It Starts With Me
Shaping tomorrow’s treatments through participation in clinical trials

www.itstartswithme.ca
Created by N2
Did you know?

• Anyone – healthy or ill – can think about participating in clinical trials

• By participating in a clinical trial, you may:

  - Help yourself
  - Help someone you know and love
  - Help find new treatments
Why participate
By participating in a clinical trial, you may help researchers find:

**The safest options**
By monitoring treatment closely and watching for side effects, researchers will learn if the treatment is safe.

**The best treatments**
By comparing two or more treatments, researchers will learn which treatment works better.

**The right uses**
By finding new ways and methods to use existing treatments, researchers may advance medicine.

**The right patients**
By testing in different groups of people such as the elderly and children, researchers will learn who will benefit the most.
How it works
What are clinical trials?

• Studies that involve people & are a type of clinical research

• Carried out to:
  – test new treatments
  – discover how to prevent or diagnose a disease
  – learn how an illness affects a person’s life
  – provide information about a disease.
Different types of clinical trials

<table>
<thead>
<tr>
<th>Prevention trials</th>
<th>Screening trials</th>
<th>Treatment trials</th>
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<tbody>
<tr>
<td>To look for new ways to prevent illness.</td>
<td>To help detect diseases or conditions.</td>
<td>To test new types of treatments.</td>
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How do clinical trials work?

• Clinical trials involving new medications are done in a series of steps called **phases**

• Participants are closely monitored throughout each phase

• Information and results from one phase are used to help design the next phase

• The clinical trial only moves on to the next phase when the previous phase’s results were considered to be positive.
Phase 1 – Is it safe?

• Involve 20-80 participants

• Healthy participants take the treatment to:
  – ensure it is safe
  – determine how much is needed, and
  – determine side effects

• Sometimes this phase occurs in participants with a disease such as cancer.
Phase 2 – Does it do what it’s supposed to do?

• Involve 100-300 participants

• Participants with the medical condition being studied are watched to:
  – see if the treatment works as expected and
  – further evaluate safety and dose.
Phase 3 – How does it compare?

• Involve 1000-3000 participants

• Larger groups of participants are monitored to:
  – continue observing side effects
  – see how well a treatment works in the long-term
  – how long a treatment’s effects last, and
  – how it compares to current treatments or a placebo.
Phase 4 – What happens long-term?

- Involve a large population

- After a treatment is shown to work and is approved, the long-term effects and safety are studied and to determine if existing therapies should be replaced.
Where do clinical trials happen?

- Depending on the research that is being done, clinical trials may happen in many different places, including:
  - doctors’ offices
  - hospitals
  - medical centres
  - community nursing stations
  - academic centres, such as universities and medical schools
  - clinics
  - and even in your own home.
Who is involved in a clinical trial?

- Participant
- Principal Investigator
- Clinical Research Coordinator
- Other Members of the Clinical Trial Team
- Sponsor
- Research Ethics Board
Getting started
What to expect

All clinical trials follow a protocol

- Ask any and all questions of your doctor, healthcare and clinical trial team
- Determine if you can be in the clinical trial
- Sign an informed consent form
- Start the clinical trial
- Complete the clinical trial

Complete the clinical trial

Sign an informed consent form

Start the clinical trial

Determine if you can be in the clinical trial

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Potential benefits & risks

Benefits
- Help find a new treatment
- People like you benefit
- Medicine advances
- Canadians get healthier

Risks
- Uncertain benefits
- Side effects
- Treatment changes
- Commitment
Protection of participants

- There are a number of ways that participants in a clinical trial are protected in real time, including requirements for:
  - Research Ethics Board review before the clinical trial begins and periodically once it starts
  - Informed consent
  - Oversight of the scientific & medical aspects of the clinical trial
  - Following Good Clinical Practice Guidelines
  - Following Health Canada regulations, including inspections and audits.
It’s up to you

• Clinical trial participation is *voluntary* and *completely up to you*.

• Being part of a clinical trial you have the right to:
  ✓ Decide if you wish to take part in the clinical trial
  ✓ Withdraw at any time for any reason without this affecting your medical care
  ✓ Confidentiality of all information.
Where to find a clinical trial

• Ask your doctor or another member of your healthcare team
• Health Canada’s clinical trials database
• International Standard Registered Clinical/trials Number (ISRCTN)
• World Health Organization
• Canadian Cancer Trials
• Clinicaltrials.gov
To learn more

• Visit www.itstartswithme.ca

• Talk to your healthcare providers.
About these slides

These slides were created by N2 (www.n2canada.ca) with input from patients and caregivers.