Observational Cohort Study Evaluating
Real-World ABRYSVO Vaccine Effectiveness
and Impact Against Medically-Attended
RSV-related and All-Cause Outcomes
Among Infants Born to Individuals
Vaccinated During Pregnancy

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### Administrative details

#### **EU PAS number**

EUPAS1000000295

#### Study ID

1000000295

#### **DARWIN EU® study**

No

#### **Study countries**

#### Study description

This study will be conducted in collaboration with an integrated delivery health care organization in the United States using electronic medical record (EMR) data, collected during routine standard of care clinical encounters. This study will use a retrospective cohort design to study the vaccine effectiveness (VE) and impact of ABRYSVO vaccination during pregnancy in a real-world population over multiple RSV seasons.

#### **Study status**

**Planned** 

Research institutions and networks

**Institutions** 

Kaiser Permanente Northern California (KPNC)

### **Networks**

Kaiser Permanente Northern California

### Contact details

Study institution contact

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Study contact

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### Primary lead investigator

Nicola Klein

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 18/06/2024

Actual: 13/11/2024

#### Study start date

Planned: 01/12/2025

#### Date of final study report

Planned: 31/03/2028

# 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	
<b>Is the study require</b> Not applicable	ed by a Risk Management Plan (RMP)?
Other study rand links	egistration identification numbers
C3671048	
Methodologic	al aspects
Study type	
Study type lis	st
<b>Study topic:</b> Human medicinal pro	duct
Study topic, other:	

### Study topic, other:

Vaccine effectiveness

### **Study type:**

Non-interventional study

# **Scope of the study:**

Effectiveness study (incl. comparative)

#### **Data collection methods:**

Secondary use of data

#### Study design:

This study will use a retrospective cohort design to assess ABRYSVO VE and impact in a large, diverse, real-world setting. This NI study will be conducted within an integrated delivery health care organization using EMR data, collected during routine standard of care clinical encounters.

#### Main study objective:

The overall aim of this study is to evaluate the effectiveness and impact of maternal ABRYSVO vaccination during pregnancy for the prevention of medically-attended (MA) respiratory syncytial virus (RSV)-associated and all-cause infant outcomes in a large, diverse, real-world population.

# Study Design

#### Non-interventional study design

Cohort

Other

#### Non-interventional study design, other

The overall aim of this study is to evaluate the effectiveness and impact of maternal ABRYSVO vaccination during pregnancy for the prevention of medically-attended respiratory syncytial virus associated and all-cause infant outcomes in a large, diverse, real-world population. Primary objective is to estimate vaccine effectiveness of ABRYSVO vaccination during pregnancy against polymerase chain reaction-confirmed RSV lower respiratory tract disease among infants from birth through 6 months of age. Key secondary

objective will estimate VE of ABRYSVO vaccination during pregnancy against PCR-confirmed RSV LRTD hospitalization among infants from birth through 6 months of age. Additional secondary objectives for infants from birth through 6 months of age include estimating VE of ABRYSVO vaccination during pregnancy against: PCR-confirmed RSV, PCR-confirmed RSV hospitalization, all-cause LRTD, all-cause LRTD hospitalization, acute otitis media, and new antibiotic prescriptions. Additional secondary objectives for infants from birth through 12 months of age include estimating VE over the entire interval and intervalspecific VE against: PCR-confirmed RSV, PCR-confirmed RSV hospitalization, PCR-confirmed RSV LRTD, and PCR-confirmed RSV LRTD hospitalization. Exploratory objectives for infants from birth through 6 months of age include estimating VE against PCR-confirmed RSV LRTD and PCR-confirmed RSV LRTD hospitalization, stratified by: time from vaccination to birth, gestational age at vaccination, infant high-risk status for severe RSV, with/without coadministration with other vaccines. Exploratory objectives for infants from birth through 24 months of age (0 to ≤720 days) include 1)describing the timing, severity, and sequelae of the first PCR-confirmed RSV illness among infants up to 24 months of age, by maternal ABRYSVO status; 2)estimating VE against allcause LRTD; 3)estimating VE against all-cause LRTD hospitalization; and 4) estimating VE against acute otitis media.

# Study drug and medical condition

#### Name of medicine

**ABRYSVO** 

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

(J07BX05) respiratory syncytial virus vaccines respiratory syncytial virus vaccines

# Population studied

#### Short description of the study population

The study population will comprise eligible maternal-infant pairs over a 2-year study period, identified from EMR records in the existing databases, which accrue in real-time as pregnancies/births occur. All pregnancies that reach 32 weeks of gestation during the 2-year study period, from September 22, 2023 (start of ABRYSVO vaccination season 1 as of the date of the ACIP recommendation) to January 31, 2025 (estimated end of ABRYSVO vaccination season 2) will be eligible for inclusion, along with all live born infants from the eligible pregnancies.

#### Age groups

Neonate

Preterm newborn infants (0 - 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days - 23 months)

#### **Estimated number of subjects**

39456

# Study design details

#### Setting

The study setting will be KPNC, which is an integrated delivery healthcare organization in Northern California with over 4.5 million members and approximately 40,000 births each year. KPNC members receive almost all their health care within KPNC clinics, hospitals, pharmacies, and laboratories. Information from encounters within these clinical settings are captured in EMRs which can be linked at an individual level across KPNC settings using a unique medical record number (MRN). The KPNC pregnancy database will be used to

identify the maternal-infant study population. This database links records of newborn infants with their mother, enabling integration of maternal data from across pregnancy and delivery encounters, along with infant birth information and longitudinal follow-up for infants who remain enrolled with KPNC. Infant healthcare encounters after the birth and throughout the follow-up period will be identified in the EMR. As routinely-recommended vaccinations are provided free of charge to KPNC members and can be electronically linked with the pregnancy database and other EMR data, the receipt and gestational timing of ABRYSVO vaccination during pregnancy can be determined.

#### **Outcomes**

Medically-Attended Endpoints

Primary: PCR-confirmed RSV LRTD occurring ≤180 days after birth (first episode).

Key Secondary: PCR-confirmed RSV LRTD hospitalization occurring ≤180 days after birth (first episode).

Secondary:

Follow-up from birth through 6 months of age: PCR-confirmed RSV occurring  $\leq 180$  days after birth (first episode), PCR-confirmed RSV hospitalization occurring  $\leq 180$  days after birth (first episode), LRTD (any cause) occurring  $\leq 180$  days after birth (first episode during the RSV season), LRTD hospitalization (any cause) occurring  $\leq 180$  days after birth (first episode during the RSV season), Acute otitis media occurring  $\leq 180$  days after birth (first episode during the RSV season), New antibiotic prescriptions occurring  $\leq 180$  days after birth (first prescription during the RSV season).

Follow-up from birth through 12 months of age:PCR-confirmed RSV occurring ≤360 days

after birth (first episode), PCR-confirmed RSV hospitalization occurring  $\leq$ 360 days after birth (first episode), PCR-confirmed RSV LRTD occurring  $\leq$ 360 days

after birth (first episode), PCR-confirmed RSV LRTD hospitalization occurring ≤360 days after birth (first episode).

#### Exploratory:

Follow-up from birth through 6 months of age: PCR-confirmed RSV LRTD occurring ≤180 days after birth (first episode), stratified by: time from vaccination to birth, gestational age at vaccination, infant high risk status for severe RSV, with/without co-administration with other vaccines PCR-confirmed RSV LRTD hospitalization occurring ≤180 days after birth (first episode), stratified by: time from vaccination to birth, gestational age at vaccination, infant high-risk status for severe RSV, with/without coadministration with other vaccines.

Follow-up from birth through 24 months of age: Among PCR-confirmed RSV-positive cases through 24 months of age, describe timing, severity, sequelae, LRTD/LRTD hospitalization/acute otitis media (any cause) occurring ≤720 days after birth (total number of episodes)

#### Data analysis plan

RSV-specific infant analyses

RSV-specific from birth through 6 months of age:

Outcomes among infants born to ABRYSVO-vaccinated and ABRYSVO-unvaccinated mothers will be compared using multivariable Cox proportional hazards regression models, generating aHR and 95% CI. IPTW derived from propensity scores may be considered, instead of conventional multivariable adjustment, to account for confounding bias. Calendar date will be used as the underlying time scale in the Cox models and VE will be calculated as (1 - aHR) and expressed as a percentage.

RSV-specific from birth through 12 months of age:

This analyses will stratify the Cox model by infant age; the exact width of discrete time intervals will be determined based on outcome incidence and ABRYSVO uptake.

RSV-specific from birth through 24 months of age:

Timing, severity, and sequelae will be described according to maternal ABRYSVO status. Among infants born to individuals who received ABRYSVO vaccine during pregnancy, we will describe the gestational age at ABRYSVO vaccination and the time interval from vaccination to birth.

Non-specific all-cause analyses

To be assessed for two overlapping follow-up periods: from birth through 6 months of age and from birth through 24 months of age.

All-cause analyses from birth through 6 months of age:

Multivariable Cox proportional hazards regression models will be used to estimate VE. VE will be calculated as (1 - aHR) and expressed as a percentage. All-cause analyses from birth through 24 months of age:

Will the total number of episodes of each outcome during follow-up. Poisson regression to generate aIRR for comparison. VE will be calculated as (1 - aIRR) and expressed as a percentage.

# 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)

# Electronic healthcare records (EHR) Laboratory tests and analyses

# 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**

No