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Clinical Trials Video Transcript

Today we will be talking about clinical trials. During this lesson, you will learn how clinical trials work, how molecular pathology is involved in clinical trials and what to expect should you join a clinical trial.

Clinical trials are a type of research study designed to evaluate the effectiveness of new medical treatments called “interventions.” They usually involve large teams that include clinicians and informed patients willing to be a part of the study.

Clinical Trials try to answer questions about interventions like:

- Can it improve or cure a disease?
- Can it help patients live longer with a disease compared to existing treatments?
- Can it help patients to feel better and enjoy a better quality of life?

How do Clinical Trials work?

They are performed by a research team, led by a Principal Investigator and one or more co-investigators. Members of the research team closely monitor experiments that take place in the lab and monitor patients who are receiving treatments. Treatments are typically performed at either a hospital research institution or a private research facility.

Clinical Trials can be sponsored by public institutions, private companies, government agencies or other organizations. These sponsors initiate, manage, or finance the clinical trial but they do not conduct the clinical research themselves.

During a clinical trial, participants receive certain interventions according to the research design plan or “protocol” formulated by the research team.

Some key aspects of a clinical trial protocol are:

- Identifying study goals
- Defining who is eligible to participate
- Identifying risks to participants and the related safety measures
- Detailing tests, procedures and treatments
- Estimating the duration of the trial
- Identifying the key data points that will be analyzed

The protocol is designed to achieve specific outcomes in a way that balances participant safety with the benefits of the new intervention.

To determine the effectiveness of an intervention, researchers compare the effects of the new medical intervention in the “experimental group” of patients to current existing methods given to patients who are in the “control group”.

Patients in the control group are usually given a “placebo,” which is a treatment that contains no active ingredients.

Phases of a clinical trial

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Clinical trials are performed in several stages or “phases.” Trials are usually based on studies performed on cells or animals in a lab*. This is called the preclinical development phase and occurs well before the intervention is tested on patients.

There are 4 main phases of a clinical trial in which human participants are involved.

- In Phase I, Small-scale tests are done on an experimental treatment. These typically involve a few dozen subjects. The main goal is to determine the safety of the treatment and identify any side effects.
- In Phase II - The new treatment approach is given to a larger group of patients, usually less than 100, to determine how effective it is and to further assess safety.
- In Phase III - The new treatment approach is given to hundreds of patients to verify its effectiveness, monitor potential side effects, compare it with standard or similar treatments, and to collect valuable information that will allow the new treatment approach to be used safely by the public.
- Phase IV Occurs after a new treatment approach is approved by federal and provincial regulators and made available to the public. Researchers track its use to define the best treatment regimen and assess the long-term risks and benefits.

Clinical trials that are currently accepting new participants are referred to as open clinical trials. Those that are no longer accepting new participants are referred to as closed clinical trials.

Next, we will look at who can be included in the trial:

As clinical research has a multi-faceted approach, they take interest in how medical intervention affects people with a certain disease, family history, or lifestyle.

Patients from diverse backgrounds and ethnicities help to ensure that a well-rounded study is completed to test the efficacy of the new treatment on a larger scale.

Participants may be excluded from a trial if they have another disease or condition that may mask the effect of the intervention being studied.

Now for the Role of Molecular Pathology in Clinical Trials:

In recent years, emphasis has been placed on the importance of treating medical conditions based on a patient’s unique cellular and genetic makeup – this approach to healthcare is called precision medicine.

Molecular pathology is critical to precision medicine and can play and important role in clinical trials, as well.

Molecular pathologists perform test to measure the amount of molecular and cellular indicators present in a patient’s blood or tumour sample. These indicators are called “biomarkers”, and they can help predict and manage the course of personalized treatments during a clinical trial and eventually in clinical practice.

During a clinical trial, many samples in the form of blood and tissue samples are collected either through a clinical visit or a medical procedure. These specimens enable pathologists and lab professionals to complete their molecular pathology assessment.

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In this assessment, molecular pathologists use cutting-edge tools for their analysis and apply their medical knowledge from a variety of medical disciplines.

Molecular pathology professionals are key members of the clinical trial research team with the goal of improving cancer patient outcomes in healthcare.

People are motivated to participate in clinical trials for many reasons:

- Some may want to help others move science forward for the benefit of society,
- Patients with a disease may also want to help others but also benefit from receiving a new and potentially more effective treatment from clinical research team that will closely follow their progress,
- Clinical trails may also offer hope for patients who may have exhausted all other treatment alternatives.

Patients may be made aware of a trial through a medical professional responsible for their care, through a patient support organization or take it upon themselves to research possibilities they may be interested in and confer with their doctor.

The online resources shown here can be used by patients wishing to explore applicable clinical trials. Note these results and informational content should be reviewed with your doctor.

- (Clinical Trials Ontario)
- (National Institute of Health – USA)
- (Canadian Cancer Trials)

You can consult the video description for a direct link to these websites.

Staying safe during clinical trials.

Participation in a clinical trial is voluntary. It is critical that before you commit to participating that you are given the following:

- A thorough understanding of the clinical trial's risks and benefits,
- Understanding of how it works,
- the time and personal costs, and
- the ability for you to ask questions that help you to make an informed decision if your participation is right for you.

This process is called Informed Consent and will require your signature before taking part in the trial. It is important to note that regardless of your signed intent to participate, you can leave the trial at any time if you wish.

Other safety measures built into clinical trials include:

- Strict ethical guidelines designed to protect the well being of participants and to maintain research integrity throughout the design and operations of the trial.
- Research Ethics Board Approvals – An independent committee that consists of physicians, administrators, lawyers, statisticians, and members of the community

who ensure that clinical trials are ethical and that the rights of participants are protected.
- Health Technology Approvals (HTA) – Regulatory examination at the federal and provincial level that weighs evidence related to the effectiveness, safety, accessibility and cost-efficiency of the design and outcomes of a clinical trial.

What happens after the Trial is Completed?

The research team analyzes data collected during the study and make decisions on the significance of the results and if further testing is necessary.

You will likely continue to be followed by a clinical team to monitor your progress and deal with any complications should they arise.

You may also be asked to contribute a voluntary testimonial in support the approval of the treatment with regulatory bodies and government agencies.

Results are usually published in peer-reviewed scientific journals. Peer review is a process by which experts review the report before it is published to ensure that the analysis and conclusions are reliable.

If the results are important to the public and patient community, the trial may receive media coverage, be presented at scientific meetings and by patient advocacy groups and be published in a scientific journal.

Once a new approach has been proven safe and effective in a clinical trial, it may become a new standard of medical practice once approved by the health care regulator.

Clinical Trials Making a Difference

Some Key take away points regarding clinical trials:

- Ground-breaking scientific advances, past, present and future, were possible due to the participation of volunteer participants in clinical research.
- Molecular pathology has aided in many new personalized medical approaches based on biomarkers. Continued advances in personalized medicine requires a sufficient supply of patient volunteers.
- Clinical trials employ rigorous design protocols to achieve optimal safety and benefits while minimizing risk to participants.
- If you are a patient suffering form a rare, chronic or acute disease, the consideration of participation in a clinical trial is a discussion you should have with your medical team.