

Phase III Immunotherapy RECIST and iRECIST

90+ sites in 18 countries

CT, MRI

RECIST 1.1 and iRECIST

Challenge

Immunotherapy trials present a distinctive interpretive challenge: apparent radiographic progression may reflect treatment-related inflammation rather than true tumor growth. The sponsor required central reviewers to distinguish pseudoprogression from genuine disease progression with consistency across more than 90 sites in 18 countries, while applying two response frameworks—RECIST 1.1 and iRECIST—in parallel. Any variability in how unconfirmed progression was identified, confirmed, or dated threatened to distort the trial's efficacy conclusions and invite regulatory scrutiny.

Our Solution

Intrinsic Imaging assigned subspecialty oncologic radiologists to perform dual independent assessments under both response frameworks, with each reader blinded to the other's determinations. Automated discordance triggers within our reading platform flagged unconfirmed progression findings and routed them immediately to adjudication, ensuring that no progression event was finalized without the confirmatory review iRECIST demands. Standardized reader training and ongoing calibration sessions maintained uniform application of both criteria sets throughout the trial's duration.

Results

- Consistent central assessment of 12500+ timepoints
- Full audit trail supported the BLA submission
- Zero Form 483 observations during the sponsor inspection

Read the full study online: <https://www.intrinsicimaging.com/case-studies/oncology>

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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 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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