Clinical trials

For better cancer treatment

If you have cancer, taking part in a clinical trial may offer some benefits. This brochure answers questions you may have on this topic.

What is an oncology clinical trial?

An oncology clinical trial is a research project relating to cancer. It can also be called a «clinical study». It's done to evaluate new cancer treatments: drugs, procedures, devices, and technological advances.

Some of these treatments have not yet been approved by Health Canada. They also may not have been tried in certain situations or in conjunction with other treatments. This is why they're called "experimental". Before they become "standard treatments", they need to be tested to see whether they are promising, safe, effective, and as good as or better than treatments already in use.

Afterwards, researchers can also determine whether a treatment:

- is effective for other cancers or other diseases
- causes unexpected side effects after several years of use

Who conducts these trials?

They're conducted by research teams whose goal is to find the best treatments. Their aim is to:

- help people with cancer to live as long as possible
- improve quality of life
- prevent disease recurrence
- cure them for good

What's the difference between a standard treatment and a clinical trial?

In a clinical trial, a patient could:

– Receive the standard treatment. Receive a new treatment in addition to the standard treatment or a modified version of the standard treatment. The goal is to assess whether these changes represent improvements over ususal care.

– Receive only a new treatment. In that case, the aim is to assess whether it's more or less effective than the standard treatments.

Often, participants in a clinical trial are **followed more closely.** They undergo tests and examinations more often, to **monitor their health status in greater detail.** They may also see their care team **more often.** This allows the team to **react quickly** in order to adjust the treatments, if needed.

How can I find out whether I can take part in a clinical trial?

Your treating physician will assess this with you. Eligibility for a clinical trial depends on several criteria, including:

- the type of cancer
- its stage
- whether this is the first occurrence of the cancer or a relapse
- reactions to treatments already received
- your overall health status, aside from the cancer

Can I participate if I live far from a major centre?

It's not possible for all clinical trials, but it can be done. In such cases, arrangements can be made for exams or visits to be done near your home or via telemedicine. You can discuss the possible options with the research team. Clinical trials are also conducted outside a major centre.

What can help me to decide whether I want to participate?

As you're the one taking the decision, you need to consider the pros and cons. You will receive a document that explains clinical trials in detail: the "Information and Consent Form". Read it carefully and consider all the factors involved. Make sure you're comfortable with all the following points:

- The reason for testing the treatments
- How long the trial will take and its various steps
- The number and frequency of hospital visits
- The exams, blood tests, and samples that will need to be taken
- What experimental treatments you might receive
- How the treatments are given
- The use or not of a placebo (inactive substance) given in addition to standard treatment
- Possible risks (e.g., side effects)
- Potential benefits, such as an improvement in your condition
- Advantages: close follow-up, free access to experimental treatments, etc.
- Disadvantages, such as more frequent travel
- Confidentiality of your personal information
- How much you are compensated for participating

Members of the research team can also help you fill out the form. Ask them any questions you may have. Also look at the table on page 6.

If, and only if, you're comfortable with everything, you can sign to accept to participate in the clinical trial.

Can I stop participating?

You can withdraw from a clinical trial at any time and for any reason. It can be because the treatment has too many side effects, or it's not effective, or for personal reasons. Your health and your choice are the priority. Usually, if you withdraw, you will then receive the standard treatment.

How do I find a clinical trial?

If you're interested in participating in a clinical trial, discuss it with your care team. They can help you find the trials that are most relevant to your case.

You can also visit the following websites to consult a listing of current clinical trials:

In Québec:

> **oncoquebec.com**

In Canada:

> **canadiancancertrials.ca**

Internationally:

> **clinicaltrials.gov**

The table below is useful to better understand clinical trials, with the research stages and the «phases» of a trial treatment. You can participate in phases 1, 2, 3 and 4.

The stages of clinical research

The laboratory testing stage, before testing in humans			
	Is the treatment:	**What is the treatment tested on?**	**What are the benefits?**
PRECLINIC PHASE	Promising	Laboratory animals. Human cells in the laboratory.	Making sure human trials are worthwhile.

Human testing stages, before Health Canada approves the treatment				
	Is the treatment:	**Who is the treatment being tested on?**	**What are the advantages?**	**What are the disadvantages?**
PHASE 1	Safe	A few people at an advanced stage of cancer or whose other options are limited.	Close medical follow-up. The knowledge that we're helping others.	Going to the hospital more often. Having more samples taken than usual. Possible side effects. Rarely, developing other health problems besides cancer.
PHASE 2	Effective (at what dose, and how is it given?)	Several people with the same type of cancer, often in relapse.	Close medical follow-up. Free access to a treatment not available to everyone. Potential for improved health. Potential for longer life. The knowledge that we're helping others.	
PHASE 3	Better than the standard treatment	Many people with the same type of cancer or a different cancer, and to whom a standard treatment could still be given.		

Human testing stages, after the treatment is approved				
	Is the treatment:	**Who is the treatment being tested on?**	**What are the advantages?**	**What are the disadvantages?**
PHASE 4	Causing rare or delayed side effects	A large group of patients in the general population.	Close medical follow-up. The knowledge that we're helping others.	Occasional travel.

For more information

The Patient page on the Quebec Cancer Consortium website provides several interesting sources of information.

- Videos of patients talking about their experience. The best way to understand how a clinical trial works.
- Videos of researchers, nurses, physicians, and other specialists answering questions about clinical trials.
- Brochures like this one to give you more information on clinical trials.

> cqc-qcc.ca/en/patient

The **Quebec Cancer Consortium** for Novel Therapeutics and Biomarkers (QCC) is a **collaborative network** of four hospitals, with their respective research centres, and two university-based cancer research centres. **Its goals are to standardize and harmonize practices** in clinical and translational **research**, to **improve cancer treatment** by accelerating advances in precision medicine and immuno-oncology, and to **engage with cancer patients to develop educational material and raise awareness** of clinical trials of precision medicine and immunotherapies.

We acknowledge the financial support of the Ministère de l'Économie et de l'Innovation du Québec through the Fonds d'accélération des collaborations en santé.

QCC
Quebec Cancer Consortium

Québec