

Pivotal Reader Study for Liver Lesion CAD

Multi-reader multi-case

Contrast-enhanced CT

Standalone and aided performance

Challenge

A developer of a computer-aided detection algorithm for liver lesions required a pivotal reader study capable of demonstrating a statistically meaningful improvement in detection sensitivity with algorithmic assistance. The case set had to span the full spectrum of lesion size, conspicuity, and underlying hepatic disease, and every case required a reference standard established independently of the algorithm's output. The sponsor also needed the reading environment, randomization scheme, and statistical analysis plan to satisfy FDA expectations for a De Novo classification request.

Our Solution

Intrinsic Imaging assembled a pathology- and follow-up-confirmed case collection enriched for small and subtle lesions, with truth established by an expert panel blinded to algorithm output. Board-certified abdominal radiologists read each case in randomized, counterbalanced sessions with and without CAD assistance, separated by washout periods sufficient to eliminate recall effects. All interpretations were captured in our Part 11 compliant reading environment, and the statistical analysis plan—covering area under the ROC curve, sensitivity, and specificity endpoints—was finalized before the first reading session began.

Results

- Aided sensitivity improvement demonstrated at $p < 0.01$
- De Novo classification granted
- Complete audit trail accepted without FDA information requests

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

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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