

## 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

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.

## 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.

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.

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.

## 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 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](http://www.IntrinsicImaging.com).

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