CASE STUDY · MEDICAL DEVICE

Phase II Evaluation of a Novel Tumor Imaging Platform

Diagnostic device trial · Novel imaging platform vs reference standard · Sensitivity and specificity endpoints

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 medical device developer sought Phase II evidence that its novel imaging platform could help physicians distinguish malignant from non-malignant tissue across several tumor types. Unlike a therapeutic trial, the endpoint was diagnostic performance, which meant every case needed a reliable reference standard, and the novel images had to be evaluated by readers under conditions that neither overstated nor understated the device's contribution.

The sponsor also needed a protocol that captured the platform's images alongside conventional imaging and pathology without introducing bias through case selection or reading order, and a core lab experienced enough with diagnostic device development to advise on endpoint definitions that regulators would accept. Diagnostic discrimination must be interpreted in relation to the tissue spectrum represented, because performance in clearly malignant or clearly benign lesions may not describe performance in equivocal cases. The relationship between the index images and the reference evidence is therefore central to determining what the resulting accuracy estimates can legitimately establish.

Intrinsic Imaging’s Solution

Intrinsic Imaging worked with the sponsor on protocol and charter development, defining the reference standard hierarchy, the case-mix requirements for malignant and non-malignant tissue types, and the blinded reading design. Site qualification and training covered acquisition of both the novel platform data and the conventional comparator imaging, and image transfer was configured to handle the platform's proprietary output format. A defined reference hierarchy makes the evidentiary basis of each classification explicit rather than treating pathology and clinical observation as interchangeable. Specifying case mix also provides context for interpreting diagnostic performance across tumor types, where differences in lesion appearance and underlying disease prevalence can influence the apparent difficulty of the reading task.

Readers evaluated cases in randomized order, blinded to the reference standard, using a structured case report form that captured a lesion-level malignancy assessment and confidence score. The charter specified how multiple lesions per patient would be handled and how the reference standard would be adjudicated when pathology and clinical follow-up disagreed. Confidence scoring preserves information about diagnostic uncertainty that a binary classification alone would discard. Randomized presentation limits systematic reading-order effects, while the handling of multiple lesions matters because observations from the same patient may share biological and imaging characteristics rather than represent fully independent evidence.

Quality control and processing were centralized so that each case's platform data, comparator imaging and reference-standard documentation were linked and complete before reading, and the dataset was delivered in a form suitable for ROC-based analysis. Case-level completeness supports traceability between the diagnostic judgment and its supporting evidence. Readiness for ROC analysis nevertheless describes the organization of the evidence, not proof of clinical utility or equivalent performance across every tissue subgroup.

Intrinsic Imaging’s Results

- Approximately 420 lesions from 310 patients at 12 sites evaluated against a documented reference standard
- Blinded, randomized reading design with lesion-level confidence scoring delivered a dataset ready for sensitivity, specificity and ROC analysis
- Proprietary platform output integrated with conventional imaging and pathology records at case level with 100% linkage before reading
- Imaging charter and endpoint definitions structured to support the sponsor's subsequent pivotal study design

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

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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