CASE STUDY · CENTRAL NERVOUS SYSTEM

Mid-Study Transfer of a Phase III MS MRI

80 sites · Brain MRI · Gd-enhancing and new T2 lesions

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 Phase III multiple sclerosis program experienced persistent central review deficiencies under its previous core laboratory. Lesion assessments demonstrated weak inter-reader agreement, calling into question the reliability of the gadolinium-enhancing and new T2 lesion counts on which the trial's endpoints depended. Compounding the problem, more than 1,800 MRI examinations awaited central review across 80 sites, and the backlog continued to grow. The sponsor needed to transfer the program mid-study while preserving interpretive continuity with assessments already completed.

The transfer carried considerable methodological risk. MS lesion counting involves numerous interpretive decisions: how to identify new lesions, distinguish enlarging lesions and handle confluent or ambiguous findings. Had the replacement readers applied conventions that differed from those used before transfer, the change itself could have produced artificial shifts in lesion counts indistinguishable from treatment effect. The sponsor required timely backlog resolution without a discontinuity in lesion-counting methodology, which meant reconstructing the prior conventions, calibrating replacement readers and documenting the reconciliation so that pre- and post-transfer reads could be assessed for comparability. Methodological continuity matters because a transfer-related shift in lesion-counting conventions could resemble a biological change. Reconciling prior assessments therefore addresses comparability, not simply the speed with which an inherited backlog is cleared.

Intrinsic Imaging’s Solution

Intrinsic Imaging began by reviewing the prior charter, reading records and examples of completed assessments, identifying where conventions had been inconsistently documented or applied. These findings informed a single harmonized charter that clarified each decision rule while remaining faithful to the methodology already in use, so that post-transfer assessments would extend the existing dataset rather than restart it.

The complete image archive was transferred onto our validated platform with full data-integrity verification. Checks confirmed that every examination, timepoint and prior assessment had been migrated completely and accurately; discrepancies were investigated and resolved before reading resumed, and the reconciliation was documented so the sponsor could demonstrate continuity of the imaging record from the previous core laboratory to the new platform.

Before central review resumed, our neuroradiologists completed focused training on the prior reading conventions and calibration exercises against previously assessed cases. The accumulated backlog was then worked through systematically under the unified charter, with repeat-read samples used to monitor agreement as reading progressed. Our project team tracked backlog completion closely and gave the sponsor regular visibility into progress and any issues requiring attention, so that the endpoint timeline could be protected while the inherited deficiencies were corrected rather than carried forward.

Intrinsic Imaging’s Results

- 60 days to clear a backlog of more than 1,800 MRI examinations under the harmonized charter, without interrupting central review of newly acquired scans
- 95%+ lesion-count agreement in repeat-read samples, restoring the inter-reader reliability that the gadolinium-enhancing and new T2 lesion endpoints required
- Zero change to the primary endpoint timeline despite a mid-study change of core laboratory across 80 sites and an inherited, still-growing backlog of unread examinations
- Documented reconciliation of pre- and post-transfer reading conventions gave the sponsor a defensible basis for assessing continuity across the combined longitudinal dataset

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Read the full study online: https://intrinsicimaging.com/case-studies/study-rescue-cns

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 650 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.

Contact:
Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com