



Clinical Trial Basics

Clinical trials evaluate the safety and effectiveness of new treatments.

Clinical researchers may study many kinds of cancer treatment including:

- Anti-cancer drugs like traditional chemotherapy drugs, immunotherapy drugs, and targeted therapies
- Radiation therapy
- Surgery
- Treatment aspects such as the order and timing of drugs, radiation, surgery, etc.
- Different methods of post-treatment surveillance to monitor for cancer recurrence, such as blood ctDNA testing, PET scans, etc.

Clinical Trials progress through four phases.

Each phase of a clinical trial has different goals and different numbers of participants.

PHASE 1 (PHASE I)

25 or fewer participants

Goals: Test treatment safety and side effects. Test treatment delivery route, such as oral (by mouth), intravenous (by vein), etc.

PHASE 2 (PHASE II)

100 or fewer participants

Goals: Test how the cancer responds to the treatment. Test treatment safety and side effects.

PHASE 3 (PHASE III)

100 to several thousands participants

Goal: Test how the treatment performs in comparison to the standard of care treatment.

PHASE 4 (PHASE IV)

Thousands of participants

Goal: Test safety and side effects over time in approved treatments. May also study quality of life or other outcomes of treatment.

Patients who participate in a clinical trial will always get at least the standard of care for their cancer.

Patients and their doctors do not choose whether they will receive the experimental treatment studied in a clinical trial. While this may discourage some patients, it is important to be able to directly examine the experimental treatment results against established treatment outcomes. In oncology (cancer) trials, patients who do not receive the experimental treatment will receive the usual standard of care for their cancer. The only time patients will receive a “sugar pill” placebo treatment is when there is no existing standard care for their disease.

Participating in a clinical trial can expand your treatment options.

Clinical trials are often incorrectly seen as a “last option” for cancer treatment. In fact, clinical trial participation should be discussed from the start. Some clinical trial eligibility may even be limited by how many types of treatment a patient has previously received.

Many current clinical trials are looking at treatments for cancers with specific biomarkers. Knowing your biomarkers can help your medical team understand your prognosis and guide your treatment, as well as help match you with a clinical trial that could benefit you. For more information about biomarkers, please visit [knowyourbiomarker.org](https://www.knowyourbiomarker.org)

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For more information about clinical trials, visit globalCCA.org/clinical-trials