Navigating Breast Cancer Clinical Trials: A Patient Guide

Navigating breast cancer clinical trials can feel overwhelming, but it doesn't have to. Could a clinical trial help you in your fight against breast cancer?

We will dive into clinical trials, what they are, discover the myths and barriers that keep patients away from them and discover how to join one, and questions to ask before you do. Clinical trials are one of the best ways for breast cancer patients to gain access to new and groundbreaking treatments.

This guide offers all of the information needed to demystify clinical trials. It will help patients navigating breast cancer clinical trials move confidently through understanding what they offer and if joining a clinical trial is a good fit in your breast cancer fight.

Find out why cures start with clinical trials.

What are clinical trials?

The World Health Organization defines clinical trials as a type of research that studies new treatments and evaluates their effects on human health outcomes. Clinical trials are carefully designed and reviewed by doctors and researchers and must be approved by the U.S. Food and Drug Administration (FDA) before they begin. People of all ages and ethnicities can participate in clinical trials.

That's the definition of a clinical trial and its design, but what does it mean for you as a breast cancer patient? A clinical trial is truly a way for breast cancer patients to gain access to cutting-edge treatments and drugs that are not part of the current standard of care.

What are the four different types of clinical trials?

There are four different types of clinical trials, not to be confused with the four phases of clinical trials, which we will discuss a bit later in this guide.

Clinical trials for new treatments. Most clinical trials are about utilizing new treatments invented to treat cancer. They might involve a new drug or combination of them or a new surgery or way to administer radiation.

Clinical trials for side effects and symptoms. Early on in cancer treatment, many people became nauseous and ill from chemotherapy. Clinical trials for drugs to prevent nausea were run and now there are anti-nausea medications that aid cancer patients in helping prevent the side effects of nausea. These trials try to limit side-effects felt by patients and discover ways to help them feel better during their treatment protocols.

Clinical trials for long-term side effects. Doctors call side effects that happen years post-cancer treatment “late effects.” Some clinical studies are designed to study late effects and try to prevent them.

Clinical trials to detect and prevent cancer. There are many clinical trials to find new ways to prevent cancer, detect it earlier or reduce the risk of it. Early treatment of any type of cancer is usually much more effective than treatment in later stages.

Why join a clinical trial?

There are many reasons you might choose to join a clinical trial. The decision is a personal one, but the biggest reason most people join is to maximize their breast cancer treatment options. Cancer patients report joining clinical trials because:

- the standard therapies have been tried with limited or no success
- there is no currently effective treatment for their specific type of cancer
- the current standard of care is too debilitating or dangerous for them
- they want to help others by contributing to cancer research in hopes of better future treatments in fighting their specific type of cancer

All of those reasons may compel breast cancer patients to join clinical trials.

When people participate and help move science forward with new treatments, the standard of care becomes better for all. Clinical trials help move us closer to a cure and closer to the best cancer care and treatment possible.

Slaying the Myths Surrounding Clinical Trials

While clinical trials hold a lot of promise for breast cancer patients, many patients are reluctant to join them. According to a study published by the National Center for Biotechnology Information (NCBI), fewer than 1 in 20 adult cancer patients enroll in cancer clinical trials.

That study goes on to say the vast majority (more than 95%) of adult cancer patients do not participate in clinical trials, even though 70% of Americans are estimated to be inclined or very willing to participate in clinical trials.

If such a large percentage of people want to participate but fewer than 1 in 20 do, why don’t they join? There are many myths and misconceptions surrounding clinical trials that may hold potential participants back from joining. Let’s explore some of the myths and how they hold people back from participating in clinical trials.

Myth 1: Clinical trials are not effective in fighting breast cancer

Researchers and doctors are always looking for the best new ways to treat all different forms of breast cancer. Great strides in the fight against breast cancer have been made through clinical trials. The American Society of Clinical Oncology (ASCO) believes that clinical trials are often **the best option to treat breast cancer.**

Clinical trial participants are often the first people to get new treatments for all stages and types of breast cancer. Some trials study the side effects and ways to lessen the severity while others

test new types of treatment. They help not only the patients enrolled but doctors and future breast cancer patients. The National Cancer Institute reports increased survival rates in the past five years are directly attributable to breast cancer clinical trials for new drugs and treatments.

Myth 2: I will receive a placebo and not receive adequate cancer treatment

Placebos are exceedingly rare in cancer trials.

According to Richard L. Schilsky, MD, FACP, FSCT, FASCO, the Chief Medical Officer (2013–2021 of the American Society for Clinical Oncology (ASCO), "a placebo is an inactive drug or treatment used in a clinical trial. It is sometimes referred to as a "sugar pill." A placebo-controlled trial compares a new treatment with a placebo. The placebo is usually combined with standard treatment in most cancer clinical trials. People who receive a placebo are in the control group."

If you were given a placebo, it would be something that would not impact the progression of your breast cancer. You would be made fully aware of the placebo before joining the trial as part of the transparency of the study. Additionally, you would still be given the standard of care along with the placebo.

The reality is that cancer patients participating in clinical trials will receive either the best current treatment, called standard of care (the treatment they would receive from their doctors), or they will receive the treatment being studied in the trial, which is believed to exceed the current standard of care, which puts them in a win-win situation.

Myth 3: I won't know what treatment I will receive during the trial

Before joining the clinical trial, as part of informed consent, the clinical trial volunteer is made aware of what they will and won't know about the treatment they will receive.

Some clinical trials are designed with randomization where one group receives the new treatment, and the other group receives the standard of care treatment. People are randomly assigned to groups by a computer to help prevent bias. That way, a clinical trial's results wouldn't be impacted by bias.

If you join a clinical trial that randomizes which treatment you will receive, you need to understand that neither you nor your doctor can choose which treatment you will receive. But **not** all clinical trials are randomized, though some are.

The research team of the clinical trial will let you know before you join the trial what situation you will be involved in, again, coming to you as part of informed consent before joining. It will be up to you to understand the type of trial you will be joining if you choose to do so.

Myth 4: I have to go through all phases of a clinical trial

Each clinical trial of a treatment or drug must follow certain steps in order. They are called phases. There are four phases of clinical trials in the United States. Each phase is a step in the process towards FDA approval of a treatment or drug.

- **Phase I - Safety**. This phase discovers if a drug or treatment or a combination of both is safe for humans. Researchers are looking at the proper dose or treatment, how often a volunteer takes it, how it affects cancer, and if it causes side effects in volunteers. Phase I is usually done with a small group of people.

- **Phase II - Effectiveness**. This phase measures treatment safety and effectiveness. Once Phase I is complete and it has been deemed safe, more volunteers can join Phase II, which measures cancer and volunteer response to the treatment. It usually lasts about two years.

- **Phase III - Comparison**. This phase compares the new treatment with standard of care treatment to see if the new treatment is better for a population. It is usually done in multiple regions and even countries. Researchers want people of all ages and ethnic groups to join the study so they can measure how it impacts different populations. It can take many years and utilize thousands of volunteers. This is the phase just before a drug or treatment being approved for all to use. Once it meets FDA criteria, it can be approved for general use.

- **Phase IV** - The FDA sometimes requires a treatment sponsor to keep studying its effects on the general population or look for more side effects over a wider population for a longer period. Pharmaceutical manufacturers sometimes also do a Phase IV trial to get FDA approval to use their drug in a new way or for a new type of cancer.

The important thing to remember is **patients do NOT have to go through all phases** of a clinical trial. It is a misconception that you must participate in all phases.

Myth 5: I have to finish the clinical trial if I begin it

If you choose to join a clinical trial and you do not feel able to finish the trial, you will not be forced to stay in the trial against your will. You have the right to withdraw for your own personal reasons, including, if you are unable to tolerate the treatment or the side effects.

If you believe the treatment isn't working for you or you are having an adverse reaction, or you just don't want to continue, you may switch to the current standard form of treatment instead of the treatment or drug being studied.

Before joining a clinical trial, a physician or nurse associated with the clinical trial will advise you of your freedoms and choices during the trial. You will receive what is known as **informed consent**, where every step of the process will be detailed for you. You will know how many treatments you will receive, how many tests will be conducted to evaluate your health, and the risks and benefits of your participation.

Regardless of whether you can participate for the full duration of the trial or not, your experience will still help medical staff assess the risks and benefits of the new drug or treatment. You will still be contributing to learning about the new treatment.

It would be a violation of ethics and medical code to force any participant to stay in a clinical study if they did not wish to do so.

Myth 6: My medical insurance won't cover my participation in clinical trials

Most often health insurance companies will cover clinical trial costs since it is the standard of care they would pay for regardless of where the treatment is received. Sometimes clinical trial sponsors cover any remaining treatments or tests not covered by health insurance companies.

Before enrolling in a clinical trial, it is best to check with your health insurance provider and the clinical trial sponsor to see what coverage is available and what gaps might occur. ASCO also has information about insurance coverage and clinical trials.

Barriers and Solutions to Participating in a Breast Cancer Clinical Trial

Myths and misconceptions are not the only barriers to breast cancer clinical trial participation. Unfortunately, other barriers prevent many people interested in joining a clinical trial from doing so. Navigating breast cancer clinical trials is not easy, but armed with knowledge, patience, and determination, it can be done.

Finding a clinical trial right for you

Finding and applying to the right clinical trial can feel like a daunting task if you are doing it on your own. Asking your doctor may not always be the best option, as doctors and oncologists may be more focused on the care and treatment that currently exists for their patients rather than knowing about clinical trials and what the specific eligibility criteria might be.

Additionally, your doctor may only know about clinical trials in your area, not necessarily all of the potential trials nationwide. There are thousands of clinical trials happening at any given time, enrolling patients in various stages of cancer, with very specific entry requirements.

Clinical trials can take place in hospitals, cancer centers, and university facilities, along with other settings. It's a lot of information for any single person to manage.

Fortunately, many organizations that can help you discover clinical trials and whether they might be right for you.

- **The American Cancer Society** has information about the latest advancements in breast cancer care and information that can help you pick a clinical trial.
- **BreastCancerTrials.org** lists breast cancer trials and has a tool that helps browse ongoing trials by location, phases, and stages of breast cancer that can be centered on where you live.
- **Ciitizen** is a private company that offers a free clinical trial matching service for advanced and metastatic breast cancer patients through its partnership with IQVIA, the world's largest clinical research organization.
- Clinicaltrials.gov lists clinical trials for cancer and many other diseases. It's affiliated with the National Library of Medicine.

- The National Cancer Institute (NCI) has a website that can help you find NCI-supported clinical trials that are taking place across the United States, Canada, and internationally.

Compiling medical records

Once you've decided to apply to a clinical trial, one of the requirements will be submitting your medical records to the clinical trial to learn if you're the right fit for their study. If you haven't previously collected your medical records and now need to compile them, know that it may take some time for all of your providers to release and forward them to you.

If you have recently been diagnosed, now is the time to begin creating a plan to coordinate and compile them. There are digital tools available that can make it easier for you to view and organize them. These include patient portals provided by clinical providers' practices, hospitals, mobile apps, and personal health records (PHRs).

Sometimes the collection and compilation of the medical records become burdensome and frustrating. As a consequence, the breast cancer patient might decide to either repeat costly tests or not to enter the clinical trial. In that case, the collection of the records becomes a barrier to participation.

There are digital tools that can help overcome this potential barrier to breast cancer patients. Ciitizen offers free tools designed for cancer patients navigating breast cancer clinical trials who want to utilize one electronic source to collect and compile their health data and keep it secure.

I've found a clinical trial that looks like a fit, now what?

Once you've identified one or more breast cancer clinical trials that look promising to you, what should you do?

Reach out to a contact person or medical center listed for the trial. The listing usually provides a phone number and/or an email. Once you contact them, they will likely ask you some questions to see if you are right for the trial. Factors that mean you are right for the trial are called inclusion criteria and those that mean you cannot participate in a certain trial are called exclusion criteria.

Usually, you will be asked what type of cancer you have, the stage, any previous treatments you have had or are currently undergoing, any other medical conditions you might have, and your age, gender, and any specific criteria to the trial.

It's important to ask questions of the trial representative as well so you can learn all about it. Speak with a research coordinator so that you understand the study protocol and what you can expect if you are accepted to it. Talk to your primary care doctor or oncologist about your participation too.

Do your research, speak to friends and family and then make your decision about participating if you are the right fit for it.

Are there age restrictions to clinical trials?

Most clinical trials do not have age restrictions to participation. Patients older than 70 are often underrepresented in clinical studies despite outreach by doctors and studies to increase their numbers.

If you find a study that might suit your cancer and you are 70+ years, reach out to them and see if you are a candidate for their breast cancer clinical trial.

What is a clinical trial protocol?

A clinical trial protocol is a written plan for the trial that has been sent to the FDA. It gives information about the treatment being tested, names and doses of drugs or radiation, what phase the trial is, how many people they hope to enroll in it, who can participate and how the treatment will be given.

Once reading through the trial protocol, questions that you might think about asking could include:

- How will I benefit from joining this clinical trial?
- What do researchers hope to find out?
- Who or what organization is sponsoring this clinical trial?
- Do I have to be in the hospital during the clinical trial?
- What are the possible risks and benefits?
- How many doctor visits and tests will be required during the trial?
- Who will pay for the cost of the trial or extra care if you need it during the trial?
- Can you leave the trial?
- Will your identity be protected during the trial?
- Who can you contact if you have questions during the trial or after the trial?

Before joining a clinical trial, you will be asked to sign a consent form. It might be helpful to bring along a family member or a trusted friend when you are going to sign the consent form so that you can be sure all of your questions have been asked and answered satisfactorily. You should never feel pressured to join a clinical trial. Only you can make the best decision for your health and know what you are willing to try in your fight against breast cancer.

Be sure to understand all that is involved and required of you before signing the consent. Once you understand all of the risks and benefits and have asked all of your questions, you need to sign the consent form, known as informed consent, because you have been informed about all aspects of your participation.

Once you've signed the consent form, there will likely be a physical and/or bloodwork and tests to help ensure you meet the eligibility requirements.

Who supervises clinical trials?

If you enroll in a clinical trial, rest assured the trial is being monitored by several groups of experts who have made the rules for clinical trials. Clinical trial doctors and researchers must abide by these rules exactly so you and other volunteers in the trial will be safe during the

treatment. Who specifically is watching? Three main groups make the rules for clinical trials in the United States.

An Institutional Review Board (IRB) makes sure a clinical trial is designed correctly, safely, and fairly to protect the well-being of the volunteers enrolled in it. The IRB mostly oversees the trial before it comes into being, doing its work upfront, and approves the clinical trial once it is satisfied that it has been designed properly.

Several U.S. government institutions oversee clinical trials.

- **The U.S. Department of Health and Human Services** provides clarification and guidance on the process. They develop materials and educational programs about the trials and provide advice on ethical and regulatory issues.

- **The Food and Drug Administration (FDA)** makes rules for clinical trials that involve new, experimental drugs or medical devices.

- **The National Institutes of Health (NIH)** oversees clinical trials.

Data and Safety Monitoring Board (DSMB). A DSMB board is made of experts who check on how the trial is going as it progresses. They monitor data and make sure the clinical trial is safe for participants and that doctors are getting information from the trials. A DSMB sometimes performs site visits or goes to the facilities where the clinical trial is being run. They can decide if a clinical trial should change, stop or continue forwards.

Clinical trials are closely monitored for volunteer safety and to ensure the trials meet government standards.

Navigating Breast Cancer Clinical Trials

Clinical breast cancer trials are the gold standard of breast cancer care. Participating in a clinical trial means you will receive at least the current standard of care your doctors would provide you. Many times, you will receive the very cutting edge of care with new drugs and therapies, which may become the standard of care for future breast cancer patients.

All clinical trials hope to advance the fight against breast cancer and lead to a cure.

Frequently Asked Questions

1. **How will participation in a clinical trial affect my daily life?**
   That is a question to ask the research team of the clinical trial before signing on to the trial. It may be what your standard of treatment care would be like, appointments for doctor visits and treatment visits. A clinical trial may require more appointments for additional follow-ups and to measure your response more closely.

2. **Will my oncologist or primary care doctor be informed about my treatment during a clinical trial?**
   Each clinical trial may be different in reporting results to your oncologist. This is another excellent question to ask the research team before joining a trial so that you know who will be coordinating care and receiving updates to your care.

3. **Are clinical trials for breast cancer free?**
   Many times, the care received during a clinical trial is covered by your insurance company. Sometimes the clinical trial sponsor will pick up costs not covered by your insurance. Each individual's health insurance plan is different. Reach out to your health insurance provider before joining a clinical trial to find out what will be covered and if anything will not be covered. Also, ask the clinical trial research staff about costs prior to joining a clinical trial.