

Clinical Trials

Testing new ways to prevent, diagnose and treat disease

Your physician may suggest participation in a clinical trial as part of your care. 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.

SalinasValleyHealth.com/clinicalresearch



What are clinical trials?

The many state-of-the-art 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 disease. In the United States, clinical trials of drugs or medical devices are conducted under Food and Drug Administration (FDA) oversight.

There are four phases of clinical 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.

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 disease in order to see how well the drug works against that disease. 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 Health, compare the new treatment with existing treatments.

Phase IV — Are there better ways to use the treatment?

In Phase IV trials, treatments are tested again to make sure they are safe and effective over a longer period of time. Phase IV studies take place after the FDA approves the treatment.

Participating in research is a choice

Joining a research study is an important personal decision. Before deciding to participate, researchers will talk about the goals of the study and possible risks and benefits. They will also explain the rules and policies in place to protect a person's safety and privacy. Our staff is available to answer any questions you may have, or to further explain information that has been provided.

Our goal is to make sure patients are comfortable with the clinical trial. You should never feel rushed or pressured to make a decision. Being part of a research study is completely voluntary - it's your choice.

What is informed consent?

After the study is fully explained, and if you decide to join the clinical trial, you will be asked to sign a document called an "informed consent form."

Informed consent means that you understand the voluntary nature of the clinical trial, the treatments and tests to be used as well as the related risks and benefits. However, at any time, for any reason, you can change your mind even after the informed consent form has been signed.



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.

How are clinical trials managed at Salinas Valley Health?

A physician who is member of our medical staff manages each clinical trial. 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.

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: Today's treatments are yesterday's clinical trials.

What are the risks?

- The treatment being studied may not be better than the standard treatment.
- New treatments may have unexpected side effects.
- For randomized trials, you will always receive the best FDA-approved treatment, but you and your doctor are not able to choose if you are getting the additional experimental treatment or the placebo.
- Health insurance may not cover all of the costs.
- You may need to make more frequent visits to your doctor.



Salinas Valley Health is committed to providing the highest quality patient care. Patients are followed very closely by our team of doctors, nurses and allied health professionals.

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 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. How will being in the study affect my daily life?
9. What types of therapies, procedures and/or tests will I have during the trial?
10. How do the tests in the study compare with those I would have if I do not participate in the trial?
11. What are my other treatment options?
12. Will I be able to take my regular medications while in the clinical trial?
13. Where will I go for my medical care?
14. Who will be in charge of my care?
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 research groups, Salinas Valley Health helps refine new treatments. Some of the sponsors of clinical trials include:

- Physicians, cancer centers and hospitals
- Pharmaceutical companies
- The National Institutes of Health (NIH)

The NIH is made up of 27 Institutes and Centers, each with a specific research agenda, often focusing on particular diseases or body systems. At Salinas Valley Health, available clinical trials are sponsored by:

- National Cancer Institute (NCI)
- National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute of Neurological Disorders and Stroke (NINDS)

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. Your doctor and research team are available to answer any questions you may have.

Talk with your physician for more information, or contact the Salinas Valley Health Research Department: email research@SalinasValleyHealth.com or call 831-759-1838.

Notes:
