UNDERSTANDING CLINICAL RESEARCH TRIALS

Clinical trials are part of clinical research and at the heart of all medical advances. Clinical trials look at new ways to prevent, detect, or treat disease.

Types of Clinical Research

Epidemiology research seeks to improve the understanding of a disease by studying patterns, causes, and effects of health and disease in specific groups.

Behavioral research is used to improve the understanding of human behavior and its relation to health and disease.

Health Services research looks at how people access health care providers and health care services, how much care costs, and what happens to patients due to this care.

Clinical Trials evaluate the effects of an intervention on health outcomes.

Clinical Trials

Clinical trials can study:

- New drugs or new combinations of drugs
- New ways of doing surgery
- New medical devices
- New ways to use existing treatments
- New ways to change behavior to improve an individual's health
- New ways to improve the quality of life for people with acute or chronic illnesses

Clinical trials follow a plan known as a protocol. The protocol is carefully designed to balance the potential benefits and risks to participants and answer specific research questions.

A protocol describes the following:

- The goal of the study
- Who is eligible to take part in the trial
- Protections against risks to those participating
- Details about tests, procedures, and treatments
- How long the trial is expected to last
- What information will be gathered

A principal investigator, who is often a medical doctor, leads every clinical trial. A clinical trial also has a research team that may include doctors, nurses, pharmacists, social workers, and other health care professionals.

The Role of the Institutional Review Board

Most clinical trials in the United States are approved and monitored by an Institutional Review Board (IRB) to ensure that the risks are reduced and are outweighed by potential benefits. This board is responsible for reviewing research to protect the rights and safety of people who participate in the clinical trial, both before it begins and as it proceeds.

Clinical Trial Sponsor

Clinical trials may be sponsored or funded by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations and federal agencies such as the National Institutes of Health, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. Doctors and other health care providers, and other individuals can also sponsor a clinical trial.

Informed Consent

Informed consent is a process used by researchers to provide potential and enrolled participants with information about a clinical trial. This information helps people decide whether they want to register or continue to participate. This process is intended to protect participants and provide enough information to understand the risks of, potential benefits of, and alternatives to the study.

Who Can Participate

Clinical trials have standards outlining who can participate. The factors that allow someone to participate in a clinical trial are called inclusion criteria. The factors that disqualify someone from participating are called exclusion criteria. They are based on age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

Why Participate in a Clinical Trial

Clinical trials offer hope for many people and a chance to help researchers find better future treatments for others. They can help participants gain access to new research treatments before they are widely available.

Clinical research trials offer those enrolled regular and careful medical attention from a research team that includes doctors and other health professionals.

Phases of Clinical Research Trials

Clinical trials are conducted in a series of steps called "phases." Each phase has a different purpose and helps researchers answer different questions.

Phase I: Researchers test a drug or treatment in a small group of people (20-80) for the first time. The purpose is to study the drug or treatment to learn about safety and identify side effects.

Phase II: The new drug or treatment is given to a larger group of people (100-300) to determine its effectiveness and further study its safety.

Phase III: The new drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it with standard or similar treatments, and collect information that will allow the new drug or treatment to be used safely.

Phase IV: After a drug is approved by the FDA and made available to the public, researchers track its safety in the general population. They are seeking more information about a drug or treatment's benefit and optimal use.

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