IT'S YOUR HEALTH

Clinical Trials and Drug Safety

THE ISSUE

Every year, Health Canada receives hundreds of new clinical trial applications for testing new drugs or new uses of approved drugs on humans. These trials give Canadians a chance to take part in research that could improve their health. Clinical trials can be an important treatment option, but like all drugs, the ones used in clinical trials have potential benefits as well as risks because there is usually limited information about the safety and efficacy of the drug being studied.

Before you take part in a clinical trial, you should discuss the potential risks and benefits with your health care provider, so that you can make an informed decision about your health and participation in a study.

THE BASICS ON CLINICAL TRIALS INVOLVING DRUGS

When researchers develop new drugs, the first tests are called pre-clinical studies. These tests are done using cells, tissue samples, or animals. If the results are promising, the next step is a clinical trial.

Clinical trials are studies to find out whether the drug is safe and effective for people. The people who take part in trials are volunteers. They may be patients with a specific disease, or healthy people wanting to contribute to the advancement of medical knowledge.

The individual or organization that wants to test the drug is called the sponsor. Health Canada does not sponsor or conduct drug research. Clinical trial sponsors are usually drug companies, or researchers from a hospital, university, or research organization.

Before conducting a trial, the sponsor submits a clinical trial application to Health Canada. Our scientists review the application to make sure:

- the use of the drug in the patients being studied is appropriate
- any risk associated with use of the drug is minimized as much as possible
- the best interests of the people participating in the trial are upheld
- the objectives of the trial are likely to be achieved

Canada

Clinical trials in Canada are done under strict conditions defined in Canadian *Regulations* and must follow Good Clinical Practices. The regulatory framework was put in place to:

- protect the health of the people in the trial
- make sure the trials are well-designed and conducted properly by trained professionals
- make sure that trials are monitored adequately and potential side effects are reported to Health Canada
- require that trials are reviewed by a Research Ethics Board

The people who carry out clinical trials are called investigators. Canadian law requires that investigators are physicians or dentists. Other staff that could be involved in a clinical trial includes researchers, nurses, or other health professionals. Most often, the trials have research teams and take place in hospitals, medical clinics, doctors' offices, and universities.

THE FOUR PHASES OF CLINICAL TRIALS

Clinical trials are done in phases. Each phase has a different purpose and helps researchers answer specific questions.

Phase I – These trials test an experimental drug on a small group of people for the first time. The purpose is to:

- assess the drug's safety
- find out what a safe range would be for dosage
- identify side effects

Phase II – The drug is given to a larger group of people (usually 100 or more) to:

- obtain preliminary data on the effectiveness of the drug for a particular disease or condition
- further assess the drug's safety
- determine the best dose

Phase III – The drug is given to even larger groups of people (usually 1,000 or more) to:

- confirm its effectiveness
- monitor side effects
- compare it to commonly used treatments
- collect information that will allow the drug to be used safely on the market

Phase IV – These trials are done after the drug is approved and is on the market. They gather information on things like the best way to use a drug, and the long-term benefits and risks.

POTENTIAL BENEFITS

When you take part in a clinical trial, you help others by advancing medical research. If you have a disease, there could be personal benefits.

- You may get early access to a new promising treatment.
- The treatment may cure or control your condition. Even if you are not cured, your quality of life might improve.
- You may get additional access to expert health care because of the time you will spend with the research team involved in the study.

POTENTIAL RISKS

If your reason for being in a clinical trial is to get access to a new treatment, be aware that this may not happen. Clinical trials often compare a new drug to:

- an approved drug that is already on the market
- a placebo (a dummy treatment with no active ingredients)

In many cases, people are not told which treatment they are getting in order to generate unbiased results. Even if you get the new drug, it may not help you. It might be less effective than a treatment you were using before the trial. There is also a risk of serious side effects (short-term and long-term) as the safety profile of an investigational drug is not as well understood as an approved drug.

A clinical trial can take up a lot of your time for things like travel, tests and even hospital stays.

REDUCE YOUR RISK

Every person who participates in a clinical trial must give their informed consent before beginning in the trial. Study the Informed Consent form before you decide whether to join a clinical trial. It tells you the benefits and risks so you can make an informed decision about your health and your decision to participate. Discuss it with your family and friends. If you have concerns, talk them over with your health professional.

Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

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If you decide to join a clinical trial:

- Take medications exactly as instructed. Follow all directions given by the clinical trial doctors and staff.
- Attend all scheduled visits.
- Report any symptoms right away, even if you are not sure they are related to the trial.

You have the right to quit a clinical trial at any time. If you quit, the trial's medical staff will make sure you are taken off the medication safely.

THE ROLE OF CLINICAL TRIALS IN DRUG APPROVALS

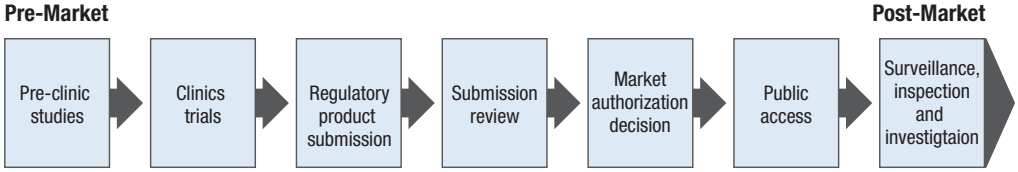
The diagram below shows how clinical trials fit into Canada's system for drug approvals.

If clinical trials prove that a drug's benefits outweigh the risks, and the company that makes the drug wants to market that drug in Canada, it applies to Health Canada for market approval. This involves submitting detailed information about the drug's safety, effectiveness and quality, like:

- the results of pre-clinical studies and clinical trials
- details about the way the drug is produced, packaged and labelled
- information about health claims and side effects

Health Canada's scientists review this information. If they conclude that the benefits outweigh the risks, and that risks are being kept as low as possible, the drug is approved for sale in Canada. The new drug then gets:

- a Notice of Compliance (NOC)
- a Drug Identification Number (DIN)



Canada

THE GOVERNMENT OF CANADA'S ROLE

Health Canada plays an active role in making sure Canadians have access to safe and effective drugs. As part of this work, we protect the health of Canadians who take part in clinical trials. For example, we:

- review clinical trial applications
- make sure drug companies do all of the safety tests needed to reduce the risk of side effects
- visit sites where clinical trials take place to make sure patients are being monitored properly by their doctors and that the trials are conducted properly
- keep track of negative side effects that occur in clinical trials and take action when needed

If there are severe side effects, we may stop the trial or require that patients be monitored more closely.

We also give Canadians information about clinical trials so that they can make informed decisions about their health. Our website lists all the phase I, II, and III drug patient clinical trials in Canada. The list is updated each night, and has information like:

- the sponsor and title of the study
- the drug being tested
- the start and end dates
- the type of volunteers needed (age range, sex, medical condition, etc.)

In addition, the Canadian Institutes of Health Research provides funds to support all areas of health research, including clinical trials.

FOR MORE INFORMATION

- Search our list of drug clinical trials in patients in Canada: http://ctdb-bdec.hc-sc.gc.ca/ctdb-bdec/index-eng.jsp
- Read more about informed consent: www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php#a4.8
- How Drugs are Reviewed in Canada: www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/fs-fi/reviewfs_examenfd-eng.php
- Canadian Institutes for Health Research: http://cihr-irsc.gc.ca/e/9466.html
- Search for Canadian clinical trials registered on reliable international web sites:
  - ClinicalTrials.gov: http://clinicaltrials.gov
  - Current Controlled Trials: http://www.controlled-trials.com
- Summary Report of Inspections of Clinical Trials Conducted from April 2004 to March 2011: www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/report-rapport/2004-2011-eng.php

FOR INDUSTRY AND PROFESSIONALS

- Clinical trials—guidance documents: www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/index-eng.php
- Clinical trials manual: www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_intro-eng.php
- Improving our Competitiveness in Conducting Clinical Trials: www.cihr-irsc.gc.ca/e/45852.html

RELATED RESOURCES

- For safety information about food, health and consumer products, visit the Healthy Canadians website: www.healthycanadians.gc.ca
- For more articles on health and safety issues go to the *It's Your Health* web section: www.health.gc.ca/iyh

You can also call toll free at **1-866-225-0709** or TTY at **1-800-267-1245***

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