Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2025/2026 trivalent seasonal influenza vaccine in children, adolescents, adults and elderly subjects (3Fluart-H-36)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000581

EU PAS number

EUPAS1000000581

Study ID

1000000581

DARWIN EU® study

No

Study countries

☐ Hungary

Study description

The aim of this observational study, which will be initiated right after 3Fluart 2025/2026 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 2025/2026 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.

Study status

Planned

Research institutions and networks

Institutions

Fluart Innovative Vaccines Ltd.

Contact details

Study institution contact

Gábor Ráday

Study contact

raday@radaydrug.com

Primary lead investigator

Gábor Hacsek

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/05/2025

Study start date
Planned: 13/10/2025

Data analysis start date
Planned: 13/10/2025

Date of interim report, if expected
Planned: 12/10/2025

Date of final study report
Planned: 12/06/2026

Sources of funding

- Pharmaceutical company and other private sector

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:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Prospective, non-interventional, cohort, non-randomized, open-label study.

Main study objective:

- To evaluate the occurrence of defined AEIs and other AEs in vaccinated subjects participating in the study;
- 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 ARs in vaccinated subjects participating in the study.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

3Fluart 2025/2026 seasonal influenza vaccine

Population studied

Short description of the study population

- Children aged 3-12 years;
- Adolescents aged 13-17 years;
- Adults aged 18-65 years;
- Elders aged over 65 years.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 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)

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