CASE STUDY · ONCOLOGY

Breast Cancer Trial With 3,000 Multimodality Breast Imaging Reviews

~3,000 reviews · Digital mammography, breast ultrasound, breast MRI · Lesion detection and BI-RADS assessment

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 clinical trial evaluating the safety and effectiveness of a new breast cancer product required nearly 3,000 central reviews of breast imaging. Breast imaging assessment is multimodal and interpretive: lesion detection and BI-RADS categorization on mammography, ultrasound and MRI vary between readers, and the product's effectiveness depended on consistent lesion-level assessment across modalities and timepoints.

The sponsor needed fellowship-trained breast imagers reading to a fixed standard, lesion-level correlation across modalities, and management of a sizeable review volume from two locations without variation in reading convention. The same breast lesion may have different appearances across mammography, ultrasound and magnetic resonance imaging, while nearby findings can be mistaken for a shared target. Consistent lesion identity is therefore essential before changes in size, morphology or assessment category can be interpreted. A large review volume increases the importance of keeping these distinctions explicit rather than relying on an overall impression of agreement between examinations.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with acquisition standards for full-field digital mammography, breast ultrasound and breast MRI, and lesion-level case report forms capturing location, size, morphology and BI-RADS assessment. Sites were qualified and trained on submission of complete multimodal examinations. Location, size and morphology provide complementary descriptors for maintaining lesion identity across modalities and timepoints. The acquisition standards and complete examination submissions supply the context needed to interpret those descriptors. A lesion that is conspicuous on a particular modality may be less apparent on another, so absence of an equivalent appearance does not necessarily establish disappearance or a contradiction between imaging assessments.

Breast imaging radiologists performed blinded reads under the charter, with lesion correlation across modalities governed by defined location-matching rules and with independent double reads on primary endpoint assessments. Discordant lesion detection or BI-RADS categorization was adjudicated. Defined location-matching rules constrain how readers connect findings across examinations, reducing discretionary assumptions about correspondence. Independent double reading exposes interpretive differences before adjudication establishes the assessment used for the endpoint. Agreement within a category interval should nevertheless be distinguished from exact categorical agreement, and neither measure alone establishes that imaging assessments correspond to pathology or demonstrate a treatment effect.

The trial was managed from the Bolton and San Antonio locations under a single quality system, with centralized image transfer, quality control and processing and periodic reader calibration across both locations. A shared quality system addresses the possibility that separate operating locations develop different submission practices or reading conventions. Periodic calibration reinforces the charter as the common interpretive reference without implying that all reader variability can be eliminated. Central processing also keeps technical completeness distinct from diagnostic judgment, since an examination can meet submission requirements while still presenting legitimate uncertainty about lesion detection or categorization.

Intrinsic Imaging’s Results

- Nearly 3,000 breast imaging reviews completed across mammography, ultrasound and MRI by fellowship-trained breast imagers
- Lesion-level cross-modality correlation applied under defined matching rules for approximately 1,100 lesions
- Reader agreement on BI-RADS category within one level above 92% on primary endpoint assessments
- Single quality system and reading convention maintained across the Bolton and San Antonio locations throughout the trial

---

Read the full study online: https://intrinsicimaging.com/case-studies/oncology-breast-disease-3000-reviews

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.

Contact:
Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com