

Clinical Trials at MD Anderson

THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer Center~~

Making Cancer History®



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Decision Guide

Clinical Trials at MD Anderson

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, research experts 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 3 to 4 steps or phases.

Your doctor may offer you a clinical trial as a treatment option. Use this booklet to help make the best decision for you and your family.

How am I protected?

MD Anderson's most important job is to care for patients. First, MD Anderson protects patients in clinical trials by following well-planned protocols.

A protocol:

- Explains the treatment plan
- Lists the medical tests patients receive
- Gives the number of how many patients take part in the clinical trial
- Lists eligibility criteria, which are guidelines to decide who may join the clinical trial
- Explains safety information

Second, MD Anderson protects patients by using a careful informed consent process.

Third, our Institutional Review Boards (IRBs) protect patients by reviewing protocols and monitoring trials. The IRBs are committees of doctors, nurses, chaplains, social workers, lawyers and patients. They make sure that trials follow federal laws and that patients are protected.

The U.S. Food and Drug Administration (FDA) audits the IRBs' files. Also, FDA officials may visit MD Anderson at any time and review anything they choose related to clinical trials.

How do I find a clinical trial at MD Anderson?

- Ask your doctor
- Call askMDAnderson at 877-632-6789
- Visit The Learning Center.
- Go to <http://www.clinicaltrials.org>



Making a Decision

As a patient, it is your decision whether or not to take part in a clinical trial. Ask as many questions as you need to ask until the answers are clear to you.

Here are some questions you may want to ask your doctor. Use the space below to write down the answers. Later, add the information and your thoughts to the decision guide on page 12.

What are my treatment options?


Treatment options may include:

- **Standard treatment** — treatment accepted by medical experts as proper treatment for a certain type of cancer. Standard treatments change over time as doctors learn from experience and research. In some cases, the standard treatment may be no treatment at all. For example, standard treatment may be to watch the cancer and wait to see if it grows.
- **Clinical trials** — many clinical trials are for new medicines or treatments that the FDA has not yet approved. However, some trials study treatments that the FDA has already approved. In these trials, doctors may look at new ways to give the treatments or study different doses. Also, doctors may test treatments in different types of cancer.

Both standard treatment and clinical trials may involve:

- Chemotherapy
- Surgery
- Radiation
- Combined treatments (more than one kind of treatment used together)
- No treatment or delayed treatment

? What are my treatment options?



All people who join clinical trials are volunteers. We want you to make a choice that is based on your health and your values. If you are offered a clinical trial, it is your right to decide whether to take part.

What is my prognosis?

Your prognosis is what may happen with your cancer and how your cancer might respond to treatment. It is important to ask your doctor about your prognosis. This may affect your choices about treatment.

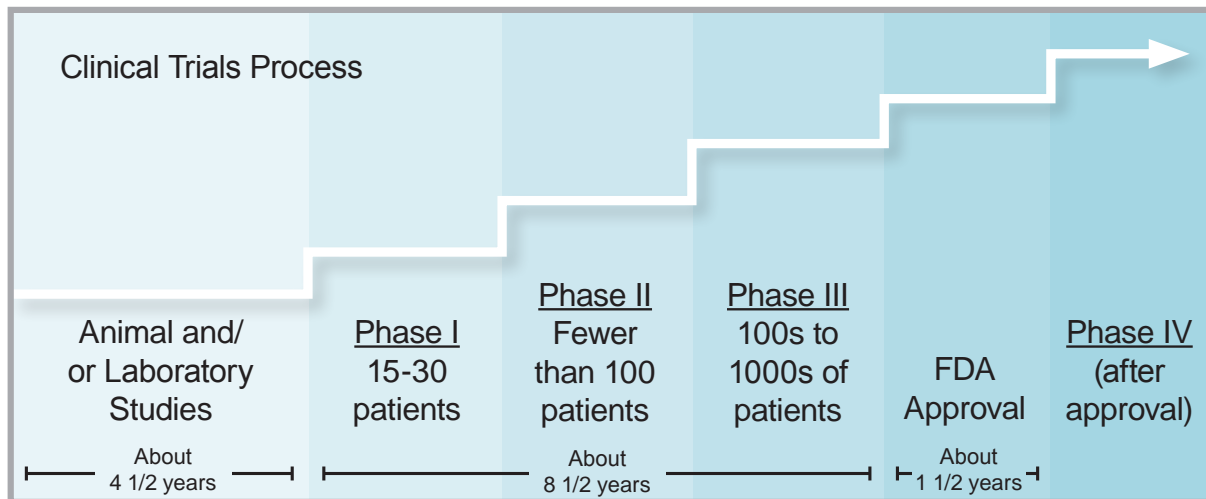
? How might standard treatment affect my prognosis?

? How might the clinical trial affect my prognosis?

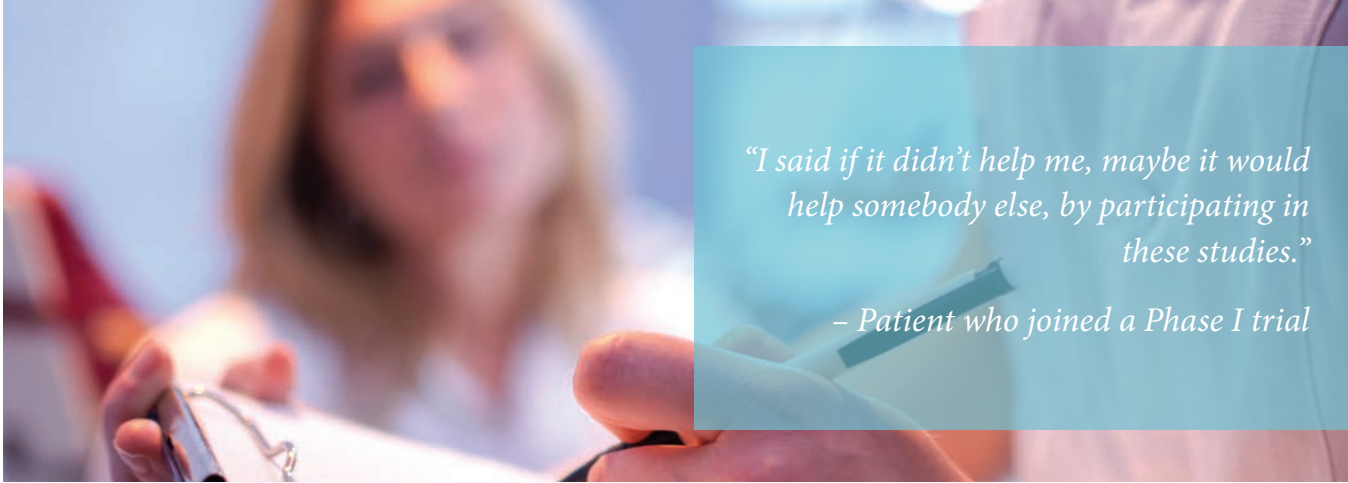
What phase is the clinical trial?

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.

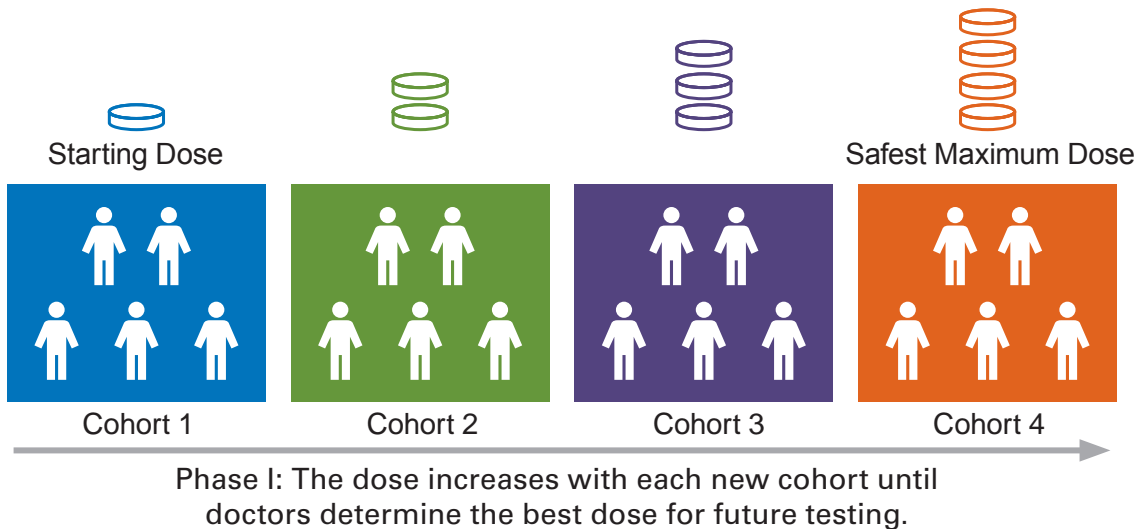


Most of the time, when you take part in a clinical trial, you will only be in that one phase of the study. Treatments move through the phases, but patients do not.



“I said if it didn’t help me, maybe it would help somebody else, by participating in these studies.”

– Patient who joined a Phase I trial



? What phase is this clinical trial?

? What is the purpose of this clinical trial?

Phase I Trials – Test if a new treatment is safe in people. Doctors also find the best way to give the treatment.

- The goals of a Phase I trial are to:
- Find out if a new treatment is safe
 - Find the best way to give the new treatment, such as by mouth or by vein
 - See if there are signs that cancer responds to the new treatment

Phase I trials usually include 15 to 30 patients who are divided into small groups. These

groups are called cohorts. The first cohort gets a dose of the new medicine. Doctors may collect blood or urine samples to measure medicine levels in these patients.

If the first cohort does not have any severe side effects, then a new cohort gets a higher dose of the same medicine. The dose increases with each new cohort until doctors find the best dose for future testing. With each increasing dose, doctors test each patient to see if he or she is responding to the treatment.

If doctors find that the treatment is safe, then it moves forward to be studied in a Phase II trial.

Phase II Trials – Test if a new treatment works in one type of cancer.

Fewer than 100 patients usually join a Phase II trial. Even though the main goal is to see if the

“MD Anderson assured me that the protocol was not a lesser treatment. In fact, they weren’t sure which one was better, but they weren’t offering an inferior, and they assured me that they never do that. All of their protocols are between equals or something that they think will be better, never between something that they think will be worse.”

Patient who joined a Phase III trial



treatment works, doctors still closely watch patients’ side effects. If the new treatment works, doctors may go on to study it in a Phase III trial.

Phase III Trials – Test if a new treatment is better than standard treatment.

Phase III trials may include hundreds to thousands of patients around the country or world. Each patient enrolled in a Phase III clinical trial has a chance of being in one of the following groups:

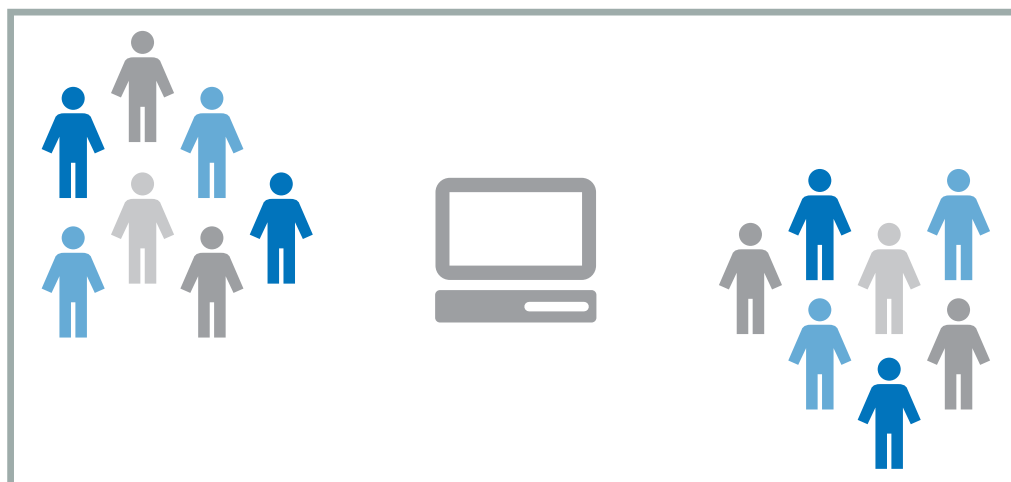
- Control group – the group that gets the standard treatment

- Study group – the group that gets the new treatment being tested

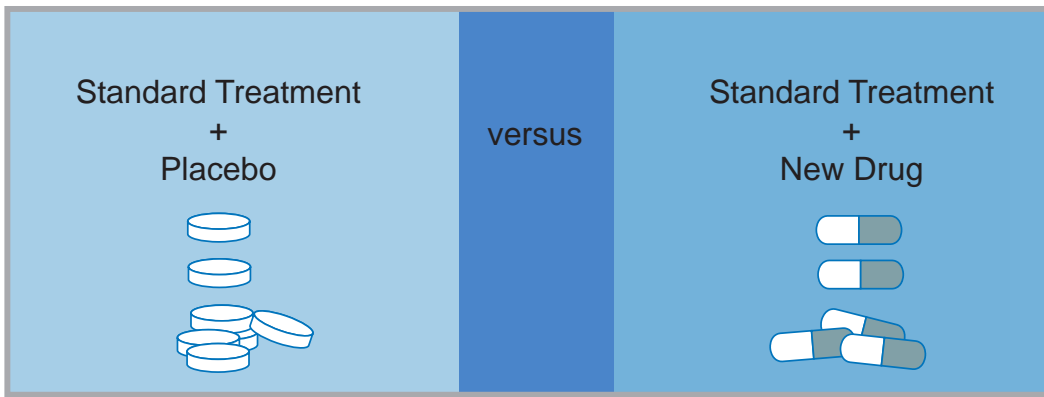
Doctors do not know if the new treatment is better than the standard treatment. They believe it is as good and may be better.

How are patients put into groups?

A computer decides which patients are in the control group and which patients are in the study group. Patients have a chance of being in either group. The patient and doctor do not decide. It is random and due to chance alone. This helps to avoid bias in the clinical trial. (Bias happens when human choices affect a study’s results.)



A computer decides which patients are in the control group and which patients are in the study group.



If a placebo is used, it is given together with the best standard treatment.

Does my doctor know which group I am in?

In single blind studies, you do not know whether you are in the control or study group, but the doctor knows. In double blind studies, neither you nor the doctors know which patients are in each group. (In case of an emergency, doctors can find this information in the study file.)

Am I given a placebo?

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 medicine. If there isn't a standard treatment, then the placebo may be given alone, but this is not common in cancer trials.

After the Phase III trial, the FDA reviews the clinical trial results to make sure the treatment is safe and effective for people to use. The FDA decides whether to approve the treatment so that it is available for all patients.

Phase IV Trials – Find more information about long-term side effects.

In Phase IV trials, doctors study treatments that the FDA has already approved. The goal is to continue studying side effects of a new treatment.

? Why do doctors believe this new treatment being tested might work for me?

? Has it been tested before?

? What has been written about this treatment?



“We strive to provide the most cutting edge, innovative treatment through our clinical trials.”

*Karen Lu, M.D.
Chair, Gynecologic Oncology and
Reproductive Medicine*

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.
- You may receive additional expert medical care

Some possible risks include:

- Expected side effects
- Side effects that the doctor does not expect may occur
- 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

? What are the possible short-term and long-term benefits and risks of this clinical trial?

? How do the possible benefits and risks in this clinical trial compare with the standard treatment for my cancer?

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. Ask your patient access specialist to explain how your insurance benefits apply to clinical trials and to learn more about what you might have to pay.

? Who pays for the clinical trial?

? What would I have to pay for?

Joining a Clinical Trial

Am I able to take part?

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 which doctors must follow to decide who may join the clinical trial. These rules are called eligibility criteria. This protects you from getting treatment that may harm you.

Eligibility criteria include information about:

You and Your Overall Health

- Age and gender
- Results of medical tests
- Medicines you take
- 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 with your doctor to see if you are eligible to take part.

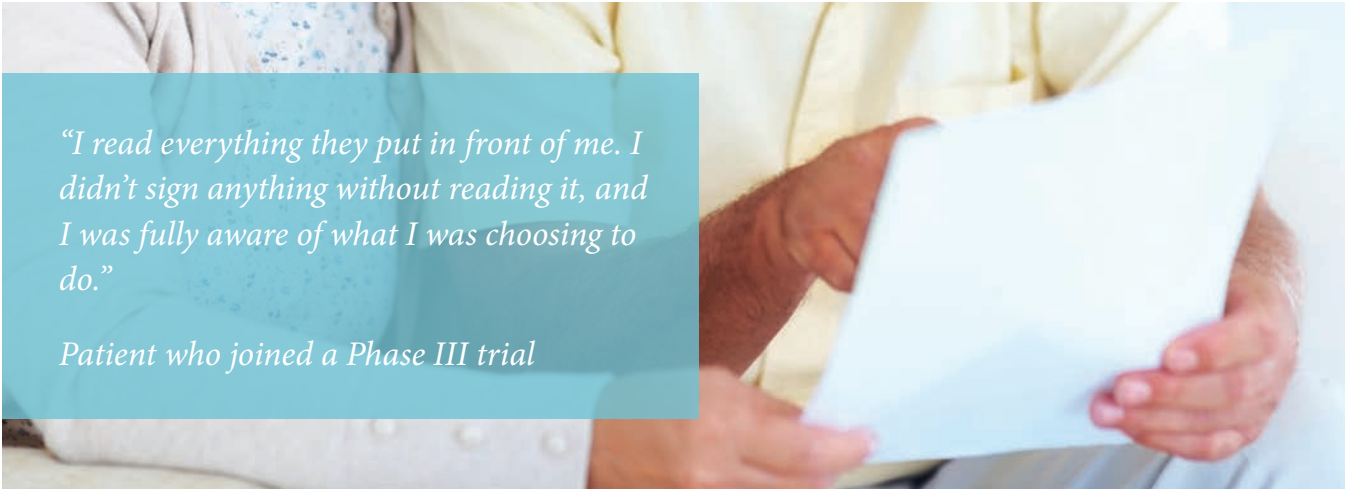
How do I sign up?

If your doctor offers you a clinical trial, you will first go through a process called informed consent. The goal of informed consent is to make sure you understand the clinical trial's plan.

The research team reviews the informed consent form with you. This form explains the clinical trial's purpose, plan, risks and benefits.

This is a great time to ask questions. Try to bring a family member or friend to help you ask questions and write down answers. You may also want to record this meeting so that later you can listen to what was said.

Take time to make your decision. You may take the informed consent form home with you to review before signing it.



"I read everything they put in front of me. I didn't sign anything without reading it, and I was fully aware of what I was choosing to do."

Patient who joined a Phase III trial

“If you find anything that you don’t understand, get a marker and mark that. And when you come back, they’ll answer the questions for you. There are no stupid questions. There are no dumb questions.”

Patient who joined a Phase II trial



What should I look for on the informed consent form?

Look for the following information on your informed consent form:

Treatment

- The reason for the clinical trial (what the doctors hope to learn)
- Who is eligible to take part in the clinical trial
- What is known about the type of treatment being studied
- Possible risks and benefits (based on what is known so far)
- Other treatment options

Tests

- Types of tests
- How often you need tests
- How often you meet with the doctor

Costs

- Who pays for the clinical trial
- If the clinical trial causes you to need more medical care, who pays for those costs

Other

- A statement about conflicts of interest (any direct financial benefit to MD Anderson Cancer Center or your doctor from the sponsor of the trial)
- A statement about how your privacy is protected
- Who to call if you have more questions

If you decide to join the clinical trial, you are asked to sign an informed consent form. The doctor also signs the form and gives you a copy.

The informed consent process does not end once you sign the informed consent form. For example, your doctor must tell you if new risks or side effects of the treatment are found during the trial. Ask any questions you may have at any time during the trial.

? What will I need to do if I join this trial?

? Where will I receive treatment? How often will I have to come to MD Anderson? How does this compare with standard treatment?

? How often and for how long will I receive treatment?

? How long will each treatment appointment last?

? How will this clinical trial change or affect my daily activities?

Can I get in touch with other people who are in this clinical trial?

Who is in charge of my care in the clinical trial?

Your research team will still care for you. In a clinical trial, you will also have a:

Principal Investigator (PI): The PI is usually a doctor. He or she runs the clinical trial and makes sure the health care team follows the plan.

Research Nurse: The research nurse teaches you about the trial and collects data from patients on the trial. The research nurse is a good contact if you have questions during a clinical trial. My main contact if I have problems or questions is:

Is there any follow-up after the clinical trial?

Yes, you continue to see your research team, if necessary, for treatment and follow-up care.

Am I allowed to quit the clinical trial?

All patients in clinical trials are volunteers. You can choose to quit a clinical trial at any time, but talk with your doctor first. Your doctor can tell you how quitting the trial might affect your health and if there are other treatment options. Your doctor can also tell you the safest way to stop taking any clinical trial medicines. Your relationship with your health care team is not changed by your decision.



“There are clauses in the protocol that state you can discontinue the trial any time you want to. There is no problem with getting out of the trial. It’s not forced on you.”

Patient who joined a Phase I trial

Decision Guide

A decision guide may help you see your options clearly. While completing the guide, you may want to review your answers from the other sections of the booklet. This information may help you decide which choice is best for you.

? What decision(s) do I face?

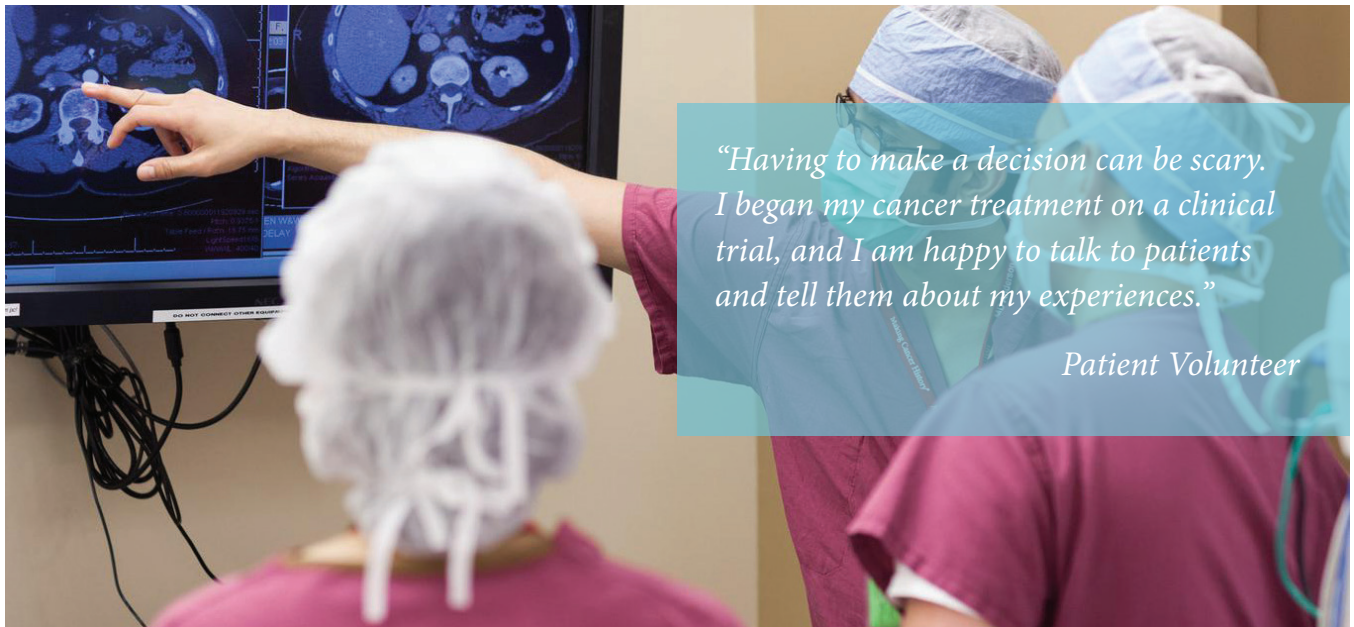
? What is my reason for making this decision?

? When do I need to make a choice?

- ? How far along are you with making a decision?
- I haven't thought about my options yet.
 - I am thinking about my options.
 - I am close to making a decision.
 - I have already made a decision.

- ? Are you leaning toward one option?
- Yes
 - No

If yes, which one?



“Having to make a decision can be scary. I began my cancer treatment on a clinical trial, and I am happy to talk to patients and tell them about my experiences.”

Patient Volunteer

Support from Family and Friends

Family members and friends may play a role in helping you make a decision. Answer the following questions to help you think about your family's and friends' support.

- ? Do you have enough help from others to make a decision?
- Yes
- No

- ? Are you choosing without pressure from others?
- Yes
- No

Who is helping you make a decision?	Name:	Name:	Name:
Which option does this person prefer?			
Do you feel pressure from this person?	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No
How can this person support you?			

- ? What role do you prefer in making your decision?
- I prefer to share the decision with _____
- I prefer to decide myself after hearing the views of _____
- I prefer that someone else decides. Who? _____

If you feel you do not have enough support, then:

- Talk about your options with a person you trust, such as doctor or nurse, chaplain, social worker, family member or friend.
- Find out what help is available to support your choice. You may need help with things like money, transportation, housing or child care.

If you feel pressure from others to make a certain choice, then:

- Focus on the opinions of those who matter most.
- Share this decision guide with others. You may also ask a family member or friend to complete this decision guide. Listen to each other's thoughts and opinions, focus on what matters most to each of you.

“I was delighted, first of all, what it did for me. But secondly, that it gave hope to so many others that were coming after me that, ‘If this happens for one person, maybe it could happen for me, too.’”

– Patient who joined a Phase III trial



Know the Facts

It is important to know the facts before you make a decision. Know what matters most to you.

Do you know which options are available to you?

- Yes
- No

Do you know both the pros and cons of each option?

- Yes
- No

Are you clear about which pros and cons matter most to you?

- Yes
- No

What Matters Most to You

Use the table on the next page to determine what matters most to you:

Step 1: List the options with the main pros and cons you already know.

Step 2: Underline the pros and cons that you think are most likely to happen.

Step 3: Use stars (*) to show how much each pro and con matters to you. Five stars means that it matters “a lot.” No star means “not at all.”

Step 4: In the table, circle the option with the underlined pros that have the most stars. These are the pros that matter most to you and are most likely to happen.

Also, look at the option with the underlined cons with the most stars. You may not want to choose this option since it has the cons that are most important for you to avoid.

	Pros	How much it matters	Cons	How much it matters
Option #1				
Option #2				
Option #3				

If you feel you do not have enough facts, then:

- Learn more about the pros and cons. How likely are they to happen?
- List your questions and write down where you will go to find the answers (for example, from your doctor or nurse, The Learning Center or social worker):

If you are not sure which pros and cons matter most to you, then:

- Review the stars in the table to see what matters most to you.
- Find people who know what it is like to experience the pros and cons.
- Talk with others who have made the decision.
- Discuss with others what matters most to you.

Making a Choice

Do you feel sure about the best choice for you?

- Yes
 No

What other factors are making this a hard decision?



