# 202055 - European Medicines Agency (EMA) post-authorisation safety study of influenza vaccine

**First published:** 14/09/2015

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS10632

**Study ID**

31683

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

The purpose of this study is to conduct a pilot study to explore the potential use of routinely collected data in General Practitioner (GP) practices to conduct enhanced safety surveillance of seasonal influenza vaccines in the UK, as recommended in the EMA interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU. Data routinely collected as part of clinical consultations in primary care will be extracted from nine General Practitioner (GP) practices in order to estimate medically attended Adverse Events of Interest (AEIs), for people who have received an influenza vaccine. This study will also actively follow patients who were exposed to seasonal influenza vaccination for 7 days in three of the nine GP practices using a customised card-based adverse drug reaction reporting system, in order to determine whether a more active approach to surveillance can capture higher rates of AEIs.

**Study status**

Finalised

## Research institutions and networks

### Institutions

University of Surrey

Department of Health Care Management and Policy, University of Surrey, UK

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Simon de Lusignan

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 27/03/2015

**Study start date**

Actual: 03/10/2015

**Date of final study report**

Actual: 16/02/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GSK Biologicals

# Study protocol

gsk-202055-protocol-redact.pdf (273.54 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

# Methodological aspects

# Study type

# Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Other

**If ‘other’, further details on the scope of the study**

Pilot study to explore the use of routinely collected data in GP practices in the UK to provide timely and relevant information on influenza vaccine safety.

**Data collection methods:**

Combined primary data collection and secondary use of data

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**Main study objective:**

To conduct a pilot assessing adverse event of interest (AEI) frequencies among flu-vaccinated subjects using routinely collected data in nine primary care practices. Although primary surveillance is of 7-day AEI, events recorded outside this window will not be excluded but will be analysed separately. Three practices will take part in the active surveillance sub-study.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Descriptive safety surveillance study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BB01) influenza, inactivated, whole virus

influenza, inactivated, whole virus

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

influenza, inactivated, split virus or surface antigen

(J07BB03) influenza, live attenuated

influenza, live attenuated

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**Medical condition to be studied**

Influenza

# Population studied

**Short description of the study population**

Individuals who receive influenza vaccination in the 9 GP practices between 1 September and 30 November 2015.

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**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)

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**Estimated number of subjects**

11530

# Study design details

**Outcomes**

o Weekly estimation of vaccine coverage, by age strata, and vaccine brand.o Weekly reporting of AEI rates among subjects vaccinated against seasonal influenza, by age strata, co-morbidity and vaccine brand, from nine GP practices using CMR data and from three GP practices using a card-based adverse event system. Assessment of completeness and timeliness of vaccination data in the CMR, completeness and timeliness of AEI reporting in the CMR and through ADR card reporting (within 14 days of vaccination) and assessment of incidence rates of 5 most frequently reported AEIsreported alongside those available in the literature from a similar population between 1 September 2015 and 30 November 2015.

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**Data analysis plan**

This pilot project will extract routinely collected primary care data from 9 GP practices and an active surveillance approach in 3 of the 9 GP practices to estimate proportions of Adverse events of interest (AEIs) among influenza-vaccinated individuals. Coded data will be extracted and interpreted through the creation of case-definition ontologies, that can be mapped to relevant clinical codes (Read codes). Statistical analysis will consist primarily of reporting rates and proportions. Confidence intervals will be calculated.

## Documents

**Study results**

gsk-202055-clinical-study-report-redact.pdf (4.93 MB)

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## 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

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**Data sources (types), other**

Prospective patient-based data collection, General Practitioner (GP) computerised medical record (CMR) system and card-based adverse drug reaction forms (MHRA Yellow Card)

# 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**

Unknown