Cancer Clinical Trials Webinar

June 12, 2017

Welcome!

Today's Agenda

Topic	Speaker
Welcome, Introduction & Goals	Renée Leduc (BioCanRx) & Dawn Richards (N2)
Introduction to Clinical Trials	Dr. Natasha Kekre (Ottawa Hospital Research Institute)
The Coordination of Clinical Trials & What to Expect	Faye Aspelund (The Ottawa Hospital Cancer Centre)
The Trial Participant's Experience	Jill Hamer-Wilson
N2 & Ottawa Hospital Resources	Dawn Richards & Faye Aspelund
Questions & Wrap Up	Mod. Renée Leduc & Dawn Richards

Introduction to Clinical Trials:

Why do we do cancer clinical trials? What are cancer clinical trials? Why might someone want to participate?

Dr. Natasha Kekre

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

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

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.

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 up to 30 participants
- Participants take the treatment to:
  - ensure it is safe
  - determine how much is needed, and
  - determine side effects

Phase 2 – Does it do what it's supposed to do?

- Usually involves about 20 to 100 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?

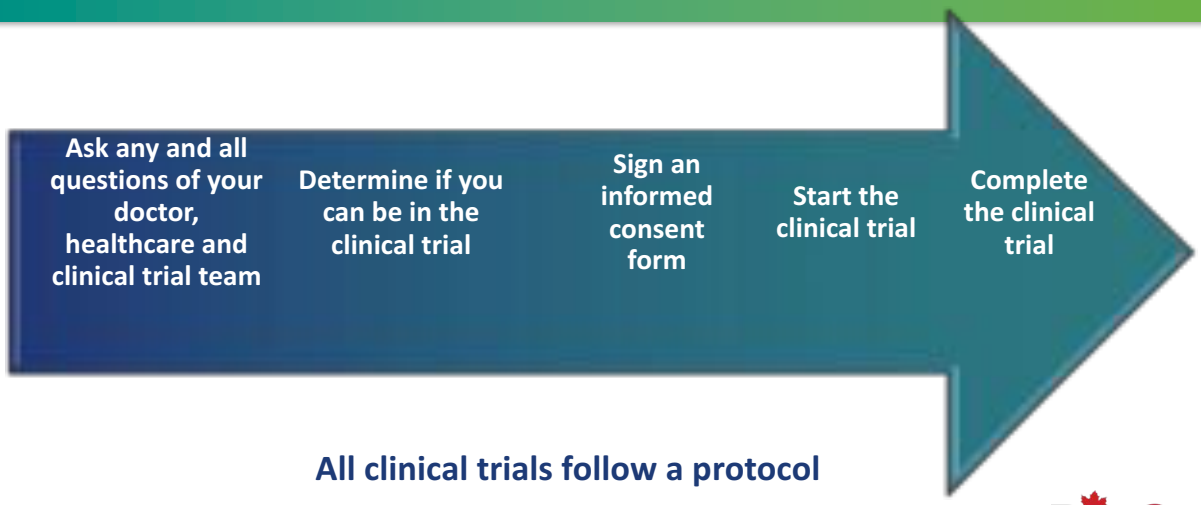
- Depending on the research that is being done, clinical trials may happen in many different places, including:
  - doctors' offices
  - hospitals
  - medical centres
  - community nursing stations
  - academic centres, such as universities and medical schools
  - clinics
  - and even in your own home.

Who is involved in a clinical trial?

- Participant
- Principal Investigator
- Clinical Research Coordinator
- Other Members of the Clinical Trial Team
- Sponsor
- Research Ethics Board
- Participant's family and caregivers

Getting started

What to expect



All clinical trials follow a protocol

Potential benefits & risks

Benefits	Risks
Help find a new treatment	Uncertain benefits
People like you benefit	Side effects
Medicine advances	Treatment changes
Canadians get healthier	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.

To learn more

- Talk to your healthcare providers
- Be your own advocate
- More resources in the webinar to come…

The Coordination of Clinical Trials and What to Expect

Faye Aspelund

Agenda

- Who are we
- Clinical Trials – Part of the Research Process
- Steps to Activating a Protocol
  - Research Ethics Board (REB)
  - Site Initiation
- Patient Enrollment
  - Informed Consent
  - Eligibility
- Ongoing Participation

The Ottawa Hospital Cancer Program

- Comprehensive cancer treatment facility:
  - Medical, Radiation, Surgical Oncology at one site
  - Program embedded in a large academic health sciences centre
- Academic affiliations with:
  - University of Ottawa (teaching hospital)
  - Ottawa Hospital Research Institute (research facility)
- Patient care divided into disease-site specific practice:
  - Investigational New Drug (IND), Lung, Breast, GI, GU, etc.

Steps To Activating A Clinical Trial: Protocol Development

- A Sponsor or an individual oncologist develop a concept and a protocol to answer a research question
- The protocol is developed with the following in mind:
  - does the study ask an important scientific question
  - will it be potentially beneficial to our patients
  - do we have the patient population
  - are there competing studies

Steps To Activating A Clinical Trial: Trial Selection

- Oncologists work together in multidisciplinary teams that study specific types of cancer (Disease Sites)
  - Medical, Radiation, Surgical Oncologists
  - Pathologists
  - Radiologists
  - Others
- Together they decide which clinical trials are beneficial for their patient population
- Each trial is reviewed by
  - Disease Sites
  - Internal Review Committees
  - Research Ethics Board
  - If applicable Regulatory bodies – Health Canada/FDA

Steps To Activating A Clinical Trial: Research Ethics Board Review

- Most important aspect of clinical research
  - The protocol and any relevant materials must be approved by the REB prior to any participant becoming involved in the trial
  - All participant study materials must be approved by the REB. This would include the informed consent form, patient diaries, patient quality of life questionnaires etc.
  - The review ensures the patients rights, safety and privacy are protected
  - Board includes
    - Physicians
    - Lay representatives
    - Other professional and ethics specialists

Steps To Activating A Clinical Trial: Site Initation

After REB Approval

- The Investigator has a Site Initiation Visit (SIV)
  - All the study staff, participating oncologists and departments that are involved with the study meet to discuss and train on the appropriate aspects of the study
  - If drug is involved as part of the treatment, Pharmacy will train and prepare any materials that are required for the participant to receive treatment
  - The Investigator and study coordinator attend and ensure all study personnel are trained and ready to go
  - Once the SIV takes place, the study coordinator will let all staff know the study is opened for recruitment

The Coordination Of Clinical Trials: Informed Consent Process

What Can the Patient Expect

- At the patient's visit the oncologist generally reviews the patient's chart to check if a Clinical Trial might be a beneficial option
- This can be at new diagnosis, when there is progressive disease, or when there is a change in treatment
- The patient can also ask the oncologist about potential clinical trials
- The Investigator will briefly explain the study to the patient, if the patient is interested the Clinical Study Coordinator (CSC) is called
- The CSC will meet with the patient, discuss the study and review the Informed Consent Form and any other materials the patient may need to be aware of

The coordination of clinical trials: Informed Consent Process

- Informed consent is a critical part of ensuring participant safety in research.
- The patient is generally sent home with the Informed Consent Form and given time to review it and discuss with family members, family physician, etc.
- The patient will be given the CSC's contact information if further questions arise
- Informed consent is an ongoing process through out the study – patients are informed of any new information
- A patient can withdraw their consent at any time

The coordination of clinical trials: Patient Enrollment And Eligibility

- Once all the questions are answered and the patient agrees to participate in the Clinical trial, he/she signs and dates the informed consent form (ICF)
- A copy of this is given to the participant
- Once the ICF is signed the CSC and Investigator can begin to order study specific tests and review the eligibility criteria in detail

The coordination of clinical trials: Patient Enrollment And Eligibility

- Patients medical records are reviewed for past history and results of diagnostic tests
- Most eligibility criteria are very in depth and require testing at very specific time points so past diagnostics may need to be repeated e.g.
  - CT scans
  - MRI's
  - Physical assessments
  - Blood work and review
- Many of the studies require a sample from the patient's original biopsy (which is stored in pathology)
  - At times a fresh biopsy may be required
  - Biopsies are often used to look at or study biomarkers

The coordination of clinical trials: Patient Enrollment And Eligibility

- When all tests are completed the results are reviewed by the Investigator and the CSC to determine if the participant meets the study eligibility criteria
- The participant will be informed if he/she meets or does not meet the criteria
- If the participant meets eligibility criteria they are enrolled in the trial
- Once the participant is enrolled further visits are scheduled e.g.
  - Treatment (drug or radiation)
  - Surgery
  - Ongoing diagnostics to assess response or results

The Coordination of Clinical Trials : Ongoing Participation

- The participant will need to have various tests performed at specific time points during the trial
- The CSC will coordinate this and many times escorts the participant to the various departments
- The participant will be monitored closely for any side effects and if the treatment is beneficial
- Once the treatment portion of the clinical trial is over, the participant continues to be monitored at specific time points with specific test
- This could be for many years

The Coordination of Clinical Trials : Ongoing Participation

- All required data that is collected is entered in an electronic Sponsor Database
- Patients personal information is not used – patients have a coded identifier
- The participant is always informed of any safety updates and of changes to the protocol
- This is usually done by reviewing an REB approved updated ICF and having it signed

The Coordination of Clinical Trials : Trial Completion

- Patient is finished the clinical trial once all protocol treatments/procedures/visits are completed
- At anytime during the trial the participant may decide to discontinue participation
- If the investigator feels the trial is no longer beneficial, he/she will discuss this with the participant and review other options
- If the participant is experiencing a toxic effect(s) the investigator may stop the treatment
- At times the Sponsor may stop the study early
  - Trial proves successful at an early stage
  - Trial does not benefit patient

Clinical Trials : PART OF THE RESEARCH PROCESS

- Clinical trials are a critical part of the research process. Clinical trials help to move basic scientific research from the laboratory into treatments
- Through Clinical trials we can find better treatments and ways to prevent, detect, and treat cancer
- We need to test the best cancer prevention, detection, and treatment ideas in the shortest time possible, and this can only happen if more people participate in clinical trials

Clinical Trial Participant's Experience

Jill Hamer-Wilson

My Family (before my diagnosis)

My blog https://throughthevalley23.wordpress.com

My husband designed this shirt for the National Capital Race Weekend 2016, when he raised funds for the Ottawa Regional Cancer Foundation (and ran a personal best in the Marathon!).
The picture is of me holding my middle child!

N2 & Ottawa Hospital Resources

Dawn Richards & Faye Aspelund

It Starts With Me

Shaping tomorrow's treatments through participation in clinical trials

www.itstartswithme.ca

Created by N2

www.itstartswithme.ca / www.cacommenceavecmoi.ca


It Starts With Me
What are clinical trials?


It Starts With Me
Can I participate in a clinical trial?

Short Video

- English & French
- With and without subtitles
- Available on Youtube www.youtube.com/channel/UCRs8FirAy9HAdoXopBYoEDg

Pamphlet

- English & French versions
- Basic overview of clinical trials
- Available on the N2 Resources page: http://n2canada.ca/news-resources/resources/

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

- Disease-specific societies, e.g. Leukemia & Lymphoma Society

The Ottawa Hospital Resources

- http://www.ohri.ca/Patients/
- **http://ottawahospital.libguides.com/cancer_patient/clinical_trials**
  - Patient Resource Centre at TOHCC
  - Canadian Cancer Society
  - Canadian Cancer Trials
  - Ontario Cancer Trials
  - National Cancer Institute List of Trials US

It Starts With Me video https://youtu.be/uwrNR54_qQs

Questions?

Thank you!