Stanford Cancer Clinical Studies

Some patients may be eligible to participate in a clinical study, which is an important aspect of the advanced care that Stanford offers.

What are Clinical Studies?
Clinical studies (or clinical trials) are studies that evaluate new cancer therapies, diagnostics, preventive measures and quality of life or supportive care. Such studies typically compare the most effective treatment in use with a promising approach or a new treatment that may improve outcomes. All advances in cancer treatment were developed and evaluated using clinical studies.

Why Would I Want to Participate in a Clinical Study?
One significant benefit to participating in a clinical study is that if a drug or therapeutic approach works better than existing alternatives, participating patients are the first to be able to take advantage of the new treatment. For some people, the knowledge that they are contributing to the advancement of cancer treatment, research, and improved therapies that will benefit others is a meaningful reason to take part in a study.

What are the Different Types of Cancer Clinical Studies?
- **Treatment studies** test treatments such as a new cancer drug, novel approaches to surgery or radiation therapy, innovative combinations of treatments, or the latest methods of treatment.
- **Prevention studies** test new approaches to preventing cancer or its recurrence, through the use of medicines, vitamins, minerals, or other supplements that doctors believe may lower the risk of developing certain types of cancer.
- **Screening studies** test the best ways to detect 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 into phases. This structure allows researchers to gather reliable information about the new drug’s safety and effectiveness.
- **Phase I studies** help determine how a new drug affects the human body, the safest dosage of the drug, and how it may best be administered (for example, by mouth, by injection, etc.).
- **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** test the new drug, combination of drugs, or a new surgical procedure in comparison to the current standard.
- **Phase IV 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.

The Informed Consent Process
Choosing to take part in a clinical study is a decision that only you can make. It is important that you are thoroughly informed about a trial’s treatments and tests, including possible benefits and risks, before you decide whether or not to participate. This process is called *informed consent* and will require signing a series of forms. At any point in time, you can opt out of participating in the study. Your physicians and nurses can discuss available clinical studies, their eligibility criteria, the potential benefits and the possible side effects. There is always a possibility that the treatment on a clinical study may not be as effective as current methods, may not work, or may have side effects unknown to researchers.
**Asking Questions**
You should ask questions until you have all the information you need to make a decision about whether or not to participate in a clinical study. The clinical study team consists of a physician, research nurse or study coordinator and you. When you talk with your doctor or the clinical study team, you should consider taking a family member or friend along for support and to help ask questions. It is most helpful when someone writes down the answers to the questions for later review. The following are some of the questions to consider discussing with the clinical study team:

**About the study itself**
- What is the purpose of the study?
- Why do researchers think the approach may be effective?
- What organization is sponsoring the study?
- How long will my participation in the study last?
- What will my responsibilities be if I participate?

**About cost issues**
- 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?

**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?
- What are the potential side effects of the therapies?
- How could being in this study affect my daily life?

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

**What Happens During a Study?**
Once you have decided and been accepted to participate in a clinical study, you will work together with the clinical study team. The clinical study team will provide care, monitor your health, and give specific instructions for you to follow. You are a key member of this team. When participating in the clinical study, it is important that you:
- Schedule and participate in all related appointments and tests
- Take medicines on time and as directed
- Complete logs or answer questionnaires as instructed

**Who Pays for the Study? Will My Insurance Cover It?**
There are two types of costs associated with clinical trial participation: 1) routine care costs usually covered by health insurance and 2) research costs associated with the clinical trial such as extra tests and procedures that are not part of routine care. Research costs are usually covered by the sponsor of the trial. As part of the informed consent process regarding study participation, your physician or research coordinator will review the costs associated with your care.

**Contact Information**
Stanford Cancer Clinical Trials Office: 650.498.7061 or ccto-office@stanford.edu or cancer.stanford.edu/trials

**Resource Guide**
The following resources, available by phone or web, can provide additional information and may answer some of your questions:
- National Institutes of Health (NIH) Clinical Trials: www.clinicaltrials.gov