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

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. 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. Metastatic breast cancer can involve disease sites with different imaging characteristics, making consistency more complex than obtaining examinations on schedule. Across a multinational trial, differences in modality use and interpretation can affect whether an apparent change reflects measurable tumor burden, non-target disease or an acquisition limitation. Comparable imaging evidence is therefore necessary for interpreting response across countries without assuming that local assessment practices are interchangeable.

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. The modality-specific guidance provides a shared technical basis while recognizing that anatomical imaging and bone scintigraphy contribute different information. Complete submissions matter because an apparently adequate examination of measurable lesions may not describe the full distribution of disease. Training in the languages needed by sites addresses understanding of acquisition and submission requirements rather than changing the underlying response criteria or the clinical meaning of each modality.

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. Explicit handling of bone and non-target disease is important because not every metastatic finding can be evaluated through serial diameter measurements. The charter links these findings to a common response framework. Central review of queried or protocol-specified examinations provides interpretive oversight, but should not be described as independent central reassessment of every examination when that broader reading scope is not documented.

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. Country-level compliance tracking helps distinguish recurring acquisition problems from isolated submission issues. Completeness remains a property of the available imaging record rather than evidence that missing examinations are clinically unimportant. Similarly, prompt return of acquisition queries supports timely correction where feasible, but cannot by itself establish that every deviation was recoverable or that incomplete follow-up had no effect on interpretation.

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

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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 50 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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