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 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**

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

Study start date

Planned: 16/09/2019

Actual: 16/09/2019

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

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

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).

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)

Estimated number of subjects

200000

Study design details

Outcomes

laboratory confirmed influenza, by type and subtype/lineage

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