# Multi-country, non-interventional, cohort study of the effectiveness, safety, adherence, and health-related quality of life in HIV-1 infected adult patients receiving Bictegravir/ Emtricitabine/Tenofovir alafenamide (B/F/TAF) (BIC-STaR)

**First published:** 09/02/2018

**Last updated:** 17/09/2025

Study Finalised

## Administrative details

**EU PAS number**

EUPAS22185

**Study ID**

40000

**DARWIN EU® study**

No

**Study countries**

France
Germany
Ireland
Italy
Netherlands
Spain
Türkiye
United Kingdom

**Study description**

GS-EU-380-4472: This non-interventional cohort study aimed to evaluate the effectiveness, safety, adherence, resource utilization and participants' health condition via Patient Reported Outcome (PRO) questionnaires, during treatment with B/F/TAF in routine clinical care.

**Study status**

Finalised

## 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**
Actual: 11/09/2017

**Study start date**
Actual: 27/06/2018

**Data analysis start date**
Actual: 29/03/2019

**Date of final study report**
Actual: 15/05/2025

# Sources of funding

# More details on funding

Gilead Sciences Europe Ltd

# Study protocol

GS-EU-380-4472-appendix-16.1.1-protocol_f-redact.pdf (1.13 MB)

GS-EU-380-4472-appendix-16.1.1-protocol amendment 4_f-redact.pdf (2.46 MB)
GS-EU-380-4472-appendix-16.1.1-protocol amendment 4_f-redact.pdf (2.46 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:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

**Main study objective:**

The primary objective of this study was to evaluate the effectiveness, safety, adherence, and health-related quality of life in HIV-1 infected adult patients receiving bictegravir/ emtricitabine/tenofovir alafenamide (B/F/TAF).

## Study Design

**Non-interventional study design**

Cohort

Other

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**Non-interventional study design, other**

Prospective, non-interventional

## Study drug and medical condition

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

BICTEGRAVIR

EMTRICITABINE

TENOFOVIR ALAFENAMIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(J05AR20) emtricitabine, tenofovir alafenamide and bictegravir

emtricitabine, tenofovir alafenamide and bictegravir

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**Medical condition to be studied**

HIV infection

## Population studied

**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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**Estimated number of subjects**

1.435

## Study design details

**Outcomes**

To evaluate HIV-1 RNA suppression, defined as HIV-1 RNA < 50 copies/mL, at 12 months after initiating or switching to B/F/TAF.
To evaluate HIV-1 RNA suppression (<50 copies/mL) at Months 3, 6, and 24
To evaluate changes in cluster determinant 4 (CD4) cell count, CD4/CD8 ratio at Months 3, 6, 12, and 24 for all patients after initiating or switiching to B/F/TAF
To assess rates of adverse events (AEs) and serious AEs
To evaluate long-term effectiveness and safety of B/F/TAF in an extension phase through Month 60 in a subgroup of patients in Germany & France

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**Data analysis plan**

For categorical variables, numbers and percentages of patients were reported including the according 95% confidence intervals.
For continuous variables, mean, standard deviation (SD), minimum, first and third quartile (Q1, Q3), median, maximum and 95% confidence intervals were calculated, together with the total number of observations and the number of missing values.
Descriptive statistics were summarized demographics and baseline characteristics (including the type of regimen at enrolment).
Once data is available from more than one country, descriptive analyses by country was done to determine if patient heterogeneity exists across countries and sites.

The questionnaires scores were calculated according to the algorithms elaborated for these questionnaires.

## Documents

**Study report**

GS-EU-380-4472_Abbreviated NIS_CSR_synopsis_f-redact.pdf (1.43 MB)

# 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**

Yes

**Check completeness**

Yes

**Check stability**

Yes

**Check logical consistency**

Yes

## Data characterisation

**Data characterisation conducted**

Yes