

CASE STUDY · MEDICAL DEVICE

Clinical Study of a Novel Neurointerventional Device

Neurovascular device study · Catheter angiography, CT, MRI · Angiographic outcome and procedural safety

Challenge

A clinical study of a novel neurointerventional device required central review of catheter angiography and cross-sectional imaging to assess technical success, angiographic outcome and procedural complications. Neurovascular imaging endpoints such as recanalization grade, aneurysm occlusion class and vessel injury depend on frame selection, projection and timing within angiographic runs, and are among the most reader-dependent assessments in device trials.

The sponsor required interventional neuroradiologists experienced with the device class, a charter that fixed how angiographic runs would be evaluated, and a documentation standard appropriate for a device submission.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter defining angiographic acquisition requirements, the projections and phases to be submitted, and the grading scales to be applied, together with CT and MRI requirements for assessing hemorrhage, infarction and other procedural complications. Sites were qualified and trained on complete angiographic run submission.

Board-certified interventional neuroradiologists performed blinded reads of pre-, intra- and post-procedure angiography and of follow-up cross-sectional imaging under the charter, with independent double reads on primary angiographic endpoints and adjudication of discordant grades.

Angiographic runs and cross-sectional studies were transferred and quality-controlled centrally, with incomplete runs returned to sites for resubmission, and endpoint data were delivered with frame-level references supporting each grade.

Intrinsic Imaging's Results

- Approximately 160 procedures at 15 sites graded by interventional neuroradiologists under independent double reads
- Angiographic grading documented with frame-level references for every primary endpoint assessment
- Incomplete angiographic submissions identified at central quality control in about 10% of initial cases and corrected before reading
- Procedural complication findings captured on follow-up CT and MRI under predefined safety definitions

Read the full study online: <https://intrinsicimaging.com/case-studies/device-neurointerventional-2014>

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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