

Oncology Research Clinical Trials At Kaiser Permanente

What is a Clinical Trial?

Clinical trials are research studies designed to improve treatment for cancer patients. Some trials investigate new cancer drugs and treatments while others compare standard treatments against new treatments. Before a new treatment is offered to a patient in a clinical trial, it is carefully studied in the laboratory. All our current standard cancer therapies were once experimental research therapies evaluated in clinical trials. Only after clinical trials show one treatment to be superior can that therapy become a new standard treatment. All cancer treatment advances must pass through clinical trial evaluation.

Clinical trials fall into 4 Phases:

Phase 1- Experimental treatments are evaluated to determine the best dosage and evaluate for side effects. Many treatments do not progress past phase 1.

Phase 2- Once dosage and side effects are known, trials are conducted to get an idea if the new treatment has beneficial effect (a response rate) in a certain disease. More toxicity information is learned.

Phase 3- The new therapy is compared to the current standard therapy in a randomized trial to see which therapy is better.

Phase 4- After a therapy or drug is approved and felt to be a standard therapy, many more cases are reviewed in order to detect uncommon side effects or outcomes.

Kaiser Permanente, Northern California participates in mostly phase 3, and some phase 2 trials.

Clinical Trials at Kaiser Permanente

At Kaiser Permanente, we have a commitment to offer "state of the art" treatment to our members with a diagnosis of cancer. At any one time, there are 30+ cancer trials available for Kaiser Permanente patients within the KP Oncology Clinical Trials program. More than 300 Kaiser Permanente patients enter oncology clinical trials in Northern California every year. Interested members may be able to participate in promising new cancer treatments even before they are FDA approved and available commercially to the general medical community. These new treatments are offered through the Kaiser Permanente Oncology Clinical Trials Program. (KPOCT) This program consists of a team of oncologists, nurses, and research specialists who review and select clinical trials for our program.

95% of the clinical trials offered at KP are multi-center trials being conducted at university medical school cancer centers and other cancer treatment research centers across the US. Kaiser Permanente participates in national trials through national cooperative research groups such as NSABP (National Surgical Adjuvant Breast and Bowel Project), SWOG (Southwest Oncology Group), CTSU (Clinical Trials Support Unit), as well as selected pharmaceutical industry sponsored studies. Most people are not aware that Kaiser Permanente in Northern California is a major participant in these organizations and their trials.

You May Qualify for a Clinical Trial If You:

- Have a cancer diagnosis
- Are an adult member of Kaiser Permanente in Northern California
- Are interested in access to new treatments
- Want to take an active role in your own health care

How Would You Know If You Are Eligible For a Clinical Trial at Kaiser Permanente?

Your Kaiser Permanente oncologist and the research team at your facility have access to and know the ever changing menu of oncology clinical trials offered at KP. This team will assist you in determining if you are eligible for a clinical trial. Simply ask your oncologist if a clinical trial is available for your type and stage of cancer. Most clinical trials enroll patients who are in reasonably good health other than a cancer diagnosis. A number of "eligibility criteria" exist to make sure the trial is safe for the participants. The oncologist and research team will determine final medical eligibility in accordance with the criteria of the trial protocol.

How Are Clinical Trials Conducted?

The doctors who conduct a clinical trial follow a carefully designed treatment plan called a "protocol." This spells out what will be done and why. Our clinical research study protocols are designed by national experts to safeguard the medical health of patients and answer important research questions. Often an established standard therapy is compared to a new interesting therapy hoped to be an improvement. The trial is the test to see which treatment is better. FDA unapproved but promising drugs are only given within the context of a clinical trial.

What is it like to be a patient in a clinical trial?

Whether cancer patients are in a research study or not, they face many medical appointments, examinations, procedures, and therapies. Your physician and the research team will explain in detail the risks and benefits and answer all the questions you might have concerning the specific clinical trial you may participate in. If you join a research study, data on your case will be carefully recorded. Patients in clinical trials are followed very closely according to the research protocol. This close follow up is often more structured than observation off of a clinical trial.

Important Questions to Ask:

If you are thinking about taking part in a clinical trial, here are some important questions to ask:

- What is the purpose of this study?
- What kinds of tests and treatments are there? How does this compare to standard therapy?
- What are my alternative choices for treatment?
- What side effects can I expect? How does this compare to standard therapies?
- How long will the study last?

What if I don't want to participate?

Not every patient chooses to participate in a clinical trial. Clinical trial participation is completely voluntary. Your physician will discuss clinical trials as an option to standard therapy. You will never be enrolled in a trial without your knowledge and informed consent. Your treatment at Kaiser Permanente will not be effected in any way if you decline participation in a clinical trial.

Why do patients participate in clinical trials?

People who participate do so for different reasons. Participation in clinical trials may offer the possibility of new therapies not available to all patients. Some of the research therapies prove to be major advances in treatment, some don't. Research trial protocols are created by the national experts in those particular diseases, so the quality of treatments chosen is high. Some people participate in hopes of helping future patients and generations.

What is Informed Consent

Informed consent, and understanding the research program you are agreeing to, is an important part of a clinical trial. It is a requirement in all research. Patients are given an explanation as well as written information in order to understand what is involved in the trial. This includes possible risks and benefits.

Patients are given time to consider taking part in the trial, ask all necessary questions, and freely choose to participate. Patients who decline to participate or later withdraw will continue to receive the best medical care from your health care provider. If you enter a trial you will be advised of new developments as the trial goes on. After signing the consent form, patients are still free to leave the trial at any time. However patients are encouraged to take their participation in the trial seriously and to agree to participate only after thoughtful consideration.

For Information

Speak to your Kaiser Permanente oncologist who is aware of the clinical trial opportunities at your facility. Call the Kaiser Permanente Oncology Clinical Trials Program: Phone: (707) 651-2786 For more information regarding clinical trials. The National Cancer Institute (NCI of federal government) also has a web page with more information about clinical trials. <http://www.cancer.gov/clinicaltrials>

Cancer Information Service:

The CIS is a nationwide telephone service that answers questions from patients and their families . Spanish-speaking staff members are available. **Call 1-800-4CANCER**