CASE STUDY · CENTRAL NERVOUS SYSTEM

Pivotal Multi-Center Acute Ischemic Stroke Trial

Pivotal multi-center trial · Non-contrast CT, CT angiography, MRI · Infarct volume, hemorrhagic transformation, recanalization

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 pivotal multi-center trial evaluated a new treatment for acute ischemic stroke. Stroke imaging is acquired under extreme time pressure on whatever scanner is available, and the efficacy and safety endpoints depend on neuroradiological assessment of infarct extent, hemorrhagic transformation and vessel status, assessments that vary considerably between readers without a shared framework.

The sponsor needed a pragmatic acute protocol that sites could execute without delaying treatment, consistent application of infarct scoring and hemorrhage classification across readers, and a team of neuroradiologists able to sustain time-sensitive reads for a pivotal program. Acute stroke findings evolve over time, so differences between examinations can reflect both disease progression and the interval from presentation. Infarct extent, vessel patency and hemorrhage describe different dimensions of the event and should not be collapsed into a single interpretation. The reading framework therefore needs to preserve those distinctions while accommodating the realities of emergency acquisition.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter around a baseline and follow-up protocol achievable in the acute setting, with non-contrast CT and CT angiography at presentation and CT or MRI at defined follow-up windows, and trained sites to submit complete acute imaging promptly after enrollment. A protocol achievable during acute care addresses the tension between research completeness and urgent clinical management. Presentation angiography supplies vascular information that non-contrast imaging alone does not provide, while follow-up examinations characterize subsequent tissue findings. Allowing follow-up CT or MRI requires attention to the different appearance and conspicuity of abnormalities on each modality when interpreting longitudinal assessments.

Board-certified neuroradiologists performed blinded reads under a charter defining ASPECTS scoring, infarct volume measurement, hemorrhagic transformation classification and recanalization grading. Primary endpoint assessments were double-read with adjudication, and reader calibration used reference cases spanning the acute stroke imaging spectrum. Explicit scoring and classification conventions make reader judgments interpretable within a common framework rather than relying on individual reporting habits. Reference cases provide context for ambiguous appearances, and adjudication establishes how discrepant primary assessments are resolved. High agreement on hemorrhage classification supports consistency for that task but does not establish equivalent reproducibility for infarct volumetry or recanalization grading.

Image transfer, quality control and processing were centralized with rapid receipt confirmation, and safety findings including symptomatic hemorrhage were reported to the sponsor on a defined schedule. Receipt confirmation and centralized quality review address whether the expected evidence has arrived and can support interpretation. Reporting hemorrhagic findings contributes imaging information to safety monitoring, but imaging appearance alone cannot establish symptom attribution or treatment causality. Likewise, completeness at baseline supports assessment of the presenting event without demonstrating that every subsequent imaging endpoint is available or equally informative.

Intrinsic Imaging’s Results

- Approximately 480 patients at 42 sites assessed under blinded double reads with adjudication on primary endpoints
- ASPECTS, infarct volume and hemorrhagic transformation assessed under fixed conventions with reader agreement on hemorrhage classification above 90%
- Pragmatic acute protocol achieved baseline imaging completeness above 95% without delaying treatment
- Imaging safety findings reported to the sponsor's monitoring process within 48 hours of receipt

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Read the full study online: https://intrinsicimaging.com/case-studies/cns-acute-ischemic-stroke

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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