A Post-Authorization Safety Study of Guillain-Barré Syndrome (GBS) Following ABRYSVOTM Among Older Adults in the United States (C3671031)

First published: 06/10/2025

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Study | Planned

Administrative details

EU PAS number

EUPAS1000000753

Study ID

1000000753

DARWIN EU® study

No

Study countries

United States

Study description

This non-interventional post authorization safety study (PASS) will assess the risk of Guillain-Barré Syndrome (GBS), acute polyneuropathies, and other immune-mediated demyelinating conditions following receipt of ABRYSVO among US Medicare beneficiaries 65 years of age and older, as well as commercially insured adults aged 60-64 years, from the earliest date of vaccine availability to 31 December 2027.

Study status

Planned

Research institutions and networks

Institutions

Pfizer

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Institution

Analysis Group

Contact details

Study institution contact

Julia Beasley julia.munroe@pfizer.com

Study contact

julia.munroe@pfizer.com

Primary lead investigator

Joanne (Juan) Wu

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/06/2023

Actual: 02/06/2023

Study start date
Planned: 28/02/2026

Data analysis start date
Planned: 01/06/2029

Date of interim report, if expected
Planned: 18/12/2026

Date of final study report
Planned: 31/05/2030

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

C3671031_RSV VACCINE PROTOCOL AMENDMENT 4 V5.0_11SEP2024.pdf
(746.46 KB)

C3671031_RSV VACCINE PROTOCOL AMENDMENT 5 V6.0_15APR2026.pdf
(858.9 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

C3671031

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 non-interventional PASS will assess the risk of GBS, acute polyneuropathies, and other immune-mediated demyelinating conditions following receipt of ABRYSVO among US Medicare beneficiaries 65 years of age and older, as well as commercially insured adults aged 60-64 years.

Main study objective:

This primary objective of the study is to estimate the incidence of GBS, acute polyneuropathies, and other immune-mediated demyelinating conditions following administration of ABRYSVO among adults 60 years and older.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ABRYSVO

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Medical condition to be studied

Guillain-Barre syndrome

Additional medical condition(s)

Prevention of respiratory syncytial virus

Population studied

Short description of the study population

The study population will be US Medicare beneficiaries 65 years of age and older, and commercially insured adults 60-64 years of age captured in the IQVIA PharMetrics® Plus (PharMetrics Plus) database, who receive ABRYSVO from the earliest date of ABRYSVO availability until 31 December 2027.
Individuals will be included if they have a claim for at least one dose of ABRYSVO. For the Medicare population, individuals must have aged into Medicare and be at least 65 years of age on the date of receipt of ABRYSVO (i.e., index date). For the commercially insured older adult population, individuals must be 60-64 years of age on the index date.
Contemporary unvaccinated controls will be included if they have no record of any vaccination on the index date, no record of ABRYSVO vaccination during the baseline period or on the index date, and at least one vaccination claim in the year prior to the index date.
The unvaccinated controls will be assigned an index date matched to a

corresponding ABRYSVO vaccinee’s vaccination date and will be required to be at least 65 years of age (for Medicare) or 60-64 years of age (for commercially insured adults in PharMetrics Plus) on the matched index date.
Contemporary vaccinated controls will be included if they have no record of an ABRYSVO vaccine, but have a claim for another vaccine within 30 days of a corresponding ABRYSVO vaccinee’s vaccination date which will serve as the vaccinated control’s index date.
They will be required to be at least 65 years (for Medicare) or 60-64 years of age (for commercially insured adults in PharMetrics Plus) on the matched index date.
All individuals will be required to have at least 12 months of continuous enrollment (i.e., baseline period) prior to the index date.

Study design details

Setting

This study will be conducted among US Medicare beneficiaries 65 years of age and older, as well as US commercially insured adults 60-64 years of age who receive the ABRYSVO vaccine, and index-matched vaccinated and unvaccinated controls, between the earliest date of ABRYSVO vaccine availability and 31 December 2027.

Comparators

Incidence rates for the primary and secondary outcomes will be compared to rates observed in the following control groups for the Medicare population 65 years and older:

Self-controls: cases who experience safety events following vaccination using the SCRI design to compare the risk interval following vaccination to post-

vaccination non-risk intervals in the same individual. Individuals must have post-index enrollment equivalent to the duration of the risk and control intervals to be included in this analysis. A conditional Poisson regression model will be used to compare the rates of safety events in the risk interval vs post-vaccination control time period. From this model we will report rate ratios and 95% CIs that will be interpreted as the relative incidence for the safety event in the risk interval compared to the control interval.

Internal comparator cohorts: two random samples of contemporaneous vaccinated and unvaccinated matched controls. ATT weighting, based on propensity scores, will be used to ensure baseline comparability between the ABRYSVO vaccinated cohort and contemporary unvaccinated controls, as well as the ABRYSVO vaccinated cohort and contemporary vaccinated controls. ATT weighted Cox regression with robust standard errors to account for within-subject correlation will be conducted to compare the risk of safety events between cohorts. Hazard ratios and corresponding 95% CIs will be summarized.

Outcomes

The study’s primary outcome, new onset GBS, will be identified by an inpatient claim with GBS as the primary diagnosis. This will represent the date of GBS onset unless there is a claim with a GBS diagnosis in another medical setting in the 7 days prior to the inpatient claim. In that case, the earlier medical claim will represent the date of onset. To be considered a new onset case, there should be no diagnosis for GBS observed in the 12 months prior to the index date (i.e., “clean window”). Secondary outcomes will include new onset acute polyneuropathies and other immune-mediated demyelinating conditions. Claims for outpatient (including emergency department) and/or inpatient settings will be used to identify secondary outcomes, depending on the type of event.

A clean window without a claim with diagnosis of the safety event in the 12 months prior to the index date will also be required for each individual safety event risk analysis.

Data analysis plan

Analyses will be conducted separately for commercially insured adults 60-64 years and for Medicare insured adults 65 years and older.

Baseline demographics and clinical characteristics for individuals administered ABRYSVO and contemporary vaccinated and unvaccinated controls will be summarized using descriptive statistics.

Descriptive statistics will also be used to summarize vaccination patterns for ABRYSVO. Incidence rates per 100,000 patient-years (and corresponding 95% CIs) will be calculated for GBS, acute polyneuropathies, and other immune-mediated acute demyelinating conditions as the total number of incident events divided by the total observation time.

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 source(s), other

Centers for Medicare & Medicaid Services (CMS)

Chronic Conditions Data Warehouse (CCW)

Medicare administrative database

PharMetrics Plus database

Data sources (types)

Administrative healthcare records (e.g., claims)

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