What are Clinical Trials?

- A clinical trial is the word used by researchers to describe a health-related intervention to scientifically evaluate the effects on participants.
- Clinical trials investigate the effectiveness and safety of specific medical procedures and treatment products before they can be used across Canada.
- Clinical trials may compare a new medical approach to a widely used method, and/or to a placebo (a harmless substance that contains no active ingredients) and/or to no intervention.
- Canadian clinical trials are strictly regulated and must be approved by Health Canada, the hospital or clinic where it takes place, and a Research Ethics Board (REB), which protects the participants of the clinical trial until it is completed.

Children and Clinical Trials

- Adult treatments may have different effects on children.
- Until recently (and still not very often) little testing has been done on drugs and medical procedures performed on children.
- It is important to conduct clinical trials on children to evaluate if a new proposed method is effective for children.

What is a Trial Protocol?

- Each clinical trial has a written action plan or description of the study, known as the protocol.
- The protocol includes information such as why the trial is being done, how it is conducted, what it entails for the participant, and how safety is ensured.
- It is extremely important to read and understand the trial protocol before deciding whether or not you would like to participate.

What is Informed Consent?

- A very important process in clinical trials is to ensure that all facts are provided before you decide to participate.
- An informed consent is the voluntary agreement of a person to participate in a clinical trial after understanding the nature of the study, potential risks and benefits, and all other information required to make an informed decision.
- Parental permission is a type of informed consent given by parents or guardians for their child to participate in a clinical trial.
- An informed assent expresses the willingness of a child, who is old enough to understand but is legally too young to give consent, to participate in a clinical trial.
- Even if assent is obtained from a child, informed consent must still be provided by his or her parents.
Potential Benefits and Risks
• Potential benefits and risks vary between different clinical trials and are outlined in the trial protocol specific to the study.

Potential Benefits
• You develop a greater understanding of your condition under close monitoring, care, and support by a research team of doctors and health professionals.
• You can gain access to new treatment which are not yet available to the public.
• New drugs or treatments may be more effective than the standard approach.
• Although most benefits are for finding future cure, you are actively contributing to medical research and are informing the community that these diseases exist!
• Research in kids helps kids.

Potential Risks
• Clinical trials may require more time than non-clinical trial treatments, such as more follow-ups, etc.
• There may be other specific risks which will be discussed with your physician (extra blood work, additional tests, X-ray scans, and confidentiality).
• New drugs or treatments may not always be better or as good as the standard ones.
• You may experience unexpected side effects from the new treatment.

References
• http://www.centerwatch.com/clinical-trials/overview
• https://clinicaltrials.gov
• http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/clinical_trials-essais_cliniques-eng.php
• http://www.nihbi.nih.gov/studies/clinicaltrials
• https://www.nichd.nih.gov/health/clinicalresearch/Pages/index.aspx
• http://www.phsa.ca/our-research/participate/clinical-trials

FAQs & Checklist
• Make sure you understand the clinical trial before being involved. Don’t participate if you don’t understand what’s going on or have unanswered questions.
• You become a part of the team when you enroll in a study. We are working for the same goal: to find a cure!
• Weigh pros and cons. Don’t participate if it’s not helping anybody!
• Our biggest concern: SAFETY. Researchers are as concerned with safety as parents.
• If you say yes, your child’s care won’t be compromised.
• It’s okay to say no! Your treatment won’t change and you will still receive the standard treatment if you decide not to participate.
• THERE ARE NO SILLY QUESTIONS! → This is about you/your child! If you are uncertain or uncomfortable about anything, please ask!

Four Phases of Clinical Trials
Phase 1: I am tested on a small group of people (<100) for the first time to assess my safety.
Phase 2: I am tested on a larger group of people (100 or more) to determine how effective I am.
Phase 3: I am tested on an even larger group of people (1000 or more) to be compared to other treatments.
Phase 4: Much more of my long term risks and benefits are identified.

If clinical trials show promising results, I can be sold in the market!