

MRMC Reader Study for AI 510(k) Submission

Multi-reader multi-case

Reference-standard panel

Part 11 reading environment

Challenge

An AI developer preparing a 510(k) submission required a pivotal multi-reader multi-case study capable of demonstrating that reader performance improved with algorithmic assistance. The study's credibility rested entirely on the quality of its reference standard: every case needed a rigorously established truth determination that could withstand FDA review. The design also had to control for recall bias and ordering effects across reading sessions, while documenting every step in a manner suitable for regulatory inspection.

Our Solution

Intrinsic Imaging convened a consensus reference-standard panel of fellowship-trained subspecialists to establish truth for each case, with documented adjudication of every disagreement. Reading sessions were randomized and counterbalanced across readers, with carefully spaced washout periods to eliminate recall bias between aided and unaided interpretations. The entire study was conducted within our Part 11 compliant reading environment, producing a complete, audit-ready record of every assessment, annotation, and consensus decision.

Results

- Audit-ready reference-standard datasets delivered
- 510(k) clearance received
- Reader study design reviewed without FDA questions

Read the full study online: <https://www.intrinsicimaging.com/case-studies/ai>

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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 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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