WHAT IS A CLINICAL TRIAL?

Huntington Society of Canada
HUNTINGTON
Société Huntington du Canada

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies.

Clinical Trials

In a clinical trial, participants receive specific intervention (a medical treatment or change to the participants' behaviour) according to the research plan created by the researcher. Clinical trials may compare a new medical approach to a standard one that is already available or to a placebo (a substance that has no active ingredients, used to measure the results of the new medical product or behaviour that has been introduced). When a new product or approach is being studied, it is not usually known whether it will be helpful, harmful, or no different than available alternatives (including doing nothing). The investigators try to determine the safety and the ability to produce the desired result of the medical treatment or new behaviour by measuring the results in the participants.

Observational Studies

In an observational study, researchers study the health outcomes in groups of participants according to a research plan. Participants may receive interventions, which can include medical treatments, such as drugs or devices, or procedures as part of their routine medical care, but participants are not assigned to specific interventions by the researcher (as in a clinical trial).

Why Conduct a Clinical Trial?

A clinical trial is conducted according to a research plan. The plan is designed to answer specific research questions as well as safeguard the health of participants. It contains the following information:

- The reason for conducting the study
- Who may participate in the study (the eligibility criteria)
- The number of participants needed
- The schedule of tests, procedures, or drugs and their dosages
- The length of the study
- The information that will be gathered about the participants

Who Can Participate in a Clinical Trial?

Clinical studies have standards called eligibility criteria, which are the factors that allow someone to participate in a clinical trial. These factors or criteria include things like age, gender, the type and stage of a disease, previous and current treatments and other medical conditions.

Some research studies include a broad range of particpants, while others are very specific and may be limited to a predetermined group of people who are asked by researchers to enroll.

Why Are Clinical Trials so Important to the HD Community?

When you take part in a clinical trial, you help others by advancing medical research. This is the main reason for participating. However, if you have a disease, there could be personal benefits. For example, you may get early access to a new promising treatment. The treatment may provide benefits to your condition and may improve your quality of life. You may also get additional access to expert health care because of the time you will spend with the research team involved in the study.

Huntington Society of Canada • 20 Erb St. W • Suite 801 • Waterloo, ON N2L 1T2
1-800-998-7398 • info@huntingtonsociety.ca • www.huntingtonsociety.ca

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The Four Phases of Clinical Trials

Clinical trials are done in phases. Each phase has a different purpose and helps researchers answer specific questions.

PHASE I

These trials test an experimental treatment on a small group of people for the first time. The purpose is to:

- Assess the treatment's safety
- Find out what a safe range would be for dosage
- Identify side effects

PHASE II

The treatment is given to a larger group of people (usually 100 or more) to:

- Obtain preliminary data on the effectiveness of the treatment for a particular disease or condition
- Further assess the treatment's safety
- Determine the best dose

PHASE III

The treatment is given to even larger groups of people (usually 1,000 or more) to:

- Confirm its effectiveness
- Monitor side effects
- Compare it to commonly used treatments
- Collect information that will allow the treatment to be used safely on the market

PHASE IV

- This phase is completed after the treatment is approved and is on the market
- Gather information on things, like the best way to use a treatment, and the long-term benefits and risks

What is the Huntington Society of Canada's (HSC) Role?

HSC plays a key role in bridging the relationship between researchers and individuals by educating Canadians on the importance of the clinical trial process, how they can get involved, and why their participation is so crucial.

What Current Clinical Trials are Happening in Canada?

This information is ongoing and is constantly updated. Visit www.huntingtonsociety.ca/hd-clinical-trials for the most current information.

Suggested Resources for People Interested in Clinical Trials

- www.huntingtonsociety.ca
- www.HDBuzz.net

RESOURCES

Ongoing support, education and information is available from the Huntington Society of Canada (HSC). You can find a listing of our Family Services team members at www.huntingtonsociety.ca/family-services-team.

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