CASE STUDY · AI/CAD

Pivotal MRMC Trial of AI Detection Software With 14,000 Radiology Reviews

14,000+ reader reviews · Fully crossed multi-reader multi-case · Reader AUC with and without AI

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 leading artificial intelligence company needed a pivotal multi-reader multi-case study to support its FDA submission for software that detects pathology on medical images. The study design called for more than 14,000 individual radiology reviews, each reader interpreting every case both with and without AI assistance, within a timeline set by the sponsor's submission plan.

At that scale the risks are operational as much as scientific: recruiting and qualifying enough readers, preventing recall bias between reading sessions, keeping the reading environment compliant with 21 CFR Part 11, and delivering a dataset in which every one of 14,000 interpretations is traceable to a reader, a case, a session and a timestamp. A single inconsistency in session logistics can compromise the statistical model that FDA expects for MRMC analysis. The large review count does not make interpretations statistically independent, because observations share readers and cases. Preserving these relationships is central to distinguishing an assistance effect from variation attributable to individual diagnostic thresholds or differences in case difficulty.

Intrinsic Imaging’s Solution

Intrinsic Imaging managed all aspects of the trial. The case set was assembled against a reference standard established by an independent truth panel, with case-mix targets for positive and negative cases, pathology subtypes and difficulty, and the reading protocol specified a fully crossed design with randomized case order and a washout period between unaided and aided sessions. Case-mix targets make the diagnostic spectrum explicit, helping readers of the evidence understand which findings and difficulty levels contributed to the comparison. An independent reference panel supports consistent classification without making the selected population equivalent to routine clinical practice.

Readers were sourced from the company's network of more than 200 qualified reviewers, screened for board certification, subspecialty and absence of prior exposure to the software, and trained on the reading platform and the case report form before the first session. Reading took place in a validated, Part 11 compliant environment that captured each mark, confidence score and timestamp. Screening for prior software exposure addresses a potential source of differential familiarity. Platform training serves a different purpose: it establishes how assessments should be recorded without demonstrating that diagnostic behavior will be uniform across qualified readers.

Quality control monitored session completion, case-order compliance and washout intervals in real time, and project managers scheduled readers in parallel cohorts so the full review volume was completed within the sponsor's window. The locked dataset was delivered in the format required for the sponsor's MRMC statistical analysis. Session and timing records make adherence to the intended comparison assessable. Their value is evidentiary rather than a substitute for statistical analysis, since traceable observations still require appropriate treatment of reader and case variability.

Intrinsic Imaging’s Results

- More than 14,000 reader reviews completed in a fully crossed, randomized MRMC design within the sponsor's submission timeline
- 24 readers sourced, qualified and trained from a 200-plus reviewer network with zero reader dropouts after enrollment
- Every interpretation captured in a Part 11 compliant reading environment with a complete reader, case, session and timestamp audit trail
- Reference standard established by an independent truth panel with documented adjudication of every discordant truth determination

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Read the full study online: https://intrinsicimaging.com/case-studies/ai-pivotal-mrmc-14000-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.

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