CASE STUDY · ONCOLOGY

Hepatocellular Carcinoma Trial Using mRECIST

50 sites in 12 countries · Multiphase CT, MRI · mRECIST and LI-RADS

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. Assessment of hepatocellular carcinoma under mRECIST relies on measuring viable, arterially enhancing tumor rather than overall lesion size, making arterial-phase timing essential to reliable measurement. Across 50 sites in 12 countries, variation in multiphase acquisition timing had compromised viable tumor measurements, since a poorly timed arterial phase renders enhancement unassessable. The trial's response-based endpoints required that every examination capture the contrast phases necessary for valid mRECIST assessment.

The patient population and imaging environment added further complexity. Many participants had underlying cirrhosis, which alters hepatic enhancement and complicates lesion characterization. Sites used both CT and MRI with differing contrast agents, injection techniques and scanner capabilities, so that the same tumor could appear differently from one examination to the next for purely technical reasons. The sponsor required prospective control of multiphase acquisition across an international network, submission-level verification of technical adequacy and consistent mRECIST interpretation, with acquisition limitations and assessment decisions documented so that biological response could be distinguished from technical variation and each determination reconstructed during review. Reduced enhancement and reduced lesion size are not equivalent observations. Preserving the viable-tumor measurement definition is therefore essential when the treatment-associated imaging change differs from conventional anatomical shrinkage.

Intrinsic Imaging’s Solution

Intrinsic Imaging standardized multiphase acquisition protocols across all participating sites, developing modality-specific guidance and training each site before activation. Phase timing was verified on every submission at the point of receipt, together with phase completeness, coverage and image quality. Non-conformant studies were flagged immediately and sites received specific feedback, allowing acquisition technique to be corrected before further patients were affected rather than after the deficiency had propagated through the dataset.

Only examinations of verified technical adequacy proceeded to central review by abdominal radiologists trained and calibrated on mRECIST and LI-RADS conventions, including the measurement of viable tumor and the assessment of new lesions. Longitudinal examinations were reviewed under a consistent charter, reducing the potential for acquisition variability to confound assessments of change in viable tumor over time.

Adjudication was invoked when readers disagreed on response category, viable tumor measurement or the presence of new lesions. Adjudicators reviewed the complete imaging history under the same criteria, and each decision was documented, providing a transparent record for data review and regulatory inspection. By addressing imaging quality at its source rather than attempting to interpret technically compromised examinations, the core laboratory improved evaluability throughout the remainder of the study, protected the response endpoint and reduced the need for queries and repeat imaging across a geographically diverse program.

Intrinsic Imaging’s Results

- 97%+ evaluable scan rate across 50 sites in 12 countries, achieved by verifying arterial-phase timing and phase completeness on every submission at receipt
- Reliable viable tumor measurements obtained from multiphase CT and MRI of consistent, verified technical quality, assessed by abdominal radiologists under mRECIST and LI-RADS
- Central review supported the sponsor's regulatory filing, with documented adjudication of response category, viable tumor and new lesions available for inspection
- Fewer queries and repeat examinations as site technique improved, easing the operational burden on sites and patients with cirrhosis across the international network

---

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

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.

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