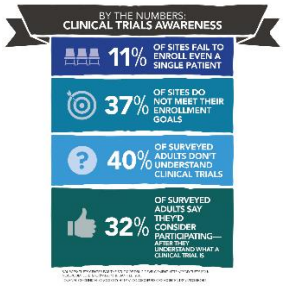
Main Topic: Phases of Clinical Trials

Learning Objectives/Outcomes:

Topic 1: Phase I	**Topic 2:** Phase II	**Topic 3:** Phase III	**Topic 4:** Phase IV
Ideas **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 people or animals. **What is the objective of Phase I?** - Phase I is meant to analyze the safety of the tested product or procedure and determine its side effects. **Where do human test participants come from?** - Those who participate in clinical trials are volunteers.	**Ideas** **What happens in Phase II of clinical trials?** - Researchers give the experimental drug or treatment to a larger group of people or animals. **How big is the test group in Phase II?** - Around 100 – 300 people or animals. **What is the objective of Phase II?** - Phase II is meant to determine the effectiveness of a product or procedure and further analyze its safety.	**Ideas** **What happens in Phase III of clinical trials?** - Researchers test the experimental drug or treatment on a large group of people or animals. **How big is the test group in Phase III?** - Around 300 – 3,000 or more. **What is the objective of Phase III?** - Phase III is meant to confirm the effectiveness of a new product or procedure, 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.	**Ideas** **What happens in Phase IV of clinical trials?** - In Phase IV, researchers continue to track the safety of the product or treatment. **What information do researchers seek in Phase IV of clinical trials?** - They continue to evaluate the risks, benefits, and optimal use of the product or procedure. They also seek to determine if unexpected sided effects will occur in a small percentage of individuals. **Describe the size and duration of Phase IV of clinical trials.** - Phase IV studies are long-term and involve large groups of participants.

How are test subjects rewarded by participating in clinical trials? - They are often paid and have access to a potentially effective disease treatment that isn't available to anyone else. **What challenges are researchers face with in recruiting participants for clinical trials?** - Many drugs and medical devices are intended for a subset of the population that has a certain disease, so not everyone can participate. Some trials require patients to have unusual combinations of disease characteristics. It is hard to find the right patients and get their consent to participate, especially if they don't directly benefit from the study.		**List what researchers must include in the documentation of new medical products and procedures.** - Descriptions of the methods and results of human and animal studies, manufacturing procedures, formulation details, and shelf life. **What is this collection of information called?** - It is called the "regulatory submission." **Why is it provided?** - It must be reviewed by regulatory agencies like the U.S. Food and Drug Administration (FDA). **If the product or procedure passes its FDA review, what then happens?** - The FDA grants the sponsor approval to market the product or procedure.	

Key Vocabulary	**Key Vocabulary**	**Key Vocabulary**	**Key Vocabulary**
Phase I: The first stage of clinical trials that involves testing the drug, device, or treatment on a small number of people to determine its safety and side effects.	**Phase II:** The second stage of clinical trials that involves testing a larger group to determine the effectiveness of a drug, device, or treatment and further evaluate its safety.	**Phase III:** The third stage of clinical trials that involves testing the drug, device, or treatment on a large group to confirm its effectiveness, monitor side effects, and compare it with standard or equivalent treatment. **Regulatory Submission:** The documentation researchers must provide the FDA about a drug, device, or treatment after it passes Phase III of clinical trials.	**Phase IV:** The fourth stage of clinical trials that involves long-term tracking of the safety of a drug, device, or treatment in a large group to determine its risks, benefits, and optimal use. It is also meant to discover whether any unexpected side effects emerge in a small percentage of individuals.
Pictures 	**Pictures** 	**Pictures** 	**Pictures**