

ECOG TAILORx PROTOCOL CARD

**Breast Cancer
Version 8/23/06**

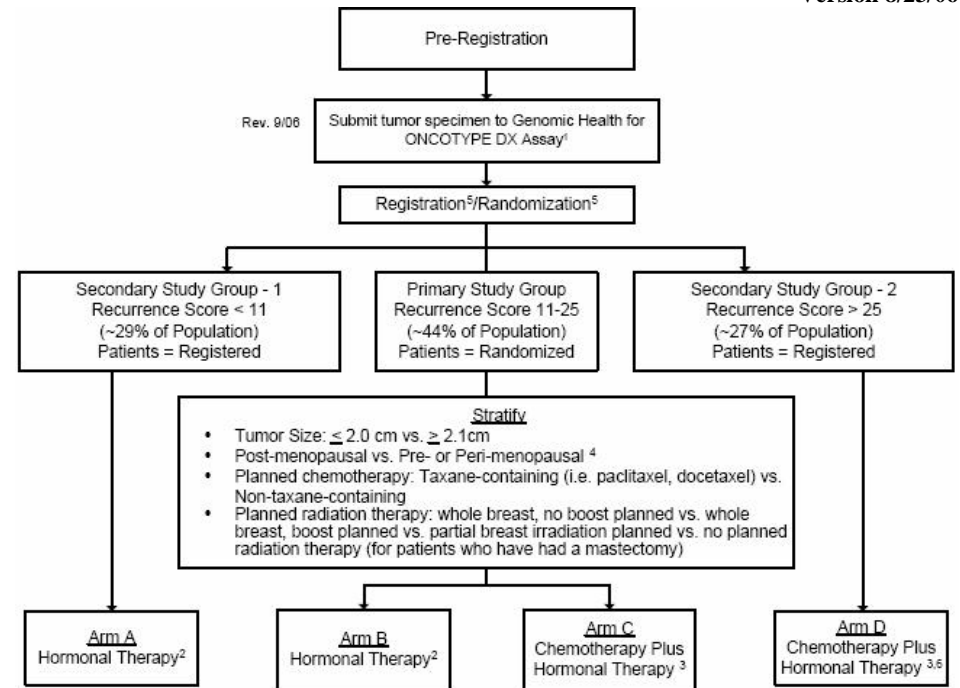
Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment (Rx): The TAILORx Trial

Eligibility

- Patients must have operable histologically confirmed adenocarcinoma of the female breast and must have completed primary surgical treatment.
- Patients must have tumor that is ER and/or PR positive.
- Patients must have negative axillary nodes as assessed by sentinel lymph node biopsy, an axillary dissection, or both.
- Tumor size must be 1.1-5.0cm (or 5mm-1.0cm plus unfavorable histological features [i.e., intermediate or poor nuclear and/or histologic grade, or lymphovascular invasion]).
- Tumors must be Her2/neu negative by FISH or immunohistochemistry.
- Patients and physicians must be agreeable to initiate standard chemotherapy and hormonal therapy as adjuvant therapy (see Appendices II and III for permitted chemotherapy and hormonal therapy options).
- A tissue specimen from the primary breast cancer must be located and ready to be shipped after consent is obtained and within 3 days of pre-registration.
- Patients must be ≥ 18 years and ≤ 75 years and must have an anticipated life expectancy of at least 10 years.
- Patients must be disease-free of prior invasive malignancies for ≥ 5 years with the exception of curatively-treated BCC or SCC of the skin or carcinoma in situ of the cervix. Patients may not have had previous contralateral or ipsilateral invasive breast cancer or DCIS, or bilateral synchronous cancers.
- Patients must pre-register within 84 days from the final surgical procedure required to adequately treat the primary tumor.
- Patients must have undergone a modified radical mastectomy or local excision plus acceptable axillary procedure. There must be adequate (at least 1mm) tumor-free margins of resection (for invasive and DCIS). LCIS involving the resection margins is acceptable.
- Patients must **NOT** have had any prior chemotherapy or radiation therapy for this malignancy.
- Patients may have received up to 8 weeks of a SERM or aromatase inhibitor for this malignancy. Patients may **NOT** have developed breast cancer while receiving a SERM or an aromatase inhibitor for breast cancer prevention, or a SERM for other indications (e.g., osteoporosis).
- Patients should **NOT** have COPD requiring treatment, chronic liver disease, previous history of CVA, history of CHF or other cardiac disease that would preclude the use of an anthracycline, or any chronic psychiatric or other condition that would impair compliance with the treatment regimen.
- Patients must **NOT** be pregnant or breastfeeding. Women of childbearing potential must be strongly advised to utilize an accepted and effective form of non-hormonal contraception.
- Patients must **NOT** have previously had the Oncotype DX assay performed, unless they had a Recurrence Score of 11-25.

THIS INFORMATION IS INTENDED TO BE USED AS A SCREENING TOOL ONLY AND SHOULD NOT BE USED IN PLACE OF THE PROTOCOL.

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Accrual Goal = 10,048 patients

Patients who have had breast conservation surgery will also be treated with radiotherapy.

Refer to Section 5.2 for RT guidelines

1. A tumor specimen MUST be sent to Genomic Health for the Oncotype DX assay (see Section 10 and Appendix V for details). 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 11-25, the patient has signed consent, 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 of the treating physician's choice (see Appendix III for details).
3. Patients will receive chemotherapy plus hormonal therapy of the treating physician's choice (see Appendices II & III for details).
4. See Appendix III for status definitions
5. See Section 10.2 for submission of samples to the ECOG-PCO.
6. For patients with a RS ≥ 26 who do not register on another CTSU study, the enrolling site is asked to provide baseline and follow-up information on a voluntary basis. Requested information will include the following: (1) a baseline case report form, (2) a report of disease relapse event (as defined in Section 6), and/or second primary cancer, and/or death (if any of these events occur), (3) and a report of disease and survival status 5 years after registration.

Required Laboratory / Tests

(Labs must be completed within 4 weeks prior to pre-registration)

- CBC with Differential
- Leukocytes $\geq 3,500/\text{mm}^3$
- Platelet count $\geq 100,000/\text{mm}^3$
- Serum Creatinine $< 1.5 \text{ mg/dL}$
- AST $\leq 3 \times \text{IULN}$
- Pregnancy test if applicable, within 2 weeks prior to pre-registration on primary pathology specimen
- Hormone receptor status mammogram obtained as part of original diagnosis, biopsy, and surgery will suffice
- Mammogram