2015 HD Clinical Trials

Huntington Society of Canada
HUNTINGTON
Société Huntington du Canada

# 2015 HD Clinical Trials

The Huntington Society of Canada (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 to get involved and why participation is so crucial. The urgency lies in not only educating as many people as possible, including efforts in rural and culturally diverse communities, but also ensuring clinicians have sustainable mechanisms in place to support the process.

HSC is emerging as a leader in linking researchers and clinicians in order to continually prepare for future trials. Drugs being tested now have been specifically designed for Huntington disease (HD). This is a significant step forward. Managing HD will take the collective efforts of researchers, scientists, clinicians, the Huntington Society of Canada and HD families all have to work together. It is our best chance for success.

2015 is an important year for HD clinical trials. Participation in Enroll-HD will facilitate your involvement in clinical trials when they are available in your area. 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 33 countries. Visit www.Enroll-HD.org to learn more and to find out the closest site for you to participate.

## Clinical trials starting in 2015

- Deep Brain Stimulation (DBS) is a common treatment for Parkinson's. A small pilot trial involving five individuals with HD has already happened in Europe. A larger multicentre trial to include more individuals with HD is now underway in Europe, with the intended outcome of providing more definitive results.
- Amaryllis is a multicentre Pfizer trial of a PDE10 Inhibitor drug that may help neurons to communicate more effectively.
- Pride-HD (Pridopidine) may help with movement symptoms. A Teva sponsored trial.
- Legato-HD aims to calm down the immune system in HD. A Teva sponsored trial.
- Isis-HTT$_{RX}$ is the first huntingtin-lowering treatment trial in HD. The drug will be injected into the spinal fluid and hopefully reach the brain, then tell the cells not to make the harmful huntingtin protein that causes HD. This is a world first for this method, which most HD researchers consider to be the most promising approach to treating HD. It is scheduled to begin in the first half of 2015.

## Resources

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

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

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## Why conduct a clinical trial?

A clinical trial is conducted according to a research plan 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 number of participants needed
- The schedule of tests, procedures, or drugs and dosages
- The length of the study
- What information will be gathered about participants

## 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.

## Who can participate in a clinical trial?

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.

## 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

- Done 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

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