# Invasive Breast Case Study

**PATIENT** | 40 Year-Old Female Patient
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**TUMOR SIZE (cm)** | 5.8
**MENOPAUSAL STATUS** | Pre-Menopausal
**TUMOR TYPE** | Lobular
**ER STATUS (IHC)** | ER positive
**PR STATUS (IHC)** | PR positive
**HER2/NEU STATUS** | Negative
**HISTOLOGIC GRADE** | 2
**LYMPH NODE STATUS** | Negative
**GENERAL HEALTH** | Good
**OTHER INFORMATION** | African American

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Invasive Breast Case Study

CLINICAL EXPERIENCE

The Distant Recurrence Risk at 9 Years (Prognosis), in patients with N−, ER+ breast cancer treated with endocrine therapy alone, is provided by the TAILORx¹ trial for RS 0-25 and by the NSABP B-14² trial for RS 26-100. Risk is for individual RS results. The 95% confidence intervals for distant recurrence at 9 years are ±2% or less for RS 0-22, and range from ±3% to ±11% as RS increases from 23-50. The TAILORx trial enrolled 10,273 patients and 5,018 patients with RS 0-25 were treated with endocrine therapy (tamoxifen or an aromatase inhibitor) alone. The NSABP B-14 trial enrolled 668 patients who were treated with tamoxifen alone.
The Absolute Benefit of Chemotherapy for all ages is provided by the TAILORx trial for RS 11-25 and by the NSABP B-20³ trial for RS 0-10 and RS 26-100. Results for the reduction in distant recurrence at 9 years are for the TAILORx-defined RS groups 0-10, 11-25, and 26-100. TAILORx trial enrolled 10,273 patients and 6,711 were randomized to endocrine therapy (tamoxifen or an aromatase inhibitor) alone or endocrine therapy plus chemotherapy (including anthracyclines and/or taxanes). The NSABP B-20 clinical trial enrolled 651 patients who were randomized to treatment with tamoxifen alone or tamoxifen plus CMF/MF chemotherapy. The magnitude of the absolute benefit of chemotherapy was ~6% at RS 26, and increased as the RS results increased from 26-100, with an average absolute benefit of ~24% and a conservative group estimate of >15% based on the width of the confidence intervals.

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RESULTS

Recurrence Score®

17

**Distant Recurrence Risk at 9 Years**

<table>
<thead>
<tr>
<th>With AI or TAM Alone</th>
</tr>
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<tbody>
<tr>
<td><strong>5%</strong></td>
</tr>
<tr>
<td>95% CI (4%, 6%)</td>
</tr>
</tbody>
</table>

**Group Average Absolute Chemotherapy (CT) Benefit**

<table>
<thead>
<tr>
<th>RS 11-25 All Ages</th>
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<tbody>
<tr>
<td><strong>&lt;1%</strong></td>
</tr>
<tr>
<td>95% CI (-1%, 2%)</td>
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</tbody>
</table>

AI - Aromatase Inhibitor / TAM - Tamoxifen
CI - Confidence Intervals

*For estimated CT benefit for individual RS results, see page 2.
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CLINICAL EXPERIENCE

Exploratory Subgroup Analysis for TAILORx and NSABP B-20 indicate that RS and age are the strongest predictors of chemotherapy benefit. The absolute reduction of distant recurrence from chemotherapy for patients >50 years and ≤50 years is shown here for RS groups: 11-15, 16-20, and 21-25 from TAILORx, and 0-10 and 26-100 from NSABP B-20.

<table>
<thead>
<tr>
<th>Age</th>
<th>RS 0-10</th>
<th>RS 11-15</th>
<th>RS 16-20</th>
<th>RS 21-25</th>
<th>RS 26-100</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50 years</td>
<td>No CT Benefit (&lt;1%)</td>
<td>&gt;15% CT Benefit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤50 years</td>
<td>No CT Benefit (&lt;1%)</td>
<td>~1.6% CT Benefit</td>
<td>~6.5% CT Benefit</td>
<td>&gt;15% CT Benefit</td>
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</table>
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ESTIMATED CHEMOTHERAPY BENEFIT FOR INDIVIDUAL RECURRENCE SCORE RESULTS

Recurrence Score ranges shown reflect randomized patients in NSABP B-20 and TAILORx.

**TREATMENT GIVEN:** Patient decided neoadjuvant HR therapy based on RS
Quantitative Single-Gene Scores for quality control. The Oncotype DX test uses quantitative RT-PCR to determine the RNA expression of ER, PR, and HER2, using the published validated cut-offs⁴. The standard deviations of single-gene results are less than 0.5 units. The RT-PCR single-gene results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.

References
2. ER Score based on quantitative ESR1 expression (estrogen receptor); PR Score based on quantitative PGR expression (progesterone receptor).