



# TAILORx

## Breast Cancer Clinical Trial Overview

### Trial Assigning Individualized Options for Treatment (Rx)

*The TAILORx clinical trial is sponsored by the National Cancer Institute and administered by the Eastern Cooperative Oncology Group.*

#### Purpose of Trial:

The TAILORx trial is designed to determine whether adjuvant hormonal therapy alone is as effective as adjuvant hormonal therapy in combination with chemotherapy for certain women with breast cancer. Trial results will help individualize treatment for each breast cancer patient, for improved clinical outcomes.

#### Eligibility Criteria:

Women must have estrogen receptor- and/or progesterone receptor-positive, axillary node-negative, HER2/neu-negative breast cancer. The tumor size must be 1.1 to 5.0 cm (or 5.0 mm to 1.0 cm, with unfavorable histological features). Participants must meet standard clinical criteria and be medically suitable candidates for adjuvant chemotherapy.

#### Primary Objectives:

- A. To determine whether adjuvant hormonal therapy is not inferior to adjuvant chemohormonal therapy in women whose tumors fall in the Primary Study Group category (as indicated by an Oncotype DX™ Recurrence Score™ result of 11 to 25). The primary study endpoint is disease-free survival. Other co-primary endpoints include distant recurrence-free interval, recurrence-free interval, and overall survival.
- B. To create a tissue and specimen bank for patients enrolled in this trial, including formalin-fixed, paraffin-embedded tumor specimens, tissue microarrays, plasma, and DNA obtained from peripheral blood. This resource will be critical for evaluating emerging clinical cancer tests.

Please refer to the Schema on the other side of this document for details.

[For eligibility questions on the TAILORx trial, please contact:](#)

Eastern Cooperative Oncology Group (ECOG)

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[www.ecog.org](http://www.ecog.org)

[For protocol and general information, please contact:](#)

Clinical Trials Support Unit (CTSU), 1-888-823-5923, [CTSUcontact@westat.com](mailto:CTSUcontact@westat.com), [www.ctsu.org](http://www.ctsu.org)

[For information on the Oncotype DX assay, please contact:](#)

Genomic Health Customer Service, 1-866-ONCOTYPE (1-866-662-6897)

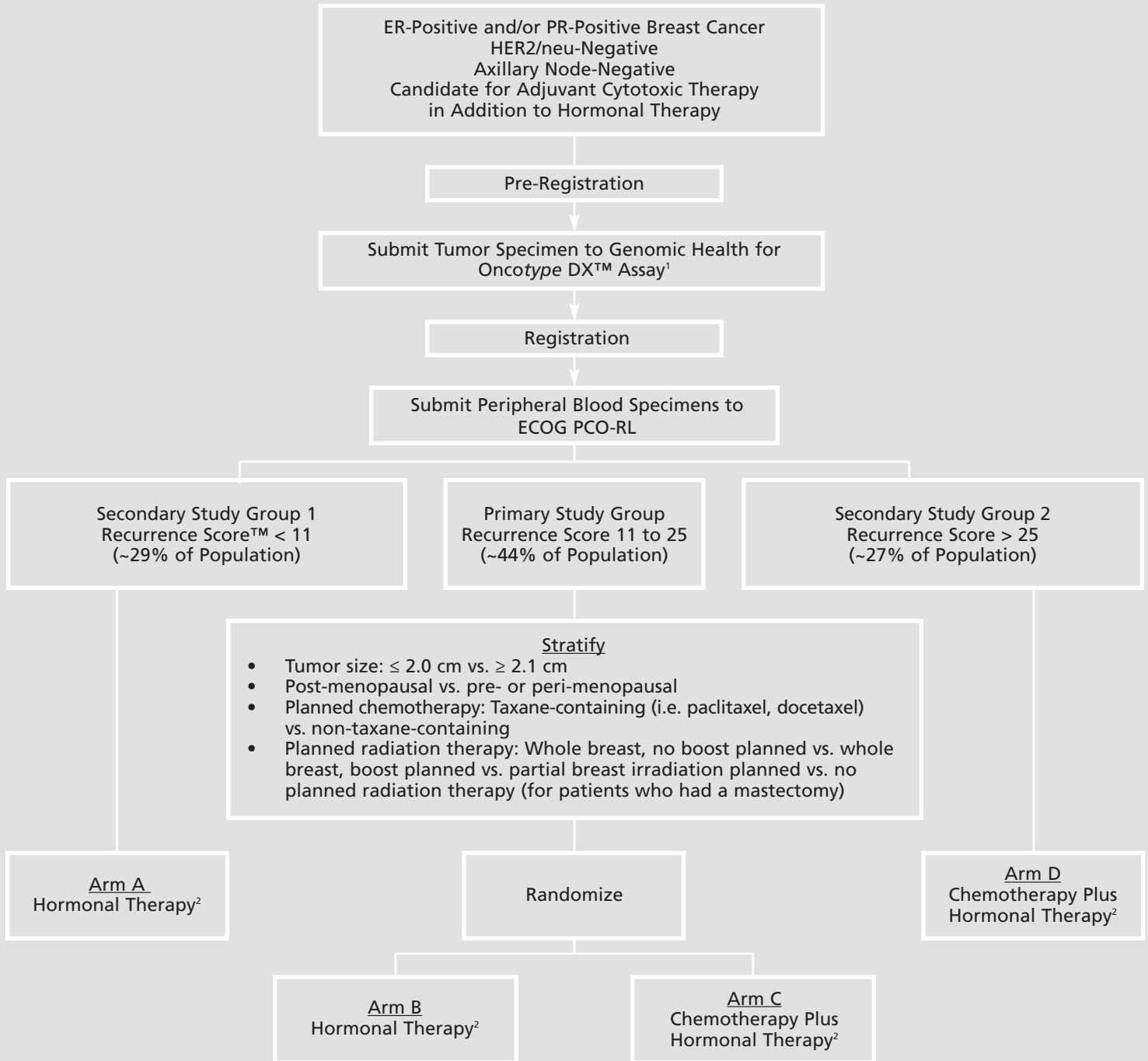
[www.oncotypedx.com](http://www.oncotypedx.com)

Activation Date: April 7, 2006



# Schema

*This schema outlines the pre-registration, registration and randomization process for the TAILORx breast cancer clinical trial.*



Accrual Goal = 10,046 patients  
Patients who have had breast conservation surgery will also be treated with radiotherapy.

1. A tumor specimen MUST be sent to Genomic Health for the Oncotype DX assay. Residual tumor tissue and RNA will be forwarded to the ECOG PCO-RL by Genomic Health, and will be retained by the ECOG PCO-RL for individuals who have consented to use of tissue for future research (or returned to the site if consent was not granted). Patients who have had the Oncotype DX assay performed prior to pre-registration may also enroll if the RS was 11 to 25, the patient has signed consent form, and all eligibility criteria are met. In this case, tumor specimen must be sent directly to the ECOG PCO-RL.  
2. Patients will receive hormonal therapy or chemotherapy plus hormonal therapy of the treating physician's choice.  
Oncotype DX and Recurrence Score are trademarks of Genomic Health, Inc.