# Invasive Breast Case Study

**Patient**  
54 Year-Old Female Patient

<table>
<thead>
<tr>
<th><strong>Node Status</strong></th>
<th><strong>Tumor Size (cm)</strong></th>
<th><strong>Menopausal Status</strong></th>
<th><strong>Tumor Type</strong></th>
<th><strong>ER Status (IHC)</strong></th>
<th><strong>PR Status (IHC)</strong></th>
<th><strong>HER2/NEU Status</strong></th>
<th><strong>Histologic Grade</strong></th>
<th><strong>Lymph Node Status</strong></th>
<th><strong>General Health</strong></th>
<th><strong>Other Information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>6.0</td>
<td>Pre-Menopausal</td>
<td>Ductal</td>
<td>ER positive</td>
<td>PR negative</td>
<td>Equivocal</td>
<td>1</td>
<td>Negative</td>
<td>Patient is quite healthy, no chronic medical conditions, no rashes or lumps found anywhere</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Sarah Sammons  
Durham, NC
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.

<table>
<thead>
<tr>
<th>Distant Recurrence Risk at 9 Years</th>
<th>Group Average Absolute Chemotherapy (CT) Benefit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>With AI or TAM Alone</td>
<td>RS 11-25 All Ages</td>
</tr>
<tr>
<td><strong>4%</strong></td>
<td><strong>&lt;1%</strong></td>
</tr>
<tr>
<td>95% CI (3%, 5%)</td>
<td>95% CI (-1%, 2%)</td>
</tr>
</tbody>
</table>

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

*For estimated CT benefit for individual RS results, see page 2.
Invasive Breast Case Study

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></td>
<td>&gt;15% CT Benefit</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>
<td></td>
</tr>
</tbody>
</table>
Invasive Breast Case Study

ESTIMATED CHEMOTHERAPY BENEFIT FOR INDIVIDUAL RECURRENCE SCORE RESULTS

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

TREATMENT GIVEN: No chemo at this time, patient will pursue endocrine treatment
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.

Invasive Breast Case Study

**ER Score**

10.1

**PR Score**

5.3

**HER2 Score**

9.8

References

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