



Clinical Trial Phases

Cancer Research Trials: What Does the Trial Phase Mean?

Cancer clinical trials are used for a variety of reasons. Some of the most common reasons include:

- Testing new cancer treatments
- Testing existing cancer treatments on a different type of cancer
- Understanding how to use approved treatments in new combinations for better results

Placebos in Cancer Research Trials

Many patients ask if there's a chance that they will be given an inactive treatment, called a placebo. The use of placebos in cancer clinical trials is rare, but it does happen. In most trials, cancer research participants are either given the new treatment or they are given an existing treatment already approved to treat their cancer.

What Do the Research Phases Mean?

When a clinical trial is initiated by a lead physician(s), called the lead investigator(s), the trial will be categorized in one of four different phases. Most new cancer treatments will typically go through Phases I, II and III. Not all therapies have a Phase IV clinical trial associated with them because this phase is not always necessary for proving a new cancer treatment safe and effective.

Phase I

In Phase I cancer clinical trials, researchers test a study drug for the first time to primarily evaluate the safety of the new drug. This typically involves a small group – 15-30 people – who are monitored very carefully. A placebo is not used in this phase.

This phase may also look at:

- Dosage range
- How the new treatment should be given (by mouth, vein, etc.)
- The therapy's side effects

Phase II

In Phase II cancer clinical trials, special emphasis is given to determining whether the therapy is effective at treating a specific type of cancer. There is no placebo given, but participants may be divided into groups where each group gets a slightly different dose or schedule that will tell the investigators which way appears to work best with tolerable side effects.

Phase II trials usually involve more people than the Phase I trials, but less than 100 people who all meet specific requirements set by the investigators.

Phase III

In Phase III cancer clinical trials, the new cancer therapy is compared carefully to the current treatment(s) available for that type of cancer. In this phase, patients may be broken into smaller groups and randomized into different treatment groups. Some will receive the standard treatment that is already available, and some will receive the new treatment being tested. Many times, neither the doctor nor the patient know which cancer treatment they are receiving so that results cannot be influenced with conscious or unconscious bias.

Phase IV

In Phase IV cancer clinical trials, the cancer therapy is tested after it has been approved for a specific use. They are used to collect information about a therapy's long-term effect on the patient's quality of life, length of life and any unexpected long-term side effects.

Phase IV trials may also be used to try new combinations of approved therapies to determine if there are better outcomes.