It Starts With Me

Shaping tomorrow's treatments through participation in clinical trials

www.itstartswithme.ca

Created by N2

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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

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Why participate

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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.

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How it works

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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

Prevention trials	Screening trials	Treatment trials
To look for new ways to prevent illness.	To help detect diseases or conditions.	To test new types of treatments.

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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.

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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

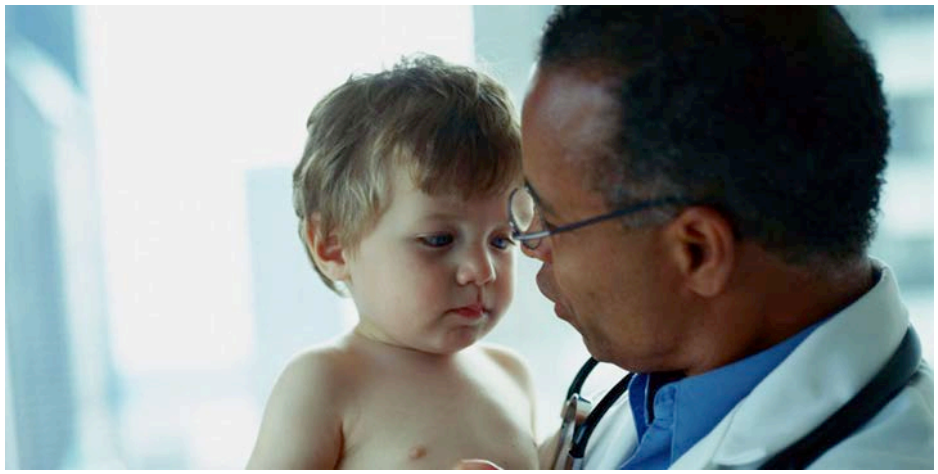
- After a treatment is shown to work and is approved, the long-term effects and safety are studied and to determine if existing therapies should be replaced.

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



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Getting started

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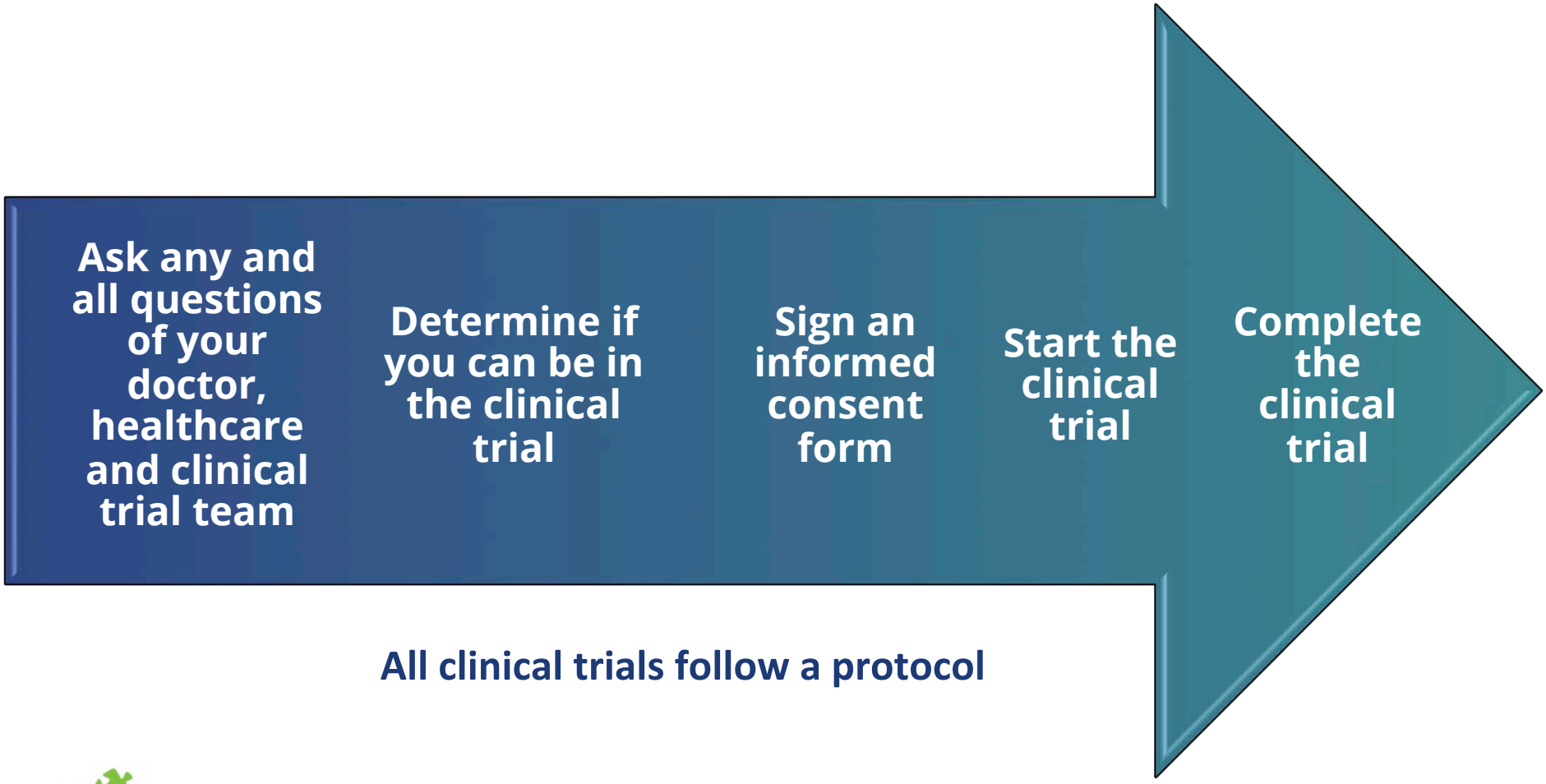
What to expect



All clinical trials follow a protocol

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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

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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.

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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/soCialsTudy Number (ISRCTN)
- World Health Organization
- Canadian Cancer Trials
- Clinicaltrials.gov

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To learn more

- Visit www.itstartswithme.ca

- Talk to your healthcare providers.

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About these slides

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

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