

Main Topic: Clinical Trials

Learning Objectives/Outcomes:

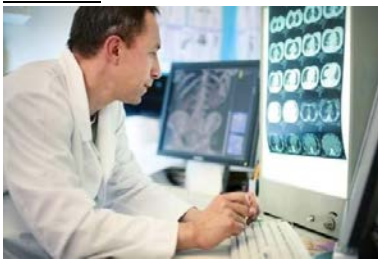
| Topic 1: What are clinical trials? | Topic 2: Types of Clinical Trials | Topic 3: Sponsors, Preclinical Trials, & Animal Research |
|---|--|---|
| <p><u>Ideas</u></p> <p>What are clinical trials?</p> <ul style="list-style-type: none">- Clinical trials are extensive evaluative processes involving medical or health-related research studies that determine that medical drugs, treatments, preventions, and devices are safe before they are available to you. <p>Are clinical trials done in human beings or in animals?</p> <ul style="list-style-type: none">- They can be done in both. If the product or procedure being tested is for human medicine, human beings are used in the clinical trial. If it is for veterinary medicine, animals are used. <p>Why are clinical trials important?</p> <ul style="list-style-type: none">- Researchers use clinical trials to translate scientific research into ways to prevent, treat, or diagnose disease safely. Without clinical trials, safety and effectiveness could not be ensured. <p>How do clinical trials use the scientific method?</p> <ul style="list-style-type: none">- Clinical trials are “real world” applications of the scientific method. When new drugs, medical devices, or procedures are tested, the steps of the scientific method are followed. | <p><u>Ideas</u></p> <p>What are treatment trials?</p> <ul style="list-style-type: none">- Treatment trials test new treatments, drug combinations, and approaches to surgery or radiation. <p>What are prevention trials?</p> <ul style="list-style-type: none">- Prevention trials try to find better ways to prevent diseases. <p>What are diagnostic trials?</p> <ul style="list-style-type: none">- Diagnostic trials seek out better tests or procedures for diagnosing particular diseases or conditions. <p>What are screening trials?</p> <ul style="list-style-type: none">- Screening trials tests for better ways to detect or treat diseases. <p>What are quality of life trials?</p> <ul style="list-style-type: none">- Quality of life trials explore and evaluate ways to improve the comfort and quality of life for people with chronic illness. | <p><u>Ideas</u></p> <p>How are clinical trials normally sponsored or funded?</p> <ul style="list-style-type: none">- Clinical trials are normally sponsored or funded by pharmaceutical or medical device companies. <p>What are some locations where clinical trials may take place?</p> <ul style="list-style-type: none">- Hospitals, universities, doctors’ offices, community clinics, and the offices of clinical-trial contractors may host clinical trials. <p>When do pre-clinical trials occur?</p> <ul style="list-style-type: none">- Pre-clinical trials must be done before clinical trials. <p>What is a pre-clinical trial?</p> <ul style="list-style-type: none">- Pre-clinical trials are research studies conducted on new drugs, medical devices, or procedures, usually with animal subjects. <p>What is the purpose of pre-clinical trials?</p> <ul style="list-style-type: none">- Pre-clinical trials are done to learn about the mechanisms of action, effectiveness, and safety of new drugs, medical devices, and procedures before they are tested on human subjects. |

| | | |
|--|---|--|
| | | <p>Why are animals good models to test the safety and effectiveness of new drugs and medical treatments?</p> <ul style="list-style-type: none"> - 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. <p>How are animals useful in studying the progression of different diseases?</p> <ul style="list-style-type: none"> - Animals have shorter lives than humans, allowing scientists to use them in studies throughout their entire lifespans and across multiple generations. <p>How does animal research benefit animals?</p> <ul style="list-style-type: none"> - Advances made in human medicine through animal research also advances veterinary medicine, improving the health of pets and wildlife. |
| <p>Key Vocabulary Clinical Trials: Research studies which use the scientific method to evaluate the safety and effectiveness of new medical drugs, devices, and procedures.</p> | <p>Key Vocabulary Treatment Trials: Research studies that test the safety and effectiveness of new treatments, drug combinations, and approaches to surgery or radiation.</p> <p>Prevention Trials: Research studies that evaluate new ways to prevent disease.</p> <p>Diagnostic Trials: Research studies that determine better tests or procedures for diagnosing particular diseases or conditions.</p> | <p>Key Vocabulary Pre-clinical Trials: Research studies that determine the mechanisms of action, effectiveness, and safety of new medical drugs, devices, or treatments before human subjects are used in testing. They occur before clinical trials and normally use animal subjects.</p> |

Screening Trials: Research studies that test new ways to detect or treat diseases.

Quality of Life Trials: Research studies that measure and explore ways to improve comfort and quality of life for people with chronic illness.

Pictures



Pictures

A poster for a clinical trial titled "HEALTHY OLDER DOGS WANTED FOR CLINICAL TRIAL". It features a photograph of a black and white dog sitting in a grassy field. The text on the poster includes: "The Texas A&M Veterinary Medical Teaching Hospital in College Station, Texas, is investigating the medication rapamycin for its possible mitigating effects on the aged process. Dogs will be randomly chosen to receive either rapamycin or a placebo and will be evaluated over a 12 month period." It lists "WHO QUALIFIES?" with criteria: "Healthy dogs", "at least 6 to 10 years of age", "40 to 80 pounds in weight", and "who live within driving distance". It also states "WHAT HAPPENS WHEN A DOG IS ENROLLED?" with benefits: "Free baseline evaluation", "free study medication", and "free re-check examinations". Contact information includes "#TAMU #CVM #VMTI #ClinicalTrial", "For more information, please contact the study team at: rapaphase2@dogproject.com", and "www.tamuvet.com/veterinary-medicine-and-biomedical-sciences".

Pictures

A flyer for a clinical trial titled "Have your previous MIGRAINE medications failed you?". It features a photograph of a woman holding her head in pain. The text includes: "YOU MAY QUALIFY FOR A RESEARCH STUDY IF YOU:" followed by criteria: "Have 2-8 moderate/severe migraine attacks per month", "Have had migraines for at least a year", and "Over 18 years old". At the bottom, it says "For more information, contact Clinical Research Associates of Tidewater, 400 Gresham Dr. Suite 402 Norfolk, VA 23507, Patient Recruitment Department, Phone (757) 627-7446 or the 24 Hr. Hotline (757) 627-6798, recruitment@cra.org". There is a logo for "Allergon" in the bottom right corner.