

# Post-Licensure Observational Study of the Safety of GARDASIL(TM) in Males (V501-070)

**First published:** 01/06/2017

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17675

---

### Study ID

50012

---

### DARWIN EU® study

No

---

### Study countries

 United States

---

### Study description

This is a post-licensure observational cohort study to describe the general safety of GARDASIL(TM) in males by estimating the rate of health outcomes resulting in an emergency room visit or hospitalization in a pre-defined risk period after vaccination, the rate of specific events (e.g. syncope, epilepsy, convulsions, and allergic reactions) on the day of vaccination, and the rate of new-onset autoimmune conditions after vaccination.

---

## Study status

Finalised

## Research institutions and networks

### Institutions

[Merck Sharp & Dohme LLC](#)

 United States

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

**Last updated:** 08/07/2025

**Institution**

**Pharmaceutical company**

### Networks

[Large healthcare claims database in the United States](#)

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@merck.com

Study contact

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

### Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 06/04/2010

---

### Study start date

Actual: 23/06/2011

---

### Data analysis start date

Planned: 01/06/2019

Actual: 01/06/2019

---

### Date of interim report, if expected

Actual: 09/12/2016

---

### Date of final study report

Planned: 31/12/2019

Actual: 28/06/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.

## Study protocol

[V501-070-01 Protocol Summary.pdf](#) (319.33 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

NCT01567813,V501-031

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

This is a post-licensure observational cohort study to describe the general safety of GARDASIL(TM) in males.

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Descriptive observational study

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J07BM01) papillomavirus (human types 6, 11, 16, 18)

papillomavirus (human types 6, 11, 16, 18)

## Population studied

### Short description of the study population

Male patients who received at least one dose of GARDASIL® identified from the Optum research database in the US from 16 October 2009 to 31 December 2016 with follow up through 31 May 2017.

---

### Age groups

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 years)
  - Adults (18 to < 46 years)
- 

### Estimated number of subjects

44000

## Study design details

### Outcomes

The primary outcome is the incidence of health outcomes resulting in an emergency room visit or hospitalization after receipt of GARDASIL(TM) compared to post-vaccination self-comparison periods. The secondary outcomes are (1) Incidence of health outcomes resulting in an emergency room visit or hospitalization following the first dose of GARDASIL(TM), (2) incidence of syncope, convulsive syncope, epilepsy, convulsions, head trauma, and allergic reactions on the day of vaccination, and (3) incidence of new-onset

autoimmune conditions.

---

### **Data analysis plan**

Incidence and relative risks will be calculated for primary and secondary outcomes. Relative risks will be calculated as the ratio of the incidence of the health outcome in the risk and comparison periods. Confidence intervals (CIs) will be calculated using the mid-probability exact method.

## Documents

### **Study results**

[p070v501\\_final-redaction.pdf](#) (7.22 MB)

---

### **Study report**

[V501-070-01 Study Results-Interim Report.pdf](#) (2.01 MB)

[V501-070-supplemental-report-aug-2020\\_Final Redaction Pages 1-73.pdf](#)  
(935.81 KB)

### **Study, other information**

[V501-070-supplemental-report-aug-2020\\_Final Redaction Pages 1-73.pdf](#)  
(935.81 KB)

### **Study publications**

[Amend KL, Turnbull B, Zhou L, Marks MA, Velicer C, Saddier P, Seeger JD. Vaccin...](#)

[Seeger JD, Amend KL, Turnbull BR, Zhou L, Marks MA, Velicer C, Saddier P. Incid...](#)

[Amend KL, Turnbull B, Zhou L, Marks MA, Velicer C, Saddier P, Seeger JD. Safety...](#)

---

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)

[Administrative healthcare records \(e.g., claims\)](#)

[Other](#)

---

### Data sources (types), other

Medical chart review

## 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