CASE STUDY · MEDICAL DEVICE

Clinical Study of a Novel Neurointerventional Device

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

Challenge

Intrinsic Imaging supported this study's imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. 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. A selected angiographic image can support a grade only in the context of the run from which it was drawn. Apparent filling, occlusion or vessel irregularity may depend on the view and phase represented. This makes the evidentiary link between the submitted acquisition and the assigned endpoint particularly important when technical performance and procedural complications are evaluated together.

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. Specifying projections, phases and grading scales establishes what evidence is needed before an angiographic classification can be interpreted consistently. Complete run submission preserves the temporal context that isolated images may omit. The cross-sectional requirements address a different question: whether tissue findings accompany the vascular result, rather than assuming that angiographic appearance alone characterizes the consequences of the procedure.

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. Specialist interpretation is relevant because the distinction between an expected procedural appearance and a potentially adverse vascular finding can be subtle. Independent grading exposes differences in how the same evidence is interpreted, and adjudication supplies a documented resolution. Neither process eliminates uncertainty when the available projection or image quality limits the visibility of the feature being graded.

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. Frame-level references connect the reported classification to inspectable imaging evidence, making the basis for a grade more transparent than a categorical label alone. Correcting incomplete submissions before interpretation addresses missing acquisition information rather than merely resolving reader disagreement afterward. These functions are complementary: submission quality determines what can be assessed, while reading conventions govern how assessable findings are classified.

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

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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 50 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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