

# Postmarketing Safety Study of Q/LAIV in Subjects 2 Through 49 Years of Age

**First published:** 11/10/2013

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4848

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### Study ID

15446

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

Children and adults will be immunized with Q/LAIV as part of routine clinical practice at Kaiser Permanente Northern California (NCKP) sites. Using existing data on healthcare utilization, rates of medically attended events (MAEs) of

interest will be evaluated in all eligible Q/LAIV recipients who are vaccinated in the Kaiser Permanente (KP) Northern California Health Care Plan during the 2013-2014 influenza season. Enrollment must include a minimum of 10,000 children 2 through 8 years of age, based on previous utilization of FluMist at NCKP, enrollment is expected to include approximately 80,000 children and adults 2 to 49 years of age. Similar to previous postmarketing safety studies conducted with trivalent LAIV, this study will be conducted using data collected by the KP Vaccine Study Center. Incidence rates of MAEs and hospitalizations during periods at risk after Q/LAIV vaccination will be compared versus incidence rates during reference periods later in the follow-up (within-cohort analysis) and versus rates in 2 nonrandomized control groups: matched unvaccinated controls and matched concurrent inactivated influenza vaccine (IIV) recipient controls identified from the KP healthcare database. Trivalent inactivated vaccine (TIV) recipients will serve as controls along with quadrivalent inactivated influenza vaccine (QIIV) recipients if a QIIV is approved and administered during the study period.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Kaiser Permanente Southern California (KPSC)**

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

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**Institution**

# Contact details

## Study institution contact

Herve Caspard [caspardh@medimmune.com](mailto:caspardh@medimmune.com)

Study contact

[caspardh@medimmune.com](mailto:caspardh@medimmune.com)

## Primary lead investigator

Roger Baxter

Primary lead investigator

# Study timelines

## Date when funding contract was signed

Planned: 18/10/2013

Actual: 18/10/2013

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## Study start date

Planned: 18/10/2013

Actual: 18/10/2013

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## Data analysis start date

Planned: 15/04/2015

Actual: 15/04/2014

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## Date of interim report, if expected

Planned: 30/11/2014

Actual: 21/11/2014

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## **Date of final study report**

Planned: 30/06/2018

Actual: 09/08/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

MedImmune

## Study protocol

[pass-protocol-ma-va-medi3250-1115.pdf](#) (1.82 MB)

## Regulatory

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

Yes

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

Non-EU RMP only

## Methodological aspects

### Study type

### Study type list

**Study topic:**

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 Q/LAIV vaccination in children and adults 2 through 49 years of age within 180 days after vaccination

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BB03) influenza, live attenuated

influenza, live attenuated

## Population studied

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

Individuals aged 2 through 49 years (prior to 50th birthday) at the time of vaccination (or index date for unvaccinated controls) who had membership in the Kaiser Permanente (KP) Health Care Plan for at least 12 months prior to vaccination/index date and continuous enrollment in the KP Health Care Plan through 6 months following vaccination/index date.

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## **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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## **Estimated number of subjects**

80000

# Study design details

## **Outcomes**

Rates of medically attended events from 0 to 3 days: hypersensitivity, seizures/convulsions  
Rates of medically attended events from 1 to 42 days: lower respiratory tract infection, wheezing, Guillain-Barré syndrome, Bell's palsy, encephalitis, neuritis, vasculitis, any hospitalization and respiratory hospitalizations  
Rates of medically attended events from 1 to 180 days: narcolepsy/cataplexy

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## **Data analysis plan**

Incidence rates of adverse events of interest during periods at risk after quadrivalent live attenuated influenza vaccine (Q/LAIV) vaccination will be

compared to incidence rates during reference periods later in the follow-up (within-cohort analysis) and to incidence rates in controls (matched unvaccinated subjects and matched inactivated vaccine recipients). Relative risks (RR) and corresponding 95% confidence intervals (CIs) will be constructed for each event for safety comparisons with control groups. Crude RR and adjusted hazard ratio (HR) and corresponding 95% CIs for each event will be derived. Crude RR and exact 95% CI will be calculated without adjustment of any covariate. Adjusted HR and corresponding 95% CI will be obtained using Cox proportional hazards model with calendar time data input adjusting for seasonal changes in background rates and other confounders.

## Documents

### Study results

[MEDI1115 CSR Synopsis FINAL 02Sept2016.pdf](#) (250.99 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.

### Conflicts of interest of investigators

[Declaration of Interests - R. Baxter.pdf](#) (686.54 KB)

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## **Signed code of conduct**

[Annex 3 - Declaration - signed.pdf](#) (233.83 KB)

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## **Signed code of conduct checklist**

[Annex 2 - Checklist - signed.pdf](#) (1.32 MB)

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## **Signed checklist for study protocols**

[ENCePP checklist completed and signed.pdf](#) (821.13 KB)

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# Data sources

## **Data sources (types)**

[Other](#)

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## **Data sources (types), other**

Kaiser Permanente/Northern California clinical databases

# 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