

Spinal Fusion Endpoint Adjudication

38 sites

CT, flexion-extension radiographs

Fusion status adjudication

Challenge

Determining whether a spinal arthrodesis has achieved solid fusion is among the most subjective assessments in musculoskeletal imaging, yet it was the primary endpoint of this medical device trial. Site investigators' fusion determinations diverged substantially from one another and from imaging evidence, threatening the endpoint's credibility. The sponsor needed an independent, reproducible fusion assessment combining thin-slice CT morphology with functional flexion-extension radiographs.

Our Solution

Intrinsic Imaging established a dual-reader adjudication model in which two fellowship-trained musculoskeletal radiologists independently assessed bridging bone on thin-slice CT and angular motion on flexion-extension radiographs, applying pre-specified quantitative thresholds. Discordant determinations proceeded to a third senior reader whose assessment was documented with full rationale. Standardized acquisition requirements ensured that CT slice thickness and radiographic positioning supported reliable measurement at every site.

Results

- Reader concordance of 96% before adjudication
- Fusion determinations upheld at FDA panel review
- Endpoint variability reduced by half versus investigator assessment

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

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.

Contact:

Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com