

Chest CT Lung Nodule MRM Reader Study

Low-dose chest CT

18 readers

Aided and unaided reads

Challenge

Demonstrating the clinical value of a lung nodule detection tool required a multi-reader multi-case study comparing reader performance with and without algorithmic assistance. The design demanded readers spanning a range of experience levels to support generalizable conclusions, together with a reading workflow that would prevent recall of prior interpretations from contaminating the comparison between aided and unaided sessions. Every element of the design had to satisfy the evidentiary expectations of a 510(k) submission.

Our Solution

Intrinsic Imaging recruited and trained a reader group of 18 radiologists spanning the required experience spectrum, then administered randomized reading sequences separated by a four-week washout period to eliminate recall bias between sessions. A reference-standard panel of thoracic radiologists established truth for every case, and all reading activity was captured in a controlled, fully documented environment suitable for regulatory review.

Results

- All reader assessments completed within 10 weeks
- Improved reader sensitivity with algorithmic assistance
- Study data accepted in the 510(k) submission

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

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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