My MBC & Me
Clinical Trials Navigation Guide

DEDICATED EXPERIENCED SUPPORT

SHARE

for women facing breast or ovarian cancer

About Clinical Trials

Clinical trials are research studies that evaluate how effectively medicines or interventions work in people. Often a clinical trial establishes if a new treatment is more effective and/or has fewer harmful side effects than standard treatment. Sometimes a clinical trial might be the best option for a patient; sometimes the standard of care is best. All patients should understand clinical trials and be able to talk to their doctor about what, if any, trials are right for them.

What to Know About Clinical Trials

1. Participation is voluntary. Patients are able to leave the trial at any time for any reason.
2. There are different types of trials. Some clinical trials test new therapies or procedures. Others look at ways to improve quality of life for people with chronic or life threatening illness.
3. Clinical trials are conducted in phases.
    - Phase I trials assess safety, dose levels and side effects in small groups of people.
    - Phase II trials assess safety and effectiveness in larger groups of people.
    - Phase III trials strive to confirm effectiveness, monitor side effects, and compare results to existing therapy options in still larger groups of people.
    - Phase IV trials include thousands of people for additional research on benefits, risks and most advantageous usage after FDA approval of the drug.
    - In the U.S. all clinical trials are evaluated for risk and benefit to the participant by an Institutional Review Board (IRB).
4. Participating in a trial may have some risks. The investigational treatment given during the trial may not help. Unfortunately, some patients may not respond and others may develop serious side effects.
5. It can be time consuming. Participants may have to visit their care team several times over the course of the trial for ongoing examinations and testing.
6. Clinical trials require informed consent, but this is not a binding document. Informed consent is a process where patients learn the details of the clinical trial they are considering; it is required for all clinical trials. These details include the purpose of the study, its length, all required procedures and risks as well as

potential benefits. Medical translation must be provided for those who are not native English speakers. It is important to remember that informed consent documents are not contracts. Patients can withdraw from the study at any time for any reason.

Common Fears

Many people have concerns or fears about participating in clinical trials. These concerns could be based on historical events or because of misinformation. Oftentimes, these fears can be allayed with more information. Below are some fears that are common among patients.

Fear: "I will be treated like a guinea pig."
Fact: All current FDA-approved medications were first tested in clinical trials. There are significant safeguards in place by institutions (hospitals and clinics) to protect patients.

Fear: "Clinical trials are a last resort."
Fact: Clinical trials are used at all stages of treatment and life stages.

Fear: "If I get a placebo, I may not receive any treatment at all."
Fact: In cancer trials, participants are always treated with the standard of care. A trial allows them the opportunity to receive new treatments.

Fear: "Once I enroll, I have to finish the trial."
Fact: Participants are able to leave the trial at any time for any reason.

Fear: "My insurance won't cover a clinical trial."
Fact: Federal law requires most health insurance plans to cover routine patient care costs in clinical trials. This may be determined on a case by case basis.

Qualifying for Clinical Trials

To enroll in a clinical trial, a patient must meet specific criteria. Every study has guidelines for who can and cannot participate. These guidelines are also called eligibility criteria and are shared by all participants. Eligibility criteria may include a particular type or stage of cancer, age range, gender, current health status and treatment history.

Eligibility criteria also help researchers ensure that results are due to the investigational treatment and not to other factors. The criteria also

protects patients for whom risks may outweigh benefits.

Your doctor may recommend specific clinical trials you may qualify for, but may not always recommend trials outside of his/her institution. You may want to search for clinical trials at other medical centers. There are dedicated clinical trial matching services for metastatic breast cancer that can help you find trials you qualify for. See “Resources” for more information.

Choosing to Participate in a Clinical Trial

Determining whether a clinical trial or the standard of care is best for you requires conversations with your doctors and careful thought to the following:

1. Possible risks and benefits
2. Eligibility requirements
3. Cost of participating in clinical trials (including costs such as parking, travel, lodging)
4. Insurance coverage
5. Potential side effects
6. Patient protections
7. Privacy
8. Details of informed consent for this particular trial

Once you have basic information about clinical trials you might be eligible for, there are other considerations to take into account:

1. Will participation in one trial exclude me from participating in another in the future?
2. How will the requirements of the trial affect my daily life?
3. Is traveling to the trial site manageable?
4. What if I am eligible for several trials? How do I choose? What factors should I consider in making a decision?
5. If my disease progresses on this trial, what are my options at that time?
6. Do the possible benefits outweigh the risks?

In addition, it may be good to know:

1. Who is conducting the clinical trial?

2. Does the trial doctor have financial or special interests in the trial drug?
3. Is a placebo is being used? Is it possible I would only get a placebo or will I receive standard of care treatment?

Before enrolling in a clinical trial, patients should know the answers to the questions above. The Center for Information and Study of Clinical Research Participation (CISCRP) has created a list of questions to ask as you are considering a clinical trial. You can download the list here at this link: **https://www.ciscrp.org/wp-content/uploads/2019/06/Questions-to-Ask.pdf**

Genetic and Genomic Testing and Clinical Trials

Genetic Testing

Genetic testing uncovers inherited mutations that may put a person at higher risk for certain diseases like cancer. Genetic testing may also expand your treatment options. Knowing your genetic mutations may increase your eligibility for additional clinical trials which may have some treatment benefit. There are also medications that are FDA-approved or in clinical trials designed for people with specific mutations.

Genomic Testing

The term "genomic" is typically used in reference to a tumor's molecular make up. Every cell contains tens of thousands of genes, but mutations in a single gene can cause cells to grow out of control and lead to the growth of tumors. Tumors are often tested at the time of diagnosis to determine any mutations that may exist, but genes in tumors can mutate over time, causing tumors to change and require different treatment approaches. For example, a patient might be diagnosed initially with HER2+ MBC but later have a metastasis that is HER2-. Whenever possible, biopsy and genomic testing of new metastases is encouraged so that patients and doctors can offer those treatments with the greatest chance of success.

It is a good idea to discuss both genetic and genomic testing with your doctor to see if and when these tests are right for you.

Precision Medicine and Clinical Trials

Precision medicine focuses on identifying which approaches will be effective for which patients based on genetic, environmental, and lifestyle factors. Medicines which target genes expressed only by cancer cells are often better tolerated by patients than chemotherapy, which kills both cancerous and healthy cells and is often more toxic. According to the Tufts Center for the Study of Drug Development, 42 percent of medicines currently in development for all diseases are associated with precision medicine strategies. When it comes to cancer care, the number is even higher: 73 percent of cancer drugs in development are aimed at use in personalized medicine, and this number is likely to grow in the coming years.

In clinical trials for precision medicines, physicians utilize patients' genomic testing data, as well as their individual medical history, circumstances, preferences, and values to develop targeted treatment plans tailored to individual patients.

What Happens When a Patient Does Not Qualify for a Clinical Trial?

Clinical trial eligibility is subject to strict guidelines, and some patients who do not qualify may still want access to the medicine being tested. There are a couple of ways a patient might gain access to experimental drugs they cannot receive through a trial.

According to the founder of The Center for Information and Study on Clinical Research Participation (CISCRP), "clinical research professionals are looking for new ways to engage patients as partners in clinical research." In 2018, the Right to Try Act gave terminally ill patients the "right to try" experimental treatments if they've exhausted other options. Patients, together with their doctors, may petition the pharmaceutical company to provide the investigational treatment. But, because state laws vary, and pharmaceutical companies have additional rules, the process can be complicated. Additionally, insurance may not cover the investigational drug, so the patient may have to pay for the drug out of pocket as well as provide complete consent.

“Compassionate use” or “expanded access” programs may be another option for those people who are facing a life-threatening, but not necessarily terminal condition. To access a drug for compassionate use, a physician can seek FDA approval of the drug on behalf of the patient. The patient must also get permission from the Institutional Review Board (IRB), which is the ethical oversight committee for clinical trial participation.

Resources

TalkMets Metastatic Helpline: Call to speak with a trained peer volunteer living with metastatic breast cancer. She can assist you and provide information as you determine which trials may be right for you.
844.ASK.SHARE, option 6

Metastatic Breast Cancer Trial Search: This site will assist you in finding trials specifically for those diagnosed with MBC.
https://www.sharecancersupport.org/metastatic-breast-cancer/clinical-trial-matching-service/

What to know when considering clinical trials: This site provides more information from the Metastatic Breast Cancer Alliance about clinical trials, including a Clinical Trial Checklist for Patients.
https://www.mbcalliance.org/mbc-alliance-cted

Paying for clinical trials: Triage Cancer offers an animated video on how to find and pay for clinical trials.
https://triagecancer.org/animatedvideos

MBC Connect: The Metastatic Breast Cancer Alliance has developed a patient registry that, beginning in September 2019, will match users to clinical trials they may be eligible for. Users must enter their treatment history to facilitate a possible match.
https://www.mbcconnect.org/

Metastatic Trial Talk - Carefully selected news and features about metastatic breast cancer research.
https://metastatictrialtalk.org/

DEDICATED EXPERIENCED SUPPORT

SHARE

for women facing breast or ovarian cancer

Download the My MBC & Me app, available for iPhone:
mymbcandme.org