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CLINICAL TRIALS

Q: If I want to participate in a clinical trial, what should I know?

A: Clinical trials are an important step in bringing new drugs to the market. They are designed to test the safety and effectiveness of medications, before they are made available to the public. The clinical trial (also called clinical research) involves human volunteers and helps pharmaceutical companies find treatments for various diseases that improve health and quality of life.

Before drugs are available for public use through pharmacies and other providers, they must go through several phases in the drug development process. The entire process takes 10 to 15 years and can cost the pharmaceutical companies over $1 billion for a single new drug. The phases of the process are as follows:

1. **Research discovery**. This involves the Preclinical Testing Phase. In this step, scientists evaluate the toxicology (chemical effects) and biological activity of the drug in the laboratory and in animal studies. If this phase is successful, the company can file a Clinical Trial Application (CTA) with Health Canada or an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA).

2. **Clinical trials**. There are three phases involved in clinical trials. Before starting a new phase, the pharmaceutical company must send a progress report to Health Canada or the FDA.

    - **Phase One** requires 20-100 healthy volunteers, and assesses the safety and dosage of the medication.

    - **Phase Two** requires 100-500 patient volunteers, and observes the effectiveness and the side effects of the medication

    - **Phase Three** requires 500-10,000 patient volunteers, and again observes the effectiveness and the side effects of the medication over a longer period of time.

3. **Health Canada or FDA Review Process.** After the pharmaceutical company has completed the clinical trials and the drug is proven to be safe and effective, a New Drug Submission (NDS) is filed with Health Canada or a New Drug Application (NDA) with the FDA. Sometimes these

government agencies will require the company to do additional testing on the drug. This is conducted through a Phase Four trial.

Q: How are clinical trials monitored?

A: Clinical trials are closely monitored at every stage by Health Canada or the FDA. The trials are also monitored by Research Ethics Boards (REB) or Institutional Review Boards (IRB). These boards ensure that the trial is conducted by qualified physicians and that the safety of the participant is not at risk.

REBs and IRBs follow guidelines set out in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. These guidelines were released in 1998 by the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council. For more information, visit www.pre.ethics.gc.ca

Q: Why should I participate?

A: Participating in clinical trials allows persons who are affected by disease to access some of the newest, most innovative drugs and products available. Although there is no guarantee that the treatment will work, many participate in research in the hope of helping others and contributing to drug development. It is also important for ethnic groups to participate, in order to have a patient sample that is reflective of the Canadian population. It is always recommended that you speak to your doctor and be sure to ask a lot of questions before participating in clinical trials.

Q: What questions should I ask if I want to participate?

A: It is important to ask about the purpose of the trial, any known side effects of the medication, how long you will be required to participate, the chances you will get the actual drug or a placebo (an inactive pill) and if there are any interactions with your current medication regimen. Although most of this information will be provided through the “informed consent process,” it is important to have these and any other questions answered before agreeing to participate.

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