CASE STUDY · ONCOLOGY

Global Hepatocellular Carcinoma Trial With Dynamic Contrast-Enhanced MRI

Global trial, Asia-weighted enrollment · DCE-MRI · mRECIST and perfusion parameters

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 global clinical trial of a new therapy for hepatocellular carcinoma used dynamic contrast-enhanced MRI to assess tumor response, with heavy enrollment in Asia where HCC incidence is highest. DCE-MRI requires precise contrast timing and multiphase acquisition, and the arterial-phase enhancement on which modified RECIST depends is easily lost with mistimed acquisition or respiratory motion in patients with cirrhosis and ascites.

The sponsor needed multiphase acquisition standardized across continents and vendor platforms, response assessed under mRECIST with reproducible identification of viable enhancing tumor, and quantitative perfusion parameters extracted consistently where the protocol required them. In hepatocellular carcinoma, enhancement-based response assessment depends on observing viable tumor during an appropriate contrast phase rather than relying solely on total lesion dimensions. Cirrhotic background liver and respiratory limitations complicate that observation. A technically mistimed examination can therefore create uncertainty about apparent loss of enhancement, making acquisition quality integral to the biological interpretation of response rather than merely an operational concern.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the protocol imaging section and charter with a DCE-MRI protocol specifying bolus timing, phase acquisition and sequence parameters for each vendor platform, and qualified every site with test acquisitions reviewed for arterial-phase timing. Site training addressed breath-hold coaching in patients with limited respiratory reserve. Vendor-specific parameters translate a common imaging objective into acquisition instructions suited to different platforms. Test acquisitions address whether the intended arterial phase can actually be obtained at a participating site, while breath-hold coaching addresses a patient-related source of motion. These measures support comparability but cannot guarantee that every subsequent examination will capture enhancement equally well in patients with changing clinical status.

Oncology and abdominal radiologists performed blinded independent reads under mRECIST, with the charter defining viable tumor measurement, handling of treated lesions and new lesion criteria in the cirrhotic liver. Quantitative perfusion parameters were extracted under fixed region-of-interest conventions, and discordant response categories were adjudicated. Viable tumor measurement and quantitative perfusion describe related but distinct features of contrast behavior. Fixed region-of-interest conventions limit variation in where perfusion is sampled, whereas the response charter governs categorical interpretation of enhancing disease. Neither standardization nor adjudication removes all uncertainty from heterogeneous tumors, and numerical perfusion changes should not be treated as interchangeable with an enhancement-based response classification or direct evidence of clinical benefit.

Image transfer, blinding and processing were centralized across regions, with arterial-phase timing verified at receipt and deviations returned to sites with specific corrective guidance. Central verification makes arterial-phase adequacy an explicit part of deciding whether images support the intended assessment. Improved timing compliance documents better adherence to the acquisition requirement, not proof that all response measurements are unbiased. Delivering perfusion observations alongside response categories preserves their complementary roles and allows interpretation within the protocol, without assuming that either measure independently establishes the therapy's effect on patient outcomes.

Intrinsic Imaging’s Results

- DCE-MRI standardized across 44 sites in 11 countries with vendor-specific protocols and arterial-phase qualification
- Approximately 1,900 timepoints assessed under blinded mRECIST double reads with adjudication
- Arterial-phase timing compliance improved from 81% at qualification to above 95% during enrollment through targeted site feedback
- Quantitative perfusion parameters delivered under fixed conventions alongside mRECIST response for the sponsor's analysis

---

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

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