A GUIDE TO UNDERSTAND

Clinical Trials

The George Institute for Global Health

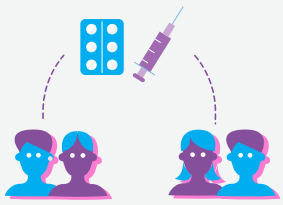
What is a clinical trial?

- A clinical trial is a type of research study that involves human participants to evaluate treatment options (also known as interventions) that promote health, prevent diseases, or treat illnesses.
- Treatment options could include medications, vaccines, procedures, medical devices, behavior-change interventions, etc.

Why do we need to conduct clinical trials?

To find **safe & effective** treatment options for promoting health, preventing diseases or treating illnesses.

Before any treatment can be approved for public use, it must undergo **rigorous testing** through clinical trials.



Academic researchers can also conduct clinical trials to find the **best treatment** among already existing therapies.

These experimental studies provide evidence of **benefits** and potential **risk** of the interventions, that ultimately can i**nform clinical practice and policies.**

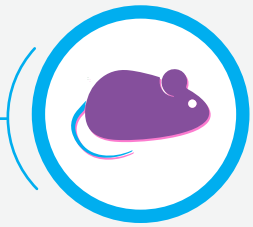
Medical treatment development process

1. Discovery

A new treatment option is developed by scientists.

2. Pre-clinical testing

The treatment goes through laboratory and animal studies to assess safety, and toxicity.



3. Clinical trials

Step 1: To assess safety & maximum tolerated dose in a few healthy volunteers.

Step 2: To assess benefits and safety at various doses among few volunteers.

Step 3: To assess benefits, and potential harms in a large set of diverse volunteers.

4. Regulatory approval

Permission to market the treatment for wider use.

5. Available for public use

Treatment enters the market and can be prescribed by doctors.

6. Post-marketing studies

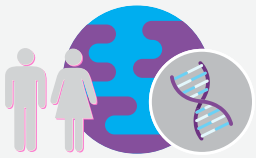
Monitoring the safety and responses of the treatment in general population.

It is a long journey for treatments to reach the people who need them!

Why should someone participate in a clinical trial?

Contribute to generating evidence about new treatments.

Get access to the newest treatment.



Advance science that contributes to welfare of humans.

What happens in a clinical trial?

Assess eligibility & willingness

Sign an informed consent

Get randomly assigned to test or control group

Monitored for any adverse effects

Follow-up visits for assessments

Analysis of data

Publishing of findings in scientific journals

Inform clinical practice guidelines

What should one know before participating in a clinical trial?

- Why is the trial being conducted?
- What is the treatment/intervention being tested?
- What is the alternative intervention (comparison group)?
- What is the chance of getting into the test or comparison group?
- What treatment will you get if not participating in the trial?
- What do the researchers expect from you?
- What are the clinical procedures you will be going through due to the trial participation?
- What will be the frequency of follow-up assessments?
- What are the possible benefits of trial participation?
- What are the risks due to trial participation?
- What will happen if you want to discontinue the trial intervention?
- How will your data be used?
- How will you be compensated in case you encounter any major adverse effects?
- Who can you contact in case of any queries?

What are the rights of a trial participant?

- Right to information about research study in an understandable language.
- Right to be informed about the risks, benefits about the test intervention.
- Right to privacy & confidentiality.
- Right to access clinical records.
- Right to receive compensation for any harm caused.
- Right to quality health care for any trial related injury/adverse event.
- Right to be informed about alternative treatments.
- Right to be informed about any new information that may change your decision to continue in the trial.
- Right to refuse participation.
- Right to raise any concerns.
- Right to withdraw from study.
- Right to be informed of the final findings after trial completion.

The George Institute for Global Health

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We're improving the lives of millions of people worldwide through innovative health research. Working across a broad health landscape, the Institute conducts clinical, population and health systems research aimed at changing health practice and policy worldwide.

Contact:

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