CASE STUDY · ONCOLOGY

Imaging Core Lab Support Through NDA Submission and FDA Inspection

55 sites · CT, MRI · RECIST 1.1 BICR and FDA inspection

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. Progression-free survival by blinded independent central review was the primary endpoint of this Phase III solid tumor trial, which meant the imaging core laboratory's work would be examined by the FDA as closely as the sponsor's own clinical data. The sponsor planned to file a New Drug Application within months of database lock and anticipated both information requests during review and a pre-approval inspection of the imaging vendor.

Three risks dominated. First, every element of the independent review, from reader qualification to the handling of each discordant assessment, had to be reconstructable from documentation rather than recollection. Second, the agency's information requests typically arrive with short response windows, and an imaging question left unanswered can stall a review clock. Third, the inspection would test the quality management system in operation: training records, system validation, audit trails, deviation handling and the chain of custody for more than 3,100 subjects' imaging across 55 sites. The sponsor needed a core laboratory whose documentation, responsiveness and quality system could each withstand that scrutiny without remediation under time pressure.

Intrinsic Imaging’s Solution

Intrinsic Imaging wrote the independent review charter to the structure of the FDA's guidance on clinical trial imaging endpoint process standards, with explicit sections on reader selection and training, the two-reader-plus-adjudicator paradigm, the reading sequence, the handling of new lesions and non-target disease, and the statistical monitoring of reader performance. Reader qualification was documented against predefined criteria, and reader-performance reports were produced throughout the study rather than reconstructed at its end.

Every assessment was performed in our validated, 21 CFR Part 11-compliant reading environment, which recorded a complete audit trail of image receipt, quality control, read assignment, assessment entry and any amendment. Deviations were logged and closed under a quality management system examined in three FDA inspections without a Form 483 observation and certified to five ISO standards. Before database lock, an independent quality auditor conducted a mock inspection, tracing sample subjects from image receipt through final assessment and verifying training records and adjudication rationale; the few gaps identified were closed before the sponsor filed.

During the review period we committed to a 48-hour turnaround on imaging-related information requests, staffed by the project's medical lead, data manager and quality representative. Requests concerning reader discordance rates, out-of-window scans and adjudicator independence were each answered from the study record with supporting extracts. For the inspection, we prepared a document index mapped to the inspector's likely lines of enquiry and hosted the three-day visit with the study team available for interview.

Intrinsic Imaging’s Results

- 48 hours or less to answer every FDA information request concerning imaging, each response supported by documented extracts drawn directly from the study record
- Zero Form 483 observations at the conclusion of the three-day pre-approval inspection of the imaging core laboratory and its quality management system
- 3,100+ subjects' imaging across 55 sites maintained under a complete chain of custody and Part 11 audit trail from receipt to final assessment
- BICR dataset supported approval of the sponsor's product, and the sponsor subsequently awarded Intrinsic Imaging its follow-on program on the strength of that performance

Read the full study online: https://intrinsicimaging.com/case-studies/oncology-nda-inspection

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.

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