

PACCT-1 Trial: TAILORx

*A Clinical Trial Assigning Individualized
Options for Treatment (Rx)*

Breast Cancer Clinical Trial Announcement

What are Clinical Cancer Tests and Why Do We Need Them?

When you are newly diagnosed with breast cancer, you and your doctor have to decide on treatment(s) and you need the answers to questions like: Which treatment will work best for me? Should I have hormonal and/or chemotherapy? Why do I need additional treatment after surgery?

Hormonal therapy and/or chemotherapy is usually recommended after surgical treatment because there is a chance of recurrence. Treatment given after surgery is called "adjuvant therapy" and it significantly reduces the chance of the cancer returning. Hormonal therapy is always recommended if the tumor expresses the estrogen receptor (ER). Adding chemotherapy reduces the risk of recurrence, but for many women, the chance of benefit may be less than five percent. Current practice guidelines recommend chemotherapy for most women with early-stage, ER-positive breast cancer. However, because we are unable to precisely identify who benefits from chemotherapy, many receive chemotherapy unnecessarily.

A clinical cancer test has now been developed that can tell you the likelihood of your cancer coming back or recurring. It is called the Oncotype DX Assay and the test result is reported as a Recurrence Score (RS) that ranges from 0 to 100. Patients with a low Recurrence Score have been found to have fewer recurrences and often receive only hormonal therapy. Patients with a high RS have more recurrences and usually have hormonal plus chemotherapy. At this time, researchers do not know which treatment(s) work best for patients with a mid-range RS. Researchers have developed the TAILORx trial to try and determine which patients in the mid-range group would do well with only hormonal therapy and which need both therapies.

What is the purpose of this study?

The purpose of TAILORx is to determine whether hormonal therapy is adequate treatment for patients who have a tumor with a mid-range RS of 11 to 25. In the TAILORx trial all participants will be assigned to a study group based on their RS on Genomic Health's Oncotype DX Assay. The Assay determines each patient's RS by running tests on a sample of your tumor after it has been removed during surgery.

Can I participate?

You can, if you are newly diagnosed with early stage (I or II) breast cancer, are a candidate for standard chemotherapy, are not pregnant, and if your tumor is:

- estrogen and/or progesterone receptor positive
- HER2 receptor negative
- between 1.1 and 5 cm
- has no positive lymph nodes

How is the study designed?

If you qualify and consent to participate in this study, you will be pre-registered and a sample of your tumor will be submitted to Genomic Health for testing with the Oncotype DX Assay. After your doctor receives the results of the test you will proceed to the registration stage and specific treatments based on your RS will be recommended.

- If your RS is 10 or less you will receive hormonal therapy, but no chemotherapy
- If your RS is 26 or more you will receive chemotherapy plus hormonal therapy
- If your RS is 11-25 you will be randomly assigned (by chance, like a coin flip) to treatment with either:
 - hormonal therapy alone
 - chemotherapy plus hormonal therapy

It is by studying the patients in the mid-range group that researchers hope to discover if hormonal therapy alone is as effective as hormonal therapy plus chemotherapy for patients in this group.

The National Cancer Institute (NCI) is sponsoring the TAILORx trial. It is conducted by all the NCI-funded cooperative groups in the US.

TAILORx is coordinated by the Eastern Cooperative Oncology Group (ECOG)

Oncotype DX is a registered trademark of Genomic Health, Inc.

