

Rescuing a Global Phase III Solid Tumor Trial

70+ sites

CT, MRI, PET/CT

RECIST 1.1 BICR

Challenge

Midway through a global Phase III solid tumor program, the sponsor confronted a central review operation in crisis. The incumbent core lab's reads were marked by substantial inter-reader disagreement, and a growing backlog of unresolved queries was eroding confidence in the imaging dataset. Protocol adherence varied widely across more than 70 sites spanning multiple continents, compounding the inconsistency of the response assessments on which the trial's primary endpoint depended. With the NDA submission timeline already fixed, the sponsor needed a partner capable of assuming control of the program mid-study without sacrificing continuity, data integrity, or regulatory defensibility.

Our Solution

Intrinsic Imaging executed a carefully orchestrated mid-study transition. We rewrote the blinded independent central review charter to mandate dual independent reads with formal adjudication of discordant assessments, then migrated more than 4,200 subject scan series onto our validated imaging platform with full chain-of-custody documentation. In parallel, our team delivered targeted retraining to every participating site on image acquisition and submission standards, addressing the root causes of non-compliance rather than merely its symptoms. Dedicated project management oversight ensured the transition proceeded without interrupting ongoing enrollment or follow-up imaging.

Results

- Outstanding imaging queries resolved within 45 days
- 98.4% reader concordance after transition
- Database locked two weeks ahead of the revised deadline

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

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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