PLAIN LANGUAGE SUMMARY OF CLINICAL STUDY RESULTS

Study Sponsor: Gilead Sciences

Gilead Study Number: GS-US-292-0106

Date of Study: May 2013 to June 2025

Short Study Title: Study of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Single Tablet in Adolescents with HIV-1 who were Untreated and Children with HIV-1 who were Virologically Suppressed

Date of this Plain Language Summary: April 2026

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 **E/C/F/TAF**, Brand Name: **Genvoya (GEN)**. In addition, thank you to the parents and caregivers of the participants.

Gilead Sciences sponsored this study. This summary is prepared for 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 of the study

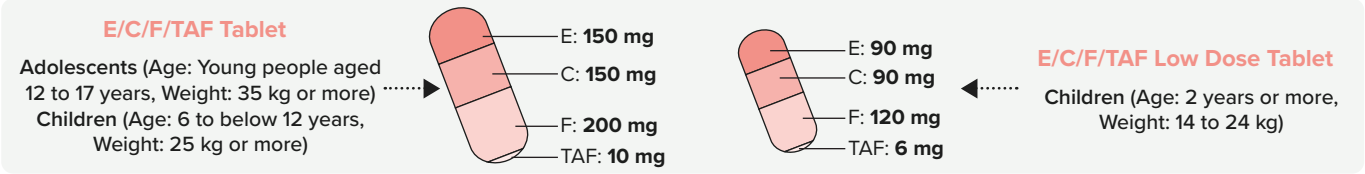
What is Human Immunodeficiency Virus (HIV)?

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. It can be passed on to others, through bodily fluids like blood, semen, and breast milk. If HIV 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 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. **ARVs** stop the virus from growing or making copies of itself. To keep HIV in control, the doctors give a combination of ARVs. However, it can be hard to keep taking many medicines everyday. These medicines can have side effects as well. Adolescents and children therefore need ARVs that work well, are safe and simple to take.

E/C/F/TAF is also an ARV. It is a single pill (tablet) that has a combination of 4 medicines—**elvitegravir (EVG/E)**, **cobicistat (COBI/C)**, **emtricitabine (F)**, and **tenofovir alafenamide (TAF)**.

This medicine is approved for adults. It is also approved in children as young as 2 years and 14 kg in some regions. It helps keep HIV-1 under control. In this study, researchers wanted to confirm whether the adult dose of E/C/F/TAF is safe and effective for adolescents (young people aged 12 to 17 years) who had not received HIV-1 treatment before. They also studied a lower dose of E/C/F/TAF in children below 12 years old who already had well-controlled HIV-1.



This was a **Phase 2/3** clinical study. In this study, the researchers measured how much of the medicine gets in the body and the medicine's level over time before the next dose. They also checked how well it works, and monitored its safety. By combining Phase 2 and Phase 3, researchers can learn more quickly whether a treatment works and is safe enough to use.

What was the purpose of the study?

The main purpose of the study was to measure EVG and TAF levels and help confirm the dose of E/C/F/TAF in adolescents and children. It also checked the safety and effectiveness of the medicine in the participants.

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

- What was the total amount of EVG and TAF found in participants' blood?
- How many participants had **unwanted medical events** during the first 24 weeks of the treatment, and how many of these events were serious?

An **unwanted medical event** is any unwanted sign or symptom that participants may have during the study.

An 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

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

An unwanted medical event may or may not be caused by the study treatment. **Side effects** are unwanted medical events that the study doctors thought might be caused by the study drug.

Who took part in the study?

A total of 129 adolescents and children with HIV-1 from 5 different countries, took part in this study.

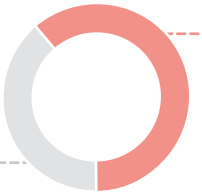
Adolescents and children took part in the study if they:

- Met required criteria for the age and weight group
- Did not receive any treatment for HIV-1 and had high levels of virus (adolescents)
- Were taking treatment for HIV-1 and had no or low levels of virus detected (children)

The map below shows the number of participants (%) from South Africa, Thailand, Uganda, the United States, and Zimbabwe.

The age of participants is shown below (Number of participants (%))

Adolescents
(12 to 17 years of age)
50 participants **(39%)**



Children
(2 to below 12 years of age)
79 participants **(61%)**

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

Black or African American	105 (81%)
Asian	22 (17%)
White	2 (2%)

The sex at birth of participants is shown below (Number of participants (%)).

Female
75 participants **(58%)**

Male
54 participants **(42%)**

All participants in the study were not Hispanic or of Latino ethnicity.

What happened during the study?

This was an **open-label**, **multi-cohort**, and **single-arm** study.

Open-label means the participants, their parents or caregivers, doctors, and study staff knew the treatment the participants received.

Multi-cohort means more than one cohort. A cohort is a group of individuals who share something in common. This study had 3 cohorts, participants of the same age and weight were included in the same cohort.

Single-arm means all participants received the same medicine, E/C/F/TAF.

The study had 48 weeks of the **Main Treatment Period**, followed by an **Extension Period**. The researchers assigned participants to 3 cohorts based on their age and weight.

Main Treatment Period consisted of 2 parts: **Part A** (for all Cohorts) and **Part B** (for Cohorts 1 and 2).

Cohort 1: Adolescents (Age: 12 to 17 years, Weight: 35 kg or more)

- **Part A (24 Participants):** At the start of the study, only a small number of participants joined initially. The researchers first checked how much of the study medicine (E/C/F/TAF) entered the participants' blood before giving it to the rest of the participants in each group. To do this, they measured the levels of EVG and TAF in the blood at Week 4. They compared these levels to those already known in adults.
- **Part B (26 Participants):** After Part A, further participants joined Part B to check the safety and effectiveness of E/C/F/TAF.

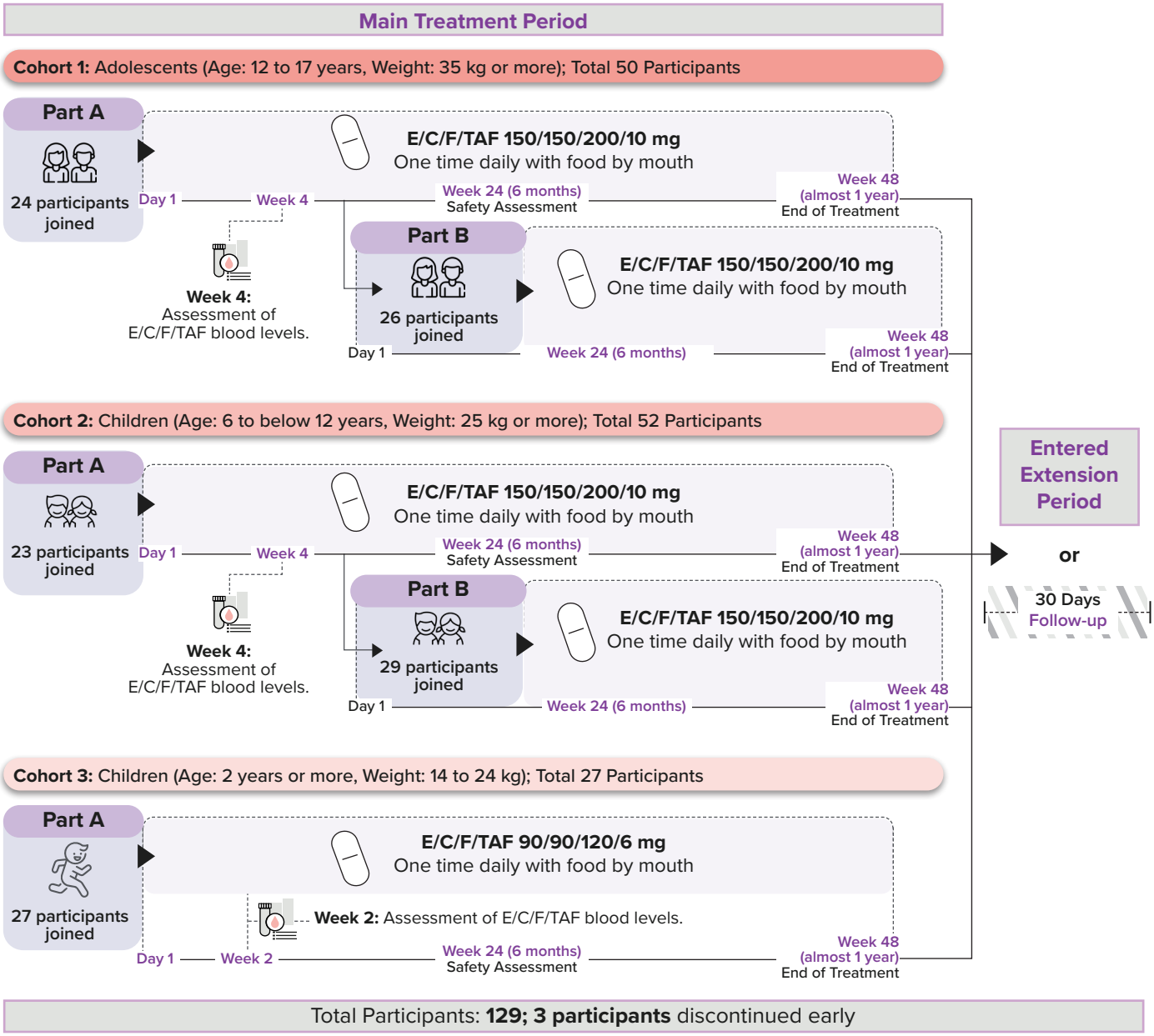
Cohort 2: Children (Age: 6 to below 12 years, Weight: 25 kg or more)

- **Part A (23 Participants):** Similar to Cohort 1, at the start of the study, only a small number of participants joined Part A. The researchers measured the levels of EVG and TAF in the blood at Week 4. They compared these levels to those already known in adults.
- **Part B (29 Participants):** After Part A, further participants joined Part B to check the safety and effectiveness of E/C/F/TAF.

Cohort 3: Children (Age: 2 years or more, Weight: 14 to 24 kg)

- **27 participants** joined this cohort in **Part A**. Part B was not applicable. The researchers measured the levels of EVG and TAF in the blood at Week 2 and compared these levels with what is already known in adults. The researchers also checked the safety and effectiveness of the study medicine (E/C/F/TAF) in these participants.

The graphics below show how the study was done.



Of the 129 participants who received the medicine, 3 participants discontinued the medicine early. All other participants completed the Main Treatment Period.

Extension Period: After 48 weeks, all participants had the choice to continue in the study Extension Period, where they continued receiving E/C/F/TAF. Gilead provided E/C/F/TAF until **a)** the participant turned 18 years of age and E/C/F/TAF was available for adults in their country, or **b)** E/C/F/TAF became available for adolescents and children in their country.

Safety was monitored throughout the Main Treatment Period and the Extension Period. In case a participant did not continue to Extension Period or stopped treatment at any time, they were followed up for safety up to 30 days after the end of treatment.

A total of 125 participants chose to take E/C/F/TAF in the Extension Period and 120 continued to take it until the end of study. Participants who continued returned for check-ups every 3 months. After 5 years for Cohorts 1 and 2, and after 2 years for Cohort 3, they switched to 6-monthly check-ups for the remainder of the Extension Period.

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.

What was the total amount of EVG and TAF found in the participants' blood during Part A?

The researchers took blood samples from the participants before and after taking E/C/F/TAF. Part A of the study included 24 participants in Cohort 1, 23 in Cohort 2, and 27 in Cohort 3. The results are based only on those with available data. The researchers measured the average total amount of EVG and TAF as time × amount of medicine (hour × nanogram per milliliter of blood, h*ng/mL) over one day.

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

			The average total amount of EVG and TAF in participant's blood (h*ng/mL)		
Cohort 1	**Age**	**Body Weight**	**Number of participants with results**	**EVG**	**TAF**
E/C/F/TAF 150/150/200/10 mg	12 to 17 years	35 kg or more	24	24000	[a]190
Cohort 2					
E/C/F/TAF 150/150/200/10 mg	6 to below 12 years	25 kg or more	23	[b]34000	[c]330
Cohort 3					
E/C/F/TAF 90/90/120/6 mg	2 years or more	14 to 24 kg	24	33000	[d]370

a: results for 23 participants; b: results for 22 participants; c: results for last measurement; d: results for 17 participants.

The researchers compared the levels of EVG and TAF in the blood of adolescents and children to the known levels of EVG and TAF in adults.

They found that the levels of EVG and TAF in adolescents (Cohort 1) and children (Cohort 2) were almost the same as the levels seen in adults. This showed that the chosen dose of E/C/F/TAF 150/150/200/10 mg was safe for adolescents and children in Cohorts 1 and 2. In younger children (Cohort 3), the EVG and TAF levels were a little higher from adult levels, but these differences did not cause any safety problems. Overall, the chosen dose in children, E/C/F/TAF 90/90/120/6 mg was also safe and effective as seen in earlier studies.

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. By Week 24, the study treated 48 participants in Cohort 1, 23 in Cohort 2, and 27 in Cohort 3. Their initial safety results are shown below.

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

Unwanted Medical Events up to Week 24			
	Cohort 1 **E/C/F/TAF** 150/150/200/10 mg (Out of 48 participants)	**Cohort 2** **E/C/F/TAF** 150/150/200/10 mg (Out of 23 participants)	**Cohort 3** **E/C/F/TAF** 90/90/120/6 mg (Out of 27 participants)
	Number of participants (%)		
How many participants had **any** unwanted medical events?	39 **(81%)**	17 **(74%)**	19 **(70%)**
How many participants had **any serious unwanted** medical events?	4 **(8%)**	0	1 **(4%)**

What side effects did participants have during the study?

The researchers also checked if participants had any side effects during the study. The results from several studies are usually needed to help decide if a study drug actually causes a side effect.

The table below shows participants with side effects during the study.

Overall Side Effects				
	Cohort 1 **E/C/F/TAF** 150/150/200/10 mg (Out of 50 participants)	**Cohort 2** **E/C/F/TAF** 150/150/200/10 mg (Out of 52 participants)	**Cohort 3** **E/C/F/TAF** 90/90/120/6 mg (Out of 27 participants)	**Total** (Out of 129 participants)
	Number of participants (%)			
How many participants had **any** side effects?	22 (44%)	14 (27%)	4 (15%)	40 (31%)
How many participants had **any serious** side effects?	1 (2%)	0	0	1 (below 1%)

None of the participants stopped taking E/C/F/TAF or died due to any side effects during the study.

What were the serious side effects during the study?

One participant in Cohort 1 had 2 serious side effects. The participant developed inflammation in the eyes (uveitis) and had trouble seeing clearly (visual impairment). Both side effects resolved without interruption of the study medicine.

What were the non-serious side effects during the study?

The table below shows the most common non-serious side effects that occurred in **at least 8%** of the study participants. These side effects did not meet the definition of 'serious side effects' mentioned above in this summary.

The table below shows participants with most common non-serious side effects during the study.

Most Common Non-Serious Side Effects

	Cohort 1 **E/C/F/TAF** 150/150/200/10 mg (Out of 50 participants)	**Cohort 2** **E/C/F/TAF** 150/150/200/10 mg (Out of 52 participants)	**Cohort 3** **E/C/F/TAF** 90/90/120/6 mg (Out of 27 participants)	**Total** (Out of 129 participants)
	Number of participants (%)			
Vomiting	5 (10%)	8 (15%)	2 (7%)	15 (12%)
Feeling sick to the stomach (Nausea)	11 (22%)	0	0	11 (9%)
Belly pain (Abdominal pain)	6 (12%)	4 (8%)	0	10 (8%)

There were other non-serious side effects, but those occurred in fewer participants. Some participants may have had more than 1 side effect.

? How has this study helped researchers?

The researchers learned more about the levels of E/C/F/TAF in blood. They also learned about its safety and effectiveness in adolescents and children with HIV-1.

The results from several 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 does not plan to have further clinical studies with E/C/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: 2013-002780-26
United States National Institutes of Health (NIH) www.clinicaltrials.gov	ClinicalTrials.gov Number: NCT01854775
Gilead Website www.gileadclinicaltrials.com	GS-US-292-0106

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 Study of the Pharmacokinetics, Safety, and Antiviral Activity of the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Single Tablet Regimen (STR) in HIV-1 Infected Antiretroviral Treatment-Naive Adolescents and Virologically Suppressed Children

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

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Thank you

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