

# A Post-licensure Surveillance Program for the Safety of GARDASIL™ in a Managed Care Organization Setting (V501-031)

**First published:** 04/05/2017

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17730

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### Study ID

17731

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### DARWIN EU® study

No

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### Study countries

United States

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### Study description

This study describes the general safety of Gardasil™ when administered to females as part of routine medical care at a large integrated healthcare system.

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## 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**

Two large integrated healthcare systems in the  
United States California

## Contact details

### Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme Corp.  
ClinicalTrialsDisclosure@merck.com

## Study contact

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

### Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

## Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 04/11/2007

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### Study start date

Actual: 08/01/2007

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### Data analysis start date

Actual: 06/01/2008

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### Date of final study report

Actual: 13/12/2010

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Corp.

## Regulatory

## Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

Study Number: V501-031NCT number: NCT01078220

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the general safety of Gardasil™ when administered to females as part of routine healthcare.

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Observational surveillance

## 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)

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**Medical condition to be studied**

Human papilloma virus immunisation

## Population studied

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

Females who received GARDASIL™ vaccination.

### **Inclusion Criteria for the Primary Populations**

#### **For Monitoring Short-Term Safety**

1. a female between ages 9-26 years at the time of first dose of GARDASIL™
2. completes the series of 3-dose regimen of GARDASIL™ within 12 months of time (between the first and third doses) with at least an interval of 28 days between dose 1 and dose 2 and 12 weeks between dose 2 and dose 3.

#### **For Evaluation of Inadvertent Exposure to GARDASIL™ During Pregnancy**

1. receives at least one dose of GARDASIL™ either up to 30 days prior to the date of conception during the study period in which accrual of the primary population takes place or at any time between conception and the day the pregnancy is resolved.

#### **For Evaluating Select Autoimmune Conditions**

1. a female who has received at least one dose of GARDASIL™
2. has been a member within the same MCO for at least 12 months prior to the receipt of GARDASIL™ (for medical record review)

### **Inclusion Criteria for the Reference Groups**

#### **For Monitoring Short-Term Safety**

1. females between ages 9-26 years at the time of first dose of GARDASIL™

### **Inclusion Criteria for the Secondary Short-term Safety Analysis Cohort**

1. receives one or two doses of GARDASIL™; or
2. Off -label use of at least one dose of GARDASIL™

## **SUBJECT/PATIENT EXCLUSION CRITERIA**

### **2.3.1 Exclusion Criteria for the Primary Populations**

#### **For Monitoring Short-Term Safety**

1. males
2. receives incomplete regimen of GARDASIL™
3. completes the 3-dose regimen of GARDASIL™ in more than 12 months of

time.

4. Less than a 28 day interval between doses 1 and 2 or less than a 12-week interval between doses 2 and 3 of GARDASIL™.

5. younger than 9 or older than 26 years of age at receipt of first dose

For Evaluation of Pregnancy Safety

1. males

2. no record of pregnancy at the MCO

For Evaluating Select Autoimmune Conditions

1. have been member of the same MCO for less than 12 months prior to receiving the first dose of GARDASIL™ (for medical record review)

2. males

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### **Age groups**

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 years)
  - Adults (18 to < 46 years)
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### **Estimated number of subjects**

189629

## **Study design details**

### **Outcomes**

The primary outcome is incidence rates of health outcomes resulting in emergency room visits or hospitalizations following receipt of Gardasil™, compared to post-vaccination self-comparison. The secondary outcomes are: 1. To provide the descriptive epidemiology of the outcomes of pregnancy exposures to Gardasil™ 2. To provide the descriptive epidemiology of the

outcomes of 16 pre-specified new onset autoimmune conditions after receipt of Gardasil™

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### **Data analysis plan**

For each health outcome that results in a hospitalization or emergency room visit during the risk and/or self-comparison periods, the incidence rates will be calculated and the relative risk of health outcomes as estimated by the odd ratios and 95% confidence intervals will be estimated with conditional logistic 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 sources (types)**

[Electronic healthcare records \(EHR\)](#)

## 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