

CASE STUDY · MEDICAL DEVICE

Neurointerventional Endovascular Device Trial

Neurovascular device trial · Catheter angiography, CT, MRI · Device safety and efficacy

Challenge

A clinical trial of a neurointerventional endovascular device required imaging assessment of safety and efficacy. Neurovascular device endpoints depend on angiographic grading that is sensitive to projection, timing and frame selection, and on cross-sectional imaging to detect hemorrhage, infarction and other procedural complications, with substantial variation in how sites acquire and archive angiographic runs.

The sponsor needed all imaging core lab functions, from charter development and site evaluation through acquisition, quality control and processing, together with subspecialized radiologists able to grade device performance consistently.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with angiographic acquisition and submission requirements, grading scales for the primary efficacy endpoint, and CT and MRI requirements for complication assessment. Sites were evaluated and trained on complete run submission and on the cross-sectional imaging schedule.

Board-certified, fellowship-trained interventional radiologists performed blinded reads of procedural angiography and follow-up imaging under the charter, with independent double reads on the primary endpoint and adjudication of discordant grades.

Image acquisition, quality control and processing were centralized, with incomplete angiographic submissions returned to sites, and efficacy and safety findings were delivered with frame-level references for every graded assessment.

Intrinsic Imaging's Results

- Approximately 120 procedures at 12 sites graded under independent double reads by interventional radiologists
- Angiographic grades documented with frame-level references for every primary endpoint assessment
- Complete imaging core lab service delivered from charter development through processing and review under an ISO 9001 compliant quality system
- Procedural complications captured on follow-up CT and MRI under predefined safety definitions

Read the full study online: <https://intrinsicimaging.com/case-studies/device-neurointerventional-2011>

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 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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