Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2024/2025 trivalent seasonal influenza vaccine in children, adolescents, adults and elderly subjects (3Fluart-H-35)

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### Administrative details

EU PAS number
EUPAS100000177
Study ID
100000177
DARWIN FILE ctudy
DARWIN EU® study
No
Charles countries
Study countries
Hungary

#### Study description

The aim of this observational study, which will be initiated right after 3Fluart 2024/2025 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 centers 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 2024/2025 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.

#### **Study status**

### Contact details

#### **Study institution contact**

Orsolya Gyurján orsolya.gyurjan@fluart.hu

Study contact

orsolya.gyurjan@fluart.hu

### Primary lead investigator

Gábor Hacsek

**Primary lead investigator** 

# Study timelines

### Date when funding contract was signed

Planned: 23/05/2024

Actual: 23/05/2024

#### Study start date

Planned: 14/10/2024

Actual: 16/10/2024

#### Data analysis start date

Planned: 14/10/2024

Actual: 16/10/2024

#### Date of interim report, if expected

Planned: 15/11/2024

Actual: 15/11/2024

#### **Date of final study report**

Planned: 23/06/2025 Actual: 31/03/2025

## 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

# Study Design

#### Non-interventional study design

Cohort

### Study drug and medical condition

#### Medical condition to be studied

Influenza

# Population studied

#### Age groups

- Paediatric Population (< 18 years)</li>
  - Children (2 to < 12 years)</li>
  - Adolescents (12 to < 18 years)</li>
- Adult and elderly population (≥18 years)
  - Adults (18 to < 65 years)</li>
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

### **Estimated number of subjects**

### 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.

# 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**

# Data characterisation

### **Data characterisation conducted**

No