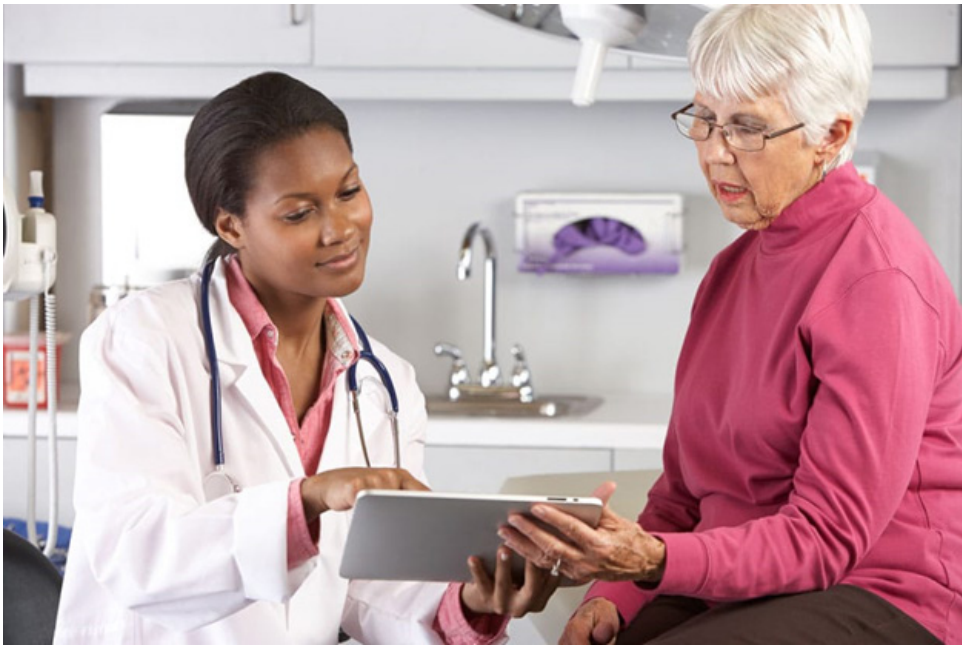
Clinical Trials at Princess Margaret

What you need to know: A guide for patients, their families and friends



The Princess Margaret Cancer Centre (PM) is a research hospital. Patients at PM may be asked if they would like to be involved in a clinical trial. The staff at PM created this brochure to provide patients, their families and friends with some basic information about clinical trials. Participating in a clinical trial is always voluntary.

What's inside

What is a clinical trial?

A clinical trial is a type of research study that tests new interventions, such as a new drug or procedure, on people who choose to participate. Cancer clinical trials are done to learn new ways to:

- Treat cancer
- Find and diagnose cancer
- Prevent cancer
- Manage symptoms and side effects of cancer or cancer treatment

Clinical trials can involve:

- A drug, immunotherapy or cell therapy
- New radiation techniques
- New surgical techniques
- New ways to diagnose (for example, new imaging methods or blood tests)
- A change in how we help patients manage their disease (for example, new approaches to education, mental health and healthy living)
- A combination of any of the above

Why are clinical trials important?

Clinical trials are the best way to find out whether a new treatment, device or procedure is safe and works in people.

For a new treatment or approach to be approved and used in everyday medicine, it must first be tested in clinical trials.

Clinical trials are usually the last step in a long process. The process begins with many years of laboratory research to understand how the treatment or procedure works and what side effects it might cause. If results from these studies are promising, researchers can then move on to developing clinical trials involving people.

What are the types of clinical trials?

There are several types of clinical trials. Each type tries to answer a different research question, or address a different concern.

Prevention Trials – Studies that try to find ways to prevent or reduce a person's chances of getting cancer.

Diagnostic Trials – Trials that try to improve how we find (detect) cancer or decide what is a person's risk of getting cancer. People might have a better chance of survival when the cancer can be found early.

Treatment Trials – Trials that try to find better ways to treat cancer. They might involve using drugs, cell therapy, vaccines, surgery, radiation or a combination of these.

Quality of Life or Supportive Care Trials – Studies that try to find better ways to improve the comfort or well-being of patients who have or had cancer.

Correlative Studies – As a patient at Princess Margaret, you might be asked to take part in a research study that involves giving blood samples or studying cancer tissue. These are called "Correlative Studies".

Correlative Studies try to improve our understanding of how cancer develops and responds to different types of treatment. These studies can help researchers develop new or improved treatments for future patients.

Molecular profiling or "tumour genomic profiling" is testing that looks at the genetic make-up of tumours. You will usually need to have a blood test or biopsy so researchers can look at the DNA of cancer cells. They look for changes in the genes of cancer cells to help diagnose and treat cancer.

Why do people choose to join clinical trials?

Clinical trials can help improve our understanding of cancer and find ways to help people living with cancer. Clinical trials can help advance medical care by developing new procedures, treatments or new ways of using existing procedures or treatments.

Clinical trials might offer some patients access to new treatments or procedures that would not otherwise be available to them.

It is important to know what is involved in a clinical trial before deciding to join. Talk to your doctor about the benefits and drawbacks of a clinical trial their before you make your decision. Deciding to take part in a clinical trial is always your choice. We will continue to give you excellent care no matter what you decide.

Is a clinical trial right for me?

The decision is always up to you. It depends on the trial, your care and your personal situation. It is your right to ask your doctor and study team as many questions as you like before, during and after the study.

Some important questions to consider:

- What is the study about and why is it being done?
- What is required of me if I choose to participate?
- What is the study schedule and what procedures are involved?
- Will I have extra tests and procedures because I am in a study (compared to if I was not on the study)?
- How often will I have to come to the hospital?
- What are the risks and benefits of participating?
- How long will I be in the study?

How are clinical trials done?

Clinical trials take place in steps called “phases”. Before a new treatment can be used in everyday medicine, it must first go through 3 or 4 clinical trial phases.

The early phases make sure the treatment is safe. Later phases show if it works better than the typical or traditional treatment being used. Participants will not have to take part in all phases.

Phase 1

Phase 1 trials try to find the best dose of a new drug or treatment. The drug or treatment is tested in a small group (about 15 to 30 patients). Phase 1 trials test a drug or treatment’s safety and learn how it affects the human body. If it is found to be safe enough, it can be tested in a phase 2 clinical trial.

Phase 2

During phase 2 trials, researchers continue to look at safety and how the drug or treatment affects the human body. They also do research to see if a drug works on a certain type of cancer. Phase 2 trials usually involve 100 or more patients. If a drug or treatment looks like it might be effective, it can be tested in a phase 3 clinical trial.

Phase 3

Phase 3 trials compare a new drug or treatment to what is currently available. These trials compare how well each treatment works and their side effects. If a treatment is equal or better than the currently available treatment, it may become the new treatment for patients. Phase 3 trials involve between 100 and several thousand patients.

Phase 3 trials are often “randomized”. This means that patients are put into a treatment group by chance. One group will get the usual drug or treatment, and the other group(s) will get the new one. Neither the patient nor their doctor can choose the group. By assigning someone to a group randomly, the results of the clinical trial come from the drug or treatment, and not differences between the groups.

Health Canada usually requires a phase 3 clinical trial before approving a new drug.

Phase 4
Phase 4 trials test new drugs or treatments that are approved by Health Canada. These trials involve several hundreds or thousands of patients. They are designed to find out more about short-term and long-lasting side effects and safety.

Who can join a clinical trial?

Clinical trials follow rules that decide who will be able to join the study. These are called “eligibility criteria”. The eligibility criteria are different for each clinical trial. They depend on the goals of the clinical trial and the question(s) the research is trying to answer.

If a person has the type of cancer that is being studied in the trial, they might be able or “eligible” to join. Eligibility criteria might also include the stage of cancer, the cancer’s genetic or molecular make-up, a person’s age, or the types of treatment they had in the past.

Eligibility criteria are important because they help make sure:

- patients are not put at higher risk
- the research results are accurate and meaningful
- researchers identify the people who will most benefit from the treatment

What about risks?

It is important to know what the possible risks are before agreeing to join a clinical trial. The study team will do their best to reduce any risks by closely watching your treatment and any side effects.

When you take part in a clinical trial, you can expect the study team to:

- review the possible risks and side effects with you
- receive information about the known risks before you decide to join
- inform you if any of this information changes during the trial

There may be other, unexpected side effects that happen during a clinical trial. If you have a side effect while on a clinical trial, you will receive the medical attention or treatment you need.

How are my health and safety protected if I join a clinical trial?

Protocol

All clinical trials follow a protocol. A protocol is the plan for the study that the research team must follow during the clinical trial. The protocol describes when, how and why the steps in the study should be done.

Research Ethics Board (REB)

In Canada, a Research Ethics Board (REB) oversees all clinical trials. An REB is an independent group of doctors, scientists, community members and other professionals that reviews all clinical trials to make sure your rights are protected. An REB must review and approve all clinical trials before they can begin. The REB continues to provide review while the study progresses.

Professional Guidelines

All medical professionals and research staff involved in clinical trials must follow certain professional guidelines called “Guidelines for Good Clinical Practice”. These guidelines help protect your rights, health and safety.

Health Canada

Health Canada reviews clinical trials which use a new drug, treatment or device that has not been used in patients with a specific disease before. This branch of the federal government gives permission for clinical trials to start and oversees them to protect your health and safety.

Your rights as a study participant

- ✓ You have the right to receive information that may affect or change your decision to join or continue participating in a clinical trial.
- ✓ It's your choice to be involved in a clinical trial. You should not feel pressured to join or to continue participating.
- ✓ Your privacy, confidentiality and decisions must be respected and protected.

What is informed consent?

The informed consent process is a discussion between you and the clinical research team about the clinical trial. The doctor and research staff share information about the clinical trial and answer any questions you have.

The topics you will discuss include:

- Why the clinical trial is being done
- Other available treatment options (besides the clinical trial)
- Extra visits and time commitments
- Risks and benefits
- Confidentiality and privacy – who will have access to your personal information

The informed consent process continues throughout the clinical trial. The research team will give you any new information that comes up during the study.

Informed consent form

The informed consent form is a document that you will receive from the study team. It describes important information about the study and covers the topics you discussed with the study team.

If you decide to join a clinical trial, you are asked to sign the informed consent form and given a copy. You can take as much time as you need to decide.

Your signature on a consent form does NOT mean that you must stay in the study. You can leave at any time, for any reason.

What can I expect if I join a clinical trial?

If you join a clinical trial, you can expect these stages in the informed consent process:

Screening Stage

After signing the Informed Consent Form, you enter the screening stage.

The screening stage determines if you are eligible to participate in the clinical trial. You may need to have extra tests or procedures.

Active Stage

The active stage is when you receive the study treatment and/or go through the study procedures.

Follow-up Stage

The research team continues to check your health after finish the active phase. Follow-up allows research teams to see the long-term outcomes of the clinical trial.

How do I join a clinical trial at Princess Margaret?

1. Talk to your doctor first. Your doctor might be involved in a trial or might be able to refer you to another doctor who is involved in a trial. There may or may not be a trial that is right for you. It is up to you and your doctor to decide if a trial is best for you.
2. Check the Princess Margaret website www.theprincessmargaret.ca for all the trials available at our centre.

What happens if I don't want to join a study?

If you choose **not** to join a clinical trial, your care is not affected negatively. If you **do** choose to join a clinical trial, you have the right to change your mind at any time. Your decision to stop participating in the clinical trial will not affect your medical care.

Note: Your doctor wants to make sure that you are told about any available clinical trials, because they might be an option available to you. Your doctor understands that your situation is unique and that you have the right to decide whether to be involved in a clinical trial.

Where can I find more information?

There are many resources available to learn about oncology clinical trials.

This list includes only a few available sources:

- **Your Doctor**
- **The Princess Margaret website**: Visit the website to find information on clinical trials and a database where you can search for clinical trials available at Princess Margaret.
  Website: https://www.uhn.ca/PrincessMargaret
- **It Starts with Me:** This website provides information on how clinical trials work and includes answers to common questions.
  Website: https://itstartswithme.ca/getting-started
- **Ontario Cancer Trials website:** This website includes a database of cancer clinical trials in Ontario. See also general information about clinical trials.
  Website: http://www.ontario.canadiancancertrials.ca
- **Canadian Cancer Society:** The Canadian Cancer Society provides information about cancer and cancer research.
  Visit http://www.cancer.ca or call 1-888-939-3333.

- **National Institutes of Health:** This website includes a database of clinical trials for many diseases and conditions across North America and parts of Europe.
  Website: http://www.clinicaltrials.gov
- **Health Canada:** The Health Canada website has information about different drugs and health products. See also information about how clinical trials are regulated in Canada.
  Website: http://www.hc-sc.gc.ca
- **PM Patient & Family Library:** The main PM Patient and Family Library is located on the main floor of Princess Margaret in the Atrium. The staff and volunteers can help you, your family and friends find information about any topic. Computers are available in the library area.

The development of patient education resources is supported by the Princess Margaret Cancer Foundation.

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