CASE STUDY · ONCOLOGY

Phase I/IIa Imaging Endpoint Strategy for a Biotech Go/No-Go Decision

12 sites · FDG PET/CT, contrast CT · RECIST 1.1, PERCIST and CT volumetrics

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. An emerging biotechnology company was taking its first oncology asset into a Phase I/IIa study and faced a single decision at the end of dose escalation: whether to open an expansion cohort, a step that would commit most of its remaining capital. The board wanted evidence of biological activity by week 8 of treatment in the recommended-dose cohort. Conventional RECIST 1.1 response at that timepoint would almost certainly be stable disease in most patients, which answers nothing.

The sponsor had no in-house imaging expertise, and the protocol was already drafted with RECIST as the only imaging assessment. The question put to Intrinsic Imaging before protocol finalization was whether imaging could be designed to detect an early signal with sufficient statistical weight to support a decision, across 12 sites and roughly 40 patients, without adding burden that would slow enrollment. Any exploratory measure would also need to be prespecified rather than post hoc if it was to carry weight with the board, with future investors and with regulators reviewing the subsequent development program, and it would need to coexist with RECIST so that regulatory continuity was preserved.

Intrinsic Imaging’s Solution

Intrinsic Imaging's medical and scientific team reviewed the asset's mechanism and the published imaging behavior of related agents, then proposed a layered imaging strategy. RECIST 1.1 remained the protocol-defined efficacy assessment for regulatory continuity. Two exploratory measures were added at baseline and week 8: metabolic response on FDG PET/CT under PERCIST, and volumetric change of target lesions on contrast CT, both of which can register treatment effect before unidimensional measurements cross the RECIST threshold. We drafted the imaging sections of the protocol, the imaging manual and a brief charter, and advised on the analysis plan so that the exploratory measures were prespecified.

The imaging manual kept site burden low. FDG PET/CT was limited to the two decision timepoints, acquisition parameters were set to match each site's routine clinical oncology protocol wherever the protocol allowed, and no additional sequences were introduced. Because every patient mattered, we qualified the 12 sites for both PET/CT and CT within three weeks and read each week-8 examination within five business days of receipt, with the same radiologist and nuclear medicine physician reading each patient's baseline and follow-up pair.

At the decision point, we delivered an interim imaging package to the sponsor: per-patient RECIST, PERCIST and volumetric results, waterfall plots of metabolic and volumetric change, and a short interpretive summary from the medical lead, structured so that the board could weigh the imaging evidence directly alongside safety and pharmacokinetic data.

Intrinsic Imaging’s Results

- Week-8 PERCIST and volumetric data demonstrated a treatment signal in the recommended-dose cohort that conventional RECIST 1.1 assessment classified only as stable disease
- Five business days from the final week-8 scan to delivery of the interim imaging package, after which the board approved opening the expansion cohort
- Four months earlier, by the sponsor's estimate, than waiting for confirmed RECIST responses would have permitted the expansion cohort to open and enroll
- Imaging strategy, manual and charter carried forward unchanged into the expansion cohort and the sponsor's subsequent Phase II protocol, preserving methodological continuity

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

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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