

WHY DO RESEARCHERS DO DIFFERENT KINDS OF CLINICAL STUDIES?



Clinical research is the study of health and illness in people.






Scientists may have many reasons for doing a clinical study, such as:

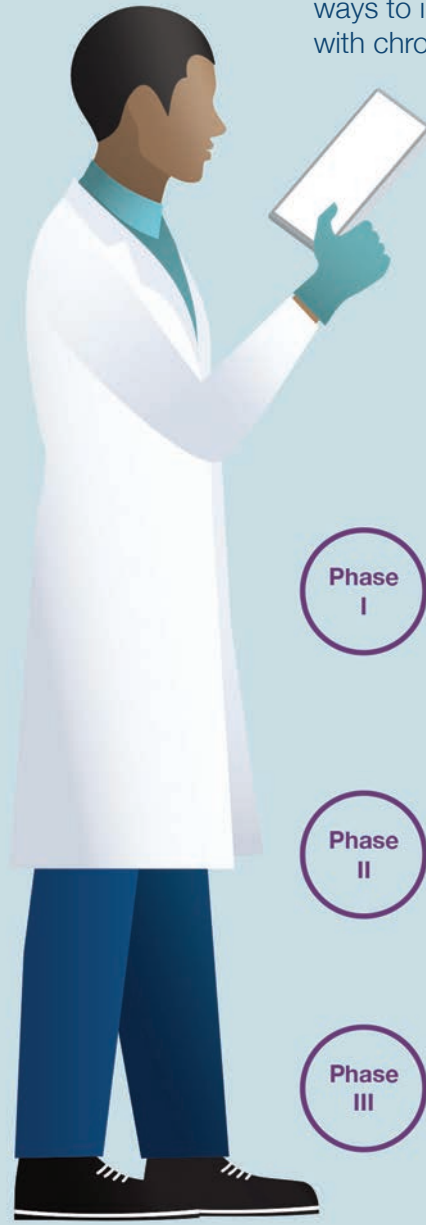
- To explore the cause of a disease or a set of symptoms
- To test if a treatment will help with a symptom or condition
- To learn how a certain behavior affects people's health

Different types of clinical studies are used in different circumstances. Depending on what is known and what isn't, scientists may even study the same research question using different kinds of studies and in different groups of people. Here are different types of clinical studies and why they might be used.

Observational Studies

In many studies, researchers do not do experiments or test new treatments; they *observe*. Observational studies help researchers understand a situation and come up with hypotheses that can be put to the test in clinical trials. Observational studies can find associations between things but can't prove that one thing causes another. Types include:




- 
Case Study/Case Series
 A detailed description of one or more patients. By documenting new and unusual cases, researchers start to generate hypotheses about causes or risk factors.
- 
Ecological Study
 Compares the rate of a disease or condition for groups of people, such as towns in different climates or with different average incomes.
- 
Cross-Sectional Study
 A snapshot of many people at one moment in time. These studies can show how common a condition is and help identify factors associated with it.
- 
Case-Control Study
 A group of people who have a condition is compared to a control group of people who don't. Possible causes or risk factors can emerge.
- 
Cohort Study
 A large group of people is observed over time. Some eventually develop a disease or condition. Researchers can learn how often the condition occurs and find possible causes or risk factors.



Clinical Trials

In these studies, researchers test new ways to prevent, detect, or treat disease. Treatments might be new drugs or combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments. Clinical trials can also test other aspects of care, such as ways to improve the quality of life for people with chronic illnesses.

A well-designed clinical trial is the gold standard for proving that a treatment or medical approach works, but clinical trials can't always be used. For example, scientists can't randomly assign people to live in different places, or ask people to start smoking or eating an unhealthy diet. Clinical trials are conducted in phases:

- 
Phase I
 - Purpose: Find out whether a medical approach (e.g., drug, diagnostic test, device) is safe, identify side effects, and figure out appropriate doses.
 - Number of people: Typically fewer than 100
- 
Phase II
 - Purpose: Start testing whether a medical approach works. Continue monitoring for side effects; get information that goes into designing a large, phase III trial.
 - Number of people: Typically 100-300
- 
Phase III
 - Purpose: Prove whether a medical approach works; continue monitoring side effects.
 - Number of people: As many as needed or able to enroll—can be 1,000 or more
- 
Phase IV
 - Purpose: When a medical approach is being marketed, continue gathering information on its effects.
 - Number of people: Thousands

How good are these kinds of studies at showing cause and effect?

The strength of a study depends on its size and design. New results may confirm earlier findings, contradict them, or add new aspects to scientists' understanding. In the end, cause and effect are usually hard to establish without a well-designed clinical trial.



What can I do to help?

You've begun! Learning about what results mean will help you make good choices with your health care provider.

You could also consider volunteering either as a healthy volunteer or as a participant who has a particular disease or condition.

For more information about clinical trials: ClinicalResearchTrials.nih.gov

CRAY@mail.nih.gov



Produced by the National Institutes of Health, the largest source of public funding for medical research in the world. NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.