

# DRIVE - Brand-specific influenza vaccine effectiveness in Europe, season 2021/22 (DRIVE 2021/22)

**First published:** 26/04/2022

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/46889>

### EU PAS number

EUPAS46888

### Study ID

46889

### DARWIN EU® study

No

### Study countries

Austria

Finland

France

Iceland

Italy

Romania

Spain

United Kingdom

## Study description

The Development of Robust and Innovative Vaccine Effectiveness (DRIVE) project is a public-private partnership aiming to build capacity in Europe for estimating brand-specific influenza vaccine effectiveness (IVE). The DRIVE Project, which is funded by the Innovative Medicines Initiative (IMI), was initiated as a response to the changes for licensing of influenza vaccines in Europe. The new guidance on influenza vaccines by the European Medicines Agency (EMA) came into effect in the beginning of 2017. This guidance states that the performance of influenza vaccines should no longer be assessed based on serological assays, but should be based on post-authorization effectiveness studies 1. The main objective of the 2021/22 season is to estimate brand-specific seasonal IVE in Europe by health care setting and age group. In DRIVE, data from several independently operating national or regional study sites is analysed jointly to obtain sufficient geographical coverage and sample size for brand-specific IVE estimates. This document describes the characteristics of the participating study sites, the site-specific statistical analysis as well as the statistical analysis to pool data across study sites for the 2021/22 influenza season. Committee for Medicinal Products for Human Use. Guideline on Influenza Vaccines - Non-clinical and Clinical Module. EMA/CHMP/BWP/310834/2012. In. London: Eur Med Agency, 2016.

## Study status

Finalised

## Research institution and networks

### Institutions

#### P95 Epidemiology & Pharmacovigilance

Belgium

Colombia

Netherlands

South Africa

Thailand

United States

**First published:** 07/11/2022

Last updated

09/04/2024

Institution

Non-Pharmaceutical company

Laboratory/Research/Testing facility

ENCePP partner

## Medical University of Vienna

Austria

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

Last updated

26/02/2024

Institution

Educational Institution

Hospital/Clinic/Other health care facility

## The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

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

Last updated

01/02/2024

Institution

Medical University Vienna Austria, Directorate of Health (Embætti landlæknis ) Iceland, Istituto Superiore di Sanità Italy, Royal College of General Practitioners Research and Surveillance Centre & University of Oxford United Kingdom, Innovative clinical research network in vaccinology (I-REIVAC INSERM) France, Centro Interuniversitario di Ricerca sull'Influenza e sulle altre infezioni trasmissibili Italian Hospital Network Italy, National Institute for Infectious Disease “Prof. Dr. Matei Bal?” Romania, Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO) Spain, Germans Trias i Pujol University Hospital Spain

## Networks

# Development of Robust and Innovative Vaccine Effectiveness (DRIVE)

Belgium

European Union

Finland

France

Italy

Netherlands

Spain

United Kingdom

**First published:** 22/05/2019

Last updated

08/05/2020

Network

ENCePP partner

## Contact details

### Study institution contact

Javier Diez-Domingo

Study contact

[javier.diez@fisabio.es](mailto:javier.diez@fisabio.es)

### Primary lead investigator

Anke Stuurman

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned:

23/05/2017

Actual:

23/05/2017

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### Study start date

Planned:

01/10/2021

Actual:

01/10/2021

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**Data analysis start date**

Planned:

11/05/2022

Actual:

09/05/2022

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**Date of final study report**

Planned:

30/06/2022

Actual:

05/07/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Abbott, GSK, SP, Seqirus, Innovative Medicines Initiative 2 (IMI-2)

## Study protocol

[DRIVE\\_SAP\\_Season2021-22\\_v3.0\\_20220408.pdf](#)(1.29 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 type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

To estimate brand-specific seasonal influenza vaccine effectiveness in Europe by health care setting and age group, influenza season 2021/22.

## Study Design

**Non-interventional study design**

Case-control

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BB) Influenza vaccines

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**Medical condition to be studied**

Influenza

## Population studied

**Age groups**

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**Estimated number of subjects**

200000

## Study design details

## Outcomes

laboratory confirmed influenza, by type and subtype/lineage

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## Data analysis plan

Site-specific confounder-adjusted influenza vaccine effectiveness estimates will be obtained using logistic or Poisson regression, depending on the study design. The site-specific estimates will be pooled using random effects meta-analysis.

## Documents

### Study results

[DRIVE\\_D7.9-IVE-Results-Report\\_Season-2021-22\\_FINAL.pdf](#)(6.51 MB)

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## Data management

## Data sources

### Data sources (types)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection, Exposure registry, Case-control surveillance database

## 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**

No