

Clinical Trials

Should you be a guinea pig?

Ten things you need to know about participating in HIV clinical trials

by Chrystal Palaty

Clinical trials test new therapies and treatment strategies to determine whether they're effective and safe for humans. Clinical trials don't just test drugs; they also test behaviour interventions, food, supplements, and prevention methods. If you've ever thought about participating in a clinical trial, here are ten important things you need to know.

1. There are many good reasons to participate. You may be one of the first to try a potentially beneficial new treatment. Your health will be closely monitored during the trial, which may be a benefit for you. You'll get to see the clinical trial process first-hand. Also, you'll contribute to the development of new medications and strategies that may help others with HIV.

2. There are also risks to participating. There's no guarantee that you'll benefit from the trial, and you may experience side effects from the treatment. If you're participating in a trial where two treatment options are being compared, the treatment assignments are usually pre-determined by the researchers organizing the study, and aren't typically made by your study doctor. As a result, you might not know which treatment you're receiving until after the trial. You may have to make some lifestyle changes such as taking medications on a set schedule or not taking any other medications or recreational drugs during the trial.

3. You need to find the right trial for you. The CIHR Canadian HIV Trials Network (CTN) and the Canadian AIDS Treatment Information Exchange (CATIE) collaborate on a registry of Canadian clinical trials; you can access this registry from each of their websites. In addition, the ClinicalTrials.gov website (<http://clinicaltrials.gov/>) has a searchable directory of clinical trials in North America and the world. Not all trials have sites in each region; the websites list all participating sites and contact information for each trial.

4. Anyone can apply, but not everyone is eligible. Each clinical trial has well-defined criteria or characteristics that study participants need to fulfill. These include inclusion criteria, which are things that study participants need to have or be to ensure they represent the intended treatment population. Trials also have exclusion criteria, which are things participants can't have, such as health conditions or taking certain medications that may interfere with the treatment or cause an increased risk of side effects. The eligibility criteria differ depending on the medication being tested and the phase of the trial, and can include things such as age, gender, previous medications, viral load, or CD4 counts.



5. Participating in a trial is a commitment and a responsibility. Clinical trials have specific procedures and guidelines that need to be followed. By agreeing to participate in a clinical trial, you're committing to follow these procedures exactly, because if you don't comply, the researchers may withdraw you from the trial. When you first speak to a research coordinator or nurse, they'll tell you about all trial procedures, including the schedule for clinic visits and laboratory tests; you need to decide if you can make this work for you. You need to find out if there are any associated costs, such as dispensing fees, and if you're able to cover that.

6. Read the fine print in the informed consent form. If you decide to participate in a clinical trial and you fulfill the eligibility criteria, you'll first meet with the research coordinator or nurse. They'll provide you with a detailed information package called an informed consent form, which you need to read and sign before taking part in a study. You should be allowed to take the form home to discuss the study with your family and/or your doctor. Review all this information carefully, ask lots of questions, and make sure you fully understand the answers. Do you know what the trial is really about? Do you know all the potential benefits and risks? How will the trial impact your schedule? What do you do if you experience any problems? Also find out if there are certain activities you can't do or medications you can't take when you're in the trial.

7. Health Canada is watching out for your rights and well-being. In Canada, clinical trials are extremely well regulated to ensure that the rights, safety, and well-being of study participants come first. All Canadian trials are regulated by Health Canada, according to Good Clinical Practice guidelines. In addition, the Research Ethics Board of each institution needs to review and approve studies in advance.

8. You can quit anytime. One of your rights as a clinical trial participant is that you can withdraw from the trial at any time, for any reason. As part of the trial, the trial investigators are required to provide you with any new information about the drugs you're taking; this may influence your decision to continue in the trial. If you do decide to withdraw from the trial, it shouldn't influence your future care. Also, if you decide to withdraw, don't just stop the treatment—you need to let your study monitor or nurse know. He/she will tell you what you need to do.

9. Report any changes or side effects as soon as possible. When you're enrolled in a trial, you need to be very aware of any changes or symptoms you're experiencing and report them to your research coordinator or nurse. Although any new symptoms you have may be completely unrelated to the medication or the trial, you need to report them. Sometimes if several patients experience this same event, the trial may be stopped or the regimen may be revised.

10. The end of the trial is not the end. Near the end of the trial, you'll have a final study visit to discuss the trial. You likely won't find out which treatment you received until all other participants have completed the trial and the results are analysed. You should receive the results once the trial is complete. Some trials include a follow-up to find out how participants are doing long-term or if they are experiencing any persistent symptoms or side effects.

Although the decision to participate in a trial requires a lot of careful thought, it's well worth considering for the difference you're making to improve the care and long-term well-being of other people. ☺

For more information

- ▶ To learn more about participating in clinical trials, contact Chuck Osborne at Positive Living BC's Health Promotion Department at 604.646.5366 or chucko@positivelivingbc.org. He's a member of the Community Advisory Committee at the CTN.
- ▶ For lots of great information for trial participants, visit CTN at www.hivnet.ubc.ca, CATIE at www.catie.ca, and the Center for Information and Study on Clinical Research Participation at www.ciscrp.org.
- ▶ *Clinical Trials: What You Need to Know* is a joint publication of the CTN and the Canadian AIDS Society; it's available through their websites as well as through CATIE's website. This publication has an excellent explanation of the purpose and rationale behind clinical trials; although published in 2004, it's still relevant.

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