CASE STUDY · AI/CAD

Tenth MRMC Trial for CAD, AI and Deep Learning Software

15 to 30 readers sourced from a 200+ network · Multi-reader multi-case · FDA submission support

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 developer of CAD, AI and deep-learning software required an MRMC study in support of an FDA submission, and needed the reader panel recruited, qualified and reading within weeks of contract. Reader recruitment is the most common cause of MRMC schedule slippage: panels of 15 to 30 readers must be board certified, representative of intended users, free of conflicts and prior exposure to the software, and available for multiple reading sessions separated by a washout period.

The sponsor also needed the study conducted by a core lab whose MRMC processes had already withstood FDA inspection, so that the design, reading environment and documentation would not become a point of regulatory discussion. Rapid recruitment had to preserve the distinction between operational availability and scientific suitability. A reader panel can complete the required workload yet still differ from intended clinical users in experience or familiarity with assisted interpretation, making documented selection criteria important when judging the applicability of the findings.

Intrinsic Imaging’s Solution

Intrinsic Imaging drew on its network of more than 200 qualified reviewers to recruit, screen and contract the reader panel within the sponsor's start-up window, documenting each reader's credentials, conflict-of-interest status and prior-exposure attestation. Reader training on the platform and case report form was completed before the first session. Credential and exposure documentation makes the composition of the panel interpretable rather than treating readers as interchangeable observers. Training on data entry and the reading environment also helps separate errors in recording an assessment from genuine differences in diagnostic judgment, without implying that training eliminates clinical variability.

The study followed the company's established MRMC methodology: a case set assembled against a documented reference standard, a fully crossed design with randomized case order, a washout period between unaided and aided sessions, and a validated Part 11 compliant reading environment capturing every interpretation and timestamp. Having each reader assess the same cases permits comparisons that account for differences in case difficulty and reader performance. The washout period is intended to reduce memory of earlier interpretations, although elapsed time cannot establish that all recognition has disappeared, particularly for distinctive or unusually challenging cases.

Project management ran parallel reader cohorts so the full case review volume was completed on schedule, and the dataset and documentation were delivered in the structure the sponsor's statisticians required for MRMC analysis and FDA submission. Parallel scheduling addresses workload without changing the scientific unit of comparison. Consistent documentation across cohorts is important because session timing and completion patterns provide context for the final analysis, while prior inspection experience does not itself establish the validity of every subsequent study or determine its regulatory outcome.

Intrinsic Imaging’s Results

- Reader panel of 22 recruited, qualified and trained within four weeks of contract from a 200-plus reviewer network
- Approximately 9,500 case reviews completed on schedule across two reading sessions separated by a documented washout period
- Study conducted under the same MRMC methodology previously inspected by FDA with zero Form 483 observations
- Complete reader credential, conflict-of-interest and prior-exposure documentation delivered with the dataset for the sponsor's submission

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Read the full study online: https://intrinsicimaging.com/case-studies/ai-tenth-cad-mrmc

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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