

For your ER+ early-stage breast cancer patient who is disease free

Use predictive power to personalize her path

Only commercially available test validated to help inform your decision to extend or end endocrine therapy



- Would she be among the 3% to 5% of patients who benefit from extended endocrine therapy?¹⁻⁴
- Will she face years of safety (eg, endometrial cancer, bone fractures) and tolerability (eg, hot flashes) challenges associated with the treatment?⁵

THE ENDOCRINE BIOMARKER



Breast Cancer
INDEXSM

Prediction. Personalized.

Predictive

(low/high binary result):

Predicts likelihood of benefit from extended endocrine therapy (years 5-10)⁶

Prognostic

(low/high risk category):

Assesses late recurrence risk (years 5-10)^{7,8}

Clinically actionable information

that can impact her treatment plan*

Low Risk/Low Likelihood of Benefit

- Consider completion of endocrine treatment at 5 years
- For patients already on extended endocrine treatment, consider stopping endocrine treatment

Low Risk/High Likelihood of Benefit

- Consider continuation of endocrine therapy depending on patient tolerability and comorbidities

High Risk/Low Likelihood of Benefit

- Consider additional and alternative therapeutic approaches for risk reduction

High Risk/High Likelihood of Benefit

- Consider extending endocrine therapy beyond year 5
- For patients beyond year 5 who are off treatment, consider restarting endocrine treatment
- Emphasize importance of compliance and adherence

For all patients, clinical decisions require incorporation of BCI results with all other clinical and pathologic risk factors, patient tolerability, and comorbidities

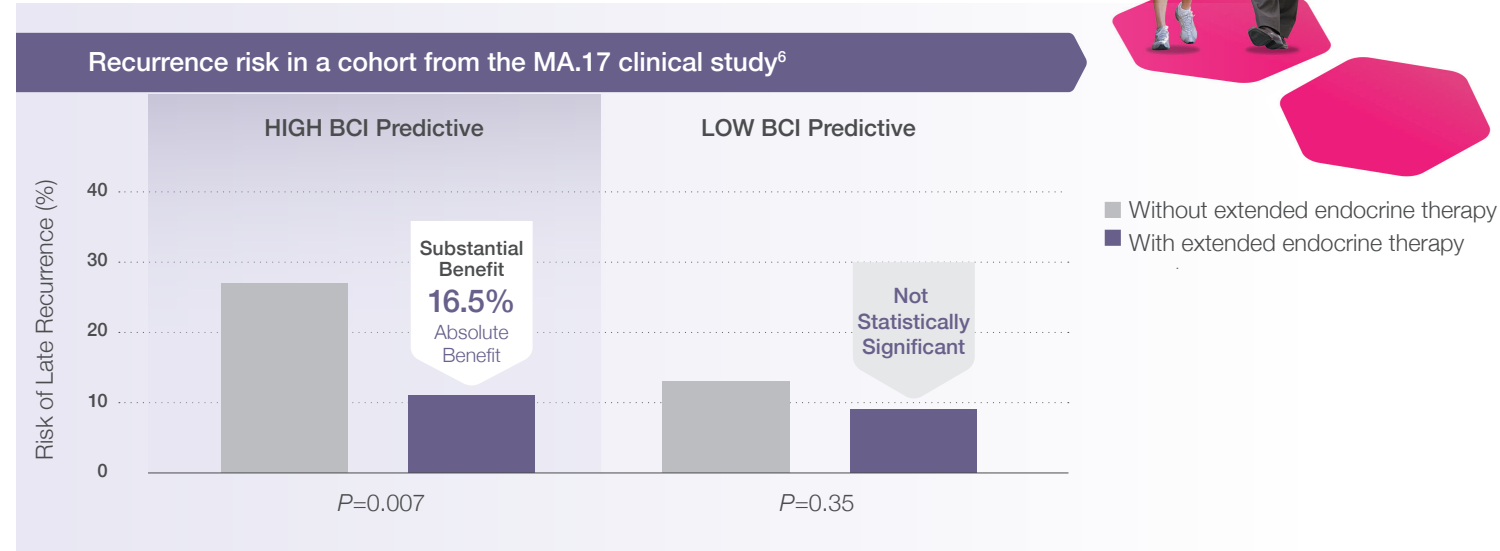
*For node-negative patients. Node positive patients should be considered to have a high risk of recurrence

Risk = Prognostic Risk of Recurrence in Years 5-10; Benefit = Predicted Benefit from Extended Endocrine Therapy

Strong clinical validation

BCI Predictive

- **Predictive** power demonstrated with multiple treatment histories (tamoxifen, aromatase inhibitor)^{6,8,9}



In women diagnosed with ER+ early-stage breast cancer who are disease free

When to consider using BCI

BCI will provide an individualized risk of late recurrence and likelihood of extended endocrine treatment benefit

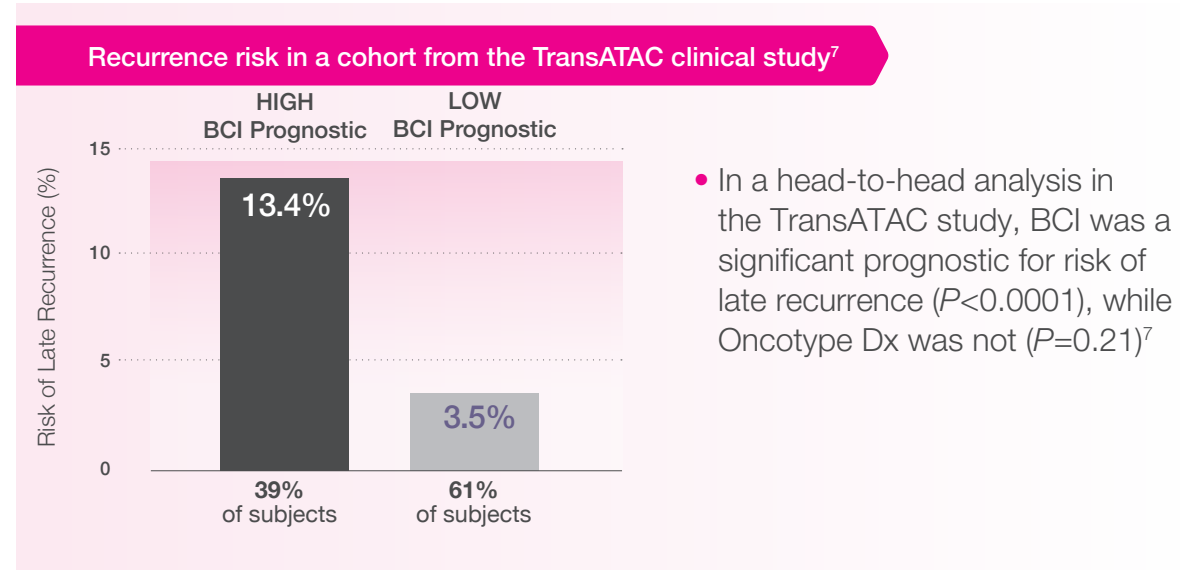
For Patients:

BCI May Help:

Dx	For Patients:	BCI May Help:
Dx	<ul style="list-style-type: none"> • Struggling with tolerability challenges • Who are poorly compliant 	Provide clarity on treatment road-map (5 or 10 years); encourage compliance
5	<ul style="list-style-type: none"> • All patients approaching 5 year anniversary (4-5 years post-diagnosis) 	Further inform whether to extend or end endocrine treatment beyond 5 years
10	<ul style="list-style-type: none"> • All patients 5-9 years post-diagnosis who are either: <ul style="list-style-type: none"> - Already on extended endocrine treatment - Have already stopped endocrine therapy after completing 5 years 	Further inform a previous decision related to extended endocrine treatment: <ul style="list-style-type: none"> - To continue or stop

BCI Prognostic

- **Prognostic** power demonstrated in 3 large studies, including 2 randomized control studies and multiple treatment histories (tamoxifen, aromatase inhibitor)^{7,8*}



* In the studies, prognostic scores were stratified by low, intermediate, and high risk of late distant recurrence. Because patients with intermediate- and high-risk scores had about the same late recurrence rate, patients with intermediate-risk scores are now designated as high risk.

BCI Indications for Use and Limitations

BCI provides a quantitative assessment of the likelihood of distant recurrence in patients diagnosed with ER+ node-negative breast cancer, and prediction of likelihood of benefit from extended (>5 year) endocrine therapy in patients who are recurrence-free after an initial 5 years of adjuvant endocrine therapy. Treatment decisions require correlation with all other clinical findings. This test was developed and its performance characteristics determined by bioTheranostics, Inc. It has not been cleared or approved by the US Food and Drug Administration. This test is used for clinical purposes. It should not be regarded as investigational or for research. How this information is used to guide patient care is the responsibility of the physician. bioTheranostics is certified under the Clinical Laboratory Improvement Amendments of 1988 to perform high complexity clinical laboratory testing.

Predictive power to personalize her path



The information you need to help decide whether to **extend** or end endocrine therapy

Order **BREAST CANCER INDEXSM** to help you decide

- Test Requisition Form downloadable at: biotheranostics.com
- Best-in-class sample retrieval program takes the work out of your hands
 - Complete the Test Requisition Form with physician signature and ICD-9 code.
 - Fax with pathology report, and patient insurance information to Client Services at **858-587-5874**
 - bioTheranostics will request the specimen from pathology
- 7-day turnaround time
- We handle the billing
- Covered by Medicare—and reimbursed by a growing list of other healthcare plans
- Generous patient assistance program available

For more information, visit

www.biotheranostics.com

Reach Client Services at (877) 886-6739

or

contact your local representative



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Breast Cancer Index addresses a critical unmet need

Experts agree that better predictive tools are a priority

The ASCO 2014 practice guidelines identified the need for a biomarker to "...selectively predict early versus late recurrence" and "determine whether longer durations of adjuvant endocrine therapy are clinically indicated."⁵

Only BCI offers validated predictive power

"Our biomarker should allow many women to avoid unnecessary treatment and for the focus to center on those in most need of therapy. This, in turn, could improve compliance with medication and further improve outcomes."⁶

—SgROI et al. MA.17 cohort study, *J Natl Cancer Inst*, 2013



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