DRIVE Brand-specific influenza vaccine effectiveness in Europe, season 2020/21 (DRIVE 2020/21)

First published: 03/05/2021

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS40875

Study ID

43939

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Finland
- [ ] France
- [ ] Iceland

- [ ] Italy
- [ ] Romania
- [ ] United Kingdom (Northern Ireland)

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**

Medical University Vienna (MUV) Austria, Istituto Superiore di Sanità (ISS) Italy, Royal College of General Practitioners Research and Surveillance Centre (RCGPRSC) & University of Oxford (OX) United Kingdom, Centro Interuniversitario di Ricerca sull'Influenza e sulle altre infezioni trasmissibili Italian Hospital Network (CIRI-IT BIVE) Italy, National Institute for Infectious Disease

“Prof. Dr. Matei Balș”, Bucharest Romania, Vall d’Hebron University Hospital (HUVH), Barcelona, Spain & Hospital Universitari Doctor Josep Trueta (HUJT), Gerona Spain, Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO) Spain, Hospital Universitario La Paz (LPUH), Madrid Spain, Germans Trias i Pujol University Hospital (GTPUH), Badalona Spain, Institut National de la Santé et de la Recherche Médicale (INSERM) France

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

Anke Stuurman

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/05/2017

Actual: 23/05/2017

Study start date

Planned: 01/10/2020

Actual: 01/10/2020

Data analysis start date

Planned: 10/05/2021

Date of final study report
Planned: 30/09/2021

Actual: 19/08/2021

Sources of funding

- Non-for-profit organisation (e.g. charity)
- 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_v1.3_clean-.pdf (1.26 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:

Disease /health condition

Human medicinal product

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 2020/21.

Study Design

Non-interventional study design

Case-control

Cohort

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 is the general population. In the 2020/21 season, the NIID hospital is dedicated to the treatment of COVID-19, hence, for NIID the study population is the general population with a hospitalized COVID-19 infection.

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 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)

Special population of interest

Other

Special population of interest, other

Influenza patients

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_Report_Season-2020-21.pdf (2.7 MB)

Study publications

D7.8 Brand-specific influenza vaccine effectiveness in Europe Season 2020/21 RE...

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.

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