# FAQ

Frequently Asked Questions

What is a clinical trial?

A carefully designed and supervised scientific research trial involving people. Clinical trials may involve treatment, such as drugs or devices, or an intervention, such as procedures or techniques.

- Treatment Trials  The use of drugs, radiation, surgery, and/or devices to treat cancer. The goal of treatment is to get rid of, stop, slow, or reduce the growth of your cancer.
- Intervention Trials  The use of investigations, procedures or techniques, such as blood tests to detect cancer, newer methods to scan for cancer, or prescribed diet and exercise programs. The goal is usually to prevent cancer, detect cancer earlier, or improve symptoms.

Why are cancer clinical trials done?

The ultimate goal of cancer clinical trials is to cure cancer by finding better ways to:

- Prevent cancer (finding new ways to stop cancer from occurring in patients who have never had cancer)
- Detect cancer earlier (testing ways to better screen and diagnose cancer in the earliest stages to hopefully increase the chance of a cure)
- Treat cancer (using new drugs, radiation therapy, or surgical techniques, using older treatments in newer ways, or a combination of any of these)
- Control symptoms or side effects (using drugs, techniques, or interventions to improve the quality of daily life)
- Help people live better and longer with cancer (survivorship)

What types of clinical trials are there for cancer?

Cancer clinical trials can cover all areas including:

- Prevention
- Diagnosis (cancer screening or early detection)
- Treatment, and
- Supportive and Palliative Care (quality of life).

The goal of treatment is to get rid of, stop, slow, or reduce the growth of your cancer. In clinical trials that use an intervention, the goal is usually to prevent cancer, detect cancer earlier, or improve symptoms.

What is meant by Phases of clinical trials?

Phase refers to the stage of development in the clinical research process.

- Phase 1 is when an experimental treatment is first used in patients with the goal of finding out how safe the treatment is, what the best dose is, and how it affects the cancer.
- Phase 2 studies the effectiveness of the experimental treatment in patients with a specific type of cancer.
- Phase 3 compares the experimental treatment with the standard treatment in patients with a specific type of cancer.
- Phase 4 gathers more information about the long-term side effects after the treatment is approved and is on the market.

What is a clinical trials protocol?

The protocol describes how the clinical trial will be done. It is the research plan of action, like a recipe or instruction manual, describing the "who, what, when, where, why and how" of the clinical trial. It is carefully designed with strict instructions to protect patient safety.

What is the informed consent form?

It is very important for patients participating in a clinical trial know what is involved. The informed consent form is a paper form that contains all the facts about the trial, including the treatment, tests, possible side effects, benefits, contact person and many more details, to help you make an informed decision about taking part in a clinical trial. The consent form is discussed, read, and signed by the patient and the clinical trials research team.

What if I do not speak or read English?

You may bring a person to translate for you or we will provide a translator.

Do clinical trials only test new drugs?

No. New techniques using radiation, surgery or devices are also tested in clinical trials. Older treatments being used in newer ways or new combinations of treatments are tested as well. Some clinical trials are conducted with treatments that are already approved to allow earlier access to these new treatments and/or to watch for any long-term side effects. There are also clinical trials that use interventions to

improve cancer prevention, diagnosis, and treatment. As well, some clinical trials test ways to help improve symptoms and side effects.

Are clinical trials a last resort?

No. It is a myth that clinical trials are only for people who have no other treatment options. There are many clinical trials for those who are newly diagnosed, those who have responded to previous treatments, those in remission, and those whose cancer has returned. You will be given all of your other options when you talk to your oncologist about clinical trials.

What do you mean by treatment options?

Your oncologist will discuss treatments such as radiation, surgery, chemotherapy, or other types of drugs which have been shown to help your type and stage of cancer. Sometimes no treatment is a good option; your condition will be watched with follow-up exams, blood work, and/or scans. Clinical trials simply offer another option for you to consider. You are the best person to decide what is best for you.

Will I be a guinea pig?

No. Clinical trials are highly regulated to ensure ethical treatment of patients. You will never be denied any standard treatment options available to you. Participation is always voluntary. You can withdraw from a clinical trial at any point in time for any reason.

What if I am feeling overwhelmed by all of the information?

There is a lot of information, especially when you first learn that you have cancer. Sometimes the informed consent form for a clinical trial is quite long. If you are feeling overwhelmed with all the information,

- Ask your nurse to clarify what the oncologist has said
- Ask for another appointment to continue the discussion
- Take some time to think and write down your questions
- Bring a loved one to your appointment and encourage them to ask questions
- Take notes during the discussion
- Do some research on your own, talk to other patients with cancer, your aboriginal navigator, or pastor or join a patient support group
- Take your time to ensure you understand and make decisions you are comfortable with
- You will never be forced to sign the informed consent form

Will I be eligible for a clinical trial?

Not always. You have to be the right fit for the trial and the trial has to be the right fit for you. Each clinical trial has specific eligibility criteria, such as:

- Type and stage of cancer,
- Age,
- How close you live to the cancer centre,
- Where the trial will take place,
- Previous treatments you must have had or have not had,
- Your other medical conditions and overall health, and
- Results of screening tests and procedures.

In order to protect your safety, you can only join a clinical trial if all of the necessary criteria are met.

Will my own oncologist take care of me while I am on a clinical trial?

Only if your oncologist is one of the doctors involved in the trial, i.e. an investigator, otherwise another oncologist at the Juravinski Cancer Centre who is an investigator trained in the trial will take care of you until you complete the trial. Your oncologist will be informed about your care and they will resume your care once you complete the clinical trial.

Will the doctor be upset if I say no to the clinical trial?

No. The oncologist and clinical trials research team want you to be aware of all of your treatment options. They will discuss any implications of saying no with you. They understand your right to make your own decision. Your decision will not affect the quality of your care.

Will I be treated at the Juravinski Cancer Centre?

Yes, if one of the many clinical trials we offer is the best option for you. If you are currently treated in a centre which offers the same clinical trial, you can be treated there. Occasionally, the best clinical trial for you may only be available at a nearby centre, such as Cambridge Memorial Hospital, Walker Family Cancer Centre, or Princess Margaret Hospital; in this case you would be referred there if you wish.

Will this cure me?

Your oncologist will discuss clinical trials options with you that they feel may help to slow or stop your cancer from growing or provide a better quality of life. However, the effectiveness of the new treatment is being studied and may not be known. This is one of the reasons the clinical trial is being offered.

How do I find a clinical trial for my kind of cancer?

Ask your doctor if there are any clinical trials that may be right for you. There are also things that you can do to become more informed about clinical trial options:

- Use our "Find a Trial" page to search our current clinical trials.
    - We have many clinical trials that are recruiting (readily available and open for patients to join), however some of our trials are pending (trials that are coming soon but are first undergoing regulatory review and approval before being offered to patients to join) or closed (patients are no longer able to join the trial either permanently or temporarily for data analysis).
- Ask your doctor about clinical trials, particularly at a first visit or whenever there is a need to change from one treatment to another.
- Search the internet.
    - The Ontario Institute of Cancer Research (OICR) keeps a current list of the clinical trials that we have available here at the Juravinski Cancer Centre and other cancer centres in Ontario. You can visit the OICR website here.
        - Enter your cancer type, your city/town, Hamilton Health Sciences, Juravinski Cancer Centre, or other keywords to find the clinical trials options we have for your type of cancer.
    - The Canadian Cancer Trials website includes clinical trials available across Canada.
    - The Canadian Cancer Trials Group (CCTG) website and the National Institutes of Health Clinical Trials.gov include clinical trials available in the US and worldwide.
    - Save or print the clinical trial details you find and review them with your oncologist at your next appointment. If your oncologist is not involved with a particular trial they may be able to refer you to a doctor who is.
- If you want to speak to us about a clinical trial option, you can Contact Us.
    - You do not have to be a patient at the Juravinski Cancer Centre to contact us. If you are interested in learning more about our clinical trials or whether one of our trials is right for you, we can answer your questions and help you in the referral process.

How will I know if the treatment is working?

You will have assessments and medical tests at regular time-points to determine how well the treatment is working for you. The effectiveness of the treatment is determined by your cancer's response, meaning whether you have:

- A complete response (the cancer disappears)
- A partial response (the cancer shrinks)
- Stable disease (the cancer stops growing or grows more slowly)
- Progressive disease (the cancer continues to grow)

What is a treatment group?

A clinical trial may have more than one treatment group. The group that receives the standard treatment is called the control group; the group that receives the new treatment is the experimental group. There may be other groups that combine the standard treatment with the new treatment. You will always know your chances of being placed in any group.

Will I get a placebo?

In some cases when a new treatment is being compared to the standard care of simply watching over your health or when a new treatment is being added to a standard treatment, a placebo may be used. You will be told if a placebo is being used in the clinical trial and your chances of receiving placebo. Usually you, your doctor, and the clinical trials research team will not know if you are receiving placebo or actual treatment. This is called "blinding." It is important to know that, in certain circumstances, such as a medical emergency, you can be "unblinded" to reveal whether you are receiving the actual treatment or placebo.

What is Randomization?

Used most often in Phase 3 clinical trials, you will be assigned randomly, like flipping a coin, to one of the treatment groups by a computer or number chart. This is done to make sure that patients are not chosen for either group in a way that could affect the clinical trial results. Neither you nor your oncologist will choose your treatment group.

If I do not get randomized to get the experimental treatment am I still in the trial?

Yes. The control group is very important for comparison to find out if the new treatment is better or not. You will have all the same assessments at the same times as those in the experimental group. If the new treatment turns out to be better, you may have a chance to switch over to the new treatment.

How soon can I start?

Once you have had time to make an informed decision about taking part, screening tests are performed to determine if you are eligible. On a Phase 2 or 3 clinical trial, you can start very soon after eligibility has been confirmed. Phase 1 trials enroll patients in small groups of 3 to 4 at a time so you may have to wait a few weeks for the next group of patients to be enrolled. The timeframe of starting the clinical trial will be discussed with you.

What inconveniences might I face?

You are watched very closely while on a clinical trial and may have extra visits or longer visits. More tests and procedures may be done. Depending on the phase of the trial, you may have to stay all day or overnight for blood tests or a biopsy (for example, on a Phase 1 trial). You may have to fill out extra paperwork, such as questionnaires or pill diaries. You may need to have follow up visits or phone calls for several years after the treatment is complete (for example, on a Phase 3 trial).

Can I choose to stop being in a clinical trial?

Yes. You can stop participating in a clinical trial at any time for any reason and discuss your other treatment options with your oncologist. Withdrawing from a clinical trial will not affect the quality of your care.

Will there be side effects or risks?

There might be. You will be made aware of all the known side effects and risks when the informed consent is reviewed with you. Unexpected side effects are also possible. You will be watched very closely for side effects and will receive the needed medical care. You may have to pay for medications to control side effects depending on your personal drug coverage. You will be encouraged to call a contact number if you are concerned about new side effects between visits or after hours.

What are the benefits?

As a patient taking part in a clinical trial at the Juravinski Cancer Centre, you have the opportunity to:

- Get access to the newest ideas about cancer care under the close watch of the clinical trials research team.
- Have treatment close to home.
- Take an active part in decisions affecting your treatment.
- Consider treatment options that may not be available otherwise.
- Contribute to the knowledge in the fight against cancer.
- Shape the future of cancer care.
- Leave a lasting legacy by helping to find better treatments for future cancer patients.
- Provide hope for the future.

What if the clinical trial treatment doesn□t work?

You will be watched closely and if your cancer is getting worse or your side effects are not manageable the clinical trial treatment will be stopped and you will be offered other treatment options.

Can I talk to other patients on the trial?

Yes, if other patients express an interest in talking to others on the same clinical trial. Each patient's privacy is protected.

What happens after the clinical trial treatment or intervention is finished?

You will continue to be followed for the period of time that is stated in the protocol. Follow-up can range from a few months (e.g. Phase 1 trials) to up to several years (e.g. Phase 3 trials). The length of follow-up will be discussed with you. Direct contact with you during this follow-up period may or may not be required as sometimes the information needed for follow-up can be found in your medical records. After the necessary follow-up is complete, your care will transfer back to your original primary care team. During follow-up, you will still be provided with other treatment options and you can start a new treatment as soon as you and your oncologist feel you are ready.

Will I get the results of the trial?

It could be many years for all the patients to complete the clinical trial and for the data to be analyzed. Once the results are available, a paper will be published in a scientific journal. You will be kept informed with any new information about the clinical trial on an ongoing basis and may receive the results.

Am I paid to be in a clinical trial?

No. You are not paid to be in a clinical trial, however the treatment or intervention given as part a clinical trial is given free of charge. In some trials that have lengthy visits, parking may be paid for, but this is not guaranteed.

Are there any additional costs?

The treatment given on a clinical trial is given free of charge. You may have to pay for medications to control side effects depending on your personal drug coverage. Clinical trials usually have more frequent visits which means you will need to come in more often and meals are not provided. Parking may be an extra cost. In some trials that have lengthy visits, parking may be paid for, but this is not guaranteed.

Is my privacy protected?

Yes. Your medical information is confidential. Clinical trials are monitored by individuals from the sponsor, such as the drug company supplying the drug. The sponsor is always listed in the informed consent form. These individuals monitor the progress of the clinical trial and have access to your medical information. Health Canada may chose to inspect the clinical trial and would also have access to this information. Any individual that views your personal information is bound by law not to disclose your information. Any forms or computer entries recording your information identifies you by a code number and/or your initials. Your name or personal information will never appear at any external centre or in publications.