

# WHAT IS A CLINICAL TRIAL?

**Clinical trials are how researchers test new investigational medicines or treatments before they are widely available to patients. The goal of a clinical trial is to collect information on the safety and effectiveness of a drug.**

Every new drug or treatment must complete the clinical trial process before being submitted for Food and Drug Administration (FDA) approval. Clinical trial researchers partner with study participants to help advance science in the treatment of diseases.

Every clinical trial is guided by a study protocol (plan) that is reviewed for safety and designed to answer specific research questions.

When you are offered an opportunity to join a trial, the purpose of the study, tests and procedures conducted, and medications you will be taking will be clearly explained. Potential benefits and risks will also be explained by clinical research staff before you consent to participate in any trial. Clinical trials are conducted in phases. There are three to four phases that must be completed before a new medication or treatment is approved by the FDA and each phase has a specific purpose.

- Phase 1 is tested on a small group of usually healthy study participants to test safety and dosage limitations.
- Phase 2 involves a larger group of study participants and seeks to determine if a drug is effective in people with specific medical conditions. Safety and side-effects are monitored, and this phase may extend for several years.
- Phase 3 involves an even greater amount of study participants and continues to gather information on safety and effectiveness. If the results of Phase 3 are positive, the study treatment will be submitted for approval to the FDA.
- Phase 4 studies are conducted if additional research questions need to be answered. Phase 4 studies are conducted after FDA approval when the treatment is already available to the public. This phase tests the long-term effectiveness and side effects of the new treatment over a large population in real life scenarios.

People like you participate in clinical trials every day. Some study participants choose to participate because they have limited treatment options or no current treatment exists for their disease state. Some study participants may decide a clinical trial is the best chance to possibly prevent a disease that runs in their family. Others want to contribute their time to help other people who are living with their disease state.

**The decision to join a clinical trial is a personal decision. We encourage you to consult with your doctor, talk to your family, and ask questions.**

