

CASE STUDY · ONCOLOGY

Four-Year Multinational Phase II Metastatic Breast Cancer Trial Across 60 Sites

60+ sites in 10 countries · CT, MRI, bone scan · RECIST

Challenge

A four-year multinational Phase II trial in metastatic breast cancer spanned more than 60 investigator sites in 10 countries. Over that duration and geography, the sponsor faced the operational risks of inconsistent acquisition, delayed image transfer and variable site interpretation of RECIST, any of which could compromise the response dataset.

The sponsor required a core lab to manage acquisition, transfer and processing across all sites and to provide oncology-subspecialized radiologists for guidance on RECIST interpretation, keeping the trial's imaging consistent and on schedule.

Intrinsic Imaging's Solution

Intrinsic Imaging developed acquisition guidelines for CT, MRI and bone scintigraphy, qualified and trained the 60-plus sites in their local languages where needed, and established centralized image transfer with receipt confirmation and quality control at every timepoint.

Oncology-subspecialized radiologists provided RECIST interpretation guidance under a charter defining target lesion selection, handling of bone and non-target disease and progression confirmation, and reviewed examinations where site assessments raised queries or where the protocol required central confirmation.

Project management maintained the imaging schedule across four years, tracked site compliance by country and escalated recurring acquisition issues, with periodic reader calibration to maintain consistency across the trial.

Intrinsic Imaging's Results

- Imaging from more than 60 sites in 10 countries acquired, transferred and processed centrally over four years
- Approximately 3,200 timepoints quality-controlled with acquisition deviations returned to sites within two business days
- RECIST interpretation guidance and central confirmation delivered under a single charter across all countries
- Timepoint completeness above 92% through active schedule tracking across the four-year duration

Read the full study online: <https://intrinsicimaging.com/case-studies/oncology-mbc-phase-ii-2011>

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.

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