

# Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry

**First published:** 29/09/2021

**Last updated:** 16/12/2024

Study

Ongoing

## Administrative details

### **EU PAS number**

EUPAS42869

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### **Study ID**

47692

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### **DARWIN EU® study**

No

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## Study countries

 Canada

 United States

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## Study description

This study aims to answer the question "Is the risk of pregnancy and infant safety outcomes increased among pregnant women in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry ("OTIS Pregnancy Registry") who were vaccinated with the Pfizer-BioNTech COVID-19 vaccine during pregnancy compared with those who did not receive any COVID-19 vaccine during pregnancy?" The study objective is to assess whether pregnant women who received the Pfizer-BioNTech COVID-19 vaccine during pregnancy experienced increased risk of pregnancy and infant safety outcomes, including major congenital malformations, spontaneous abortion, elective termination/abortion, stillbirth, preterm delivery, small for gestational age, and small for age postnatal growth at one year of age, relative to pregnant women who received no COVID-19 vaccines during pregnancy. This study is a prospective, observational cohort study of pregnancy and infant safety outcomes in pregnant women with exposure to the Pfizer-BioNTech COVID-19 vaccine using data from the OTIS Pregnancy Registry. The birth prevalence, incidence rates, and incidence proportion of pregnancy outcomes and incidence proportion of the infant outcome for women exposed to any dose of the Pfizer-BioNTech COVID-19 within one month prior to the first day of the last menstrual period to end of pregnancy will be compared to those observed in a comparator cohort unexposed to any COVID-19 vaccine during this period.

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## Study status

Ongoing

## Research institutions and networks

## Institutions

Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

University of California

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Jenny Sun [jenny.sun@pfizer.com](mailto:jenny.sun@pfizer.com)

Study contact

[jenny.sun@pfizer.com](mailto:jenny.sun@pfizer.com)

### Primary lead investigator

Jenny Sun

Primary lead investigator

# Study timelines

## **Date when funding contract was signed**

Planned: 06/05/2021

Actual: 06/05/2021

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## **Study start date**

Planned: 01/10/2021

Actual: 01/10/2021

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## **Date of final study report**

Planned: 28/02/2026

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Pfizer Inc.

# Study protocol

[C4591022\\_PROTOCOL AMENDMENT 1\\_20AUG2021.pdf](#) (3.37 MB)

[C4591022\\_PROTOCOL AMENDMENT 3\\_V4\\_09MAY2022.pdf](#) (3.39 MB)

# 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)

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Main study objective:**

To assess whether pregnant women who received the Pfizer-BioNTech COVID-19 vaccine during pregnancy experienced increased risk of pregnancy and infant safety outcomes relative to pregnant women who received no COVID-19 vaccines during pregnancy.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(J07BX03) covid-19 vaccines

covid-19 vaccines

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## **Medical condition to be studied**

COVID-19 immunisation

# Population studied

## **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)
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## **Special population of interest**

Pregnant women

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## **Estimated number of subjects**

2000

# Study design details

## **Outcomes**

Pregnancy outcomes of interest include major congenital malformations, spontaneous abortion, elective termination/abortion for any reason, stillbirth, preterm delivery, and small for gestational age. The infant outcome of interest is small for age postnatal growth of live born infants at one year of age.

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### **Data analysis plan**

The distributions of demographic and baseline characteristics will be summarized within the exposure and comparator cohort. The following measures will be calculated for the pregnancy and infant outcomes: birth prevalence of major congenital malformations, incidence rates of spontaneous abortion, elective termination/abortion, stillbirth, and preterm delivery, and incidence proportions of small for gestational age and small for age postnatal growth at one year of age. For each outcome, risk estimates will be described separately for the Pfizer-BioNTech COVID-19 vaccine exposure cohort and the comparator cohort. The outcomes will be compared between the Pfizer-BioNTech COVID-19 vaccine-exposed and vaccine-unexposed cohorts. Where feasible, comparisons will also be made using methods to control potential confounding and to evaluate outcomes following receipt of specific doses (i.e. 1st, 2nd, 3rd, booster) in pregnancy.

## 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**

Exposure registry

## **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