

What are Clinical Trials?

Clinical trials, a type of clinical study, are research studies that test how well potential new therapies work in people.

Each clinical trial is designed to answer specific scientific questions around finding new or better ways to treat a particular condition.

Clinical trials of potential new therapies typically proceed through four phases*:

Phase 1

Test for the first time in a small group of volunteers (~10 to 80), usually healthy individuals, to study safety and determine a dosage range.

Phase 2

Test in a larger group of people (~50 to 300), including people with a particular condition, to study if and how well it works and further study safety.

Phase 3

Test in an even larger group of people (~100 to 3,000) to confirm safety and effectiveness, monitor side effects, and determine benefit vs risk.



Based on review of all data collected in relevant clinical studies and other research, a regulatory agency may approve the potential new therapy for use in routine medical care.

Phase 4

Studies of the now approved treatment to continue collecting information about safety and effectiveness.

*Depending on the condition and therapy being studied, there may be variation in trial design, including number of participants and aims.



Clinical trials are an important part of developing new treatments. They are required before a new treatment can be used in routine medical care for people living with a particular condition.



Although efforts are made to control risks to clinical trial participants, some risk may be unavoidable because of the uncertainty inherent in research involving potential new therapies.



It's important that people make their decision to participate in a clinical trial only after they have talked with their healthcare team and fully understand the entire process, including any and all risks that may be involved.

To learn more about clinical trials:

US Food and Drug Administration, Clinical Research

<https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>

National Institutes of Health, Clinical Research Trials and You

<https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics>

MedlinePlus, Clinical Trials

<https://medlineplus.gov/clinicaltrials.html>

Thank you to those individuals who have participated in a clinical study. Without you, medical research and treatment advances would not be possible.
