# BREAST CANCER Breakthroughs Fact Sheet



## Breast Cancer Index Registry

TRIAL TITLE: Breast Cancer Index (BCI) Registry

TRIAL STATUS: Active, not recruiting

TRIAL NUMBER: NCTO4875351

**TRIAL PHASE:** Observational (Patient Registry)

### PARTICIPANTS IN THE STUDY:

- Diagnosed with hormone receptor-positive breast cancer that is stage 1, 2 or 3.
- Participants may have 0-3 positive lymph nodes (lymph nodes with cancer cells in them).
- Participants must have completed 4-7 years of hormone therapy after their initial surgery.
- · Participants must have their pre-treatment tumor sample available for testing.

### **TRIAL DETAILS:**

- Approximately 3,000 participants were recruited across 30-50 sites in the United States.
- Participants enrolled in study after completing their initial hormone therapy and completing Breast Cancer Index testing as part of their clinical care.
- The study will follow the outcomes of the study participants to confirm that the test can effectively predict the risk of recurrence (return of cancer).
- The study will also determine how the results of the test impact treatment decisions.

## ABOUT THE BREAST CANCER INDEX TEST AND TREATMENT OF EARLY-STAGE HORMONE RECEPTOR-POSITIVE BREAST CANCER:

- Studies have shown that an extended course of hormone therapy (over 5 years) can improve outcomes for some, but not all, people with early-stage hormone receptor-positive breast cancer.<sup>1-4</sup>
- The Breast Cancer Index test is a tumor profiling test that was evaluated for its ability to predict a patient's risk of recurrence and to pinpoint patients that receive a benefit from extended hormone therapy.<sup>5-7</sup>
- In 2021, the use of the Breast Cancer Index test to determine which patients benefit from extended hormone therapy was included in the National Comprehensive Cancer Network Guidelines.<sup>8</sup>
- Initial results from this study found that doctors change their recommendation for extended hormone therapy 40% of the time after Breast Cancer Index testing.<sup>9</sup>

For more information, go to komen.org/breakthroughs





# BREAST CANCER Breakthroughs Fact Sheet



## Breast Cancer Index Registry

#### **REFERENCES:**

- Davies C. et al. Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years after diagnosis
  of oestrogen receptor-positive breast cancer: ATLAS, a randomized trial. Lancet. 2013. https://pubmed.ncbi.nlm.nih.
  qov/23219286/
- 2. Gray R. et al. aTTom: Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years in 6,953 women with early breast cancer. J Clin Oncol. 2013. https://ascopubs.org/doi/10.1200/jco.2013.31.18\_suppl.5
- 3. Jin H. et al. Longer-term outcomes of letrozole versus placebo after 5 years of tamoxifen therapy for early-stage breast cancer. N Engl J Med. 2012. https://pubmed.ncbi.nlm.nih.gov/22042967/
- 4. Goss P. et al. Extending aromatase-inhibitor adjuvant therapy to 10 years. N Engl J Med. 2016. https://pubmed.ncbi.nlm.nih. gov/27264120/
- 5. Sgroi D. et al. Prediction of late disease recurrence and extended adjuvant letrozole benefit by the HOXB13/IL17BR biomarker. J Natl Cancer Inst. 2013. https://academic.oup.com/jnci/article/105/14/1036/964978?login=false
- 6. Bartlett J. et al. Breast Cancer Index and prediction of benefit from extended endocrine therapy in breast cancer patients treated in the Adjuvant Tamoxifen-To Offer More? (aTTom) trial. Ann Oncol. 2019. https://www.annalsofoncology.org/article/S0923-7534(20)32589-8/fulltext
- 7. Noordhoek I. et al. Breast Cancer Index Predicts Extended Endocrine Benefit to Individualize Selection of Patients with HR+ Early-stage Breast Cancer for 10 Years of Endocrine Therapy. Clin Cancer Res. 2021. https://aacrjournals.org/clincancerres/article/27/1/311/83398/Breast-Cancer-Index-Predicts-Extended-Endocrine
- 8. National Comprehensive Cancer Network. Breast Cancer Version (1.2024). https://www.nccn.org/professionals/physician\_gls/pdf/breast.pdf. Accessed March 7, 2024.
- 9. Sanft TB. et al. Impact of the Breast Cancer Index for Extended Endocrine Decision-Making: First Results of the Prospective BCI Registry Study. J NCCN. 2024. https://pubmed.ncbi.nlm.nih.gov/38437792/

For more information, go to komen.org/breakthroughs



