Clinical trials are research studies that test new medicines and treatments with people who choose to participate. Clinical trials help to find new and better ways to prevent, find, and treat diseases. Cancer clinical trials help scientists and doctors learn if a new treatment is safe and effective for people with cancer. The cancer treatments used today were first tested in clinical trials.

**How clinical trials are done**
Clinical trials are done in phases, from Phase 1 through 4. Each phase gathers information about the safety of the treatment and how well it works.

Most people who agree to be in a cancer clinical trial will be in a Phase 3 trial. A Phase 3 trial compares a new treatment to standard treatment (the treatment most often used for a certain type of cancer). If the new treatment works better, it often becomes the standard.

People in clinical trials have a team of experts taking care of them. The team watches the people in the trial closely to see how they’re doing. This might include more clinic visits and lab tests than with standard treatment.

**Risks and benefits of being in a clinical trial**
There are some risks to being in a clinical trial. Researchers don’t always know if the new treatment will work or what all the side effects might be. Most side effects go away over time, but some may last a long time. Some side effect could also be severe. You’ll be told about any known risks before you agree to be in a clinical trial.

There can also be benefits. Being in a clinical trial gives you more treatment options. You might get a new treatment that you couldn’t get otherwise. This treatment might be safer or work better than standard treatment. Some people also like knowing that what is learned from the clinical trial might help others in the future.

**Deciding whether to be in a clinical trial**
Before deciding to be in a clinical trial, find out as much as you can about the treatment and what you will have to do. The research doctor or nurse will explain what to expect and talk to you about the risks and benefits of being in a clinical trial. They will also give you materials to review. You have the right to get these materials in your preferred language.

You might want to talk to trusted family members and friends before you decide. Make sure the research doctor or nurse answers any questions you or your loved ones have.

If you agree to be in the clinical trial, you will be given a written consent form to read and sign. Be sure you understand the information given to you. Don’t be afraid to ask questions if something isn’t clear or you have any concerns.

It’s your choice whether to be in – or stay in – a clinical trial. You can choose to leave the trial at any time for any reason, and still get the care you would receive if you hadn’t chosen to be in a clinical trial.
Questions to ask

There are many things you may want to know before you agree to be in a clinical trial. You might want to ask the research doctor or nurse:

- Why is this study being done?
- How long would I be in the clinical trial?
- How often would I need to be seen?
- Where would I have to go for treatment and tests?
- What side effects might I have with this treatment? How will they be managed?
- Who would I call if I have problems?
- Will I have to pay for anything?
- What are my other cancer treatment options?
- What will happen if I decide not to be in the clinical trial?
- What if I agree to be in the clinical trial and then change my mind?

You might have other questions based on the type of treatment you’re being offered in a clinical trial. Learn as much as you can about any clinical trial that you are interested in so you can make the choice that’s best for you.

Glossary

Informed consent: When a person and their health care provider share information so the person can decide whether they want to get certain care, treatment, or services. This is required before a person goes into a clinical trial.

Phase 1: The new treatment is tested for safety and to find out what dose works best without causing severe side effects.

Phase 2: The new treatment is tested to see if it works against certain types of cancer.

Phase 3: The new treatment is compared to standard treatment to see which might work better for certain cancers. At this point, researchers don’t know which treatment is better. So, about half of the people in the clinical trial get the new treatment and the other half get standard treatment. This is often chosen at random (called randomized).

Phase 4: The new treatment is studied over a longer time to learn about long-term safety and how well it works. This phase happens after the new treatment has been approved for use in certain types of cancer.

Standard treatment: The treatment most often used for a certain type of cancer.

For more information and answers, visit the American Cancer Society website at cancer.org/clinicaltrials or call us at 1-800-227-2345. We’re here when you need us.