NON-INTERVENTIONAL/LOW-INTERVENTIONAL STUDY TYPE 1 INTERIM STUDY REPORT 3 ABSTRACT

Title: 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

Date: 20 January 2026

Name and affiliation of the main author: Christina Chambers, University of California San Diego (UCSD) and the Organization of Teratology Information Specialists (OTIS)

Keywords: COVID-19 vaccine, pregnancy, registry

Rationale and background: Information regarding the real-world safety of COVID-19 vaccination during pregnancy is essential. This non-interventional study is designated as a Post-Authorization Safety Study (PASS) and is a postmarketing commitment (PMC) to the FDA.

Research question and objectives: 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?

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: This study is a prospective, observational cohort study of pregnancy and infant safety outcomes in pregnant women the OTIS Pregnancy Registry who reside in the US or Canada.

Setting: This study uses data that are collected as part of the existing OTIS Pregnancy Registry and converted to a structured database for analysis.

Subjects and study size, including dropouts: The study population included pregnant women participating in the OTIS Pregnancy Registry on or after 11 December 2020. The target sample size was 1,100 exposed to the Pfizer-BioNTech COVID-19 vaccine in pregnancy and 900 unexposed to any COVID-19 vaccine in pregnancy.

Variables and data sources: Exposure is defined as receipt of the Pfizer-BioNTech COVID-19 vaccine from 30 days before the first day of LMP through the end of pregnancy. The comparator group is defined as pregnant women with no exposure to any COVID-19 vaccine from 30 days before the first day of LMP through the end of pregnancy.

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Pregnancy and infant outcomes include major congenital malformations, spontaneous abortion, elective termination/abortion, stillbirth, preterm delivery, small for gestational age at birth, and small for age postnatal growth at one year of age. Data on exposure, outcomes and covariates are obtained by maternal report and/or medical record review.

Results: Study enrollment closed on 31 May 2023 when study enrollment met the recruitment goal of 1,100 participants in the Pfizer-BioNTech COVID-19 vaccine exposure cohort and 900 in the comparator cohort. Data collection was completed on 11 August 2025.

Overall, there was no evidence of a statistically significant increased risk for any of the study outcomes (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).

Discussion: The overall study results do not suggest increased risks for any of the study outcomes related to vaccination in pregnancy with the Pfizer-BioNTech COVID-19 vaccine.

These findings are consistent with the previously published literature of safety data on the class of mRNA-based COVID-19 vaccines and add to the literature with respect to the Pfizer-BioNTech COVID-19 vaccine brand.

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