CLINICAL TRIALS

Huntington Society of Canada
HUNTINGTON
Société Huntington du Canada

Living with Huntington disease (HD) involves unique challenges, from changes in movement and thinking to the emotional weight of an unpredictable future. These challenges can affect the clinical trial participation decisions made by individuals and families living with HD. Choosing whether or not to participate is a personal decision that comes with risks and benefits. For example, participating in a trial could limit the opportunity to participate in future trials. This factsheet is designed to help you understand what these trials involve and how to decide if participating in a trial might be right for you.

DID YOU KNOW? CLINICAL TRIALS:

- Are done across Canada – there are thousands happening right now
- Depend on people to volunteer
- Don't just happen in hospitals or doctors' offices
- Study more than just drugs
- Help us learn more about how to treat people and improve their health

What are clinical trials?

Clinical trials involve people and test many types of interventions, including drugs, devices, genetic therapies, natural health products, psychotherapies, and lifestyle and preventative care interventions.

Why are clinical trials done?

Clinical trials provide research data, or evidence, about the intervention(s) tested. This evidence helps make decisions about the therapies or other interventions that might work best for people.

Clinical trials answer questions about an intervention(s) such as:

- Is it **safe?**
- Can it **improve** or **cure** disease?
- Can it help people **live longer** with the disease?
- Does it help people **feel better**?

Types of health interventions studied

Clinical trials study treatments or interventions on their own or in combination with each other.

These might include:

- Drugs
- Devices
- Surgery
- Radiation therapy
- Diagnostic procedures
- Diet and lifestyle

Phases of clinical trials for drug development

Clinical trials are classified by their phase. There can be differences in design depending on the disease or health condition being studied.

Phase 1: Small number of participants; tests safety, dose and how the drug is processed by the body.

Phase 2: Slightly larger participant group; continues to evaluate safety and ensures the intervention is doing what it is intended to do.

Continued on next page

Phase 3: Larger number of participants; confirms safety and effectiveness, compares to standard care, and measures possible clinical benefits and collects data for regulatory approval.

Phase 4: Post-regulatory approval, very large number of participants; involves monitoring an intervention while it is available on the market to learn about long-term effects.

How are clinical trials designed?

Clinical trials are designed to answer specific questions about an intervention. They are usually designed by a group of people that can include researchers, doctors, scientists, statisticians, sponsors, patients, and caregivers.

There are different types of designs for clinical trials. The design will depend on many things, including what is already known about the intervention(s), and what questions need to be answered.

What does randomization mean?

In randomized trials, two or more interventions (also called treatment arms) are compared to each other, and participants are assigned by chance to one of the interventions or treatment arms. Assigning participants by chance helps to ensure the results are not biased.

Questions to help you determine if a clinical trial is credible or reputable

- Are all of the costs of the clinical trial covered (for example, the study treatments)?
- What are the qualifications of the clinical trial team?
- Has the clinical trial application been reviewed by a regulatory agency? (for example, Health Canada)?
- Has the clinical trial been reviewed and approved by a research ethics board?

Acknowledgement: The Huntington Society of Canada gratefully acknowledges Clinical Trials Ontario for providing the valuable information shared within this fact sheet and to Alexander Maxan, PhD (HSC Director of Research & Strategic Partnerships) for his expert contributions, professional review, and research insight.

RESOURCES

Contact info@ctontario.ca or learn more at https://ctontario.ca/

For a list of HD clinical trials in Canada, visit: huntingtonsociety.ca

Reach out to your local Resource Centre Director (RCD) of the Family Services Program at HSC for ongoing support and education at hdsupport.ca

If you are ready to receive individual or group support from the Huntington Society of Canada, you can self-refer here: https://contactme.cloud/form/huntingtonsociety

Informational fact sheets for family and friends impacted by HD are available to view, print and download at hdfactsheets.ca

Healthcare professionals and caregivers needing a more in depth understanding on caring for someone with HD can find guides at hdresources.ca