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

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.

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.

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.

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.

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 750 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 andOphthalmology. 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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