How Do Clinical Trials Work?

Cancer clinical trials have steps called phases. The bullet points below explain these phases.

**Phase 1 Trial**
- Tests how much of the new treatment should be given
- Tests safety of the new treatment
- Tests the new treatment in different types of cancer

**Phase 2 Trial**
- Tests the new treatment in one type of cancer to see how effective it is
- Tests safety of the new treatment

**Phase 3 Trial**
- Tests to see how effective the new treatment is
- Compares new treatment with standard treatment to see if it is better
- Tests safety of the new treatment
- Usually tested in many patients

The Cancer Centers of Southwest Oklahoma only participate in Phase II and III clinical trials.

Standard treatment is what experts agree is the current best treatment. This treatment has been tested in past clinical trials. It is often widely used by doctors. It has been proven effective. It is also called “best practice” or “standard of care.”

We participate in Clinical Trials through the Mayo Clinic via the Academic Community Cancer Research United Group, Sarah Cannon Research Institute, the National Cancer Institute via the University of Oklahoma and various Pharmaceutical trials.

If you want to learn more about clinical trials, visit the National Cancer Institute’s website: www.cancer.gov/clinicaltrials, call 1-800-4-CANCER or visit www.cancertrialshelp.org

**“Fight for your good health...**

I received the best possible care and a new drug only available to me through a clinical trial.”
“Clinical trials save lives...”

As a person who has been diagnosed with cancer, you should be well informed. You may have several treatment choices. It is important to learn about your options. One choice you may have is a cancer clinical trial. Your doctor may suggest this option for you. This booklet contains information about cancer clinical trials. You can use it to make an informed decision about your treatment.

WHAT IS A CANCER CLINICAL TRIAL?
A cancer clinical trial is a research study. It is done with new ways to treat cancer by studying:

• A new way to do surgery or give radiation treatment
• A new combination of drugs
• A new drug

All cancer treatments you can take now have been tested in past clinical trials.

“Is a clinical trial right for you...”

All you have to do is ask.” — ROGER NEAL

MAKING THE DECISION ABOUT YOUR CANCER CLINICAL TRIAL

Q What are the possible benefits of participating in a Cancer clinical trial?

A The possible benefits of participating in a Cancer clinical trial are:

• You will be watched very closely - perhaps even more closely than if you were not in a trial.
• You may be the first to benefit from the new treatment if it is found to be helpful.
• You have the chance to make a valuable contribution to cancer research.
• The standard treatments available today are the result of people participating in clinical trials.

Q What are the possible risks of participating in a Cancer clinical trial?

A The possible risks of participating in a Cancer clinical trial are:

• All treatments may have side effects and/or risks.
• The new treatment may not be as effective as standard care or may not be effective at all.
• The new treatment may not work for you even if it has worked on others.
• There may be costs that are not covered by insurance or the trial sponsor.

COMMON FEARS & CONCERNS
Here are some answers to common fears or misconceptions about clinical trials:

• There may be costs that are not covered by insurance or the trial sponsor.
• You may learn that the choices are not as intimidating as they seem.
• Will I know all of the risks?

A Absolutely. One of your key rights in a Cancer clinical trial is the right to informed consent. You must be given all of the known facts about a study before you make a decision to participate. Then you will know about the possible benefits, known risks and/or side effects that may affect you. You also have the right to opt out of a study at any time.

Q Will I understand what it all means?

A It can easily be overwhelming: the diagnosis, the information, the choices. If you feel overwhelmed about the amount or type of information you are given, ask to talk with an oncology Nurse Navigator. You may learn that the choices are not as intimidating as they seem.

Q Aren’t clinical trials a “last resort”?

A No. Some clinical trials can be considered before you start any other treatment, at any time throughout treatment, or at time of recurrence, depending on available studies. Cancer clinical trials come in many forms and test many aspects of cancer care, including ways to reduce infection or pain, nausea, or other side effects, as well as ways to potentially cure the cancer.

Q Will I be treated like a “guinea pig”?

A No. You will receive either the new treatment or the best standard treatment available. People who received treatment through a clinical trial generally find it to be a very positive experience and feel that they received good care and attention, no matter what the outcome of the disease.

Q What if my doctor didn’t mention this option to me?

A Schedule a meeting to talk with your oncologist about clinical trials. Bring a list of questions and a family member or friend to help. You may also wish to seek a second opinion at an NCI cancer center where they specialize in clinical trials. You should be open to options throughout the course of your treatment because it’s never too late to access the best care available to you.

Q What is a Placebo?

A A placebo is designed to look like the medicine being tested, but it is not active. In some cases, a study may compare standard treatment plus a new treatment, to standard treatment plus a placebo. You will be told if the study uses a placebo.

Q What is Randomization?

A Randomization is a process used in some clinical trials to prevent bias. Bias occurs when a trial’s results are affected by human choices or other factors not related to the treatment being tested.

BENEFITS OF A CLINICAL TRIAL:
Clinical trials offer high-quality cancer care. If you are in a randomized study and do not receive the new treatment being tested, you will receive the best-known standard treatment. This may be as good as, or better than, the new approach.

If a new treatment is proven to work and you are taking it, you may be among the first to benefit. You have the chance to help others and improve cancer treatment.

Thanks to clinical trials, Michael is cancer free today.”

— MICHAEL AND MURIEL FAHRION