LIVING BEYOND
BREAST CANCER®

Session 4 | Understanding Clinical Trials: How to Find One and What to Expect

Effective treatment & side effect support | Innovations in breast cancer care

Understanding Clinical Trials: How to Find One and What to Expect

Living Beyond Breast Cancer Webinar
October 15, 2025

Sara Horton, MD
Medical Oncologist. Strategic Clinical Trial Access
Quantam Leap Healthcare Collaborative
Affiliate Associate Professor, Howard University Cancer Center

Quantum Leap
Healthcare Collaborative

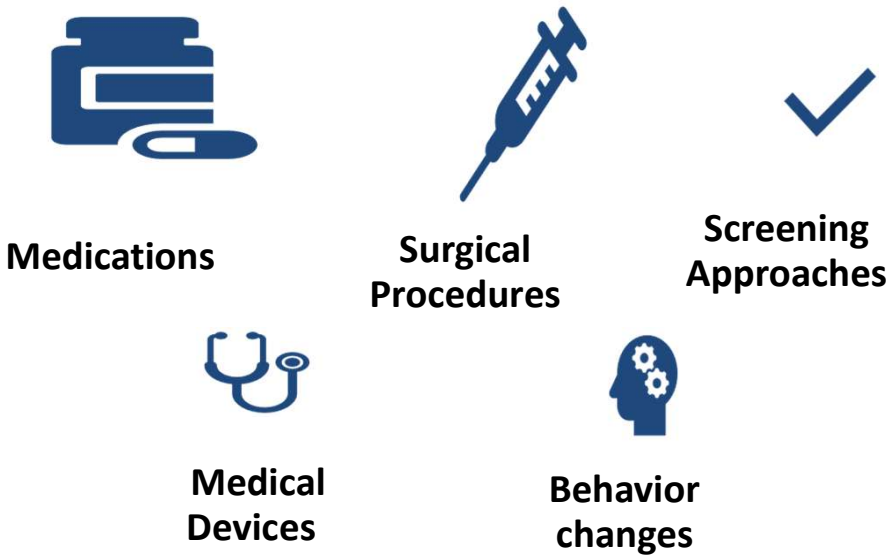
Agenda

- What is a Clinical Trial
- How To Search for Trials
- Common Barriers
- What To Expect
- Diversity in Trials
- Becoming An Advocate
- Resources
- Q&A

What is a Clinical Trial?

A clinical trial is a research study involving people who volunteer. These studies determine if a new treatment is safe and effective (if it works).

"Treatment" can mean:



Clinical Trials: Why They Matter

- All **standard treatments** today came from trials

Clinical Trial Phases

Clinical trials occur in 4 phases, each with a different purpose asking an important question:

1 → 2 → 3 → 4

Phase I

First-in-human **safety**/dosing; small numbers.

15-50 pts

Phase II

Is it **effective** and work against this cancer type?

Approx 100 pts

Phase III

compares to standard treatment; larger, randomized.

Hundreds of pts

(FDA Approval)

Phase IV

treatment is **approved and available**. Long-term effects are observed.

Thousands of pts

Types of Breast Cancer Trials

Early-Stage

- Neoadjuvant/adjuvant optimization
- De-escalation/escalation
- Survivorship

Metastatic

- New targeted/Biomarker-matched
- Quality-of-life
- Access to novel therapies

Different Types of Trials

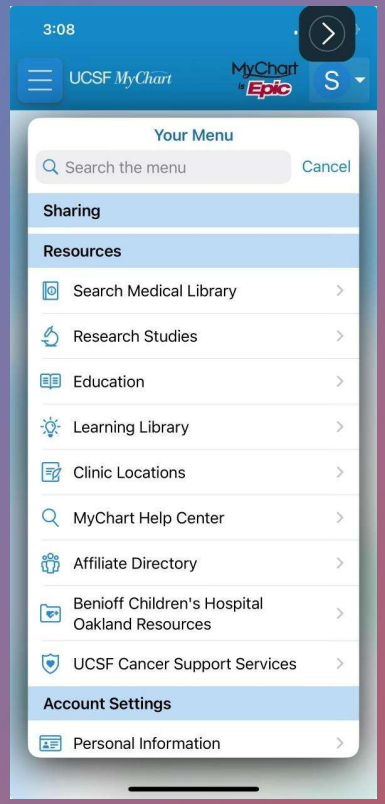
- Screening
- Prevention
- Treatment of a disease
- Quality of life studies
- Survivorship

Pros and Cons of Clinical Trials

Potential for better, safer treatment	Increased number of treatment options
Some study sponsors may pay for all or part of your medical care and other expenses during the trial	Closer monitoring by your cancer care team
Uncertain side effects	Treatment not working as well as expected
If randomized, may not have a choice on which treatment	If blinded, you and possibly your doctor won't know which treatment you're getting

No matter the outcome, participating in a clinical trial allows you to take an active role in your care and can help improve cancer care for others

Where to Search for Trials



BreastCancerTrials.org
find a trial that's right for you

ClinicalTrials.gov

ClinicalTrials.gov

(ALL clinical trials, comprehensive)

BreastCancerTrials.org

(Breast Cancer specific, patient-friendly matching)

Ask your Oncologist/Oncology provider/Navigator/check patient portal

Academic centers/University based practices

NCORP/Community sites

(NCI Community Oncology Research Program)

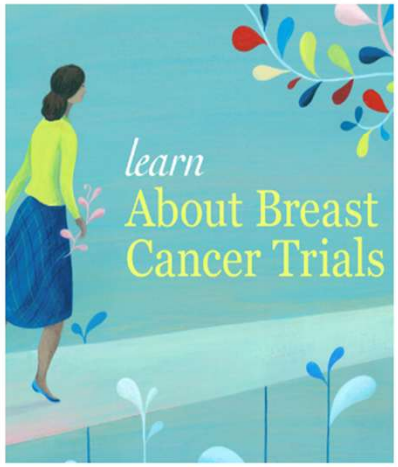
Advocacy organizations (e.g., LBBC, ACS)

BreastCancerTrials.org

Personalized clinical trial matching

Breast Cancer Trial Search

For DCIS, stage I-III breast cancer, survivors & healthy/high risk

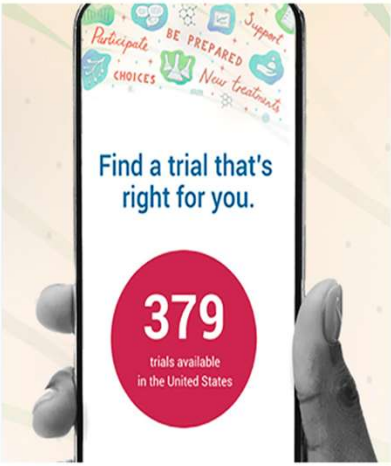


- Browse or match to over 700 trials in the U.S.
- Trial information displayed in patient-friendly language

BreastCancerTrialSearch.org

Metastatic Trial Search

For stage IV breast cancer



- Designed specifically for metastatic breast cancer
- Easy to use on phones, tablets, and laptops

MetastaticTrialSearch.org

Metastatic Trial Talk

Carefully selected information about MBC research

- Stay current on metastatic breast cancer research
- Learn about clinical trials
- New trials listed monthly

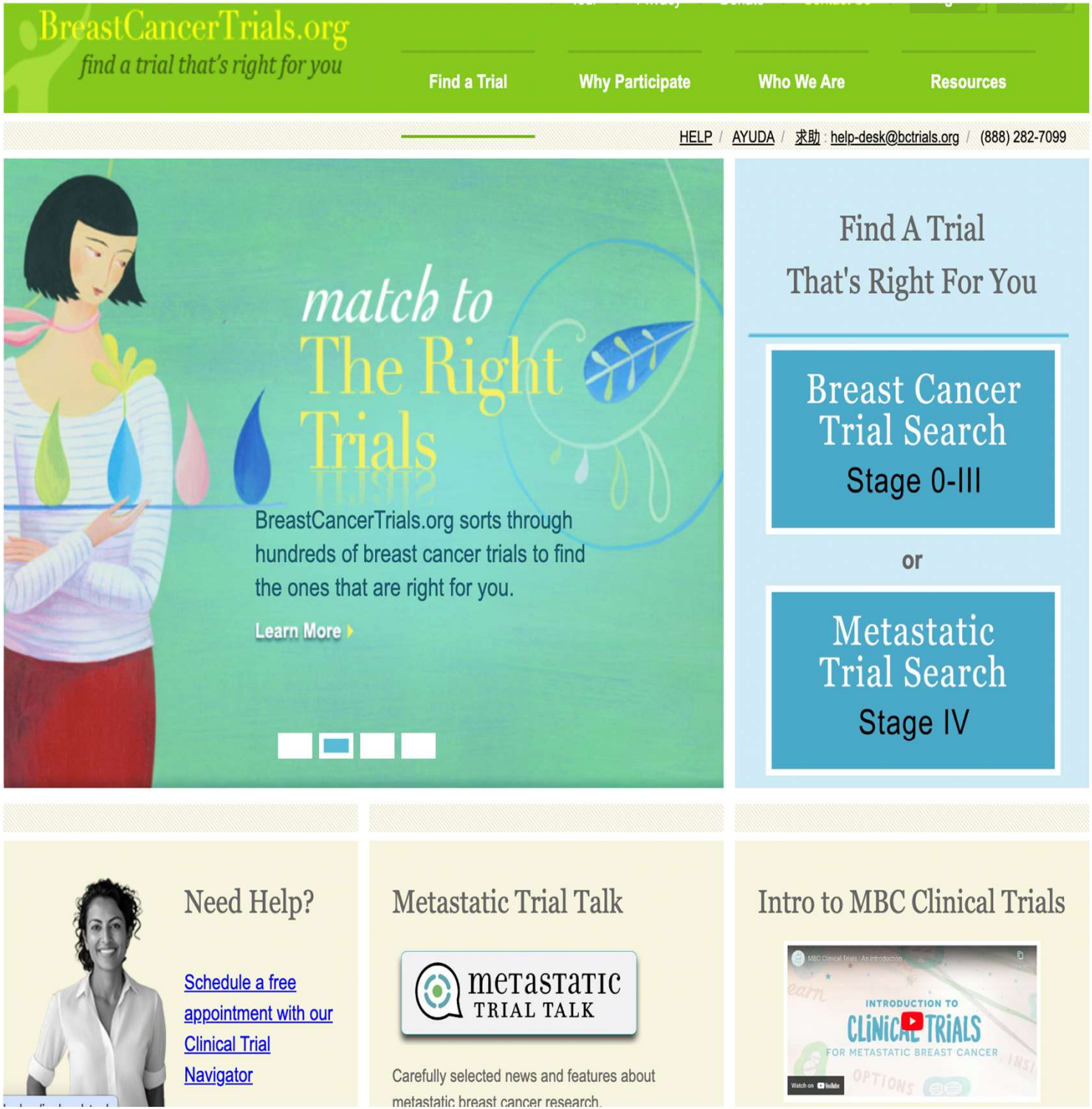
MetastaticTrialTalk.org

Clinical Trial Navigation

Free expert support with finding trials

- Get support with finding and understanding trials
- Free virtual appointments and group sessions

Call or Email



BreastCancerTrials.org

Mission:

To empower people affected by breast cancer to consider clinical trials as a routine option for care.

Common Barriers

- **Geography & time** (travel, time off work, caregiving)
- **Costs & insurance** (routine care vs research costs)
- **Language** barriers/health literacy
- Local trial **not available**
- **Trust**, prior experiences and cultural fit
- **Eligibility criteria** that excludes many patients
- **NOT ASKED BY DOCTOR**

Overcoming Barriers: Practical Steps

Request	Request financial navigation early (travel/lodging, copay help)
Bring	Interpreter/translated materials; bring an advocate
Discuss	Discuss visit schedules and remote monitoring possibilities
Ask about	If excluded, ask about ‘expanded access’ or future eligibility
Ask about	Ask about NCORP/community sites options

What to Expect: Informed Consent & Safety

- Plain language explanation of purpose, procedures, risks/benefits, alternatives
- You can ask questions; take time; and withdraw at any point
- Independent ethical review (IRB) and Safety Monitoring (DSMB) oversight
- Adverse events tracked; your well-being remains the priority

Costs & Coverage Basics

Research items (study drug/tests only done for the trial)often covered by sponsor

Routine care (standard tests/visits you'd get anyway) typically billed to insurance/Medicare

Ask the site for a **coverage analysis and financial navigator**

Travel/lodging help may be available via nonprofits

How to Talk With Your Provider

- Share your goals; ask if a trial aligns with them
- Bring NCT (National Clinical Trial) IDs to discuss pros/cons
- Clarify logistics, time on study, and back-up plan
- Ask how and what results will be shared and what follow up looks like

Diversity in Trials: Why It Matters

- Ensures treatments work for everyone
- Reduces disparities; builds trust
- Community sites + language access + flexible designs boost inclusion
- Patient feedback improves access

Underrepresented in Clinical Trials

- Racial/Ethnic Minorities (Blacks, Hispanics, Native Americans)
- Socioeconomically disadvantaged
- Patients in Rural Areas
- Sexual and Gender Minorities (LGBTQ)
- Older patients
- Pediatric patients
- Adolescents and Young Adult (15-39)

Becoming an Advocate

- Join patient advisory/protocol review groups
- Give feedback on consent forms and visit schedules
- Share experiences with advocacy orgs to improve designs
- Help others learn to search and ask about trials

Helpful Resources

- ClinicalTrials.gov — https://clinicaltrials.gov/
  - • Global registry; filter by status/location
- BreastCancerTrials.org — https://www.breastcancertrials.org/
  - • Patient-friendly matching for breast cancer
- NCI Trial Costs & Insurance — https://www.cancer.gov/about-cancer/treatment/clinical-trials/search/trial-costs
  - • What's covered and by whom
- FDA: Informed Consent — https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials
  - • Consent requirements
- NCORP — https://ncorp.cancer.gov/
  - • Community research sites near you
- Lazarex Cancer Foundation — https://lazarex.org/patient-programs/travel-reimbursement-program/
  - • Travel & lodging reimbursement
- ACS Hope Lodge — https://www.cancer.org/support-programs-and-services/hope-lodge.html
  - • Lodging near treatment
- Triage Cancer — https://triagecancer.org/
  - • Financial & legal navigation
- PAF Co-Pay Relief — https://www.copays.org/
  - • Co-pay assistance

Thank You!

Q&A

- What else would help you feel confident searching for trials?

CONTACTS:

- Sara Horton, MD

S.horton@qlhc.org

- BCT.org

bctrials@quantumleaphealth.org

+

-

o

BreastCancerTrials.org

find a trial that's right for you

Patient-friendly Matching

Free online tool

Create a free profile with diagnosis details

Matched trials by subtype/history

Refine by distance, biomarkers, type

Save/email matches to your clinician