

# Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2016/2017 trivalent seasonal influenza vaccine in children, adolescents, adults and elderly subjects (3Fluart-H-19)

**First published:** 13/09/2016

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS15172

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### Study ID

21264

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### DARWIN EU® study

No

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### Study countries

 Hungary

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## **Study description**

The aim of this observational study, which will be initiated right after 3Fluart 2016/2017 seasonal influenza vaccine is licensed and used in a mass vaccination campaign, is to detect a potential increase in reactogenicity and allergic events that is intrinsic to the product in near real-time aiming to mitigate risks before the peak period of seasonal immunisation. The objectives are to evaluate the occurrence of defined Adverse Events of Interests (AEIs) and other Adverse Events (AEs) in vaccinated subjects participating in the study and to rapidly detect any clinically significant change compared to what was known or expected with the previous vaccine compositions in the frequency and severity of Adverse Reactions (ARs) in vaccinated subjects participating in the study. Defined cohorts of children and adults will be actively followed-up seven (7) days after immunisation for AEIs and other AEs following vaccination, with the aim to detect eventual changes in the frequency and severity of related events. Patients will be vaccinated according to the Summary of Product Characteristics (SmPC), in compliance with national vaccination policy decisions in Hungary and standard practice, then, will be involved into the study by signing the patient information and informed consent and forms. Relevant information on AEs will be collected during a follow-up phone contact seven (7) days after vaccination. The duration of the study on a patient basis will be seven (7) days. The study will be conducted in multiple study centres in Hungary. A maximum of six hundred (600) and a minimum of five hundred (500) male and female subjects will be vaccinated with 3Fluart vaccine containing influenza virus virus strains recommended for the 2016/2017 seasonal epidemics in accordance with the SmPC and involved into the study according to Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU.

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## **Study status**

Finalised

## **Research institutions and networks**

## Institutions

### Gyermek Háziiorvosi Rendelő

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Institution

Gyermek háziiorvosi Rendelő Hungary-1174

Budapest, Kép u. 1/B. Gyermek háziiorvosi Rendelő

Hungary-1046 Budapest, Galopp u. 6. Gyermek

háziiorvosi Rendelő Hungary-4034 Debrecen,

Faraktár u. 74. Gyermek háziiorvosi Rendelő

Hungary-4031 Debrecen, Tócsóskert tér 4.

Gyermek háziiorvosi Rendelő Hungary-4025

Debrecen, Bajcsy-Zs. u. 32. Gyermek háziiorvosi

Rendelő Hungary-4027 Debrecen, Ibolya u. 17.

Háziiorvosi Rendelő Hungary-2339 Majosháza,

Árpád u. 30. Háziiorvosi Rendelő Hungary-2111

Szada, Rákóczi Ferenc u. 1/A. Háziiorvosi Rendelő

Hungary-1083 Budapest, Szigony u. 2/B.

# Contact details

## Study institution contact

Gábor Hacsek hacsek.gabor@gmail.com

Study contact

[hacsek.gabor@gmail.com](mailto:hacsek.gabor@gmail.com)

## Primary lead investigator

Gábor Hacsek

Primary lead investigator

# Study timelines

## Date when funding contract was signed

Planned: 29/06/2016

Actual: 29/06/2016

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## Study start date

Planned: 07/11/2016

Actual: 18/10/2016

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## Data analysis start date

Planned: 14/11/2016

Actual: 25/10/2016

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## Date of interim report, if expected

Planned: 07/12/2016

Actual: 14/11/2016

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## Date of final study report

Planned: 29/06/2017

Actual: 29/05/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Fluart Innovative Vaccines Ltd.

## Study protocol

[3Fluart-H-19 Vizsgálati terv\\_v03\\_20160915.pdf](#) (5.24 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)?

EU RMP category 3 (required)

## 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

Disease epidemiology

**Data collection methods:**

Primary data collection

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**Main study objective:**

To detect a potential increase in reactogenicity and allergic events that is intrinsic to the product in near real-time as part of the active surveillance of subjects vaccinated with 3Fluart vaccine containing influenza virus strains recommended for the 2016/2017 seasonal epidemics in accordance with the Summary of Product Characteristics.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Intensive monitoring schemes

## Study drug and medical condition

**Medicinal product name, other**

3Fluart suspension for injection (influenza vaccine, whole virion, inactivated, adjuvanted)

## Population studied

**Short description of the study population**

Subjects who have already received a dosage of 3Fluart 2016/2017 vaccine according to the SmPC.

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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)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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**Estimated number of subjects**

600

## Study design details

**Data analysis plan**

The assessment of safety and tolerability will be primarily based on the occurrence rates of adverse reactions. The occurrence rates of adverse reactions will be summarized by SOC (System Organ Class) and PT (Preferred Term) and compared to what was already known or expected with 3Fluart

vaccine as follows: Evaluation of the occurrence of AEs and other AEs in vaccinated subjects participating in the study. Occurrence rate of each AE will be presented by age group and severity. Rapid detection of any clinically significant change compared to what was known or expected with the previous vaccine compositions in the frequency and severity of ARs in vaccinated subjects participating in the study. Comparison will be performed between ARs of the study and ARs observed in the last post-authorization safety study performed with 3Fluart influenza vaccine, further, between ARs of the study and with those defined in the SmPC of 3Fluart influenza vaccine.

## 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)**

[Disease registry](#)

[Drug registry](#)

[Spontaneous reports of suspected adverse drug reactions](#)

## 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