CASE STUDY · ONCOLOGY

Five-Year Multicenter Metastatic Colorectal Cancer Trial Across 40 Sites

40+ sites, hundreds of patients · Contrast CT, MRI · RECIST

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 five-year multicenter clinical trial of a treatment for metastatic colorectal cancer enrolled hundreds of patients at more than 40 investigator sites. The length of the trial and the volume of imaging created operational risk: sites changing scanners and staff, image transfer delays accumulating over years, and the potential for reader drift across a long program.

The sponsor needed a core lab to manage acquisition, transfer and processing for the full duration and to provide oncology-subspecialized radiologists for consistent image interpretation from first patient to database lock. Longitudinal response assessment depends on distinguishing biological change from changes in how images are acquired or interpreted. In metastatic colorectal cancer, a lesion may be followed across many examinations, so apparently modest shifts in contrast appearance, measurement convention or lesion selection can complicate an otherwise coherent disease trajectory. A lengthy multicenter program therefore places particular weight on continuity of both technical and interpretive standards.

Intrinsic Imaging's Solution

Intrinsic Imaging established acquisition guidelines for contrast-enhanced CT and MRI, qualified the 40-plus sites and set up centralized transfer with receipt confirmation and quality control, including requalification when sites changed scanners during the five-year program. Acquisition guidance establishes the technical context in which serial measurements can be compared. Requalification after equipment changes addresses a specific threat to that context: a new scanner may alter image appearance even when the underlying disease has not changed. Receipt confirmation and centralized quality control address a complementary issue, ensuring that an expected examination is available and assessable rather than assuming successful acquisition guarantees usable longitudinal evidence.

Oncology-subspecialized radiologists performed blinded reads under a RECIST charter defining target lesion selection, liver lesion measurement conventions and progression confirmation, with adjudication of discordant assessments and periodic calibration sessions to maintain consistency across the program. The charter provides a stable framework for deciding which lesions represent measurable disease and how progression is determined. Blinding reduces the opportunity for treatment expectations to influence assessment, while adjudication resolves disagreements within the specified framework. Calibration is relevant over extended follow-up because interpretive conventions can gradually diverge even among experienced oncology readers working from the same written criteria.

Project management tracked the imaging schedule for hundreds of patients over five years, monitoring per-site compliance and reader agreement at planned intervals. Tracking compliance and agreement provides context for the reliability of the accumulated imaging record. Agreement indicates consistency between assessments, not independent proof that every response category is biologically correct. Likewise, successful longitudinal imaging management supports interpretation of the response dataset but does not establish treatment efficacy without the trial's clinical and statistical evidence.

Intrinsic Imaging’s Results

- Imaging from hundreds of patients at more than 40 sites acquired, transferred and processed centrally over five years
- Approximately 4,100 timepoints read under a single RECIST charter with adjudication and documented calibration
- Site requalification completed after 14 scanner changes with no loss of longitudinal comparability
- Reader agreement on response category maintained above 88% at each annual monitoring interval

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Read the full study online: https://intrinsicimaging.com/case-studies/oncology-mcrc-five-year

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.

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