CASE STUDY · CENTRAL NERVOUS SYSTEM

International Phase III Severe Traumatic Brain Injury Trial Across 100+ Sites

1,000+ patients at 100+ sites · Head CT, brain MRI · Intracranial pathology progression

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 large international Phase III trial of a treatment for severe traumatic brain injury enrolled more than 1,000 patients across more than 100 investigator sites. Imaging was acquired in emergency settings on whatever scanner was available, often at night, and the endpoint depended on neuroradiological assessment of the progression of intracranial pathology including contusion expansion, hematoma volume, edema and midline shift.

The sponsor needed standardized reading of highly heterogeneous acute imaging, volumetric measurement of hemorrhagic lesions that is sensitive to window settings and slice thickness, and a team large enough to handle a continuous, time-critical volume from more than 100 sites. Traumatic intracranial abnormalities can coexist and evolve differently, making progression more complex than an isolated increase in lesion size. Apparent differences between serial scans may also arise from reconstruction or display conditions. The scientific value of longitudinal assessment therefore depends on distinguishing changes in traumatic pathology from changes in how that pathology is represented.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter around a pragmatic acute head CT protocol achievable in emergency settings, with minimum requirements for slice thickness and reconstruction, and trained sites to submit serial imaging within defined windows. Image acquisition, transfer and quality control were centralized with 24-hour receipt confirmation. Minimum acquisition requirements provide a common technical foundation without assuming the uniformity of an elective imaging environment. Defined submission windows are relevant because the interpretation of progression depends on when serial observations occur. Central quality review can identify departures from the intended protocol, although it cannot restore anatomical information that was not adequately captured during the original emergency examination.

A dedicated team of eight board-certified neuroradiologists performed blinded reads under a charter that defined hemorrhage classification, volumetric measurement methods, midline shift measurement and progression criteria. Primary progression assessments were double-read with adjudication. Shared definitions constrain how readers classify mixed traumatic findings and delineate hemorrhagic boundaries. Midline shift offers information about displacement that is distinct from lesion volume, so the measures contribute complementary descriptions of intracranial pathology. Double reading and adjudication address disagreement in applying progression criteria rather than establishing that imaging progression necessarily predicts an individual patient's clinical course.

Reader calibration used reference cases spanning the range of traumatic pathology, and agreement was monitored at planned intervals across the trial. Project managers maintained the imaging schedule for more than 1,000 patients and chased missing serial scans with sites. Calibration across the spectrum of traumatic findings supports consistent application of the charter beyond straightforward cases. Monitoring agreement over time is relevant to a sustained reading workload, where interpretive conventions may otherwise drift. Tracking missing serial scans supports longitudinal completeness, but high completeness alone does not exclude differences between patients with available follow-up imaging and those whose examinations remain unavailable.

Intrinsic Imaging’s Results

- Imaging from more than 1,000 patients at more than 100 international sites processed and read by a dedicated eight-neuroradiologist team
- Hemorrhage volumetry and midline shift measured under fixed conventions with reader agreement on progression above 88%
- Unevaluable acute examinations held under 6% despite emergency-setting acquisition through pragmatic protocol design and site feedback
- Serial imaging completeness above 90% through active tracking of protocol-defined imaging windows

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Read the full study online: https://intrinsicimaging.com/case-studies/cns-traumatic-brain-injury

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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