

# 207644 - Meta analysis of HPV-associated CIN2, CIN2+ and CIN3+ cases in efficacy studies according to baseline cytology and DNA status.

**First published:** 21/02/2017

**Last updated:** 01/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS17902

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### Study ID

31689

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### DARWIN EU® study

No

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### Study countries

 Belgium

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### Study description

This analysis is performed following the outcome of discussion in the HPV Safety Review Team about the potential imbalance observed in the incidence of Cervical Intraepithelial Neoplasms (CIN)2+ and CIN3+ in HPV-015 study: more CIN2+ cases were accrued in the vaccine group in subjects with high grade cytology and who were DNA positive at baseline (before vaccination). This was noticed while preparing a response to questions received by EMA on the submission for HPV-015 study and was decided to investigate further by looking to other efficacy studies including younger subjects (<25 years) and pooled.

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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

### Contact details

#### Study institution contact

Nicolas Folschweiller Vx.publicdisclosureglobal@gsk.com

Study contact

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

## Primary lead investigator

Nicolas Folschweiller

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 30/01/2017

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### Study start date

Actual: 31/01/2017

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### Date of final study report

Actual: 30/06/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GSK Vaccines

## Study protocol

[gsk-207644-sap-redact.pdf](#) (405.36 KB)

## Regulatory

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

No

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

Not applicable

## 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:**

Other

**If 'other', further details on the scope of the study**

Safety Pooling

**Data collection methods:**

Secondary use of data

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**Main study objective:**

- Provide a summary table on incidence of cases of CIN2, CIN2+, CIN3+ in each group and study, according to baseline status. - Cumulative incidence of CIN2, CIN2+ and CIN3+ will be presented in the form of a graph. - Type distribution for CIN2, CIN2+ and CIN3+ cases will be provided overall and by cytology status at baseline (Normal/Low/High).

## Study Design

### **Non-interventional study design**

Systematic review and meta-analysis

## Study drug and medical condition

### **Medicinal product name**

CERVARIX

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### **Medicinal product name, other**

Havrix

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### **Medical condition to be studied**

Human papilloma virus test

## Population studied

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

Female subjects with high grade cytology and who were DNA positive at baseline (before vaccination).

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## **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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## **Estimated number of subjects**

1

# Study design details

## **Outcomes**

- Demographic characteristics presented by pooled studies. - Baseline cytology and DNA status. - Baseline cytology and DNA status by HPV serostatus. - Summary on incidence of CIN2, CIN2+, CIN3+ cases, in each group and study. - Cumulative incidence of CIN2, CIN2+ and CIN3+. - Type distribution for CIN2, CIN2+ and CIN3+ cases: overall and by baseline cytology status.

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## **Data analysis plan**

All analysis will be descriptive in nature with the intent to understand the difference in incidence of CIN cases. Interpretation from this analysis needs to be made carefully by considering that this is a post-hoc analysis and no formal sample size computations were done for evaluation of the study objectives. Subjects enrolled in the Clinical studies in this analysis were not randomised for DNA status and cytology status at baseline.

# Documents

## **Study results**

## 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](#)

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### Data sources (types), other

Study results

## 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