CLINICAL TRIALS

A Treatment Option for Me?

INSTITUTE FOR HEALTH PROMOTION RESEARCH

UT HEALTH SCIENCE CENTER®

SAN ANTONIO

What Are Clinical Trials?

Clinical research allows scientists to find new, improved treatments and cures. Medicines used now to treat cancer were studied and tested before patients actually used them as part of their standard treatment. New treatments that look promising, and have already been tested extensively in the laboratory in cells or animals, are then tested with patients who volunteer to participate in what we call “clinical trials.”

Clinical trials may involve treatments under development by pharmaceutical or biotechnology companies or directly by the treatment center. These studies may also test new combinations of already available drugs.

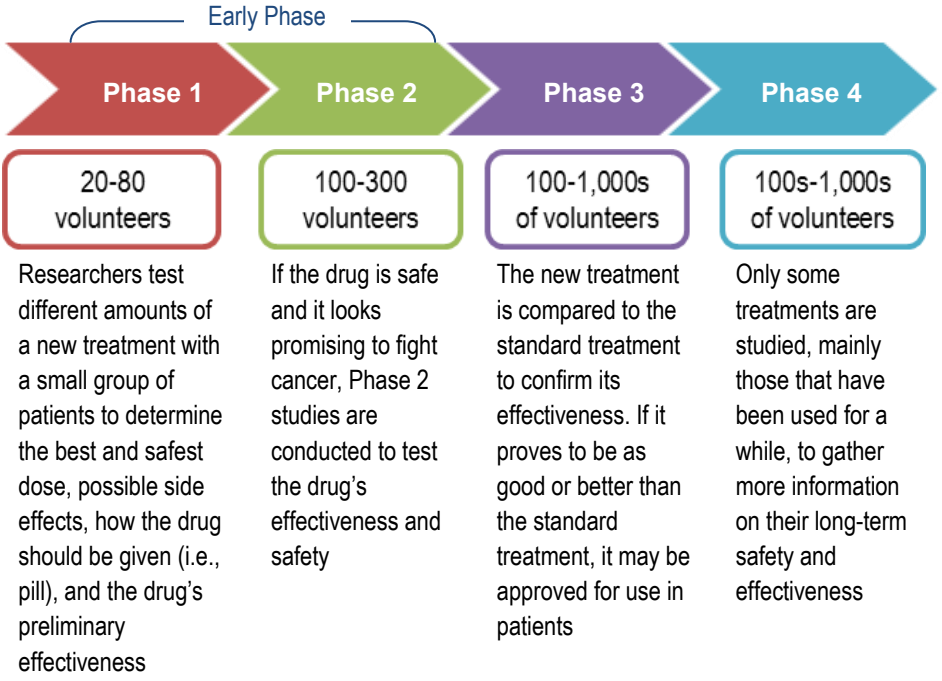
Types of Clinical Trials

Clinical trials are one of the first steps in the process of finding new methods to prevent, detect or treat cancer. There are many types of clinical trials, from testing new drugs and other treatments to looking at new ways to improve everyday life for patients and their families. People who volunteer for clinical trials make it possible for new treatments to become standard treatments in the future. Without going through clinical trials, many treatments would not be available for people with cancer to use today.

Clinical Trial Phases

Developing new drugs and treatments to treat cancer involves four phases of clinical testing, called Phase 1, Phase 2, Phase 3 and Phase 4. During these phases, a treatment can only go on to the next phase once it has proven safe, effective results in the previous phase.

Each clinical trial must follow a detailed plan that explains the trial's purpose and what will happen during the study. Patients who participate in these trials are monitored very carefully.



Mrs. Diana Lopez

"I did not know anything about clinical trials until my doctor told me about them.

I didn't know what they were about or what to expect."

Phase 1 Clinical Trials

Phase 1 clinical trials are the first step in testing a new drug or treatment. In general, Phase 1 clinical trials study:

- Whether the new treatment is safe
- Possible side effects
- The best way to give the new treatment (i.e., pill or injection)
- How much of a new medicine should be given (called dosage)
- How often it should be given
- How the drug affects cancer cells
- Whether the treatment can shrink tumors

Because less is known about the possible risks and benefits in Phase 1 clinical trials, these studies usually include a small number of 20-80 patients who had not been helped by standard treatments. They may benefit from the new treatment in the trial, or they may not.

The first group of Phase 1 study patients usually get a low dose of the new treatment. If there are minor or no side effects, the next patients get a slightly higher dose. Patients are carefully monitored for side effects. This process continues until doctors know safe dosages and how best to deliver treatment.

Mr. Tom Chavez and Dr. Ian Thompson

"Research is how we move forward in society. I'm a team player and wanted to help others.

That's why I enrolled in a clinical trial."

Phase 2 Clinical Trials

When a new treatment is found to be safe in a Phase 1 clinical trial, it usually moves to a Phase 2 trial. Here doctors study how well the new treatment works in a group of 100 or more patients with a similar type of cancer. Patients are treated using the dose and method found to be safest and most effective in Phase 1 clinical trials, and patients usually get the same dose.

Phase 2 clinical trials study:

- Whether the treatment works (i.e., if a tumor shrinks)
- Which types of cancer the treatment works for
- More about the dose to use
- Side effects and how to manage them

If a new treatment continues to be promising—in other words, it is found to be safe and effective—then it may proceed to a Phase 3 clinical trial.

Phase 3 Clinical Trials

After a treatment study is found to be safe in Phase 1 and Phase 2 trials, the study can then move to Phase 3. In Phase 3, scientists compare two groups: one group receives the test treatment (investigational group) and the other receives the existing standard treatment (control group). Standard treatment is the treatment that is currently used and approved to treat that particular disease.

In Phase 3 clinical trials:

- 100-1,000s volunteers are included
- People in the study are assigned by chance (through a process called "randomization") to either group
- Neither the participant nor the doctor can choose which group the participant will be in
- Effectiveness of the treatment may be confirmed
- Side effects continue to be monitored

If phase 3 trials prove to be as safe and effective as the standard treatment, then the treatment may be approved for use with patients.

Phase 4 Clinical Trials

Even after testing a new medicine on thousands of people, the full effects of the treatment may not be known. Phase 4 clinical trials further assess the long-term safety and effectiveness of a new treatment. Phase 4 looks at drugs that have already been approved by the FDA. Not all drugs and treatments go through this phase. Studies in this phase are usually done after the drug or treatment has been marketed. This phase can include from several hundred to several thousand participants.

How Do I Know If I Am Eligible?

To be eligible to participate in a clinical trial, participants must meet certain criteria. Trials have different criteria for eligibility. Factors that allow someone to participate in a clinical trial are called "inclusion criteria"; factors that disqualify someone from participating are called "exclusion criteria." Factors for inclusion and exclusion can be age, gender, the type and stage of a disease, medical history and others. If all criteria are met, a person is eligible to participate in the trial. Your doctor will discuss with you specific conditions and requirements for a particular clinical trial that may be a good fit for you.

Informed Consent

Before agreeing to be in a clinical trial, participants will be informed about the trial's detailed plan, possible risks and benefits, and their protections and rights, including their right to leave the study at any time. This is called "informed consent." You should only sign the informed consent form once you understand and are satisfied with the information. This form also includes research staff contact information.

"The doctor told me that I can leave the study for whatever reason if I didn't like it. That made me feel in control of my situation and in control of my health."

Mrs. Maria Lambert

Who Monitors Clinical Trials?

The review process for research and clinical trials is very careful and thorough. Experts review the details of the study from beginning to end to protect participants. Federal laws and regulations also protect and ensure patients who participate in trials are safe and well-informed about the study, including the risks, benefits and potential side effects.

One of the groups that oversees clinical trials is the Institutional Review Board, or the IRB. This board is made up of cancer research experts from the medical field and community leaders in education, ethics and other fields. The IRB, as well as several other boards and committees, such as the Data Safety and Monitoring Committee, are in place to review and monitor trials regularly.

Participating Is Completely Your Decision!

Think about how being in a clinical trial will work for you. Think about any concerns you may have, and get informed. It is also a good idea to get input from family and trusted friends as you make your decision. But remember that the final decision is yours. It's what you feel most comfortable with—what is right for you!

Ask Questions!

Getting all of your questions answered by your doctor will be important as you make a decision about your treatment options.

Think about any questions and concerns you may have about clinical trials. Write them down and bring them with you to your next doctor's visit. Planning to ask questions and finding out the steps you need to take are positive ways to take control of your treatment decision. The "Questions to Ask" section of this booklet (Page 9) offers a set of common questions and concerns to think about and provides space to write your own questions (Page 10).

We hope that this booklet encourages you to find out more about clinical trials as a treatment option, and will help you as you make an informed decision that is best for you—and your family!

Mrs. Christina Guerra

"We need to get informed, and we need to ask questions, get all the information, and not make a decision out of fear or because we are out of control."

Questions to Ask

- What is the purpose of this study? How it will help me?
- What kind of tests and treatments will I receive if I participate?
- How much will it cost? Will my insurance cover the trial treatment?
- What will happen to my cancer with or without this treatment?
- Am I going to need hospitalization?
- How will I know if the trial treatment is working?
- What are the possible short-and long-term side effects of the clinical trial treatment?
- How could the clinical trial change what I do every day?
- What treatment could I get if I do not take part in the clinical trial?
- How do the risks and side effects of the standard treatment compare with the new treatment?
- How long will the clinical trial last?
- How frequently do I have to come to the clinic?
- Will I have check-ups after the clinical trial?
- How long do I have to make my decision about joining the trial?
- Is my primary health care provider still in charge of my overall health?
- Will I be reimbursed for my travel and other expenses?

Questions to Ask

Write Your Own Questions....

- _____
  _____
- _____
  _____
- _____
  _____
- _____
  _____
- _____
  _____
- _____
  _____
- _____
  _____
- _____
  _____

Don't forget to bring these questions on your next doctor's visit.

For more information on early-phase clinical trials, please call the Cancer Therapy and Research Center (CTRC) in San Antonio. CTRC staff has instant access to a computerized database of all available clinical trials.

7979 Wurzbach Road
San Antonio, TX 78229
Phone: 210-450-5798
Fax: 210-616-5844
Email: onctrial@idd.org
www.ctrc.net/clinicaltrials

Published by the Institute for Health Promotion Research and the
CTRC Cancer Prevention and Population Science Research Program
at The University of Texas Health Science Center at San Antonio

Project Supported by the National Cancer Institute (Grant No. 3 U54 CA153511-02S1)