

# A retrospective observational study on effectiveness of influenza vaccine Supemtek® compared to other vaccines in adults aged 18 years and above in the United Kingdom – a feasibility study

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS50220

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### Study ID

50746

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study status

Ongoing

## Research institutions and networks

### Institutions

#### OPEN Health

**First published:** 01/02/2024

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Institution

### Contact details

#### Study institution contact

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Study contact

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#### Primary lead investigator

Fatemeh Saberi Hosnijeh

Primary lead investigator

### Study timelines

**Date when funding contract was signed**

Actual: 01/02/2022

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**Study start date**

Actual: 01/03/2022

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**Data analysis start date**

Actual: 01/06/2022

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**Date of final study report**

Planned: 31/07/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Sanofi

## 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 type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Main study objective:**

The general aim of the study is to gain a better understanding of patients who received influenza vaccine and to evaluate the feasibility to run an effectiveness study of Supemtek® vaccine using UK databases.

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BB02) influenza, inactivated, split virus or surface antigen

influenza, inactivated, split virus or surface antigen

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**Medical condition to be studied**

Influenza

Pneumonia influenzal

Cardiopulmonary failure

## Population studied

## **Age groups**

- 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**

165331

# Study design details

## **Outcomes**

Type and brand of vaccine, Age at flu vaccination, Sex, Ethnicity, Index of multiple deprivation, Smoking status, Weight/BMI, Regions, Charlson Comorbidity Index score, Comorbidities recorded during baseline, Pregnancy status for women at vaccination, Primary care visits (GP) in baseline period, Influenza Vaccination status last 2 years, Pneumonia vaccination status, COVID-19 vaccination status. • Influenza hospitalisations • Pneumonia/influenza hospitalisations • Cardiorespiratory hospitalisations • Death (all cause, cause-specific)

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## **Data analysis plan**

The analysis of the primary objectives will be descriptive. Distributions and descriptive statistics of central tendency (medians and arithmetic means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables wherever possible. Categorical variables will be described with frequencies and percentages. To evaluate differences between groups of patients, Chi-square test will be used for categorical variables Student's t-tests

or Wilcoxon rank sum tests (if distribution was not normal) for continuous variables. The incidence (and confidence intervals (CI)) of influenza and related hospitalization will be estimated as the number of new diagnoses during the study period dividing by the number of total person-years at risk.

## 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 source(s)

Optimum Patient Care Research Database

Hospital Episode Statistics

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### Data sources (types)

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

[Other](#)

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### Data sources (types), other

Secondary care 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