

# Effectiveness of ABRYSSVO® maternal respiratory syncytial virus (RSV) vaccine against RSV in infants in Western Pennsylvania (CASSATT)

**First published:** 28/01/2025

**Last updated:** 17/02/2025

Study

Planned

## Administrative details

### **PURI**

<https://redirect.ema.europa.eu/resource/1000000389>

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### **EU PAS number**

EUPAS1000000389

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### **Study ID**

1000000389

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### **DARWIN EU® study**

No

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## Study countries

United States

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## Study description

Globally, respiratory syncytial virus (RSV) is the leading cause of lower respiratory tract disease (LRTD) in infants. Pfizer has developed ABRYSSVO—a bivalent RSV prefusion F protein-based vaccine (RSVpreF) composed of two prefusion F proteins to protect against both RSV-A and RSV-B.

In the United States, ABRYSSVO has been approved and recommended for active immunization of pregnant individuals from 32 0/7 to 36 6/7 weeks' gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

To generate critical evidence to support vaccine policy and implementation, Pfizer will collaborate with University of Pittsburgh to study vaccine effectiveness (VE) of ABRYSSVO vaccination during pregnancy against RSV-associated outcomes in infants. The study will take place in a real-world population in Western Pennsylvania over multiple seasons, beginning in the 2023-2024 season, and will use a test negative design (TND approach).

There will be no active enrollment of study participants, no direct contact with study participants, and no collection of any primary data outside of the Standard of Care (SOC).

This study will use a TND to evaluate real-world VE of maternal ABRYSSVO against RSV-associated outcomes in infants. Additionally, we will describe RSV-associated medically-attended visits for infants exposed to ABRYSSVO and Beyfortus (monoclonal antibody (MAB) administered to babies up to 24 months for protection against RSV).

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## Study status

Planned

## Research institutions and networks

# Institutions

University of Pittsburgh

## Contact details

### Study institution contact

Anne-Marie Rick

Study contact

[Annemarie.rick@chp.edu](mailto:Annemarie.rick@chp.edu)

### Primary lead investigator

Anne-Marie Rick

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 16/10/2024

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### Study start date

Planned: 24/02/2025

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### Date of interim report, if expected

Planned: 30/04/2025

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### Date of final study report

Planned: 20/12/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer, Inc

## Regulatory

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

No

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

This study uses UPMC electronic medical records to evaluate the real-world vaccine effectiveness of maternal ABRYSV0 vaccination against RSV in infants and describes medically-attended visits for infants exposed to ABRYSV0 and Beyfortus, with no active enrollment or direct participant contact.

**Main study objective:**

Estimate ABRYSV0 VE against RSV positive acute respiratory illness (ARI) hospitalization among infants from birth through 3 months (0 through 90 days of age).

## Study Design

**Non-interventional study design**

Case-control

## Study drug and medical condition

**Name of medicine**

ABRYSV0

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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 immunisation

## Population studied

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

The study population will include infants who were hospitalized with ARI, have documented RSV test results and born to an individual eligible for ABRYSV0 vaccination in pregnancy based on the timing of birth relative to the local seasonal ABRYSV0 vaccination program.

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### **Age groups**

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 - 27 days)

Infants and toddlers (28 days - 23 months)

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### **Special population of interest**

Pregnant women

## Study design details

### **Setting**

This health network-based retrospective study will be conducted using data from University of Pittsburgh Medical Center (UPMC), a semi-closed health network in Western Pennsylvania.

Two UPMC hospitals will be utilized to identify the source population in this study - UPMC Magee-Women's Hospital, which serves Pittsburgh, Pennsylvania and the surrounding area and has over 9,000 deliveries per year, and UPMC Hamot Hospital, which serves Erie, Pennsylvania and has over 3,000 deliveries per year. The integrated electronic health record at these hospitals allows for >95% of mothers and their infants to be linked within the EHR allowing for accurate characterization of maternal immunization. Furthermore, both hospitals participate in the Magee Obstetric Maternal & Infant (MOMI) Database, which collects over 300 maternal and infant variables from pregnancy, delivery, and postpartum for every pregnancy, allowing for standardized data collection for >95% of deliveries occurring in these hospitals.

The University of Pittsburgh and UPMC's bioinformatics group (R3) can routinely obtain structured data elements from the electronic health record including maternal and infant immunization records, laboratory results, medications, diagnosis codes, demographic and birth characteristics. Additional details of specific medical encounters, including details on reported clinical symptoms, vital signs, and physical exam findings, can be obtained using unstructured data abstraction with trained data abstractors, who enter data directly into electronic data collection tool. This detailed abstraction will allow for accurate characterization of viral infection that includes LRTD.

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## **Outcomes**

The outcome for the primary objective is RSV-positive ARI hospitalization confirmed by  $\geq 1$  acute respiratory illness symptom, laboratory testing, and hospitalization occurring 0 to  $\leq 90$  days of life during RSV season based on local epidemiology.

Outcomes for the secondary objective include:

- RSV-positive ARI hospitalization confirmed by  $\geq 1$  acute respiratory illness symptom, laboratory testing, and hospitalization occurring 0 to  $\leq 180$  days of life during RSV season based on local epidemiology.
- RSV -positive ARI hospitalization confirmed by  $\geq 1$  acute respiratory illness symptom, laboratory testing, and hospitalization occurring 90 to  $\leq 180$  days of life during the RSV season based on local epidemiology.
- RSV-positive ARI hospitalization with study-defined LRTD occurring 0 to  $\leq 90$  days of life during RSV season based on local epidemiology.
- RSV-positive hospitalization with study-defined LRTD occurring 0 to  $\leq 180$  days of life during RSV season based on local epidemiology.
- RSV-positive ARI hospitalization with study-defined LRTD occurring 90 to  $\leq 180$  days of life during RSV season based on local epidemiology.
- Number, age and characteristics of infants whose birth parent received ABRYVVO during pregnancy who present for a medical visit (outpatient, urgent care, emergency room, hospital) and have laboratory confirmed RSV between 0 to  $\leq 90$  days of life.
- Number, age and characteristics of infants who received Beyfortus between 0 to  $< 7$  days of life who present for a medical visit (outpatient, urgent care, emergency room, hospital) and have laboratory confirmed RSV between 1 to  $\leq 90$  days post-Beyfortus exposure.

The exploratory outcome is RSV-positive ARI hospitalization confirmed by  $\geq 1$  acute respiratory illness symptom, laboratory testing, and hospitalization occurring 0 to  $\leq 30$  days of life during RSV season based on local epidemiology.

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### **Data analysis plan**

For the TND study, baseline characteristics of the study population will be described by case/control status and by exposure status. A logistic regression model will be used to compute an odds ratio (OR), comparing the odds of maternal ABRYVVO vaccination during pregnancy between test-positive cases



and test-negative controls. From the OR, the VE will be calculated as  $(1-OR) \times 100\%$ . A multivariable logistic regression model will be used to compute an adjusted OR (aOR) from which we will derive final VE estimates, adjusted for potential confounding, according to the formula:  $VE = (1-aOR) \times 100\%$ . The same approach will be utilized for secondary and exploratory VE objectives.

For descriptive objectives, age at RSV+ medically attended visit as well as other descriptive characteristics such as demographics, co-morbid medical conditions, and location of medical visit will be described for infants exposed to ABRYSV0 and Beyfortus.

## Data management

### Data sources

#### **Data source(s), other**

University of Pittsburgh Medical Center electronic health record data

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#### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Laboratory tests and analyses](#)

[Non-interventional study](#)

### 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**

Unknown