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 trial includes the use of vitamins or other medications to test whether a treatment may reduce the risk of developing cancer.
- **Screening Trials** examine individuals who do not have symptoms of cancer and identify best methods to detect the disease.
- **Diagnostic Trials** are conducted to determine how to identify cancer using new tests or procedures. These tests often involve participants who show signs or symptoms of a particular cancer.
- **Treatment Trials** are designed to answer questions about new treatments such as drugs, surgical procedures, or therapies. These trials are conducted with cancer patients.

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. 15-50) and are designed to determine the dosage safety of a drug, the delivery method, and dosage frequency. Once researchers have determined the appropriate dose amount, 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. 25-100), usually with the same type of cancer. The trials examine the effectiveness of the treatment.
- **Phase III** trials compare a new drug or intervention with the current available treatment. 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 (several hundred to several thousand).
- **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 physician 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 and have had several hundred to thousands of people participate in the trial. 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 mild 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, date of last treatment, lab results, current medications, history of other cancers, and physical activity level. Patients interested in participating should research current available trials to determine which trial is right for them. To view a list of clinical trials offered by Texas Oncology, visit *http://texasoncology.com/ClinicalTrials.aspx*.

Sources: American Cancer Society and National Institutes of Health

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