Strength & Knowledge
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Embracing our Strength
our future
our vision
our story

HSC National Conference 2014

Winnipeg, MB
October 24 & 25, 2014
For more information or to register visit www.huntingtonsociety.ca

Enroll!
Updates from the Enroll-HD global community

Physician's Guide

HSC has published the 3rd edition of A Physician's Guide to the Management of Huntington Disease, with the assistance of HDSA. For a copy please contact us at info@huntingtonsociety.ca or 1-800-998-7398.

RESOURCES

Suggested resources for people with HD and families interested in HD research:

- www.huntingtonsociety.ca
- www.HDBuzz.net
- www.HDSA.org
- www.Enroll-HD.org
- www.Huntington-Study-Group.org
- www.HDTrials.org
- www.ClinicalTrials.gov

Sources:

- The Physician's Guide Third Edition
- ClinicalTrials.gov
- Health Canada www.hc-sc.gc.ca

Clinical Trials

What is a clinical trial?

A clinical trial (or 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).

Who Can Participate in a Clinical Study?

Clinical studies have standards outlining who can participate, called eligibility criteria, which are the factors that allow someone to participate in a clinical study. These are based on things such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

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

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.

Continued on page 2

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

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
- What information will be gathered about the participants?

PHASE IV

- Done after the treatment is approved and is on the market
- Gather information on certain items, like the best way to use a treatment, and the long-term benefits and risks

What current clinical trials are happening in Canada?

This information is ongoing and is constantly being updated. The best sources of information are the Huntington Study Group (www.Huntington-Study-Group.org) and CHDI (www.chdifoundation.org).

What is the Huntington Study Group?

The non-profit Huntington Study Group (HSG) was formed in 1993 by a small group of neurologists and researchers. HSG carries out cooperative therapeutic research in order to advance knowledge about the natural history and treatment of HD.

What is Enroll-HD?

Enroll-HD is a platform that allows health-care professionals, scientists, and families affected by HD to work together towards a better understanding of HD and identify effective treatments. Their objective is to create the world's largest database for clinical research on HD, eventually including information from as many as 20,000 people in around 33 countries. Visit www.Enroll-HD.org for more information.

What is HDTrials.org?

HDTrials.org has been created to enable clinical trial participation. The HDTrials.org website will provide quick notification to Huntington families of opportunities for participation in clinical trials and studies through a confidential email list. Visit www.HDTrials.org for more information.

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