UNDERSTANDING

CLINICAL STUDIES

What you will find in this book

This book is meant to help you understand what clinical studies are, why they are done and how they work.

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What is a clinical study?

Clinical studies are research studies that help doctors and scientists find out if an investigational medicine works the way it is expected to and does so safely.

When an investigational medicine is discovered, it is usually not known whether it will be helpful, harmful or no better than treatments that are already available.

Clinical studies test investigational medicines to make sure they are safe and helpful for a specific disease, medical condition or group of people. When an investigational medicine is being studied, it is called a study medicine because it has not yet been approved.

CLINICAL STUDIES RELY ON VOLUNTEERS WHO CHOOSE TO PARTICIPATE AND CONTRIBUTE TO RESEARCH.

Different diseases and medicines can affect people differently

Many factors affect how a person experiences a disease and responds to medicine, such as:

- Age, sex and gender
- Ethnic, cultural and family background
- Lifestyle in terms of nutrition, exercise, stress and sleep
- Education, employment and access to healthcare
- Exposure to pollution and other environmental factors

Having people from diverse backgrounds helps to ensure that the information learnt in a clinical study will apply in the real world.

IT'S IMPORTANT FOR CLINICAL STUDIES TO REPRESENT THE REAL-WORLD POPULATION.

Developing medicines

Study medicines go from the lab to the real world through a highly regulated process. Clinical studies are a very important part of that process.

1 LAB RESEARCH

When a study medicine is being developed, lab tests provide information about:

- What the study medicine does
- The best way to deliver the study medicine into the body (for example as a pill or injection)
- Whether the study medicine is safe enough to test it in humans

2 CLINICAL STUDIES

Clinical studies are the next step. They help answer questions about if the study medicine works and whether potential benefits outweigh risks. Typically, a study medicine is tested for a specific disease, medical condition, age group or population of people, such as those for whom another medicine didn't work.

3 THE REAL WORLD

When a study medicine has been found to work safely and effectively, it is approved by a country's government health agency. This means that doctors can then prescribe the approved medicine to patients who may benefit from it.

IT CAN TAKE DECADES FOR A STUDY MEDICINE TO GO FROM THE LAB TO BECOMING AN APPROVED MEDICINE.

Phases of clinical studies

Clinical studies are usually done in three to four phases. Each phase involves a larger group of people and is designed to answer different questions about the study medicine. Each phase must also show that the study medicine is safe before it can move on to the next phase. Clinical studies can last for months or years, depending on what is being studied.

PHASE 1

- The safety of the study medicine
- The highest amount (dose) of study medicine that can be given to treat the disease safely

PHASE 2

- The safety of the study medicine in a larger group of people
- Whether the study medicine is effective
- The safety of the study medicine in unique situations, such as interacting with certain foods or other medicines

PHASE 3

- The safety of the study medicine over a long period of time
- Whether the study medicine works as planned in large groups of people
- Whether the study medicine is better than currently available treatments

PHASE 4

- How the study medicine works in the real world once it's approved
- Side-effects that may happen over a long period of time when used by the general public

The Informed Consent process

Every clinical study includes a process called Informed Consent. This is when people learn all about the study and ask any questions they have.

The study staff will explain:

- ✓ Why the study is being done
- ✓ How long the study lasts and the schedule of visits
- ✓ Health checks and tests that will be done
- ✓ Possible benefits and risks
- ✓ Who will be involved in their care
- ✓ Time and financial considerations

A person considering a clinical study should take as much time to think about it as they need. Joining a study is their choice. They can choose not to join and to continue with their usual medical care.

Agreeing to join involves signing an Informed Consent form. A study participant does not give up any legal rights by signing it.

THE STUDY STAFF WELCOMES ANY QUESTIONS.

A participant's well-being is the number one priority

Participants' health and safety are the most important things in clinical studies. Many processes are put into place to make sure:

- Rights and well-being are protected
- Any possible risks are minimal
- The study is ethical (fair)
- Personal information is appropriately protected

Many people are involved in ensuring that a person is protected while participating in a clinical study. They include:

- Your country's government health agency
- An independent committee at the hospital/clinic where the study is taking place
- The doctors and nurses involved in running the study
- The company or organisation sponsoring the study

What happens during a clinical study?

Most clinical studies follow a similar process that includes a Screening Period, a Study Treatment Period and a Follow-up Period.

1 SCREENING

The study staff will check to see if the participant is eligible for the study. This involves answering questions and completing a check-up and some tests.

2 STUDY TREATMENT

The participant is assigned by chance to receive the study medicine, an already available treatment or sometimes a placebo. Not all studies include a placebo.

There are regular visits with the study doctor in person or virtually by computer/phone.

Some common tests may include:

PHYSICAL EXAM | BLOOD TEST | URINE TEST | IMAGING

The participant may be asked to do things at home, like complete a diary about their experience with the study medicine or side-effects.

3 FOLLOW-UP

After the final dose of study medicine, there may be a few more visits.

Benefits and risks

Every clinical study has possible benefits and possible risks.

Possible benefits

- The study medicine may help the participant
- The participant's health will be closely monitored by a team of doctors and nurses
- Study-related medicine, tests and doctor's visits are provided at no cost
- Participation may contribute scientific knowledge to a treatment option that may benefit others in the future

Possible risks

- The study medicine may not help the participant
- Study visits require time and commitment
- There could be side-effects from the study medicine or study procedures

Sometimes people have heard misconceptions or incorrect information about clinical studies. By being open and honest with your concerns, the study staff can help make sure you have accurate and up-to-date information about the possible benefits and drawbacks or risks.

Summary of key points

- Clinical studies help doctors and scientists learn if an investigational medicine works the way it is expected to and does so safely
- It's important for clinical studies to represent the diversity of the real world to ensure that a study medicine is safe and effective for everyone who would need it
- Clinical studies are only started after enough lab data suggest a study medicine may be safe
- Participants' health and safety are the most important things to everyone involved in running a clinical study

PARTICIPATION IS 100% UP TO THE PERSON WHO IS CONSIDERING JOINING THE STUDY.

Words to know

Approval: A country's government health agency approves a study medicine once data from clinical trials shows sufficient evidence of safety and efficacy. Doctors can then prescribe the approved medicine to patients who may benefit from it.

Informed Consent: The study staff will go over all the details of the study. If the participant understands and agrees with the information, they can choose to sign the Informed Consent form before any study procedures begin.

Phase: Clinical studies are divided into phases, or stages, that are designed to answer different questions about the study medicine. Each phase must show that the study medicine is safe before the next phase can begin.

Placebo: A placebo looks just like the study medicine but contains no active medicine. Placebos give researchers something to compare with the study medicine to better understand the study medicine's effects.

Screening: Screening is the first part of a study where the study staff checks to determine whether a participant is eligible to join and whether the study is right for them.

Study medicine: This is the investigational medicine being tested in the clinical study. In some studies, it may be a medicine that is already approved for another medical condition or age group but not for the medical condition or age group being tested.

Notes