

Topic: Clinical Trials

Learning Objective/Outcome:

Keywords/Questions	Notes
What are clinical trials?	Extensive evaluative processes involving medical or health-related research studies.
What do clinical trials determine?	Whether or not a drug, device, treatment, or prevention is safe to make available for medical use.
Explain why some clinical trials are done with animals rather than humans.	Animal subjects are used when the product or procedure being tested is for veterinary medicine. If it is for human medicine, human subjects are used.
Explain why clinical trials are important.	They help researchers determine safe and effective methods of preventing, treating, or diagnosing disease.
What do treatment trials test?	The safety and effectiveness of new treatments, drug combinations, and approaches to surgery or radiation.
What do prevention trials test?	Better ways to prevent diseases.
What do diagnostic trials test?	Better tests or procedures for diagnosing diseases or conditions.
What do screening trials test?	Better ways to detect or treat diseases.
What do quality of life trials test?	The effectiveness of different ways to improve the comfort and quality of life for people with chronic illness.
What organizations normally sponsor or fund clinical trials?	Pharmaceutical or medical device companies.
List some locations where clinical trials may take place.	Hospitals, universities, doctors' offices, community clinics, and the offices of clinical-trial contractors.

Why are animals good models to test the safety and effectiveness of new drugs and medical treatments?	Many animals have organ systems and structures that are very similar to those of humans, and they are prone to many of the same diseases and conditions.
How are animals useful in studying the progression of different diseases?	Animals have shorter lives than humans, allowing scientists to use them in studies throughout their entire lifespans and across multiple generations.
How does animal research benefit animals?	Advances made in human medicine through animal research also advances veterinary medicine, improving the health of pets and wildlife.
Define “pre-clinical trial.”	Research studies conducted on new drugs, medical devices, or procedures before clinical trials take place, usually with animal subjects.
What is the purpose of pre-clinical trials?	To learn about the mechanisms of action, effectiveness, and safety of new drugs, medical devices, and procedures before they are tested on human subjects.

Summary

Clinical trials allow researchers to scientifically determine whether a new medical drug, device, or procedure is safe and effective before it is made available to the medical community for use. Clinical trials are preceded by pre-clinical trials, which use animals rather than human subjects to make sure that the product or procedure is safe to test in humans. There are many types of clinical trials.