

# 209452 - A targeted safety study, EPI-ZOSTER-030 VS US DB, to evaluate the safety of Shingrix in adults $\geq 50$ years of age in the United States

**First published:** 11/09/2020

**Last updated:** 14/01/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS37156

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### Study ID

50411

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### DARWIN EU® study

No

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### Study countries

 United States

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### Study description

Targeted safety study to assess the real-world safety of Recombinant zoster vaccine (RZV) in the US using a large distributed data network with a focus on specific health outcomes of interest in adults aged 50 and older.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

[Harvard Pilgrim Health Care Institute](#)

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

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**Institution**

### Networks

[Harvard Pilgrim Health Care](#), [Aetna](#), [CVS Health Company](#), [Carelon Research](#), [Humana](#), [Optum](#)

## Contact details

### **Study institution contact**

Call Center EU Clinical Trials  
Vx.publicdisclosureglobal@gsk.com

Study contact

[Vx.publicdisclosureglobal@gsk.com](mailto:Vx.publicdisclosureglobal@gsk.com)

**Primary lead investigator**  
Call Center EU Clinical Trials

Primary lead investigator

## Study timelines

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

Actual: 27/08/2020

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### **Study start date**

Planned: 14/09/2020

Actual: 14/09/2020

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### **Date of final study report**

Planned: 05/08/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

# Study protocol

[Protocol\\_Amendment\\_2\\_Anonymized\\_209452.pdf](#) (1.11 MB)

[Protocol\\_Amendment\\_5-Anonymised.pdf](#) (1.84 MB)

[Protocol Amendment 4 Anonymised 16 May 2025.pdf](#) (2.96 MB)

[Protocol Amendment 3 Anonymised 20 May 2025.pdf](#) (3.5 MB)

## Regulatory

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

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Safety study (incl. comparative)

**Main study objective:**

To assess whether there is an increased risk of new-onset Guillain-Barré Syndrome (GBS), Gout, Polymyalgia Rheumatica (PMR), Giant Cell Arteritis (GCA), Ischemic Optic Neuropathy (ION) or Supraventricular Tachycardia (SVT) within specified time periods after RZV vaccination in people  $\geq 50$  years of age enrolled starting in January 2018 at any of the participating U.S. Research Partners.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Self-controlled risk interval design (a version of the self-controlled case series and the case-crossover designs)

## Study drug and medical condition

**Medicinal product name**

SHINGRIX

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

RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E

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

(J07BK) Varicella zoster vaccines

Varicella zoster vaccines

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## **Medical condition to be studied**

Herpes zoster

# Population studied

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

The study population will be commercially insured people in the US who are  $\geq 50$  years of age at the time of their qualifying visit date (i.e., RZV vaccination date for RZV recipients or preventive care visit date for cohort study comparators) during the study period, from 01 January 2018 on. Administrative-services-only enrollees will be excluded, as their medical records may not be available for review; however, ASO enrollees may be considered for inclusion on an as-needed basis, if allowable and medical records are available.

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## **Age groups**

- Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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## **Estimated number of subjects**

723000

# Study design details

## **Comparators**

For GBS, the risk during Days 1-42 after RZV vaccination will be compared with the risk in a post-vaccination control interval starting on Day 43 after Dose 1. For gout and SVT, the risk during Days 1-30 after RZV vaccination will be compared with the risk in a post-vaccination control interval starting on Day 31 after Dose 1

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## **Outcomes**

The risk of new onset GBS (within 42 days) and Gout (within 30 days) following RZV vaccination using a Self-controlled Risk Interval (SCRI) design and the risk of new onset PMR (within 183 days) and GCA (within 183 days) following RZV vaccination using a cohort design. The risk of new onset SVT within 30 days following RZV vaccination using a SCRI design and the risk of new onset ION within 183 days following RZV vaccination using a cohort design.

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## **Data analysis plan**

The analysis plan includes descriptive measures to characterize exposed and unexposed individuals, conditional Poisson regression models for the SCRI, and Cox proportional hazards regression models for the cohort design outcomes. Sentinel analytic tools will be used for the distributed analyses, modifications to the tools may be needed to meet study objectives. For each outcome there is a primary analysis, secondary analysis and sensitivity analysis. All the statistical calculations will be done in SAS 9.2 or higher.

## **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)

Network of Sentinel General Practitioners

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### Data source(s), other

Sentinel Distributed Database (SDD) United States

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### 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

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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