# Impact of KEYNOTE-522 on BneoCT: An Institutional Quality Measure Improvement Analysis

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## BACKGROUND

- Early stage HER2-positive breast cancer (HER2+) and triple-negative breast cancer (TNBC) are associated with a high recurrence risk.
- In 2022, BneoCT was formally introduced as a Commission on Cancer (CoC) breast quality measure.
- The metric focuses on the timely initiation of neoadjuvant therapy in eligible patients.
- More specifically, BneoCT is a measure of patients 75 years of age or younger, with early stage HER2-positive breast cancer or TNBC, for whom neoadjuvant chemotherapy, targeted therapy, and/or immunotherapy is initiated within 60 days of diagnosis.

## STUDY DESIGN

January 2021 - June 2025

**Retrospective Review**

**Patient cohort:** Early-stage breast cancer patients eligible for neoadjuvant therapy

**Data Collection:**
- Annual BneoCT performance rates from 4 Icahn School of Medicine/Mount Sinai campuses:
  - Mount Sinai Downtown
  - Mount Sinai Brooklyn
  - Mount Sinai West
  - Mount Sinai Morningside

**Statistical analysis:** The benchmark for BneoCT is 95%

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## RESULTS

**Table 1: Annual Performance Rates for BneoCT at Icahn School of Medicine/Mount Sinai**

| | Annual Performance Rates | | | | |
|---|---|---|---|---|---|
| **Year** | **2021** | **2022** | **2023** | **2024** | **Jan – June 2025** |
| **BneoCT (%)** | 84.93 | 81.82 | 86.67 | 91.18 | 95.24 |
| **95% CI** | 76.72 - 93.14 | 72.51 - 91.12 | 78.07 - 95.27 | 81.64 - 100.00 | |

- The integration of KEYNOTE-522 into the NCCN Guidelines in May 2021 played a substantial role in driving improvements in the BneoCT quality measure over the subsequent years.
- This quality measure improvement analysis illustrates how high-impact clinical trial data, when rapidly translated into national guidelines, can meaningfully influence patient care outcomes and institutional quality metrics.
- Sustained performance improvement at or above benchmark levels will require continued investment in multidisciplinary coordination, treatment pathway optimization, and early diagnosis-to-therapy transitions.

- At our institutions, performance on the BneoCT measure improved steadily over 4 consecutive years (Table 1).
- This upward trend reflects a 6.25% absolute increase from 2021 to 2024, and a 10.31% absolute increase from 2021 to 30th June 2025.
- While multiple factors likely contributed, we believe that results from the KEYNOTE-522 trial, which demonstrated that the addition of pembrolizumab to neoadjuvant chemotherapy in high-risk early-stage TNBC significantly improved pathologic complete response (pCR) rates and event-free survival, followed by the National Comprehensive Cancer Network's (NCCN) endorsement of KEYNOTE-522 in May 2021 (NCCN Version 4.2021), was a critical driver for earlier multidisciplinary coordination and greater utilization of neoadjuvant therapy pathways.
- The inclusion of pembrolizumab in NCCN Version 4.2021 marked a pivotal shift in practice standards for TNBC, prompting widespread institutional adoption of this immunotherapy-based neoadjuvant regimen.
- This facilitated earlier referrals and systemic therapy initiation, directly improving adherence to the BneoCT benchmark.
- Although HER2+ breast cancer cases were not directly affected by KEYNOTE-522, the broader trend toward aggressive, guideline-aligned neoadjuvant therapy likely enhanced care timeliness across both TNBC and HER2+ populations included in BneoCT.