CASE STUDY · ONCOLOGY

Phase II Metastatic Pancreatic Cancer Trial With RECIST and PERCIST

Phase II efficacy trial · Contrast CT, FDG PET/CT · RECIST 1.1 and PERCIST

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 Phase II efficacy trial of a novel investigational biologic enrolled patients with metastatic pancreatic adenocarcinoma or advanced colorectal cancer refractory to standard therapy. Pancreatic tumors are poorly marginated on CT and respond slowly in size, so the sponsor required metabolic response assessment under PERCIST alongside anatomic RECIST assessment to detect early biologic activity.

PERCIST depends on standardized uptake values that are sensitive to uptake time, glucose level, scanner calibration and reconstruction, and few of the participating sites had experience acquiring PET/CT to a quantitative research standard. The sponsor needed both criteria applied consistently and a dataset that let anatomic and metabolic response be compared. Metabolic and anatomical criteria describe different aspects of disease, so disagreement between them can be scientifically informative rather than evidence that either assessment is erroneous. Early changes in glucose uptake may precede measurable shrinkage, but metabolic response alone does not establish durable tumor control, symptomatic improvement or survival benefit in these heavily treated populations.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with contrast-enhanced CT acquisition parameters and a quantitative FDG PET/CT protocol specifying fasting, glucose thresholds, uptake time windows and reconstruction, and qualified each site's PET/CT system for quantitative consistency. Sites were trained on the protocol and on paired CT and PET/CT scheduling. The quantitative acquisition requirements address variation that could otherwise resemble a treatment-related change in tracer uptake. Fasting, glucose control, uptake timing and reconstruction each influence the conditions under which serial measurements are compared. Coordinating anatomical and metabolic examinations also matters because differences in examination timing can complicate interpretation when disease is changing between assessments.

Oncology radiologists performed blinded reads under RECIST 1.1 and nuclear medicine-trained readers measured SUL-peak in the reference lesion and liver under PERCIST, with the charter defining target lesion selection, reference region placement and the handling of new lesions under each criterion. Discordant response categories under either criterion were adjudicated. Separate assessment frameworks preserve the distinction between changes in lesion dimensions and changes in metabolically active disease. Defined reference region placement helps maintain a consistent basis for uptake interpretation, while explicit new-lesion rules prevent informal transfer of assumptions between criteria. Adjudication addresses disagreements within each framework; it does not require anatomical and metabolic response categories to converge.

Images were quality-controlled centrally for uptake time and reconstruction compliance, and the dual-criteria dataset was delivered in a structure allowing direct comparison of anatomic and metabolic response per patient. The paired dataset permits examination of response discordance within patients rather than comparison of unrelated group summaries. Uptake-time compliance provides useful technical context, but does not remove every biological or measurement influence on tracer uptake. The reported early metabolic responses among patients with anatomically stable disease should therefore be interpreted as a difference between response classifications, not as independent confirmation of clinical benefit.

Intrinsic Imaging’s Results

- Paired RECIST 1.1 and PERCIST assessment delivered for approximately 95 patients at 14 sites
- Quantitative PET/CT protocol achieved uptake-time compliance above 90% after site qualification and feedback
- Metabolic response detected under PERCIST at the first follow-up in roughly 30% of patients classified as stable disease under RECIST 1.1
- Dual-criteria dataset structured for per-patient comparison of anatomic and metabolic response in the sponsor's efficacy analysis

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Read the full study online: https://intrinsicimaging.com/case-studies/oncology-pancreatic-percist

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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