

# A Postmarketing Observational Evaluation of the Safety of FLUENZ in Children and Adolescents With High-risk Conditions

**First published:** 12/04/2017

**Last updated:** 17/09/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS18527

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### Study ID

18619

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### DARWIN EU® study

No

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### Study countries

United Kingdom

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### Study description

This was a post-marketing, observational, prospective cohort study. LAIV recipients were identified from records made available by the Clinical Practice Research Datalink (CPRD), which maintains a large database of anonymised longitudinal medical records from primary care in the UK. These records were then linked to the Hospital Episode Statistics (HES) database. Incidence rates of all-cause hospitalisations were monitored through 42 days and 6 months following LAIV administration and compared with rates observed among inactivated influenza vaccine (IIV) recipients and unvaccinated controls, matched by high-risk condition, age, healthcare utilisation and region. Incidence rates of hospitalisation for lower respiratory events (LRE) were also analysed.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**MedImmune**

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

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**Institution**

## Contact details

### **Study institution contact**

Herve Caspard ClinicalTrialTransparency@astrazeneca.com

Study contact

[ClinicalTrialTransparency@astrazeneca.com](mailto:ClinicalTrialTransparency@astrazeneca.com)

### Primary lead investigator

Herve Caspard

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 07/05/2012

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### Study start date

Actual: 17/09/2013

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### Data analysis start date

Actual: 01/01/2015

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### Date of final study report

Actual: 16/12/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

MedImmune

# Study protocol

[MI-MA194 Protocol\\_ENCePP.pdf](#) (365.95 KB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

D2660C00001

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

to assess the safety of FLUENZ in regard to rates of serious adverse events (SAEs) relative to matched trivalent inactivated influenza vaccine (TIV) recipients, matched unvaccinated comparison groups, and within cohort (a self-controlled analysis) among children 2 to 17 years of age who have high-risk underlying medical conditions.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective cohort

## Study drug and medical condition

**Medicinal product name**

FLUENZ

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## **Medical condition to be studied**

Asthma

Diabetes mellitus

Cystic fibrosis

## **Population studied**

### **Short description of the study population**

Children 2 to 17 years of age who have high-risk underlying medical conditions.

Following Patients were included:

1. Age 2 through 17 years (prior to 18th birthday) of age at date of vaccination or index date
2. Evidence of a diagnosis of at least one of the following high-risk underlying medical conditions:

Asthma, Cystic fibrosis, Congenital lung abnormalities, Heart disease (significant congenital, valvular, and/or rheumatic heart disease), Renal disease (glomerulonephritis, chronic or congenital kidney disease), Sickle cell anemia, White blood cell disorders, Immunosuppressive disorders (excluding malignancy), Malignancy, Diabetes mellitus, Lipid metabolism disorders, Cerebral palsy, Down syndrome, Any medical condition being treated with chronic aspirin therapy, Pregnancy

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### **Age groups**

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 years)
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### **Special population of interest**

Hepatic impaired

Immunocompromised

Renal impaired

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### **Estimated number of subjects**

10000

## Study design details

### **Outcomes**

Rate of serious adverse events, rates of lower respiratory serious adverse events and other incident medically attended events of interest among FLUENZ recipients relative to comparison groups

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### **Data analysis plan**

Incidence rates were reported as number of subjects with an incident event per 1,000 person-years. If a subject had more than one event in the time period, only the incident event was counted and the child censored afterwards. When comparing LAIV recipients with matched IIV recipients or unvaccinated controls, relative risks, and corresponding 95% confidence intervals (CI) were estimated using conditional Cox proportional hazards models. A period effect defined as a time-varying covariate was added to the model for within-cohort analyses.

## Documents

### **Study results**

[MI-MA194 Final CSR ENCePP.pdf](#) (483.81 KB)

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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 source(s)

Clinical Practice Research Datalink

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### Data sources (types)

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

[Other](#)

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### Data sources (types), other

Hospital Episodes Statistics 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