CASE STUDY · ONCOLOGY

Phase II Immuno-Oncology Trial in NSCLC and SCLC

45 sites in 8 countries · Contrast CT, MRI · RECIST 1.1 with immune-response flagging

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 multi-year Phase II immuno-oncology program enrolled patients with both non-small cell and small cell lung cancer under a single imaging charter. Checkpoint-inhibitor therapy produces atypical response patterns, including transient lesion enlargement and new lesions that later regress, and the sponsor needed RECIST 1.1 applied consistently across two histologies while retaining enough information to interpret suspected pseudoprogression at the program level.

Lung cancer imaging adds its own variability: pleural effusions, post-obstructive atelectasis and treatment-related pneumonitis complicate target-lesion selection and measurement, and chest CT protocols differed across the 45 participating sites. The sponsor required a central review process that selected measurable disease reproducibly at baseline, carried that selection through every follow-up, and documented every unconfirmed progression so that the efficacy analysis would survive regulatory scrutiny. The central distinction is between applying the prespecified response criteria and recognizing an imaging pattern that may warrant later clarification. Suspicion of pseudoprogression does not itself establish that apparent worsening is benign or justify substituting a different response framework.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter alongside the protocol, specifying contrast-enhanced chest and abdominal CT acquisition parameters, slice thickness limits and timepoint windows, and qualified each site against those parameters before first patient imaging. Site training addressed the common sources of unevaluable examinations in thoracic oncology, and image transfer and quality control were centralized so that technical issues were resolved before the images reached the readers. Consistent chest acquisition supports comparison of lesion boundaries when adjacent collapsed lung or inflammatory change complicates measurement. Resolving technical issues before interpretation addresses evaluability without resolving the biological ambiguity of a thoracic abnormality.

Two oncology-trained radiologists from the company's 12-member oncology group read every timepoint independently under RECIST 1.1, with a third adjudicating discordant response categories or progression dates. The charter defined how non-target pleural disease, atelectasis and inflammatory change would be handled, and readers flagged any progression event that could represent treatment-related inflammation so the sponsor could apply confirmatory follow-up where the protocol allowed. Flagging possible inflammation preserves relevant uncertainty alongside the formal response assessment. It does not establish pseudoprogression or imply that confirmatory imaging was appropriate outside the protocol's provisions. The distinction protects the separation between an observed imaging pattern and its eventual clinical interpretation.

Reader calibration used reference cases drawn from both histologies before reading began, and project managers tracked confirmatory scans, query turnaround and read timelines across the trial's multi-year duration, with periodic reader-agreement monitoring to detect drift. Calibration across histologies addresses differences in presentation within the shared charter. Tracking confirmation and queries maintains visibility of unresolved assessments, while agreement monitoring evaluates consistency rather than diagnostic certainty.

Intrinsic Imaging’s Results

- Approximately 2,800 timepoints read across 45 sites in 8 countries with blinded double reads and adjudication on every discordant response assessment
- Adjudication required on roughly 14% of timepoints, with all adjudicated outcomes documented against the complete imaging history
- Every unconfirmed progression flagged for potential pseudoprogression, giving the sponsor a traceable basis for confirmatory imaging decisions
- Median read turnaround of five business days maintained throughout the multi-year program under an ISO certified quality management system

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

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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