

213825-Non-interventional (observational) post-licensure study to assess the vaccine effectiveness and safety of recombinant zoster vaccine (RZV) in the rheumatoid arthritis (RA) and inflammatory bowel disease (IBD) patient populations in adults 18 years of age and older (EPI-ZOSTER-044 VE US)

**First published:** 21/07/2022

**Last updated:** 17/12/2025

Study

Finalised

## Administrative details

**EU PAS number**

EUPAS48157

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**Study ID**

48446

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**DARWIN EU® study**

No

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### Study countries

United States

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### Study description

An observational retrospective study using existing data sources.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### GlaxoSmithKline (GSK)

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

**Last updated:** 01/02/2024

Institution

#### Kaiser Permanente Southern California (KPSC)

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

**Last updated:** 01/02/2024

Institution

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Call Center EU Clinical Trials

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 09/03/2022

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**Study start date**

Planned: 21/07/2022

Actual: 21/07/2022

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**Date of final study report**

Planned: 10/12/2025

Actual: 10/12/2025

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline Biologicals SA

## Study protocol

[gsk-213825-protocol-redact.pdf](#) (702.08 KB)

[Protocol Amendment 2 Anonymized 17 Apr 2025.pdf](#) (822.17 KB)

[Protocol Amendment 1 Anonymized 16 Jul 2024.pdf](#) (1.73 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:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

For the VE objectives, an observational matched cohort design will be used. For the safety objectives, a self-controlled case series (SCCS) analysis will be conducted.

**Main study objective:**

To estimate the VE of 2 doses of RZV, given 4 weeks to 6 months apart, in preventing HZ in adults  $\geq 18$  years of age with RA and IBD.

To assess the risk of RA and IBD flares within 30 days following any RZV vaccination as compared to the risk in self-controlled comparison periods, in adults  $\geq 18$  years of age with RA and IBD respectively.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Self-controlled case series

## Study drug and medical condition

**Medicinal product name**

SHINGRIX

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

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BK03) zoster, purified antigen

zoster, purified antigen

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**Medical condition to be studied**

Herpes zoster

## Population studied

**Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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**Special population of interest**

Immunocompromised

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**Estimated number of subjects**

21500

## Study design details

## **Outcomes**

Number of incident HZ cases in participants with RA and IBD

Incidence rate of HZ in participants with RA and IBD

Number of incident RA and IBD flare cases

Number of incident HZ cases in participants with:

-IBD stratified by condition and age

-RA, stratified by age

-RA or IBD, stratified by condition (in those receiving second dose  $\geq 4$  weeks after first dose and those receiving second dose  $> 6$  months after first dose)

-RA and IBD (from 1st dose)

Incidence rate of HZ in participants with:

-IBD, stratified by condition and age

-RA, stratified by age

-RA or IBD, stratified by condition (in those receiving second dose  $\geq 4$  weeks after first dose and those receiving second dose  $> 6$  months after first dose)

-RA and IBD (from 1st dose)

Number of incident IBD flare cases stratified by condition

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## **Data analysis plan**

For the VE analyses, the number and characteristics of individuals in each cohort will be described and compared.

Overall incidence rates of HZ for the 2-dose (4 weeks to 6 months) RZV vaccinated cohort and the matched unvaccinated cohort will be calculated by dividing the number of HZ cases by the total number of person-years.

Adjusted HRs and 95% confidence intervals (CIs) comparing HZ incidence rates in the 2-dose (4 weeks to 6 months) RZV cohort, and the matched unvaccinated cohort will be estimated by Cox proportional hazards regression models adjusting for potential confounders.

VE will be calculated from the hazard ratio (HR) obtained from Cox regression analysis.

For the primary safety analyses, characteristics of individuals with RA or IBD who meet inclusion criteria will be described.

Incidence rates for RA or IBD (UC or CD) flare for risk periods and comparison periods will be calculated by dividing the number of flares by person-time.

Relative risks (95% CI) for flare comparing risk and comparison periods overall and by first dose and second dose will be estimated using conditional Poisson regression.

## 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**

Kaiser Permanente Health Connect 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