# A Post-Marketing Safety Study using a Pregnancy Registry to Evaluate the Safety of Respiratory Syncytial Virus Vaccine (ABRYSVO™) Exposure During Pregnancy (C3671041)

**First published:** 07/06/2024

**Last updated:** 03/06/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000179

**Study ID**

1000000179

**DARWIN EU® study**

No

**Study countries**

☐ United States

**Study description**

The research question is: What is the risk of adverse pregnancy outcomes, including preterm birth, hypertensive disorders of pregnancy, and other maternal and neonatal/infant outcomes, following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation in the CorEvitas RSV Vaccine Pregnancy Registry (RSV-PR)?
The primary study objective is to estimate the risk of (1) preterm birth and (2) hypertensive disorders of pregnancy following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation.

The secondary study objective is to estimate the risk of the following other safety outcomes of interest following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation:
(1) pregnancy-related outcomes: stillbirth, premature labor, premature rupture of membranes (PROM), preterm premature rupture of membranes (PPROM), cesarean delivery, prolonged maternal duration of hospital stay,
(2) maternal outcomes: thrombocytopenia, Guillain-Barré Syndrome (GBS), other immune-mediated demyelinating conditions, polyneuropathies, atrial fibrillation, maternal death, and
(3) neonatal/infant outcomes: small for gestational age (SGA), large for gestational age, low birth weight (LBW), admission to a neonatal intensive care unit (NICU), NICU duration of stay, mechanical ventilation in neonatal period, neonatal death, postnatal growth at 1 year of age.

The exploratory study objective is to describe the most frequently reported maternal adverse events (AEs) following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation.

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**Study status**

Ongoing

## Research institutions and networks

## Institutions

### Pfizer

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

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**Institution**

### CorEvitas

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Sarah MacDonald

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 19/09/2023

Actual: 19/09/2023

**Study start date**
Planned: 31/07/2024

Actual: 31/07/2024

**Data analysis start date**
Planned: 01/10/2030

**Date of interim report, if expected**
Planned: 30/11/2024

**Date of final study report**
Planned: 30/09/2031

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer 100%

## Study protocol

C3671041_RSV VACCINE PROTOCOL AMENDMENT 1 V2.0_15MAY2024.pdf

(309.99 KB)

## Regulatory

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

Yes

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

Not applicable

## Other study registration identification numbers and links

C3671041

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

**Study design:**

This will be a US-based, observational, secondary database cohort study using primary data collected by the RSV-PR.

**Main study objective:**

The research question is:

What is the risk of adverse pregnancy outcomes, including preterm birth, hypertensive disorders of pregnancy, and other maternal and neonatal/infant outcomes, following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation?

The primary study objective is to estimate the risk of

(1) preterm birth and

(2) hypertensive disorders of pregnancy, following exposure to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days of gestation.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

ABRYSVO

**Name of medicine, other**

Respiratory syncytial virus vaccine (bivalent, recombinant)

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**Study drug International non-proprietary name (INN) or common name**

RESPIRATORY SYNCYTIAL VIRUS, SUBGROUP A, STABILIZED PREFUSION F PROTEIN 847A

RESPIRATORY SYNCYTIAL VIRUS, SUBGROUP B, STABILIZED PREFUSION F PROTEIN 847B

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

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**Medical condition to be studied**

Respiratory syncytial virus infection

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**Additional medical condition(s)**

Prevention of respiratory syncytial virus

# Population studied

**Short description of the study population**

The study population will include 2 cohorts of individuals enrolled in the RSVPR:

(1) those exposed to ABRYSVO between 32 weeks 0 days and 36 weeks 6 days and

(2) those unexposed to ABRYSVO during pregnancy.

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**Age groups**

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

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**Special population of interest**

Pregnant women

# Study design details

**Setting**

This study will use data collected as part of the RSV-PR.

The RSV-PR will collect data from participants and the healthcare providers (HCPs) involved in their care or the care of their infants via concise data collection forms at pre-defined timepoints during pregnancy, at pregnancy outcome, and up to 1 year of infant age.

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**Comparators**

Comparators must be enrolled in the RSV-PR, for which the following inclusion criteria apply:

(a) a resident of the US at enrollment,

(b) 18 to 50 years of age at enrollment,

(c) gestational age greater than or equal to 32 weeks 0 days at enrollment,

(d) evidence of a personally signed and dated informed consent document or, upon waiver of written consent by the relevant IRB/independent ethics committee (IEC), verbal consent indicating that the individual (or a legally acceptable representative) has been informed of all pertinent aspects of the study,

(e) authorization obtained for the relevant health care providers to provide data to the registry, and

(f) contact information available (for participant and health care provider).

Individuals excluded from the RSV-PR will not be included in the study (this includes individuals who meet any of the following:
(a) receipt of an RSV vaccine during pregnancy before 32 weeks 0 days gestation,
(b) multi-fetal pregnancy, or
(c) enrolled in the RSV-PR with a previous pregnancy.
Comparators are not exposed to ABRYSVO during pregnancy.

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**Outcomes**

Pregnancy related outcomes: preterm birth, hypertensive disorders of pregnancy, gestational hypertension, preeclampsia/eclampsia, HELLP (hemolysis, elevated liver enzymes and low platelets) syndrome, chronic hypertension superimposed with preeclampsia/eclampsia, postpartum hypertension, cesarean delivery, premature labor (without preterm delivery), premature rupture of membranes, preterm premature rupture of membranes, stillbirth, prolonged maternal duration of hospital stay

Maternal outcomes: Thrombocytopenia, Guillain-Barré syndrome (GBS), polyneuropathies (excluding GBS), other immune-mediated demyelinating conditions, atrial fibrillation, maternal death, most frequently reported maternal adverse events (exploratory outcome)

Neonatal/infant outcomes: small for gestational age, large for gestational age, low birth weight, admission to a neonatal intensive care unit, mechanical ventilation in the neonatal period, neonatal death, postnatal growth deficiency at 1 year of age.

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**Data analysis plan**

Participant characteristics will be summarized with descriptive statistics for each cohort. Comparative analyses will be conducted for each outcome, if

sample size permits.
Supplementary analyses will be conducted that include pregnant individuals who were excluded from the analysis population (i.e., those lacking health care provider confirmation of ABYRSVO exposure, pregnancy, or outcomes of interest).
If sample size permits, subgroup and sensitivity analyses will be performed to examine the extent to which changes in certain methods or assumptions affect the results.

# Data management

## Data sources

**Data source(s), other**

This study will use data collected as part of the CorEvitas RSV Vaccine Pregnancy Registry (RSV-PR).
The RSV-PR will collect data from participants and the health care providers involved in their care or the care of their infants via concise data collection forms at pre-defined timepoints during pregnancy, at pregnancy outcome, and up to 1 year of infant age.

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**Data sources (types)**

Pregnancy registry

## 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**

Unknown