TEXAS ONCOLOGY
More breakthroughs. More victories.®

Clinical Trials

A clinical trial is a research study that examines how patients respond to different medical approaches for various types of cancers. Studies address scientific challenges and identify better ways to treat, diagnose, and prevent cancer-related diseases. Patients who participate in clinical trials are volunteers who provide a tremendous service to further cancer research.

Types of Trials

Several types of clinical trials help physicians understand and treat cancer more effectively:

- **Prevention Trials** involve people who want to prevent cancer or cancer recurrence. The two types of prevention trials include action studies and agent studies. Action trials focus on actions such as following a specific diet or exercise plan, whereas agent trials focus on the effectiveness of taking certain medications or vitamins. Both trial types aim to test whether these measures reduce the risk of developing cancer.
- **Screening Trials** examine individuals who do not have symptoms of cancer, and they identify the best methods to detect the disease at the earliest stages when it is easier to treat.
- **Diagnostic Trials** are conducted to determine how best to accurately identify cancer using new tests or procedures.
- **Behavioral Trials** assess ways to encourage behavioral changes in patients to improve their overall health.
- **Treatment Trials** are designed to answer questions about new treatments, such as drugs, surgical procedures, vaccines, radiation therapies, or a combination of procedures. These trials are conducted with cancer patients.
- **Supportive Care Trials** investigate methods for improving the quality of life of cancer patients who have experienced side effects from cancer and treatment. These trials test drugs and activities designed to maximize comfort and manage side effects of treatment or cancer.

Phases of Trials

Clinical trials involving new drug therapies, combinations, or interactions are conducted in four phases and in some cases lead to breakthrough drugs or therapies.

- **Phase I** trials usually involve a small number of participants (approx. 20-80) and are designed to evaluate and determine the safe dosage of a drug, delivery methods, and side effects. Once researchers have determined the treatment is safe and effective, the therapy or technique moves on to Phase II.
- **Phase II** trials generally test for a response and include a slightly larger group of participants (approx. 100-300), usually with the same type of cancer. The trials examine the effectiveness of the treatment and side effects.
- **Phase III** trials compare a new drug or intervention with currently available treatments. Patients are randomly assigned to the current treatment group or the new treatment group. Studies are moved to this stage only after showing promise in the earlier phases, and these trials include larger numbers of people (approx. 1,000-3,000).
- **Phase IV** trials occur with treatments that have already been FDA-approved for standard use. These studies examine the safety and effectiveness of a treatment over a longer period of time in larger, more diverse populations.
- **The Food and Drug Administration** is involved in every phase of research and must give final approval before a drug can be released for general use. After a treatment has passed Phase III, it is submitted for approval by the FDA. Once the treatment is FDA-approved, it is made available to the general population.

Benefits and Risks of Clinical Trials

Participating in a clinical trial is a personal decision that should be made in consultation with a physician to discuss the benefits and risks. Patients may experience unpleasant or serious side effects, treatment may not be effective, and the trial may require more effort and time than standard treatment. However, clinical trials allow patients to be actively involved in their healthcare, to access new treatments and expert medical care, and to help further medical research.

Patient Eligibility for Clinical Trials

Eligibility for clinical trials may depend on several criteria, including age, sex, cancer type, stage of cancer, previous treatments, and general medical history. Patients interested in participating should speak with their doctor to determine which trial is right for them. To view a list of clinical trials offered by Texas Oncology, visit TexasOncology.com/Clinical-Trials.

About Texas Oncology

With more than 530 physicians and 280 locations, Texas Oncology is an independent private practice, a member of The US Oncology Network, that sees more than 71,000 new cancer patients each year. Founded in 1986, Texas Oncology provides comprehensive, multidisciplinary care, and includes Texas Center for Proton Therapy, Texas Breast Specialists, Texas Colon & Rectal Specialists, Texas Oncology Surgical Specialists, Texas Urology Specialists and Texas Infusion and Imaging Center. Texas Oncology's robust community-based clinical trials and research program has contributed to the development of more than 100 FDA-approved cancer therapies. Learn more at TexasOncology.com.

Sources: American Cancer Society, National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and World Health Organization

Updated: 7/5/2024

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