











https://www.ISPYpatient.org

WHAT IS THE I-SPY2 TRIAL?

The I-SPY 2 Trial is a clinical trial for women and men with newly diagnosed Stage 2 or Stage 3 breast cancer. It tests whether specific investigational chemotherapy drugs are better than standard treatment. The investigational drugs may be given with or instead of the standard treatment. Treatment is given before surgery so you'll know whether the drug has worked.

AM I ELIGIBLE TO BE SCREENED?

- ✓ I am newly diagnosed with invasive breast cancer.
- ✓ My tumor is 2.5 cm or larger in size.
- ✓ I am 18 years or older.

The purpose of the Screening Phase of this study is to find out more about your cancer and if you are eligible to participate in the Chemotherapy or Endocrine Therapy Treatment Track.

WHAT SHOULD I DO NEXT?



If you are interested in the **I-SPY 2 Trial**, print this Fact Sheet to take to your doctor to discuss the trial or contact the nearest **I-SPY 2** site on the map at ISPYpatient.org.

WHAT IS INVOLVED IN THE SCREENING PHASE?

In the Screening Phase your study care team will assess your overall health, heart, liver and kidney function. You will have an MRI, a biopsy of your tumor and blood samples collected. The biopsy will be used to learn more about your cancer and tailor your treatment.

WHAT TO EXPECT IN THE TREATMENT PHASE

If you are eligible and agree to participate in the Treatment Phase, you will be assigned to a treatment based on your tumor's biology. You will join either the Chemotherapy Track or the Endocrine Therapy Track. On the Chemotherapy Track you will start with treatment A, which will include a novel targeted treatment for your tumor. If Treatment A is not right for you, you may start with Treatment B. If you are eligible for the Endocrine Treatment Track you will be randomly selected to receive either a standard of care treatment with an aromatase inhibitor or one of several investigational drugs for six months.

Whichever type of therapy you get, the goal is to shrink your tumor and give you only as much treatment as you need. During

treatment you will be monitored closely by your study care team, including having several MRIs and biopsies to assess your tumor's response to therapy.

After each MRI you will meet with your doctor to review your tumor's response and decide whether to continue the current treatment, move to the next treatment (on the Chemotherapy Track) or have surgery.

At the end of treatment, you will get an MRI and then have surgery to remove any remaining tumor cells. After surgery you will have follow-up visits with your care team.

HOW LONG DOES THE STUDY LAST?

The Screening Phase takes about two weeks, the Treatment Phase ranges from 3 to 9 months. After surgery, you will be followed for up to 10 years.

WILL IT COST ME MORE THAN REGULAR CARE?

You or your insurance will pay for care that you would normally receive for treatment of breast cancer. The study will pay for additional tests and the investigational drugs.