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. Trials can be action focused, such as a change in diet/exercise, or agent focused, such as the use of vitamins or other medications, to test whether it may reduce the risk of developing cancer.
- **Screening Trials** examine individuals who do not have symptoms of cancer and identify the best methods to detect the disease. These trials test new ways to detect cancer at the earliest stage, when the disease is easier to treat.
- **Diagnostic Trials** are conducted to determine how to identify cancer using new tests or procedures.
- **Behavioral Trials** access methods to encourage behavioral changes in patients to improve overall health.
- **Treatment Trials** are designed to answer questions about new treatments, such as drugs, surgical procedures, vaccines, radiation therapy, 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 during cancer and its treatments. 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 determine the dosage safety of a drug, the delivery method, 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 current 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).
- **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.
- **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.

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 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 *www.TexasOncology.com/Clinical-Trials.*

About Texas Oncology

Texas Oncology is an independent private practice with more than 500 physicians and 210 locations across the state. Meeting the oncology needs of Texans for more than 35 years, the practice includes Texas Center for Proton Therapy, Texas Breast Specialists, Texas Oncology Surgical Specialists, Texas Urology Specialists, and Texas Center for Interventional Surgery. As a lead participant in US Oncology Research, Texas Oncology played a role in the development of more than 100 FDA-approved therapies. For more information, visit www.TexasOncology.com.

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

Updated: 3/4/2022