Canadian Cancer Society
Société canadienne du cancer

Clinical Trials

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Clinical Trials

This brochure is for people making decisions about cancer treatment. You may be thinking about a clinical trial for you or your child but need to know more before you decide. You're not alone. Throughout this booklet, you'll hear from Canadians who've participated in cancer clinical trials and want to share their experience.

> I didn't know anything about clinical trials. I'd never been in one before and just never thought of it. ~ Albert

Along with learning about the basics of clinical trials, you'll learn about:

- why clinical trials matter and how they work
- how you're protected during a trial
- important things to think about before taking part
- what happens after a trial
- where to get more information

The information in this brochure is mainly about trials that test new treatments, but it's also useful if you're considering other types of trials, like trials to prevent cancer or trials to improve ways of coping with side effects.

The Canadian Cancer Society would like to thank the people who shared their personal stories. To protect their privacy, and with their permission, we have changed their names unless asked not to.

Clinical trials – the basics

Most research starts in a lab. The next step may involve animals, such as mice. If the results still look good, then a clinical trial can begin. A clinical trial is a research study that involves people. It's something you volunteer to do, not something you have to do.

There are different kinds of cancer clinical trials.

Treatment trials test new treatments or ways to make existing ones better. Maybe it's new drugs or methods of surgery and radiation.

Prevention trials look at new ways to lower the risk of getting cancer – or stop it from coming back. If you're at risk for a certain type of cancer, these trials may interest you.

Screening trials are about finding cancer early, before you notice symptoms.

Supportive care trials study how to improve comfort and quality of life for people with cancer or cancer survivors.

> "I've been in 2 trials – one to deal with the cancer itself and the other to deal with long-term side effects of some of the current treatments. ~ Sean

Why clinical trials matter

Clinical trials lead to progress being made against cancer. The standard treatment you've been offered to treat the cancer you have today was likely first developed and tested in clinical trials. This kind of research answers important scientific questions, and it offers you the chance to help others by making cancer treatments better.

> "I was hoping that something good would come out of what I had done. That if 20 years down the road my daughter ever needed anything like this, hopefully she would benefit from my participation. ~ Carrie

If you join a clinical trial, you may get a new treatment that could help you.

> "I wanted to support the doctor and do it for the sake of science. I also read up on prostate cancer and came to the conclusion that there was uncertainty about the best way to treat it. ~ Michael

Who runs clinical trials?

Trials are normally led by a doctor. They usually take place at a cancer centre, hospital, clinic or doctor's office. Each trial site has an investigator who runs the trial at that location. Nurses, pharmacists, research assistants and other healthcare professionals help make sure the trial runs smoothly. A clinical research associate or clinical research nurse watches you closely during your treatment.

> "The clinical trial team was fabulous. Any time I had any questions, concerns, anything, I could call them. If they didn't have the answer right there, they would get back to you. ~ Carrie

Funding for clinical trials may come from public sources, such as government and non-profit organizations, and private sources, such as pharmaceutical companies.

Who can join a clinical trial?

Every clinical trial has its own rules about who can take part. Trials look for people who are similar. This helps researchers rule out other things that could affect the study's results.

You'll need to find out if you qualify. Conditions for joining a trial may include:

- your age and sex
- the type or stage of cancer
- whether you've been treated for cancer before
- your overall health and whether you're being treated for other medical problems

> From my experience, I would recommend that anybody listen to their doctor if a trial is offered. Read about it and understand as much as you can. ~ Sean

If you don't qualify for a treatment clinical trial or you cannot take part for some reason, your doctor may be able to arrange for you to get the treatment through Health Canada's Special Access Programme.

How to find a trial

If you're interested in clinical trials but your doctor hasn't suggested one, you can check these websites of current trials and then talk to your doctor:

Canadian Cancer Trials
www.canadiancancertrials.ca

(clinical trials in all Canadian provinces)

National Cancer Institute
www.cancer.gov/clinicaltrials/search

(clinical trials in Canada, United States and around the world)

You may also want to ask your doctor about other trials that may not be listed on these websites.

How clinical trials work

Clinical trials take place in phases. Each phase answers specific questions.

Phase 1 trials see how safe a treatment is and what the best dose is. They may be riskier than later phases because this is often the first time a new therapy is being tested in people.
Usual number of participants: **15 to 30**

Phase 2 trials show how well a drug or other treatment works for a specific type of cancer. They continue to look at how safe the drug or treatment is and how it affects the body.
Usual number of participants: **fewer than 100**

Phase 3 trials compare a promising new treatment to the standard treatment already in use.
Usual number of participants: **100s to 1000s**

Phase 4 trials gather more information on possible effects – good and bad. This includes long-term effects after a drug or treatment is approved.
Usual number of participants: **100s to 1000s**

What's randomization?

People are sometimes put into groups in clinical trials. A computer assigns you randomly, or by chance, to one group or the other. This is called randomization. The makeup of the groups can vary. Randomization helps make sure the study results are accurate.

Randomization happens most often in phase 3 trials when a new treatment is being compared to a standard treatment.

> I'm in what's called a double-blind trial. I don't know if I'm getting the experimental drug or not. My doctor doesn't know either. I did experience the very common side effects of the experimental drug, so I'm pretty sure I'm on it. Even if I'm not, I have pretty good peace of mind. ~ Lara

What is a placebo?

A placebo is a pill or injection that looks like the substance being tested but doesn't actually do anything. Giving placebos to one group in a clinical trial lets researchers compare the new treatment to the placebo. For example, a trial may compare a new treatment that is given along with the standard treatment to a placebo given along with the standard treatment. This tells researchers whether the new treatment is effective.

If a trial does use a placebo, you will be told, but you won't know if you're in the group receiving it.

"Knowing there was a placebo really didn't change my outlook about going into the trial ... It didn't bother me because I knew that I was still being watched very closely." ~ Sean

It's all in the protocol

Before you decide to join a trial, you need to understand the trial's protocol so that you know why the trial is being done, how it will be run and how your safety will be protected.

The protocol is a written description of the trial that includes information about:

- who can join the trial
- how many people will take part
- what medical tests you will have and how often
- what type of treatment you will be given and how often
- how long the trial is expected to last
- how the researchers will know if a treatment is working

> "My doctor gave me the protocol and left us alone so that we could go through it before she came back, so that we could ask her anything. It was very well explained. ~ Carrie

Learning as much as you can about the study will help you decide if it's right for you.

How you're protected

> I just felt confident. I felt I'd be looked after well ... and everything went as they said it would. ~ Albert

To protect your health, safety and privacy, every trial must follow strict rules and meet high standards. These include:

- government and international policies to make sure a trial follows strict scientific and ethical guidelines
- approval by the hospital or clinic where the trial will take place
- approval of the trial's protocol by a research ethics board
- approval by Health Canada in many cases
- monitoring by Health Canada and a research ethics board until a trial ends

From start to finish, you can be sure that your safety is always being considered and monitored. In extreme cases, a trial might even be stopped early if there are serious side effects or if it's obvious that the treatment being tested doesn't work. While this doesn't happen very often, you would continue to be offered the standard treatment if your trial was stopped early.

Trials can also be stopped early when there is clear evidence that the tested treatment does work – and then every effort is made to offer everyone in the trial the new treatment.

Informed consent

> I was happy that they gave me time to think about it. I asked a bunch of questions. I took home all the information they gave me and read through everything about the trial.
> ~ Lara

Before you decide to take part, you should feel sure that you've been given all the information you need about a clinical trial. This is called informed consent.

You will get a printed consent form that has key facts about:

- the treatment
- tests
- any possible benefits, risks or side effects
- the contact person for the study, in case you have questions

If you agree to participate, you will be asked to sign the consent form and then given a copy to take home.

> The consent form explains everything and you have a chance to ask questions before you sign. Ask all the questions that you need to. ~ Carrie

If the trial is for your child

Children aren't able to give true informed consent, so they are asked for their assent, or agreement, to take part in a clinical trial. Before they can assent, the trial must be explained in language that they can understand or by using visual aids.

As the parent or guardian, you will be asked to give your permission for your child to take part.

Deciding to take part

> I'm glad I participated in the study and I hope it improves the treatment for other men. As far as my sons are concerned, there is prostate cancer in our family and it's possible this research will also benefit them. ~ Michael

How do you know if a clinical trial is right for you? While a clinical trial may be a good choice for some people, it may not be for others. Talk to your doctor so you can make the best choice for you.

Benefits and risks

Deciding whether or not to take part in a clinical trial can be hard. Clinical trials are set up to get the best results possible and minimize risks for people who take part. It's important to discuss the benefits and risks with your doctor.

> It's definitely a personal decision. To me, there was no question. I didn't hesitate in the least. But I understand why some people would hesitate. ~ Carrie

The possible benefits are:

- You may get access to a treatment that isn't available anywhere else. It may turn out to be safer or more effective than current treatments.
- Even if you're not in the group that gets the new treatment, you will receive the best standard treatment available.

- By learning about clinical trials and treatment options, you're taking part in a decision that affects your life.
- You have a chance to help others and add to what we know about cancer.
- You may be helped by the extra follow-up care.

> Every month, I was essentially having a full physical and blood work done. They would keep a really close eye on you. I felt good about that. ~ Sean

The possible risks are:

- New treatments are not always better than, or as good as, standard ones.
- There may be unexpected side effects.
- The new treatment may be good, but it may not work for you.
- If you're in the group that gets standard treatment, you may not do as well as people who get the new treatment.
- Being in a clinical trial may be inconvenient or take extra time. You may need more tests or medicines.

> I was so worried about side effects. I had just finished treatment and chemo was so hard. The thought of going on another drug really bothered me at first. But I'm not having any bad side effects – and I feel like I have this added protection. ~ Lara

Are there extra costs?

In most cancer treatment trials in Canada, your provincial health insurance plan or study sponsor will cover the cost of care, medicine and testing. But you may have some expenses if you take part. These could be costs for getting to the treatment centre or buying medicine to treat side effects. It's a good idea to ask your healthcare team about possible extra costs.

> "I wasn't that far from the hospital so it worked out quite well. I got home after work, got on the bike and went over there. There were no costs at all. I even saved on parking! ~ Albert

Questions to ask

Before you decide if a trial is right for you, you may want to ask your doctor questions such as:

- Why is this study being done?
- Why do researchers think the new treatment being tested may work?
- What will go on in the study?
- What kinds of tests, procedures and treatments are done?
- How long will the study last?
- What are the benefits and risks of participating?
- What are the possible side effects of the new treatment?
- Are there any activities or other treatments that can't be done during this study?
- Will the trial involve extra time, money or travel?

Know your rights

It's important to know your rights when you participate in a clinical trial. Your rights include:

- being given all the facts about a clinical trial before deciding to take part
- having your reactions to the new treatment watched closely
- having your personal information kept private
- being able to quit the trial at any time

Leaving a trial early

Taking part in a clinical trial is voluntary. You can leave a trial at any time – even after you've signed a consent form.

> If it wasn't working out for me or I didn't like it or it didn't make me feel well, I wasn't obligated to stay in the trial. I could quit. Knowing that made me feel better. ~ Lara

If you decide to leave a trial, you will continue to receive the best standard treatment possible.

> At any point, if my doctor saw something that wasn't going the way she wanted, we would just go back to the standard treatment. ~ Carrie

What happens after a trial?

> I felt relieved. You are glad because your treatments are all finished. I got a clean bill of health. And I had done my part to help others. ~ Carrie

The end of the trial may bring mixed emotions. You may be glad the treatments are over. But you may feel anxious as well. Some people miss the extra care they've had during the trial. Others are nervous while waiting for the results.

If you're worried about the trial ending, talk to your healthcare team. They are there to help you during this time.

> Knowing that there are other types of trials out there, I keep telling my doctor that I'm ready, willing and looking forward to participating again. ~ Sean

Finding out the results

While your part in the trial may be done, all participants have to finish treatment and follow-up before any results can be analyzed. This could take a while because not everyone started at the same time.

Once the trial is over, researchers look carefully at all the results before making any conclusions. The results of clinical trials are often published in scientific journals. A really important finding may also be reported in the media.

> It was written up in a medical journal, and it was a success. They learned a lot. I made the right decision. ~ Albert

How new drugs are approved

If clinical trials show that a new drug or treatment works and is safe, it goes to Health Canada for approval. Once approved, doctors can then recommend this as a treatment to people with cancer.

Where to get more information

Now that you know the basics of clinical trials, you may want to learn more. If you need more in-depth information on any of the topics in this brochure, the Canadian Cancer Society can help. We can also help you search for a trial and answer questions about current trials in Canada. Our services are free and confidential.

To contact us:

- Call us toll-free Monday to Friday at **1-888-939-3333** (TTY 1-866-786-3934). If you need help in another language, interpreters are available.
- Email **info@cis.cancer.ca**.
- Visit **cancer.ca**.

Notes

Tell us what you think

Email cancerinfo@cancer.ca and tell us how we can make this publication better.

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 and our services or to make a donation.

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