CASE STUDY · MEDICAL DEVICE

Neurointerventional Endovascular Device Trial

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

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 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. Angiographic efficacy and cross-sectional safety findings answer related but distinct clinical questions, and neither should be treated as a substitute for the other. A favorable procedural image does not alone establish freedom from tissue injury. Conversely, an abnormality on follow-up imaging requires interpretation within the predefined safety framework rather than automatic attribution to device failure.

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. Acquisition and submission requirements are particularly important for angiography because the visible appearance of vascular filling can depend on projection and the selected portion of a run. Complete submissions preserve the temporal and anatomical context needed to apply the grading scale. The accompanying CT and MRI requirements address a different evidentiary need: assessment of tissue abnormalities that may not be characterized by procedural angiography alone.

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. Subspecialty review connects grading conventions with the technical characteristics of neurovascular imaging. Independent assessment of the primary endpoint makes differences in interpretation visible before adjudication establishes the reported grade. That resolution provides a consistent analytical classification, but does not imply that projection-dependent or otherwise limited angiographic evidence becomes unambiguous. Blinding addresses potential expectation bias without replacing the need for adequate image content.

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. Returning incomplete runs addresses missing interpretive context rather than simply an administrative omission. Frame-level references make the selected evidence for an angiographic grade identifiable, allowing the reported assessment to be understood in relation to the submitted sequence. Safety findings on cross-sectional imaging remain complementary observations, and their capture under predefined definitions does not by itself establish causality or encompass complications outside the sensitivity of the imaging examination.

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

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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 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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