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

Study ID

26881

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Netherlands
- [ ] Norway
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Multiple centres: 200 centres are involved in the study

Contact details

Study institution contact

Gilead Study Director GileadClinicalTrials@gilead.com

Study contact

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

Study start date

Planned: 31/07/2017

Actual: 04/10/2017

Date of interim report, if expected

Planned: 30/11/2017

Actual: 30/11/2017

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

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

Study type:

Non-interventional study

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

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.

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)

Special population of interest

Immunocompromised

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)

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No