

# What are Clinical Trials?

**Clinical trials, a type of clinical study, are research studies that test whether potential new therapies work for 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 effectiveness 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 medical care for the condition in which it was studied in.

**Phase 4**

Studies of the now approved therapy 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 drug therapies. They are required before a new drug therapy can be used in 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 or discomforts 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>

### **European Medicines Agency, Clinical Trials Clinical Trials Information System**

<https://euclinicaltrials.eu/>

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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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This infographic was developed by Viridian Therapeutics.

Material is intended for educational purposes and does not constitute diagnosis or treatment recommendations. Please speak with a healthcare professional for all medical questions.

For more information on Viridian Therapeutics, please visit [www.viridiantherapeutics.com](http://www.viridiantherapeutics.com) or contact the patient advocacy team at [patientadvocacy@viridiantherapeutics.com](mailto:patientadvocacy@viridiantherapeutics.com).

If you are participating in a Viridian clinical trial and have a question about this trial, please contact your local site or [privacy@viridiantherapeutics.com](mailto:privacy@viridiantherapeutics.com).

