available, by lineage (B Victoria/B Yamagata); and
- laboratory-confirmed influenza by clade/genetic variant (where possible).

### CVE studies

The primary outcome of interest will be PCR laboratory-confirmed SARS-CoV-2 in symptomatic patients of all ages consulting at primary care level.

Confirmation with rapid-diagnostic tests can be considered if highly specific and sensitive tests are used (see section 3.6 on 'laboratory methods').

Secondary outcomes of interest, in the same patient group at primary care level, will be genetic variants of SARS-CoV-2.

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### **Data analysis plan**

See protocol: <https://www.ecdc.europa.eu/sites/default/files/documents/Core-protocol-ECDC-COVID-19-vaccine-studies-october2023.pdf>

## Documents

### **Study publications**

[Interim 2022/23 influenza vaccine effectiveness: six European studies, October ...](#)

[Interim 2023/24 influenza A vaccine effectiveness: VEBIS European primary care ...](#)

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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.

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown