CLINICAL TRIALS

What you need to know

Dedication

This document is dedicated to the memory of three people:

- Claude Lachapelle who died May 1, 1995
- Kalpesh Oza who died June 4, 1995
- Brian Farlinger who died July 3, 1995

Thanks to Brian, a lawyer and a leading activist with AIDS ACTION NOW!, many restrictive government policies, federal and provincial, have changed and a great deal of progress has been made by the pharmaceutical industry for people living with HIV/AIDS.

Kalpesh, a pure scientist by training and activist by nature, was on the Board of Directors of the Comité des personnes atteintes du VIH/sida du Quebec (CPAVIH) in Montreal, and of the Canadian AIDS Society. He was also extremely active within both AIDS ACTION NOW! and the Canadian HIV Trials Network.

Claude was general coordinator of CPAVIH in Montreal for many years and a member of the administrative council of COCQ-sida in Montreal. He was also an active member of the Community Advisory Committee of the Canadian HIV Trials Network.

These three gifted, militant and courageous people are deeply mourned, and sorely missed. Their presence in our lives and contributions to the struggle will be with us always.

Second printing, March, 1999

Acknowledgements

The Canadian AIDS Society and the Canadian HIV Trials Network would like to thank:

- AIDS ACTION NOW! for permission to use material from its publication, *AIDS and HIV Drug Trials in Canada*, seventh edition.
- the Canadian AIDS Treatment Information Exchange (CATIE), and particularly Deirdre Maclean, for permission to excerpt information from the booklet, *HIV Related Clinical Trials in Ontario*.

An Introduction to HIV Clinical Trials is a joint development effort between the Canadian AIDS Society (CAS) and the Canadian HIV Trials Network (CTN).

CAS would also like to thank the following people who contributed to this project: Fred Aoki, Russell Armstrong, Maggie Atkinson, Sharon Baxter, Raymond Beaulieu, Reeta Bhatia, Claudia Brabazon, Paula Braitstein, Constance Campbell, Suzanne Desbiens, Alain Descours, Pierre Desmarais, Marcel Dufour, Richard Lalonde, Catherine L'Homme, Megan MacLennan, Nancy Meagher, Wayne Moore, Wayne Rush, Kathy Sayers, Bob Shearer, José Sousa, Robyn Sussel, Darien Taylor, Emil Toma, and Donald Zarowny.

CAS would like to thank Susan McCaron of the UpJohn Company of Canada for financial support.

This project was funded by the AIDS Care, Treatment and Support Program of Health Canada under the National AIDS Strategy, Phase II. This program also made the second printing possible with a special grant.

The opinions expressed in this document do not necessarily reflect the policies of Health Canada.

Ce document est également disponible en français. Pour obtenir une copie, veuillez vous adresser au Réseau canadien pour les essais VIH, 620 – 1081 Burrard Street, Vancouver (Canada) V6Z 1Y6.
Tél: 1-800-661-4664. Internet: www.hivnet.ubc.ca/ctn.html

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Introduction

About this Booklet

This booklet is intended to give people living with HIV, their families and friends — and anyone else who is interested — some basic information about clinical trials. It does not endorse any particular trial or try to persuade people to participate in a clinical trial. It explains the purpose of clinical trials, how they are conducted, how people can join a trial and what they can expect from a trial if they decide to participate.

Every effort has been made to keep the language understandable. Technical terms are in **bold** type the first time they appear, and are defined either in the text or in the glossary.

Over the last couple of years, research into HIV has been changing rapidly. This means that clinical trial design — and the information in this booklet — may also change. For more information or to ensure the information here is still up-to-date, refer to the list of resources at the end. For more detailed information about HIV clinical trials, please contact the Canadian HIV Trials Network, the Community AIDS Treatment Information Exchange, or your local AIDS organization (see page 25 - 28 for details).

An Overview

Clinical trials are carefully designed experiments that allow scientists to test newly developed drugs on a small group of people. They are a logical, structured way to answer questions about how to control HIV, and how to prevent and cure many infections associated with AIDS. Clinical trials are the most effective way for scientists to assess whether the benefits of using a drug outweigh any risks, and if the drug will improve life for people living with HIV.

Researchers have used clinical trials to develop effective treatments for many types of cancer and bacterial infections, and vaccines for many childhood illnesses. Over the last 10 years, clinical research in HIV has led to treatments for many **opportunistic infections**, and treatments against HIV itself. These treatments help people with HIV live longer, with a better quality of life than was possible ten, five or even two years ago.

Clinical trials are one stage in the whole process of developing a new drug treatment. The entire process — identifying a possible drug treatment, testing it on animals, getting approval for a clinical trial with people, running the trial, analyzing the results, applying for a license and getting approval to use the drug in regular treatment — takes a long time, sometimes many years.

Clinical trials are one stage in the whole process of developing a new drug treatment.

Planning and running a clinical trial involves teamwork. To find effective treatments, people living with HIV, scientists, doctors, drug companies and governments must work together. People living with HIV help ensure researchers are aware of their needs and concerns, and they participate in the trials. Researchers ensure that the trials are of the highest scientific quality, and they analyze the results. Physicians monitor the progress of people involved in the trial, and pass that information to the researchers. Drug companies provide the drugs and usually fund the trials. Governments and other funding bodies may also help pay for the trials. And government regulatory agencies are responsible for reviewing the results of the trials and deciding, based on the scientific evidence, whether to approve the drug for wider use.

People living with HIV have been particularly active in scientific research — more so than groups of people organized around other illnesses. They have worked with researchers, drug companies and governments to ensure that clinical trials reflect their concerns, and that policies and practices are fair and ethical.

About Clinical Trials

What is a Clinical Trial?

A clinical trial is a scientific test of new drugs or treatments on people, designed to find out if new drugs are safe and how well they work.

How Do Trials Work?

Before a drug is given to people

When a new drug is developed, it must be carefully tested before it can be given to people. These pre-clinical tests include *in vitro* studies and animal studies:

- *In vitro* studies are laboratory experiments to find out if a new drug works on human cells in test tubes. For example, the new drug may be mixed with some healthy cells and some HIV-infected cells to see if it will kill infected cells without damaging healthy ones. *In vitro* studies are repeated many times to ensure the results are dependable and not just due to chance. If the drug shows promise, researchers then go to the next stage: animal studies.

- In animal studies, the new drug is given to animals to see how it works in a living creature. Some animal studies are **toxicity** studies designed to find out if a drug is dangerous to the body or to some of its organs or systems. Sometimes drugs can cause illnesses or reactions that don't show up unless they are used for a long time. Other drugs may be fine for the people taking them but cause birth defects in the next generation. Because animals, such as mice and rats, have short life spans and reproduce quickly, they can be used to study both these problems. Other animals, such as monkeys or chimpanzees, are used because they are more like people or can get the same diseases as people. Testing the drug on them can give scientists a better idea of how it will affect people.

Testing new drugs in people

If, after pre-clinical studies, the drug seems to be useful and safe in animals, the drug company asks the federal government for permission to test the drug in people. To get approval for the clinical trial, the company must submit all documents and data on pre-clinical studies as well as a detailed plan or protocol for the trial to the Health Protection Branch (HPB) of Health Canada. If the HPB gives approval, clinical trials can start.

Clinical trials are done to determine the safety and efficacy of a new treatment. They are designed to answer one or more of the following questions:

1. **Is it safe?**
2. **Does it work?**
3. **Is it safe over a longer period?**
4. **Does it work in many people over a long period of time?**
5. **Are there any long term side effects?**

Once approved, a clinical trial goes through four phases:

- in the first phase, researchers give the drug to a small number of people to see what dose is safe.
- in the second, they give a larger number of participants the appropriate dose over a longer period of time to see if the drug is working and whether it has any long-term side effects.
- in the third phase, researchers give the drug to a much larger group of people over several months or years to see whether the drug remains useful or has any side effects that only show up after a longer period of time.
- in the fourth phase, researchers continue to study the drug even after it has been approved in what are called "post-marketing" trials. They can then watch for any side effects or problems that may show up after several years of treatment.

Today, many clinical trials combine phases. For example, Phase 1/2 trials might study both drug dose and how it works, or Phase 2/3 trials might study both how the drug works and how well it works at the same time. Combined phase trials are more common with drugs that are already used to treat other illnesses and are being tested as an HIV therapy. They have the advantage of moving more quickly than single phase trials.

Measuring the Effects of a New Drug

Monitoring the trial

At each phase of the clinical trial, the drug must be reassessed and approved by the Bureau of Human Prescription Drugs before it can go on to the next stage of testing. Once a drug has been tested successfully in the lab, in animals and in people in the first three phases, the drug manufacturer applies to the Health Protection Branch for formal approval to market or sell the drug. The company must provide all the results from the clinical trials, and the Health Protection Branch reviews the information and decides, based on the scientific evidence, whether to permit the sale of the new drug.

Federal government approval doesn't necessarily mean the drug is effective or safe for all people at all times. It only means that it has proven useful in enough people that it's worth trying, and that its known side effects are considered "satisfactory" or not dangerous.

Types of Clinical Trials

All clinical trials compare a new drug with something else to find out which is better and safer. In the early days of the HIV epidemic, many trials compared a drug with a **placebo**. A placebo is something that looks, smells and tastes like the drug, but has no drug in it. In these trials, one group of people is given the drug, another group the placebo, and both groups are studied to see their reactions. Placebo trials are a quick, accurate way to assess whether the drug is better than doing nothing. However, in Canada we consider it unethical to give a placebo to people who are participating in a trial if a standard therapy is available. For this reason, placebo-controlled trials are rarely used in HIV.

Most trials now compare one treatment with another.

Most trials are **controlled, comparison trials** which compare one treatment with another in the following ways:

- One type of trial compares a new treatment with a commonly used treatment. In these trials, one group receives the commonly

used treatment, another group the new treatment. Scientists compare the two to see which works better.

- Another type of trial compares a new treatment combined with commonly used treatments to the commonly used treatments alone. Both groups receive commonly used treatments, but one group also receives the new treatment. Researchers then assess whether adding the new treatment has a positive effect on health and/or quality of life.
- A third type of trial compares the use of a new drug at different doses (**dose comparison**). Researchers then assess which dose works best and has the fewest side effects.

Other measures researchers use to ensure accurate results are called **controls**. These are the specific rules that researchers and participants must follow to reduce any "bias" that could affect the results. For example, personal beliefs, interests or emotions can influence or "bias" someone's judgement and affect the results of a trial. Controls include:

- **Randomized, controlled trials**, which divide participants randomly into the two test groups using a computer. This helps remove any bias from deciding which participants receive the new drug or treatment.

- **Double-blind, controlled trials**, which ensure that neither the participants nor the doctors know who has received which treatment. The trial remains blinded until the last person to volunteer has completed the trial.

What Treatments Do HIV Trials Test?

Most treatments tested on people living with HIV fall into six categories:

- drugs that fight the virus, called **antiretrovirals** or anti-HIVs
- treatments that prevent or treat HIV-related illnesses (opportunistic infections such as thrush or pneumocystic carinii pneumonia [PCP])
- drugs that treat cancers
- treatments that reinforce the immune system, known as immunostimulators or **immunomodulators**
- vaccines that could prevent or cure HIV infection
- **gene therapies**.

Who Conducts Clinical Trials?

Clinical trials in Canada are usually sponsored (designed and paid for) by the company that developed the new drug. The principal investigator is the researcher supervising the trial, usually a doctor with a lot of experience running clinical trials. The trial may take place at several locations across the country. Each of these locations is called a trial site, and each site has a doctor in charge of the trial, called a site investigator. Most HIV-related clinical trials in Canada take place in cities that have university teaching hospitals with clinics specializing in HIV disease. Sometimes family doctors will be investigators and run trials from their offices.

How do researchers assess the results?

Investigators use certain tests and measurements, often called **surrogate markers**, to assess the effect a trial drug has on participants' health. For example, researchers may take blood or tissue samples and measure the amount of virus present (i.e., a **viral load** test) before participants take the trial drug, while they are taking the drug, and after. If your viral load is high, it means the virus is replicating quickly in your body. If your viral load is low it

Researchers will test for surrogate markers, hoping to see signs that the drug is having a positive effect on health.

means your body itself or your treatment is keeping the virus in check. Another commonly used surrogate marker is the **CD4+ count**, blood test that measure the white blood cells that regulate the immune system. A low or dropping CD4+ count is a sign that HIV disease may be progressing.

Throughout the clinical trial, researchers will test for these and other surrogate markers, hoping to see signs that the drug is having a positive effect on health.

Participating in Clinical Trials

Where to Start

If you are living with HIV and interested in participating in a clinical trial, talk to your doctors or local AIDS organization about treatments in which you are interested and trials going on in your area. You can also get information from:

- the **Canadian HIV Trials Network (CTN)**, a federally funded organization whose mandate is to develop treatments, vaccines, and a cure for HIV disease and AIDS through the conduct of scientifically sound and ethical clinical trials. The CTN publishes a bimonthly newsletter, including a directory of enrolling clinical trials (compiled in conjunction with CATIE), and operates an information line at 1-800-661-4664. The CTN will provide phone numbers of the trial site nearest you.

- the Treatment Information Network is a national service operated by the Canadian AIDS Treatment Information Exchange (CATIE), at 1-800-263-1638. CATIE offers mainly treatment information, helping people living with HIV/AIDS and their caregivers make informed healthcare decisions (see page 26 - 29 for website information for both the CTN and CATIE).

If you find a particular trial in which you are interested, you can contact your family doctor who can refer you to the site investigator, or you can call the site directly. A telephone interview with the trial nurse or other member of the trial staff will likely provide enough information for you to decide whether you want to participate. Anyone who is interested can make an appointment for a screening interview.

The Screening Interview

To qualify for the trial, participants must be assessed against strict requirements, called **inclusion** and **exclusion criteria**.

Inclusion criteria make sure that a fairly similar group of people take part in a trial and allow researchers to make reliable comparisons about the way the drug works. For example, to be included in a trial, participants: "must be HIV+" and "must have a CD4+ (T4) cell count between 100 and 300."

Exclusion criteria protect people who might be harmed by the study drug. For example, anyone who is being treated for an active illness, such as PCP, or who is pregnant will likely be excluded from a trial. Until recently, pregnant women have almost never been allowed to enter drug trials in case the drug harms the foetus. However, recent guidelines in the United States and Canada have made it increasingly acceptable to include pregnant women in particular circumstances.

To determine whether people qualify to participate, researchers use a screening interview. At the interview, you will be:

- asked detailed questions about your health, your medical history, and the drugs and treatments you use; and
- given an extensive physical examination, along with lab tests (usually blood tests, sometimes x-rays or other tests).

At the end of the interview, you may be asked if you want to enter the trial or you may be asked to return to the clinic for a second interview, when the lab test results are available.

Making a Decision

Anyone considering taking part in a trial should obtain an information package with all the details, and should also discuss with trial staff what the trial will mean to them and their lifestyle. People invited to participate in a trial should take the time needed to make this decision. They may want to talk it over with a partner, friend, relative or local AIDS group. In making the decision, they should consider all the potential benefits and problems or risks:

Benefits

- helping other people living with HIV and AIDS by being part of a process that develops new treatments
- being one of the first to benefit if an experimental therapy turns out to be effective
- receiving the regular health monitoring that is part of the trial, which may be beneficial.

Risks

- having no guarantee of a personal benefit from the trial
- having side effects that could be dangerous or make health worse
- having to stop taking other medications that are working well
- not being eligible for other trials
- not knowing who is receiving the experimental drug
- having to make changes in lifestyle, such as taking medication at very regular intervals, or not eating certain foods
- having to go into hospital.

Trial staff should explain all the known benefits and risks.

The Informed Consent Process

If you meet the entry criteria and decide to take part in the trial, you will be asked to give your **informed consent**.

Giving informed consent means that you:

- understand that the trial is a scientific experiment and there may be risks and dangers to your health
- have been told about the reasons for doing the trial, the drugs you might be given, the number of visits and the kinds of lab tests required
- have been given the information you need to decide whether to take part in the trial.

Once you sign the Informed Consent Form, you are considered enrolled in the trial.

If you are concerned about any of the requirements of the trial you should talk to trial staff about them before giving informed consent. Staff may be able to make some exceptions, or you may decide not to take part in the trial after all.

When you have all the information about the trial, you are asked to sign an informed consent form, which should explain the trial and the possible risks or dangers in plain language. Informed consent forms usually require the participant's signature, the signature of a witness and the signature of the principal or site investigator.

Once you sign the Informed Consent Form, you are considered enrolled in the trial.

However, informed consent is an ongoing process. The investigators have a responsibility to give participants any new information about the drug they are taking. Participants have the right to leave a clinical trial at any time. Leaving a trial will not affect your regular health care or your ability to participate in other trials for which you meet the entry criteria.

The Role of the Family Doctor

Clinical trial participants have their health monitored at the trial site. However, participants should also continue to see their own doctors — who continue to be responsible for their overall health — for regular check-ups and lab tests. It is not ethical for the trial doctors to take over participants' general medical care. To avoid having the same tests repeated in both places, family doctors and site investigators usually work out a way to share test results.

When family doctors are also trial investigators, they should ask another doctor to go over the trial protocol and informed consent with their patients. In addition, they may recommend that any of their patients who are participating in the trial see another doctor for their regular care during the trial. This is one way to ensure that the doctors' interest in enrolling volunteers for the trial does not conflict with the obligation to provide the best possible patient care.

Once Participants are Enrolled

The Stages of Trial Participation

You may wait a few days or even weeks before starting to take the trial medication. During this time, investigators observe your health before treatment begins. You may also be asked to go through a waiting period when you stop taking a drug or medication before you start taking the trial drug. This is called the **washout period**, and it allows participants to get rid of all traces of a drug in their bodies. The treatment period is the length of time participants take the study drug. If a trial is designed to last for six months, then the treatment period is six months from when the participant starts taking the drug.

The treatment period is the length of time participants take the drug.

The post-treatment period is the length of time participants are followed after the treatment period. You may be asked to return to the clinic and check in with the investigator after they complete the trial. The follow-up can be once a month for the first six months or one visit six months after participants finish the trial, depending on the protocol.

It is important for participants and investigators to stay in touch after a trial ends, so participants can report any recurring symptoms or side effects, and investigators can give participants any new information about the drug.

As noted earlier, if any new information about the trial drug becomes available during the trial, the sponsors and the investigators must tell all trial participants.

What are Your Responsibilities During the Trial?

Your main responsibility is to be sure you understand the rules of the trial and are realistic about their ability to follow them. Participants who won't be able to keep appointments or follow the schedule should talk to trial staff. There may be ways to work around people's schedules. Participants who do not follow the trial rules can be withdrawn.

Can participants leave a trial?

Participants can leave a trial at any time, for any reason.

What happens when the trial ends?

When your time in a trial comes to an end, you will be asked to participate in an exit interview. During this interview, you may be told what drug you were taking (if you didn't already know) — depending on the type of trial and the time you exit. Since the code in double blind trials is not broken until everyone has completed the trial, participants in those trials may not find out what treatment they were getting until some time after they finished the trial.

You should expect to receive the results of the trial when it is finished. If information about how these results will be given to you is not in the informed consent form, ask the study staff.

You should expect to receive the results of the trial when it is finished. If information about how these results will be given to you is not in the informed consent form, ask the study staff. Keep in mind that because enrollment is staggered, a two year trial may take several years to reach conclusion because the last person enrolled must have been on the study for a full two years.

What does it cost to participate in a trial?

Provincial health insurance and the drug manufacturer typically cover the cost of drugs and lab tests. However, there may be other costs involved, such as time off work, transportation costs, babysitting or daycare. If you need help with childcare or transportation costs, you should ask the trial staff. In some cases, funds are available to cover these costs, and trial organizers should explain what costs will be reimbursed, how, and when.

It is illegal for anyone to sell a drug that hasn't been approved by the Health Protection Branch of Health Canada. However, if trial participants receive their trial drug through a hospital or local pharmacy, there may be a dispensing fee.

What if you get sick during a trial?

If you become sick while in a trial, you should let trial staff know as soon as possible. You may be experiencing side effects from the drug or an illness the study drug could make worse.

You should keep the informed consent form and trial information package handy. A 24-hour toll-free number is usually included to call for advice if there are problems with the trial medication. Because the drugs being tested are experimental, doctors in emergency rooms may not be able to help participants who become ill. However, if you are very ill, go to Emergency but take your Informed Consent Form with you so the emergency doctors can contact your trial doctor.

Can you take other drugs while in a trial?

While in the trial, you may not be permitted to take certain medications if:

- the trial medication interferes with other drugs, making one or more less effective;
- the trial medication causes a reaction that another drug may make worse.

To protect yourself, you should keep a list of all the medications you take, even over-the-counter drugs like cold tablets or cough syrup. Also be aware that the potential for interactions with street drugs (e.g. heroin, cocaine, ectasy, etc.) is unknown for most experimental HIV drugs.

Alternatives to Clinical Trials

People who are not accepted into a trial or who don't want to participate may still be able to get experimental treatments through:

- **Compassionate access**. The drug manufacturers may make a limited amount of the drug available through a less restrictive type of trial called compassionate access. People must still meet certain requirements, such as "CD4+ count below a specified level" or "intolerant to usual treatment," to receive the drug.

- **Special Access Programme** (formerly the Emergency Drug Release Programme, EDRP). The Bureau of Human Prescription Drugs of Health Canada can authorize a manufacturer to release any drug that has not yet been approved for sale in Canada — including drugs in clinical trials — on an emergency basis. To receive a drug that is not yet licensed but has been listed in the Special Access Programme, you must have your doctor contact the Bureau. The release of a drug in this way does not mean that the Bureau believes the drug is safe. It is a means to give people in need legal access to the treatment. Drug companies are not required to provide a drug through the Special Access Programme. Each request is reviewed on an individual basis. Drug companies may charge a fee for the drug, including full retail cost.

- **Buyers' Clubs**. Buyers' Clubs, which are more common in the United States than Canada, are co-operative organizations that provide easier access to treatments for people living with HIV. They may be able to provide access to some experimental drugs, although they usually deal more in vitamins and other complementary therapies. For more information about Buyers' Clubs, contact local community AIDS organizations.

Issues Facing Certain Populations

Certain populations, such as women, prisoners, intravenous drug users and people of colour, have had problems accessing clinical trials. They face issues, such as sexism, racism and other forms of discrimination that may keep them from participating. Many of the member groups of the Canadian AIDS Society represent special populations and may be able to help you advocate for inclusion in a clinical trial. Check the CAS website or call CAS for the group in your community (see page 25).

Glossary of Terms

Antiretroviral: A substance that stops or suppresses the activity of a retrovirus such as HIV. AZT and ddI are examples of antiretroviral drugs.

Buyers' Club: Cooperative organizations that provide easier access to treatments for people living with HIV.

Canadian HIV Trials Network (CTN): An organization set up by the federal government to encourage and coordinate clinical trials in Canada. The CTN has a Community Advisory Committee that reviews each clinical trial they sponsor.

CD4+ count: A measure of the helper blood cells which generally, but not always, indicates the strength of the immune system.

Clinical trial: An experiment to see how well a new drug works in people and how safe it is.

Compassionate access: An arm of a clinical trial which allows people who do not participate in the research study (because they do not satisfy the inclusion criteria, the trial is not available where they live or for other reasons) to have access to the drug or treatment being tested. Most compassionate arms are restricted (e.g. CD4+ count below specified amount, intolerant to usual treatment, etc.).

Controls: Specific rules that researchers and participants must follow to reduce any "bias" that could affect the results of a trial. (e.g. randomization).

Controlled, comparison trials: Trials in which one group gets the experimental drug and another gets either a placebo or an approved drug therapy. Participants do not usually know which group they are in.

Dose comparison: A trial that uses different amounts of the same drug. Sometimes different doses are tested against a placebo.

Double-blind: People in this trial are divided into two or more groups. One group takes the experimental drug, and the other takes the standard therapy or a placebo. Neither the researchers nor the people in the trial know who is taking which drug until the trial is over.

Gene Therapy: An approach to preventing and/or treating diseases by replacing, removing, or altering key genes, or otherwise manipulating genetic material.

Immunomodulators: Drugs that strengthen the immune system and help the body to fight off infections or other diseases which attack people living with HIV and AIDS.

Inclusion\exclusion criteria: The medical or social reasons why a person may or may not be allowed to enter a trial. For example, most trials do not allow pregnant women to join. Others do not allow people to take certain drugs, and others exclude people with certain illnesses.

Informed consent: A process in which the risks, benefits, and requirements of a trial are explained to people thinking of joining the trial. Before entering the trial a participant should sign an informed consent form, which should contain in writing the benefits, risks, and basic structure of the trial.

Opportunistic Infection: Illnesses such as *Pneumoncystis carinii* pneumonia (PCP) that people with AIDS can get and which can be life-threatening. People with healthy immune systems do not usually get these illnesses, even though most people have the organisms that cause these illnesses in their bodies already. When the immune system is damaged, the organisms take advantage of the "opportunity" to cause illness.

Placebo: A substance that has no effect on the body (often referred to as a "sugar pill") that is given to one group in a controlled trial. Placebo trials are no longer considered ethical in trials when a standard treatment exists. Their use remains controversial.

Randomized: A trial in which people are assigned to one of two treatments by chance. Usually a computer is used to be sure that everyone has the same chance of getting either drug. This ensures that other factors which might affect how people respond to treatment are equally distributed in the control and test groups.

Special Access Programme (formerly Emergency Drug Release Programme, EDRP): A participant's doctor may ask the Bureau of Human Prescription Drugs of Health Canada for the release of an experimental drug on an emergency basis, if the drug manufacturer has authorized its release. The programme applies to new drugs not yet approved for sale in Canada and drugs currently used in clinical trials, as well as drugs approved for use in other countries, but not yet in Canada.

Surrogate markers: A surrogate is a substitute. If something under study is not readily measurable because it takes a long time to show up, researchers may use a "surrogate" to predict the eventual measurement. Viral load counts and CD4 counts are examples of HIV surrogate markers.

Toxicity: The unwanted effects (side-effects) or damage caused by a drug.

Viral Load (also called viral burden): Amount of HIV virus in the blood.

Washout period: A waiting period before starting the trial when participants do not take certain drugs so all traces of those drugs can be washed out of the body before they start taking the trial drug.

Where to Find Help

The following list includes organizations or programmes engaged in HIV treatment advocacy and/or who provide information on HIV treatments, clinical trials, and drug access.

ADVOCACY

AIDS Action Now!
Box 25Station F
Toronto, ON
M4Y 2L4
Tel: (416) 977-5903

Canadian AIDS Society (CAS)
4th Floor 309 Cooper Street
Ottawa, ON
K2P 0G5
Tel: (613) 230-3580
casinfo@cdnaids.ca
www.cdnaids.ca
National coalition of over 100 community-based AIDS organizations across Canada. A list of these organizations can be found on their web site or by contacting CAS by phone or fax.

Canadian Treatment Action Council (CTAC)
Box 116, Station F
Toronto, ON
M4Y 2L5
Tel: (416) 410-6538
ctac@ctac.ca
www.ctac.ca

Voices of Positive Women

P.O. Box 471, Station C
Toronto, ON
M6J 3P5
Tel: (416) 324-8703
vopw@idirect.com
webhome.idirect.com/~vopw

TREATMENT/CLINICAL TRIAL INFORMATION

Canadian HIV Trials Network

National Office
620 - 1081 Burrard Street
Vancouver, BC
V6Z 1Y6
Tel: 1-800-661-4664 or (604) 806-8327
ctn@hivnet.ubc.ca
www.hivnet.ubc.ca/ctn.html

Canadian AIDS Treatment Information Exchange (CATIE)
The Treatment Information Network

555 - 505 Richmond Street West
Box 1104
Toronto, ON
M5V 3B1
Tel: 1-800-263-1638 or (416) 203-7122
info@catie.ca
www.catie.ca

Local CAS Member Groups

Also, many of CAS' member organizations have locally-based treatment information programmes. A list of these organizations can be found on their web site or by contacting CAS by phone.

DRUG ACCESS INFORMATION

Special Access Programme (SAP)

Therapeutic Products Programme
Finance Building 2nd Floor
Tunney's Pasture A.L. 0202C1
Ottawa, ON
K1A 1B9
Tel: (613) 941-2108 or 941-3061 (After hours)
EDR_Drugs-BPA@hc-sc.gc.ca

REFERENCE

American Foundation for AIDS Research

120 Wall Street
Thirteenth Floor
New York, NY
10005-3902
(Publishes HIV/AIDS Experimental Treatment Directory, as well as a directory of all clinical trials in the United States)
Tel: (212) 806-1600
txdir@amfar.org
www.amfar.org

Canadian HIV/AIDS Clearinghouse

1565 Carling Avenue
Suite 400
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