

## CASE STUDY · ONCOLOGY

# Global Phase III Oral Chemotherapeutic Trial in Metastatic Breast Cancer

110 sites in 20 countries · CT, MRI, bone scan · RECIST 1.1 BICR

## Challenge

A global pivotal Phase III trial of a new oral chemotherapeutic for metastatic breast cancer required blinded independent central review of thousands of radiological examinations. Metastatic breast cancer frequently involves bone, where lesions are non-measurable under RECIST 1.1 and progression judgments depend on consistent interpretation of bone scans and correlative CT or MRI, and across 110 sites in 20 countries acquisition practice varied considerably.

The sponsor needed a central review that handled mixed measurable and non-measurable disease consistently, maintained reader blinding across a long follow-up period, and sustained throughput as enrollment accelerated, all under a quality system suitable for a registration submission.

## Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with a standardized acquisition protocol for CT, MRI and bone scintigraphy, qualified each site before first patient imaging, and provided training on timepoint scheduling and bone-scan correlation. Image transfer and quality control were centralized, with acquisition deviations returned to sites with specific corrective guidance.

Two oncology radiologists performed blinded independent reads under RECIST 1.1 at every timepoint, with adjudication on discordant response categories and progression dates. The charter defined how new bone lesions would be confirmed, how flare phenomena would be handled, and how non-target disease would contribute to progression determinations.

Reader agreement was monitored across the trial and recalibration sessions were held when drift was detected. Data management delivered a locked imaging dataset aligned with the sponsor's statistical analysis plan at each planned analysis.

## Intrinsic Imaging's Results

- Approximately 7,200 blinded independent reads completed across 110 sites in 20 countries
- Unevaluable timepoints held under 3% through site qualification and rapid feedback on acquisition deviations
- Adjudication on roughly 15% of timepoints with documented rationale, supporting a defensible progression-free survival analysis
- Imaging datasets delivered on schedule for interim and final analyses under an FDA-audited, ISO certified quality management system

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Read the full study online: <https://intrinsicimaging.com/case-studies/oncology-mbc-phase-iii-2016>

## About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 750 board-certified and fellowship-trained physicians, Intrinsic Imaging's team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System, Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit [www.IntrinsicImaging.com](http://www.IntrinsicImaging.com).

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