

EVOLVE-BDT

TRIAL TITLE
Evolutionary Clinical Trial for Novel Biomarker-Driven Therapies (EVOLVE-BDT)

TRIAL STATUS
Recruiting

TRIAL NUMBER
NCT07340541

TRIAL PHASE
Phase 2

PARTICIPANTS ELIGIBLE FOR THE STUDY*:

- Adults (women and men) diagnosed with metastatic estrogen receptor-positive (ER+)/HER2-negative (HER2-) or metastatic triple negative breast cancer (TNBC).
- Participants with ER+/HER2- metastatic breast cancer must have previously received endocrine therapy (hormone therapy) plus a CDK4/6 inhibitor as first-line treatment or experienced recurrence while receiving adjuvant (after surgery) hormone therapy plus a CDK4/6 inhibitor.
- Must have cancer progression after first-line treatment but must not have started second-line treatment before enrolling in the study.
- Must have at least one tumor lesion that can be evaluated on imaging scans.
- Willing to undergo a research biopsy before starting treatment in the study. The biopsy requirement may be waived if a suitable biopsy was performed within 4 months before the date of study consent and sufficient tissue is available.
- Willing to provide previously collected tumor tissue from the primary and/or metastatic lesion.

*Additional eligibility criteria may apply.

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Spotlight on Clinical Trials
FACT SHEET

TRIAL DETAILS:

- EVOLVE-BDT is a multicenter, biomarker-guided, phase 2 clinical trial for people with metastatic ER+/HER2- or metastatic TNBC whose cancer has progressed after first-line treatment.
- This study plans to enroll approximately 700 participants.
- Tumor tissue and blood samples will be analyzed to identify biomarkers, which are measurable features of a tumor that may help predict which treatments are most likely to work.
- Based on the biomarker results, participants may be assigned to a treatment group matched to the biology of their cancer.
- New treatment groups may be added over time as researchers learn more about breast cancer biomarkers and treatment approaches.
- Participants will undergo regular blood tests, imaging scans and clinical assessments to monitor their response to treatment.
- Treatment will continue until the cancer progresses, side effects become not tolerable or the treating physician recommends stopping treatment.

ABOUT BIOMARKER-DRIVEN THERAPIES IN METASTATIC ER+/HER2- BREAST CANCER AND TNBC:

- Biomarkers are found in a tumor or blood sample that can provide information about how cancer may behave or respond to treatment.
- Estrogen receptor, progesterone receptor, HER2 and certain gene mutations in cancer cells are examples of biomarkers that can help guide treatment decisions in metastatic breast cancer.
- However, many patients eventually develop resistance to standard therapies and researchers are working to identify additional biomarkers that may help match patients with more effective treatments.
- Biomarker-driven clinical trials use information from a patient's tumor to help identify treatments that may be more likely to work for that person's cancer.
- The goal of this study is to learn whether a personalized, biomarker-guided approach can improve outcomes for patients with metastatic ER+/HER2- breast cancer and metastatic TNBC.
- Data collected through this study may help researchers better understand why some tumors respond to treatment while others do not, potentially leading to more personalized treatment options in the future.

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