

# 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 health 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.**

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## **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>

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

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