

# STudy of Real world vaccinE Effectiveness of maTernal RSVpreF vaccinatiON against respiratory syncytial virus (RSV) in hospitalised infants in Australia (STREETON)

**First published:** 21/07/2025

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Study

Planned

## Administrative details

### EU PAS number

EUPAS1000000598

### Study ID

1000000598

### DARWIN EU® study

No

### Study countries

☐ Australia

### Study description

This Pfizer-sponsored real-world retrospective non-interventional (NI) study will be conducted within a research network comprised of independent hospitals across Australia using data collected during routine standard of care (SOC) clinical encounters available in health records (including both digital and/or paper records), supplemented with information from the official national immunisation registry, the Australian Immunisation Register (AIR). Additional data from accredited pathology laboratories will be included.

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 SOC.

This study will use a TND to evaluate real-world VE of ABRYSCO vaccination during pregnancy against RSV-associated outcomes in infants.

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## **Study status**

Planned

## Contact details

### **Study institution contact**

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**Study contact**

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### **Primary lead investigator**

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**Primary lead investigator**

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# Study timelines

## **Date when funding contract was signed**

Planned: 01/07/2025

Actual: 30/06/2025

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## **Study start date**

Planned: 11/08/2025

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## **Date of final study report**

Planned: 30/07/2027

# Regulatory

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

No

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

Non-EU RMP only

# Methodological aspects

## Study type

## Study type list

**Study type:**

### **Study design:**

This retrospective NI study will be conducted within a research network comprised of independent hospitals across Australia using data collected during routine

SOC clinical encounters available in health records, supplemented with information from the official national immunisation registry, AIR.

### **Main study objective:**

Primary Research Question: What is the real-world effectiveness of ABRYSV0 vaccination during pregnancy against respiratory syncytial virus (RSV)-associated outcomes in infants in Australia?

Primary Research Objective: The primary objective is to estimate vaccine effectiveness (VE) of ABRYSV0 during pregnancy against RSV-positive lower respiratory tract disease (LRTD) hospitalisation among infants from birth through 6 months (0 to  $\leq 180$  days) of age using a case-control study with a test negative design (TND).

## Study drug and medical condition

### **Medicinal product name**

ABRYSV0

## Population studied

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

### Inclusion Criteria:

Participants must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. Infant  $\leq 12$  months ( $\leq 360$  days) of age on the hospitalisation date.
2. Index date within the time period for data collection (approximately 01 March 2025 – 28 February 2027; Refer to Section 9.1.).
3. Hospitalised with ARI meeting the protocol-defined clinical case definition, and for whom RSV testing results from a specimen collected 10 days prior to hospital admission through 3 days after a hospital admission are known. See Section 9.3.2. for ARI hospitalisation definition.
4. Infant date of birth on or after 17 February 2025 ( $\geq 14$  days after start of the first national ABRYSV0 vaccination campaign to ensure potential to have been born to an ABRYSV0-vaccinated mother).
5. Infant born to a birth mother eligible to receive ABRYSV0 vaccination \*h
- ...

\*h: Birth mothers who were expected (based on estimated date of delivery) to reach  $\geq 28$  % wGA on or after 03 February 2025.

### Exclusion Criteria

Participants meeting any of the following criteria will not be included in the study:

1. Infant born at  $< 28$  % weeks of gestational age.
1. Infant received any licensed or investigational RSV preventive product (e.g., palivizumab, nirsevimab, active RSV vaccine) since birth.
2. Infant received  $\geq 1$  blood transfusion or other blood products containing antibody (e.g., fresh frozen plasma) since birth.

3. Infant born to a birth mother who received any other licensed or investigational RSV vaccine during this pregnancy.
4. Infant born to a birth mother for whom ABRYSV0 vaccination status cannot be confirmed in available data sources.

## Study design details

### Setting

This hospital-based retrospective study will be conducted in a research network of up to 9 independent hospitals across 6 states/territories in Australia. A list of each hospital, with accompanying details, will be provided in the statistical analysis plan (SAP).

Given the retrospective nature of this study, hospitals that already function as national sentinel units for respiratory virus surveillance, or that have robust clinical, laboratory or epidemiological surveillance will be included. Each participating hospital conducts year-round SOC testing for ARI which includes respiratory virus panel test using polymerase chain reaction (PCR).

## 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.

## 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

No