Key Terms on Clinical Trials

Clinical research is medical research that involves people to test new treatments and therapies.

A **clinical trial** is a research study in which one or more human subjects are prospectively assigned to one or more interventions, which may include a placebo or other control to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Exclusion criteria are factors that do not allow someone to participate in a clinical trial.

A **healthy volunteer** is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

Inclusion criteria are factors that allow someone to participate in a clinical trial.

Informed consent explains risks and potential benefits about a clinical trial before someone decides whether to participate.

A **patient volunteer** has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition.

Clinical trials are conducted in **phases**. The trials at each phase have a different purpose and help researchers answer different questions.

- **Phase I trials:** An experimental drug or treatment is administered to a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects.
- **Phase II trials:** The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.
- **Phase III trials:** The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, and compare it with standard or equivalent treatments.
- **Phase IV trials:** After a drug is licensed and approved by the FDA, researchers track its safety, seeking more information about its risks, benefits, and optimal use.

A **placebo** is a pill or liquid that looks like the new treatment but does not have any treatment value from active ingredients.

A **protocol** is a carefully designed plan to safeguard the participants' health and answer specific research questions.

A **principal investigator** is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants' health to determine the study's safety and effectiveness.

Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice.

Single- or double-blind studies, also called single- or double-masked studies, are studies in which the participants do not know which medicine is being used, so they can describe what happens without bias. In single-blind studies, you are not told what is being given, but the research team knows. In a double-blind study, neither you nor the research team are told what you are given; only the pharmacist knows. Members of the research team are not told which participants are receiving which treatment to reduce bias. If medically necessary, however, it is always possible to find out which treatment you are receiving.

TYPES OF CLINICAL TRIALS

Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition.

Natural history studies provide valuable information about how disease and health progress.

Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning.

Quality of life trials, or supportive care trials, explore and measure ways to improve the comfort and quality of life of people with a chronic illness.

Screening trials test the best way to detect certain diseases or health conditions.

Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

References

Courtesy: National Institutes of Health