CASE STUDY · ONCOLOGY

Rescuing a Global Phase III Solid Tumor Trial

70+ sites · CT, MRI, PET/CT · RECIST 1.1 BICR

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. Midway through a global Phase III solid tumor program, the sponsor confronted a central review process in evident disrepair. The incumbent core laboratory's assessments were marked by substantial inter-reader disagreement, an expanding backlog of unresolved queries was eroding the reliability of the imaging dataset, and protocol adherence varied widely across more than 70 sites on several continents. Because the primary endpoint rested on blinded independent central review under RECIST 1.1, these deficiencies bore directly on the credibility of the trial's efficacy conclusions.

The NDA submission date was fixed, which left no latitude for the transition itself to become a source of uncertainty. The sponsor's clinical team lacked a reconciled account of completed examinations, pending assessments and disputed timepoints, and could not readily distinguish acquisition deficiencies from unresolved reading decisions. Any successor core laboratory would therefore need to assume control mid-study while preserving the provenance and methodological continuity of assessments already completed, and to do so without interrupting enrollment or follow-up imaging.

Intrinsic Imaging’s Solution

Before any data moved, Intrinsic Imaging conducted a forensic review of the prior charter, reading conventions and outstanding query log, establishing a reconciled inventory of every subject and timepoint. That inventory became the single shared reference for the sponsor, the sites and our readers, so that every party worked from an identical understanding of the program's status.

We then rewrote the blinded independent central review charter to mandate dual independent reads with formal adjudication of discordant assessments, and migrated more than 4,200 subject scan series onto our validated imaging platform with complete chain-of-custody documentation. Every participating site received targeted retraining on acquisition and submission standards directed at the specific deficiencies observed in its prior submissions, and dedicated project management ensured the transition proceeded without interrupting ongoing enrollment or follow-up.

Once the transfer was complete, our readers worked through the accumulated backlog under the revised charter, with discordant assessments routed promptly to adjudication. Regular status reporting gave the sponsor a transparent view of progress against the submission timeline, and site-level performance metrics allowed early intervention wherever acquisition problems re-emerged. Every change to the review process, including charter revisions, retraining records and the rationale for each methodological decision, was documented in the trial master file so the sponsor could demonstrate how the transition had been governed.

Intrinsic Imaging’s Results

- 45 days to resolve every outstanding imaging query inherited from the incumbent core laboratory, clearing the backlog that had threatened the completeness of the imaging dataset
- 98.4% reader concordance after transition, restoring the inter-reader agreement on which a RECIST 1.1 primary endpoint under blinded independent central review fundamentally depends for regulatory acceptance
- 4,200+ subject scan series migrated with complete chain-of-custody documentation, preserving the provenance of every assessment completed before the transfer from the incumbent laboratory
- Two weeks ahead of the revised deadline, the database locked on a reconciled, consistently assessed imaging record constructed to withstand regulatory scrutiny of the NDA

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

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.

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