CASE STUDY · MEDICAL DEVICE

Interventional Device Trial for Percutaneous Tumor Ablation

Interventional oncology device · Contrast CT, MRI, ultrasound · Ablation zone and local tumor progression

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 developer of a percutaneous tumor ablation device required imaging evidence of technical success and durable local tumor control for primary and metastatic tumors. Assessment of ablation zones is multimodal and time-dependent: the zone evolves over months, benign periablational enhancement can mimic residual tumor, and the margins that predict local recurrence must be measured in three dimensions against the pre-procedure tumor.

The sponsor had not yet fixed its imaging endpoints and needed expert guidance on which measurements would be reproducible, which timepoints would be informative, and how to acquire images so that pre- and post-ablation findings could be compared reliably across sites and operators. Technical coverage immediately after treatment and sustained absence of local progression are related but distinct claims. An adequately characterized ablation zone provides anatomical evidence about treatment extent, whereas follow-up establishes how that region evolves. Endpoint selection therefore needed to preserve the difference between an early procedural assessment and a later judgment about local disease control.

Intrinsic Imaging's Solution

Intrinsic Imaging's interventional radiologists advised the sponsor on the imaging charter, recommending contrast-enhanced CT or MRI at defined post-ablation intervals, standardized acquisition parameters, and endpoints based on ablation zone volume, minimal ablative margin and local tumor progression. Sites were qualified and trained on the protocol, including the immediate post-procedure imaging used to confirm technical success. Volume and minimal margin characterize different features of the treated region: overall extent and the narrowest coverage around the original tumor. Standardized contrast imaging gives these measures an acquisition context and supports interpretation of enhancement. Defined intervals also provide a temporal framework for evaluating evolving tissue appearances rather than treating examinations obtained at different stages as equivalent.

Interventional radiologists performed blinded reads of pre-procedure, immediate post-procedure and follow-up imaging, measuring the tumor and ablation zone in three dimensions, computing the minimal margin and classifying enhancement patterns as expected periablational change, residual tumor or local progression under charter-defined criteria. Discordant classifications were adjudicated. Spatial measurement against the original tumor is important because an extensive ablation zone can still have an uneven margin. Enhancement classification addresses a separate interpretive question about the tissue within or around that zone. Adjudication supports consistent application of the categories, while preserving the limitation that imaging appearance is not direct histological confirmation of residual tumor.

Image transfer, quality control and processing were centralized so that each patient's serial imaging was co-registered and complete before reading, and project managers tracked the follow-up schedule to protect the durability endpoint. Co-registration supports comparison of spatial relationships across the treatment sequence, although it does not remove all uncertainty associated with changing tissue geometry. Follow-up tracking addresses the availability of later evidence needed to interpret durability. Strong compliance supports longitudinal assessment, but the observed imaging record should not be taken to establish outcomes after the documented observation period.

Intrinsic Imaging’s Results

- Imaging charter and endpoint definitions established with the sponsor before enrollment, giving the trial reproducible measures of technical success and local control
- Approximately 180 ablations at 14 sites assessed with three-dimensional ablation zone and minimal-margin measurement
- Periablational enhancement distinguished from residual or recurrent tumor under documented criteria with adjudication of discordant reads
- Follow-up imaging compliance above 92% at the 12-month timepoint through active schedule tracking

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Read the full study online: https://intrinsicimaging.com/case-studies/device-tumor-ablation

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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