

Kaiser Permanente
Research

Advancing care and saving lives

Clinical Trials Division



New drugs to prevent a recurrence of breast cancer. New therapies to cure hepatitis C. New devices for coronary diagnostic and intervention procedures.

The Clinical Trials Division advances medical innovation by evaluating next-generation treatments that prevent illness, treat health problems, and save lives.

By participating in clinical trials, Kaiser Permanente members gain access to treatments not yet available to the general public; it gives our physicians advance knowledge about new therapies before they come onto the market.

William Towner, MD, FACP, FIDSA, *Regional Physician Director for Clinical Trials:*

There's no question that offering clinical trials helps us get the latest investigational agents to patients who need them the most.

Jonathan Polikoff, MD, *Director of Cancer Clinical Trials Access Program:*

Since I started practicing oncology in the 1980s, I've seen steady progress leading to improved survival and quality of life for our cancer patients. This would not have been possible without the innovations established through well-conducted clinical trials.

Lisa Nyberg, MD, MPH, *Principal Investigator, San Diego Hepatology Research Program:*

It's very gratifying to see many of the hepatitis C treatments we've tested in clinical trials now approved and being used to cure a disease that was once thought to be incurable.

Kaiser Permanente Southern California conducts well over 300 active clinical trials at any one time.

Dr. Towner: What makes Kaiser Permanente such fertile ground for clinical trials is our sheer size and our integrated health care system. Our electronic medical record makes it easy to search for and identify potential study subjects. That—and the dedication of our clinicians—is why we've been so successful in enrolling so many patients.

Kaiser Permanente Southern California has been named as a "Top-Accruing Affiliate Institution" by the Southwestern Oncology Group (SWOG), a cooperative group within the National Cancer Institute's National Clinical Trials Network. The recognition is based on the number of patients enrolled in clinical trials.

"It's wonderful to be part of a team that's striving to improve medical care and medical knowledge through our participation in clinical trials."

— *William Towner, MD, Regional Physician Director for Clinical Trials*

Robert Cooper, MD, *Principal Investigator for the Kaiser Permanente Southern California Pediatric Clinical Trials Program:*

Our pediatric oncologists always look first for clinical trials when planning care for our patients, which is why we have such high enrollments. All our clinicians consider offering clinical trials as a standard of care. We regularly enroll upwards of 30 to 40% of all our new pediatric cancer patients in clinical trials.

Our clinical trials programs give more than 1,500 Kaiser Permanente Southern California members access to investigational drugs, devices, and procedures every year.

Dr. Towner: We are very fortunate at Kaiser Permanente to have so many dedicated and passionate researchers who are interested in advancing medical knowledge and providing new treatments to patients before they can get them elsewhere.

Dr. Cooper: During my career at Kaiser Permanente, I've seen a huge change in the investments that Southern California Permanente Medical Group and the Department of Research & Evaluation have made in supporting our participation in clinical trials. I believe our leadership truly understands how much clinical trials benefit our patients and has worked diligently to provide the infrastructure necessary to provide this type of very sophisticated medical care.

On the cover: William Towner and Myleine Wong

Opposite: (clockwise, from top) Lisa Nyberg and Anders Nyberg, Robert Cooper, and Jonathan Polikoff



Clinical Trials Division

Kaiser Permanente Southern California has formal clinical trials programs in several areas, including oncology, pediatric oncology, infectious disease, and hepatology. Independent investigators also conduct clinical trials in at least 2 dozen different specialties and sub-specialties.

Adult Oncology

Dr. Polikoff: Kaiser Permanente played a very important role in securing FDA approval for raloxifene to reduce the risk of breast cancer in postmenopausal women, Avastin to prolong the life of colon cancer patients, and Herceptin for HER2-positive breast cancer. We are currently involved in 3 major adjuvant breast cancer studies with the potential to change clinical practice and save even more lives. First, to help determine which patients will benefit from chemotherapy and which won't; second, to evaluate metformin (commonly used to treat diabetes) in preventing recurrence in women with early stage breast cancer; and third, to determine if adding Herceptin to chemotherapy enhances survival for women with invasive disease and low HER2 levels — this has the potential to more than double the number of women Herceptin benefits. Next up for us is to study an immune therapy for lung and bladder cancer. Of course, until we cure every patient with cancer, our job's not done. That's why we have to keep doing this.

Pediatric Oncology

Dr. Cooper: I credit the success of our program to the commitment and enthusiasm of our clinicians in offering and enrolling children in clinical trials. For example, we have a long-running trial for the chimeric monoclonal antibody 14.18 to treat neuroblastoma, a common cancer that affects small children. This antibody has proven to be a very beneficial treatment and our children would not have had access to it outside of a clinical trial setting. Clinical trials have also proven that adding a first-generation Tyrosine Kinase Inhibitor (TKI) to chemotherapy dramatically increased survival without the need for a bone marrow transplant in children with Philadelphia-positive acute leukemia. We are currently evaluating a second-generation TKI with a somewhat reduced chemotherapy regimen for that disease.

"Our participation in cutting-edge studies gives our patients access to novel treatments they can only receive on a clinical trial."

— Jonathan Polikoff, MD, Director of Cancer Clinical Trials Access Program

HIV/AIDS

Dr. Towner: Kaiser Permanente has been conducting HIV/AIDS clinical trials since the beginning of the epidemic in the 1980s when it was almost always a uniformly fatal disease. Since then, we've played a major role in securing FDA approval for virtually all of the therapies currently used to treat HIV. With so many good HIV therapies now in the pipeline, our next big step is to help mitigate the toxicity of these therapies and, of course, to find a cure.

Hepatology

Dr. Nyberg: In 2011, we were one of the very few sites in the country involved in early clinical trials for sofosbuvir (then called Pharmasset, PSI-7977), a breakthrough drug for hepatitis C, a condition that has long defied a cure. Through our clinical trials we were able to offer sofosbuvir to our patients long before it came on the market, saving many from liver transplant, liver failure, and even death because we were able to cure their disease. We are also conducting many other hep C clinical trials to develop different oral regimens that are well tolerated with cure rates in the 95% range. We are now also involved in several clinical trials to develop new novel therapies to cure chronic hepatitis B, a disease that puts countless people around the world at risk of liver failure and liver cancer. A cure for chronic hepatitis B is now within sight.

Kaiser Permanente Southern California clinical trials...the next step

Dr. Towner: We've done an outstanding job in using clinical trials to get the latest investigational agents to our patients who need them the most, and we'll certainly continue along that path. But beyond new drug therapy, I see us expanding the scope of our clinical trials to include the study of how we deliver care. I think there is a tremendous need for us to more rigorously study what it is we do in terms of care implementation and delivery.

After all, we do a fantastic job caring for our members and oftentimes we use very innovative approaches that are way ahead of the pack, so we need to scientifically evaluate those approaches and then disseminate our successes—and even our failures—to the greater medical community. This process will take time to develop, but we are in the planning stages to bring this to fruition.

