

# 212853 - Shingrix for intramuscular injection Drug Use Investigation

**First published:** 26/04/2022

**Last updated:** 04/04/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS46662

---

### Study ID

46663

---

### DARWIN EU® study

No

---

### Study countries

Japan

---

### Study description

The purpose of this prospective, descriptive, multi-center, drug utilization study is to assess the safety of Shingrix vaccine when administered in Japanese adults for the first time.

---

## Study status

Ongoing

## Research institutions and networks

### Institutions

**GlaxoSmithKline (GSK)**

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

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

**Institution**

### 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**

Planned: 14/09/2020

Actual: 14/09/2020

---

### **Study start date**

Planned: 31/10/2020

Actual: 09/10/2020

---

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

Planned: 15/04/2026

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[gsk-212853-protocol-redact.pdf](#) (176.84 KB)

## Regulatory

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

Yes

---

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

Non-EU RMP only

## Methodological aspects

Study type

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Safety study (incl. comparative)

**Main study objective:**

To assess the presence or absence of issues and concerns related to safety of Shingrix under practical use conditions.

## Study drug and medical condition

**Medicinal product name**

SHINGRIX

---

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

HERPES ZOSTER VACCINE (RECOMBINANT, ADJUVANTED)

---

**Anatomical Therapeutic Chemical (ATC) code**

(J07BK03) zoster, purified antigen

zoster, purified antigen

---

**Medical condition to be studied**

Herpes zoster

## Population studied

## Age groups

- Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
- 

## Estimated number of subjects

7500

## Study design details

### Outcomes

Occurrence of Solicited adverse events and Unsolicited adverse events

---

### Data analysis plan

Analytical methods include:

- Safety: calculate incidence proportion of vaccine related adverse reaction.
- Consideration of covariates: consideration for covariates which may relate to safety (incidence proportion of vaccine related adverse reaction) by calculation odds ratio and 95% confidence interval, figure out forest-plot if necessary.

## 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)

Other

---

### Data sources (types), other

Prospective patient-based data collection

## 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