CASE STUDY · MEDICAL DEVICE

International Trial of a Medical Device for the Treatment of Lung Cancer

International device trial · Contrast chest CT, PET/CT · Local control and device-related change

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. An international clinical trial evaluated a medical device designed to treat lung cancer. Device-based tumor treatment produces local tissue changes, including consolidation, cavitation and fibrosis, that evolve over months and can be confused with residual or recurrent tumor on both CT and PET. Response assessment therefore required criteria adapted to a local therapy rather than conventional systemic RECIST alone.

The sponsor selected Intrinsic Imaging in part because of its ISO 13485 certification for medical device core lab services, and needed a charter, reader methodology and documentation standard that would satisfy device regulators across the participating regions. The central interpretive distinction was between treatment effect at the intervention site and evidence of viable disease. Local anatomical change and metabolic activity cannot be treated as interchangeable signals, particularly while the treated tissue is evolving. A framework adapted to this setting is therefore necessary to avoid equating every persistent abnormality with treatment failure or every size reduction with local control.

Intrinsic Imaging’s Solution

Intrinsic Imaging developed the protocol imaging section and charter with contrast-enhanced chest CT and PET/CT acquisition standards and a local response framework combining size, density and metabolic criteria, with explicit rules for distinguishing expected post-treatment change from local progression. Sites were qualified, trained and supported through centralized image transfer, blinding and processing. Combining size, density and metabolic criteria recognizes that local treatment response has several imaging dimensions. Explicit classification rules give these observations a common interpretive structure without implying that any individual feature is definitive. Acquisition consistency is relevant because differences in enhancement or metabolic appearance may otherwise complicate comparison of the treated region across examinations.

Thoracic and oncology radiologists performed blinded independent reads of the treated lesion and of regional and distant disease, with adjudication of discordant local response classifications. Device-related findings such as pneumothorax, effusion and airway change were captured under safety definitions in the charter. Assessing regional and distant disease separately from the treated lesion preserves the distinction between local control and the broader disease course. Similarly, predefined safety findings describe potential consequences of treatment rather than tumor response. Independent review and adjudication address classification variability, but imaging interpretation alone does not establish pathological viability or the cause of every post-treatment abnormality.

Quality control at receipt verified contrast phase, coverage and PET acquisition parameters, and the local control dataset was delivered with the safety imaging findings for the sponsor's regulatory submissions. Receipt checks address whether submitted images contain the acquisition information required by the response framework. They do not themselves determine whether an abnormality represents progression. Delivering local control assessments alongside safety findings maintains complementary views of the intervention, while preserving the need to interpret each endpoint according to its own definition and the timing of the examination.

Intrinsic Imaging’s Results

- Approximately 210 treated patients at 24 sites in 7 countries assessed under a local response framework combining CT and PET criteria
- Expected post-treatment change distinguished from local progression under documented rules, with adjudication on discordant classifications
- Device-related imaging safety findings captured under predefined definitions for every post-procedure examination
- Documentation produced under an ISO 13485 certified quality system for medical device core lab services

---

Read the full study online: https://intrinsicimaging.com/case-studies/device-lung-cancer-treatment

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.

Contact:
Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com