

Comprehensive Cancer Center

CLINICAL TRIALS

For treatment of people with cancer

Your physician may suggest participation in a clinical trial as part of your cancer treatment. It's important to us that you understand and are comfortable with clinical trials so that you can make an informed decision about your care. Here is information that may help.



What are clinical trials?

The many state-of-the-art cancer treatments available today are a result of clinical trials. Clinical trials are research studies that test new ways to prevent, screen for, diagnose and treat cancer. They also review new ways to manage symptoms, pain and the side effects that can accompany cancer treatment. There are four phases involved in each clinical trial. Those offered at Salinas Valley Memorial's Comprehensive Cancer Center are phase three trials.

PHASE I — IS THE TREATMENT SAFE?

In the first step of research, doctors gather information about the side effects of the treatment and decide on the safest dose. Only about 15 to 30 patients take part in this phase.

PHASE II — DOES THE TREATMENT WORK?

In this step, doctors test the treatment to see how well it works. They also continue to test its safety. Phase II trials test treatments for a particular type of cancer in order to see how well the drug works against that cancer. Usually fewer than 100 patients are part of this step.

PHASE III — IS THE TREATMENT BETTER?

Phase III trials, like those conducted at Salinas Valley Memorial, compare the new treatment with existing treatments. Patients are assigned to one of two groups (randomized) and all receive excellent care—either the current state-of-the-art treatment or the new treatment. Thousands of people at cancer centers and hospitals around the country take part in this step.

PHASE IV — ARE THERE BETTER WAYS TO USE THE TREATMENT?

In this final step, treatments are tested again to make sure they are safe and effective over a longer period of time. Typically, phase IV studies take place after the Food and Drug Administration approves the drug.

Types of cancer clinical trials

PREVENTION

As the name suggests, these trials test new ways of potentially reducing a person's risk of developing cancer. Most prevention trials involve healthy people who have never had cancer. Others involve prevention of a recurrence for patients who have had cancer.

SCREENING

Screening trials test the best ways to detect cancer, especially in its early stages.

TREATMENT

Treatment trials find out if a new treatment is more effective than the current standard treatment. These can involve new drugs, methods of surgery or radiation, possible vaccines or combinations of treatments.

QUALITY OF LIFE

Quality of life trials explore ways to reduce the impact of side effects and improve the comfort and quality of life of cancer patients.

GENETIC STUDIES

Genetic studies look at how a patient's genetic makeup influences the presence of cancer or how he or she responds to treatment. These studies are usually conducted in combination with other clinical trials.



Who participates in clinical trials?

To join a clinical trial, you must meet specific guidelines and be referred by your doctor. Participation in a clinical trial is voluntary and you can leave the trial at any time.

What are the benefits?

- Access to promising new treatments that are not otherwise available.
- The treatment being studied may be better than the standard treatment.
- A research team made up of doctors and other healthcare professionals will oversee and closely monitor your care.
- You may be the first to benefit from the new method.
- Results from the study may help others in the future.

What are the risks?

- The new drugs or treatments involved in the trial may not be more effective than the current standard.
- New treatments may have unexpected side effects.
- For randomized trials, you may not be able to choose if you are getting the new treatment or the standard treatment.
- Health insurance may not cover all of the costs.
- You may need to make more frequent visits to your doctor.

What is informed consent?

Informed consent means that you understand the nature of the clinical trial, the treatments that will be given and the tests to be used as well as the related risks and benefits. You will be asked to sign a consent form before being enrolled in a clinical trial.

How are clinical trials managed at Salinas Valley Memorial?

A physician who is member of our medical staff manages each clinical trial at our Comprehensive Cancer Center. He or she is called the Principal Investigator. Before enrolling patients in a trial, the trial must be approved by an Institutional Review Board (IRB). IRB members include doctors, nurses and residents of the community.

Everyone at Salinas Valley Memorial is committed to providing the highest quality patient care. Our Comprehensive Cancer Center works with The Eastern Cooperative Oncology Group and Stanford University Medical Center to enroll patients in the most appropriate, current clinical trials for their type of cancer. Patients are followed very closely by our team of doctors, radiologists, pathologists, nurses and therapists.

Questions to ask your doctor

When you talk with your doctor or a member of our clinical trials team, consider taking a family member or friend along for support and to ensure that your questions are answered. That person can also take notes or tape-record the session so that you can review the information later. Here is a list of questions that you may want to ask.

1. What are researchers hoping to learn from the study?
2. What do doctors already know about the treatments being studied?
3. How long will the study last?
4. What are my responsibilities?
5. How will I know if the study is successful?
6. What are the potential risks and benefits?
7. How do the possible risks and benefits of this trial compare with my other treatment options?
8. What types of therapies, procedures and/or tests will I have during the trial?
9. How do the tests in the study compare with those I would have if I do not participate in the trial?
10. What are my other treatment options?
11. Will I be able to take my regular medications while in the clinical trial?
12. Where will I go for my medical care?
13. Who will be in charge of my care?
14. How will being in the study affect my daily life?
15. How long will I be in the study?
16. What will I be asked to pay?
17. Will my health insurance pay for costs not covered by the clinical trial?
18. Who can answer questions about my insurance coverage?



Who organizes and sponsors clinical trials?

Working with national cancer research groups, Salinas Valley Memorial helps refine new treatments for people with cancer. Some of the sponsors of clinical trials include:

- The National Cancer Institute
- The American Cancer Society
- Physicians, cancer centers and hospitals
- Pharmaceutical companies

How are clinical trials paid for?

In most cases, the sponsor of the study, insurance companies and/or Medicare cover the costs of participating in clinical trials. Many trial costs are covered under California law (Senate Bill 37, effective August 2001). Your doctor will answer any questions you may have and will work to ensure that the costs are paid for.

For more information, talk with your physician or contact Carol Maynard, RN, OCN, Breast Health and Clinical Trials Specialist at the Cancer Resource Center (831) 755-0791; or Jean Aromin, RN, BSN, OCN, Director, Comprehensive Cancer Center at (831) 757-4333, extension 2655; or visit www.svmh.com.

Additional resources

- The National Cancer Institute, **1-800-4-CANCER**, www.cancer.gov
- American Cancer Society, www.cancer.org (site features a Clinical Trial Matching Service)
- www.clinicaltrials.gov
- www.centerwatch.com
- California State Capitol hotline, **1-916-445-3614**
- Coalition of Cancer Cooperative Groups, www.cancertrialshelp.org



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