

You've just been diagnosed with breast cancer.
Should you consider a clinical trial?



Only you can answer this question. But one thing is certain. You deserve to know all the options available to you before you begin treatment.

This informational booklet was conceived and developed by women with breast cancer for women newly diagnosed with breast cancer, a recurrence or if their cancer has spread. We know this is a difficult time for you. There are so many decisions to be made, but it is important for you to focus on what is most important for you at this time in your life. Take the time to discuss treatment options with your doctor. You deserve to know ALL the treatment options available to you, including those available only through clinical trials, before you make your final decision.

Clinical trials were once thought to be a last resort for people who had run out of treatment choices. Today, many patients are choosing to receive their first treatment in a clinical trial. Trials are also available throughout breast cancer treatment and if cancer should spread. Regardless of the therapy you and your doctor have agreed upon, ask at the outset if this treatment is available within the context of a clinical trial.

Being in a clinical trial may not be right for you. But bottom line, if you feel strongly about being in one, you may need to SPEAK UP and ACTIVELY PURSUE getting the information you need, and referral for, any clinical trials for which you may be eligible.

Patients in clinical trials can derive satisfaction from knowing that scientists may learn more about the disease that will be helpful in developing new and better therapies in the future.

What is a clinical trial?

Clinical trials are research studies used to find out if new treatments work better, the same, or worse than the standard treatment for the same disease. Clinical trials are strictly monitored and carefully evaluated on both a national and local level.

Why should I consider joining a clinical trial?

1. High Level of Patient Care

An important benefit to participating in a clinical trial is the high level of patient care. Patients who participate in clinical trials are closely monitored and guided through treatment by clinical trial staff in addition to your doctor and his/her staff.

2. Access to Promising New Treatments

Being in a clinical trial means you might receive a treatment that doctors hope will be better than the standard treatment. These treatments may not be available outside of a clinical trial.

3. Paving the Way for Better Treatments

Clinical trials are the only way we will ever ultimately find a cure for breast cancer. Only 7% of adults with cancer are currently receiving treatment as part of a clinical trial. Cures for childhood cancers have outpaced those of adult cancers in part due to the fact that many more children with cancer are enrolled in clinical trials.

Where are clinical trials conducted?

There are thousands of clinical trials currently underway across our country, many of them for breast cancer patients. Clinical trials are conducted by National Cancer Institute cancer centers, cancer cooperative

groups, community clinical oncology programs, the pharmaceutical industry and others all over the country. It is not always necessary to travel far for treatment if you don't live near a major academic medical center. Actually, the majority of patients in cooperative group trials are treated at sites close to their homes or in their communities.

What will it cost to be in a clinical trial ?

The trial sponsor usually pays for the cost of the investigational drug or other treatment that is being studied. The trial sponsor may be a drug company or the National Cancer Institute. Routine patient care costs, not formerly covered for patients in trials, are now covered by Medicare. But there may be other costs involved in taking part in a clinical trial.

It is important to discuss with your doctor at the outset, exactly what the trial sponsor will cover and what your costs, if any, might be.

How can I find trials?

First, ask your doctor to let her or him know you are interested in a clinical trial. However, your doctor may not know of any trials for you. Here are a few other resources that may be helpful to you:

- National Cancer Institute (NCI)

Visit www.cancer.gov/research/participate or call the Cancer Information Service at 1-800-4-Cancer (1-800-422-6237), where trained information specialists from the NCI can provide referrals to clinical trials appropriate for you in a location closest to you and answer your questions about cancer and cancer treatment.

- The Library of Medicine. One of the best web sites for clinical trials information is sponsored by the Library of Medicine. It lists all National Cancer Institute trials and others: www.clinicaltrials.gov

Do I have to be in a clinical trial?

NO. Joining a clinical trial or research study is voluntary. Inquire about all your treatment options. Discuss them with your doctor, family members or friends. Then, make your decision.

Are there risks?

New treatments under study are not always better than, or even as good as standard care. It is important to discuss with your doctors the risks and benefits associated with standard treatments and potential new treatments before making your decision. One risk is not fully understanding what is involved if you choose to participate in a clinical trial. Get informed!

Will I get information in writing about my treatment if I am in a trial?

Yes. Before joining a clinical trial, you will be given a consent form that will explain why the study is being done and what will happen during the study. The goal of the consent form is to provide patients with sufficient information to make an informed decision about participating in the clinical trial. The most important part of the consent form is to learn about the treatment's risks and benefits.

It is important that you 1) understand what is going to happen to you in the research study and 2) be able to distinguish what is standard care from what is investigational care. Research suggests that patients may overestimate benefits and forget risks.

To ensure you fully understand what is being asked of you, the following is recommended:



In your own words, explain to your doctor or the study coordinator:

- 1) the purpose of the trial and what would be expected of you and
- 2) describe in your own words possible benefits and risks of taking the new investigational drug.

Ask for copies of the consent form to take home to review with family or friends before you join a clinical trial, begin a new treatment or schedule surgery. Ask for a copy of the consent form early on in your discussion with your doctors regarding treatment options, before making your final decision. Informed consent should be an integral part of the decision making process.

Can I drop out of a clinical trial once treatment has started?

YES. You can stop at any time, for any reason, even if you signed the consent form, without compromising your ability to receive standard care for your cancer.

Who should consider being in a clinical trial?

Adult women of ALL ages: premenopausal and postmenopausal

Whether you are a young woman in your twenties or a woman over seventy, there may be a clinical trial for you. It is important when considering a clinical trial to look for one that is specific to your age group. Young women (premenopausal) with breast cancer may respond differently to treatments than older, postmenopausal women. Only through research and clinical trials will researchers be able to determine the best treatment options for each age group. We can no longer use one standard treatment for all breast cancers.

Women of all ethnic backgrounds: White, African American, Asian, Latino and Native Americans.

What's important for you to know, regardless of your age or race, is that there may be a clinical trial right for you.

What you should know about clinical trials

Developing new drugs and treatments for diseases is a long, tedious and difficult process. It takes many years and up to three or four phases (clinical trials) for a drug to go from the laboratory research stage to the point it becomes available for patient use.

Clinical trials are divided into phases:

PHASE I:

In these studies, researchers look for the best way to give a new treatment and to determine how the treatment can be given safely. These studies usually include only a limited number of patients who would not be helped by other known treatments.

PHASE II:

Phase II trials focus on learning whether the new treatment has an effect on a particular cancer and researchers watch for any harmful side effects. As in Phase I trials, only a small number of people take part because of the risks and unknowns involved.

PHASE III:

These trials compare the results of people taking the new treatment with results of people taking standard treatment. In most cases, studies move into Phase III studies only after a treatment shows promise in Phases I and II. Phase III trials may include hundreds of people around the country.

PHASE IV:

Phase IV trials are used to further evaluate the long-term safety and effectiveness of a treatment. Less common than phase I, II and III trials, Phase IV trials take place after the new treatment has been approved for standard use.

Patients are divided into two groups or “arms”

Investigational group: patients in this group receive the new treatment being studied.

Control group: patients in this group receive the standard treatment, the best accepted treatment for the kind of cancer you have.

Groups are compared to see which treatment works better.

How do I know which “arm” I will be in?

There are different methods of assigning patients into either the Control group (standard treatment) or the Investigational group (new treatment being studied).

Randomization - patients are grouped by chance, similar to “flipping a coin”. Patients do not choose whether they will receive either the new treatment (Investigational group) or the standard treatment (Control group). You will be told which group you are in and what treatment you will receive.

Single blind study - patients do not know whether they are in the Investigational group (new treatment) or the Control group (standard treatment). Only the doctor knows.

Double blind study - neither the patient nor doctor knows which “arm” the patient is on.

Questions to consider asking:

The National Cancer Institute (NCI) suggests the following questions you may wish to ask your doctor or nurse before agreeing to take part in a clinical trial:

- Why is the study being done?
- How will it help me?
- What kinds of tests and treatments are part of the study?
- How am I protected?
- How could the study change what I do every day?
- What will happen to my cancer with or without this treatment?
- What other treatments could I get if I don't take part in the study?
- What are possible short- and long-term side effects for me and my family to think about?
- How do the risks and side effects of the standard treatment compare with the treatment being studied?
- How long will the study last?
- Will insurance cover my being in the study?
- Will I have to stay in the hospital during the study? If so, how often and how long?
- Will I have extra costs because of the study?
- How will I be checked after the study?
- How long do I have to make up my mind about joining this study?

Tip: Write out a list of your questions and concerns to ask your doctor.

Free Resource Guide

This booklet is brought to you by the Wisconsin Breast Cancer Coalition (WBCC). Content reviewed March 2026. To learn more about WBCC or to download this booklet from our website, visit wibreastcancer.org.

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