



Canadian Cancer Society  
Société canadienne du cancer

# Clinical Trials

*A guide for people with cancer*



Let's Make Cancer History

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## Introduction

All around the world, people take part in clinical trials in all areas of medicine. Clinical trials are very important because they help us learn more about diseases such as cancer. Thousands of people are helped each year because they decided to take part in a clinical trial and many more benefit from their participation.

### About this booklet

This booklet focuses on cancer treatment trials, the most common type of clinical trial for people with cancer. In this booklet you will find some basic information about clinical trials: how and why they are done, how you can join a trial and what you can expect if you decide to take part in a trial. The information we provide can help you discuss the subject with your doctor and family.

## About clinical trials

### What is a clinical trial?

A clinical trial is a type of research study. Clinical trials help find new methods for diagnosing, treating, managing and preventing cancer. There are four main kinds of clinical trials in cancer research:

**Cancer treatment trials** look for better ways to treat cancer and help improve cancer care. If a new or improved drug or treatment method is proven to be safe and works well, then it can be made available to the public. Trials are the only reliable way to find out if new drugs and new methods of surgery or radiation are better than the cancer treatments being used today. Studies may look at new types of treatment, such as gene therapy, but they can also look at how to combine therapies or whether an existing drug can be used in a new way.

**Cancer prevention trials** look for ways to reduce the risk of developing cancer or prevent it from coming back. This may include using drugs, or making changes to lifestyle (for example, diet or activity levels).

**Cancer screening trials** test the best ways to detect cancer, especially in its early stages.

**Quality-of-life trials** study ways to improve the comfort of people living with cancer or help them cope with the disease. These trials may study ways to reduce or manage nausea, fatigue, depression, pain and other problems caused by cancer or its treatment.

## Why clinical trials are important

Clinical trials show us what does and doesn't work in medicine. They answer important scientific questions and lead to future research. Through past clinical trials, doctors have developed new methods of surgery that are easier on the patient, found new and more effective drugs for specific types of cancer and found treatments that have fewer side effects.

Cancer treatments that are in use today were first developed and tested in clinical trials.

Many people who have cancer now live longer and also enjoy a better quality of life because of important improvements to care made through clinical trials.

## How clinical trials work

Cancer treatment trials are the most common type of clinical trial for people with cancer. A clinical trial is only one step in the development of a new treatment, which is a long and careful process that takes many years. The search for new treatments starts in the laboratory. Trials done in a laboratory are called *pre-clinical studies*.

Pre-clinical studies test new treatment ideas on cancer cells in a laboratory dish or a test tube. Treatments that show promise in cell studies are next tested on tumours in laboratory animals. Only when the pre-clinical studies suggest that the new treatment is likely to be safe and effective in people can Health Canada approve the treatment for further testing in clinical trials.

## *The phases of a trial*

Clinical trials take place in phases. Each phase is designed to answer specific questions. After each phase of a trial, results are analyzed. If the results are good, the study is approved to move on to the next phase. The entire process can take many years, even decades.

**Phase I trials** look at how safe a treatment is and what the best dose of a medication is. Phase I trials are riskier than the later phases because this is the first time the new drug or therapy is being tested on humans. For this reason, phase I trials usually involve only a small number of people with cancer (about 15 to 30). The first patients will receive a low dose of the treatment and are watched very closely. If there are no side effects or if the side effects are minor, then the next group of patients will receive a higher dose. This continues until the doctors find the dose that works the best with an acceptable level of side effects.

Phase I studies try to answer basic questions, such as:

- How should the new treatment be given? By mouth, by injection or by intravenous (IV) drip?
- How often should the treatment be given?
- What is the safest dose and what is the highest dose that a person can tolerate?
- What effect does the drug or therapy have on the body?
- What are the side effects of the drug or treatment? Are they harmful?
- Can the new drug be given along with existing ones?

**Phase II trials** test how well new drugs or therapies work, once they have been proven to be reasonably safe in phase I. Usually a small group of people (fewer than 100) get the same treatment in this phase of a clinical trial. The goal is to answer such questions as:

- How effective is the treatment and for how many of the people who took it?
- Which types of cancer might it be used to treat?

Researchers also continue to collect information about side effects. Because the researchers know which side effects are most likely to occur from the phase I studies, they can deal with them right away if necessary.

**Phase III trials** involve large groups of people (hundreds or thousands). In phase III trials, researchers compare treatments. They compare new treatments with the *standard treatment*, which is the best cancer treatment already in use. This means that everyone in the trial gets treatment. Researchers also gather more information about side effects that the new treatment may cause. Sometimes phase III trials are used to find out whether the new treatment is as effective as the standard treatment, but causes fewer side effects.

Phase III trials answer such questions as:

- Are people who get the new treatment less likely to have their cancer spread?
- Are people who get the new treatment likely to live longer?
- Are there fewer side effects from the new treatment?
- How has the new treatment affected the participants' quality of life?

#### **Approving a new drug or treatment**

If a new drug or treatment proves to be safe and effective in phase III trials, it can be submitted to Health Canada for approval. Once the treatment is approved, doctors can recommend it to all their patients.

Some phase III trials will study a new treatment even after it has been approved. Researchers may want to investigate new ways of using it and improving it. For example, they may try to reduce how often a medicine is given (*dosing*) or look for ways to lessen the side effects, but make sure it is still effective.

**Phase IV trials** watch for long-term risks and benefits of the treatment and look for possible rare side effects. They may also look for added benefits of the treatment. For example, a new drug may have been approved because it reduces the chance of the cancer coming back. Researchers may want to see if this also means that the treatment helps people live longer.

#### **Trial design**

Different methods are used to compare treatments. Patients taking part in a study are put into groups. Which patients go into which group is determined by chance, much like flipping a coin. This is called *randomization*. Patients are put into either a group taking the new treatment (called the *experimental group*) or a group taking a standard treatment (called the *control group*). Each of these groups is called a *study arm*.

Some studies may have several experimental groups along with a control group to study different things about a new treatment at the same time, such as different doses.

**Randomization in trials:** A computer will assign patients at random to each of the study arms so that all groups have a similar mix of patients of different ages, sex and states of health. If one group does better than the other group, it's likely to be because of the treatment, as the two groups are the same in many ways.

**Controls used in trials:** The control group is a very important part of a trial. Researchers compare the new treatment to the standard treatment (received by the control group) to see if the new treatment is more effective or has fewer side effects. Without a control group, researchers would not be able to tell if improvements in the patients were due to the new treatment or to chance.

**Blinded trials:** In a blinded trial, the researcher will know whether you are in the control group or the experimental group, but you will not. This is because knowing what treatment you are getting can affect how you feel. For example, knowing you were taking a new treatment might make you feel more positive, or more negative, and might influence what you report to the researchers. This could influence the results of the study and make the research less reliable.

In a *double-blind trial*, neither the patients nor the researchers working with them know which treatment group the patients are in

or what treatment they are getting. That information is known only to the trial organizers who do not work directly with the patients. This is done so that the researchers are not unconsciously influenced to expect or report better results for patients receiving the new treatment.

**Open and closed trials:** Open trials are studies that are still looking for patients to take part. Closed trials are no longer accepting new participants. Once a closed trial is completed and the information has been analyzed, researchers will submit the results for review and publication in a medical journal.

## How clinical trials are run

Every clinical trial has an action plan that describes how the trial will be run. This is called a *protocol*. The protocol describes what will be done in the trial and why. It outlines how many people will take part in the study, what medical tests they will receive and what treatment plans will be used. All clinical trials follow very strict ethical standards that protect your health, safety and privacy. Each year hundreds of researchers working in hospitals, universities and other research centres across Canada submit their trial protocols for approval.

## Seeking approval and protecting you

All clinical trial protocols must be approved by Health Canada and the hospital or clinic where the trial will take place. Protocols must also be approved by a research ethics board. A research ethics board is an independent group that includes doctors, nurses, medical staff, members of the public and sometimes lawyers. Many institutions have their own research ethics boards.

Health Canada and a research ethics board monitor every trial until it is completed. These groups oversee the rights, safety and well-being of all the participants and make sure that trials follow proper scientific methods.

## Funding a trial

Clinical trials are very expensive and funding may come from different sources, both private and public. Private sources include pharmaceutical companies and biotechnological companies. Public sources include government, hospital foundations and non-profit organizations such as the Canadian Cancer Society's research partner, the National Cancer Institute of Canada.

## Where trials take place

Clinical trials usually take place in the same location where standard cancer treatment is given – cancer centres, hospitals, clinics or doctors' offices. Some trials have only one or two locations, especially phase I trials. Large clinical trials (phase III) may involve thousands of people at many locations across Canada, the United States or around the world. Each location is called a *trial site*.

## Who runs them

Every trial is led by a *study chair*. Usually this is a doctor with a lot of experience in the subject that is being studied. The study chair is in charge of running the trial and coordinates with all the members of the clinical trial team at all locations. Committees of expert investigators design the trial protocol.

Every trial site has a *site investigator* who is in charge of the trial at that location. Every doctor taking part in the trial, at every location, follows the same trial protocol.

Doctors, nurses, pharmacists, lab technicians and other healthcare providers also make sure the clinical trial runs smoothly. You will work closely with some of them as part of your clinical trial team.

## Participating in clinical trials

### Joining a clinical trial

You may be thinking about taking part in a clinical trial or your doctor may have asked you about participating in one. There are many reasons why you might choose to take part. Many people like the idea that they're helping others with cancer, both now and in the future.

If you're thinking of participating in a clinical trial, talk to your doctor or someone on your healthcare team. They can answer your questions and help find out whether you're eligible to enter a specific trial. Before deciding whether a clinical trial is an option for you or someone you care about, it's important to learn all you can about the trial.

### What you need to know

Each clinical trial has its own protocol, criteria for eligibility, benefits and risks. It is important that you understand each of these before you decide to enroll in a trial. Discuss the details of the clinical trial with your healthcare team.

### What is the trial's protocol?

Learning about a trial's protocol is a good place to start. It will help you understand the study, how it will be run and how your safety will be protected. The protocol is summarized in the *informed consent form* and includes:

- how many people will take part in the trial
- what medical tests you will need to have and how often
- what type of treatment you will be given and how often
- what side effects you may experience during the trial
- how long the trial will last

### Are you eligible?

Each clinical trial enrolls people who are alike in many ways so that the study's results will be scientifically accurate. You will need to find out if you meet the conditions, or criteria, for entering the trial.

Eligibility criteria may include things like:

- your age and sex
- the type of cancer
- the stage of the cancer
- your overall health and whether you are being treated for other medical problems
- whether you have had any previous cancer treatment
- the length of time since you last received treatment
- the results of certain lab tests
- how close you live to where the clinical trial treatment will be given

### What are the possible benefits and risks?

Clinical trials are carefully designed to have as few risks and as many benefits as possible for everyone who takes part, whichever treatment they get. But each clinical trial offers its own possible benefits and risks. It is important to discuss these with your doctor.

### Possible benefits

- You may receive treatment that is not otherwise available, which might be safer or more effective than current treatment options.
- Even if you do not receive the new treatment being tested, you can be sure that you will receive the best standard cancer treatment available.
- You may benefit from the extra follow-up care provided for participants.
- You take an active role in a decision that affects your life. This can be personally empowering and give you a sense of control.
- You have a chance to help others and to improve how cancer is treated.

### **Possible risks**

- New treatments under study are not always better than, or as good as, the standard ones.
- There may be unexpected side effects that may be worse than those caused by standard treatments. Your trial team will carefully watch your reactions during the study.
- The new treatment may not work for you, even if it helps others. This is true for all treatments, even the ones that are currently used as standard treatment.
- Being in a trial may take more time than standard treatment would or it may be inconvenient. You may need to have more tests or take extra medicines.

### **Making a decision**

Choosing whether or not to take part in a clinical trial is a difficult decision and the answer is not the same for everyone. There is no right or wrong answer. When you're trying to decide, first ask yourself some basic questions:

- Why do I want to take part in a clinical trial?
- What are my goals and expectations if I decide to participate?
- Are they realistic?

The following steps can help you organize your thoughts and make an informed decision about taking part in a clinical trial. Take the time you need to decide.

### **Know your rights**

It is important to know your rights when participating in a clinical trial. Your rights include:

- Being given all the facts about a clinical trial before deciding to take part. This important process is known as *informed consent*.
- Having your reactions to the new treatment monitored carefully.

- Being part of the clinical trial voluntarily. You can leave the trial at any time. If you choose to leave the trial, you will continue to receive the best standard treatment possible.

### **Think about what's important to you**

While some people might feel more comfortable getting the best standard care for their cancer, others don't feel satisfied unless they have explored every possible option for themselves or a loved one. Only you know what matters most to you.

### **Be sure you have all the facts**

Before joining a clinical trial, gather all the information you can. Talk to your doctor, the clinical research associate or someone who is familiar with the study protocol. Read the informed consent form. Take some time to read and absorb the facts about the study, as well as the information in this booklet. Write down any questions you have.

### **Don't be afraid to ask questions**

If you have questions about the information you receive, or about anything else, don't be afraid to ask. If possible, have a friend or relative go with you when you talk to your doctor, the clinical research associate or the clinical trials nurse. It's a good idea to write down the answers to your questions or ask if you can record the conversation. If you're not sure that you've understood the information, try repeating it back to the doctor or nurse using your own words. You might also want to check with another healthcare professional who is not part of the clinical trial team to get another opinion on the study.

Here are some questions you may want to ask:

### **About the purpose of the clinical trial**

- Why is this study being done?
- Why do researchers believe the new treatment being tested may be effective?

- Has the treatment been tested before?
- Who is funding the study? Who has reviewed and approved it?

#### **About the possible risks and benefits to you**

- What is the standard treatment for the type of cancer I have?
- What is likely to happen in my case, with or without this new research treatment?
- What are the possible short-term and long-term risks, side effects and benefits to me of this new treatment or approach?
- How do these risks and benefits compare with the risks and benefits of standard treatment?

#### **About your care**

- What kinds of treatment, medical tests or procedures will I receive during the study?
- How do they compare with what I would receive if I do not take part in the study?
- How often and for how long will I receive the treatment?
- How long will I need to remain in the study?
- Where will my treatment take place?
- How will I know if the treatment is working?
- Who will be in charge of my care?
- Will I be able to see my own doctor?
- Will there be follow-up after the study? For how long?

#### **About personal issues**

- Will the study require extra time, work or expenses on my part?
- If I need to travel, will my expenses be paid back?
- What does my family need to know about the treatment? Can they help?
- Can I talk to other people who are in this study?
- What support is there in the community for me and my family?

## **Giving informed consent**

You will be asked to give informed consent before taking part in a clinical trial. You will receive a printed *informed consent form* that outlines key facts about the study in plain language. The form should include details about the treatments, tests and any potential benefits, risks or side effects of the treatment. It should explain anything else that you may have to do. If you agree to take part in the study, you will be asked to sign the consent form and you will be given a copy of it.

Giving your informed consent means:

- You understand that the trial is a scientific experiment, and there may be risks to your health.
- You have been told why the trial is being done, the drugs you might be given, the number of clinic visits and the kinds of lab tests required.
- You have all the information you need to decide whether to take part in the trial.
- You understand your rights and responsibilities.

The informed consent process continues throughout the study. You will be told about any new information that develops during your clinical trial, such as new risks. You may be asked to sign a new consent form as things develop during the study.

#### **Even after you have given your consent, you can leave the trial any time**

You are in control and have the right to leave a clinical trial at any time. You do not need to give a reason.

If you are getting a new treatment as part of a trial you may not be able to continue having the new treatment, but you will be given the best standard treatment available for your type of cancer.

Your personal information will still be kept private and confidential.

## Concerns you may have about taking part in a clinical trial

If you have concerns about taking part in cancer research, you're not alone. Here are some of the concerns that other people have had as they were deciding whether or not to enter a trial. Talk to your doctor if you have more questions.

***“I must be really sick, or my cancer must be getting worse. Otherwise my doctor wouldn't have suggested a clinical trial to me.”***

Many people believe that if their doctor suggests a clinical trial, they must be very ill or dying. If your doctor talks to you about taking part in a trial, ask why. Clinical trials aren't just for people with the most advanced stages of the disease. Phase III trials, for example, can include patients with all stages of cancer.

***“If I join a research study, I'll become a guinea pig in an experiment where no one cares about me.”***

Some people fear the idea of taking part in an experiment. The design of the trial and how it's carried out follow strict procedures, and are observed carefully and reviewed regularly. This ensures that your safety and well-being are maintained.

***“I might be put in the placebo group, and then my cancer will get worse.”***

A placebo is a pill or injection that looks like the drug or other substance being tested, but the placebo doesn't contain an active drug. If you do take part in a trial with placebos, you will still receive the best standard treatment available for your type and stage of cancer. Using placebo groups in cancer research is quite rare and would be done for two reasons:

- to test a new treatment that is given with the standard treatment
- when there is no treatment for a certain group of patients

These types of studies are allowed because the patient is not being denied the standard treatment. If a placebo is part of the clinical trial, you will be informed before entering the study, but you will not know whether you will receive a placebo or the new treatment.

***“Once I sign up, I won't be able to quit.”***

You can drop out of the study at any time, even if you have signed the informed consent form. Also, if your doctor feels it's in your best interest, you may be removed from a study and offered other treatment. This can happen if a treatment is found to be harmful or not effective. If there is clear evidence that the new method is better than the others before the study is complete, the trial will be stopped and everyone enrolled in the trial will be given the new treatment.

***“Does participating in a clinical trial cost me anything?”***

In most cancer treatment trials in Canada, provincial health insurance or the group sponsoring the study will cover the cost of care, medicine and testing. But you may also have additional personal costs or expenses by taking part in a study. It's a good idea to ask the healthcare team about possible additional costs before you start the trial.

Here is a list of things that you may need to consider.

- **Medication costs:** You may need medicine to treat side effects of treatment, such as anti-nausea drugs. These may be covered by your personal insurance or the study sponsor, but not in all cases.
- **Travel costs:** Getting to and from the treatment centre may be an extra cost for you. If you live in a small town or rural area, you may have to travel to a bigger city for your treatment and follow-up tests.
- **Loss of wages, child-care costs:** The clinical trial may involve more of your time than standard treatment would and you may need to take time off work. Depending on your work situation, this may mean a loss of pay. You may also have increased costs for child care.

## What to expect during a clinical trial

### The people on your clinical trial team

Your clinical trial team will include doctors, nurses, social workers and other healthcare professionals. They will follow your care throughout the trial. Your family doctor or *oncologist* (cancer specialist) will either be involved in the trial or will be informed that you are taking part in the trial. Your doctor will continue to manage your overall cancer care.

A *clinical trials nurse* or *clinical research associate* will meet with you if you want to know more about a trial or find out if you are eligible. If you decide to take part in a study, the clinical research associate will support you throughout the trial and answer your questions. Your clinical research associate will work with you and your doctor to set up tests or exams and will help you fill out any questionnaires that are part of the trial.

The *site investigator* is the doctor in charge of the clinical trial at your specific location. Your site investigator may or may not be the principal investigator of the trial.

Other team members work behind the scenes. A research coordinator works closely with the doctor to make sure the study runs smoothly. Others, such as data managers and data analysts, manage, record and analyze all the information gathered during the study.

### Your role

It is important that you understand the rules of your clinical trial and that you follow the instructions you are given. Your progress will be watched closely and a few extra clinic visits may be needed to collect information. Depending on the type of clinical trial you're enrolled in, you may need more blood tests or x-rays than you would if you were having the standard treatment. Be sure you know how often you're expected to go to the clinic or doctor's office. Let your team know if you can't stick to the schedule.

For some studies, you may be asked to make changes to your lifestyle habits, such as changing your diet, exercising more or quitting smoking. Sometimes you may have to keep track of certain things. For example, you may be asked to keep a record of your symptoms or your feelings. Filling out forms or answering questionnaires about your health may also be needed.

Many studies continue these checks (clinic visits and questionnaires) on patients after their treatment is finished.

### The stages of trial participation

Clinical trials have different stages. The length of each of these stages is different for every trial. Some trials take months to complete, while others may take several years or even decades. Be sure to tell your healthcare team if you're planning to move during the trial. You may be able to continue the trial at your new location.

#### **Randomization**

At the beginning of the trial you will be randomly assigned to a study group or arm.

#### **Treatment**

During this stage, you will be treated with the experimental treatment or the standard treatment for your type of cancer.

#### **Follow-up**

Once you finish treatment, your healthcare team will discuss your follow-up care with you. Follow-up care helps you and your clinical trial team monitor your progress and your recovery from treatment. At first, your follow-up care may be managed by a member of your clinical trial team. Later on it may be managed by your family doctor. The schedule of follow-up visits is different for every trial and every person. When you complete the follow-up period, you may also be asked to take part in an exit interview or to fill out a questionnaire.

Even when your treatment and follow-up are finished, the clinical trial may not be complete. The study isn't over until all the participants have finished treatment and follow-up.

## Once the trial ends

### After the trial

Not all participants in a trial are enrolled at the same time. You may have to wait for a period of time after you're finished before the trial is over. For example, a two-year trial may take several years to reach its conclusion because not everyone enrolls at the same time and the last person enrolled must be in the study for two full years.

During your exit interview, you may be told what treatment you were given during the trial. In double-blinded studies, this information can be given out only after everyone has completed the trial. You will be asked to contact your clinical trials team if you experience any unexpected symptoms or side effects even after the trial ends.

The end of the trial treatment and follow-up may bring mixed emotions. You may be glad the treatments are over and may look forward to returning to your normal activities. But you may feel anxious as well. You may worry about no longer being closely monitored or you may be nervous while waiting for the results of the trial. If you're worried about the trial ending, talk to your healthcare team. They are there to help you through this transition period.

## Finding out the results

After a clinical trial, researchers look carefully at all the results before making any conclusions about the study's medical importance. Phase I and II trial results are analyzed to see if the study can enter the next phase.

The first outcome that researchers observe in phase III trials is how effective the new therapy was in treating cancer. They will look to see if the cancer has stopped growing, shrunk or disappeared. This is called *treatment response*. Doctors and researchers monitor whether more patients survive, or live longer, with the new treatment. They will record short-term and long-term side effects.

The results of clinical trials are often first reported in scientific journals or at conferences. To find out if the results of a study you participated in have been published:

- Ask your doctor.
- Search online for the study in the *PubMed* database of medical publications. If you're not sure about how to find the study, your local librarian or the research librarian at a university may be able to help. (It's easiest to find the results if you know the full name of the study.)

Extremely positive findings from phase III trials may be fast-tracked for approval by Health Canada and the new drug or treatment may become available for general use. Particularly important results are likely to be featured in media reports and widely discussed.

## How to find a clinical trial

### **Contact the Canadian Cancer Society**

Our trained information specialists can help you search for a clinical trial. We can also provide you with information about clinical trials before you talk to your doctor. You can:

- Call us toll-free at **1 888 939-3333** Monday to Friday, 9 a.m. to 6 p.m.
- E-mail us at **info@cis.cancer.ca**.
- Visit our website at **cancer.ca**.

Our services are free and confidential.



### **Search online**

Please note that the information on clinical trials websites is often developed for researchers and may include medical language that can be difficult to understand. You may also want to ask your doctor about privately funded trials or those funded by drug companies that may not be listed on these websites.

#### **Canadian Cancer Trials**

**www.canadiancancertrials.ca**

#### **National Cancer Institute**

**www.nci.nih.gov/clinicaltrials/**

### **If you find a trial but can't participate**

If you find a trial but it's no longer accepting patients or you don't meet the eligibility criteria, your doctor may be able to help you get the treatment being studied through Health Canada's Special Access Programme.

Through this program, doctors can request access to drugs that are not generally available for sale in Canada. Doctors can use this program for patients with serious or life-threatening health problems on a compassionate or emergency basis when standard therapies haven't worked, are unsuitable or are unavailable. Each request is looked at on a case-by-case basis. Drug companies are not required to provide a drug through the Special Access Programme. They may charge a fee for the drug.

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## We'd like to hear from you

E-mail us at [publicationsfeedback@cancer.ca](mailto:publicationsfeedback@cancer.ca) if you have comments or suggestions to help us make this booklet more useful for you and other readers.

## What we do

The Canadian Cancer Society fights cancer by:

- doing everything we can to prevent cancer
- funding research to outsmart cancer
- empowering, informing and supporting Canadians living with cancer
- advocating for public policies to improve the health of Canadians
- rallying Canadians to get involved in the fight against cancer

Contact us for up-to-date information about cancer, our services, or to make a donation.



Canadian Cancer Society  
Société canadienne du cancer

Let's Make Cancer History

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