Clinical Studies
Clinical Studies at Stanford

AN IMPORTANT ASPECT OF THE ADVANCED CARE THAT STANFORD OFFERS IS THE OPPORTUNITY FOR PATIENTS TO PARTICIPATE IN CLINICAL STUDIES.

What are Clinical Studies?
Clinical studies evaluate new cancer therapies, diagnostics, and preventive measures. Such studies typically compare the most effective current treatment with a promising approach that may improve outcomes. Some studies test a completely new treatment for the first time. Clinical studies are sometimes referred to as clinical trials. All advances in cancer treatment were evaluated and developed using clinical studies.

Stanford has made a number of significant contributions to advancing cancer treatment. For example, the linear accelerator used in radiation treatments was developed here in 1955, and was the first routinely employed for radiotherapy in the Western hemisphere. Treatments for Hodgkin’s disease and non-Hodgkin’s lymphoma developed through clinical studies at Stanford have resulted in less toxic and more effective treatments as well as significant improvements in the cure rate for this disease. Stanford researchers were also the first to use monoclonal
antibodies in the treatment of human cancer. Through clinical studies and laboratory research, they developed the first monoclonal antibody approved by the FDA for cancer treatment (Rituxan). These clinical studies have changed the treatment of non-Hodgkin’s lymphoma worldwide.

In the 1960s, Stanford first began using a multidisciplinary approach to the study and treatment of cancer with the first randomized, prospective studies of the treatment of Hodgkin’s disease and other lymphomas, using a combination of high-energy radiation and chemotherapy. This successful multidisciplinary approach continues today. New patients are evaluated by a disease-specific team of specialists, referred to as a tumor board. In a single consultation, the patient receives a comprehensive evaluation by a team of specialists, which may include surgeons, medical oncologists, radiation oncologists, radiologists, pathologists, and other specialists as appropriate. The team evaluates each patient from all perspectives before reaching group consensus on the most appropriate treatment for that patient, which may include the recommendation to consider a clinical trial.

Today, Stanford is at the forefront of clinical research aimed at developing improved treatments for many different types of cancer. The physicians of the Stanford Cancer Center are engaged in a broad spectrum of more than 300 clinical studies. Most of these test the effectiveness of new cancer therapies, including new chemotherapies and drug modifiers, innovative radiotherapeutic approaches, monoclonal antibodies, vaccines,
and multidisciplinary treatments. Our physicians collaborate closely with scientists and epidemiologists as well as faculty in radiology, pathology, and related fields.

At Stanford we participate in national cooperative groups working together with other experts throughout the country on new cancer therapies. Research is supported through numerous sources including the National Cancer Institute, the American Cancer Society, the California Cancer Research Council, industry and pharmaceutical grants, gifts, and other funding sources.

**Adult Clinical Studies**

Stanford offers adult cancer patients the opportunity to participate in clinical studies for many different types of cancers including:

- Bladder
- Brain/nervous system
- Breast
- Colon & rectum
- Esophagus
- Gastrointestinal
- Gynecologic
- Head & neck
- Hematopoietic
- Kidney
- Leukemia
- Liver
- Lung & respiratory tract
- Lymphoma (both Hodgkin’s and non-Hodgkin’s)
- Melanoma
- Multiple myeloma
- Pancreas
- Prostate
- Sarcoma/soft tissue
- Spine
- Stomach
- Urinary tract

For a listing of available studies, see http://cancertrials.stanford.edu or call the Stanford Clinical Studies office at 650.498.7061.
Pediatric Clinical Studies
For information about clinical studies for children with cancer, please contact the Lucile Packard Children’s Hospital Hematology/Oncology New Patient Coordinator at 650.725.1072, or see http://oncology.lpch.org.

Is a Clinical Study Right for Me?
The remainder of this brochure is designed to help you decide if participation in a clinical study is right for you. It provides background information on cancer clinical studies and guides you to sources of additional information.

Cancer Clinical Studies
Cancer clinical studies are studies conducted with cancer patients to find out whether promising approaches to preventing, treating, or diagnosing cancer are safe and effective.

What are the Different Types of Cancer Clinical Studies?
- Treatment studies test new treatments such as a new cancer drug, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods of treatment.
- Prevention studies test new approaches, such as medicines, vitamins, minerals, or other supplements that doctors believe may lower the risk of a certain type of cancer. These studies investigate the best ways to prevent cancer in people who have never had it, or to prevent cancer from recurring in those who have.
- **Screening studies** test the best ways to find cancer, particularly in its early stages.

- **Quality of Life studies** (also called Supportive Care studies) explore ways to improve comfort and quality of life for cancer patients.

**What are the Phases of Clinical Studies?**

Studies designed to test new drugs are typically organized in one of four steps, or phases. This structure lets researchers gather reliable information about the new drug’s safety and effectiveness. The four phases of studies are outlined as follows:

- **Phase I studies** (approximately 15-30 participants): Phase I studies help determine how a new drug affects the human body, what the safest dosage is, and how it may best be administered (for example, by mouth, by injection, etc.).

- **Phase II studies** (usually less than 100 participants): Phase II studies continue to test the safety of the drug and to evaluate its effects on the body. Phase II studies usually focus on a particular type of cancer and begin to evaluate how well the drug works against that cancer.

- **Phase III studies** (from 100 to several thousand participants): Phase III studies test the new drug, combination of drugs, or a new surgical procedure in comparison to the current standard. In order to produce the most reliable results, participants are usually assigned to the standard group or the new treatment
group at random (this process is called “randomization,” and sometimes means that neither you nor your doctors will know which treatment you are receiving until the study is concluded; this is called “blind randomization”). As noted, Phase III studies often enroll large numbers of people and may be conducted at many doctors’ offices, clinics, and cancer centers nationwide.

- **Phase IV studies** (several hundred to several thousand participants): These studies further evaluate the long-term safety and effectiveness of a new treatment. Usually these studies take place after the drug is approved by the FDA.

Stanford offers studies of every type and phase described above, including screening, prevention, and treatment.

**What are the Potential Risks and Benefits of Clinical Studies?**

Clinical studies involve both risks and potential benefits. One obvious benefit is that if the drug or therapeutic approach works better than existing alternatives, patients are the first to be able to take advantage of the new treatment. Many patients also feel good about contributing to the advancement of cancer treatment, knowing that others will benefit from their participation.

Some of the risks include the possibility that the new treatment may not be as effective as current methods, may not work, or may have side effects unknown to researchers. Although clinical studies may have potential benefits, there is no guarantee that you will have a positive response when participating in a
clinical study. For some people, the knowledge that they are contributing to research and improved therapies for others is reason enough to take part.

Choosing to take part in a clinical study is a decision that only you can make. We encourage you to make use of the Stanford Cancer Center Health Library to research your disease. Discuss your treatment options with your physician, nurse, family, and friends. Your physician and nurse can discuss available clinical studies, their eligibility criteria, and potential side effects with you.

**How are Participants Protected?**

The government has a system designed to protect human research subjects. Before a government-funded clinical study can begin, the study plan (called a *protocol*) must be approved by an institutional review board that includes doctors, nurses, and community representatives. The protocol spells out what the study will do, how it will be carried out, and why each part of it is necessary. During the study, review committees confirm that the plan is being followed.

Regulations require researchers to thoroughly inform patients about a trial’s treatments and tests, including possible benefits and risks, before our patients decide whether to participate. This process is called *informed consent*, and if you agree to take part you will be asked to sign a form indicating that you’ve received this information. Note that you can also change your mind and leave the study whenever you choose—before the study begins or at any time during the study or its follow-up period.
Asking Questions

Don’t hesitate to ask questions until you have all the information you need to make a decision about whether to participate in a clinical study. Your clinical study team consists of your physician, research nurse or study coordinator and yourself. Following are some of the questions you may consider discussing with your clinical study team:

*About the study itself*
- What is the purpose of the study?
- Why do researchers think the approach may be effective?
- Who has reviewed and approved the study?
- How long will the study last?
- What will my responsibilities be if I participate?

*About risks and benefits*
- What are the possible risks and benefits?
- What other treatment options do I have?
- How do the possible risks and benefits of this study compare with my other treatment options?

*About participation and care*
- What kinds of therapies, procedures, and/or tests will I have during the study?
- How do the tests in the study compare with those I would have if I do not participate in it?
- Will I be able to take my regular medications while in the clinical study?
- Where will I have my medical care?
Who will be in charge of my care?

How could being in this study affect my daily life?

About cost issues (see page 10 for more information)

- Will my health insurance cover costs not covered by the clinical study?
- Who can help answer any questions from my insurance company or health plan?
- Will there be any travel or child care costs that I need to consider while I am in the trial? (Some studies cover hotel and travel costs.)

Tips for Asking Your Doctor about Clinical Studies

When you talk with your doctor or the clinical study team, consider taking a family member or friend along, for support and to help ask questions. We recommend that someone write down or tape-record the answers to your questions so that you can review them later.

What Happens During a Study?

Once you’ve decided to participate in a clinical study, you will work with the clinical study team. Along with the team members mentioned earlier (you, your doctor, and research nurse), the team may include additional doctors, nurses, social workers, dieticians, and other professionals who will work together to provide your care, monitor your health, and give you specific instructions. You are a key member of this team. You might have
more tests and doctor visits than if you were not enrolled in the clinical study and team members may continue to stay in contact with you after your treatment ends. To make the results as reliable as possible, it is important that you follow instructions. That means:

- Scheduling and participating in all of the doctor appointments and tests;
- Taking medicines on time and as directed; and
- Completing logs or answering questionnaires.

Who Pays for the Study? Will My Insurance Cover It?
California law generally requires insurance companies to pay for participation in clinical studies. But even if you have health insurance, your coverage may not include some or all of the costs associated with a clinical study. This is because some health plans define clinical studies as “experimental” or “investigational” procedures. Nevertheless, there are strategies to help you deal with cost and coverage barriers. See Clinical Trials and Insurance Coverage, available at the website of the National Cancer Institute (NCI), www.cancer.gov.

What Clinical Studies are Covered in California?
Many study costs are covered under California law (Senate Bill 37, effective August 2001). Phase I, II, III, and IV studies with a therapeutic intent for patients with cancer, recommended by a treating physician, are covered. The study must involve a drug
either exempt from a New Drug Application (NDA) under federal regulations, or approved by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of Defense (DOD), or the Department of Veterans Affairs (VA).

All California insurers, including the state’s Medicaid program and other medical assistance programs, are required to pay. For information from California’s Department of Managed Health Care on your health plan rights contact 1.888.466.2219 or http://hmohelp.ca.gov/. For information on Medi-Cal, California’s Medicaid program, contact 916.552.9200 or www.dhcs.ca.gov/services/medi-cal/Pages/default.aspx

Resource Guide
The following resources, available by phone or on the Web, can provide additional information and may answer some of your questions.
- The National Cancer Institute (NCI): 800.4.CANCER,
  www.cancer.gov
- www.clinicaltrials.gov
- www.centerwatch.com

Contact Information at Stanford Cancer Center
Information Desk and Concierge: 650.723.4268
Clinical Trials Office: 650.498.7061 or ccto-office@stanford.edu
Directions to the Stanford Cancer Center

From Bayshore US Highway 101 ~ North or South

- Take the Embarcadero Road/West exit.
- Follow Embarcadero Road for about two miles.
- Cross El Camino Real, after which the road becomes Galvez Street.
- Turn right at Arboretum Road. Turn left on Sand Hill Road. Turn left on Pasteur Drive.
- Turn left on Blake Wilbur Drive. Drive straight ahead at the stop signs.
- The Stanford Cancer Center is located in the Stanford Advanced Medicine Center which is just past the parking garage on your right. Valet parking is available.

From 280 ~ North or South

- Take the Sand Hill Road exit, head east. Turn right on Pasteur Drive.
- Turn left on Blake Wilbur Drive. Drive straight ahead at the stop signs.
- The Stanford Cancer Center is located in the Stanford Advanced Medicine Center which is just past the parking garage on your right. Valet parking is available.

El Camino Real ~ North or South

- Turn on Sand Hill Road. Turn left on Pasteur Drive
- Turn left on Blake Wilbur Drive. Drive straight ahead at the stop signs.
- The Stanford Cancer Center is located in the Stanford Advanced Medicine Center which is just past the parking garage on your right. Valet parking is available.