Every cancer treatment we have today was tested in a clinical trial to make sure it was safe and works well for people to use. There are now thousands of trials going on all over the world. These trials study new drugs and treatments that will become the therapies of the future. Clinical trials provide patients with access to new therapies; the next generation of cancer treatment.
GETTING ACCESS TO NEW CANCER TREATMENTS

In the United States, every drug or treatment must be approved by the Food and Drug Administration (FDA). The FDA requires proof that drugs are safe and work well before giving approval. Many new treatments are only available in clinical trials as they go through the process established by the FDA. If you are interested in gaining access to the newest, most innovative treatments, it makes sense to find out about clinical trials.
Here are different types of PHASES of clinical trials. The different phases of clinical trials are marked by roman numerals—I, II, III and IV, which stand for the numbers 1, 2, 3 and 4. All trials are done to compare new treatments to established therapies but each of these phases has a somewhat different goal. Trials are usually done in order, beginning with Phase I.

**PHASE I** trials are the first test of the dose and safety of a drug. Doctors work with small groups of patients who may have different kinds of cancer. Many phase I trials are for people with cancers that have spread to other parts of their bodies.

**PHASE II** trials are done if a phase I trial showed that the treatment is safe and works against one or more types of cancer. A phase II trial is a larger study, often done with specific cancer types. It looks at how well a treatment can work in that type of cancer.

**PHASE III** trials are large studies. They involve hundreds or thousands of patients. These studies are often done in many cancer centers in the United States or around the world. For this phase, you will be assigned to get the new treatment or the “standard of care” (current best treatment). In order to give everyone an equal chance at the new treatment, a computer decides randomly which treatment you will get. The doctor does not have any role in deciding which patients get which treatments and often does not know who is getting the standard of care.

**PHASE IV** trials are after a drug or new treatment is approved. Doctors continue to monitor it to learn how it works over the long term. They also look to see if there are any side effects that appear months or even years after treatment.
What is a Clinical Trial?

A clinical trial is a research study that compares a new drug or treatment approach with the best known available therapy, or standard of care. Clinical trials are used to find out if the new treatment is safe and effective.

WHAT DOES THAT MEAN?

For any new cancer drug or treatment, we need to know a lot about how it works before the FDA makes it available to all people. Among many things, the FDA wants to know if patients getting the new therapy live longer and/or better than those who receive existing therapies. But there are other important questions asked during a trial.

IS THE TREATMENT SAFE?

- What is the safest amount of the new treatment that can be taken at one time?
- What side effects does it cause?
- Do people getting the new treatment have an overall better quality of life than those getting the established treatment?

IS THE TREATMENT EFFECTIVE?

Doctors measure this in a couple of ways:
- Do people getting the new treatment live longer than those who get the standard of care?
- Do people receiving the new treatment have longer periods of time in which their cancers are stable or do not grow?

QUESTIONS FOR YOUR DOCTOR

1. What kind of cancer do I have?
2. What stage is my cancer?
3. Where can I get a second opinion?
4. Do I have any genetic mutations that can be targeted?
5. What trials are available for my cancer?
6. Where are these trials offered?
7. What are the possible benefits of this trial?
8. What side effects might I experience?
9. Are there extra biopsies, tests or visits that are part of this trial?
10. Have any other trials been done with this drug/treatment that are similar to my situation?
11. What support will be available to me? Who can I talk to while I am on this trial?
12. What costs will I have if I join this trial? Are all costs covered by my insurance or the trial? Can I be reimbursed for any other costs like transportation, childcare or lost job time?
Who Should Think About Being in a Trial?

Everyone diagnosed with any cancer should be aware that clinical trials can be a good option for care. There are treatment trials for every type and stage of cancer. There are trials aimed at preventing cancer for people who are at high risk. Other trials are focused entirely on improving overall health or easing anxiety and stress. In recent years, for example, clinical trials have shown that exercising is often helpful to people with cancer. In addition, a clinical trial can also be a good option for people who are:

- interested in getting access to the newest cancer treatments
- diagnosed at an advanced stage
- no longer responding to other treatments
- at high risk for recurring or spreading after primary treatment
- interested in helping other cancer patients today and tomorrow by advancing cancer treatment
- diagnosed with a rare, aggressive or difficult to treat cancer

You can always ask your doctor if there is a trial right for you. As you talk to your doctor about your treatment options, it is important to think about where you are in your life when you make decisions about your cancer treatment.

Your goals may depend on a number of factors including your age and overall health, your type and stage of cancer, any previous treatments you have had, and your interest in helping other people and advancing cancer research.

There is no one way to decide what is right for you. Ask your doctor all of your questions.

Take the time to think about these issues. Take someone with you to your doctor's visits to listen, take notes and talk things over. Talk to your family and friends.

It can also be helpful to talk to someone who has been on a clinical trial. You can often meet these people in support groups or online communities. But remember, your experience is your own and will not be exactly the same as someone else's.

HAVING AN HONEST DISCUSSION

A main reason anyone participates in a clinical trial is the hope that they will benefit from the treatment. The possible benefits of trials vary widely depending on the type and stage of the cancer and the new treatment that is being studied—everything from a cure, to a few months of life, to a better quality of life. Talk to your doctor about what you can expect to happen if you are a part of a trial. Having this honest talk can sometimes be hard, but it helps everyone understand the goals of the trial upfront.
Any cancer center or doctor who treats cancer may offer clinical trials to patients, although not all centers participate. Comprehensive cancer centers and large academic medical centers generally offer more trials for more cancer types. But community centers also participate in these studies. Sometimes you may have to change doctors or treatment centers in order to enroll in a trial that is right for you. This can mean moving from a smaller, community-based center to a larger cancer center. But, it can also mean moving from one big cancer center to another.

It can be hard to leave your doctor or deal with the logistics of going to a different treatment center. Yet there can be real benefits in enrolling in a trial that may help you. Even if you have to change doctors or treatment centers.

Where are Trials Available?

DON’T WORRY ABOUT PLACEBOS

It is very rare for people with cancer in clinical trials to get a placebo or sugar pill. In a cancer clinical trial patients will usually get at least the standard of care. This means getting the best known available treatment or practice. In the rare case that a placebo is used, it is often because there is no available treatment to compare against. Also, patients are clearly informed ahead of time if there is a chance they may receive a placebo.

WHAT ABOUT COSTS?

The costs of being on a clinical trial, including any drugs or care, are covered by your insurance company or the trial’s sponsor. There can be some costs such as transportation, childcare or lost job time from the additional doctor’s visits or tests. If these are a problem, talk to your treatment team or the financial counseling office. In many cases, there are ways of helping you with these costs.

NEED HELP MAKING A TREATMENT DECISION?

If you are facing a cancer treatment decision, Cancer Support Community’s Open to Options® program can help. Our Open to Options specialists can help you create a written list of specific questions about your concerns for your doctor. Call 888-793-9355 to set up a time or to find a Cancer Support Community near you.

Where are Trials Available?

Any cancer center or doctor who treats cancer may offer clinical trials to patients, although not all centers participate. Comprehensive cancer centers and large academic medical centers generally offer more trials for more cancer types. But community centers also participate in these studies.

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It can be hard to leave your doctor or deal with the logistics of going to a different treatment center. Yet there can be real benefits in enrolling in a trial that may help you. Even if you have to change doctors or treatment centers.
Trials are for Everyone

If you are a person of color or member of a minority group, it is important that you talk to your doctor about being on a clinical trial. People from these groups often do not participate in trials in large enough numbers. There are many reasons for this. In some cases, health care providers do not bring up the opportunity to be on a trial. In others, people may distrust the medical profession and fear being on a research study because of a history of medical procedures being forced upon or done to their community without their knowledge. Or there may be issues in getting to extra doctors’ visits, missing work or having childcare covered.

Yet, joining a trial benefits you and your community. It is important for people from all groups to participate in trials because there can be biological differences in how people process drugs. For example, one group could have more side effects to a treatment compared to another. However, by more people from all groups being involved in trials, doctors can better understand these differences and make sure the treatment fits the person. As you think about what is right for you, here are some tips:

- Ask your doctor if there is a clinical trial right for you and your cancer.
- Tell the doctor the reasons you might be worried or hesitant to go on a trial. Have a discussion about these things.
- Bring someone you trust with you to the visit so you can talk about it after. This person can help you talk through what you heard.

- Ask about resources—financial support, help with transportation or emotional support.
- Talk to the nurses or nurse practitioners. They can be great ways to learn about clinical trials.
- Schedule a special visit to talk about being on a clinical trial, so you and your doctor have the time to answer all your questions. If English is your second language, ask if there is a trained interpreter available to help you and your family.

Why Should I be on a Trial?

The main reason to be on a clinical trial is because you and your doctor believe you may benefit from the treatment. It is important to have a realistic talk about what that benefit might be. Most patients take part in clinical trials so they can live longer and better.

Everyone who is affected by cancer needs to know that clinical trials are the key to making progress against cancer. Talk to your doctor about whether there are trials that are right for you. For many people, they are not only an option, they are the best option. Ask your questions and know that you can get a second opinion if you would like to learn more about joining a clinical trial.

Another real benefit is that every trial helps move cancer treatment forward. This is true whether it works for you or not. You are still making a difference. Researchers use what they learn from every clinical trial to create new and better treatment for cancer. By joining a trial, you help move cancer treatment forward and provide real hope for a better future.
Clinical Trials Resources

AMERICAN CANCER SOCIETY’S CLINICAL TRIAL MATCHING SERVICE • 800-303-5691 • www.cancer.org/clinicaltrials
BREASTCANCERTRIALS.ORG • 415-476-5777 • www.breastcancertrials.org
CENTERWATCH • 617-856-5900 • www.centerwatch.com
CANCER SUPPORT COMMUNITY • 800-814-8927 • www.cancersupportcommunity.org/clinicaltrials
NATIONAL CANCER INSTITUTE’S CLINICAL TRIALS REGISTRY • 800-422-6237 • www.cancer.gov/clinicaltrials
NATIONAL LIBRARY OF MEDICINE’S CLINICAL TRIALS SEARCH • www.clinicaltrials.gov
TRIALCHECK • www.cancertrialshelp.org/cancer-trial-search/

CANCER SUPPORT COMMUNITY RESOURCES

The Cancer Support Community (CSC) resources and programs are available free of charge. To access any of these resources below call 888-793-9355 or visit www.cancersupportcommunity.org.

CANCER SUPPORT HELPLINE®

Whether you are newly diagnosed with cancer, a longtime cancer survivor, caring for someone with cancer, or a health care professional looking for resources, CSC’s toll-free Cancer Support Helpline (888-793-9355) is staffed by licensed CSC Helpline Counselors available to assist you Mon-Fri 9 am-9 pm ET.

OPEN TO OPTIONS®

If you are facing a cancer treatment decision, this research-proven program can help you. In less than an hour, our trained specialists can help you create a written list of specific questions about your concerns for your doctor. Appointments can be made by calling 888-793-9355, visiting www.cancersupportcommunity.org or by contacting an Affiliate providing this service.

FRANKLY SPEAKING ABOUT CANCER®

CSC’s landmark cancer education series provides trusted information for cancer patients and their loved ones. Information is available through publications, online, and in-person programs.

AFFILIATE NETWORK SERVICES

Over 50 locations plus more than 100 satellite locations around the country offer on-site support groups, educational workshops, and healthy lifestyle programs specifically designed for people affected by cancer at no cost to the member.

CANCER EXPERIENCE REGISTRY®

The Registry is a community of people touched by cancer. The primary focus of the Registry is on collecting, analyzing and sharing information about the experience and needs of patients and their families. To join, go to www.CancerExperienceRegistry.org.

The Cancer Support Community and its partners provide this information as a service. This publication is not intended to take the place of medical care or the advice of your doctor. We strongly suggest consulting your doctor or other health care professionals to answer questions and learn more.

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