

# Clinical trial summary (S1501)

## Understanding Which Patients Are More Likely to Have Heart Problems From Treatment for HER2-Positive Breast Cancer That Has Spread



### What is the purpose of this clinical trial?

Trastuzumab is a drug commonly used for HER2-positive breast cancer. It helps control cancer by targeting the HER2 protein.

Trastuzumab can work very well to treat cancer, but it can also cause side effects that affect the heart. Because of these risks, doctors carefully monitor their patients and provide medicine to help prevent heart problems.

This trial will observe patients who are receiving treatment with trastuzumab. The researchers will be looking to see what factors might make someone more likely to develop heart problems from this treatment. Understanding these factors could help doctors provide better care and prevent heart problems in patients who are at higher risk.

#### **This trial is set up to find out:**

- How many participants have heart problems over 2 years
- What factors could help doctors identify patients who are more likely to develop heart problems



### Why is this trial important?

People with breast cancer that has spread may continue trastuzumab for as long as the treatment is working. But some patients have to stop treatment because of serious side effects. This trial is a chance to learn what factors could be important for doctors to be aware of before patients begin treatment with trastuzumab. It may lead to better care in the future that helps more patients stay on treatment for longer.



## Who can be in this trial?

This trial is for adults, age 18 or older, with breast cancer that has spread to other places in the body.

### This trial is for people who:

- Are getting cancer treatment that uses trastuzumab
- Are taking medicine to help prevent heart problems during cancer treatment (a beta blocker, ARB, or ACE inhibitor)
- Received chemotherapy with an anthracycline drug **OR** have a higher risk of heart disease due to other health factors

### This trial is not for people who:

- Have abnormal echocardiogram results before starting the trial
- Need regular dialysis treatment for kidney problems
- Are pregnant

Talk with your doctor to learn more about who can join this study.



## What can I expect during the trial?

This trial does **not** involve any new or different medicines. You will continue the same cancer treatment and heart medicine that you currently use.

You will have study visits every 12 weeks to monitor your heart and overall health.

Your study visits will include:

### Echocardiogram tests



- This test is an ultrasound of the heart. It uses sound waves to create images of your heart. Echocardiograms every 12 weeks are part of the usual care during treatment for HER2-positive breast cancer.
- As part of the study, you may receive extra images using a newer technology that can look at more details of the heart. This advanced type of image is called *global longitudinal strain*.

### Blood tests



- Your study team will test your blood for certain markers (such as changes in protein levels and changes in DNA) that may be related to heart problems.
- You will have blood drawn for these tests at the same time as your routine blood work.

If you develop any heart problems, you will get medical care to treat the problem just as you would if you were not in a study.



## How long will I be in the trial?

The study team will follow how you are doing for about 2 years (25 months).



## Are there costs? Will I get paid?

If you receive extra images with your standard echocardiogram, those extra images will be provided free. The extra blood tests are also provided free in this study.

Check with your health care provider and insurance provider about what costs will and won't be covered in the study. You will not be paid for joining the study.



## Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and search the national clinical trial number: **NCT03418961**
- For a list of trial locations, visit [swog.org/NCI-S1501](http://swog.org/NCI-S1501)



## Key information

**Protocol number:** S1501

**NCT number:** NCT03418961

**Full trial title:** Prospective Observational Cohort Study of Participants with Metastatic HER-2+

Breast Cancer At Risk of Cardiac Toxicity

**Trial sponsor:** SWOG Cancer Research Network

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**Thank you!**

When you join a clinical trial,  
you're moving cancer medicine and patient care forward.