# 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)

**First published:** 29/05/2024

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS1000000177

**Study ID**

1000000177

**DARWIN EU® study**

No

**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**

Finalised

## Contact details

**Study institution contact**

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**Primary lead investigator**

Gábor Hacsek

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 23/05/2024

Actual: 23/05/2024

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**Study start date**

Planned: 14/10/2024

Actual: 16/10/2024

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**Data analysis start date**

Planned: 14/10/2024

Actual: 16/10/2024

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**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

Safety study (incl. comparative)

## 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)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

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**

600

# Data management

## 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