

ASK

BEFORE YOU PARTICIPATE

Some questions to consider asking before participating in a clinical trial:

- ? What are the potential risks of participating in this clinical trial?
- ? What are the possible benefits of participating in this clinical trial?
- ? What will I be asked to do as a research participant?
- ? How much of my time will the clinical trial take?
- ? Will I have to pay for any part of my participation in the clinical trial? Will I be paid for my participation?
- ? Will I be able to continue to see my own doctor?
- ? Will my doctor be informed of my involvement in a clinical trial?
- ? If the treatment works for me, can I keep using it after the clinical trial? What will be the cost of continued usage after the clinical trial?
- ? Will I receive any follow-up care after the clinical trial has ended?
- ? What will happen to my medical care if I stop participating in the clinical trial?
- ? Will I receive any additional information as a result of my participation in the clinical trial?

Make sure all of your questions are answered to your satisfaction before participating.

Informed Consent

Informed consent is an ongoing process of learning and understanding key facts about a clinical trial before you make a decision to participate.

Informed consent is documented by means of a written, signed and dated consent form. If you agree to participate in a clinical trial, you will be asked to sign and date the informed consent form. You will receive a copy of the signed informed consent form and any updated consent forms you sign. You can choose to withdraw at any time without providing a reason.



POINTS TO REMEMBER

We learn more about new treatments and whether they improve health through carefully conducted clinical trials.

Participation in a clinical trial is voluntary – it is up to you to decide if you want to take part.

Make sure all of your questions are answered to your satisfaction before deciding whether or not to participate in a clinical trial.

Visit n2canada.ca for more information.



ARE YOU INTERESTED IN PARTICIPATING IN A CLINICAL TRIAL?



Helping you make a decision about participating in a clinical trial

The information and content provided in this brochure is for informational purposes only. While the organizations involved in the development of this brochure strive to provide accurate and up-to-date information, the information may be out-of-date or incomplete in certain respects. The information and content presented is not intended to replace independent clinical judgment, medical advice, screening, health counseling or other interventions performed by your health care provider.



WHAT IS A CLINICAL TRIAL?

A clinical trial is an investigation, in which a medication, treatment or device is given to research participants to learn about how well it works, its safety and its side effects.

We learn more about new medications, treatments and devices and whether they improve health through carefully conducted clinical trials.

In Canada, clinical trials are conducted with oversight from Health Canada and a research ethics board.



WHY ARE CLINICAL TRIALS CONDUCTED?

- ★ To see if a new medication, treatment or device is safe and effective for people to use.
- ★ To compare two or more existing medications, treatments or devices to determine which is better.
- ★ To study new ways to use standard (approved) medications, treatments or devices.
- ★ To learn how best to use medications, treatments or devices in a different populations, such as the elderly or children.

WHY DO YOU WANT TO PARTICIPATE?



You may gain access to new medications, treatments or devices, which may be beneficial to your health.

You may receive care specific to the clinical trial, which may include additional testing and/or more frequent follow up with medical staff for the condition being studied.



You will help others by contributing to medical research and treatment advances.

You may have the opportunity to gain additional knowledge about your own medical condition.



WHAT TO BE AWARE OF?

- ⚠ There may be side effects from the new medication, treatment or device. These may be minor, unpleasant, serious or even life threatening.
- ⚠ The new medication, treatment or device may not be effective.
- ⚠ You may be required to stop using your current medication, treatment or device.
- ⚠ You may be required to try an experimental medication, treatment or device during the clinical trial.
- ⚠ Participation in the clinical trial may require more visits and tests and may be time consuming.

i There are different benefits and risks with each clinical trial. Please discuss with your family, friends and doctor before you participate.

YOUR RIGHTS AS A RESEARCH PARTICIPANT

You have the right to decide if you wish to take part in the clinical trial – it is up to you.

You have the right to refuse to take part, or to stop taking part at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You have a right to privacy – any information about you or your health collected as part of the clinical trial will be kept confidential and protected. Your rights to privacy are legally protected by federal and provincial laws.



“ I was unaware of the option for clinical trials for medical conditions. I am proud that I was able to contribute in some small way in helping other people that may have had the same condition I had. ”

— BC clinical trial participant