



Cancer Clinical Trials



A guide for patients, caregivers, and their families

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Cancer clinical trials

Clinical trials are a potential treatment option for patients with cancer and like all other options, comes with risks and benefits. Before you commit to any treatment, it is important to be familiar with all your options - including those that may only be available through a clinical trial.

This guide aims to familiarize patients, their caregivers, and their families with clinical trials so that they are better equipped to make informed decisions about their treatment.

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What is a cancer clinical trial?

A cancer clinical trial is a research study that compares the most effective known treatment (**standard of care**) for a specific type or stage of cancer with a new treatment. This may be a new drug or a combination of drugs, or a different way of using existing therapies.

Clinical trials help to answer questions like:

- Is this treatment safe?
- Does the treatment improve or cure disease, or help people live longer with the disease compared to other treatments?
- Does the treatment help people feel better?

A common misperception about clinical trials is that they are a last resort. Joining a clinical trial may be an appropriate option at any point during a patient's course of treatment.

Clinical trials are carefully designed and monitored to ensure that risks to the people participating are minimized as much as possible.

Remember that clinical trials are something you volunteer to do, not something you have to do.

Examples of health interventions that may be studied in a clinical trial:

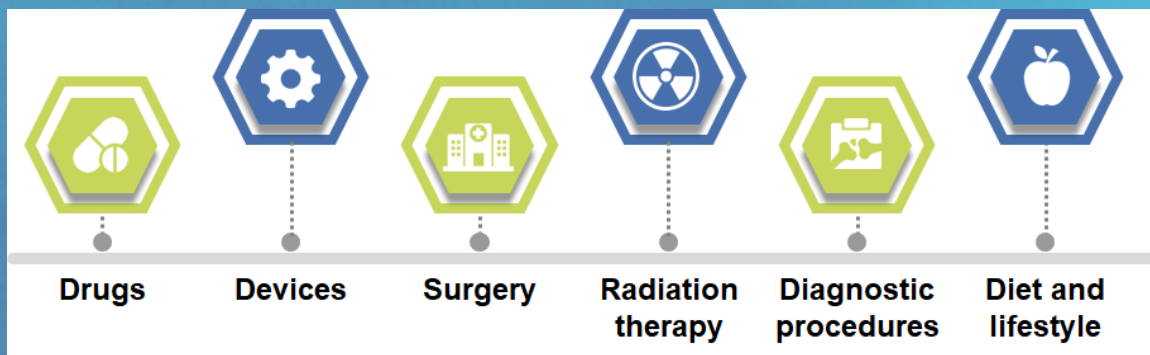


Image source: CTO

Why are clinical trials done?

Clinical trials are done to provide research data, or evidence, about the interventions being tested. This evidence helps to decide what therapies or interventions might work best for people. The goal of clinical trials is to improve medical treatments and peoples' health and well-being.

Where do clinical trials take place?

In Canada, clinical trials are conducted at cancer centres, research institutes, hospitals, and clinics. There are over one thousand cancer clinical trials currently recruiting in Canada.

Developing new drugs and treatments for diseases is a very long and rigorous process which aims to ensure their safety and effectiveness. It may take many years for a drug to go from being tested in a laboratory to being available for patient use.

Why should I consider joining a clinical trial?

High level of patient care

Participants in a clinical trial are closely monitored and guided through treatment by clinical trial staff and clinicians.

Access to promising new treatments

A clinical trial compares the most effective therapy currently available for a given cancer with a therapy that is being evaluated for future use. The new therapy may be better than the current therapy.

Contribute to improving cancer care for all

Less than 10% of patients with cancer are enrolled in clinical trials. Clinical trials are the only way to find out if a new therapy is better than the standard of care.



In a clinical trial, what makes a treatment effective?

Specific outcomes are measured in a clinical trial that will tell clinicians about the effectiveness of the treatment being tested compared to the standard of care. Common outcomes used in clinical trials include:

Overall survival

do patients live longer?

Disease-free or progression-free survival

do patients have longer periods of time when their cancer shrinks or does not grow or spread to new places in the body?

Quality of life

do patients have better quality of life with fewer side effects or symptoms of cancer?

Recurrence

how frequently does the cancer come back?

What are the risks in participating in clinical trials?

Clinical trials undergo close review by researchers, a Research Ethics Board, patient advocates, regulatory agencies such as Health Canada and the Food and Drug Administration (USA), as well as the institutions (i.e., hospitals) where the clinical trial takes place. Despite this rigorous review, clinical trials are not risk-free. It is important to consider that:

- new treatments might not be better than the standard treatment available
- there may be unexpected side effects, or side effects may be worse as compared to the standard treatment
- some costs (e.g., travel costs) associated with the clinical trial may not be covered. Be sure to check with your doctor to find out what costs are covered/not covered
- some trials may require that you travel far from where you live to receive treatment. Check with your doctor before committing to a trial to be sure that you can manage any logistical issues

Clinical trial eligibility

Each clinical trial has specific eligibility criteria which determines who can participate. For example, a clinical trial may be recruiting patients of a specific age group, with a specific type of tumour, or patients who have a certain genetic mutation present in their cancer.



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The Four Phases of Clinical Trials

Clinical trials are designed to answer specific questions about a new intervention. Generally, clinical trials are designed by a group of people that may include researchers, doctors, scientists, statisticians, sponsors, and increasingly - patients and caregivers.

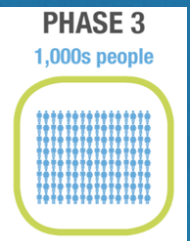
Clinical trials are usually carried out after a specific treatment or therapy has been studied for many years in the laboratory, in cells and in animals. Before a drug reaches people, a significant amount of data must be collected. The research done before the start of a clinical trial is called **preclinical research**.



Once a drug is approved for human studies, it is tested in a small number of people to determine the optimal safe dose, safety, and side effect information. Phase I trials generally have a timeframe of weeks.



If the treatment is determined to be safe after Phase I, it is tested in a Phase II study. These studies aim to ensure that the intervention does what it is supposed to do (**treatment efficacy**), and to learn more about optimal dose and potential side effects. Phase II studies are carried out in a larger number of people and have a longer timeframe of months.



Phase III trials are also known as **randomized clinical trials** and test how long the effects of an intervention last and continue to learn about possible side effects. Phase III studies involve many participants and occur over a timeframe of years.

When a trial is randomized, participants are randomly assigned to receive either the new treatment or the established standard of care. These trials are designed to provide the definitive evidence to support approval of the drug for public use.



Phase IV trials occur after a drug has been approved for public use and are sometimes called post-marketing trials/post-marketing surveillance. They monitor an intervention after it has entered the market to observe long-term side effects on a very large group of people outside the highly controlled setting of a clinical trial. These trials have a long timeframe of many years.

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Will I receive a sugar pill?

While sugar pills, or placebos, may be part of certain types of clinical trials, no patient on a cancer clinical trial will receive less than the standard of care - all patients will receive some treatment.

Are clinical trials safe?

Keeping participants safe is of utmost importance in clinical trials. In Canada, clinical trials must:

- protect the health of the people in the trial
- be well designed and conducted by trained professionals
- be monitored and side effects reported
- be reviewed by a Research Ethics Board.

Remember that participation in a clinical trial is 100% voluntary. Therefore, anyone who enrolls in a clinical trial of any kind will participate with **informed consent**. This means that your doctor will explain the trial, its potential risks and benefits and all the procedures involved. Informed consent is an ongoing process throughout a clinical trial, and *you can withdraw your consent to participate at any time*.

What will it cost to participate in a clinical trial?

In Canada, you should not be asked to pay to participate in a clinical trial. The treatments will be covered by the trial sponsor (i.e., a pharmaceutical company). You may be required to pay for certain expenses such as travelling to your appointments, parking, etc.

Be sure to discuss with your doctor exactly what costs the trial sponsor will cover and what your out-of-pocket costs might be.

If you are considering participating in a clinical trial, be sure that you are provided with enough information and the time needed to make an informed decision. You should feel free to ask questions at any time before and during a trial.



How do I find a clinical trial that is right for me?

There are different ways you can find out about participating in a clinical trial. You can:

- Talk to your doctor
- Contact a research hospital
- Contact a health charity or patient organization, such as Colorectal Cancer Canada
- Use a clinical trial finder to find out what clinical trials are available near you

For a full list of provincial, national, and international clinical trial organizations and clinical trial finders, please visit **Clinical Trials** >>

Resources on our website:

<https://www.colorectalcancercanada.com/colorectal-cancer/treatment/#clinical>

Need assistance? Talk to us.

E-mail: info@colorectalcancercanada.com

Tel.: 1 877 50 COLON (26566)

References

Clinical Trials Ontario

"Clinical Trials Basics" Presentation

Fight Colorectal Cancer Clinical Trials Factsheet

<https://fightcolorectalcancer.org/resources/clinical-trials-fact-sheet/>

Clinical trials - cancer.net

<https://www.cancer.net/research-and-advocacy/clinical-trials>

Clinical trials information for patients and caregivers

<https://www.cancer.gov/about-cancer/treatment/clinical-trials>

Find a Clinical Trial

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial>

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