Clinical Trials Quebec™

Discussion guide: Questions to ask the medical staff before enrolling in a clinical trial

Participation in a clinical trial is always voluntary. You will always be given enough time to make an informed decision. It is important for you to understand how a clinical trial works, and the risks and benefits involved if you choose to participate.

This guide has been designed to help you talk to your healthcare or research team about possibly enrolling in a clinical trial. You can also use this guide to make notes about clinical trials that you are interested in based on your medical condition.

If you are interested in enrolling in a clinical trial, the research team and the clinical trial physician will provide you with an **information and consent form** that describes the study. If you decide to participate in the clinical trial, you will have to sign this form.

Additional note:

In this guide, the term "intervention" is used to define all treatments, procedures, tests or any other action performed to prevent and treat a disease, or to improve health. Other terms frequently used in clinical research are defined in the glossary on the last page; you can refer to it at any time.

Do you need help?

We can help you find clinical trials! Clinical Trials Quebec's Personalized Support Service assists you in the search and identification of clinical trials that meet your needs.

To learn more about clinical research visit:

www.clinicaltrialsquebec.com

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NCT number[i]: _____ Title of the clinical trial: _____

_____

Contact details of the research team: _____

_____

Information about the clinical trial

What type of clinical trial is this? □ Interventional[ii] □ Observational[iii] □ Other: _____

Phase I □ Phase II □ Phase III □ Phase IV□ Not applicable □

What is the objective of the clinical trial? _____

_____

_____

Who can participate in the clinical trial? _____

_____

_____

_____

What intervention[iv] takes place in the clinical trial? _____

_____

_____

Where is the clinical trial taking place? _____

How long is the clinical trial? _____

How much time do I have to decide if I want to participate in the clinical trial? _____

Information on the intervention

What are the potential benefits and risks? _____

_____

_____

_____

_____

Does the research protocol[v] contain an arm/cohort with a placebo[vi]? □ Yes □ No

If so, what are the implications of participating in this type of study? _____

_____

_____

What kinds of side effects[vii] might I experience? _____

_____

_____

What will be done to manage the side effects? _____

_____

_____

What are my options if I can't manage the side effects I experience? _____

_____

_____

What are my options if the intervention is not efficacious?

_____

_____

Can I withdraw before the end of the clinical trial? □ Yes □ No

If so, what would happen following my withdrawal? _____

_____

_____

Have other people with a similar medical condition ever had this procedure?

□ Yes □ No

If so, in what context? _____

_____

_____

Participation and consequences on the care trajectory[viii]

Will I be able to continue taking my regular medications while participating?

□ Yes □ No □ Not applicable

_____

_____

What are the differences between the study intervention and the current standard of care[ix] ?

_____

_____

_____

_____

Participation and daily responsibilities

What will my responsibilities be if I participate? _____

_____

_____

Should I be accompanied during the study visits? _____

_____

Is there any support (linguistic, social worker, etc.) provided by the research team or research center?

□ Yes □ No □ Not applicable

_____

Information about the end of the clinical trial

Once the clinical trial is complete, could I continue to receive the same intervention if it was efficacious for me?

□ Yes □ No □ Not applicable

_____

_____

Does this clinical trial involve a long-term follow-up? _____

Cost Information

Will there be any costs associated with my participation in the clinical trial? □ Yes □ No

If so, what is the nature of these costs (transportation costs, file opening fees, etc.)? _____

Are travel, accommodation, or logistics expenses covered by the sponsor[x]

or through another financial program for participants? □ Yes □ No

If so, what costs are covered? _____

Additional notes

Glossary

[i] An **NCT identification number** refers to the National Clinical Trial number. The NCT number is written in a "NCTXXXXXXXX" format. This is an identification number assigned to a study upon registration. Until an NCT number is assigned, the study is not registered.

[ii] An **interventional trial** consists primarily of testing an intervention on humans to ensure that it is efficacious and safe, and also measures its adverse or unexpected effects.

[iii] An **observational trial** involves making observations (human behaviour, health data analysis) and gathering information to advance knowledge (to better understand a medical condition, to study whether people are correctly following their usual treatment, etc.).

[iv] An **intervention** defines all treatments, procedures, tests or any other action performed to prevent and treat a disease, or to improve the health of the participants.

[v] A **research protocol** gathers all the information related to the conduct of the clinical trial. It explains why the trial is being conducted (background, hypothesis and objectives), how it will be conducted and how the safety of the participants will be ensured.

[vi] A **placebo** is a substance that does not contain any drugs, but has the same appearance as a study treatment (same shape, size, colour and taste if it is an oral treatment). It is administered in the same way (orally or by injection). In some cases, for example, in oncology, the placebo may be the standard treatment, which ensures appropriate medical management of participants.

[vii] A **side effect** is a reaction to a health product that is different from the intended reaction. A side effect may be expected or unexpected, mild or severe, temporary or permanent, harmful, neutral or positive. The onset of side effects varies from person to person and from treatment to treatment. It is important to ask the medical staff about the possible side effects of a treatment.

[viii] The **care trajectory** is the continuum of care a person receives to treat a medical condition. The care trajectory can include multiple treatments and care services at different times and locations.

[ix] A **standard of care** is the standard treatment that is usually prescribed to cure or reduce the symptoms of a specific medical condition.

[x] A **sponsor** takes ownership of and responsibility for all stages of a clinical trial. In most cases, the sponsor also funds the clinical trial. The sponsor may be a drug or biotechnology company, a university, a healthcare institution, a volunteer group, a private organization, a government health agency, a physician or a member of the medical staff.