



Clinical Trials

Helpful information
and answers for patients

UCDAVIS
HEALTH

COMPREHENSIVE
CANCER CENTER



“I joined a clinical trial because I want to make it a better world for my daughter and grandchildren. Hopefully, by the time they’re old enough to face the possibility of cancer, there will be a cure.”

Toni Carter

SACRAMENTO, CA

BREAST CANCER CLINICAL TRIAL PARTICIPANT

Answering questions, offering hope

A cancer clinical trial offers today’s newest drugs and treatments in an effort to answer scientific questions and find better ways to treat cancer. UC Davis Comprehensive Cancer Center – recognized nationally as a leader in cancer research, care and education – offers patients throughout Northern California and beyond access to more than 150 cancer clinical trials at any given time.

Clinical trials compare standard treatment with a new treatment doctors hope will be even more effective. New cancer treatments are thoroughly tested in the laboratory, often for many years, before they become available to patients in clinical trials. Patients in clinical trials are closely followed by a team of top UC Davis physicians, researchers, nurses and staff, and receive, at a minimum, the most appropriate standard treatment.

Talk with your doctor

The more you know about cancer clinical trials, the easier your choice will be. We encourage you to have conversations with your doctor about all treatment options, including clinical trials. Consider asking questions such as:

- Is there a clinical trial going on right now for my type of cancer?
- Am I eligible for that trial?
- What drug or treatment is being studied?
- What are the potential risks and benefits compared to standard treatment?

Frequently asked questions

We hope the following questions and answers will provide you with a basic understanding about clinical trials. To learn more, visit our website at cancer.ucdavis.edu.

What is a clinical trial?

A clinical trial is a research project conducted with men, women or children to determine if an experimental drug, device or procedure is safe and effective. It may also be referred to as a study, protocol, survey or experiment. Trials are conducted in three phases:

- Phase I trials examine the side effects of a new treatment, the highest acceptable dose and how often the treatment should be given
- Phase II trials determine if the novel therapy is effective in destroying cancer cells
- Phase III trials compare a new treatment with the current standard treatment. If the new treatment is found to be superior, it becomes the new standard of care.



"I have accomplished a few things in my life, but I figured that if I participate in a clinical trial and it helps someone else and it's successful, I'll feel like maybe I was a little part of it."

John Dorton
LOCKFORD, CA: LUNG CANCER
CLINICAL TRIAL PARTICIPANT

Why should I enroll in a clinical trial?

When you participate in a clinical trial, you can play a more active role in your own health care, gain access to new treatments before they are widely available, and help others by contributing to medical research.

Who can enroll in a clinical trial?

All clinical trials have guidelines about who can participate. Often, clinical-trial literature will list medical or other conditions that must be met in order to participate in a particular study. These inclusion and exclusion criteria are not used to reject or accept people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. We encourage diversity in clinical-trial enrollments since the effects of diseases or conditions can vary with age, gender, race and ethnicity. While we confront and reject any kind of discrimination based on race, ethnicity, gender, age, disability, religion, political beliefs or sexual orientation, study criteria may exclude some patients from treatment.

Is it safe to be in a clinical trial?

Research is conducted for many years before an investigational drug, device or procedure becomes available to clinical-trial participants. Only the most promising new treatments make it to clinical trials.

Trials are conducted to confirm earlier findings that the drug, device or procedure is safe in humans. During the trial, your care team regularly and carefully monitors you to determine if the research is helpful and safe. Negative effects are possible. You will be fully informed of all risks before you start.

What safeguards are in place?

Federal regulations protect participants in research studies, and require that an institution creates an "institutional review board" (IRB) if it performs research studies that involve people. The board approves all research before it begins and periodically reviews ongoing research. The IRB's assessment of risks and anticipated benefits involves a series of steps that include:

- Identifying the risks associated with the research, compared with the risks of treatments the participants would receive even if not enrolled in the research.
- Determining that the risks will be minimized as much as possible.
- Identifying the probable benefits from the research.
- Determining that the risks are reasonable considering the benefits to the participants, if any, and the importance of the knowledge to be gained.
- Assuring that potential participants will be given a fair, accurate description of the risks or discomforts and the anticipated benefits of the research.
- Determining intervals of periodic review of the study.

For more information about the UC Davis IRB, please visit research.ucdavis.edu/faqs/irb-faqs

"It's not until your own child is diagnosed with cancer that you understand how important these clinical trials were in the past. It's why survival rates are so high now."

Kristen Rogers, mother of Shane
EL DORADO HILLS, CA: B-PRECURSOR
ACUTE LYMPHOBLASTIC LEUKEMIA
CLINICAL TRIAL PARTICIPANT



Will the research help me personally?

A clinical trial may or may not help you personally, but it will give researchers information about treating cancer in the future.

How much will I know about the benefits and risks?

Each clinical trial has a well-documented plan, or protocol, about what you will need to do and what is expected. You will be fully informed about the plan and everything that is known about the benefits and risks of the research. You can ask any questions at any time. If you decide to enroll, you will be asked to sign an informed consent form.

What do I have to do in a clinical trial?

Activities vary from one clinical trial to the next, but most require regular medical examinations. Some trials involve taking either an approved or investigational drug, while others involve a procedure. You may be asked to record information about how you are doing at home. You also may be asked to return for follow-up visits to evaluate whether the research is producing the intended results.

What if I change my mind?

If you agree to participate in a trial but later decide you want to drop out, you can do so with no change in your usual care.

How much does it cost?

California law requires most health insurers to cover the costs of cancer clinical trials. Some trials, especially those that require several visits to the researcher, may provide compensation for your time and transportation.

Will my information be confidential?

Participant information is confidential. However, your provider may be required by law to share your information in certain situations. If information from the trial is published or presented at scientific meetings, your name and other personal information will not be used. The clinical trial sponsor, as well as the U.S. Food and Drug Administration, also may review the research files and medical records.

Learn more about clinical trials

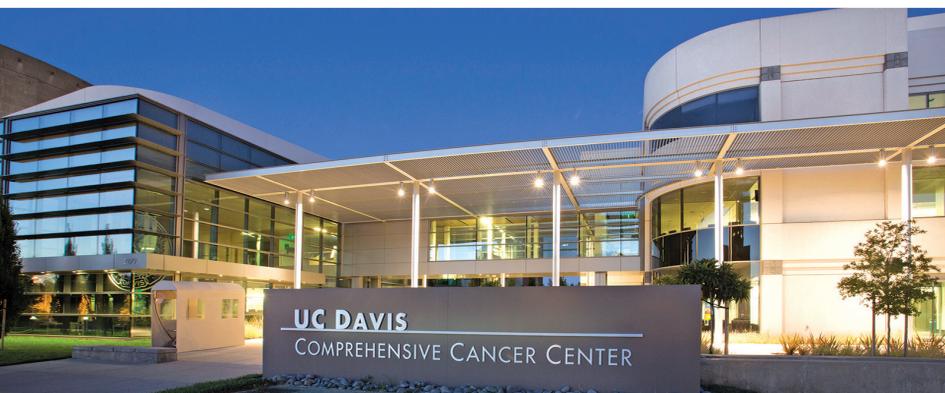
For more information about UC Davis cancer clinical trials, call 800-2-UCDAVIS (282-3284) or visit our website at cancer.ucdavis.edu/clinical_trials. You can also contact our navigators directly at 916-734-3089 for adult clinical trials or 916-734-2780 for pediatric clinical trials.



"I get up in the morning and go to work.
I wouldn't be alive today if I hadn't
gone on a clinical trial."

Alan Hans

SACRAMENTO, CA
BLADDER CANCER CLINICAL TRIAL PARTICIPANT



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