Understanding Clinical Trials

Together We Count

[ISBN XXXXXXXXXXXX]

GSK Content Library - Understanding Clinical Trials Illustrative Book - 03-APR-2023 - English (Principal) - V1.0

Interested in learning about clinical trials?

This booklet will provide you with an overview of clinical trials: what they are, when they happen, and what they involve.

What is a clinical trial?

Clinical trials, also called clinical studies, are research studies that help doctors and scientists learn more about a disease or medical condition and new ways to treat, diagnose, or prevent it.

Why are clinical trials important?

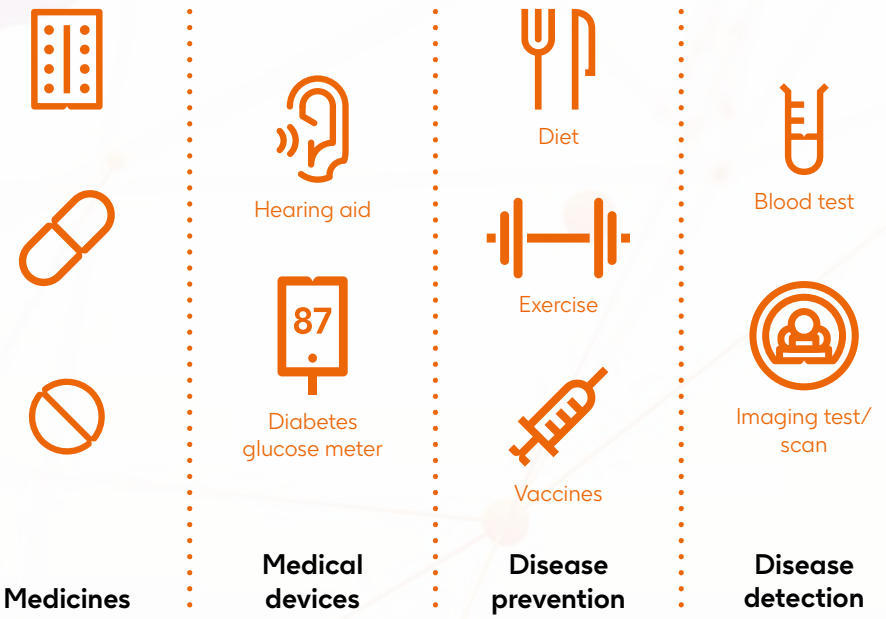
Clinical trials are important for improving health care and for finding more safe and effective treatments and vaccines for people around the world. Every medicine you have taken has gone through a clinical trial.

When a new medicine is discovered, it is usually not known whether it will be helpful, harmful, or no different than treatments that are already available.

Clinical trials help doctors and scientists understand how the human body responds to a new medicine and whether that medicine works safely for a specific disease or medical condition.

What do clinical trials test?

Clinical trials are mostly known for testing new medicines. But clinical trials are also used to test new medical devices and to find new ways to prevent and detect diseases, such as diabetes and cancer.



What role do clinical trials play in developing a medicine?

Clinical trials play a very important part in the making of a medicine, but they are only one step of this complicated process.

Clinical trials occur after a new medicine has been discovered and studied in detail in a lab. The most promising medicines are then tested with volunteers in clinical trials. Only when a medicine has been found to work safely in people does it become approved, or available, for those who may benefit from it.

The entire process, from discovery to approval, can take up to 15 years.

Steps to developing a medicine

For every several thousand discoveries made in the lab, only 1 medicine may actually make it to the pharmacy shelf!

1 Discovery:

All new medicines begin with an idea of how to treat or prevent a disease.

2 Pre-clinical (lab) testing:

The idea is studied in detail by scientists in a lab to find out:

a. What the medicine does.
b. How it works.
c. If it's safe.
d. How it would be given to people (for example, as a pill or a shot).

3 Clinical trials:

The most promising of these medicines are then carefully tested with volunteers. Clinical trials involve several steps, or phases, which are explained in more detail on the next page.

4 Approval:

Only the medicines that work the best and are the safest are made available to people who may benefit from them.

What are the different steps of a clinical trial?

Clinical trials usually have 3 stages, also called phases. Each phase 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.

With each phase, more and more volunteers are involved. This is to make sure the medicine is safe and works in a large number of people.

How long a clinical trial lasts depends on what is being studied. Trials can last for months or for many years.

This process helps to make sure that only the safest and most effective treatments are approved.

Clinical trial phase (stage)	Size of the participant group	Questions being asked
Phase 1	Small (20 to 80 healthy volunteers)	• Is the medicine safe? • What is the highest amount (dose) of medicine that can be given to treat the disease safely?
Phase 2	Larger (100 to 300 volunteers)	• Is the medicine safe in a larger group of people? • Does the medicine work?
Phase 3	Largest (1000s of volunteers)	• Is the medicine safe over a long period of time? • Does the medicine work as planned in large groups of people? • Is the medicine better than currently available treatments? Is it better than no treatment (if nothing else is available)?

Once a medicine is approved and in use by the general public, there may be a Phase 4 trial to keep track of any side effects that may happen over a long period of time.

What happens during a clinical trial?

Most clinical trials are divided into different parts that usually include *screening*, *study treatment*, and *follow-up*.

Your health is closely monitored by a team of doctors and nurses throughout the entire trial.

1 Screening

- The study team checks to see if a person is eligible to join the trial. This depends on what the trial is testing and who the study medicine is meant for. For example, a trial may be testing a medicine for people over 65 years of age with a specific heart condition.
- The study team will collect information about the person's health and run tests.

2 Study Treatment

Treatment groups

- In some trials, the study medicine is compared to a placebo or to the best available treatment.
  - → A *placebo* looks just like the study medicine but contains no active medicine. This gives researchers something to compare to the study medicine in order to better understand its effects. Placebos are only used if no effective treatment is available.
  - → If another treatment is currently available, researchers will compare it to the study medicine to see if the study medicine works better or causes fewer side effects.
- Trial participants are assigned by chance to a treatment group. In some studies, neither you nor the doctor will know which group you are in to keep the results fair.

Study visits

- While taking the study medicine, you will have visits with tests to check on your health. Visits may take place at the study site, on the computer, or over the phone. Some common tests include:

Physical exam | **Blood test** | **Urine test**

3 Follow-up

- Once you have finished taking the study treatment, the study team will continue to keep an eye on your health via in-person visits or over the phone.

Who participates in clinical trials?

People who participate in clinical trials are *volunteers.* Even if a person decides to join, they can change their mind and stop participating at any time. Their regular medical care will not be affected.

- *Healthy volunteers:* People who do not have a health problem. Researchers may need to compare a healthy person to a person who has a certain medical condition.
- *Patient volunteers:* People who have a certain disease who may be looking for another treatment option.

Clinical trials are not only for adults, but for children and teens, too. Children's bodies work differently than adult's bodies. A medical condition may not affect children the same way as it does adults, and children may also respond to medicine differently.

Why is diversity in clinical trials important?

- Clinical Trial Diversity is ensuring trial participants represent the population of people with the disease.
- Medicines and vaccines may affect people differently based on age, sex, race and ethnicity. When clinical trials include diverse participants, the study results may have a much wider applicability.

How are clinical trial participants protected?

Safety is the number one priority of a clinical trial. Many processes are put in place to make sure your rights are protected and any potential risks are minimal. Two examples of these processes are:

Institutional Review Boards (IRB)

- Clinical trials must be reviewed, approved, and monitored by an IRB.
- An IRB is made up of doctors, researchers, and members of the community.
- They make sure that the trial is ethical (fair) and that your rights and well-being are protected.

Informed Consent Process

- If you are interested in joining a clinical trial, the study doctor will explain all the details. This includes any potential risks and benefits, as well as other treatment options if you choose not to join.
- You must sign an Informed Consent Form before joining a trial to show that you understand and agree to the information. Signing the form is not a contract and you may choose to leave the trial at any time.

All personal information gathered during the clinical trial is kept confidential.

What are some benefits and challenges of being in a clinical trial?

There is a lot to think about when considering a clinical trial. Will the study medicine help? Does the study medicine have side effects? How often will I have to go to the study site?

Ask the study team any questions you have and take your time thinking it over.

Potential benefits

- You'll help improve health care and find better treatments.
- There is a chance the study medicine may help you.
- Your health will be closely monitored by a team of doctors and nurses.

Potential challenges

- You may have several checkups and hospital visits.
- As with all medicines, you may experience side effects from the study medicine.
- Not all clinical trials are successful and there is a chance that you may not feel better.

Remember, being in a clinical trial is ***voluntary****.*

Talk to your doctor for more information. You can also visit ***www.clinicaltrials.gov*** *for a list of clinical trials in the United States.*

Putting it all together

Clinical trials help doctors and scientists learn more about a disease and new ways to treat, diagnose, or prevent it.

The most promising medicines are tested in clinical trials after being studied in detail in a lab.

Clinical trials go through several phases to make sure that only the safest and most effective treatments become available.

In some trials, the study medicine is compared to a placebo or to the best available treatment to better understand its effects.

Safety is the first priority of clinical trials.

It is important for clinical trials to have participants of different ages, sexes, races, and ethnicities.

Participating in a clinical trial is voluntary.

Words to know

Approval: New medicines that are shown in clinical trials to work the best and be safe are then made available to people who may benefit from them.

Informed Consent Form: Signing this form shows that you understand and agree to the information.

Informed Consent Process: During this process, the study doctor will explain all the details of the trial. This includes any potential risks and benefits, as well as other treatment options if you choose not to join.

Institutional Review Boards (IRB): A group of doctors, researchers, and members of the community that reviews and approves the trial to make sure it is fair and that your rights and well-being are protected.

Phases: Clinical trials 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 it can move on to the next phase.

Placebo: This looks just like the study medicine but contains no active medicine. Placebos give researchers something to compare to the study medicine in order to better understand its effects.

Pre-clinical testing: Testing that is done by scientists in a lab to collect information on a new medicine. Pre-clinical tests look at how the medicine works, whether it is safe to use, and how it would be given to people.

Screening: This is the first part of a trial, in which the study team checks to see if a person is eligible to join.

Study medicine (study treatment): This is the new medicine being tested in the clinical trial.

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