

# The Evaluation of Tenofovir Alafenamide Containing Regimens vs. Tenofovir Disoproxil Fumarate Containing Regimens on Renal Outcomes for Prevention, and Treatment of HIV and/or HBV Treatment: a Systematic Literature Review and Meta-analysis

**First published:** 21/06/2024

**Last updated:** 11/03/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000194

---

### Study ID

1000000194


---

### DARWIN EU® study

No

---

## Study countries


 Australia


 Canada

 China


 France

 Italy

 Japan


 Korea, Republic of

 New Zealand

 Russian Federation

 Spain

 Taiwan

 United Kingdom

---

## Study description

GS-US-120-7229: This was a non-interventional, retrospective cohort, systematic literature review and meta-analysis in participants in randomized controlled trials or observational cohort studies with tenofovir alafenamide (TAF)-containing regimen and Tenofovir disoproxil fumarate (TDF)-containing regimen for prevention or treatment of Human Immunodeficiency Virus (HIV), and/or treatment of Hepatitis B Virus (HBV).

The primary objective of this study was to compare and quantify the renal outcomes of TAF-containing regimens versus TDF-containing regimens in people who might benefit from pre-exposure prophylaxis (PWP) and people with HBV, HIV, or HIV/HBV.

---

## Study status

Finalised

## 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](mailto:ClinicalTrialDisclosure@gilead.com)

Study contact

[ClinicalTrialDisclosure@gilead.com](mailto:ClinicalTrialDisclosure@gilead.com)

### Primary lead investigator

Gilead Study Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 31/08/2023

---

### Study start date

Actual: 01/12/2023

---

## **Date of final study report**

Planned: 02/12/2024

Actual: 24/12/2024

## Study protocol

[GS-US-120-7229-appendix-16.1.1-Original Protocol\\_f-redact.pdf](#) (1.26 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 type:**

Non-interventional study

---

## Study drug and medical condition

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

TENOFOVIR ALAFENAMIDE

TENOFOVIR DISOPROXIL FUMARATE

---

## **Anatomical Therapeutic Chemical (ATC) code**

(J05AF13) tenofovir alafenamide

tenofovir alafenamide

---

## **Medical condition to be studied**

HIV infection

Hepatitis B

Prophylaxis against HIV infection

## Population studied

### **Age groups**

- Adolescents (12 to < 18 years)
- **Adult and elderly population ( $\geq 18$  years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly ( $\geq 65$  years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

## Study design details

### **Outcomes**

Outcomes: reported renal outcomes, definition of outcomes, method of measurement, time points measured, types of effect measure (e.g., Odds ratio, Risks ratio, etc.) with 95% confidence intervals (if reported) and statistical power (i.e., p-value) (if reported), unit of measurement, number of participants who discontinued study due to renal AEs (if reported)

## Documents

### Study report

[GS-US-120-7229 CSR\\_Abtract\\_f-redact.pdf](#) (393.14 KB)

## 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.

## 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