

# GS-EU-276-4027: A Cross Sectional Post Authorization Safety Study to Assess Healthcare Provider's Level of Awareness of Risk Minimisation Materials for Truvada® for Pre Exposure Prophylaxis in the European Union

**First published:** 13/06/2017

**Last updated:** 16/02/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS19479

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### Study ID

26881

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### DARWIN EU® study

No

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### Study countries

-  France
  -  Germany
  -  Ireland
  -  Netherlands
  -  Norway
  -  United Kingdom
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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Gilead Sciences

**First published:** 12/02/2024

**Last updated:** 12/02/2024

**Institution**

**Pharmaceutical company**

**Multiple centres:** 200 centres are involved in the study

## Contact details

### Study institution contact

Gilead Study Director [GileadClinicalTrials@gilead.com](mailto:GileadClinicalTrials@gilead.com)

Study contact

[GileadClinicalTrials@gilead.com](mailto:GileadClinicalTrials@gilead.com)

**Primary lead investigator**  
Study Director Gilead

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 30/08/2016

Actual: 30/08/2016

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### **Study start date**

Planned: 31/07/2017

Actual: 04/10/2017

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### **Date of interim report, if expected**

Planned: 30/11/2017

Actual: 30/11/2017

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

Planned: 28/09/2018

Actual: 22/10/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences Europe Ltd

## Study protocol

[amd-1.2-prot-GS-EU-276-4027.pdf](#) (821.98 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:**

Other

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

Healthcare providers level of awareness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The objective is to determine healthcare providers' level of awareness of Risk Minimisation Materials and appropriate use and risks associated with Truvada for a PrEP indication

## Study Design

**Non-interventional study design**

Cross-sectional

## Study drug and medical condition

**Medical condition to be studied**

HIV infection CDC Group I

## Population studied

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

Healthcare Providers (HCPs) from France, Germany, Ireland, the Netherlands, Norway, and the United Kingdom (UK) recruited from the same population of HCPs that were targeted for the distribution of the Truvada for PrEP risk minimisation measures (RMMs) as agreed with the national competent authorities.

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## **Age groups**

- 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**

Immunocompromised

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## **Estimated number of subjects**

200

# Study design details

## **Data analysis plan**

Responses to questions for all completed surveys will be analyzed using descriptive statistical analysis. Data from partially completed surveys will be evaluated separately. Characteristics for responders and non-responders will be compared based on country and HCPs specialty. Continuous variables will be described by the mean, standard deviation, median and range. Categorical variables will be described by the number and proportion in each category. The

amount of missing data for each variable will be reported. Data will be presented by means of summary tables, graphs and listings. No formal hypothesis testing will be conducted. Gilead considers 80% the threshold for acceptable awareness of the RMMs.

## Documents

### Study results

[GS-EU-276-4027-PASS Report\\_v1.0\\_22OCT2018 with signature\\_f-redact.pdf](#)

(170.03 KB)

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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)

[Other](#)

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### Data sources (types), other

This study consists of a cross sectional survey, which will be conducted in France, Germany, Ireland, Netherlands, Norway, Spain, and the United Kingdom

in order to assess prescriber awareness of the Risk Minimisation Materials (RMMs).

## 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