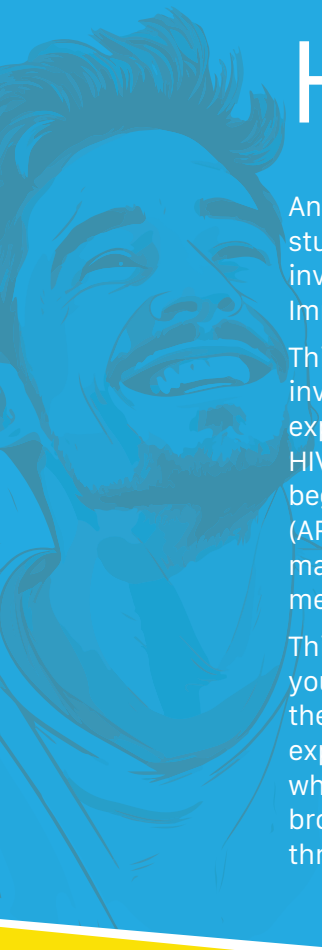
Welcome Guide

Help Turn Your Positive Status into Something Positive for HIV Research

STOPHIV-1

An ST PHARM Clinical Study



Hello,

And welcome to the SToPHIV-1 clinical research study assessing the safety and effectiveness of an investigational medication for the treatment of Human Immunodeficiency Virus, commonly known as HIV.

This study is designed to determine if STP0404, an investigational medication, could eventually be used to expand treatment options for people who are, or become HIV positive. Since you are new to HIV and have yet to begin the standard of care (SOC) Antiretroviral Therapy (ART) treatment, you are in a unique position to help us make that determination and contribute to the future of medicine for people living with HIV (PLHIV).

This welcome guide outlines what to expect during your participation in this study. Herein we go over the phases of the study, your responsibilities, our expectations, and answer some basic questions about what you can anticipate throughout the study. Keep this brochure and use it as a reference to follow your journey through the study.

You have likely learned of your positive HIV status only recently. We understand that this may have been a shock and recognize this may be an emotional time for you. But know this: SOC HIV treatment now, and the future of HIV treatment, is very promising. PLHIV commonly go on to lead long and rewarding lives. By agreeing to participate, you will be a part of fulfilling that promise. Kudos to you for persevering enough to join us. **We are grateful to you.**

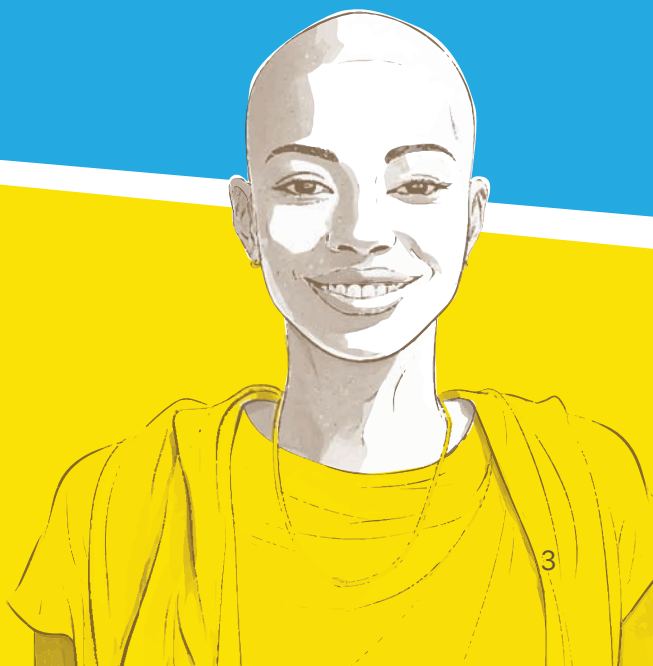
Sincerely,
Your Study Team

What We Need from You

This study can only be successful if participants complete all the requirements to the satisfaction of regulatory authorities. You are a vital part of this process. We are counting on your honesty, dedication, and perseverance.

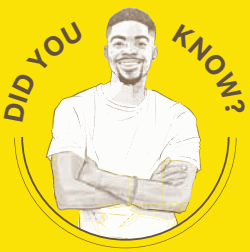
That means you will be expected to:

- Keep your study appointments, complete all study assessments, and reschedule any appointments you cannot attend.
- Stop taking HIV infection prevention medications 8 weeks before first dose of the study drug.
- Take the study drug as instructed.
- Not share the study drug with anyone else, keep it out of reach of children and bring unused doses to each visit.
- Use your electronic diary as instructed.
- Not take any other drugs, remedies or medication unless the study doctor allows them. This includes antacids, ART medications and traditional and mRNA vaccines for the duration of the study.



What We Need from You (cont.)

- Limit alcohol consumption to 1 beverage per day for women and 2 beverages per day for men.
- Refrain from marijuana use during the study.
- Report any changes in health, symptoms, or the way you feel after starting the study drug.
- Agree to not participate in any other research study until 30 days following your last dose of the study drug.
- Inform research staff if you change your mind about participating in the study.
- Male participants who are sexually active with people who can become pregnant must use acceptable methods of contraception. People who can become pregnant are not eligible for this study. If a pregnancy occurs, tell your study doctor as soon as possible.
- Inform research staff if you change your mind about participating in the study.



All study-related care and study-related medication will be provided at **no cost to you.**

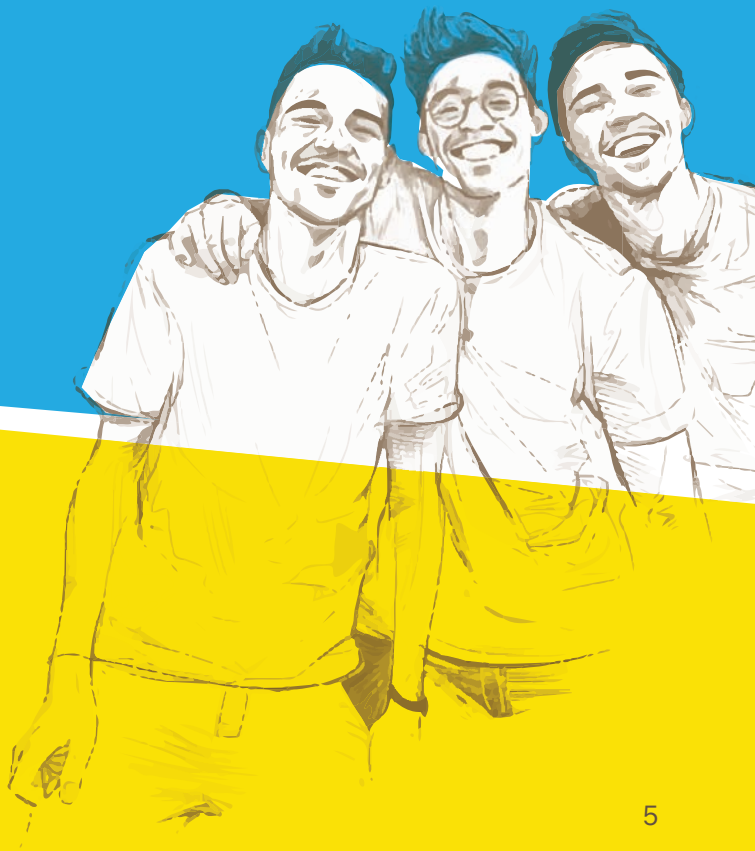
Please contact the study staff if you have any questions about your responsibilities in this study.

Goals of the Study

Our researchers are evaluating an investigational medication for its safety, effectiveness, and potential side effects at different dose levels compared to a placebo in the treatment of HIV.

The goals of this study are to see:

- If STP0404 decreases the amount of HIV in your body
- If you and other participants have any side effects
- How well you and other participants tolerate any side effects
- What your body does to STP0404
- What STP0404 does to your body

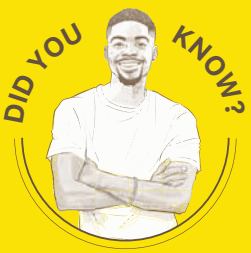


You will be part of a group of approximately 36 participants who meet the criteria for, and have agreed to take part in, the study. Depending on which cohort you are in, your participation will require up to 12 site visits over about 59 days.

The study consists of
3 periods:

1. Screening Period
(Up to 28 days):

Your screening period will take place no more than 28 days before the Treatment Period. During this period, your study team will have reviewed the Informed Consent Form with you and answered any questions you may have had. They will use this time to confirm your eligibility and give you directions about the requirements needed for the study.



- A placebo is an inactive substance that looks like the study drug but contains no medicine.
- In this guide, terms such as trial medication, investigational medicine and study drug refer to both STP0404 and the placebo.
- Side effects in clinical studies are known as Adverse Events (AEs) which may or may not be a result of the study drug and may or may not be expected and anticipated.

2. Treatment Period
(10 days):

This period begins with a process called randomization, which means a computer will randomly determine if you receive STP0404 or a placebo and which dose you receive. The first two groups, known as cohorts, will each consist of 12 participants, 9 of whom will receive STP0404, and 3 of whom will receive the placebo. Cohort 1 will receive a lower dose of STP0404, Cohort 2 will receive a medium dose of STP0404. Each group will attend study visits where the study team will ask questions, collect data and conduct tests, procedures and assessments.

A Safety Review Committee (SRC) made up of experts in the field of HIV treatment and experimental medicine will review the data from Cohorts 1 and 2 and determine if there is data to support adding a third group to the study – Cohort 3 – to assess the safety and effectiveness of a higher dose of STP0404.

Cohorts 1 or 2:

You will take the study drug daily according to the study staff's direction for 10 days. On days 3, 5, 6, 8, and 9, you will take the study drug at home and on days 1, 2, 4, 7, and 10 you will take the study drug at the site.

As part of Cohorts 1 or 2, you will be responsible for completing entries in an electronic diary (eDiary) with details of your use of the study drug and side effects if you experience them. The eDiary will either be a device provided to you by the site team or an app you download to your mobile device. You will receive training on how to complete entries at visit 1.

Cohort 3:

Out of an abundance of caution, Cohort 3 will stay at the study site for 11 days. At first, only two participants will receive the study drug, one receiving a higher dose of STP0404 and the other receiving a placebo. The SRC will again review the safety data and, if appropriate, will greenlight giving the study drug to the rest of the participants in this group (8 STP0404 recipients and 2 placebo recipients).

3. Follow-Up Period
(Approximately 20 days):

The Follow-up Period runs from Day 11 through Day 31 and is used to monitor any changes in your health once the Treatment Period is complete. Participants may also be started on ART (the current Standard of Care) after completing all study procedures on Day 11. Your study doctor will discuss treatment options moving forward.

Your Diet During the Study

It is especially important to the study that you pay particular attention to not just what you eat, but when you eat it. Often, the timing of what and when you eat can have a significant impact on the quality of data collected. For the duration of the treatment period we ask that you follow these guidelines:

Beginning 3 days prior to first dose until the day following your last dose, avoid consuming more than one of the following in a given day: glass of red wine, orange, grapefruit, grapefruit hybrids, polmelo, or exotic citrus fruit, or a glass of fruit juice.

Eat breakfast 30 minutes before taking the study drug. A sample breakfast includes:

- 2-3 Slices of bread, with 1 tablespoon of butter and 5-6 teaspoons of jam
- 1 cup of decaf coffee or tea with 1 teaspoon of sugar
- 1 Slice of cheese
- 2 Madeleines (a type of cookie)

Please Attend All Study Visits!

For Cohorts 1 and 2, to monitor your health while undergoing study procedures and treatment, it is important to attend all planned study visits. Be sure to call the study coordinator if you can't make an appointment and they'll work with you to find a new date and time.

What Will Happen at Study Visits?

When you come in for a visit, the doctor or staff member will perform clinical assessments of your health and ask you questions. The trial staff can tell you approximately how long each appointment should take. You may want to come prepared with a book, music, or another activity to pass the time.

At each visit, the trial doctors or staff will:

- Ask you about your health and overall wellbeing.
- Ask you about other medications you take now and medications you took in the past.
- Ask you about adverse events, which are possible problems you may have from the investigational medication.
- Perform other tests and assessments needed to collect the data necessary to fulfill the trial purposes. These may include physical exams, measuring height, weight and vital signs, electrocardiogram (ECG) reading, urine samples and blood draws for batteries of laboratory tests, etc.
- Review Your eDiary entries

Ultimately, results of this study will be provided to regulatory authorities as part of an approval process. Results will also be used to guide future studies and to further characterize the study medication's benefit/risk profile.

Will I be able to continue taking the study drug once the study ends? In a word, no. Or more accurately, maybe someday. Since this is an experimental medication, it has not yet been approved (and may never be) by appropriate regulatory authorities. If it receives regulatory approval, it may be a treatment option for you in the future.

Am I allowed to drop out of the study? Yes, you can withdraw from the study at any time for any reason. However, if you choose to withdraw, we will ask that you participate in an Early Termination Visit.

Do you protect my privacy? Every precaution is taken to protect your privacy. All information and samples taken are identified only by a code. All samples taken will be destroyed upon the completion of the study. Only the study doctor, approved sponsor personnel, and select personnel with the Federal Drug Administration (FDA) and Institutional Review Board (IRB) will have access to your records that identify you by name. They are required to keep your data private. Your name and identifying information will not be published in relation to this study.

Are there any benefits to my participation? Taking part in the study may or may not help treat your HIV. During the study, your health could improve, stay the same or get worse. The data you contribute to the study could help us move HIV research forward.

Are there any known side effects to STP0404? In a previous study, healthy volunteers reported headache, diarrhea, stomach pain, and vomiting as side effects. In animal tests with much higher doses of the study drug, side effects included diarrhea, weight loss, decreased appetite, and slight changes in blood and urine tests.

Are there other known risks? There is a chance that since this is a one-drug solution known as monotherapy that a resistance can be built up and may cause cross resistance to standard of care treatments.

Remember To Ask Questions!

If you don't understand something we are doing during a site visit, stop us and ask. If you think of something between visits, either make a note of it for your next visit or call us. Clinical research trials are better when conducted as a dialog. We need to know what you're thinking and concerned about. Please ask questions if you have them.

If you have any questions, contact your study staff.

Trial doctor's name:

Trial doctor's telephone number:

Trial coordinator's name:

Trial coordinator's telephone number:

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