Topic: Phases of Clinical Trials

Learning Objective/Outcome:

Keywords/Questions	Notes
What happens in Phase I of clinical trials?	Researchers test an experimental drug or treatment in a small group of people (or animals, in a veterinary study.)
How big is the test group in Phase I?	Around 20 – 80 test subjects.
State the objectives of Phase I.	To analyze the safety of the tested product/procedure and determine its side effects.
Where do the human test participants come from?	They are volunteers.
What are some potential rewards to participating in clinical trials?	Participants are often paid, and they receive disease treatments that aren't available to anyone else.
Why is it hard to recruit enough test participants for clinical trials?	Many products/procedures being tested are intended for a subset of the population with a certain disease, so only those people can participate in the clinical trials. Some trials require patients to have unusual combinations of disease characteristics. It is hard to find enough qualified participants and obtain their consent to participate, especially when they receive no benefits from participation.
What happens in Phase II of clinical trials?	Researchers give the experimental drug or treatment to a larger number of people or animals.
How big is the test group in Phase II?	Around 100 – 300 test subjects.
State the objectives of Phase II.	To determine the effectiveness of the drug or treatment and further analyze its safety.
What happens in Phase III of clinical trials?	Researchers test the experimental drug or treatment on a large number of people or animals.
How big is the test group in Phase III?	Around 300 – 3,000 or more.

State the objectives of Phase III.	To confirm the effectiveness of the new drug or treatment, monitor its side effects, and compare it to standard or equivalent treatments.
What happens after a new medical product or procedure passes Phase III trials?	Researchers compile the trials results into a large, comprehensive document.
What information is included in this report?	Descriptions of the methods and results of human and animal and animal studies, manufacturing procedures, formulation details, and shelf life.
What is this collection of information called?	A regulatory submission.
Who is this report submitted to and why?	The U.S. Food and Drug Administration (FDA), for review.
If the new drug or treatment passes FDA review, what happens next?	The FDA grants the sponsor approval to market the product or procedure.
What happens in Phase IV of clinical trials?	Researchers continue to track the safety of the drug or treatment in large groups over long-term periods.
What information do researchers want to obtain from Phase IV?	The risks, benefits, and optimal use of the drug or treatment, as well as whether any unexpected side effects will occur in a small percentage of individuals.

Summary

Throughout the four phases of clinical trials, testing objectives change and the test group size increases. Testing objective progress from simply evaluating the safety and side effects of a drug to analyzing its effectiveness, risks, and benefits in comparison to existing treatments. These phases are essential to obtaining FDA approval for a new medical product or procedure, and they heavily rely on the participation of qualified volunteers.