

WHAT IS A CLINICAL TRIAL?

Clinical trials are a form of medical research that test new developments in preventing, detecting or treating a disease. These trials use human volunteers to determine if a drug or technology is effective and safe. While some clinical trials test new treatmentsⁱ, others compare existing treatments to show which may benefit patients more or determine if an existing treatment can be used to treat other diseases or conditions.^{ii,iii}

HOW DO CLINICAL TRIALS WORK?

Clinical trials are often sponsored by drug or medical device companies, federal agencies or private individuals with a medical background, like a physician.^{iv} Clinical trials are performed with strict rules and regulations set by the U.S. Food and Drug Administration (FDA) to ensure the safety of trial participants; however, there are also risks associated with experimental treatments.

Clinical trials are conducted using strict scientific standards and a master plan called a protocol.^v The protocol includes rules on who can participate (e.g. gender, race, age, type and length of disease and treatment history) and how the treatment is provided (e.g. dose and frequency of treatment).^{vi}

CLINICAL TRIAL PARTICIPATION

There are two types of volunteers who participate in clinical trials:

- ▶ Healthy volunteers who have no known significant health problems.
- ▶ Patient volunteers who have a known health problem.
 - Some patient volunteers may benefit from clinical trial participation by having the opportunity to try a new treatment.
 - Others serve as controls and do not receive the experimental treatment or take a different dose of treatment.^{vii} Controls help researchers by providing important information on how the experimental treatment compares to others.^{viii}

In some cases, volunteers will not know if they are receiving the designated trial treatment or serving as a control, so they can describe what happens without bias. Trial participants may receive payment for participation, or reimbursement for transportation, childcare, meals or places to stay.^{ix}

REFERENCES

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