

Introduction to Clinical Trials

Prepared by Clinical Trials Ontario
Posted with permission by the Canadian Arthritis Patient Alliance
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This presentation

- ✓ Basic information about clinical trials
- ✓ Information about finding a clinical trial
- ✓ About the Canadian Arthritis Patient Alliance
- ✓ About Clinical Trials Ontario

Basic Information about Clinical Trials

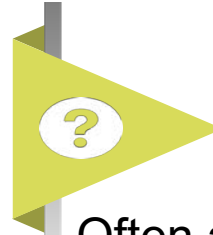
What are clinical trials?



A type of research involving people



Test health-related interventions and outcomes



Often answer questions like:

- *Is the intervention safe?*
- *Does the intervention improve or cure disease, or help people live longer with disease than other treatments?*
- *Does the intervention help people feel better?*

Health interventions studied in clinical trials

Treatments or interventions on their own or in combination with others. These might include:



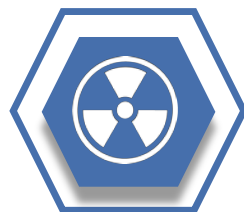
Drugs



Devices



Surgery



**Radiation
therapy**



**Diagnostic
procedures**



**Diet and
lifestyle**



To **provide**
research data
(evidence)
about the
intervention(s)
tested

Why are
clinical trials
done?

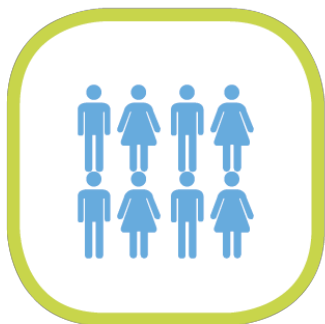


Help decide
what therapies
or other
interventions
might work
best for people

The phases of clinical trials for drugs

PHASE 1

20-80 people



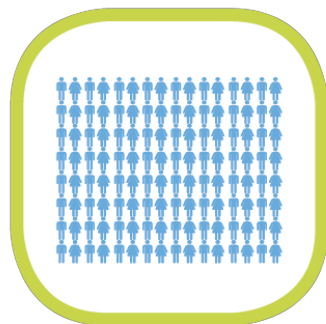
PHASE 2

100-300 people



PHASE 3

1,000s people



PHASE 4

10,000+ people



Phase 1 clinical trials for drugs

PHASE 1

20-80 people



- Also called “first in humans”
- Aim to establish safety, dose and side effect information
- Small number of participants
- Timeframe of weeks

Phase 2 clinical trials for drugs

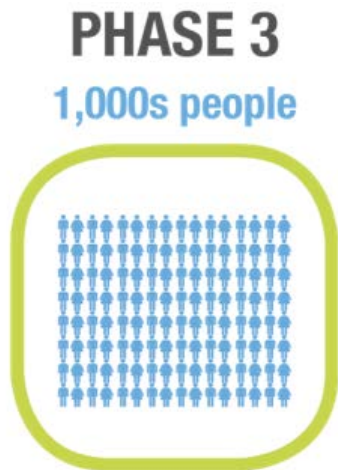
PHASE 2

100-300 people



- Aim to establish efficacy, learn more about dose and side effect information
- For a larger number of participants
- Timeframe of months

Phase 3 clinical trials for drugs



- Aim to see how long effects last, learn more about dose and side effect information
- For a large number of participants
- Timeframe of years

A *randomized* clinical trial is when **two or more interventions** or treatment arms are compared to each other.

Participants are **assigned by chance** to one of the interventions to reduce bias.

Phase 4 clinical trials for drugs

PHASE 4

10,000+ people



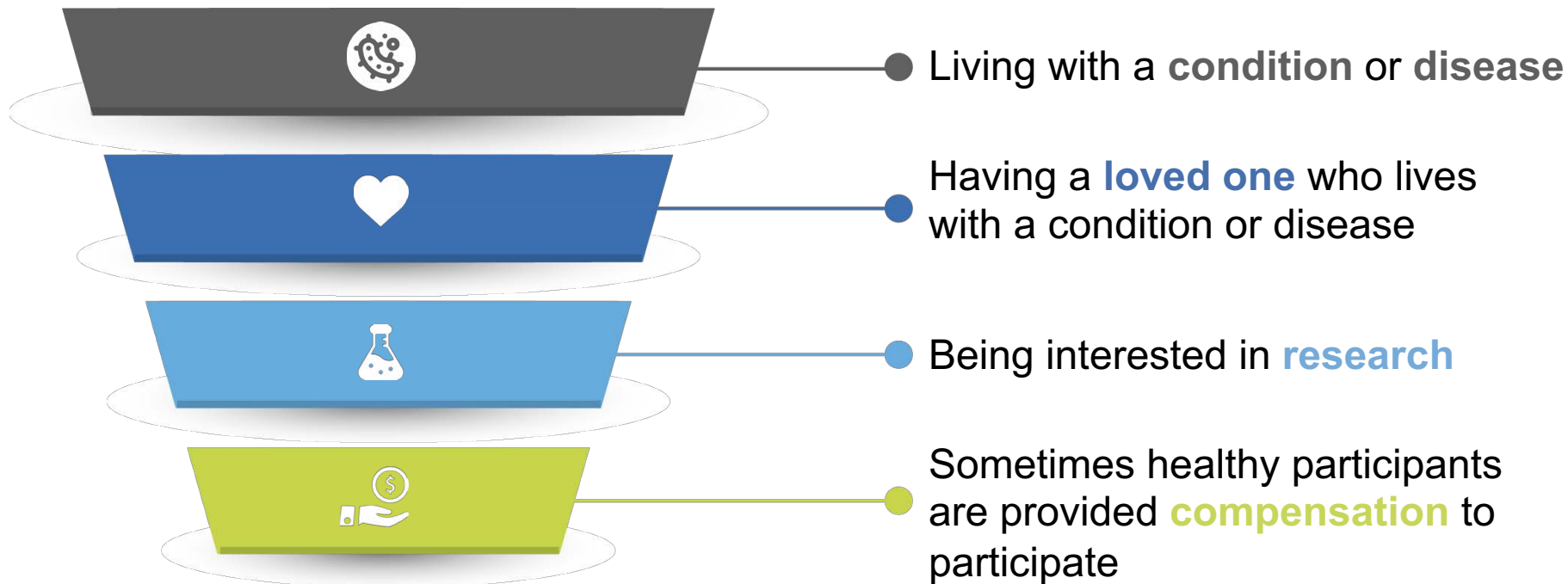
- Also called post-marketing surveillance
- Study long term side effects
- For a very large number of participants
- Timeframe of years (ongoing)

Placebo

- An inactive therapy (such as a drug, natural health product, or device) that looks like an active therapy
- Not intended to have any effect on the condition being studied
- Is used to make the results of the study more reliable
- Used if there is no 'standard of care' for a condition or disease

Looking for a Clinical Trial

Some reasons you may be looking for a clinical trial



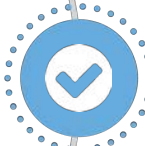
Questions to ask to determine if a clinical trial is reputable or credible



Are all **costs** of the clinical trial covered (for example, the study treatments)?



What are the **qualifications** of the clinical trial team?



Has the clinical trial application been reviewed by a **regulatory agency**?



Has the clinical trial been reviewed and approved by a **research ethics board**?



Was the clinical trial reviewed and approved by the **institution or organization** where it is taking place?

If you're offered a clinical trial, there are other options you may wish to consider

OPTION 1

Receiving no treatment

OPTION 2

Receiving standard treatment or a different form of treatment that what you are currently on if you live with a disease or condition

OPTION 3

Participation in a different research study

Talking to your doctor about potential known benefits and risks of these options (including no treatment) may be helpful

To find a clinical trial, you may wish to:



Talk to your health care provider



Ask a health charity or patient organization



Contact a hospital or organization that does research



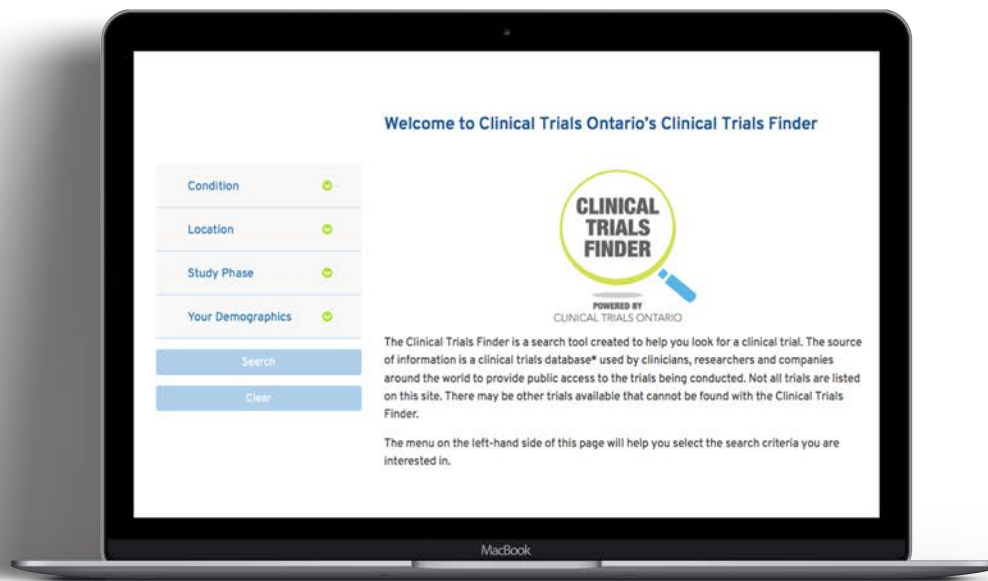
Follow up on a newspaper, TV, or radio ad



Use CTO's Clinical Trial Finder

CTO's Clinical Trials Finder

<https://trial-finder.ctontario.ca>



What if you can't find a clinical trial?



If there is a clinical trial in another location that you are interested in, **contact the study team** (*Is it possible? How will this affect you?*)



There may be ways to **bring the clinical trial closer to you**



Keep **up to date on research** and check time to time on clinical trials

Can you say no to a clinical trial if your health care provider offers one?

Yes – you can say no if you feel this clinical trial isn't the right choice for you



Your relationship with your health care provider should not change no matter what you decide about a clinical trial

What some people consider when making a decision about a clinical trial



All of the **costs** of the clinical trial covered (for example, the study treatments)



You are satisfied with the **qualifications** of the clinical trial team



The clinical trial application been reviewed by a **regulatory agency**



The clinical trial been reviewed and approved by a **research ethics board**



The clinical trial reviewed and approved by the **institution or organization** where it is taking place



You meet the **eligibility criteria** to be in the clinical trial

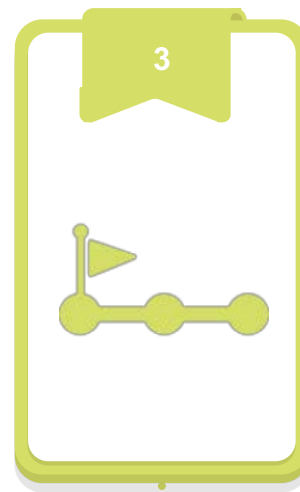
Informed consent



Consent is voluntarily



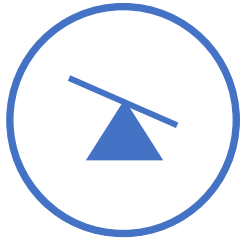
Consent can be withdrawn at any time



Consent is an ongoing process

If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

Potential benefits and risks



It is up to you to decide if the potential benefits outweigh the potential risks

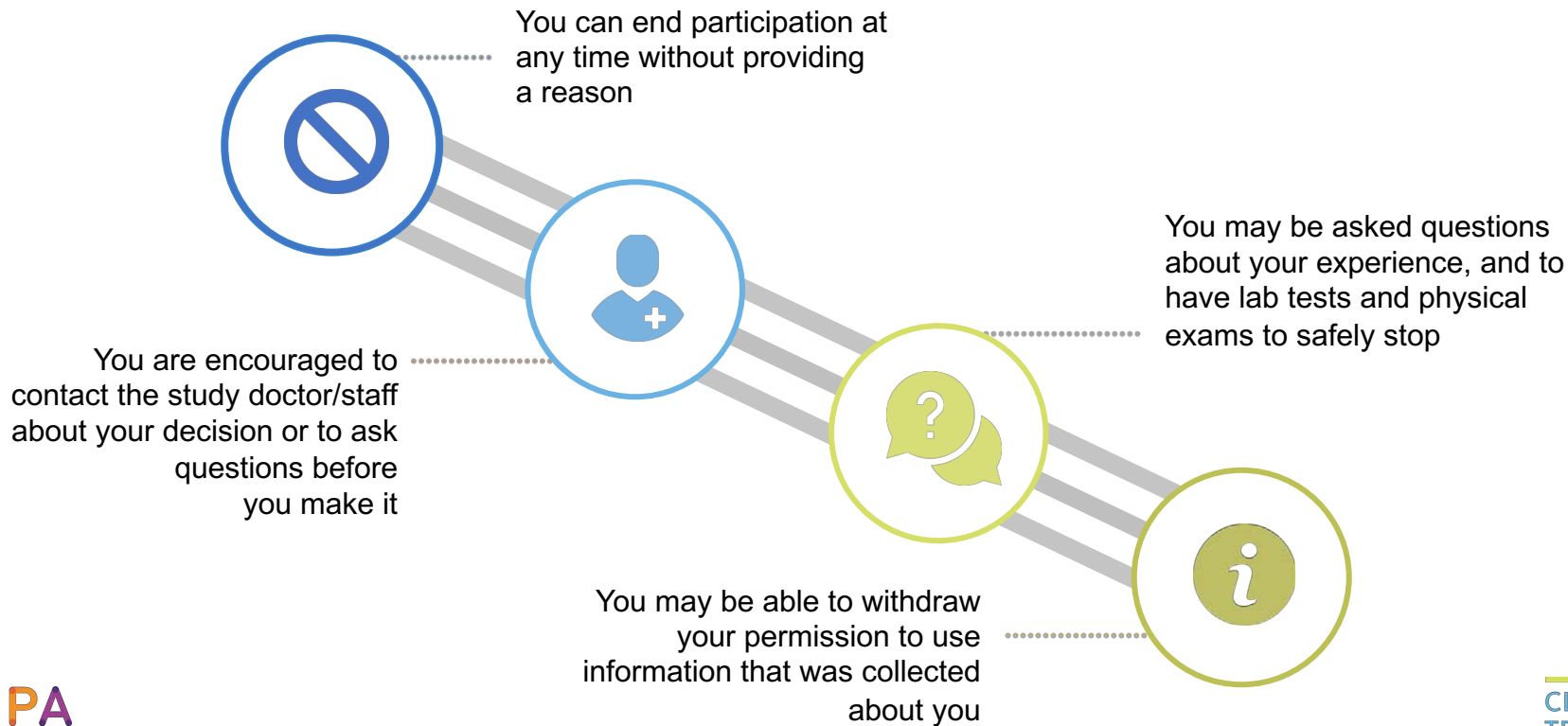


Potential benefits and risks will be different for each clinical trial and described in the informed consent form



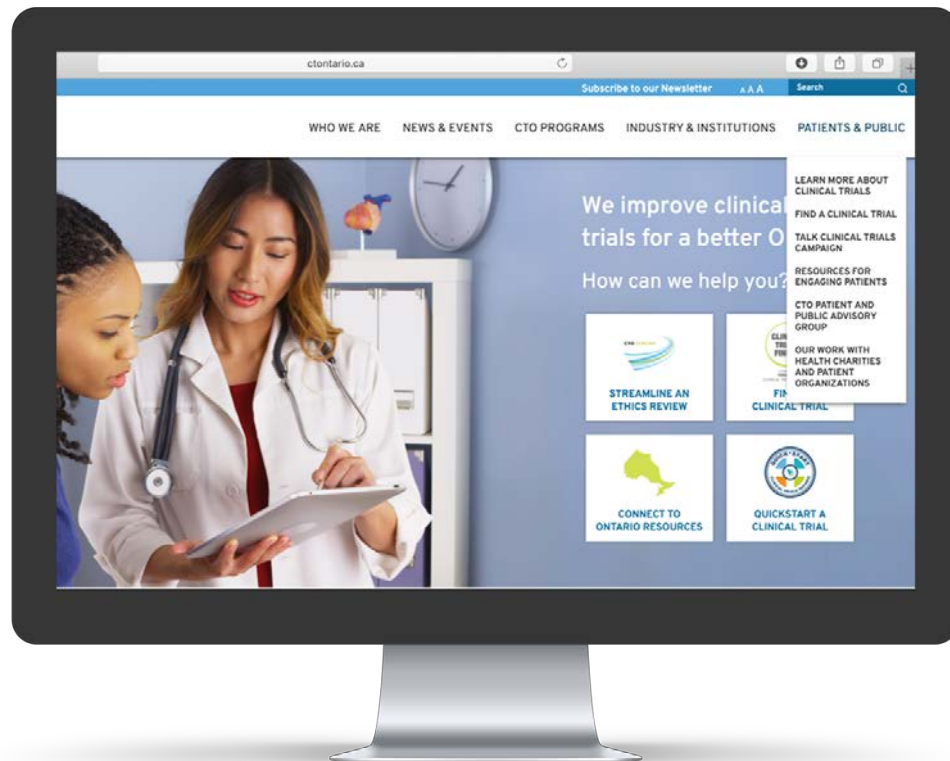
Ask questions about potential benefits and risks until you feel satisfied.

Leaving a clinical trial - Withdrawal



For more information

You may wish to visit www.ctontario.ca – and review the Patients and Public pages



About the Canadian Arthritis Patient Alliance



A grassroots, patient-driven, independent, national organization with a community of individuals across the country.

CAPA believes...

the first expert on arthritis is the person who lives with arthritis and provides a critical voice and perspective that needs to be heard in decision-making.

CAPA uses the power of information, research, and communication to help people living with arthritis find their voice and support others.

CAPA seeks to educate and empower people living with arthritis so they can continue to positively contribute to society and improve their health care experiences.

Find us at:



www.arthritispatient.ca



@CAPA_Arthritis



@CAPA.aca

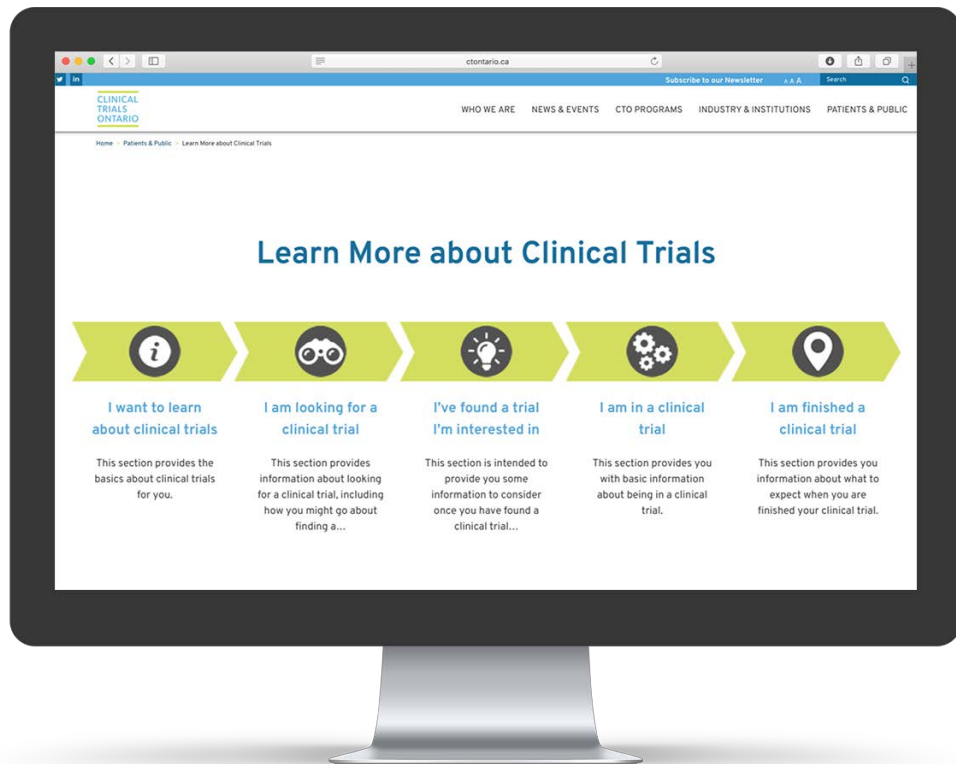


www.youtube.com/channel/UCJPvsvUYNwrEtYMKOFx1Bzg

About Clinical Trials Ontario

This presentation comes from

www.ctontario.ca/patients-public/learn-more-about-clinical-trials/



Clinical Trials Ontario (CTO)

Our Vision

To make Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards.

Our Mission

To strengthen, promote and capitalize on Ontario's competitive advantages to conduct high-quality clinical trials.

Supported by the Ontario Ministry of Colleges and Universities

What CTO does



STREAMLINE

Streamline processes to support the timely, efficient and cost-effective conduct of high-quality clinical trials.



ENGAGE

Support and promote public and patient engagement with clinical trials.



PROMOTE

Promote Ontario's competitive advantages and clinical trial capacities to attract more industry investment.