CASE STUDY · ONCOLOGY

GIST Trial With RECIST 1.1 and Choi Criteria

38 sites · Contrast-enhanced CT · RECIST 1.1 and Choi criteria

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. In gastrointestinal stromal tumors treated with targeted therapy, responding lesions often change density and become cystic or hemorrhagic without shrinking, and may even enlarge. Size-based RECIST 1.1 assessment alone can therefore misclassify responders as stable or progressive disease. The sponsor of this multi-year trial of a novel GIST therapeutic required both RECIST 1.1 and Choi criteria applied in parallel, which demands reproducible Hounsfield-unit density measurements that are highly sensitive to contrast phase and acquisition technique.

GIST lesions are frequently large, heterogeneous and located in the stomach, small bowel, mesentery and peritoneum, where bowel motion and variable distension complicate measurement. Consistent contrast timing across 38 sites, and consistent placement of density regions of interest across readers and timepoints, were prerequisites for a credible Choi analysis. Parallel criteria address different imaging manifestations of treatment response rather than providing interchangeable labels. A change in attenuation may be informative when size is stable, but its interpretation remains dependent on acquisition consistency and the heterogeneous composition of the lesion being sampled.

Intrinsic Imaging's Solution

Intrinsic Imaging developed an imaging charter specifying portal venous phase contrast-enhanced CT with defined bolus timing, slice thickness and reconstruction kernels so that density measurements would be comparable across sites and timepoints. Site qualification included review of test submissions for contrast phase, and sites received targeted feedback where phase timing fell outside the charter window. Controlling contrast phase is central to separating a plausible tissue change from a difference in enhancement caused by acquisition timing. Technical compliance supports comparison without establishing biological specificity.

Oncology radiologists experienced in sarcoma trials performed blinded double reads applying RECIST 1.1 and Choi criteria at every timepoint. The charter defined how density regions of interest would be placed and propagated across timepoints, how cystic and hemorrhagic change would be recorded, and how intra-tumoral nodules suggesting progression within an otherwise responding lesion would be captured. Adjudication was performed on discordant response categories under either criterion. Consistent region placement constrains sampling variability within heterogeneous masses. Recording internal nodules alongside cystic or hemorrhagic change preserves distinctions that an overall size or density summary might obscure. Adjudication resolves criterion-specific disagreement without making either framework an independent biological reference standard.

Image quality control and processing were centralized, with density measurements captured in the reading platform rather than transcribed, and the dual-criteria dataset was delivered in a structure that allowed the sponsor to analyze RECIST 1.1 and Choi outcomes separately and in comparison. Separate outputs retain the interpretive distinction between size-based and density-informed response. Direct capture reduces reliance on transcription, while traceability of region placement supports review of how a measurement was derived.

Intrinsic Imaging’s Results

- Dual RECIST 1.1 and Choi assessment across approximately 1,900 timepoints from 38 sites with blinded double reads and adjudication
- Contrast-phase compliance above 95% after site qualification and feedback, supporting reproducible Hounsfield-unit density measurement
- Roughly one in five patients classified as responders under Choi criteria while stable under RECIST 1.1, captured in a dataset that let the sponsor characterize the difference
- Density measurements captured directly in the reading environment with a complete audit trail of region-of-interest placement and propagation

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

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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