

# A Prospective Observational Safety Study on Pregnancy Outcomes in Women Immunized With Seasonal Cell Culture Influenza Trivalent (TIVc) or Quadrivalent (QIVc) Vaccine During Pregnancy (Flucelvax (TIVc or QIVc) Pregnancy Registry)

**First published:** 20/08/2019

**Last updated:** 17/09/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS29472

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### Study ID

41943

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### DARWIN EU® study

No

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### Study countries

## Study description

The study is a population based prospective cohort study designed to collect data on pregnancy outcomes and events of interest among women immunized with the seasonal cell culture trivalent influenza virus (TIVc) or the seasonal cell culture quadrivalent influenza virus (QIVc) vaccine during pregnancy. The study population will include pregnant women within the US who were immunized with the TIVc or QIVc vaccine as part of routine care at any time during pregnancy. Eligible pregnant women may self-enroll or voluntarily be enrolled by their health care provider (HCP). Women under 18 can be included in the study as long as parental consent can be obtained. De-identified data on minors will be accepted into the study if permitted by laws and regulations.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Syneos Health

 United Kingdom

**First published:** 23/04/2015

**Last updated:** 06/03/2024

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Contact details

### Study institution contact

Seqirus Clinical Trial Disclosure Manager Seqirus Inc.

Seqirus.Clinicaltrials@Seqirus.com

Study contact

[Seqirus.Clinicaltrials@Seqirus.com](mailto:Seqirus.Clinicaltrials@Seqirus.com)

### Primary lead investigator

Head Epidemiology Study Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 23/05/2017

Actual: 23/05/2017

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### Study start date

Planned: 01/09/2017

Actual: 01/09/2017

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### Data analysis start date

Planned: 31/08/2020

Actual: 03/11/2020

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

Planned: 30/04/2021

Actual: 01/04/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Seqirus Inc.

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

V130\_11OB, NCT03438487

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

To evaluate pregnancy outcomes as well as events of interest of major congenital malformations, preterm birth and low birth weight among women immunized as part of routine care with the seasonal cell culture influenza trivalent (TIVc) or quadrivalent (QIVc) vaccine during pregnancy

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

FLUCELVAX

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## **Medical condition to be studied**

Influenza immunisation

## **Population studied**

### **Short description of the study population**

The study population will include pregnant women within the US who were immunized with the TIVc or QIVc vaccine as part of routine care at any time during pregnancy. Eligible pregnant women may self-enroll or voluntarily be enrolled by their health care provider (HCP). Women under 18 can be included in the study as long as parental consent can be obtained.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Special population of interest**

Pregnant women

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### **Estimated number of subjects**

693

## **Study design details**

### **Outcomes**

Number of cases for pregnancy outcomes will be reported as one of the following: live birth, stillbirth, spontaneous abortion and elective termination. Number of cases with major congenital malformations, events of preterm birth,

and low birth weight among women immunized as part of routine care with the seasonal TIVc or QIVc vaccine during pregnancy.

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### **Data analysis plan**

This study is descriptive. Data analysis will be performed for both products combined as well as per product separately, if applicable. Overall and stratum-specific prevalence estimates will be calculated for pregnancy outcomes and events of interest. Associations between exposure and pregnancy outcomes or events of interest, will be evaluated for confounding and effect modification.

## 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)**

[Other](#)

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### **Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

## **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No