



LIVING BEYOND BREAST CANCER'S
GUIDE TO UNDERSTANDING

Breast Cancer Treatment Research Studies



**What to expect...
today, tomorrow and beyond**

Steps for coping with the medical,
emotional and practical concerns
of breast cancer



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FREE HELPLINE (888) 753-LBBC (5222)

Dear Friend:

After receiving a breast cancer diagnosis, you may feel scared or overwhelmed. Yet that's also the time when you need to consider your treatment options and choose the best plan for you.

Among those options may be a clinical trial, or research study. Breast cancer treatment clinical trials give you the chance to possibly receive a new therapy or approach and see whether it is more effective and safe than the standard or works as well as the standard but causes fewer side effects.

While studies may sound scary, it's important to realize that *all* the breast cancer treatment advances we have today were first proved effective in clinical trials. Without research studies, progress in breast cancer treatment cannot happen. Yet not enough adults take part in clinical trials, so advances happen slowly.

This guide will help you understand what it means to be in treatment through a clinical trial, how participants are selected, rules that protect your safety, possible benefits and risks and resources for finding trials for your diagnosis. You'll also find suggestions of questions to ask before taking part in a study and hear advice from women who participated in breast cancer treatment trials.

We encourage you to get answers to all your questions. Call our [Survivors' Helpline at \(888\) 753-LBBC \(5222\)](tel:8887537222) for information and peer support as you consider your options.

Warmly,

Jean A. Sachs, MSS, MLSP
Chief Executive Officer

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*All women pictured in this brochure
are LBBC volunteers whose lives have been
affected by breast cancer. We thank them for
sharing themselves and their experiences.*



*Looking at
Breast Cancer
Research Studies*

Years ago, most women who were diagnosed with breast cancer received the same treatment. Little was known about the different types of breast cancer or about how the traits of each cancer might affect treatment results.

Today, research studies—also called **clinical trials**—have changed breast cancer treatment from a one-size-fits-all approach to a choice of more tailored therapies that have made longer life a reality for so many women.

The advances we now rely on as standards in breast cancer treatment are available only because they were found effective through clinical trials.

These breakthroughs include:

- the surgical benefits of lumpectomy
- the use of tamoxifen to reduce the chance that cancer will come back
- the use of trastuzumab (brand name: Herceptin) in HER2 positive disease
- the benefits of aromatase inhibitors for postmenopausal women

Those studies—and many others that have increased breast cancer survival—never would have happened without thousands of women choosing to participate in them.

As science advances, the number of breast cancer clinical trials continues to grow. So, too, does the need for more women—from all racial and ethnic backgrounds, all ages and communities—to take part. Such participation is the only way to speed research and to find new ways to treat and prevent breast cancer.

Beginning with the Basics

Clinical trials, research studies—the words themselves may sound a little scary, especially if someone is using them when talking about your options for breast cancer treatment. It may seem overwhelming to be asked to take part in a clinical trial at a time when you're already feeling anxious.

It's normal to feel hesitant or even fearful about choosing treatment in a breast cancer research study. Many women find that as they discover more about what really happens in clinical trials, they feel more comfortable about deciding to take part.

First, an explanation of the words used might help: **Clinical** simply means anything related to seeing or treating people with an illness. A **trial** is a test. In this guide, we use the words clinical trial, trial, research study and study to mean the same thing. Your healthcare team may use any of these words, too.

Breast cancer treatment clinical trials are designed to find out the effects of a:

- new medicine, surgery or radiation treatment
- new combination of existing medicines or therapies
- treatment **sequence** (the order in which medicines are given)
- dosing schedule
- way that the dose is given (such as by mouth or injected)

Other breast cancer research studies test ways to screen for breast cancer, manage symptoms, prevent **recurrence** (the cancer coming back), find genetic influences and improve quality of life.

Clinical trial researchers are scientists and doctors who treat women affected by breast cancer. The treatments they study go through years of early testing before being ruled safe for research in humans. Laws protect the safety of participants in trials (see page 32).



You Will Always Get Treatment

The breast cancer treatment studies that most people join compare a new medicine or combination of medicines to the currently recommended treatment (sometimes called a “gold standard” or “standard of care”) for a certain type of breast cancer. All participants get *at least* that standard treatment.

- No one is ever given a **placebo**, an inactive substance or sugar pill, *instead of* appropriate treatments.

Although there have been many advances in breast cancer trials, the new approaches being tested in any specific study might not be better than standard treatment. Safety and review boards monitor trials and will stop a study to avoid harm (see page 33).



Where Studies Take Place

Right now, there are many breast cancer research studies going on, in more places than just a few years ago. The size and scope of each study varies greatly.

A trial may operate from one place, such as a university hospital, or it might be available in hundreds of locations—from cancer centers and large hospitals to community hospitals and local doctors' offices. Groups of cancer researchers and healthcare providers have networks that conduct studies across the country.

Trials are funded by government agencies such as the National Cancer Institute, pharmaceutical companies or other private industries, universities, foundations and organizations.

Not all studies are appropriate for every woman. When you work with your healthcare team, you can narrow the choices and make a decision that's right for you.

VOICE OF EXPERIENCE

"I finally decided science wouldn't be anywhere without people who were willing to try things. And I knew I would be getting the standard treatment and (maybe) the new drug."

Alice, Stage I breast cancer, took part in chemotherapy clinical trial, received standard treatment and investigational medicine

Timing Is Important

Some people think trials are only for those who have no other treatment options. You may be surprised to learn that it's best to look for a breast cancer clinical trial *before* you begin treatment, although you may feel overwhelmed at that time. Medicines or treatments being studied often provide the largest gains to recently diagnosed women with early-stage disease (DCIS or Stages I, II or III) who have not yet received other therapies.

What's more, each trial has precise rules for who can participate. For example, you may be ineligible if you've already had some treatment, or if you are not within a certain time period after diagnosis, such as 60 days. When first talking about and planning your treatment, talk with your doctor (see page 31) about clinical trials.



10 Key Terms to Know

- 1 **Arm:** Treatment group within a clinical trial.
- 2 **Clinical trial:** Research study conducted in people.
- 3 **Double-blinded trial:** Study in which neither the participant nor the researcher or healthcare provider knows which treatment the participant is receiving.
- 4 **Informed consent:** Process that educates about a trial's purpose, possible benefits and potential risks, rights of participants and more. After getting that information, prospective participants read, talk with a doctor or nurse and sign an informed consent document. Participants may withdraw consent at any time, for any reason, though many concerns can be lessened by talking with the healthcare team.
- 5 **Institutional Review Board (IRB):** Group of medical providers and community members that evaluates and approves study for safety before it begins and while it is going on. May change or stop trial if problems arise, or to permit effective new treatment to be made available sooner.
- 6 **Phase:** Research testing step (see page 18).
- 7 **Principal investigator:** Researcher in charge of a clinical trial.
- 8 **Protocol:** The plan that describes what will happen in the trial and how it will be conducted.
- 9 **Randomized study:** Clinical trial in which a computer randomly assigns people for each arm, or branch, of the study.
- 10 **Research nurse:** Link between participant, doctor and the clinical trial, providing information and answering questions. Collects and reports data throughout trial.



VOICE OF EXPERIENCE

"My advice is to start the discussion about clinical trials early."

Teresa, Stage II breast cancer, participated in research study on medicine to prevent recurrence and other studies on long-term side effects of treatment



Exploring Clinical Trial Details

Taking part in a breast cancer treatment study often is not much different than receiving treatment without being in a trial.

You will have a healthcare team, with a doctor-researcher who is responsible for your care. That doctor might be a **principal investigator**, or coordinator, of the entire study, or one of several **sub-investigators**—doctors at different locations where the research is done. Other team members at the treatment location can include a research nurse, data manager, therapists and technicians.

Participants often have most contact with the **research nurse**, also called the clinical trial nurse. The nurse explains what the study is about, how it will be run, how much time it might take, potential side effects and benefits, safeguards and more. The nurse also may coordinate medical tests and appointments and monitor your quality of life.

Reading the Roadmap

Each clinical trial has a scope, plan and structure. **This research roadmap, called a protocol, provides important details you need to know, including:**

- Name and phase of study
- The goals of the research
- Who is eligible to participate (age, prior treatment, medical profile)
- How many participants are needed
- Type(s) of treatment, how assigned and delivered to participants
- Follow-up schedule
- Contact information for trial staff and safety reviewers

This information is vital for decision-making about which trial may be right for you, yet the protocol itself can be very long and written in scientific language. You may find it helpful to review the protocol and then ask your provider questions about it (see section on “Informed Consent” on next page). The details listed here are required to appear in the shorter consent form you receive and review before signing up for any clinical trial.

Randomized and Blinded Studies

Many breast cancer clinical trials have several treatment groups, or **arms**. Each group may receive different medicines or treatments, or get them for different lengths of time. Treatments are tailored to the type of breast cancer and, in phase II and phase III trials (see page 18), match at least standard care.

In **randomized studies**, participants are assigned to different treatment groups by random computer selection. This gives everyone an equal chance of being assigned to a group and removes human influence. To take part in a randomized study, you must be willing to be assigned to a treatment group rather than to choose among several options.

You may or may not be told which treatment group you are in. In **blinded clinical trials** you will not know; in **double-blinded studies**, neither you nor the research team knows your grouping. This helps keep the study results free of influences such as participant or researcher expectations or bias.

A blinded trial may be **unblinded**—that is, participants are told which treatment they’ve been receiving—as part of the protocol. It also may happen if the investigational medicine is shown to be successful; in that case, participants sometimes are offered the option to use the new medicine.

Informed Consent

Enrolling as a participant in a breast cancer research study isn’t as simple as just signing up. That’s a good thing, because it’s important to take time to understand what your participation means.

Before you take part in a trial, find out as much as you can by reading about it and talking with your doctor, the research nurse and women who participated in that study or others.

This is the beginning of the informed consent process, in which you will:

- receive written material explaining trial details, treatment options, possible side effects and potential benefits
- understand your responsibilities and those of the research team
- be able to ask questions of the study team (including the doctor) before you agree to participate—and throughout your participation
- find out who oversees trial safety and how to contact that person when you need to
- learn that it is your right to leave a trial at any time, for any reason, without it affecting your future treatment
- have time to read and evaluate the information
- review, discuss with others, ask questions about and, if you decide to participate, sign the informed consent form (ask to review documents written in your native language, if it is not English)
- receive further information, if it develops, about the trial

Informed consent is an ongoing system of discussions with the research team overseeing the study. You may be given a lot to read that can seem overwhelming, but the research nurse will walk you through the details and explain complex language. The informed consent process continues even after you sign the informed consent form.

VOICE OF EXPERIENCE

“My doctor presented me with what the trial was and let me make my own decision.”

Rachel, Stage II breast cancer, chemotherapy research study participant, received standard treatment plus medicine under study



Paying Clinical Trial Costs

In a breast cancer research study, your treatment costs may include both routine care—the doctor visits, tests and x-rays you would have received in standard treatment—and the costs of the medicine or method under study and any additional tests or office visits that are needed solely for research.

- ▶ It's very important to find out the details of your coverage from your health insurer *before* you enroll in a study. Ask the research nurse or doctor if a staff member can help you get the answers you need.

Clinical trial sponsors sometimes pay for study medicine and added tests or visits but not always. Some health insurance plans and managed care groups will pay for routine care on a study; others will not. Medicare will cover routine costs in most breast cancer treatment trials funded by federal agencies.

About half of the states have laws requiring insurers to pay for your routine care costs while you are taking part in a trial. Some states cover clinical trials on Medicaid or other state-run programs. Check with your state insurance agency for laws that apply where you live.

If you do not have health insurance, or have other financial concerns, talk with the research nurse or other staff members *before* you join the clinical trial about ways to find assistance so that you can participate.

One Step at a Time—Research Study Phases

New treatments are tested in clinical trials only after several years of research in the laboratory and with animals. Those data are reviewed and the federal Food and Drug Administration (FDA) must agree that the treatment is safe before human testing can begin.

Human testing occurs in four **phases**, or steps—each is a separate trial. Data from each phase must be approved by the FDA before the next phase can begin.

- ▶ **phase I:** First human test step. Measures safety; best dosage and delivery method (by mouth, injected); side effects. Enrolls small number of participants.
- ▶ **phase II:** Determines effectiveness; watches for side effects. Usually not randomized (see page 14). Has 300 or fewer participants.
- ▶ **phase III:** Compares new treatment to current standard; measures side effects. Often randomized and double-blinded (see page 14). When phase III is completed, new treatment may receive FDA approval. More than 1,000 participants needed.
- ▶ **phase IV:** After FDA approval. Monitors effects of long-term use and compares new medicines to others. Many times, there is no phase IV trial.

VOICE OF EXPERIENCE

“My oncologist and I talked about a clinical trial after my surgery. I wanted to go forward and do everything possible.”

Ann, Stage III breast cancer, chemotherapy clinical trial participant, currently in osteoporosis prevention trial, mammography study and long-range health study





Possible Benefits and Concerns

When you think about the option of having breast cancer treatment on a clinical trial, you'll want to balance what you might gain with drawbacks that could affect you. Talk with your loved ones and healthcare team about these issues as part of your decision-making.

Potential Benefits

Having treatment in a breast cancer research study can benefit you in several ways:

- You may have access to new medicines, combinations of medicines or methods that are not otherwise available to you outside of the clinical trial.
 - ▶ **Tip:** These may be more effective or have fewer side effects than standard treatment.
- You will always receive *at least* the current standard recommended treatment for the type of breast cancer you have.
- Your cancer treatment is closely monitored by study doctors and nurses, often more closely than in standard care. An independent Data Safety and Monitoring Board also safeguards your care (see page 34).
 - ▶ **Tip:** You may get more follow-up care as well.
- If a new treatment works, you may benefit from it before it is generally available.
- Some trials give you access to medicines, complementary treatments or supportive therapies for no charge.
 - ▶ **Tip:** Check on what your insurance will cover (see page 17).
- All new breast cancer treatments must go through the clinical trial process. You may feel good knowing that your participation could help not only you but also other women affected by breast cancer.

Possible Risks or Drawbacks

Being in a clinical trial raises issues that may concern you:

- The new treatment being tested might not be more effective than the standard.
- Even if the new treatment is shown to be more effective, it might not work for you.
- You may have side effects that are worse than those in standard treatment or that researchers did not know about.
 - **Tip:** Call the research nurse to talk about side effects you may have; many side effects can be lessened.
- In a randomized trial, you won't be able to choose your treatment.
 - **Tip:** If you meet the study rules for participation, any of the proposed treatments would be appropriate for you.
- There may be costs for medicines, tests and doctor visits related to the trial that your health insurance might not cover (see page 17).
 - **Tip:** Study sponsors may cover some costs, but not always.
 - **Tip:** Read LBBC's *Guide to Understanding Financial Concerns* to learn about resources to help with added costs (visit lbbc.org).
- You may need to take extra time off from work or your personal life, or have more travel or childcare costs, because of more frequent doctor visits or distance to the research site.
 - **Tip:** If you meet certain criteria, the federal Family and Medical Leave Act of 1993 protects you and your caregiver from losing your jobs because of time missed for medical reasons.
 - **Tip:** After the treatment portion of the trial is over, you can return your care to your original doctor and possibly reduce travel.

- Each trial has its own eligibility requirements. You might not be eligible to join a specific study if you previously had treatment or if it requires that you not have a certain condition, such as high blood pressure, that is restricted from the trial.

If Side Effects Should Arise

Tell the research nurse or doctor about any side effects you have. Keep a diary to track when side effects occur, their intensity and how long they last. Call promptly with your concerns and try not to worry about being a "bother." Your healthcare team wants to know about your side effects so they can help you.

Side effects often can be managed successfully. If side effects are severe and you must exit the trial (or decide to leave it), you will be given appropriate standard treatment.

VOICE OF EXPERIENCE

"A clinical trial isn't for everyone, but there are those who say 'no' because they have wrong information or a preconceived notion...Take more control of your health during the treatment process. Get a thorough understanding of the drugs. Actively seek out clinical trials. And talk to other women who are in the same trial you're being asked to go into."

Michele, Stage II breast cancer, chemotherapy research study participant, currently in clinical trial testing effect of medicines on recurrence

10 Things YOU MIGHT NOT KNOW ABOUT BREAST CANCER CLINICAL TRIALS

- 1 There are many more clinical trials available today for breast cancer, held in many more places, than in the past. More women now take part in trials close to home at local hospitals and doctors' offices.
- 2 Breast cancer clinical trials are for women (or men) with early-stage disease as well as those with more advanced breast cancer. Studies are important to improve treatment for all breast cancer stages.
- 3 Clinical trials are one possible option among initial treatment choices, not something to consider only when there are no other options for treatment.
- 4 Participants in phase II or phase III clinical trials will receive *at least* the current standard best treatment. No one is ever given a placebo or sugar pill *instead of* appropriate treatments.
- 5 Some medicines and approaches are available only through clinical trials.
- 6 You have the right to quit a clinical trial at any time, for any reason. Many concerns can be lessened by talking with your doctor or nurse. If you are not doing well on a trial, it is unethical to keep you on it and you will be taken off. If you leave a trial, you will continue to get the best standard treatment appropriate to your condition.
- 7 New medicines go through years of review before the FDA agrees they are safe for human testing in clinical trials.
- 8 The number of people living longer after breast cancer has risen dramatically in recent years because of treatments and tests that were once under study but proved effective through clinical trials.
- 9 If a new treatment is shown to be more effective than standard treatment, the trial may be stopped, the participants told and therapy options discussed—including getting the new treatment.
- 10 Participants are protected from abuse in clinical trials. Informed consent requires that you be told on an ongoing basis about any benefits or risks found during the study.





Time for Discussion

You might first hear about enrolling in a clinical trial for breast cancer treatment from your doctor or other healthcare provider. Sometimes, however, that's not the case, especially if your doctor doesn't take part in research studies.

Despite the growing number and locations of trials, you're still more likely to hear about them from providers at larger hospitals and cancer centers than from those in smaller institutions or community-based private practices. Doctors who aren't involved in clinical trials might not know about what's available, or they may hesitate to refer you elsewhere. Some also might decide, without asking you, that you wouldn't be interested in taking part.

Your First Step

If your healthcare provider doesn't raise the subject of clinical trials during your discussion about treatment options, ask directly about them.

To prepare for that conversation, you will want to know what types of trials may be available. Searching for clinical trials on the Internet can be confusing. To help you, we've included some trustworthy groups and Web sites in this guide (see page 40) and on a bookmark attached to the back cover. Some sources have telephone helplines as well.

Because treatment studies are designed for specific types of breast cancer, gather your diagnosis and test results before starting your search. Ask your healthcare provider if you need help. Your pathology report and other records should show your breast cancer stage, hormone receptor (ER/PR) status, lymph node involvement, HER2 status and other information you might need. (To learn more about your pathology report, read LBBC's *Guide to Understanding Treatment Decisions*, at lbcc.org.)

Look for trials based on your type of breast cancer, not on what you've heard about a new treatment that's in development. That new treatment might not be ready for human testing or it could be for a different type of breast cancer than you have.

Sharing the Information

You may find one or more trials that match your diagnosis. To learn more about each of them, search Web sites run by accredited organizations, such as universities or cooperative clinical trials groups. If you don't have computer access, public libraries and those in cancer centers can help, or use the toll-free numbers for resources in this guide (see page 40). Then take the basic details of each study to the treatment discussion with your doctor or healthcare team. Talk with your providers about all of your treatment options, including participating in a clinical trial.

It is common to get a second opinion when considering your choices for breast cancer treatment. Many states require insurers to cover second opinions. Check with your state insurance agency for laws that apply where you live. If your doctor doesn't take part in studies, ask for a second-opinion referral to a doctor who does. Ask the second-opinion doctor about any trial that may be right for you. The list of questions for providers (see page 31) will help you with that discussion.

Remember, this is a time to understand *all* of your breast cancer treatment options. You might worry that you will insult your doctor by taking part in a research study elsewhere. But your doctor wants the best care for you, and sometimes that means a clinical trial at another location.

After getting a second opinion, you can decide what treatment plan best fits your needs and lifestyle.

VOICE OF EXPERIENCE

"I had no idea about clinical trials, but my doctor suggested that with my cancer one would be good. I had a better chance of no recurrence. It meant four more treatments of chemo...My sister was with me at the time. We both agreed it would be something worthwhile."

Harriet, Stage I breast cancer, chemotherapy clinical trial participant

When Your Healthcare Team Suggests a Clinical Trial

To talk about a specific study with your healthcare team, prepare a list of questions that reflects your concerns, from why the trial is right for you to what treatment will be and how your care will be managed. The questions on page 31 of this guide should help you get started. You'll also find more suggested questions to ask at our Web site, lbcc.org.

Don't hesitate to ask your doctor or nurse to explain an answer again. This is a stressful time for you, and it's not easy to understand everything you hear right away. What's more, healthcare providers may use technical words geared for medical professionals. Bring someone with you to take notes while you focus on the discussion.

Keep in mind that enrolling in a clinical trial is voluntary. After considering the options with your doctor and family, make the decision that you feel is right for you.

VOICE OF EXPERIENCE

"We don't always have the right questions. They give you all these things to read, but when you're freaking out over cancer, you're reading that and not understanding what you're reading. Nothing is going to help me more than someone sitting down and talking to me."

Delia, Stage III breast cancer, currently on chemotherapy research study testing different treatment schedules



10 Questions TO ASK YOUR BREAST CANCER MEDICAL TEAM

This list will help you begin to talk with your doctors and nurses about whether a clinical trial is right for you:

- 1 What research studies are available as treatment options for me?
- 2 What is each trial seeking to find out?
- 3 What treatment under study in the trial will be added to the standard treatment I receive?
- 4 What are the potential benefits to me—and possible side effects or risks—of each trial?
- 5 Where will I go for treatment, how often, for how long, and which doctor will be in charge of my care?
- 6 Are the study costs covered by my insurance or by the trial sponsors? Are there other options if I do not have insurance?
- 7 Can the research staff arrange for me to talk with women who are taking part in the trial or who finished it?
- 8 Who will be monitoring my condition and treatment effectiveness? Who will be helping me if I have side effects?
- 9 For how long will I have follow-up exams after I finish the study?
- 10 How and when will I find out about the results of the trial?

For more questions you may want to ask, go to lbbc.org/content/news/questions-to-ask-about-clinical-trials.asp?section_tag=G.



Study Safeguards for Your Protection

When you take part in a breast cancer trial, your safety is vitally important. The researchers are ethically bound to protect you. What's more, federal laws specify that the study be closely monitored, from its design and participant selection through treatment, help with side effects, follow-up and reporting.

Those safeguards mean that independent groups are watching and evaluating what is going on. Researchers welcome this. They know that past abuses have left some people mistrusting medical research and declining to take part in trials because of fears.

Safety Oversight

Today, people in research studies are protected in several ways:

- Before a breast cancer treatment trial begins with humans, the new medicine or method must be researched, the data reviewed and the FDA must agree it is safe to use in humans. This takes several years.
- The informed consent process (see page 15) tells you how trial safety will be monitored, both by the researchers and outside boards (see next page). It also provides you with contact information for those responsible for safety.
- Safety is closely monitored during trial treatment. If side effects occur, talk with your research nurse for help. Data on side effects and outcomes are reported to safety regulators, government agencies and the sponsor.

➤ **Tip:** If you have concerns about safety or anything else, talk with your healthcare team. It's your right.

- An **Institutional Review Board (IRB)**, made up of medical professionals, patient advocates and others, examines the protocol before the study begins, approves it if warranted, and provides ongoing review. The IRB can stop a trial that's being conducted incorrectly or causing harm—and also may stop a study that's showing success, to make the new approach available sooner.
- The **Data Safety and Monitoring Board (DSMB)**, another group of experts, reviews phase III trials to keep risks low and check reports. The DSMB can stop a study for safety concerns.
- Follow-up care on clinical trials requires your doctors to watch for late side effects. They must report them. Many studies have a follow-up schedule similar to what you would have on standard treatment.

Learning Trial Results

Each clinical trial has a goal for the number of people the researchers hope to enroll. It may take a long time to reach that number, in part because of low participation rates (see next page). After a study has enough participants, researchers must wait to see treatment results. That's why it may be several years before full study results are released.

Clinical trial researchers stay in touch with participants even after follow-up exams are complete. As part of informed consent, you should be told how you will receive study results. To make sure you get a final report, let the research staff know your current contact information.

VOICE OF EXPERIENCE

"I really liked the fact that they were going to do something with my data [results]."

Vera, Stage II breast cancer, chemotherapy clinical trial participant, currently on research study about increasing exercise after treatment





*Needed:
More Women to Play
a Vital Role*

Advances in breast cancer treatment can happen *only* through clinical trials. Yet the pace of discoveries is slowed because there aren't enough participants signing up in the United States. Just 3 percent of those in treatment for breast cancer agree to take part in studies.

What does that low participation mean to results? The Coalition of Cancer Cooperative Groups looked at breast cancer studies that were high priority because of their potential positive impact on the disease—those trials needed 43,500 participants to be completed, but had enrolled less than half that number. Advances that might be possible from those trials will have to wait until more people join.

How You Can Help

You can make important contributions to progress in breast cancer treatment, in several ways:

- Consider taking part in a clinical trial as one of your options for breast cancer treatment.
- By taking part in a trial, you add your racial, ethnic, economic, age or educational background to the scope of breast cancer research and help identify effective treatments for more diverse populations. This can help move forward breast cancer care for many more women.
- Share your clinical trial experiences with other women who are facing a breast cancer diagnosis. Encourage them to consider treatment through a clinical trial. Connect in support groups, online and through personal contacts.

- Tell your doctor or research nurse that you're willing to talk with other women who are considering clinical trial participation.
- Use your community connections to spread the word about clinical trials. Talk about being a study participant to neighbors, congregants in your place of worship, co-workers, friends and family.
- Pass along a copy of this guide to anyone facing breast cancer treatment. All Living Beyond Breast Cancer guides are free and available at lbcc.org or by calling the free Survivors' Helpline at (888) 753-LBCC (5222).

VOICE OF EXPERIENCE

"Whatever your experience is, it contributes to knowledge. If you don't have that many women of color in a clinical trial, you can't talk about how much it works for women like you."

Rose, Stage IV breast cancer, received investigational medicines as participant in chemotherapy and post-treatment research studies





*Resources to
Find the Right
Research Study for You*

The Web sites and databases below can help you search for breast cancer clinical trials. You'll also find some listed on the tear-off bookmark on the back cover of this guide.

Before searching for trials, it's helpful to get your pathology report and test results to know if you fit the medical criteria for each study. When you find trials that seem right, bring the details (including study number and sponsor) to your doctor or healthcare provider to talk about which ones you might consider.

Information is current as of December 2009 but may change.

Web Sites

These sites have searchable databases of clinical trials. Many of the trials listed will be the same. The biggest difference between sites is how you search for trials. If you don't have access to a computer, ask for help in your local library or call the phone numbers where listed:

- BreastCancerTrials.org
- CenterWatch:
centerwatch.com/clinical-trials/listings
- Coalition of Cancer Cooperative Groups (TrialCheck): (877) 227-8451,
cancertrialshelp.org
- EmergingMed: (877) 601-8601,
emergingmed.com
- National Cancer Institute (NCI):
(800) 422-6237, cancer.gov/clinicaltrials
- National Institutes of Health (NIH):
clinicaltrials.gov
- SearchClinicalTrials.org: (877) 633-4376,
searchclinicaltrials.org

Organizations

These groups have general information about clinical trials and services that may help you connect with women who participated in studies:

- Living Beyond Breast Cancer (LBBC): education and support, online message boards, Survivors' Helpline, (888) 753-LBBC (5222), lbbc.org
- Breastcancer.org: education, online discussion board, breastcancer.org
- Facing Our Risk of Cancer Empowered (FORCE): for those affected by hereditary breast or ovarian cancer, (866) 824-7475, facingourrisk.org
- Love/Avon Army of Women: seeks to increase prevention research, recruiting participants after breast cancer treatment, those at high risk and those with no breast cancer history, armyofwomen.org
- Young Survival Coalition: breast cancer support and information geared to younger women, message boards, (877) 972-1011, youngsurvival.org

Note: For privacy reasons, the names of women speaking in the Voice of Experience quotes are pseudonyms.

Many thanks to these individuals who gave their time and expertise for this guide:

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(610) 645-4567 phone
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Survivors' Helpline: (888) 753-LBBC (5222)

When you are ready, we encourage you to call our **SURVIVORS' HELPLINE** at **(888) 753-LBBC (5222)** for guidance, information and peer support. Our national, toll-free service is staffed by trained volunteers affected by breast cancer. Spanish-speaking Helpline volunteers are available.

Read about
10 good ways to
find clinical trials
on the reverse side.



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10 Good Ways

TO FIND BREAST CANCER CLINICAL TRIALS

Web sites may list many of the same trials, but differ by how specifically you can search.

- 1 Ask your healthcare provider about clinical trials when first discussing your breast cancer treatment options.
- 2 Request a second opinion from a doctor who conducts research studies.
- 3 Know your diagnosis, stage and treatment history and search emergingmed.com or call (877) 601-8601.
- 4 Check the National Cancer Institute database at cancer.gov/clinicaltrials or call (800) 422-6237.
- 5 Search TrialCheck listings from the Coalition of Cancer Cooperative Groups at cancertrialshelp.org or call (877) 227-8451.
- 6 BreastCancerTrials.org searches by medical details.
- 7 CenterWatch has trials sponsored by industry and government at centerwatch.com/clinical-trials/listings.
- 8 Get help finding studies at searchclinicaltrials.org or call (877) 633-4376.
- 9 Contact breast cancer organizations, such as Living Beyond Breast Cancer, for guidance about finding clinical trials.
- 10 Talk with other women who participated in breast cancer treatment trials.



Help us! If you have had breast cancer, please fill out the survey below and return it in the enclosed envelope or visit lbcc.kintera.org/researchstudies.

Please choose the answer that best describes how you feel about these statements.

1. After reading this brochure, I better understand the role clinical trials play in finding new treatments for breast cancer.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

2. After reading this brochure, I better understand how clinical trials work.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree


3. After reading this brochure, I better understand the benefits and risks of taking part in clinical trials.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

4. After reading this brochure, I better understand the laws that protect trial participants from abuse.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

5. After reading this brochure, I better understand how enrolling in clinical trials may benefit me and others.

- Strongly agree
 - Agree
 - Undecided
 - Disagree
 - Strongly disagree
- 

6. After reading this brochure, I am more likely to ask my healthcare provider about clinical trials that may be right for me.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

7. I found this brochure easy to read.

- Strongly agree
- Agree
- Undecided
- Disagree
- Strongly disagree

8. Which sections were most helpful to you?

Choose all that apply.

- I: Looking at Breast Cancer Research Studies
- II: Exploring Clinical Trial Details
- III: Possible Benefits and Concerns
- IV: Time for Discussion
- V: Study Safeguards for Your Protection
- VI: Needed: More Women to Play a Vital Role
- VII: Resources to Find the Right Research Study for You

9. Which sections were least helpful to you?

Choose all that apply.

- I: Looking at Breast Cancer Research Studies
- II: Exploring Clinical Trial Details
- III: Possible Benefits and Concerns
- IV: Time for Discussion
- V: Study Safeguards for Your Protection
- VI: Needed: More Women to Play a Vital Role
- VII: Resources to Find the Right Research Study for You

10. How likely is it that you will save this brochure and use it in the future?

- Very likely
- Likely
- Undecided
- Somewhat unlikely
- Definitely unlikely

11. After reading this brochure, how likely are you to use LBBC's other services?

- Very likely
- Likely
- Undecided
- Somewhat unlikely
- Definitely unlikely

12. How did you get this brochure?

- A doctor, nurse or other healthcare provider handed it to me.
- I picked it up while at a doctor's office.
- A friend or family member gave it to me.
- I got it at a support group.
- I read it on or downloaded it from lbbc.org.
- I heard about it from Living Beyond Breast Cancer, and I ordered it.
- I heard about it in a newspaper, in a magazine or on the radio, and I ordered it.
- I don't remember.
- Other.

12a. If other, please explain:

13. When did you get this brochure?

- At the appointment when I was diagnosed.
- In the first year after my diagnosis, during initial treatment (surgery, chemotherapy, radiation).
- One to three years after my diagnosis, after I finished initial treatment.
- More than three years after my diagnosis.

14. The most recent time you wanted information on cancer, where did you look first?

- Brochures or pamphlets
- Cancer organization
- Family
- Friend/co-worker
- Healthcare provider
- Internet
- Library
- Magazines or newspapers
- Another person with cancer
- Telephone information number (800 number)
- Other

14a. If other, please explain:



Please tell us a little more about you!

15. What is your home zip code? _____

16. What year were you born? _____

17. What year were you diagnosed with breast cancer? _____

18. What was the stage of breast cancer you were diagnosed with?

- Stage 0 (ductal carcinoma in situ)
- Stage I
- Stage IIA or IIB
- Stage IIIA or IIIB
- Stage IV
- I don't know.

19. What racial or ethnic background do you most closely identify with?

- African-American
- Asian
- Hispanic or Latino
- Mixed Background
- Native American or Alaska Native
- Pacific Islander
- White, not Hispanic or Latino
- Other
- I prefer not to say.

20. What is the last grade of school you completed?

- Some high school
- High school graduate/GED
- Some college or vocational/technical training after high school
- College degree
- Master's degree
- Doctorate degree

If you would like to be added to Living Beyond Breast Cancer's mailing list, please fill out the information below:

FIRST NAME

LAST NAME

EMAIL

ADDRESS

CITY

STATE

ZIP CODE

COUNTRY

I would prefer to receive information from LBBC by (choose all that apply): Email Standard Mail