

TERIS Summary

TERIS Agent Number: 6869
Agent Name: **COVID-19 PROTEIN-BASED VACCINES**

Bibliographic Search Date: 01/2023

COVID-19 vaccines provide protection against the COVID-19 virus, SARS-CoV-2, and are administered by injection. Several different COVID-19 vaccines have been developed. Protein-based vaccines contain whole or fractionated SARS-CoV-2 protein without the genetic material.

Magnitude of Teratogenic Risk to Child Born After Exposure During Gestation: UNDETERMINED

Quality and Quantity of Data on Which Risk Estimate is Based: NONE

Comments: NONE

Summary of Teratology Studies:

MAJOR CONGENITAL ANOMALIES

No epidemiological studies of congenital anomalies among infants born to women who received COVID-19 protein-based vaccines during pregnancy have been reported.

ANIMAL TERATOLOGY STUDIES

Animal teratology studies of COVID-19 protein-based vaccines conducted by the manufacturer have not been published in the peer-reviewed literature.

Selected References:

(Each paper is classified as a review [R], human case report [C], human epidemiological study [E], human clinical series [S], animal study [A], or other [O].)

None available.

COVID-19 VACCINE PREGNANCY REGISTRIES

Healthcare providers are encouraged to suggest their patients enroll in the following registries:

V-SAFE

A registry collecting health information from people who received COVID-19 vaccinations in the periconception period or during pregnancy is being maintained by the Centers for Disease Control and Prevention. The registry attempts to assist individuals and healthcare providers to make informed decisions about COVID-19 vaccination.

Pregnant vaccinated people who would like to participate must complete a registration in v-safe (a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>). People who meet the conditions of the study will be contacted by the registry staff for additional details for enrollment in v-safe.

COVID-19 Vaccine Study

An observational pregnancy study by MotherToBaby has been established for women who received one or more doses of a COVID-19 vaccine during pregnancy or within one month prior to becoming pregnant. All study research will be performed via phone and office visits will not be required.

Additional information about the study can be found at MotherToBaby's COVID-19 Vaccines (<https://mothertobaby.org/ongoing-study/covid19-vaccines/>). Healthcare providers are encouraged to enroll such patients at <https://mothertobaby.org/join-a-study-form/>.

C-VIPER (COVID-19 Vaccines International Pregnancy Exposure Registry)

A registry collecting information from pregnant women who were vaccinated against COVID-19 during pregnancy and is maintained by Pregistry in Los Angeles, Calif. This registry evaluates obstetric, neonatal, and infant outcomes among women vaccinated during pregnancy to prevent COVID-19.

Healthcare providers may find additional information about this study at: <https://www.clinicaltrials.gov/ct2/show/NCT04705116>.

CANADIAN COVID-19 VACCINE REGISTRY FOR PREGNANT AND LACTATING INDIVIDUALS

A registry collecting information from women who are currently pregnant or breastfeeding regardless of vaccination status is maintained by the University of British Columbia in Vancouver, B.C., CANADA and in partnership with other Canadian vaccine surveillance networks. The registry is a longitudinal survey monitoring the safety, effectiveness, and opinions related to the COVID-19 vaccine.

Healthcare providers may find more information about this registry at: <https://covered.med.ubc.ca/>.