CASE STUDY · ONCOLOGY

Phase III Immunotherapy RECIST and iRECIST

90+ sites in 18 countries · CT, MRI · RECIST 1.1 and iRECIST

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. Immunotherapy trials pose a distinctive interpretive problem: apparent radiographic progression may reflect treatment-related inflammation rather than true tumor growth. The sponsor required central reviewers to distinguish pseudoprogression from genuine progression consistently 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 efficacy conclusions and invite regulatory challenge.

The program's scale magnified these demands. Sites differed in scanner technology, contrast practice and imaging schedules, and investigators were accustomed to local conventions for assessing response. Because iRECIST requires that unconfirmed progression be followed by a confirmatory examination, central review also had to track each patient's status longitudinally, ensuring that confirmation windows were respected and that treatment-beyond-progression decisions at sites were informed by consistent assessments. The distinctions between the two frameworks had to be made explicit at every point in the review process rather than reconciled retrospectively. Parallel assessment preserves the distinction between RECIST 1.1 progression and iRECIST unconfirmed or confirmed progression, with subsequent imaging interpreted according to the requirements of each framework.

Intrinsic Imaging’s Solution

Intrinsic Imaging assigned subspecialty oncologic radiologists to perform dual independent assessments under both frameworks, each reader blinded to the other's determinations. The charter defined, in precise operational terms, how target and non-target lesions would be selected, measured and followed under each framework, and how unconfirmed progression would be identified, confirmed or reset. Reader worksheets captured both assessments within a single controlled workflow, eliminating transcription between systems and the inconsistent dating that accompanies it, and preserving a contemporaneous record of each reader's reasoning.

Automated triggers within our reading platform identified discordant assessments for adjudication and flagged unconfirmed progression for longitudinal tracking, so that reader disagreement was handled separately from the subsequent imaging used to establish confirmed progression. Project managers monitored confirmation windows and coordinated with sites so that the examinations required to resolve unconfirmed progression were acquired and reviewed without delay, while point-of-submission quality control intercepted incomplete or non-conformant examinations before they reached the readers.

Calibration sessions drew on representative cases from outside the study dataset, allowing readers to align on conventions without exposure to trial data. Adjudication outcomes were reviewed periodically to identify recurring sources of disagreement, and charter clarifications were issued so that the same question would not be answered differently later in the trial.

Intrinsic Imaging’s Results

- 12,500+ timepoints assessed under RECIST 1.1 and iRECIST in parallel, with response and unconfirmed progression classified uniformly across more than 90 sites in 18 countries
- Zero Form 483 observations during the FDA inspection of the imaging component, confirming the adequacy of the dual-framework charter and the fidelity of its execution
- Complete audit trail of reader decisions, adjudications and confirmatory imaging supported the sponsor's BLA submission without any supplementary reconciliation of the imaging record
- Reusable immunotherapy framework delivered to the sponsor, comprising charter language, reader training materials and adjudication procedures already proven under regulatory inspection

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

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 650 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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