# Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2022/2023 trivalent seasonal influenza vaccine in children, adolescents, adults and elderly subjects (3Fluart-H-31)

**First published:** 02/06/2022

**Last updated:** 17/04/2024

Study Finalised

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/49722

**EU PAS number**

EUPAS47317

**Study ID**

49722

**DARWIN EU® study**

No

**Study countries**

☐ Hungary

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**Study description**

The aim of this observational study, which will be initiated right after 3Fluart 2022/2023 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 strains recommended for the 2022/2023 seasonal epidemics in accordance with the SmPC and involved into the study according to Interim guidence on enhanced safety surveillance for seasonal influenza vaccines in the EU.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Gyermek Háziorvosi Rendelő

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

**Last updated:** 01/02/2024

**Institution**

### Multiple centres: 10 centres are involved in the study

# Contact details


**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Gábor Hacsek

**Primary lead investigator**


# Study timelines

**Date when funding contract was signed**
Planned: 23/05/2022

Actual: 23/05/2022

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**Study start date**
Planned: 10/10/2022

Actual: 10/10/2022

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**Data analysis start date**
Planned: 17/10/2022

Actual: 17/10/2022

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**Date of interim report, if expected**
Planned: 10/11/2022

Actual: 09/11/2022

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**Date of final study report**
Planned: 01/06/2023

Actual: 03/04/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Fluart Innovative Vaccines Ltd.

## 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:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

**Data collection methods:**

Secondary use of data

**Main study objective:**

To detect a potential increase in reactogenicity and allergic events that is instrinsic 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 2022/2023 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

## Population studied

**Short description of the study population**

The study included children and adults treated with 3Fluart vaccine containing influenza virus strains according to the SmPC, in compliance with national vaccination policy decisions in Hungary.

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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 AEIs 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

## 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

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No