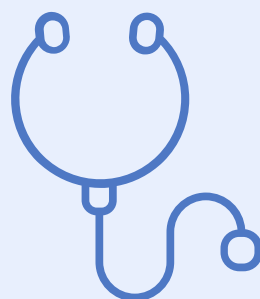


Clinical Trials

Clinical trials are research studies that look at new ways to prevent, detect, or treat disease. They are the core of medical research. Clinical trials are usually conducted in phases that build upon one another. Each phases answers a research question.

Phase 0 Trials are small pharmacodynamic, pharmacokinetics, first-in-human trials of a new, untested therapy.



Phase 1 Trials focus on determining how the treatment works in the body, the side effects, how effective, and the best way to administer the treatment to limit risks and maximize possible benefits. These studies usually include 20 to 100 healthy volunteers or people with the disease/condition.

Phase 2 Trials provide additional safety data and information that allows them to refine research questions, develop research methods, and design new Phase 3 research protocols. These studies aren't large enough to show whether the treatment will be beneficial. They may include up to several hundred people with the disease/condition.



Phase 3 Trials are designed to demonstrate whether or not the therapy offers a treatment benefit to a specific population. They may include several hundred or thousands of people with the disease/condition.

Phase 4 Trials are carried out once the drug or device has been approved by the US Food and Drug Administration as part of the Post-Market Safety Monitoring. They may include several thousand people with the disease/condition.

