

RxPONDER *a clinical trial*

Rx for Positive Node,
Endocrine Responsive Breast Cancer

Randomization Fact Sheet

All women screened for the RxPONDER trial will have their tumor tissue tested with the Oncotype DX assay. Those with a recurrence score (RS) of 25 or lower on this genomic test are eligible to continue with the study. These patients will be placed at random into one of two study groups:

1. treated with chemotherapy and hormonal therapy
2. treated with hormonal therapy alone

What is randomization?

Randomization is a process used in many clinical trials that assigns research participants by chance, rather than by choice, to one of the trial's study groups or arms.

Each study participant has a fair and equal chance of being placed into either of the study groups.

The goal of randomization is to produce comparable groups in terms of general participant characteristics, such as age, ethnic background, and other key factors that might affect the course of the disease. In this way, the two groups are as similar as possible at the start of the study so that at the end of the study, any differences in outcomes between the two groups are likely to be a result of the differences in treatment given.

A randomized, controlled trial is considered the most reliable and impartial method of determining which medical treatments work the best.

Why is randomization used?

Research participants are randomized in clinical trials so that bias does not weaken the study results. Bias consists of human choices, beliefs, or any other factors besides those being studied that can affect a clinical trial's results. If physicians or participants themselves choose the group, assignments might be personally influenced and therefore unevenly slanted toward one side or the other.

For instance, if a study is not randomized, physicians might follow their own biases and assign participants with certain characteristics (like specific age groups or racial groups) to the experimental group, so that the kinds of patients enrolled in the experimental group would not be the same as in the control group. It would then not be

possible to know if differences in outcomes between the groups were truly because of the treatment assigned, or rather because of the kinds of patients included in the group.

Randomization prevents such bias. In a randomized trial, investigators use a computer program or a table of random numbers to assign each study participant to a group.

Why should I be thinking about randomization?

Randomization of patients to one arm or another helps ensure the patients in both arms are as similar overall as possible.

You always have the right to leave a clinical trial at any time, but the more patients who leave a trial after randomization, the more bias can be introduced by those decisions. For instance, patients with a lower recurrence score might be more likely to leave if they're in the chemotherapy arm of the trial than the hormonal therapy only arm. If many patients leave this way, the benefits of randomizing patients to each group becomes lessened, and the study groups may become subtly different from each other in ways that are difficult to determine but that could affect the trustworthiness of the trial outcome.

So it's best to think carefully about the possibilities before being randomized. If there is one of the treatment arms you really wouldn't be able to accept being placed in, it's better to decide that now, if you can, before randomization. Remember that at randomization you will have a fifty-fifty chance of being placed in that treatment arm.