Comparing Weight Gain on F/TAF and Placebo Using DISCOVER and iPrEx Study Data

First published: 25/03/2025

Last updated: 08/04/2025

Study Planned

Administrative details

EU PAS number

EUPAS1000000509

Study ID

1000000509

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Brazil
- ☐ Canada
- ☐ Denmark

- [ ] Ecuador
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Italy
- [ ] Netherlands
- [ ] Peru
- [ ] South Africa
- [ ] Spain
- [ ] Thailand
- [ ] United Kingdom
- [ ] United States

Study description

GS-US-311-7562: This is a non-interventional study utilizing data from 2 Phase 3 Clinical studies, iPrEx (Study CO-US-104-0288; NCT00458393; emtricitabine/tenofovir disoproxil fumarate (coformulated; Truvada®, FTC/TDF) versus placebo) and DISCOVER (Study GS-US-412-2055; NCT02842086; emtricitabine/tenofovir alafenamide (coformulated; Descovy®, F/TAF) versus FTC/TDF) to compare F/TAF with placebo weight trajectories, using the common FTC/TDF groups as a negative control to assess the validity of the primary analysis results.

The primary objective of this study is to compare weight change/trajectory distributions between F/TAF and placebo cohorts.

Study status

Planned

Research institutions and networks

Institutions

Gilead Sciences

First published: 12/02/2024

Last updated: 12/02/2024

Institution | Pharmaceutical company

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: 01/12/2025

Study start date

Planned: 30/04/2025

Date of final study report
Planned: 31/03/2026

Study protocol

GS-US-311-7562-appendix-16.1.1-Observational Study Protocol_f-redact.pdf(1.4 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Other

Study topic, other:

Research method

Study type:

Non-interventional study

Data collection methods:

Secondary use of data

Study design:

This study will utilize existing data collected during 2 large Phase 3 clinical studies of FTC/TDF and F/TAF to conduct an indirect comparison of F/TAF (DISCOVER) and placebo treatment groups (iPrEX), using the common FTC/TDF treatment groups as negative controls.

Main study objective:

To compare weight change/trajectory distributions between F/TAF and placebo cohorts from the DISCOVER and iPrEx studies

Study drug and medical condition

Name of medicine

DESCOVY

Name of medicine, other

emtricitabine/tenofovir alafenamide

Study drug International non-proprietary name (INN) or common name

EMTRICITABINE

TENOFOVIR ALAFENAMIDE

Anatomical Therapeutic Chemical (ATC) code

(J05AR17) emtricitabine and tenofovir alafenamide

emtricitabine and tenofovir alafenamide

Medical condition to be studied

HIV infection

Additional medical condition(s)

Pre-Exposure Prophylaxis of HIV-1 Infection

Population studied

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Study design details

Setting

Both studies that will be used for this study recruited individuals not living with HIV, all of whom were adults aged at least 18 years, and with 1 or more behavioral risk factors for contracting HIV-1.

All iPrEx study participants were born male, and were recruited from North and South America, South Africa, and Thailand.

All DISCOVER study participants were born male or were TGW, and were recruited from North America, 8 European Union (EU) countries, and the UK.

Data management

Data sources

Data source(s), other

All data that will be used were collected as part of 2 Phase 3 randomized clinical studies.

Data from both studies are owned by Gilead Sciences (Gilead), and scale weight was assessed similarly across studies consistent with routine clinical practice.

Data sources (types)

Clinical trial

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes