

Mid-Study Transfer of a Phase III MS MRI

80 sites

Brain MRI

Gd-enhancing and new T2 lesions

Challenge

A Phase III multiple sclerosis program had fallen into difficulty under its previous core lab. 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, and the backlog continued to grow. The sponsor needed to transfer the program mid-study while preserving interpretive continuity with the assessments already completed.

Our Solution

Intrinsic Imaging transferred the complete image archive onto our validated platform with full data-integrity verification, then consolidated lesion-counting conventions into a single harmonized charter. Before central review resumed, our neuroradiologists underwent focused training on the prior reading conventions, ensuring that post-transfer assessments remained consistent with the existing dataset rather than introducing a methodological discontinuity. The accumulated backlog was then worked through systematically under the unified charter.

Results

- Read backlog cleared within 60 days
- Lesion-count agreement exceeded 95% in repeat-read samples
- No change to the primary endpoint timeline

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

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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.

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