CASE STUDY · ONCOLOGY

Phase I/II Biologic Trial in Metastatic Colorectal Cancer With Unresectable Liver Metastases

Multicenter Phase I/II · Contrast CT, liver MRI · RECIST 1.1 and liver-specific response

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 multicenter Phase I/II trial evaluated a novel investigational biologic in patients with unresectable colorectal liver metastases. Early-phase trials generate decisions about dose and expansion from small numbers of patients, so each response assessment carried significant weight, and liver metastases imaged with CT and MRI present measurement challenges from contrast phase, lesion conspicuity and treatment-related changes in lesion appearance.

The sponsor needed consistent response assessment under RECIST 1.1 with sensitivity to liver-specific changes such as necrosis and reduced enhancement, and a fast turnaround so that imaging results could inform dose-escalation and cohort decisions. In hepatic metastases, reduced enhancement or increasing necrosis can alter lesion appearance without producing a proportional change in diameter. These observations are relevant to biological interpretation but are not interchangeable with a size-based response category. In a small early-phase population, maintaining that distinction is especially important because an unusual imaging trajectory may influence discussion of activity without establishing a reproducible treatment effect.

Intrinsic Imaging's Solution

Intrinsic Imaging processed all study images centrally, with quality control confirming contrast phase and liver coverage at receipt. Acquisition guidance addressed portal venous phase timing for CT and hepatobiliary-phase sequences where MRI was used, and sites were supported to keep each patient on a consistent modality. Contrast phase and liver coverage determine whether serial examinations show the same disease under sufficiently comparable conditions. Consistent modality use reduces the risk of interpreting differences in lesion conspicuity between computed tomography and magnetic resonance imaging as biological change. Guidance on acquisition timing therefore supports measurement comparability, while acknowledging that technically acceptable examinations can still differ in how clearly individual liver lesions are delineated.

Oncology radiologists experienced in hepatic malignancy performed blinded reads under RECIST 1.1, with the charter additionally capturing lesion enhancement and necrosis so that the sponsor could evaluate biologic activity beyond size-based response. Discordant reads were adjudicated. Capturing enhancement and necrosis alongside the formal response assessment preserves complementary observations without redefining the response criterion. These features may help characterize treatment-related changes, but their interpretation depends on acquisition conditions and does not alone demonstrate loss of viable tumor. Blinded assessment and adjudication address reader-dependent judgment while retaining the distinction between the specified endpoint and additional descriptive imaging evidence.

Read turnaround was prioritized to support cohort decision timelines, and results were delivered in a structure suitable for both the Phase I safety review and the Phase II efficacy analysis. Rapid delivery makes imaging evidence available for time-sensitive cohort review, but turnaround is an operational measure rather than evidence of diagnostic accuracy or a favorable benefit-risk profile. Imaging can contribute to dose and expansion discussions without replacing the broader safety and clinical evidence. A dataset serving successive trial phases also requires the response categories and supplementary liver observations to remain clearly distinguishable in interpretation.

Intrinsic Imaging’s Results

- Approximately 85 patients at 9 sites assessed with blinded RECIST 1.1 reads and liver-specific enhancement and necrosis capture
- Median read turnaround of three business days to support dose-escalation and cohort-expansion decisions
- Contrast phase and liver coverage verified at central quality control for every timepoint before reader access
- Response dataset delivered in a structure serving both Phase I safety review and Phase II efficacy analysis

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

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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