Clinical Trials

Medical studies are the key to advances in HIV prevention, treatment and cure research.

June 23, 2025 By Liz Highleyman

Everything we know about HIV prevention, treatment and the potential for a cure comes from research involving people at risk for or living with the virus. Joining a clinical trial can be a good way to access new therapies and contribute to science, but it's important to weigh the pros and cons.

Clinical trials are a key part of the multistep process for testing new prevention, treatment or cure approaches.

- Preclinical: Most experimental therapies first undergo testing in a laboratory, followed by animal studies. But promising activity in a lab or in animals does not mean a drug will work in people.
- Phase I: Early safety trials usually include 10 to 100 participants, often starting with healthy volunteers. They look for common side effects and collect information about pharmacokinetics, or how a drug is processed in the body.
- Phase II: Mid-level trials typically include a few hundred participants. They assess whether a new therapy appears safe in a larger group and gather pre--liminary information about efficacy.
- Phase III: The largest and longest trials, typically involving hundreds or thousands of participants, test how well a therapy works compared with other options. Less common side effects may show up only after a drug is used by many people over a longer period.
- Phase IV: After a drug has been approved, post-marketing studies are done to see how well the therapy works in the real world.

Randomized controlled trials are the gold standard for testing new therapies. A controlled trial

means participants are assigned to get the experimental drug or a comparison intervention—for example, the current standard of care or a placebo. Randomization means participants could end up in any study arm, ensuring that the groups are otherwise similar.

Trials for new prevention methods follow a similar pathway, but the safety bar is higher because they will be used by healthy people. Other types of trials assess behavioral interventions, such as exercise or smoking cessation.

HIV cure trials are more complex and can involve greater risk. To determine whether a cure strategy leads to long-term remission, participants may need to temporarily stop their antiretrovirals, which could lead to disease progression and HIV transmission.

A good study design is essential for ensuring that trials provide reliable information. It is important that they enroll the full range of those who will use a new therapy, including women, transgender people and people from diverse racial and ethnic groups.

Your HIV care team, advocates and support groups can be good sources of information about available clinical trials. The National Institutes of Health's ClinicalTrials.gov website lists open studies for all conditions.

When considering a trial, learn all you can about the therapy being tested and what other options are available. Find out the frequency of study visits and whether the trial reimburses expenses. Don't be afraid to ask questions! Before agreeing to join, you must sign an informed consent document, but this is not a contract—you have the right to withdraw at any time for any reason.

Benefits of trial participation include early access to promising new therapies, care delivered by leading experts and altruism—knowing you are contributing to science and helping others. Drawbacks can include time-consuming study visits, the need to forgo other therapies and the risk of side effects. And in a randomized trial, you might not get the experimental treatment.

Remember, trials of new antiretroviral drugs, HIV prevention methods and cure approaches can't offer guarantees. Researchers don't yet know how effective experimental therapies will be, and they can't rule out unforeseen adverse events. Despite this uncertainty, clinical trials can be a gateway to better prevention and treatment options for yourself and others.
