PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: GS-US-311-1269

Date of Study: January 2015 to December 2024

Short Study Title: Study to Assess Emtricitabine/Tenofovir Alafenamide (F/TAF) in Children and Teenagers Living With Controlled HIV-1

Date of this Plain Language Summary: August 2025

The information in this summary does not include any information available after this date.

Thank you

Thank you to the participants who contributed to the clinical study for **Emtricitabine/ Tenofovir Alafenamide (F/TAF)**, brand name: **Descovy**. In addition, thank you to the parents and caregivers of the participants.

Gilead Sciences sponsored this study. We believe it is important to share the results with study participants and the general public.

If you participated in the study and have questions about the results, please speak with a doctor or staff member at the study site.

Always talk to a doctor or healthcare provider before making any treatment changes.

This document is a short summary of this study written for a general audience. Links to scientific summaries of this study can be found at the end of this document.

General information about the study

What is Human Immunodeficiency Virus (HIV)?

HIV is a virus that attacks the immune system (body's defense system) and makes it more likely for people to get sick. HIV-1 and HIV-2 are two main types of HIV. HIV can be passed on to others, including children (below 12 years of age) and teenagers (from 12 to 17 years of age). It can be passed on through bodily fluids like blood, semen, and breast milk. If HIV-1 infection is not treated, it can lead to AIDS (acquired immunodeficiency syndrome). If a person with AIDS is not treated, they may die. There is no cure for HIV-1 infection. Once people get it, they have it for life. But with proper treatment, it can be controlled.

There are medicines available to treat HIV. These medicines are called **antiretroviral (ARV)** medicines. To keep HIV in control, the doctors give a combination of ARVs. It can be hard to keep taking many medicines everyday. These medicines can have side effects as well. Children and teenagers therefore need ARVs that work well, are safe and simple to take.

F/TAF is also an ARV that falls in the category of NRTIs. It is a single pill that has a combination of 2 drugs, emtricitabine (F) and tenofovir alafenamide (TAF).

ARVs are medicines that stop the virus from growing or making copies of itself.

ARV medicines include:

- A nucleoside reverse transcriptase inhibitor (NRTI)
- A non-nucleoside reverse transcriptase inhibitor (NNRTI)
- A protease inhibitor (PI)
- An integrase strand-transfer inhibitor (INSTI)

It is approved for use in adults and teenagers weighing 35 kg (77 lbs) or more to help control HIV-1 infection. In the United States, it is also approved for treating HIV-1 infection in children weighing 14 kg (31 lbs) or more.

In this study, the researchers wanted to see if switching to an ARV combination containing F/TAF and a 3rd ARV could help children and teenagers living with controlled HIV-1.

This is a **Phase 2/3** clinical study. This means that the researchers looked at levels of drug in the body, its effectiveness and safety in the same study. This is a quicker way to determine if a treatment works and is safe enough to be used.

What was the purpose of the study?

The main purpose of the study was to learn about the levels of F/TAF in the body, how it works and how safe it is in children and teenagers living with controlled HIV-1.

The main questions the researchers wanted to answer in this study were:

- What was the **total amount** of **TAF** and its **breakdown product** tenofovir (**TFV**), found in participant's blood between one dose and the next?
- How many participants had unwanted medical events during the first 24 weeks of the treatment?

Total amount of drug in participant's blood helps researchers understand the appropriate dosing of the drug.

Breakdown product is a product formed after the drug breaks down in the body.

Researchers also wanted to know if there were any side effects that participants had during the study.

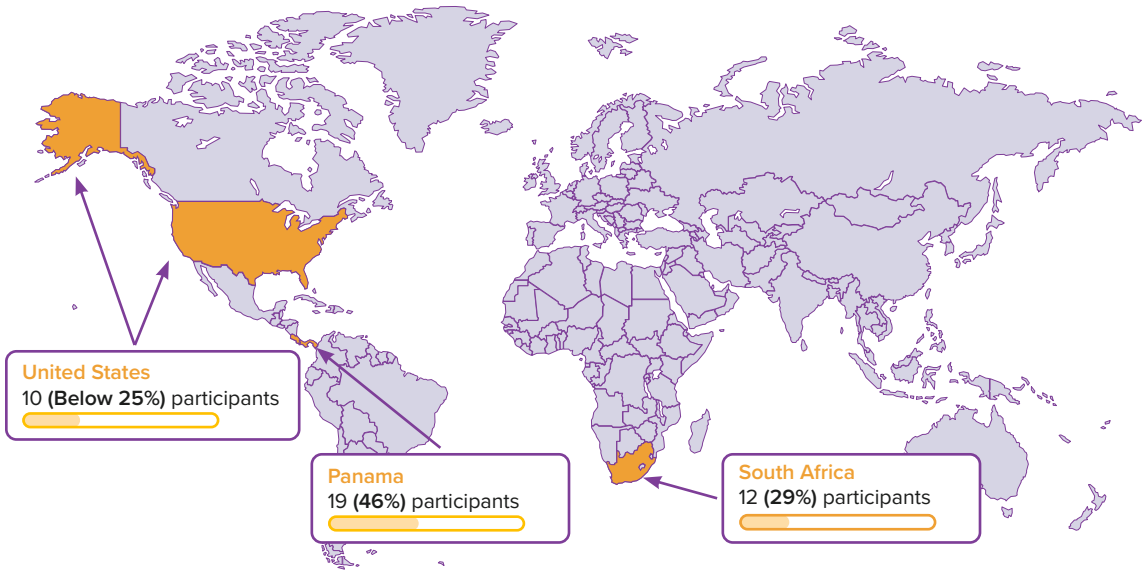
Who took part in the study?

41 children and teenagers living with HIV-1 in the United States, South Africa, and Panama took part in the study and 40 took the study treatment.

Children and teenagers could take part in the study if they:

- Met the required criteria for age and weight
- Were living with HIV-1 that was under control for at least 6 months
- Were taking combination of 2 NRTIs + 3rd ARV medicine

The participants from each country are shown below (Number (%) of participants).



The race of participants is shown below (Number (%) of participants).

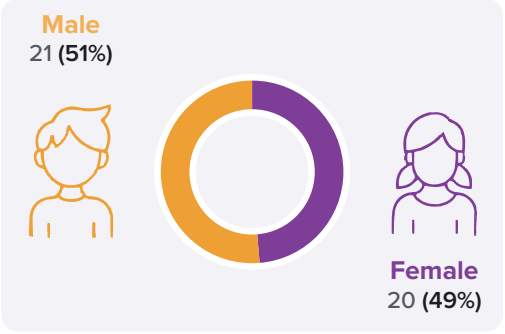
Black or African American	19 (46%)
White	3 (7%)
Other or More Than One Race	18 (44%)
Asian	1 (3%)

The ethnicity of participants is shown below (Number (%) of participants).

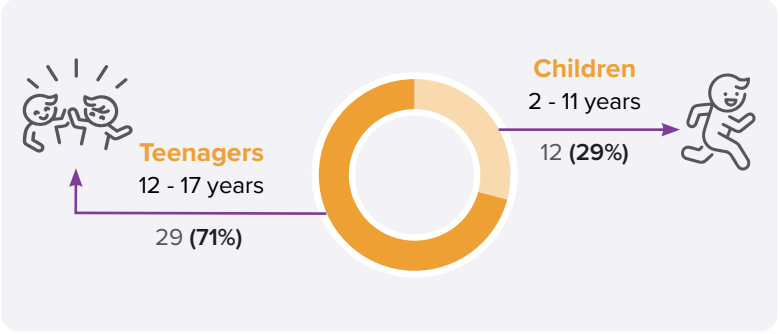
Not Hispanic or Latino	21 (51%)
Hispanic or Latino	20 (49%)

The sex and age of participants are shown below (Number (%) of participants).

Participant breakdown by sex



Participant breakdown by age



What happened during the study?

This was an **open-label** study.

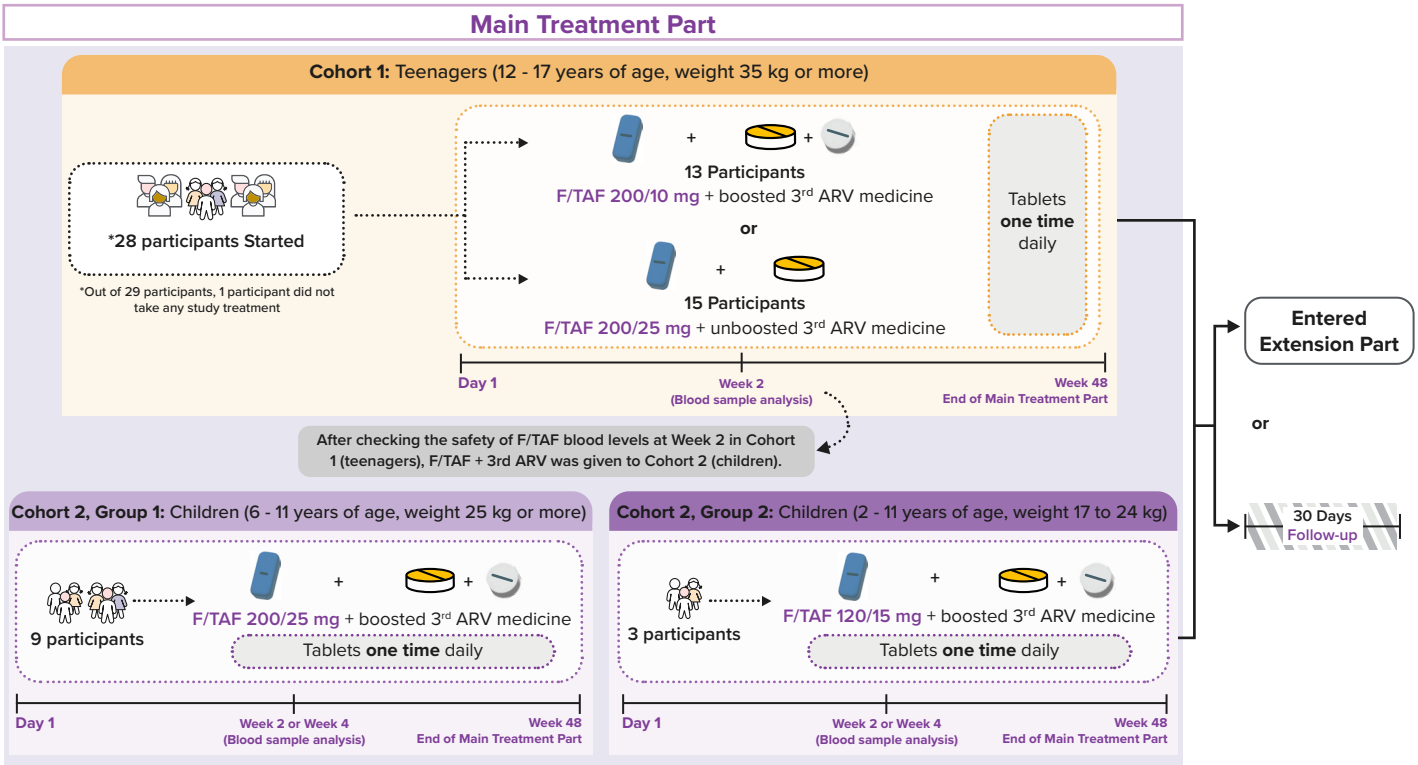
Open-label means the participant, participant's parent or caregiver, doctors, and study staff knew the treatment the participants took.

Before the study started, all participants were taking 3 HIV medicines (2 NRTIs + a 3rd ARV). In this study, they switched from 2 NRTIs to F/TAF + a 3rd ARV, which could be **boosted** or **unboosted**.

Boosted HIV medicines are taken with another drug (like ritonavir) that helps the HIV medicine to reach the required levels in the body. **Unboosted** HIV medicines are able to reach the required levels on their own and do not need a booster drug.

The study had 2 parts: **a) Main Treatment Part**, where participants took F/TAF + 3rd ARV. This lasted up to 48 weeks (almost 1 year). Researchers checked to see how much of F/TAF gets into participant's bodies, and if the F/TAF + 3rd ARV were safe, and effective in controlling HIV-1 infection. **b) Extension Part**, where the same participants could continue the same treatment.

Main Treatment Part: In this part, participants were split into 2 **cohorts**. A **cohort** is a group of individuals who share a common characteristic. **Cohort 1** included teenagers (12 to 17 years of age, weight 35 kgs or more). **Cohort 2** included children, and was further divided into 2 groups: **Group 1** (6 to 11 years of age, weight 25 kg or more) and **Group 2** (2 to 11 years of age, weight 17 to 24 kg).



Extension Part: After 48 weeks, all participants could continue in the study extension part, where they continued F/TAF along with 3rd ARV medicine. Gilead provided F/TAF through this study (or another access programme) until **a)** the participant turned 18 years of age and F/TAF was available for adults in their country, **b)** F/TAF became available for children and teenagers in their country, or **c)** Gilead decided to stop developing F/TAF in that country. Participants who did not continue in the extension part or permanently stopped the study drug were followed for safety for 30 days after the end of treatment.

What were the results of the study?

This is a summary of the main results from this study. The individual results of each participant might be different and are not in this summary. A detailed presentation of the results can be found on the websites listed at the end of this summary.

The study started with 41 participants. 40 of those participants took F/TAF, so the sections below present the results for those 40 participants.

What was the total amount of TAF and TFV, found in participant's blood between one dose and the next?

To answer this question, the researchers took blood samples from the participants before and after taking F/TAF. Out of 40 participants, the results for blood TAF levels were available for 30 participants, and TFV levels for 36 participants. The results for Cohort 1 are reported separately for participants who received F/TAF 200/10 mg with boosted 3rd ARV medicine and 200/25 mg with unboosted 3rd ARV medicine.

In these blood samples, the researchers measured the average total amount of TAF and TFV. It is measured as time * amount of drug (hour * nanogram per milliliter of blood, h*ng/mL).

The table below shows the average total amount of TAF and TFV in participant's blood.

			The average total amount of TAF and TFV in participant's blood (h*ng/mL)		
Cohort 1	**Age**	**Body Weight**	**Number of Participants with results**	**TAF**	**TFV**
F/TAF 200/25 mg + boosted 3rd ARV medicine	12 - 17 years	35 kg or more	9	201	[a]193
Cohort 1					
F/TAF 200/10 mg + unboosted 3rd ARV medicine	12 - 17 years	35 kg or more	9	140	[b]416
Cohort 2, Group 1					
F/TAF 200/25 mg + boosted 3rd ARV medicine	6 - 11 years	25 kg or more	9	211	999
Cohort 2, Group 2					
F/TAF 120/15 mg + boosted 3rd ARV medicine	2 - 11 years	17 - 24 kg	3	220	908

[a]results for 11 participants, [b]results for 13 participants

The researchers compared the levels of TAF and TFV in the blood of children and teenagers to the known levels of TAF and TFV in adults.

- **Cohort 1: The levels of TAF and TFV remained within the safe range in teenagers compared to adults, for both dose levels, whether taken with boosted or unboosted ARV medicines.**
- **Cohort 2, Group 1: Both TAF and TFV levels were higher in children compared to adults, but still within a safe range.**
- **Cohort 2, Group 2: Both TAF and TFV levels were much higher in children than adults, but still within a safe range. However, there were few children in this group, so the researchers could not make any conclusions. The Sponsor decided to do further studies to confirm the results.**

How many participants had unwanted medical events during the first 24 weeks of the treatment?

The researchers kept track of any **unwanted medical events** that the participants may have had during the study.

An **unwanted medical event** is any unwanted sign or symptom that participants may have during the study. This may or may not be caused by study treatment. The unwanted medical event is considered serious if it:

- results in death
- is life-threatening
- is considered by the study doctor to be medically important
- causes lasting problems
- requires hospital care
- causes a birth defect

The table below shows how many participants had any unwanted medical events during the first 24 weeks of the treatment.

Unwanted Medical Events

	Cohort 1 F/TAF 200/10 mg + boosted 3rd ARV medicine **or** F/TAF 200/25 mg + unboosted 3rd ARV medicine (Out of 28 participants)	**Cohort 2, Group 1** F/TAF 200/25 mg + boosted 3rd ARV medicine (Out of 9 participants)	**Cohort 2, Group 2** F/TAF 120/15 mg + boosted 3rd ARV medicine (Out of 3 participants)
	Number (%) of participants		
How many participants had any unwanted medical events?	23 **(82%)**	6 **(67%)**	2 **(67%)**
How many participants had any unwanted serious medical events?	2 **(7%)**	0	0

What side effects did participants have during the study?

Unwanted medical events can happen to the study participants when they take a study drug. In this summary, "**side effects**" are defined as unwanted medical events that the study doctors thought might be caused by the study drug. The results from several studies are usually needed to help decide if a study drug actually causes a side effect.

Below is the summary of side effects that occurred during the study:

A total of 9 out of 40 (23%) participants had side effects during the study:

- **Cohort 1: 8 out of 28 (29%) participants**
- **Cohort 2, Group 1: None reported**
- **Cohort 2, Group 2: 1 out of 3 (33%) participants**

What were the serious side effects?

- **None of the participants had any serious side effects or died due to any side effects during the study.**

What were the non-serious side effects?

- **The most common non-serious side effect was headache, reported by 3 out of 28 (11%) participants in Cohort 1.** There were other non-serious side effects, but those occurred in fewer participants. Some participants may have had more than 1 non-serious side effect. These side effects were not serious in nature and did not meet the definition of 'serious side effects'.

How has this study helped researchers?

The researchers learned about the levels of F/TAF at different doses, how safe it is, and how it works with other HIV medicines in children and teenagers living with controlled HIV-1.

The results from studies are needed to help decide which treatments work and are safe. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Gilead Sciences plans to have further clinical studies with F/TAF.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

Organization (Website)	Study Identifier
European Medicines Agency www.clinicaltrialsregister.eu	EudraCT Number: 2015-001339-19
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	ClinicalTrials.gov Number: NCT02285114
Gilead Website www.gileadclinicaltrials.com	GS-US-311-1269

Please note that information on these websites may be presented in a different way from this summary.

Full Study Title: A Phase 2/3, Open-Label, Multi-Cohort Switch Study to Evaluate Emtricitabine/Tenofovir Alafenamide (F/TAF) in HIV-1 Infected Children and Adolescents Virologically Suppressed on a 2-NRTI-Containing Regimen

To learn more about clinical trials in general, please visit this page on www.clinicaltrials.gov.website

Gilead Sciences
333 Lakeside Drive, Foster City, CA 94404, USA.
Email: GileadClinicalTrials@gilead.com

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

GILEAD