Clinical Trials
Dear Friend:

One of your options for breast cancer treatment may be a clinical trial, or research study. Breast cancer clinical trials give you the chance to receive either a new treatment or the best standard treatment available.

While joining a trial may sound scary, it’s important to realize that all the breast cancer treatments we have today were first proved effective in clinical trials. 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 and possible benefits and risks of enrolling. Here, you’ll find questions to ask and how to find trials that may be right for you. You’ll also hear advice from people who participated.

We encourage you to get answers to all your questions. Call our Breast Cancer Helpline at (888) 753-LBBC (5222), or chat with us online at lbbc.org/helpline for information and peer support as you consider your options.

Warmly,

Jean A. Sachs, MSS, MLSP
Chief Executive Officer

Note: For privacy reasons, the names of women quoted in this guide have been changed.
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Looking At Breast Cancer Clinical Trials

Years ago, most women 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 options. Today, clinical trials have changed breast cancer treatment from a one-size-fits-all approach to tailored treatment options.

You may be thinking about taking part in a clinical trial or research study and wonder what that would mean for you. Maybe your healthcare team suggested you have treatment through a clinical trial or you learned about a trial that interests you online or from a friend.

The treatments we have today are available only because they were found effective in clinical trials. Examples of these breakthroughs include:

- the benefits of lumpectomy
- the use of tamoxifen to lessen the chance that cancer will come back in hormone receptor-positive disease
- the use of trastuzumab (Herceptin) in HER2-positive disease
- the benefit of aromatase inhibitors for post-menopausal women

As science advances, the number of breast cancer clinical trials continues to grow. So does the need for more people — women and men from all racial and ethnic backgrounds, all ages and communities — to take part. By joining, you help researchers find new ways to treat and prevent breast cancer.
Clinical Trial 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 feel overwhelming to be asked to take part in a clinical trial when you’re already feeling anxious about your health.

It’s normal to feel hesitant or even fearful about choosing treatment through a clinical trial or research study. Many people find that as they learn more about how clinical trials work and how the trial treatments are given, they feel more comfortable choosing to join one.

Understanding the words you’ll hear 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
- a new combination of existing medicines or therapies
- the treatment sequence, the order in which medicines are given, or of the dosing schedule
- how medicine is given, such as by mouth or injected

Other research studies look at ways to:
- screen for breast cancer
- manage symptoms
- keep the cancer from coming back
- find genetic connections
- use complementary therapies
- improve quality of life

Clinical trials are a reasonable treatment option when you are first diagnosed with breast cancer and after you’ve started treatment. Some trials look only for people who haven’t started treatment. Other trials are designed for people who had treatment in the past, or those with metastatic disease (see page 26).

Treatments go through years of early testing before they are ruled safe for clinical trials. Laws protect your safety. An informed consent process (page 12) gives you information and allows you to leave a trial for any reason.

You Will Always Get Treatment

The clinical trials that most people join compare a new medicine or combination of medicines to the current recommended treatment, called the standard of care. If you join a trial, the researchers will assign you to one of two or more groups to get a certain treatment.

No matter which group you’re assigned to, you will get the best treatment available to you. No one is ever given a placebo, an inactive substance or sugar pill, instead of treatment unless there is no standard treatment. Everyone in the trial gets at least the standard treatment.

Every trial is monitored by a safety and review board responsible for protecting participants from harm. Learn more about this process on page 42.

Read more about how clinical trials are designed on page 18.
Timing Is Important

You may have heard that clinical trials are for people who have no other treatment options. This common myth may make you feel that choosing a clinical trial for treatment is giving up, or it should only be used as a last resort.

In reality, clinical trials are a valid treatment option for everyone with breast cancer. It’s best to look for trials before you begin treatment. The therapies under study often provide the largest gains to recently diagnosed people with early-stage disease — stages 0, I, II, and III — who haven’t yet started treatment.

Each trial has precise rules for who can participate, and when. For example, you may not be able to join 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 your treatment plan, ask your doctor about clinical trials (see page 34).

Where Studies Take Place

A trial may take place at one site, 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 and around the world.

If a trial you want to join is only being held in one place far from where you live, you may still be able to enroll. In this case, you will most likely need to travel to that site for treatment. Sometimes the research doctors may be able to speak with your oncologist so that you can take part from your home cancer center. Contact the trial team to find out whether the study is available in your area.

If you’re interested in a trial held in many places, your hospital or treatment center may offer it. Talk to your healthcare team to find out.

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

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

"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 the medicine under study

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

—TERESA

stage II breast cancer, participated in a trial of medicine to prevent recurrence and other studies on long-term treatment side effects
Details of Joining a Trial

Taking part in a breast cancer study is often similar to getting 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, he or she may be one of several doctors involved, called sub-investigators. Sub-investigators give treatment at any location where the research is done. Other team members may include research nurses, data managers, therapists and technicians.

You will likely have the 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, protections for your safety, and more. The nurse also may coordinate medical tests and appointments and monitor your quality of life.

Before starting treatment in a trial, you will go over the research protocol and give informed consent.
What Is a Research Protocol?

Each clinical trial has a scope, plan and structure. This research roadmap, called a protocol, provides important details you need to know to decide which trial may be right for you.

The protocol includes:

- the name and phase of the study
- the goals of the research
- who can take part (age, past treatment, health history)
- how many people the study needs
- the type or types of treatment being studied, how you will be assigned to treatment, and how the treatment is given
- how you will be monitored over time, including after the trial ends
- the contact information for trial staff and safety reviewers

The protocol can be very long and written in scientific language. You may want to review it and ask your healthcare team questions about it during the informed consent process. The protocol will appear on a shorter form you will get before starting the trial, which you will need to sign to give your consent.

What Is Informed Consent?

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

Before you take part in a trial, read about it and talk with your doctor, the research nurse and others involved. Connecting with people who participated in that study or other studies also may be helpful.

Informed consent is an ongoing system of conversations like these to help you fully understand what joining the trial means for you. This may take place one day or, more often, over several days. You will have informed consent discussions with the research team overseeing the study before you will be allowed to sign up. You’ll continue to have them even after you sign the informed consent form.

My job is not to tell my patients what to do but to give them information about the pros and cons of the options in a way they can fully understand, so they can make a decision for themselves.” —PALLAV MEHTA, MD

a doctor who conducts breast cancer clinical trials

During the informed consent process, you will:

- get written materials explaining trial details, treatment options, possible side effects and potential benefits
- learn your responsibilities and those of the research team
- be given time to ask questions of the study team, including the doctor, before and after you agree to take part
- find out who oversees trial safety and how to contact that person if you need to
- be advised that you can leave the trial at any time, for any reason, without it affecting your continued and future treatment
- learn about trial costs and whether your insurance will cover them
- have time to think about what you’ve learned and whether joining the trial is right for you

You will have time to read and ask questions about the informed consent information. If you are not
comfortable reading in English, it’s OK to ask for the materials and consent form in your native language so you can understand the information well.

You may be given a lot to read, and it can be overwhelming. The research nurse will walk you through the details and explain complex language. Even after you sign the informed consent form, if you have concerns about anything, talk with your nurse or doctor.

Paying for Clinical Trials

If you join a clinical trial, your treatment costs may include:

- **Routine care.** The doctor visits and tests you would have had in standard treatment
- **Research costs.** The trial medicine and any extra tests or office visits needed for the research

Under the Affordable Care Act (ACA), health insurance companies must cover costs of routine care in approved clinical trials. These costs are the same as would be covered if you were being treated for breast cancer outside a clinical trial. The only exceptions are insurance plans labeled **grandfathered.** Grandfathered plans are those that existed on or before March 23, 2010, when the Affordable Care Act became law. Grandfathered plans are not required to cover routine care in clinical trials.

Approved trials are funded by a federal agency, such as the National Institutes of Health, and have applied to the U.S. Food and Drug Administration (FDA). The clinical trial team can tell you if the study is approved.

Insurers are not required by the ACA to cover the research costs. Some clinical trials have sponsors who will cover the cost for participants, but not always. They may also reimburse you for other expenses, such as childcare and travel. You should ask about what’s covered during informed consent. It’s also important to check with your insurance company to see if you will have **in-network** or **out-of-network** costs by seeing the trial doctor.

If you do not have health insurance, or have other financial concerns, talk with the nurse or others on your healthcare team before you join the clinical trial.
Federal Insurance Programs

If you don’t have insurance and are eligible, the federal government offers two health insurance options for which you can apply.

MEDICARE

Medicare is a program for people who are over age 65, are younger than 65 and who have certain disabilities, or who have permanent kidney failure or Lou Gehrig’s disease (ALS).

Medicare typically covers 80 percent of your routine care costs in approved clinical trials, with you paying the other 20 percent. It does not cover research costs, but the trial sponsor might. If you have a Medicare supplement plan, sometimes called Medigap, it will follow the same rules as Medicare. Another plan, Medicare Advantage, may cover more. It’s possible to cover your 20 percent of the costs by getting a second health insurance plan.

MEDICAID

Medicaid is available to people with low incomes, no or not enough medical insurance, or who have any income but very high medical costs due to severe medical need.

Overall, Medicaid plans are not required to cover the costs of clinical trials. But 38 states and the District of Columbia do require Medicaid to cover the cost of routine care for their residents. Check with your state insurance agency for laws that apply where you live.

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

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, osteoporosis prevention trial, mammography study and long-term health study

LEARN MORE

Find out more about the ACA and paying for treatment in our Guide to Understanding Financial Concerns.
Researchers design clinical trials to get the most useful information they can about the trial treatment, its safety and how well it works against the cancer. There are several types and phases of clinical trials you may be able to join.

This section will help you understand how the research doctors will assign you to a treatment and what being part of the trial means for you. If you have questions, it’s OK to ask your doctor for more information.

**Trial Types**

**RANDOMIZED TRIALS**

Most breast cancer trials are randomized. This means a computer, rather than a doctor, will assign you to a treatment group. Having a computer choose the treatment group gives everyone an equal chance of being assigned to a group without bias. And remember, no matter what, you will get treatment appropriate for breast cancer.

Many trials have several treatment groups, called arms. Each arm may get different treatments, or get therapy for varying lengths of time. At the end of the trial the research team will compare the arms to each other to learn how well the treatment worked.

Outside a clinical trial, you can have a say in which treatment options you want to try. To be part of a randomized trial, you must be willing to be assigned to a treatment, rather than helping to choose the treatment yourself.
Some trials are nonrandomized, and the trial doctor chooses the treatment you get based on your needs and other factors. These trials are usually smaller than randomized trials.

**BLINDED TRIALS**
You may hear your doctor or the trial team use the terms blinded, non-blinded, double-blinded or unblinded when talking about the study. These terms tell you whether you, or the researchers, know what treatment you’re getting during the trial.

- **In blinded trials,** you won’t be told what treatment group you’re in. You won’t know whether you are getting the standard of care medicine, or the standard of care plus the trial medicine.
- **In double-blinded trials,** neither you nor the research team knows what group you are in.
- **In non-blinded trials,** you and your doctor know which treatment group you are in, from the start.

A blinded trial may become unblinded. If your trial becomes unblinded, the research doctors will tell you which medicine you’ve been getting during the trial. This usually happens if the medicine under study is getting much better results than the standard of care. If the trial is unblinded, you may be given the chance to switch to the new medicine if you were not already on it.

**BASKET TRIALS**
A newer type of clinical trial is the basket trial. Unlike most clinical trials that test medicines in cancers based on where they are found — like the breast or colon — basket trials test medicines for tumors with a certain molecular trait. The molecular subtype is based on what proteins or other pathways spur the cancer to grow and how the cancer cells behave.

Researchers believe they may be able to explore new treatments faster by enrolling people whose cancers have the same molecular traits, no matter where the cancer is. For example, a study could enroll people with breast cancer, pancreatic cancer and prostate cancer, as long as the cancer cells behave the same and respond to the same proteins, hormones and pathways.

Basket trials are very new and smaller than other types of trials.

**UMBRELLA TRIALS**
Cancer differs from tumor to tumor, even when the cancer is found in the same place in the body. In breast cancer, there are four confirmed subtypes: luminal A, luminal B, HER2, and basal-like.

**Umbrella trials** allow researchers to study treatments that target individual subtypes within one type of cancer, all at once. For example, the study might only look at breast cancer, but have four arms: one each for luminal A, luminal B, HER2 and basal-like. Each arm might be given a different treatment.

This type of trial allows researchers to look for common biomarkers, hormones, proteins, and other molecules that sometimes help cancer to grow, in large groups of people. It can help researchers test medicines for groups of people whose cancers have rare biomarkers that aren’t often studied in clinical trials.
Trial Phases

Before a new medicine can be used in people, it must first be studied in cancer cells in a lab and then in lab animals. This ensures medicines are safe and meet requirements put in place by the FDA. When the safety research is complete, the FDA allows the medicine to go to trial in people.

The new medicine goes through four phases, or steps. The FDA reviews the findings from each step and gives approval for the medicine to move on to the next phase. Each phase is a separate clinical trial.

- **Phase I**: Measures safety, dosage and how the medicine is given. Usually enrolls fewer than 50 people who are healthy or have cancer. If they have cancer, it’s likely all other treatments have stopped working. Phase I can last up to 1 year.
  - Nonrandomized

- **Phase II**: Measures how well the treatment works against the cancer and watches for side effects. May enroll fewer than 50 to up to several hundred people who have cancer. Phase II can last up to 2 years.
  - Randomized or nonrandomized

- **Phase III**: Compares new, safe treatment to the current standard of care and measures side effects. Enrolls several hundred to several thousand people who are healthy or have cancer. Phase III can last several years.
  - Randomized

After phase III, the FDA reviews the findings and may give approval, which allows the medicine to be produced, sold, and used to treat the cancer.

Medicines may also go to phase IV after FDA approval. During phase IV, researchers watch for long-term side effects and monitor the medicine’s use in people who may not have been in the original trial, such as older people or pregnant women. Many medicines do not go to phase IV.

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Programs for Faster Approval

You may have heard news outlets announce that a breast cancer treatment was granted accelerated approval or breakthrough therapy designation. Perhaps you’ve heard someone say a medicine is going to priority review, or heard a researcher mention fast track.

The FDA offers these four programs to help the teams developing new medicines research them faster. They also allow the public access to them sooner.

**FAST TRACK**

In some cases, there is no medicine available to treat a serious medical condition. Or, there may only be one or a few medicines available.

If a new medicine is developed to treat a disease that has no therapy, it can be designated to fast track. Fast track gives the researchers:

- more meetings with the FDA to go over how the medicine is doing in clinical trials
- more FDA involvement in trial design
- a rolling review process, which allows the FDA to review parts of the new medicine application, rather than waiting for the whole document
- eligibility for accelerated approval and priority review (see page 24)

A medicine can also be designated fast track if other treatments exist for the disease but the new medicine:

- proves much more effective than the existing treatment
- avoids very serious side effects the existing treatment causes
- addresses a public health need
BREAKTHROUGH THERAPY DESIGNATION
If a treatment is in early phase I trials and data suggest it may be better than the treatments now available, the FDA may grant it **breakthrough therapy designation**. Breakthrough therapy designation gives the researchers the same advantages as fast track, as well as extra guidance on developing the treatment.

PRIORITY REVIEW
After research on a new medicine is complete, its developers must apply for FDA approval to produce and sell it. The FDA has a detailed review process every new treatment goes through before it is given approval.

The standard review process typically starts within 10 months of application. But sometimes, a new treatment shows so much promise that everyone involved wants it to be reviewed earlier. If this is the case, a medicine can be given **priority review**, which means the FDA will start reviewing it for approval within 6 months of application.

ACCELERATED APPROVAL
Typically, a medicine must go through all three clinical trial phases (see page 22) before the FDA will review it for approval. But if it shows enough promise in earlier phase II trials, the FDA can consider it for **accelerated approval**. Accelerated approval is given to treatments that show signs of extending life, before phase III trials confirm that they do — making them available for use sooner. Many medicines given accelerated approval go through priority review first.

Understanding Trial Results
It may be several years before the trial results are known. Each clinical trial seeks a certain number of people to enroll, but low participation rates (see page 45) can delay or stop a trial. After a study has enough participants, researchers must wait to see treatment results.

During informed consent, you should be told how you will receive study results. Clinical trial researchers will stay in touch with you even after follow-up exams are complete. To make sure you get a final report, keep the research staff updated with your contact information.
Clinical Trials for Metastatic Breast Cancer

If you have metastatic breast cancer, you and your care team will talk regularly about your treatment options, how side effects are impacting your day to day life, and when to switch to a new medicine. During these conversations, ask about clinical trials. Clinical trials can give you access to treatments that may be effective but are not yet approved by the FDA.

Trials in stage IV breast cancer have the same structure as other clinical trials, but some may require fewer people to take part than you might see in early-stage disease. Also the goals, or endpoints, might be different. For example, a trial in metastatic disease might explore how long a medicine keeps the cancer from growing or spreading, instead of trying to find out if it gets rid of the cancer entirely.

Remember that joining a clinical trial is not a sign of giving up or a last resort. In most cases, new anticancer treatments are used in clinical trials for people with stage IV cancer before they’re used in early-stage disease. Many allow you to join even if you’ve had other treatments in the past.

You may want to join a trial early in your treatment because

1. some trials won’t allow you to join if you’ve had certain medicines in the past
2. trying a trial first will give you more treatment options over a longer period
3. if the trial medicine doesn’t work, you still have standard treatments to go back to

Most trials require you to be well enough to keep up with your regular daily activities. Your doctor might call this your performance status, which for most trials must be 0 or 1.

Some trials look for people with metastatic disease in certain areas of the body, such as the bones or lungs. These trials may also require that the lesions, or mets, can be measured on an imaging test. Others may not allow you to join if you have mets in certain areas, such as the brain, because they need to be treated differently.

Like trials that enroll people with early-stage disease, trials for metastatic breast cancer are carefully monitored for safety (see page 40). Your clinical trial experience will be the same as someone who has early-stage disease.

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 and participant in study about increasing exercise after treatment
Things to Consider

When you think about getting 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 support network and healthcare team about these issues.

Potential Benefits

- **Access to new medicines.** Clinical trials may give you access to new medicines, combinations of medicines or methods that are not available to you outside a clinical trial. These may work better or have fewer side effects than standard treatments.

- **A very involved healthcare team.** Study doctors and nurses closely monitor your treatment, often more closely than in standard care. An independent Data Safety and Monitoring Board safeguards your care (see page 42). You may also get more follow-up care after treatment ends.

- **Saved costs.** Some trials give you access to medicines, complementary therapies or supportive care for no charge. Check on what your insurance will cover and ask the trial team what’s included.

- **Helping others like you.** You may feel good knowing your participation could help not only you but also others affected by breast cancer, now and in the future.
Potential Risks or Concerns

- **Effect of medicine.** The new treatment being tested might not work better than the standard. Even if it is effective in the overall group of participants, there is still a chance it might not work for you.

- **Side effects.** You may have side effects that are worse than those in standard treatment or that researchers did not know about. Remember that you can call the research nurse to talk about any effects you have, and many can be lessened.

- **Choosing treatment.** In a randomized trial, you won’t be able to choose your treatment. If you meet the guidelines to take part, any treatment in the study will be appropriate for you.

- **Higher costs.** There may be costs for medicines, tests and doctor visits related to the trial that your health insurance might not cover. Study sponsors may cover some costs, but not always.

- **Time.** You may need to take extra time off from work or your personal life, or have more travel or childcare costs, because of the study. If you meet certain criteria, the federal Family and Medical Leave Act (FMLA) protects you and your caregiver from losing your jobs because of time missed for medical reasons. Learn more about FMLA at LBBC.ORG.

If You Have Side Effects

Tell the research nurse or your 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 don’t 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. If side effects are severe and you must exit the trial or decide to leave it, you will be given appropriate standard treatment.

A clinical trial isn’t for everyone, but there are those who say no because they have wrong information or a preconceived notion. Get a thorough understanding of the drugs. 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, clinical trial testing effect of medicines on recurrence*
10 THINGS YOU MIGHT NOT KNOW ABOUT CLINICAL TRIALS

1 Clinical trials for breast cancer are held in many more places than in the past. People 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 any stage of disease. Studies are important to improve treatment for people with all breast cancer stages.

3 Clinical trials are a valid treatment option. They are not a last resort or a sign of weakness.

4 You will always be given the best treatment available to you, as long as a standard treatment is available. In breast cancer, it’s very unusual to only receive a placebo (see page 7) in phase II or III trials. If you’re concerned, ask the trial team before you join.

5 Some medicines and therapies are only available through clinical trials.

6 You have the right to quit a clinical trial at any time, for any reason. Talking to your trial doctor or nurse can ease any worries you have, but you may choose to leave at will. If you exit a trial, you will be given the best standard treatment available to you.

7 Medicines go through years of review by the FDA before they are deemed safe for human testing in clinical trials.

8 The number of people living longer after breast cancer has risen dramatically because of treatments studied and proved effective in clinical trials.

9 If the new treatment is shown to be better than the standard treatment during the trial, you may be told what medicine you’ve been taking — the standard or the study medicine — and given the option to take the new treatment.

10 Participants are protected from abuse. Informed consent (see page 12) requires that you be told on an ongoing basis about any benefits or risks found during the study.
Talking to Your Healthcare Team

You might first hear about clinical trials from your doctor or another healthcare provider. But sometimes that may not be 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 larger hospitals and cancer centers than from smaller groups or private practices. Doctors who aren’t involved in research might not know what’s available, or may hesitate to refer you. Some also might decide, without asking you, that you wouldn’t want to take part.

If your healthcare provider doesn’t bring up clinical trials when you talk about treatment options, ask directly about them.

Look for Trials First

To prepare for that conversation, learn what trials may be available by searching trial listings. To help you, we’ve included some trustworthy groups and websites in the resource section. If you don’t have a computer, public libraries and cancer centers can help. Some resources have toll-free numbers listed in the back of this guide (see page 48).

Some studies are designed for specific types of breast cancer, so you may need certain details about your diagnosis to search for them. You can find this information in your pathology report, a document that
profiles the cancer’s stage, size, location, hormonal status, and other data. Ask your healthcare provider if you need help finding these details. If you are looking at basket or umbrella trials (see page 21), you may only need to know if you carry a gene mutation.

**LEARN MORE**

Learn more about your pathology report in our *Guide to Understanding Treatment Decisions* and at LBBC.ORG.

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**Sharing What You Find**

You may find one or more trials you’re interested in learning more about. You can try searching for them at the websites of universities or cooperative clinical trial groups. Or, call the toll-free number listed with the researcher information. You can usually find this information on a trial's detail page online.

Take the basic details of each study with you when you talk with your doctor. Ask about the trials you found and if there are others you should consider.

If your doctors don’t take part in studies, you feel they don’t support your interest or they aren’t able to answer the questions you have, it’s OK to get a second opinion. Your doctor may even be able to refer you to a doctor who knows more about trials.

It’s common to get a second opinion when making decisions about breast cancer treatment. Ask the second-opinion doctor about any trial that may be right for you.

Remember, this is a time to understand *all* your breast cancer treatment options. You might worry you will insult your doctor by taking part in a 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 you.

**LEARN MORE**

Learn more about second opinions at LBBC.ORG.

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**When Your Healthcare Team Suggests a Clinical Trial**

If your healthcare team suggests a clinical trial, it’s OK to ask questions and let them know about your concerns. Prepare a list of questions to find out why the trial is right for you, what treatment will be and how your care will be managed. The questions on page 39 will get you started.

Don’t hesitate to ask your doctor or nurse to explain an answer again. This is a stressful time, and it’s not easy to understand everything you hear right away. Healthcare providers also may use technical words. If you’d like, bring someone with you to take notes while you focus on the discussion.

It’s up to you whether you choose to have treatment in a clinical trial. Clinical trials are always voluntary.

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"Nothing is going to help me more than someone sitting down and talking to me.”

—DELIA

*stage III breast cancer, chemotherapy research study participant, clinical trial testing different treatment schedules*
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

10 QUESTIONS TO ASK YOUR MEDICAL TEAM

1. What clinical trials are available as treatment options for me?

2. What is each trial seeking to find out?

3. What treatment is under study in each trial?

4. What are the potential benefits, side effects or risks?

5. Where will I go for treatment, how often and for how long? 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 don’t have insurance?

7. Can the research staff arrange for me to talk with others taking part in the trial or who finished it?

8. Who will monitor my condition and how well the medicine works? Who will help if I have side effects?

9. How long will I have follow-up exams after the study? How often?

10. How and when will I find out about the results of the trial?
How You’re Protected

When you take part in a breast cancer clinical trial, your safety is vital. The researchers are ethically bound to protect you. What’s more, federal laws require the study be closely monitored, from design and enrollment through treatment, help with side effects, follow-up care and reporting.

Those safeguards mean that independent groups are watching what is going on. Researchers welcome this. They know that past abuses have made some people fear and mistrust medical research and avoid clinical trials.

Today, people taking part in clinical trials are protected several ways:

- **The FDA.** The new medicine or method must be researched in the lab, the data reviewed and the FDA must agree it is safe to use in humans. The process can take several years.

- **Informed consent.** Informed consent (see page 12) tells you how trial safety will be watched by the researchers and outside boards. It provides you with contact information for those responsible for your safety.

- **Close monitoring.** Safety is monitored closely during trial treatment. If side effects occur, talk with the research nurse for help. Data on side effects and outcomes are reported to safety regulators, government agencies and the sponsor. If you have concerns about safety or anything else, talk with your healthcare team. It’s your right.
The Institutional Review Board. An Institutional Review Board (IRB) of medical professionals, patient advocates and others examines the study protocol (see page 12) 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. They may also stop a study that’s showing success, to make the new approach available sooner.

The Data Safety and Monitoring Board. The Data Safety and Monitoring Board, another group of experts, reviews phase III trials to keep risks low and check reports. They can stop a study for safety concerns.

Follow-up care. 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.
How You Can Help

Advances in breast cancer treatment can happen only through clinical trials. Yet discoveries come slowly because there aren’t enough people participating. In the United States, less than 5 percent of those in treatment for breast cancer agree to take part in clinical trials. More participants are needed from all over the country and from all racial, ethnic, and income groups.

You can help move breast cancer treatment forward by:

- **Getting treatment in a clinical trial.** By taking part, you add your racial, ethnic, economic, age and other personal factors to the scope of breast cancer research and help identify effective treatments for more diverse groups of people.

- **Sharing your experience with others with breast cancer.** Encouraging others to consider treatment through a clinical trial can help researchers enroll more people. This can move treatments forward, faster. Consider connecting with others in support groups, online and through your personal networks. Tell your doctor or research nurse that you’re willing to talk with others thinking about clinical trials.

- **Spreading the word about clinical trials.** Talk about your involvement in a study to neighbors, co-workers, friends and family.

- **Sharing this guide.** Pass along a copy of this guide to anyone facing breast cancer treatment. All Living Beyond Breast Cancer guides are free and available at LBBC.ORG or by calling toll-free (855) 807-6386.
Whatever your experience is, it contributes to knowledge. If [they] don’t have that many women of color in a clinical trial, [they] can’t talk about how much it works for women like you.”

—ROSE

stage IV breast cancer, received investigational medicines as a participant in chemotherapy and post-treatment research studies
Resources

These websites and databases can help you search for breast cancer clinical trials. When you find trials that seem right for you, bring the details, including study number and sponsor, to your doctor or other healthcare provider and talk about your options.

*Information is current as of April 2016 but may change.*

**SEARCHABLE DATABASES**

- American Cancer Society Clinical Trial Matching Service: (800) 303-5691, cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/app/clinical-trials-matching-service
- BreastCancerTrials.org, (415) 476-5777
- CenterWatch: (866) 219-3440, centerwatch.com/clinical-trials/listings
- ClinicalTrials.gov
- EmergingMed: (877) 601-8601, emergingmed.com
- National Cancer Institute (NCI): (800) 422-6237, cancer.gov/clinicaltrials

**SPECIFIC TO METASTATIC BREAST CANCER**

- Metastatic Trial Search: lbbc.org/metastatic-trial-search
GENERAL INFORMATION

Living Beyond Breast Cancer: lbbc.org/learn/treatments-and-research/clinical-trials
Breastcancer.org: breastcancer.org/treatment/clinical_trials
Metastatic Breast Cancer Network: mbcn.org/education/category/clinical-trials-q-a
Susan G. Komen: ww5.komen.org/breastcancer/clinicaltrials.html
Young Survival Coalition: youngsurvival.org/breast-cancer-in-young-women/living-with-breast-cancer/clinical-trials

ORGANIZATIONS WITH TRIAL LISTINGS

Living Beyond Breast Cancer: For trials for all stages and subtypes, lbbc.org/news-opinion (select “Featured Clinical Trials”). For trials specific to metastatic breast cancer, Metastatic Trial Search: lbbc.org/metastatic-trial-search
FORCE: For trials researching hereditary breast and ovarian cancer, facingourrisk.org/research-clinical-trials/studies-enrolling-patients/enroll-in-research.php

Words to Know

Arm. Treatment group within a clinical trial.

Basket trial. A clinical trial that tests medicines in different cancers that have the same gene mutations, or errors in DNA.

Blinded trial. A clinical trial in which you, or your doctors, are unaware of the medicine you are given.

Clinical trial. A research study conducted in people.

Double-blinded trial. A study in which both you and researchers do not know which treatment you are receiving.

Gene mutation. An error in DNA.

Informed consent. The process that tells about a trial’s purpose, possible benefits and risks, participants’ rights and more.

In-network. Healthcare providers who are on your insurance plan’s list of approved providers. Their services are covered by your plan.

Institutional Review Board (IRB). A group of medical providers and community members that evaluates and approves a study for safety before and during the trial.

Non-blinded trial. A clinical trial in which you and your doctor know which treatment group you are in from the start.

Nonrandomized trial. A clinical trial in which the doctor chooses which medicine a participant will receive, based on the person’s medical needs.
**Out-of-network.** Healthcare providers who are not on your insurance plan’s list of approved providers. Your plan may not cover their services, or only cover them in part.

**Participant.** A person taking part in a clinical trial. Their results will be analyzed with others to determine findings.

**Pathology report.** A report that describes the cells and tissues of a cancer, based on looking at them through a microscope.

**Phase.** Clinical trial testing step.

**Placebo.** An inactive substance or sugar pill.

**Principal investigator.** The researcher in charge of a clinical trial.

**Protocol.** The plan that describes what will happen in the trial and how it will be conducted. Also called research protocol.

**Randomized trial.** A clinical trial in which a computer randomly assigns people for each arm of the study.

**Research costs.** The costs of the trial medicine and any other tests or office visits needed for the research.

**Research or clinical trial nurse.** A nurse who serves as the link between the participant, doctor and the clinical trial. He or she provides information, answers questions, and collects and reports data.

**Routine care.** The doctor visits and tests you would have had in standard treatment.

**Sequence.** The order in which medicines are given.

**Standard of care.** The currently recommended treatment.

**Sub-investigator.** A doctor who gives the study treatment at any location where the research is done. A study may have many sub-investigators who work alongside the principal investigator.

**Umbrella trial.** A clinical trial that allows researchers to study treatments that target individual cancer subtypes within one type of cancer, all at once.

**Unblinded trial.** A clinical trial that was blind at first but in which you are told which treatment you are taking before it ends. This is done if the study medicine is getting better results than the standard of care.
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- Guide for the Newly Diagnosed
- Complementary Therapies
- Fear of Recurrence
- Financial Concerns
- Genetics and Family Risk
- HER2-Positive Breast Cancer
- Hormonal Therapy
- Intimacy and Sexuality
- Lymphedema
- Treatment Decisions
- Triple-Negative Breast Cancer
- Yoga & Breast Cancer
- Your Emotions

Guides in our Metastatic Breast Cancer Series:

- Guide for the Newly Diagnosed
- Managing Stress and Anxiety
- Treatment Options for Today and Tomorrow
- Understanding Palliative Care
- Understanding Symptoms and Treatment Side Effects

Guides in our Breast Cancer InFocus Series:

- Breast Cancer During Pregnancy
- Breast Cancer in Men
- Getting the Care You Need as a Lesbian, Gay or Bisexual Person

This brochure is designed for educational and informational purposes only, as a reference to individuals affected by breast cancer. The information provided is general in nature. For answers to specific healthcare questions or concerns, consult your healthcare provider, as treatment for different people varies with individual circumstances. The content is not intended in any way to substitute for professional counseling or medical advice.
