Prospective non-interventional cohort study to assess safety and tolerability of 3Fluart 2019/2020 trivalent seasonal influenza vaccine in children, adolescent, adults and elderly subjects (3Fluart-H-27)

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# Administrative details

<b>EU PAS number</b> EUPAS29839	
Study ID	
34741	
DARWIN EU® study	
Study countries  Hungary	

#### Study description

The aim is this observational study, which will be initiated right after 3Fluart 2019/202 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 an 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 consent and forms. Relevant inforamtion 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 2019/2020 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** 

### Research institutions and networks

### Institutions

## Gyermek Háziorvosi Rendelő

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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: 31/05/2019 Actual: 31/05/2019

#### Study start date

Planned: 01/10/2019 Actual: 14/10/2019

### Data analysis start date

Planned: 08/10/2019 Actual: 21/10/2019

#### Date of interim report, if expected

Planned: 01/11/2019 Actual: 14/11/2019

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

Planned: 01/06/2019 Actual: 20/03/2020

## Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Fluart Innovative Vaccines Ltd.

## Study protocol

3Fluart-H-27\_Vizsgálati terv\_v01\_20190528.pdf (5.63 MB)

# 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:**

Combined primary data collection and secondary use of data

### 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 2019/2020 seasonal epidemics in accordance with the Summary of Product Characteristics.

# Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

Intensive monitoring schemes

## Study drug and medical condition

#### Name of medicine, other

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

## Population studied

#### Short description of the study population

The study participant with 3Fluart flu vaccine vaccinated according to the instructions for use persons (both men and women) designed minimal and its maximum number is between the following values: one hundred (100) - one hundred and twenty (120) children aged 3-12, one hundred (100) - one hundred and twenty (120) adolescents aged 13-17, one hundred and fifty (150)

- one hundred and eighty (180) adults aged 18-65, one hundred and fifty (150)
- one hundred and eighty (180) over 65 years of age elderly person in order to total minimum five hundred (500), maximum six hundred (600) test subject's evaluable data must be available.

Participation in the investigation is Hungarian and European Union is done in accordance with regulations and practice.

#### 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)

#### **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.

### **Documents**

#### Study, other information

3Fluart-H-27\_Vizsgálati helyszínek, vizsgálatvezetők felsorolása\_v01\_20190528.pdf (530.74 KB)

## 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

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No