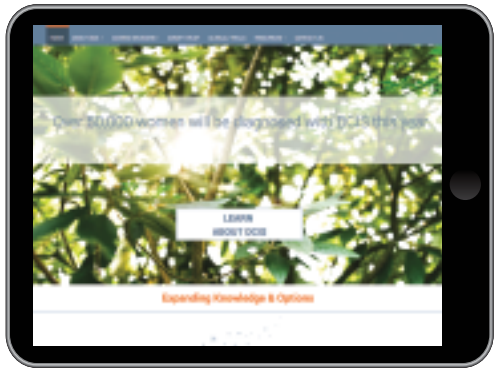
Why would women join the COMET Study?

- Low-risk DCIS is not a threat to a woman's life.
- Some women may want to avoid or delay surgery while being closely watched by their doctors.
- Close monitoring of low-risk DCIS may result in the same excellent outcomes as the standard treatments of surgery and radiation, but with fewer physical and/or emotional side effects that many women experience with standard treatment.
- Participation in this trial is valuable and appreciated. This study helps patients, researchers and doctors learn more about DCIS.
- Joining this trial is a chance for DCIS patients to improve the lives of future generations of women diagnosed with DCIS.

COMET Study (AFT-25):
A Clinical Trial for Low-Risk Ductal Carcinoma in Situ (DCIS)

To learn more about this study or see if you may be eligible, talk to your doctor or go to:

www.DCISoptions.org



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Low-risk DCIS is not a threat to a woman's life.

PATIENT BROCHURE

COMET

A DCIS STUDY

Expanding Knowledge & Options

What is COMET?

The **C**omparison of **O**perative to **M**onitoring and **E**ndocrine **T**herapy (COMET) Study is a clinical trial that looks at different treatment choices for low-risk ductal carcinoma in situ (also called DCIS).

DCIS is a non-invasive breast condition where cells that do not appear to be normal are found in the milk ducts. These cells are often harmless and may not need treatment.

The study will compare two groups of women who are 40 years of age or older and have been diagnosed with low-risk DCIS.

This is the first national study that will find out if low-risk DCIS can be safely watched with close monitoring. This may help future women to avoid breast surgery for low-risk DCIS.

We plan to enroll about 1200 patients at 100 sites across the US.

Women may be asked to join this study if the doctor thinks they are eligible. Participants will be randomized into one of two treatment groups by chance. This is done because no one knows if one treatment is better than another. The two treatment groups are:

1. Breast surgery, with the option of radiation and/or endocrine (hormone-blocking) therapy.
2. Active surveillance (sometimes called **close monitoring** or **watchful waiting**) with the option of endocrine (hormone-blocking) therapy.

Active surveillance means a condition is closely watched with more follow-up exams and tests such asmammograms. If the condition of the patient changes in some way, then they may be safely treated with breast surgery and sometimes radiation therapy.

Why is the COMET Study being done?

Currently, all types of DCIS are treated with breast surgery and often radiation therapy.

The COMET study will help researchers and doctors learn more about low-risk DCIS by closely watching some women who do not have surgery.

Our goal is to find out if some women can safely avoid surgery and radiation and their possible side effects which include pain, infection, scarring, and other changes to the breasts.

Who may be eligible to join the COMET Study?

- → Women with low-risk DCIS
- → Women who are 40 years of age or older
- → Women who do not have a personal history of breast cancer or prior treatment of DCIS.

*Active surveillance is sometimes called **watchful waiting**.*