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 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**

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: 20/08/2024

Network

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

Study start date

Planned: 15/09/2018

Actual: 15/09/2018

Data analysis start date

Planned: 15/05/2019

Actual: 15/05/2019

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

DRIVE1819_WP7_4_Season1819SAPpooledv06_clean2.pdf(1.59 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 2018/19.

Study Design

Non-interventional study design

Cohort

Case-control

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

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.

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

DRIVE_StudyReport_WP7_Season1819_v2.3_20190830_FINAL_a.pdf(6.15 MB)

Data management

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