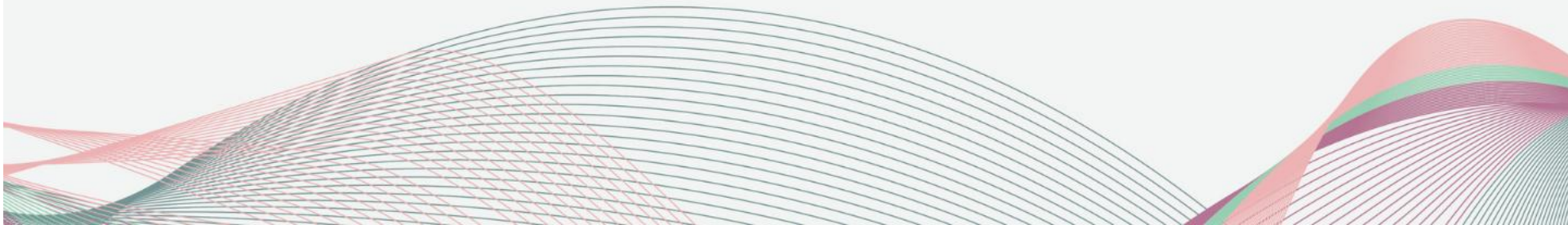
Breakout session

LIVING BEYOND
BREAST CANCER®

Clinical trials in MBC

Information and access

Speaker: Sara Horton, MD



Thriving Together: 2026 Conference on Metastatic Breast Cancer

Clinical Trials in Metastatic Breast Cancer: Information and Access

April 18, 2026 | Philadelphia, PA

Sara Horton, MD
Medical Oncologist | Clinical Trials & Trial Access
Quantum Leap Healthcare Collaborative
Affiliate Associate Professor, Howard University Cancer Center

Quantum Leap Healthcare Collaborative

HUH HOWARD UNIVERSITY HOSPITAL

Agenda

- Clinical Trials 101-metastatic focus
- Diversity in Clinical Trials
- What to Know
- What's new / emerging (SABCS 2025)
- Where to search: ClinicalTrials.gov and BreastCancerTrials.org
- Resources and Action Steps
- 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:

- **Medications**
- **Surgical Procedures**
- **Screening Approaches**
- **Medical Devices**
- **Behavior changes**

Clinical Trials:

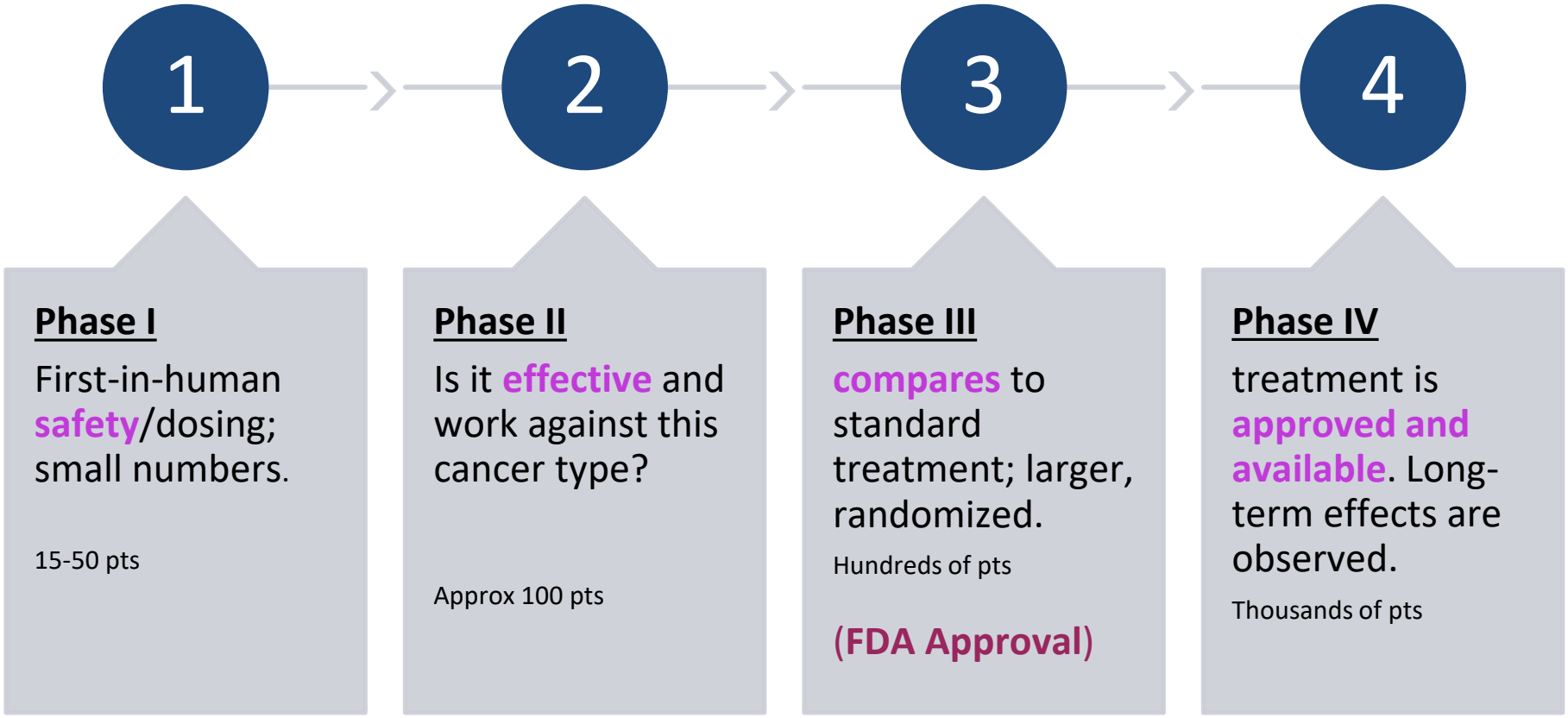
Why They Matter

All standard treatments today came from clinical trials

In metastatic breast cancer, trials not only help us find new drugs, they also inform us on how to sequence therapies so patients live better, not just longer.

Clinical Trial Phases

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



Types of Breast Cancer Trials

Early-Stage

Neoadjuvant/adjuvant optimization
De-escalation/escalation
Survivorship

Metastatic

- **New targeted**
- **Biomarker-matched therapies**
- **Antibody–drug conjugates (ADCs)**
- **Sequencing & combination studies**
- **Brain metastases / CNS-inclusive trials**
- **Quality-of-life & symptom management**

Different Types of Trials

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

Pros and Cons of Clinical Trials

Pros	Cons
Potential for better, safer treatment	Uncertain side effects
Some sponsors cover costs for all or part of your medical expenses during the trial	If randomized, may not have a choice on which treatment
Increased treatment options	Treatment not as effective as expected
Closer monitoring (more frequent visits, imaging, labs)	Patient and possibly provider blinded to which treatment patient receives

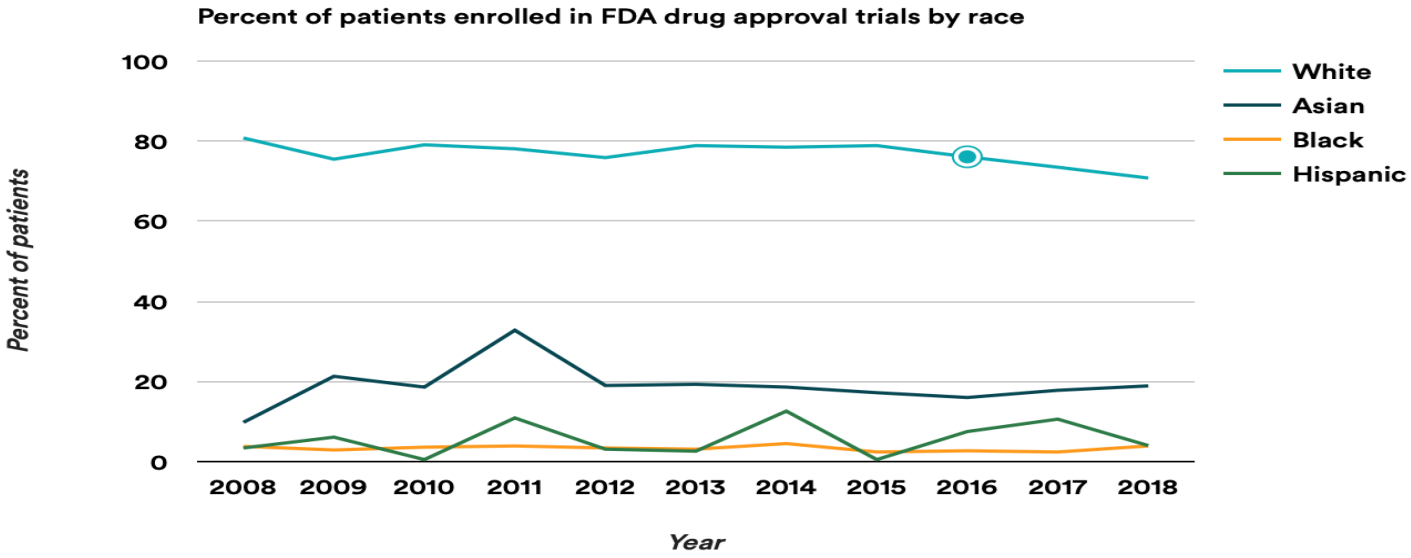
Diversity in Trials: Why It Matters

- Ensures generalizability of results across populations
- Reduces disparities

<u>Underrepresented in Clinical Trials</u>

- Racial/Ethnic Minorities (Blacks, Hispanics, Native Americans)
- Socioeconomically disadvantaged
- Patients treated in community health centers
- Patients in Rural Areas
- Sexual and Gender Minorities (LGBTQ)
- Older patients

Diversity in Trials: The Numbers



2021 general U.S. population		2021 FDA Clinical Trials
64%	White	73%
12%	Black	4%
16.8%	Hispanic	7%
6%	Asian	19%

Why Is It Important for Black Women To Participate in Breast Cancer Clinical Trials?

Black Women are:

- Twice as likely to be diagnosed with TNBC
- More likely to be diagnosed before age 40
- 40% more likely to die from breast cancer than White women, even with the same diagnosis
- 12% of the US population, but only 3-5% of cancer clinical trial participants.

When groups are not represented, we miss out on important information about how treatments work in them.

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 PROVIDER**

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

- Informed consent is a conversation (not just a signature)
- You can ask questions and take time to decide
- Safety is monitored by the study team and oversight (IRB/DSMB, as applicable)
- You can stop participating at any time
- Ask: What happens if the treatment isn't helping?

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

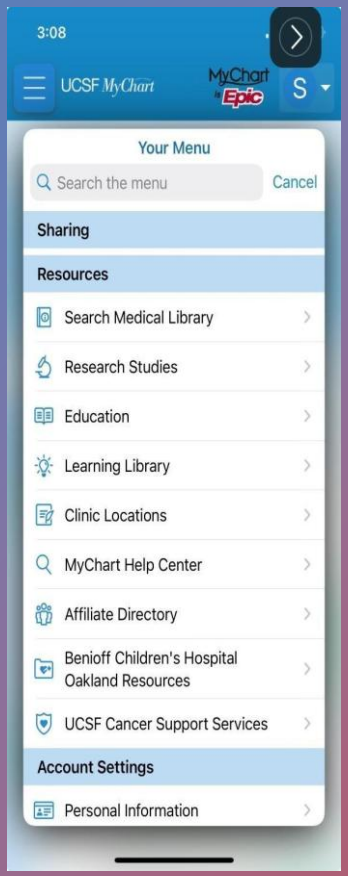
Ask the site for a **coverage analysis and financial navigator**

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 IDs (or an MTS printout) to discuss pros/cons
- Clarify logistics: visits, labs/imaging (can any be done locally?), time on study, and back-up plan
- Ask about eligibility issues that matter in MBC (e.g., brain metastases criteria)
- Ask how results will be shared and what follow-up looks like

Where to Search for Metastatic Trials



ClinicalTrials.gov

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

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)

What's New in Metastatic Breast Cancer

What's New in Metastatic Breast Cancer:

Big Themes: SABCS 2025 and beyond

- More **biomarker**-driven therapy (e.g., ESR1-elacestrant, PI3K/AKT pathway, HER2-low/ultralow-T-DXd/Enhertu)
- **Antibody-drug conjugates** (ADCs) are moving earlier and into more subgroups
- Better strategies for **sequencing**: maximize control with good quality of life
- Growing focus on **CNS disease** (brain mets/leptomeningeal trials)

HER2-Positive Metastatic Breast Cancer: Recent shifts & trial directions

More effective HER2-targeted options earlier in metastatic care

- T-DXd/Enhertu + pertuzumab in 1st line (DESTINY-Breast09)

Maintenance strategies are being tested to extend time off chemotherapy

- Tucatinib/Tukysa + Herceptin/Perjeta combinations first line (HER2CLIMB-05)

Hormone Receptor Positive (HR+) Breast Cancer: Overcoming endocrine resistance

Trials are testing next-generation endocrine therapies. Oral SERDs:

-Elacestrant/Orserdu and Imlunestrant/Inluriyo approved in ESR1 mutated disease

Camizestrant in trials

Biomarkers can guide options

ESR1 mutation: elacestrant

PIK3CA mutation: alpelisib/Piqray, inavolisib

Key question: which sequence offers the best balance of control and quality of life?

HER2-Low / HER2-Ultralow (often HR+): Why pathology details now matter

- HER2-low/ultralow categories may expand treatment options (including ADCs)
  - T-DXd/Enhertu approved for HER2-low (DESTINY-Breast04)
  - Under study for HER2-ultralow (DESTINY-Breast06)
- Discuss HER2-low/ultralow status testing with your pathology department

Triple-Negative Metastatic Breast Cancer (TNBC): Immunotherapy + ADC directions

- Trials are exploring ADCs and immunotherapy earlier in the metastatic setting

  sacituzumab govitecan/Trodelvy, dato-DXd/Enhertu plus immunotherapy pembrolizumab/Keytruda for PD-L1+ disease

- Eligibility often depends on biomarkers (e.g., PD-L1) and prior therapies

  PD-L1 CPS score for immunotherapy

  BRCA1/2 for PARP inhibitors (olaparib/Lynparza)

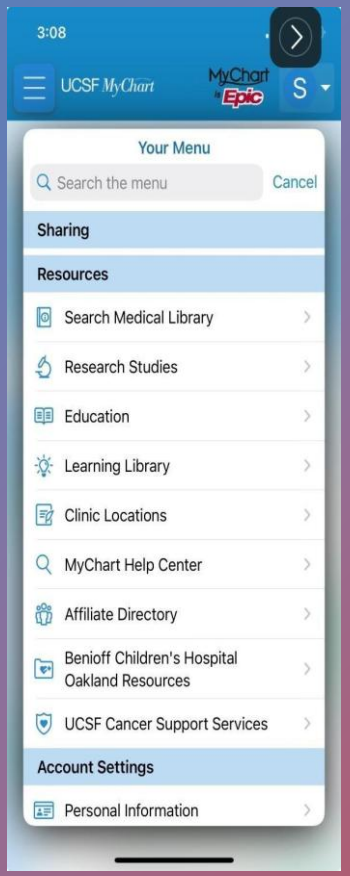
Brain Metastases / Leptomeningeal Disease: Ask specifically about CNS-inclusive trials

- Historically, many trials excluded people with active brain metastases—this is changing
  - Tucatinib oral anti HER2 therapy (HER2CLIMB) and T-DXd have demonstrated intracranial efficacy in HER2+ disease

- Ask: Is this trial CNS-inclusive?

Ask about supportive care and symptom management trials too—not just drug trials

Where to Search for Metastatic Trials



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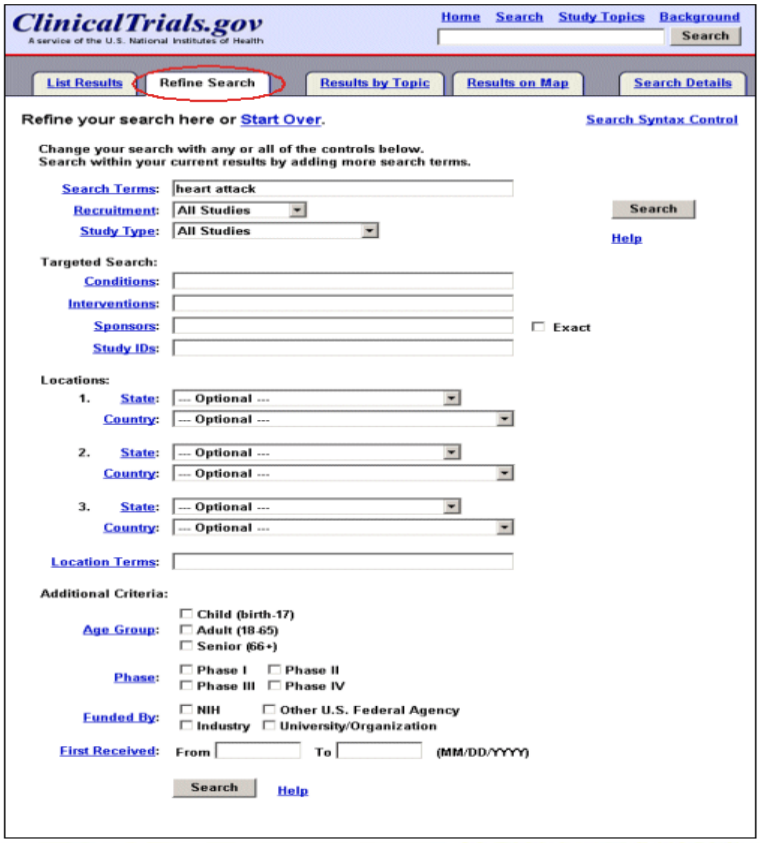


ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Home Search Study Topics Background
Search

List Results | Refine Search | Results by Topic | Results on Map | Search Details

Refine your search here or Start Over.

Search Syntax Control

Change your search with any or all of the controls below.
Search within your current results by adding more search terms.

Search Terms: heart attack
Recruitment: All Studies
Study Type: All Studies
Search
Help

Targeted Search:
Conditions:
Interventions:
Sponsors: Exact
Study IDs:

Locations:
1. State: --- Optional ---
Country: --- Optional ---
2. State: --- Optional ---
Country: --- Optional ---
3. State: --- Optional ---
Country: --- Optional ---

Location Terms:

Additional Criteria:
Age Group: Child (birth-17) Adult (18-65) Senior (66+)
Phase: Phase I Phase II Phase III Phase IV
Funded By: NIH Other U.S. Federal Agency Industry University/Organization
First Received: From To (MM/DD/YYYY)

Search Help

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Home Search Study Topics Background
Search

List Results | Refine Search | Results by Topic | Results on Map | Search Details

Found 829 studies with search of: heart attack

Hide studies that are not recruiting patients

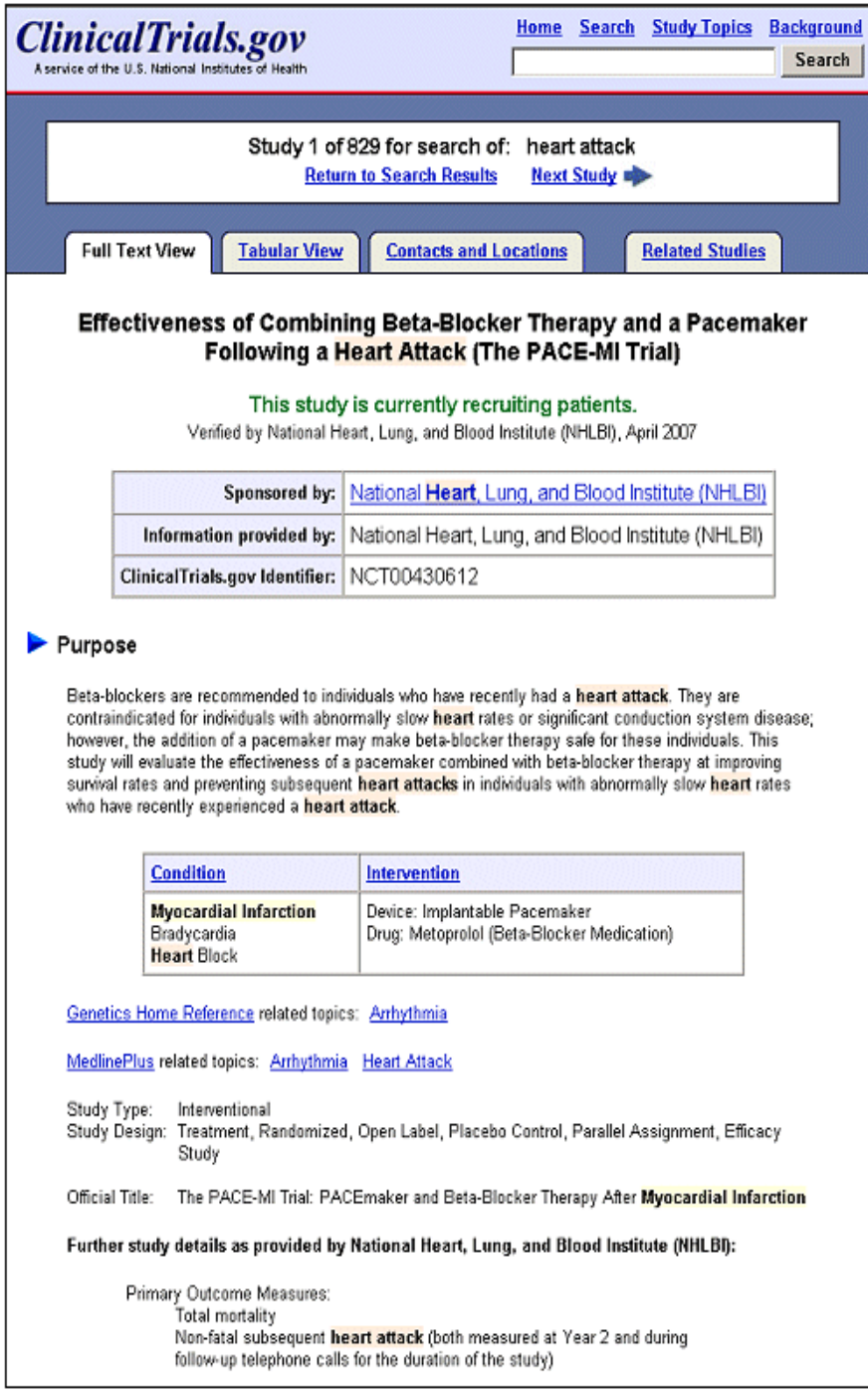
Display Options

1 Recruiting Effectiveness of Combining Beta-Blocker Therapy and a Pacemaker Following a Heart Attack (The PACE-MI Trial)
Conditions: Myocardial Infarction; Bradycardia; Heart Block
Interventions: Device: Implantable Pacemaker; Drug: Metoprolol (Beta-Blocker Medication)

2 No longer recruiting HMO Research Network CERT: Acute Myocardial Infarction
Condition: Acute Myocardial Infarction
Intervention: Behavioral: Beta-blocker adherence following a myocardial infarction

3 Completed Which Therapy for Acute Heart Attacks? (The WEST Study)
Condition: Myocardial Infarction
Interventions: Drug: tenecteplase; Drug: enoxaparin; Drug: clopidogrel; Procedure: percutaneous coronary intervention

4 Recruiting Pre-Hospital Administration of Thrombolytic Therapy With Urgent Culprit Artery Revascularization
Conditions: Heart Disease; Myocardial Infarction; Acute Myocardial Infarction
Interventions: Drug: Retavase 10 U IV Bolus (thrombolytic-clot busting drug); Procedure: Angioplasty/ Heart Catheterization; Device: Drug eluting stent placed in heart attack related artery



ClinicalTrials.gov
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Home Search Study Topics Background
Search

Study 1 of 829 for search of: heart attack
Return to Search Results Next Study

Full Text View | Tabular View | Contacts and Locations | Related Studies

Effectiveness of Combining Beta-Blocker Therapy and a Pacemaker Following a Heart Attack (The PACE-MI Trial)

This study is currently recruiting patients.
Verified by National Heart, Lung, and Blood Institute (NHLBI), April 2007

Sponsored by:	National Heart, Lung, and Blood Institute (NHLBI)
Information provided by:	National Heart, Lung, and Blood Institute (NHLBI)
ClinicalTrials.gov Identifier:	NCT00430612

Purpose

Beta-blockers are recommended to individuals who have recently had a heart attack. They are contraindicated for individuals with abnormally slow heart rates or significant conduction system disease; however, the addition of a pacemaker may make beta-blocker therapy safe for these individuals. This study will evaluate the effectiveness of a pacemaker combined with beta-blocker therapy at improving survival rates and preventing subsequent heart attacks in individuals with abnormally slow heart rates who have recently experienced a heart attack.

Condition	Intervention
Myocardial Infarction Bradycardia Heart Block	Device: Implantable Pacemaker Drug: Metoprolol (Beta-Blocker Medication)

Genetics Home Reference related topics: Arrhythmia

MedlinePlus related topics: Arrhythmia Heart Attack

Study Type: Interventional
Study Design: Treatment, Randomized, Open Label, Placebo Control, Parallel Assignment, Efficacy Study

Official Title: The PACE-MI Trial: PACEmaker and Beta-Blocker Therapy After Myocardial Infarction

Further study details as provided by National Heart, Lung, and Blood Institute (NHLBI):

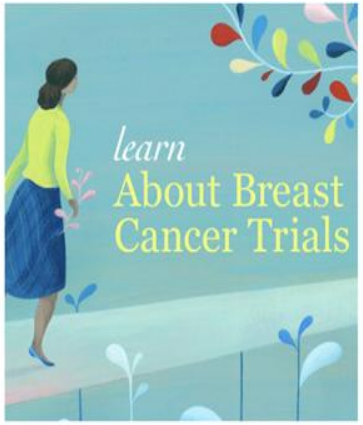
Primary Outcome Measures:
Total mortality
Non-fatal subsequent heart attack (both measured at Year 2 and during follow-up telephone calls for the duration of the study)

BreastCancerTrials.org

Personalized clinical trial matching

Breast Cancer Trial Search

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

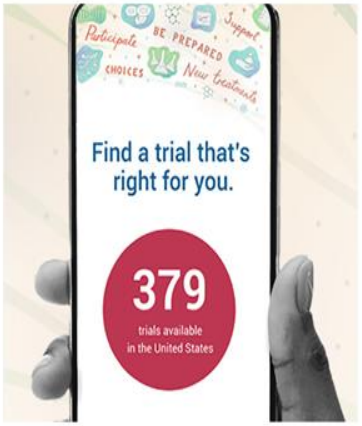


- Browse or match to over 700 trials in the U.S.
- Trial information displayed in patient-friendly language

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

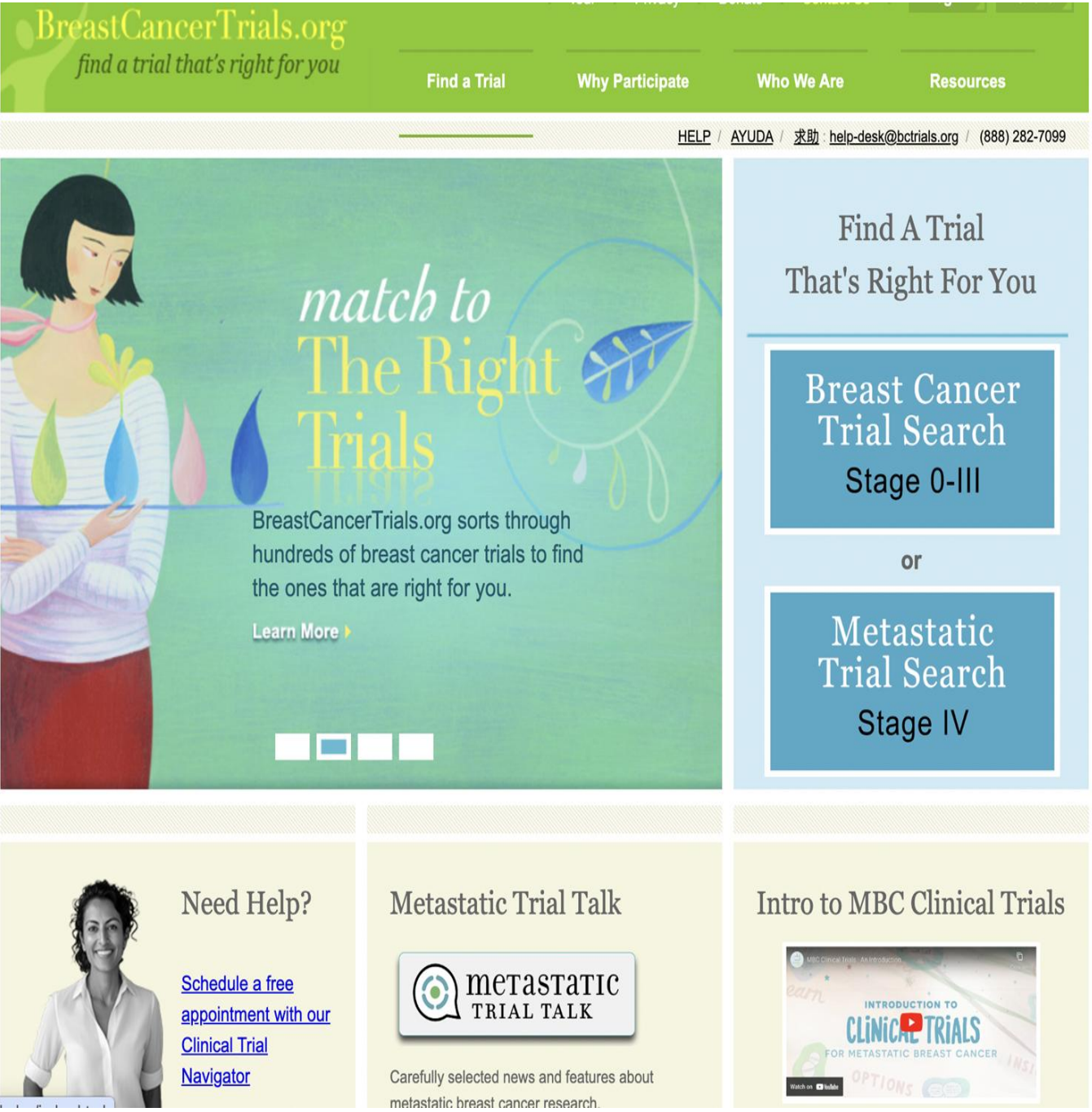
MetastaticTrialTalk.org

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.

Metastatic tools:
- Metastatic Trial Search (MTS): trial-matching designed for stage IV
- Metastatic Trial Talk (MTT): curated updates on MBC trials & research

Metastatic Trial Search (MTS):

A trial-matching tool designed for stage IV breast cancer

BreastCancerTrials.org

find a trial that's right for you

In 2 minutes

- See matched trials in patient-friendly language
- Refine by location, subtype/biomarkers, and trial type
- Answer questions about your diagnosis and prior treatments
- Create an account any time to save your profile
- Optional: weekly Trial Alerts when new matches are added
- Use Metastatic Trial Talk (MTT) for curated updates and new trials

METASTATIC TRIAL SEARCH DEMO

Helpful Resources

BreastCancerTrials.org — https://www.breastcancertrials.org/

- Metastatic Trial Search (MTS): stage IV trial-matching
- Metastatic Trial Talk (MTT): curated MBC trial updates

ClinicalTrials.gov — https://clinicaltrials.gov/

- Global registry; filter by status/location

NCI Trial Costs & Insurance — https://www.cancer.gov/about-cancer/treatment/clinical-trials/search/trial-costs

American Cancer Society (ACS)/ASCO- www.cancer.org

ACS Hope Lodge — https://www.cancer.org/support-programs-and-services/hope-lodge.html

FDA: Informed Consent — https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials

NCORP — https://ncorp.cancer.gov/

Triage Cancer — https://triagecancer.org/

PAF Co-Pay Relief — https://www.copays.org/

LBBC MBC Conference — https://www.lbbc.org/community/events/metsconf26

Action Steps

- Identify where and which clinical trials are available in your area (your site, academic sites, NCORP/community sites)
- Join patient advisory / protocol review groups. Give feedback on consent forms and visit schedules (what's realistic for MBC)
- Join advocacy organizations and share experiences
- Assist patients with searching for and asking about clinical trials (MTS/Clinicaltrials.gov)
- Make sure to know your biomarker testing results for any appropriate clinical trials
- Ask trial sites how they support participants (transport, translation, flexible scheduling)
- Partner with community to develop educational programs about clinical trials to demystify participation

Thank you

Q&A

Contact:

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BreastCancerTrials.org — https://www.breastcancertrials.org

Breast Cancer Clinical Trial Navigator bctrials@quantumleaphealth.org

NCI Clinical Trials.gov- www.clinicaltrials.gov