

# Together we can advance HIV research

Learn about a **clinical research study** evaluating an oral investigational medication for people living with HIV-1.



## Who Can Participate?

You may be eligible to join the study if\*:

- You have been diagnosed with HIV-1 infection
- You are at least 12 years old and weigh at least 78 lbs (35 kg)<sup>†</sup>
- You have tried several antiretroviral treatments, but your viral levels are no longer suppressed



*\*There may be additional requirements to participate. The study doctor can provide you with more information.*

*<sup>†</sup>Participants under the age of majority will need parent/guardian consent.*



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Illuminate HTE\_Patient Brochure\_US English\_V1\_20FEB2020

To learn more, including possible risks and benefits of participation and to see if you may qualify, please contact:

**Palmtree Clinical Research, Inc.**

**Office: 760-778-7799**

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# About the Study

The Illuminate HTE Study is evaluating the safety, tolerability, and effectiveness of an investigational medication for people whose viral levels are no longer suppressed after trying several HIV treatments. It is a combination of an investigational medication and a drug that's already approved for use.

Currently, a 3-drug combination is the standard of care for treating human immunodeficiency virus (HIV). This study aims to evaluate the safety and effectiveness of a 2-drug combination therapy taken once a day.

## Study Design

This study lasts about 16 months and includes up to 13 visits to the study doctor's office.

Approximately 1 year	<b>Screening Phase</b>	You will receive your current HIV treatment
	<b>Phase 1</b>	Along with your current HIV treatment, you will be randomly assigned to receive one of the following for 1 week with an 80% chance of receiving investigational medication: <ul style="list-style-type: none"> <li>Investigational medication (80% chance)</li> <li>Placebo* (20% chance)</li> </ul>
	<b>Phase 2</b>	You will take the investigational medication along with <ul style="list-style-type: none"> <li>a) an optimized background antiretroviral therapy (ART) that's been individualized based on discussion with the study doctor</li> <li>OR</li> <li>b) remain on current ART for 48 weeks</li> </ul>

\*Placebo looks like the study medication but contains no active ingredient.

## Why Participate?

If you qualify and decide to participate:

- Participation is voluntary, and you are free to withdraw at any time. Your privacy will be maintained throughout the study
- There is no cost to participate, and you will receive all investigational medication and study-related doctor visits for the length of your participation at no charge.
- Your HIV and overall health will be closely monitored by an experienced HIV study team
- Your participation may help advance medical knowledge about HIV and may help others

Additional potential risks and benefits of participation will be fully described by your study team.

## About HIV Clinical Research

Clinical research studies explore whether a study medication is safe and effective for patients. Clinical research has led to improvements in HIV treatments, allowing people with HIV to live with undetectable levels. HIV-1 infection has become a chronic, manageable condition. Current antiretroviral therapies have known safety and tolerability issues, which may be improved through clinical research.

**Some of the goals of HIV clinical trials are to find medications that:**

- Keep HIV at undetectable levels in the blood
- Are safe and effective to take over a long period of time
- Possess a high barrier to viral resistance
- Are easy for patients to fit into their lives – for example, pills that can be taken once a day, with or without food, etc

Qualified doctors, nurses, and other medical professionals are responsible for conducting each clinical trial. Regulatory bodies in each country provide oversight and approval after a thorough review. A study medication will be approved for use only after it is shown to be safe and effective in clinical trials.

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