

WHAT ARE CLINICAL TRIALS?

Clinical trials for cancer are medical research studies that test new ways to prevent, detect, diagnose, or treat cancer.

The goal of clinical trials is to find new, safe, and more effective ways to prevent and treat cancer, and improve well-being and quality of life.

Clinical trials can include:

- Medications / Drugs
- New approaches to surgery or radiation therapy
- Combinations of existing treatments
- New methods of treatment, such as gene therapy
- Ways to improve quality of life and side effect management

In the past, clinical trials were often thought of as *a last resort* for people who had no other treatment choices. But today, clinical trials can be integrated into care and at any point in treatment, so some people choose to **start treatment** with a clinical trial.

WHY ARE CLINICAL TRIALS IMPORTANT?

Clinical trials are important because they contribute to the scientific advancements for treating cancer.

If a new treatment proves effective, or more effective than one currently in use, it could become a standard protocol to help people - not just today, but for **future generations**.

Many of today's treatments began as clinical trials, including:

- Immune Checkpoint Inhibitors
- CAR T-Cell Therapy
- Personalized Cancer Vaccines

ABOUT CROSSROADS4HOPE

Our mission is to reach all people impacted by cancer - those diagnosed, their loved ones, and caregivers - so that **no one** faces cancer alone.

All our programs and services are **FREE** to our members.

OUR FREE SERVICES

- **MyGo2Support:** our mobile education & engagement program.
- Individual and group **support groups**
- **Mindfulness Programs**
- **Nutritional Classes**
- **Health Champion Program:** Learn how to support loved ones facing cancer.

HOW ARE PEOPLE CHOSEN TO BE PART OF A CLINICAL TRIAL?

There are very strict, study-specific criteria - called eligibility criteria - that must be met before a person can be chosen to participate in a clinical trial.

Eligibility criteria may include:

- Age
- Sex / Gender
- Type of cancer
- Stage of cancer
- Specific genetic markers that are related to - and could impact - the cancer

There are reasons which could prevent a person from being chosen to participate in a clinical trial. They are called **exclusion criteria** and they may include:

- Specific medications that could impact or affect the treatment
- Conflicting health problems that could impact or affect the treatment
- History of allergic reactions
- Pregnancy

Researchers will evaluate those who meet the eligibility criteria and, from that group, they will begin a detailed screening process:

- **Prescreening** - the researchers will talk with you and your medical team to learn about your medical history and their specific diagnosis.
- **Informed Consent** - if you pass the prescreening, researchers will provide details of the study's risks, benefits, and procedures before you formally agree to participate.
- **Clinical Screening** - After you consent, you will undergo medical testing - blood tests, imaging scans, and physical exams - to definitively confirm you are eligible.

ARE CLINICAL TRIALS SAFE?

Clinical trials have to follow strict rules to ensure safety and effectiveness.

Clinical trials must follow strict and federal institutional rules and are monitored by independent committees known as Institutional Review Boards (IRBs). These IRBs regularly review data as the study progresses, and can stop trials immediately if unexpected or severe side effects occur.

NOTE: There is no guarantee that a new treatment being tested or one already in standard practice, will produce good results. And you always have the right to ask questions and withdraw from any study at any time.

HOW ARE CLINICAL TRIALS CONDUCTED?

A cancer clinical trial begins in a laboratory, where scientists first develop and test new ideas for new treatments.

After rigorous testing, if an idea looks promising, the next step may be to test it on animals to see how it affects cancer in a living being.

While there are no guarantees that treatments that work well in a laboratory, or in animals, will work well in people - if results look promising and there are no harmful side effects, the treatment may then be approved to test on humans.

Clinical trials for humans have four phases, each that answer different questions.

In Phase I, researchers look for:

- The best way to administer the experimental drug - in a pill, through an IV, or injection
- The best and safest dosage
- Any harmful side effects

In Phase II, researchers focus on:

- Whether or not the experimental drug has an anticancer effect - if it shrinks a tumor improves blood test results.

In Phase III, researchers analyze the results and:

- Compare the results of people participating in the clinical trial with the results of people who are taking standard medical treatment to see which has a better outcome.

In Phase IV, researchers study the drug(s) in real-world settings:

- Once the medication has been approved and is put on the market, researchers will continually monitor its side effects, safety, and effectiveness.

TYPES OF CLINICAL TRIALS

- **Treatment Trials** - These trials test new treatments or new ways of using existing treatments. Every cancer treatment trial follows a plan, called a **protocol**, specific to that trial which includes a schedule of clinic / medical visits you will need to attend and tests and procedures you will have.
- **Prevention Trials** - These trials look at ways to prevent cancer or reduce risk in the future. Participants may not have cancer but have a higher risk for developing it, or they have had cancer and are at high risk for developing a new cancer.
- **Screening/Early Detection Trials** - These trials test ways to find cancer before it causes symptoms, when it may be easier to treat.
- **Supportive/Palliative Care Trials** - These trials look at ways to prevent or reduce side effects due to treatment, and improve the quality of life of people with cancer. There are also supportive care clinical trials look at **psychological and social wellbeing, not just for those diagnosed, but for families and caregivers.**

WHAT CAN IT COST TO BE PART OF A CLINICAL TRIAL?

Many research-related clinical trial costs are covered by the sponsor of the study. Your insurance may need to cover some routine medical - patient care - costs, and there are sometimes out-of-pocket costs.

Patient care costs may be covered by health insurance and could include:

- Routine medical / doctor visits
- Standard cancer treatments
- Routine lab tests and imaging

If you have to travel to take part in a study, **out-of-pocket costs** might include:

- Travel-related costs, such as gas, tolls, lodging, meals, and parking
- Life-related costs, such as child care or elder care

See if study offers any financial help or if they know of support organizations that may.

Research costs may be covered by the sponsor of the study and may include:

- Drug(s) / Medication(s) being tested in the trial
- Lab tests and imaging solely for the trial
- Additional doctor visits that you would not have as part of your usual care

NOTE: Check with your medical team, the study team, and your insurance plan to see which costs you or your insurance will pay, and which are covered by the study. Also ask your insurance plan if pre-authorization is needed to participate.

DO I NEED PRIVATE INSURANCE TO BE IN A CLINICAL TRIAL?

If you don't have private insurance, there are places to go for help.

Some **federal health insurance** programs help pay the costs of care in clinical trials.

Medicaid is a state-administered federal / state program for people who cannot afford regular medical care. Medicaid covers all routine patient care costs in a clinical trial.

Medicare is a US federal health insurance program for people aged 65 years or older and people with certain disabilities and may cover some of the routine costs of a clinical trial.

TRICARE is the Department of Defense's health care program and may reimburse for medical costs in trials sponsored by the National Cancer Institute (NCI).

The Department of Veterans Affairs (VA) allows eligible veterans to take part in NCI-sponsored clinical trials at Veterans Affairs Medical Centers.

There are also some studies available for people with low income.

NCI Community Oncology Research Program (NCORP) - through the National Cancer Institute, this national network brings cancer clinical trials and care delivery studies to people in their own communities.

National Clinical Trials Network (NCTN) - they coordinate and support cancer clinical trials at more than 2,200 sites across the United States, Canada, and internationally.

HOW CAN I FIND A CLINICAL TRIAL?

We have partnered with Carebox to help you search through their growing database of clinical trials to see if any are right for you.



Scan the QR code or visit our
Clinical Trials Resource Hub
for more information

[crossroads4hope.org/
understanding-clinical-trials](https://crossroads4hope.org/understanding-clinical-trials)



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