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

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.

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.

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.

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.

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

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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 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 andOphthalmology. 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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