# DRIVE - Brand-specific influenza vaccine effectiveness in Europe, season 2019/20 (DRIVE 2019/20)

**First published:** 05/06/2020

**Last updated:** 03/05/2021

Study Finalised

## Administrative details

**EU PAS number**

EUPAS35685

**Study ID**

40886

**DARWIN EU® study**

No

**Study countries**

- Austria
- Finland
- France
- Italy

Luxembourg

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 2019/20 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 2019/20 influenza season. The DRIVE platform is still expanding, and not all vaccine brands used in Europe will be covered during the 2019/20 season. 1 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 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**

## Centro Interuniversitario di Ricerca sull'Influenza e sulle altre infezioni trasmissibili (CIRI-IT) Italy, Helsinki University Hospital (HUS) Finland, National Institute for Infectious Diseases "Prof. Dr. Matei Balș" (NIID) Romania, Italian Hospital Network (BIVE) Italy, Medical University Vienna (MUV) Austria, Laboratoire National de Santé (LNS)

Luxembourg, Hospital Universitario La Paz (LPUH) Spain, Hospital Universitario Germans Trias i Pujol (GTPUH) Spain, Vall d’Hebron University Hospital (VHUH) 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:** 20/08/2024

**Network**

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Margarita Riera

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: 16/09/2019

Actual: 16/09/2019

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**Date of final study report**

Planned: 30/09/2020

Actual: 14/09/2020

## Sources of funding

- Pharmaceutical company and other private sector

- EU institutional research programme

## More details on funding

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

## Study protocol

DRIVE1920_WP7_Season1920SAPpooled_V2_01062020_clean.pdf (2.03 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

Disease /health condition

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**Study type:**

Non-interventional study

**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary data collection and secondary use of data

**Main study objective:**

To estimate brand-specific seasonal influenza vaccine effectiveness in Europe by health care setting and age group, influenza season 2019/20.

## Study Design

**Non-interventional study design**

Cohort

Case-control

Systematic review and meta-analysis

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BB) Influenza vaccines

Influenza vaccines

**Medical condition to be studied**

Influenza

## Population studied

**Short description of the study population**

The study population consisted of non-institutionalized subjects ≥6 months of age, with no contraindication for influenza vaccination, no prior positive influenza test in the same season, and with a swab taken < 8 days after ILI/SARI onset. In hospital settings, subjects hospitalized <48h prior to symptom onset or with symptom onset ≥48h after hospital admission were excluded (to exclude nosocomial infection).

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**Age groups**

- Infants and toddlers (28 days – 23 months)
- 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**

200.000

# 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**

D7.7.DRIVE_IVE_Study_Report_1920_Final.pdf (2.27 MB)

# 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.

**Conflicts of interest of investigators**

DOIforms_20200922.pdf (2.59 MB)

## Data sources

**Data sources (types)**

Electronic healthcare records (EHR)

Other

**Data sources (types), other**

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

## 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