

Things to consider

- Nearly 90% of eligible pediatric cancer patients enter clinical trials, resulting in an overall cure rate for childhood cancer that exceeds 75%.
- Less than 5% of adult patients participate in clinical trials.
- Institutional review boards (IRBs) watch over clinical trials to make sure that the studies are ethical and to protect the welfare of the participants.
- Before you join a study, a research team representative will explain the study to you and answer your questions. Be sure to ask as many questions as you can.
- If you decide to join the study, you will have to sign an informed consent form. This form will explain the reason for the study; provide current information about and possible side effects of the treatment; and list what you will be required to do as a participant.
- All clinical trials are voluntary. You decide if you will take part in a clinical trial. If you choose to take part but want to leave before the trial ends, trial doctors may continue to observe your records to be sure that no side effects arise.
- You may be responsible for some of the costs of the clinical trial. The informed consent form will tell you what costs the organizers of the trial will pay. You should check with your insurance company for details on what your plan will cover.
- Your medical information is confidential. Clinical trial organizers will protect your identity by assigning you a number or code that links your information with your treatment. Only people who need to know will have access to that code.
- You may be able to find a clinical trial close to your home.

Insurance

Medicare:

- If you have Medicare, it will pay for routine costs for most cancer treatment clinical trials funded by the National Cancer Institute or other federal agencies. Routine costs can be items or services provided through standard treatment, visits to your doctor, tests needed for medical care, hospital stays or surgery (if necessary) and tests and treatments for side effects.

Private Insurance:

- The New Mexico Senate passed a bill that requires health plans to cover patient participation in Phase II, III or IV cancer clinical trials through July 2009 when the trials meet certain specific criteria.
- You should check with your insurance provider for coverage details.

References

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Could you be a HERO?

Helping to Enhance Research in Oncology

A PATIENT'S GUIDE to Research Studies

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You have just been diagnosed with cancer or perhaps you have been living with cancer for some time. You and your physician are reviewing the best treatment options for your case. If you take part in a research study, you could have access to a new and potentially better treatment than the standard one for your type of cancer. However, they can be confusing and you are not sure if you should participate. The goal of the New Mexico Cancer Care Alliance is to ensure that the best cancer therapies offered through research studies are available for all New Mexicans. We are pleased to provide you with this information sheet to help you better understand clinical trials.

What are research studies?

Research studies or clinical trials are medical research studies done on people. Every drug you have ever taken from allergy medicine to eye drops has gone through a clinical trial. These studies determine that the new treatment is both safe and effective. Cancer trials test new drugs, combinations of treatments, new approaches to surgery or radiation or other methods for treating cancer.

Before a new treatment or drug can enter the clinical trial stage and involve people, researchers test it in a laboratory. If the laboratory test results show the treatment might slow the growth of or destroy cancer cells, a clinical trial is set up. Out of 1000 potential drugs tested in the laboratory, only one will go to a clinical trial. Before the Food and Drug Administration approves new drug, or new indication for an old drug, it must go through three phases of research with people.

Phase I – Phase I trials are designed to determine the highest dose possible of the new treatment and the best method of giving the treatment without serious side effects. The main concern of these trials is safety. The doctor carefully observes each patient for both good and bad reactions while also watching for effects on their tumors. The dose is usually very low at the beginning and increased only if there are no or minor side effects. Very few people take part in Phase I trials. Patients are usually people for whom existing treatments are not working. If a Phase I trial finds the treatment is reasonably safe, it can then begin Phase II.

Phase II – In Phase II trials, doctors look for evidence that the treatment is working. The evidence may be that the tumor is shrinking or has disappeared, or it may be that the remission time is longer than with other treatments. Doctors still watch closely for side effects in case new ones appear. More patients take part in Phase II trials than in Phase I trials.

Phase III – Phase III research can begin only after a treatment shows promise in Phase II trials that it is equal to or better than the standard treatment. At this level, trials take place in many cities across the country at the same time and several hundred to several thousand patients participate. Doctors compare the safety and effectiveness of the new treatment against the current standard treatment. To compare the treatments correctly, the patients are equally divided, or randomized, into two treatment arms. No matter which arm a patient is in, his or her doctor will watch carefully and provide the best possible care. Sometimes a treatment that appeared to be a big breakthrough in a Phase II trial turns out to be only slightly better than, or has no real improvement over, the standard treatment when

tested on thousands of patients in a Phase III trial. However, if those same results were achieved through a much easier treatment, like using an oral drug rather than an intravenous drug, then a new FDA-approved therapy will be born.

Is taking part in a trial right for you?

Possibly, yes. Every clinical trial has guidelines that describe what will be done in the study and why. An appropriate clinical trial may or may not be available for your particular disease. However, there are many advantages to taking part in a clinical trial, if one is available. For instance, you may have access to therapies that would not be available otherwise, the number of your treatment options may increase and the trial may provide more careful monitoring of your condition and the possible side effects of the treatment. It also will give you the chance to help find better treatments for the next generation of cancer patients.

However, there are aspects of a clinical trial that may make people nervous. In Phase I and Phase II trials, the treatments are new and the side effects may be unknown. In a Phase III trial, some people simply may feel uncomfortable about not being able to choose their treatment arm. If we knew which arm was better, there would not be a need for a clinical trial. Sometimes the clinical trial shows, in fact, that the standard arm is better. Sometimes the reverse is the case. Sometimes doctors discover that the results of the two arms are the same, but people tolerate one of the treatments better. Unless patients enroll in clinical trials, doctors can only guess which treatment will be safer and more effective.

Discuss your options with your physician, family and trusted friends before making a final decision.