



# BREAST CANCER CLINICAL TRIAL CORNERSTONE DIRECTORY



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## WHAT ARE THE GOALS OF BREAST CANCER CLINICAL TRIALS?

- Create truly curative therapies
- Develop therapies that can work when others have failed
- Decrease the side effects of treatment

### TIPS FOR LEARNING ABOUT & FINDING CLINICAL TRIALS

- Know your breast cancer stage and subtype and obtain a copy of your pathology report.
- Learn about eligibility criteria such as age and physical fitness.
- See if there are financial resources that can help assist with travel and other costs.
- Ask what the risks are to participating.

## QUESTIONS TO ASK YOUR PROSPECTIVE CLINICAL TRIAL MEDICAL TEAM

- What kinds of tests, medicines, surgery, or devices are involved in the trial? Are any procedures painful?
- What are the possible risks or side effects of taking part in the study?
- What are the potential benefits of participating in this study? How would this be more beneficial than my current treatment option or the typical standard of care?
- How will this trial affect my daily life? Will I have to be in the hospital for a long period of time?
- Will I have to travel for this trial? Where and how often? Are telehealth visits an option?
- How long will the trial last?
- What will happen after the trial?

### Cost-specific questions

- Who will pay for the tests and treatments I receive?
- Are there additional costs if I enroll in the trial?
- Does my insurance cover any of these trials?
- Will I be reimbursed by the trial sponsors for other expenses (for example, travel and childcare)?

## WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?



**Several types of treatments under study (or already approved) for people with breast cancer include combinations of:**

**Targeted Biological Therapy:** The mechanism of action blocks the function of specific normal body proteins that allow cancer cells to grow and divide. Targeted biological therapies target cancer cells, reducing toxicity and lessening side effects.

- Everolimus (Afinitor)
- Bevacizumab (Avastin)
- Trastuzumab (Herceptin)
- T-DM1 ado-trastuzumab emtansine (Kadcyla)
- Tykber (Lapatinib)
- Pertuzumab (Perjeta)

# WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

## Bisphosphonate Therapy

As a drug type that is used for osteoporosis treatment, bisphosphonates are also used to treat breast cancer that has spread to the bones.

Patients who are taking aromatase inhibitors for early stage breast cancer may also be prescribed bisphosphonates, since in some patients, aromatase inhibitors weaken the bones.

- Risedronate (Actonel)
- Pamidronate (Aredia)
- Ibandronate (Boniva)
- Alendronate (Fosamex)
- Denosumab (Xgeva)
- Zolendronate (Zometa)

# WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

## Hormone Therapy

Hormone therapies are in the prevention hormone-receptor positive cells from exposure to the hormones that cause growth in the HR-positive cells; hormone therapies are used in both prevention and treatment. There are three main types of hormone therapies: ovarian suppressors, aromatase inhibitors, and anti-estrogen drugs.

### Ovarian Suppression

- Leuprolide (Lupron)
- Abarelix (Plenaxis)
- Buserlin (Suprefact)
- Goserelin (Zoladex)

### Aromatase Inhibitors

- Anastrozole (Arimidex)
- Ememestane (Aromasin)
- Letrozole (Femara)

### Anti-Estrogen Drugs

- Raloxifen (Evista)
- Toremifine (Fareston)
- Fulvestrant (Faslodex)
- Tamoxifen (Nolvadex)

# WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

## Chemotherapy

Chemotherapies are systemic drug treatments used to stop cancer cells from dividing and growing.

Chemotherapy is often linked with unpleasant side effects since it targets all rapidly growing cells, as well as cancer cells.

## Early Breast Cancer Chemotherapy Regimens

- Doxorubicin, cyclophosphamide (AC: Adriamycin, Cytoxan)
- Doxorubicin, cyclophosphamide + paclitaxel (AC + Taxol: **Adriamycin, Cytoxan, Taxol**)
- Doxorubicin, cyclophosphamide + docetaxel (AC + Taxotere: **Adriamycin, Cytoxan, Taxotere**)
- CMF: cyclophosphamide (Cytoxan), Methotrexate, 5-Fluorouracil
- Epirubicin, cyclophosphamide (EC: Ellence, Cytoxan)
- Doxorubicin, 5-Fluorouracil, cyclophosphamide (FAC: 5-**Fluorouracil, Adriamycin, Cytoxan**)
- 5-Fluorouracil, epirubicin, cyclophosphamide (FEC: 5-Fluorouracil, **Ellence, Cytoxan**)
- Docetaxel, cyclophosphamide (TC: Taxotere, Cytoxan)
- Docetaxel, doxorubicin, cyclophosphamide (TAC: Taxotere, **Adriamycin, Cytoxan**)
- Docetaxel, carboplatin (TC: Taxotere, Paraplatin)

# WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?



## Metastatic Breast Cancer Chemotherapy Drugs

- Paclitaxel + capecitabine (Taxol + Xeloda)
- Docetaxel + capecitabine (Taxotere + Xeloda)
- Docetaxel + carboplatin (Taxotere + Paraplatin)
- Paclitaxel + carboplatin (Taxol + Paraplatin)
- Paclitaxel + gemcitabine (Taxol + Gemzar)
- Albumin-bound or nab-paclitaxel + capecitabine  
**(Abraxane + Xeloda)**
- Albumin-bound or nab-paclitaxel + carboplatin  
**(Abraxane + Paraplatin)**
- Irinotecan + Temozolomide
- Gemcitabine HCL + carboplatin (Gemzar + Paraplatin)
- Ixabepilone + capecitabine (Ixempra + Xeloda)

# WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

## Metastatic Breast Cancer Chemotherapy Drugs (cont.)

### Taxanes

- Paclitaxel Protein-bound (Abraxane)
- Paclitaxel (Taxol)
- Docetaxel (Taxotere)

### Anthracyclines

- Doxorubicin (Adriamycin)
- Liposomal doxorubicin (Doxil)
- Epirubicin (Ellence)
- Mitoxantrone (Novantrone)

### Platinum Drugs

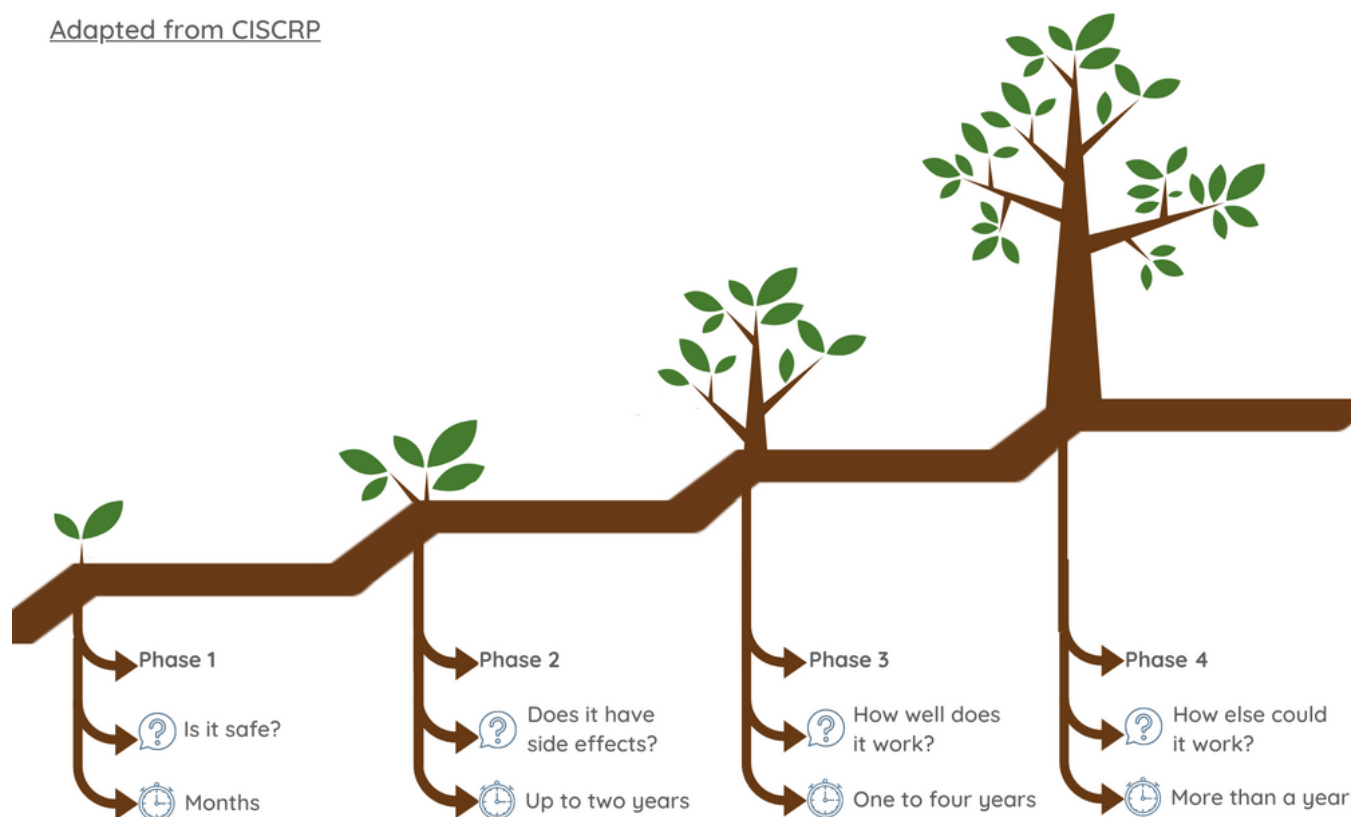
- Carboplatin (Paraplatin)
- Cisplatin (Platinol)

### Alkylating Agents

- Cyclophosphamide (Cytosan)
- Thiotepa (Tepadina)

# CLINICAL TRIALS & PHASES

Adapted from CISCPR



**Planting the seed** - In Phase I trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.



**Laying down roots** - In Phase II trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.



**Preparing for harvest** - In Phase III trials, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, & collect information that will allow the drug or treatment to be used safely.



**Expanding the yield** - In Phase IV trials, studies look at real-world experience over a long time and provide additional information on the drug's risks, benefits, and optimal use.

## OVERCOMING KNOWN DISPARITIES AND ACCESS FOR BREAST CANCER PATIENTS



For cancer patients, multiple studies have shown that there are some known barriers to equitable access to care. The overall clinical trials participation rate is only about 5 percent of adult cancer patients. Some of the disparities show lower clinical trial participation rates for adolescent and young patients, patients over age 65, women in non-sex-specific cancers, and patients who earn \$50,000 or less annually.

And though study results were somewhat mixed about whether participation rates have increased for Black, Indigenous, and People of Color (BIPOC) communities, it's vital for BIPOC patients to increase their clinical trial participation rates as the percentages of BIPOC populations continue to rise in the overall U.S. population. To increase breast cancer clinical trial participation for underrepresented groups, there are several strategies to improve rates. These strategies include:

## OVERCOMING KNOWN DISPARITIES AND ACCESS FOR BREAST CANCER PATIENTS

- Starting discussions about clinical trials early in the patient journey, beginning with diagnosis and continuing to discuss throughout their testing process up until discussions start about treatment decisions.
- Making special efforts to connect BIPOC patients, young patients, and male patients with advocates targeted to their underrepresented group to help patients feel more connected and trusting about clinical trials.
- Connecting non-native English speakers to translators early in their breast cancer journey to ensure patients understand clinical trial options.
- Continuing and extending reimbursement of food and transportation costs as part of clinical trial participation.
- Patients from underrepresented breast cancer clinical trial groups sharing their experiences about clinical trials to increase education about trials.
- Patient advocacy websites and other resources including clinical trials as part of their foundational content for patients and caregivers.
- Continuing telemedicine as a viable option for initial entry into breast cancer clinical trial

## TRIPLE-NEGATIVE BREAST CANCER: STACY'S CLINICAL TRIAL PROFILE



PLAY



"The trial is an additional drug that helps with the triple-negative, and it has been provided by FDA. So because of that, I was willing to do it."



Patient-to-Patient Diverse Clinical Trial Profiles

"What you have experienced or endured at the time, during a clinical trial and expressing it, it can only help the next person. But, in essence, I think the clinical trial is not in that only to help someone else, but it's also to help you...I think the knowledge of just knowing that you're a part of something that could be enhanced or approved or just help you with your health is a plus."

## TRIPLE-NEGATIVE BREAST CANCER: SHARON'S CLINICAL TRIAL PROFILE



A video player interface with a dark blue background. On the left, there is a white play button icon inside a circle, with the word "PLAY" in teal text below it. The main video area shows a woman with long, dark, curly hair wearing a pink shirt. To the right of the video, there is a white text box containing a quote. At the bottom, there is a white bar with the Patient Empowerment Network logo on the left and the text "Patient-to-Patient Diverse Clinical Trial Profiles" on the right.

"So I joined a clinical trial to make sure that I can help someone who will experience the same exact situation, and hopefully there will be additional drugs created or approved within the next 10 years to help someone else."

Patient Empowerment Network Patient-to-Patient Diverse Clinical Trial Profiles

Breast cancer patient Sharon was diagnosed with triple-negative invasive lobular carcinoma after she found a lump after working out.

Watch as she shares her breast cancer journey through two stages along with treatment – and what she learned and experienced with clinical trials and her advice to other patients. In Sharon's words, *"I do think that patients should be given all of their options upfront. I don't think that clinical trials should be the last resort."*

## WHAT QUESTIONS SHOULD PATIENTS ASK ABOUT BREAST DENSITY AND MAMMOGRAMS?



You are watching a Patient Empowerment Network program

How can breast cancer patients take action to improve their quality of care?

Respected breast cancer expert Dr. Regina Hampton shares advice and insights on breast imaging and some situations when additional imaging may be necessary. Learn about what questions to ask related to breast density and mammograms.

## WHAT ARE COMMON BARRIERS BREAST CANCER PATIENTS SEEKING CARE FACE?



What are some barriers breast cancer patients face in their access to care? Host Dr. Nicole Rochester asks Dr. Regina Hampton to share her perspective on obstacles that prevent optimal breast cancer care and how we can help get more patients on their path to empowerment.

## CLINICAL TRIAL RESOURCES

### [Clinicaltrials.gov](https://clinicaltrials.gov)

Provides information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The website is maintained by the National Library of Medicine at the National Institutes of Health.



**Each clinical trial record presents summary information about a study protocol and includes the following:**

- Disease or condition
- Intervention (for example, the medical product, behavior, or procedure being studied)
- Title, description, and design of the study
- Requirements for participation (eligibility criteria)
- Locations where the study is being conducted
- Contact information for the study locations

## CLINICAL TRIAL RESOURCES (CONT.)



### **Clinical Trial Finders** **CenterWatch**

Offers online tools to:

- Search clinical trials
- Receive email notifications about specific clinical trials
- Review results from completed clinical trials
- Search drug information
- Learn about the informed consent process
- Read an overview of the clinical trials process
- Find disease-specific health associations and other educational resources
- Review definitions of commonly-used clinical research terms

## **NIH National Cancer Institute**

**Contact:** Call 1-800-422-6237, live chat through [LiveHelp](#) or email [NClinfo@nih.gov](mailto:NClinfo@nih.gov)

Search portal to find National Cancer Institute (NCI)-supported clinical trials. Search by cancer type or keyword, your age (to determine which trials you could be eligible for) or U.S. ZIP code.



## **Clinical Connection**

**Contact:** 1-800-887-0639; email [info@clinicalconnection.com](mailto:info@clinicalconnection.com)

Founded by a team of medical researchers whose goal has been to efficiently connect patients with clinical trial opportunities that are relevant and timely. Options to create a free member account to be notified when clinical trials that match your health interests become available in your area.

Search for trials (both in U.S. and internally) by ZIP code, keyword, or distance (select distance ranges starting from within 5 miles up to over 250 miles)

**CISCRP**

**(Center for Information and Study on Clinical Research Participation)**

**Contact:** 877-MED-HERO (633-4376) or [info@ciscrp.org](mailto:info@ciscrp.org).

Provides education and information about clinical trials. Search Clinical Trials is a free service designed to help people find clinical trials that are relevant to their needs.

CISCRP staff will work with you to understand your options and will help you find local clinical trials in your community, or as far as you would be comfortable traveling.

**Antidote**

1-888-509-1308 (US) or +44 808-196-0665 (UK)

**Email:** [hello@antidote.me](mailto:hello@antidote.me)

Search for clinical trials by condition, city or ZIP code, age, and gender. Receive list of clinical trials that could be a match for you by answering series of questions. Watch educational webinars and patient stories.

## FINANCIAL ASSISTANCE

### Cancer Lifeline

**Contact Us: (206) 832-1282 |**

**financialassistance@cancerlifeline.org**

The fund provides financial assistance to breast cancer patients and one-time assistance to metastatic breast cancer patients.

**For more information, visit:**

**<https://cancerlifeline.org/services/financial-assistance-for-cancer-patients/>**

### Lazarex Cancer Foundation

**Contact: 877-866-9523 or 925-820-4517**

**Other language(s): Spanish, Mandarin, Korean**

Helps cancer patients navigate clinical trial options by offering financial assistance (such as lodging and transportation costs) for participation in FDA-approved clinical trials; call for eligibility details. Also provides community outreach and education.

## Clinical Trial Finders

### 21st Century C.A.R.E.

Get immediate financial assistance for incidental expenses related to active cancer treatments. Must be referred by a physician to be considered for assistance.

Applications are processed without delay. Once the application is approved, then you are eligible for financial assistance for incidental expenses related to: transportation to and from treatments, follow-up visits related to cancer-care, childcare during treatment, temporary housing due to geographical distance from the treatment center, medical supplies, and much more.

**Medicare and the National Cancer Institute** provides information on Medicare coverage for clinical trials.

**Contact:** 1-800-633-4227 or 1-877-486-2048 for hearing impaired

### **CenterWatch** offers online tools to:

- Search clinical trials
- Receive email notifications about specific clinical trials
- Review results from completed clinical trials
- Search drug information
- Learn about the informed consent process
- Read an overview of the clinical trials process
- Find disease-specific health associations and other educational resources

# UNDERSTANDING CLINICAL TRIALS:

## A JARGON BUSTER GUIDE

By: Marie Ennis-O'Connor



When it comes to cancer treatment, you or a loved one may be considering participating in a clinical trial as a treatment option.

Clinical trials are designed to evaluate the safety and effectiveness of a treatment. They may involve researchers administering drugs, taking blood or tissue samples, or checking the progress of patients as they take a treatment, according to a study's protocol.

Learning about clinical trials can be a steep learning curve – not the least because the process comes with a lot of new terms, acronyms, and jargon. To help you, we've put together this list of the most common terms you will find when you are researching clinical trial information. This is not an exhaustive list, but it is a helpful starting point. At the end of this article, you will see links to find more information.

## ADVERSE EFFECTS (AE)

Also called Adverse Events, or Adverse Drug Reaction, AEs are any harmful event experienced by a person while they are having a drug or any other treatment or intervention. In clinical trials, researchers must always report adverse events, regardless of whether or not the event is suspected to be related to or caused by the drug, treatment, or intervention.



## ARM

Subsection of people within a study who have a particular intervention.

## **BIAS**

Bias is an error that distorts the objectivity of a study. It can arise if a researcher doesn't adhere to rigorous standards in designing the study, selecting the subjects, administering the treatments, analyzing the data, or reporting and interpreting the study results. It can also result from circumstances beyond a researcher's control, as when there is an uneven distribution of some characteristic between groups as a result of randomization.

## **BLINDING**

Blinding is a method of controlling for bias in a study by ensuring that those involved are unable to tell if they are in an intervention or control group, so they cannot influence the results. In a single-blind study, patients do not know whether they are receiving the active drug or a placebo. In a double-blind study, neither the patients nor the persons administering the treatments know which patients are receiving the active drug.

## **COMPARATOR**

When a treatment for a specific medical condition already exists, it would be unethical to do a randomized controlled trial that would require some participants to be given an ineffective substitute. In this case, new treatments are tested against the best existing treatment, (i.e., a comparator). The comparator can also be no intervention (for example, best supportive care).

## **COMPLETED**

A trial is considered completed when trial participants are no longer being examined or treated (i.e., no longer in follow-up); the database has been "locked" and records have been archived.

## **CONTROL**

A group of people in a study who do not have the intervention or test being studied. Instead, they may have the standard intervention (sometimes called "usual care") or a dummy intervention (placebo). The results for the control group are compared with those for a group having the intervention being tested. The aim is to check for any differences. The people in the control group should be as similar as possible to those in the intervention group, to make it as easy as possible to detect any effects due to the intervention.

## **EFFICACY**

How beneficial a treatment is under ideal conditions (for example, in a laboratory), compared with doing nothing or opting for another type of care.

A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

## **ELIGIBILITY CRITERIA/INCLUSION AND EXCLUSION CRITERIA**

Eligibility criteria ensures patients enrolling in a clinical trial share similar characteristics (e.g., gender, age, medications, disease type, and status) so that the results of the study are more likely due to the treatment received rather than other factors.

## **FOLLOW-UP**

Observation over a period of time of participants enrolled in a trial to observe changes in health status.

## **INFORMED CONSENT**

A process (by means of a written informed consent form) by which a participant voluntarily agrees to take part in a trial, having been informed of the possible benefits, risks and side effects associated with participating in the study.

## **INTERVENTION**

The treatment (e.g., a drug, surgical procedure, or diagnostic test) being researched. The intervention group consists of the study participants that have been randomly assigned to receive the treatment.

## **INVESTIGATOR**

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (PI).

## **MULTICENTER TRIAL**

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

## **NUMBER NEEDED TO TREAT (NNT)**

The average number of patients who need to receive the treatment or other intervention for one of them to get the positive outcome in the time specified.

## **OUTCOME MEASURES**

The impact that a test, treatment, or other intervention has on a person, group, or population.

## **PLACEBO**

A fake (or dummy) treatment given to patients in the control group of a clinical trial. Placebos are indistinguishable from the actual treatment and used so that the subjects in the control group are unable to tell who is receiving the active drug or treatment. Using placebos prevents bias in judging the effects of the medical intervention being tested.

## **POPULATION**

A group of people with a common link, such as the same medical condition or living in the same area or sharing the same characteristics. The population for a clinical trial is all the people the test or treatment is designed to help.

## **PROTOCOL**

A plan or set of steps that defines how something will be done. Before carrying out a research study, for example, the research protocol sets out what question is to be answered and how information will be collected and analyzed.

### **Randomized Controlled Trial (RCT)**

A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug, treatment, or other intervention. One group has the intervention being tested; the other (the comparison or control group) has an alternative intervention, a placebo, or no intervention at all.

Participants are assigned to different groups without taking any similarities or differences between them into account. For example, it could involve using a computer-generated random sequence. RCTs are considered the most unbiased way of assessing the outcome of an intervention because each individual has the same chance of having the intervention.

## **RELIABILITY**

The ability to get the same or similar result each time a study is repeated with a different population or group.

## **SAMPLE**

People in a study recruited from part of the study's target population. If they are recruited in an unbiased way, the results from the sample can be generalized to the target population as a whole.

## **SUBJECTS**

In clinical trials, the people selected to take part are called subjects. The term applies to both those participants receiving the treatment being investigated and to those receiving a placebo or alternate treatment.

## **TRIAL SITE**

The location where trial-related activities are conducted.