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

PURI
https://redirect.ema.europa.eu/resource/26881

EU PAS number
EUPAS19479

Study ID
26881

DARWIN EU® study
No

Study countries
France
Germany
Ireland
Netherlands
Norway
United Kingdom

Study status
Finalised

Research institution 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

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