DRIVE - Brand-specific influenza vaccine effectiveness in Europe, season 2021/22 (DRIVE 2021/22)

First published: 26/04/2022

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46889

EU PAS number

EUPAS46888

Study ID

46889

DARWIN EU® study

No

Study countries

Austria

Finland

France

Iceland

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 2021/22 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 2021/22 influenza season. 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 | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Medical University of Vienna

Austria

First published: 01/02/2024

Last updated: 26/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

First published: 01/02/2024

Last updated: 05/11/2024

Institution

Medical University Vienna Austria, Directorate of Health (Embætti landlæknis) Iceland, Istituto Superiore di Sanità Italy, Royal College of General Practitioners Research and Surveillance Centre & University of Oxford United Kingdom, Innovative clinical research network in vaccinology (I-REIVAC INSERM) France, Centro Interuniversitario di Ricerca sull'Influenza e sulle altre infezioni trasmissibili Italian Hospital Network Italy, National Institute for Infectious Disease "Prof. Dr. Matei Balș" Romania, Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO) Spain, Germans Trias i Pujol University Hospital 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

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: 01/10/2021

Actual: 01/10/2021

Data analysis start date
Planned: 11/05/2022

Actual: 09/05/2022

Date of final study report
Planned: 30/06/2022

Actual: 05/07/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Abbott, GSK, SP, Seqirus, Innovative Medicines Initiative 2 (IMI-2

Study protocol

DRIVE_SAP_Season2021-22_v3.0_20220408.pdf(1.29 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To estimate brand-specific seasonal influenza vaccine effectiveness in Europe by health care setting and age group, influenza season 2021/22.

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BB) Influenza vaccines

Medical condition to be studied

Influenza

Population studied

Age groups

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_D7.9-IVE-Results-Report_Season-2021-22_FINAL.pdf(6.51 MB)

Data management

Data sources

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Exposure registry, 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