

# DRIVE - Brand-specific influenza vaccine effectiveness in Europe, season 2018/19 (DRIVE 2018/19)

**First published:** 20/05/2019

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

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/40889>

### EU PAS number

EUPAS29817

### Study ID

40889

### DARWIN EU® study

No

### Study countries

Austria

Finland

Greece

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 2018/19 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 2018/19 influenza season. The DRIVE platform is still expanding, and not all vaccine brands used in Europe will be covered during the 2018/19 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 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 Vienna Austria, Centro  
Interuniversitario di Ricerca sull'Influenza e sulle altre

infezioni trasmissibili (CIRI-IT), Italy, Royal College of General Practitioners (RCGP) & University of Surrey (UNIS) UK, Istituto Superiore di Sanita (ISS) Italy, Helsinki University Central Hospital (HUCH) Finland, Italian Hospital Network (IT-BIVE-HOSP) Italy, Vall d'Hebron University Hospital (VHUH) Spain, Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO) Spain, The National Institute for Health and Welfare (THL) Finland

## 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

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Study contact

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Primary lead investigator

Riera Marga

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:

15/09/2018

Actual:

15/09/2018

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### Data analysis start date

Planned:

15/05/2019

Actual:

15/05/2019

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### Date of final study report

Planned:

15/07/2019

Actual:

30/08/2019

## 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

## 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

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Combined primary and secondary data collection

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**Main study objective:**

To estimate brand-specific seasonal influenza vaccine effectiveness in Europe by health care setting and age group, influenza season 2018/19.

## Study Design

**Non-interventional study design**

Cohort  
Case-control

## 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

### Short description of the study population

In all TND studies and the register-based study, the population under study was the general population.

TND studies: 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.

Register-based cohort: The study population consisted of all registered Finnish residents aged 6m-6y and 65-100y.

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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

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\\_StudyReport\\_WP7\\_Season1819\\_v2.3\\_20190830\\_FINAL\\_a.pdf\(6.15 MB\)](#)

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## Data management

### Data sources

#### Data sources (types)

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

[Other](#)

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#### 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

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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