# A Prospective, Longitudinal, Observational Registry of Truvada for HIV -1 Pre-Exposure Prophylaxis (PrEP) of Adults and Adolescents in Europe

**First published:** 24/06/2020

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS35892

**Study ID**

43327

**DARWIN EU® study**

No

**Study countries**

Belgium

Denmark

France

Germany

Norway

Portugal

Sweden

United Kingdom

**Study description**

Note: This study was cancelled in agreement with the EMA. GS-EU-276-4487: This study is a prospective, longitudinal, observational, and voluntary participation registry of the real-world usage of Truvada for Pre-Exposure Prophylaxis (PrEP) to prevent Human Immunodeficiency Virus Type 1 (HIV-1) infection in adults and adolescents in Europe. The primary objectives of this study are to: (1) Describe how Truvada for PrEP is prescribed or self-initiated, including the dosing pattern (dose and schedule as daily/intermittent), (2) Characterize the demographics of adults and adolescents who were prescribed or are taking Truvada for PrEP and their HIV risk factors, (3) Characterize the nature and frequency of individual monitoring after initiating Truvada for PrEP, including any available information on adherence, (4) Document any cases of new HIV diagnoses and development of any resistance to Truvada, and selected safety data, and (5) Summarize the characteristics of healthcare professionals (HCPs) who prescribe Truvada for PrEP.

**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: 45 centres are involved in the study

# Contact details

**Study institution contact**

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

**Primary lead investigator**

Gilead Study Director

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 31/07/2020

Actual: 02/09/2021

**Study start date**
Planned: 23/12/2020

Actual: 02/09/2021

**Date of final study report**
Planned: 31/03/2025

Actual: 02/09/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Gilead Sciences

## Study protocol

GS-EU-276-4487-appendix-16.1.1-protocol v1.4_f-redact.pdf (1.43 MB)

## 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 topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of this study is to characterize the real-world use of Truvada for PrEP to prevent HIV-1 infections in adults and adolescents in Europe.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

This is a prospective, longitudinal, observational, and voluntary participation registry designed to characterize the real-world use of Truvada for PrEP to prevent HIV-1 infections in adults and adolescents in Europe.

## Study drug and medical condition

**Medicinal product name**

TRUVADA

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**Medical condition to be studied**

Prophylaxis against HIV infection

# Population studied

**Short description of the study population**

The registry population will consist of adults and adolescents who are HIV-1 negative and are taking Truvada for PrEP. Individuals who have either self-initiated Truvada for PrEP or have been prescribed Truvada for PrEP and are being monitored while on Truvada for PrEP will be informed about the registry by their HCPs at one of the participating sites.
Inclusion Criteria:
-HIV-1 negative adults and adolescents who are deemed to be at high risk for acquiring HIV-1
-HIV-1 negative adults and adolescents who provided consent / assent and, depending on local country regulations, parental or legal guardian permission to participate in the registry
-HIV-1 negative adults and adolescents who are receiving Truvada for HIV PrEP, either as a daily or intermittent regimen, and that are clinically monitored
Exclusion Criteria:
-Individuals currently participating in a clinical study of HIV PrEP

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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)
- Adults (75 to < 85 years)
- Adults (85 years and over)

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**Estimated number of subjects**

300

## Study design details

**Outcomes**

Describe how Truvada for PrEP is prescribed or self-initiated, Characterize demographics of individuals who were prescribed or are taking Truvada for PrEP, Characterize the nature and frequency of individual monitoring after initiation, Document new cases of HIV diagnoses and development of any resistance to Truvada, and Summarize characteristics of HCPs who prescribe Truvada for PrEP.

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**Data analysis plan**

Descriptive data analysis will be used to summarize the available data. There are no statistical hypotheses to evaluate. Categorical variables will be reported by proportions and continuous variables will be reported by mean, standard deviation, minimum, median, and maximum. Prescriber characteristics will be summarized. Demographics and clinical characteristics of individuals on Truvada for PrEP will be analyzed. The products prescribed and available prescription details, the frequency of monitoring, and any relevant data on adherence monitoring will be summarized. Seroconversion cases and results of resistance testing will be summarized. Reports of treatment-related renal and bone adverse drug reactions (SADRs and ADRs) will be summarized. Females

participants in the registry who are pregnant will also be analyzed. Data will be presented overall, and by age group (adolescents and young adults) and risk factors for HIV transmission.

# 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**

Prospective patient-based data collection

## 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