

217743 - An observational, retrospective database post-authorisation safety study (PASS) to assess trends and changes over time in incidence of anal cancer and feasibility for a case-control study in European countries that introduced Cervarix in their National Immunisation Programmes (NIP) (EPI-HPV-099 VS EUR DB)

**First published:** 04/08/2021

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS42373

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### Study ID

48885

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## **DARWIN EU® study**

No

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### **Study countries**

- ☐ Denmark
  - ☐ Finland
  - ☐ Netherlands
  - ☐ Norway
  - ☐ United Kingdom
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### **Study description**

The aim of this study is to assess trends and changes over time in incidence of anal cancer using data reported to the national cancer registries in Finland, the Netherlands, England, Denmark, and Norway and to carry out an assessment of feasibility to conduct a case-control study in any of these 5 European countries aiming to determine the impact and effectiveness of GSK's HPV vaccine against anal cancer in females and males.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### [Finnish Cancer Registry](#)

- ☐ Finland

**First published:** 14/09/2012

**Last updated:** 01/06/2018

**Institution**

Other

ENCEPP partner

## Finnish Cancer Registry

☐ Finland

**First published:** 14/09/2012

**Last updated:** 01/06/2018

**Institution**

Other

ENCEPP partner

## Public Health Evaluation and Projection/Vaccine Safety Evaluation, National Institute for Health and Welfare

☐ Finland

**First published:** 22/05/2018

**Last updated:** 24/10/2019

**Institution**

Educational Institution

Laboratory/Research/Testing facility

ENCEPP partner

## The Netherlands Cancer Registry Netherlands, National Cancer Registration and Analysis Service

UK, The Danish Cancer Registry Denmark, The Cancer Registry of Norway Norway, Dutch vaccination registry (Præventis) Netherlands, Child Health Information Systems England, Danish vaccination registry Denmark, Norwegian vaccination registry Norway

## 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

Eero Pukkala

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 14/07/2021

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**Study start date**

Actual: 12/08/2021

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**Date of final study report**

Actual: 27/03/2023

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

## Study protocol

[Redacted EPI-HPV-099 Protocol Amendment 2 Anonymized 27 Sep 2022.pdf](#)  
(540.92 KB)

## 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)

## 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:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess trends and changes over time in the age-standardised incidence and in the crude incidence of anal cancer by age category (in the case of crude incidence), by sex, HPV-type and histological classification for each country\* separately. \*Five European countries are considered for this study and each country will be selected based on a set of criteria.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational, retrospective database study

## Study drug and medical condition

**Name of medicine**

CERVARIX

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**Medical condition to be studied**

Anal cancer

## Population studied

**Short description of the study population**

The study population included males and females of all age groups identified from the national cancer registries in Finland, the Netherlands, England, Denmark, and Norway to understand the incidence of anal cancer.

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**Age groups**

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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**

Other

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**Special population of interest, other**

Patients with anal cancer

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## Estimated number of subjects

0

## Study design details

### Outcomes

Age-standardised and crude incidence of anal cancer by age category (in the case of crude incidence), by sex, HPV-type and histological classification for each country separately, incidence of small intestine cancer by age category and sex for each country separately. Number of anal cancer cases expected to demonstrate vaccine effectiveness for each country separately.

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### Data analysis plan

Analysis will be performed using the country-specific data extracted from the national cancer registries as per defined population and timeframe.

## Documents

### Study results

[Study\\_Report\\_Interim\\_Anonymized.pdf](#)(6.38 MB)

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## 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)

[Disease registry](#)

[Other](#)

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### Data sources (types), other

Statistical Office i.e. EUROSTAT, Office for National Statistics (UK)

## 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