

## Clinical Trials Questions and Answers

### What are clinical trials?

Clinical trials are research studies in which patients may volunteer to take part.

MD Anderson Cancer Center uses clinical trials to find better ways to prevent, diagnose and treat cancer. Doctors use treatment trials to learn more about how to fight cancer. This guide is for patients who may join a treatment trial.

Clinical trials are part of a long, careful process, which may take many years. First, doctors study a new treatment in the lab. Then they often study the treatment in animals.

If a new treatment shows promise, doctors then test the treatment in people. Doctors do this in three to four steps, or phases.

### What are the *phases* of clinical trials?

A new treatment goes through several phases. Each phase has a different purpose:

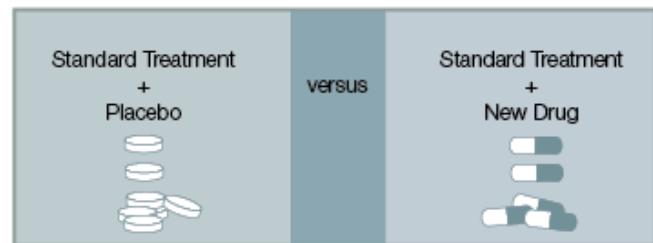
- Phase I trials test if a new treatment is safe and look for the best way to give the treatment. Doctors also look for signs that cancer responds to the new treatment.
- Phase II trials test if one type of cancer responds to the new treatment.
- Phase III trials test if a new treatment is better than a standard treatment.
- Phase IV trials find more information about long-term benefits and side effects.

Most of the time, when you take part in a clinical trial, you will only be in that one phase of the study. Treatments move through the phases, but patients do not.

### Do cancer patients ever receive placebos in a clinical trial?

A placebo is something that looks like medicine, but is not. If a placebo is used, it is given together with the best standard treatment. This allows doctors to compare standard treatment alone to standard

treatment with a new drug. If there isn't a



standard treatment, then the placebo may be given alone, but this is not common in cancer trials.

## **Am I am able to take part in a clinical trial?**

Not all clinical trials are right for all patients. A trial may be safe for one patient to join, but not safe for another.

Each protocol has strict rules that doctors must follow to decide who may join the clinical trial. These rules are called eligibility criteria. This protects patients from getting treatment that may harm them.

Eligibility criteria include information about:

### **You and Your Overall Health**

- Age and gender
- Results of medical tests
- Medicines that you are taking
- Any other health problems

### **Your Cancer**

- Cancer type and stage
- Other treatments you may have had
- How long it has been since you were last treated

If you have found a clinical trial that you think you want to join, talk to your doctor to see if you are eligible to take part.

## **What are the benefits and risks of being in a clinical trial?**

Each clinical trial has its own benefits and risks. You may benefit from joining a clinical trial in one of the following ways:

- If the new treatment works, you may be one of the first people to benefit.
- You may be able to help future cancer patients.
- The trial sponsor may pay for some of your medical care or tests. (Ask your patient access specialist about who pays for these costs before you agree to join.)
- Cancer experts design the treatments used in clinical trials.

Some possible risks include:

- Side effects may be worse than those of the standard treatment.
- Side effects may occur that the doctor does not expect.
- New treatments do not always turn out to be better than, or as good as, standard treatment.
- As with standard treatment, the new treatment may not work for you even if it works for other patients.

## Who pays for the clinical trial?

All trials are different. Your health insurance should pay for tests and doctors visits that you would need even if you were not on the trial.

New treatment, extra tests and extra doctor visits needed for the trial may or may not be covered by your health insurance. They may be covered by the clinical trial sponsor, or you may have to pay.

Please ask your patient access specialist to explain how your insurance benefits apply to clinical trials, if the clinical trial sponsor will pay for any treatment, and to learn more about what you might have to pay.

## Where can I learn more?

### **askMDAnderson**

877-MDA-6789 (877-632-6789)

<http://www.mdanderson.org/ask>

Trained health information specialists provide information about MD Anderson's clinical trials.

### **MD Anderson's Clinical Trials Page**

<http://www.clinicaltrials.org>

Find open MD Anderson trials listed by type of cancer, treatment, study number and doctor name.

### **National Cancer Institute's Cancer Information Service**

800-4-CANCER (800-422-6237)

<http://www.cancer.gov/clinicaltrials>

Call the toll-free number or search the Web site for clinical trials.

### **Coalition of Cancer Cooperative Groups, Inc.**

<http://www.cancertrialshelp.org>

Read about other patients who have taken part in clinical trials. Also, use the matching service to get a list of cancer clinical trials.

### **MedlinePlus: Clinical Trials**

<http://www.nlm.nih.gov/medlineplus/clinicaltrials.html>

MedlinePlus has information about clinical trials from the National Library of Medicine, the National Institutes of Health and other trusted sources.

### **The Learning Center**

<http://www.mdanderson.org/tlc>

The Learning Center is a free consumer health library with the latest information on cancer care, support, prevention and general health and wellness issues. These two locations are open Monday through Friday, 9 a.m.-4 p.m.:

**Theodore N. Law Learning Center**

Main Building

Floor 4, near Elevator A

713-745-8063

**Levit Family Learning Center**

Mays Clinic

Floor 2, near The Tree Sculpture

713-563-8010

The Learning Center recommends the following resources:

- Clinical Trials at MD Anderson Cancer Center: Is a Clinical Trial the Right Treatment Choice For You? The University of Texas MD Anderson Cancer Center. 2010.
- Clinical Trials at MD Anderson Cancer Center: What You Need to Know. The University of Texas MD Anderson Cancer Center. 2007. (video)
- Taking Part in Cancer Treatment Research Studies. National Cancer Institute. 2007. (pamphlet)