CASE STUDY · ONCOLOGY

International Phase III Trial of a Novel Approach to NSCLC Brain Metastases

Several thousand reads · Brain MRI, body CT · Joint oncology and neuroradiology review

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 global Phase III trial compared a novel approach to treating non-small cell lung cancer brain metastases against standard of care. The trial's efficacy conclusions depended on both intracranial control and systemic disease status, which meant brain MRI and body CT had to be reviewed under different criteria by different subspecialists while producing a single coherent assessment per patient per visit.

Over a multi-year duration with several thousand radiological reads, the sponsor needed consistent intracranial measurement despite heterogeneous MRI protocols, reliable differentiation of treatment effect from progression, and a workflow that kept the neuroradiology and oncology assessments synchronized so that progression events were dated consistently across compartments. Intracranial response and systemic response need not evolve together, so a unified patient assessment must preserve the meaning of each compartment rather than obscure discordance. Differences in acquisition timing can further complicate interpretation when an apparent progression event in one compartment precedes the available assessment of the other.

Intrinsic Imaging’s Solution

Intrinsic Imaging designed an imaging charter covering both compartments, with standardized post-contrast brain MRI parameters and body CT requirements, and qualified every site against both. Site training emphasized timepoint alignment so that brain and body imaging were acquired within the same window. Aligning acquisition windows supports interpretation of brain and body findings as components of the same clinical visit. Standardized post-contrast MRI requirements are particularly relevant to serial evaluation of intracranial lesions, where visibility and measured extent depend on acquisition technique. Site qualification addresses technical readiness across both compartments without implying identical sensitivity for every disease manifestation.

The company's nine full-time neuroradiologists reviewed intracranial disease and its ten-radiologist oncology team reviewed extracranial disease, each under blinded independent double reads with adjudication. Reading workflows were linked so that the overall response and progression date for each visit were derived from both assessments under rules defined in the charter. Subspecialty review reflects the distinct anatomical and interpretive demands of intracranial and extracranial disease. Charter-defined combination rules establish how those separate judgments contribute to the patient-level record, including when the compartments differ. This preserves a distinction between the location of progression and its consequence for overall classification, while adjudication provides a defined route for resolving reader disagreement.

Quality control, image transfer and data management were centralized, and project managers tracked read volumes across the multi-year program, scaling reader assignments ahead of enrollment peaks. Centralized handling places the separate reading streams within a common operational framework, which matters when missing or delayed assessments could complicate visit-level reconciliation. Capacity planning addresses continuity of review across changing enrollment volumes rather than the biological interpretation of a scan. Sustained agreement remains a measure of reading consistency, not independent confirmation that every suspected progression event represents active tumor.

Intrinsic Imaging’s Results

- Approximately 5,400 reads completed by coordinated neuroradiology and oncology teams across 72 sites in 13 countries
- Intracranial and extracranial assessments synchronized to a single per-visit response record with consistent progression dating
- Standardized brain MRI protocol adopted at all sites, with unevaluable intracranial timepoints below 3%
- Reader agreement on intracranial progression above 90% at each monitoring interval over the multi-year trial

---

Read the full study online: https://intrinsicimaging.com/case-studies/oncology-nsclc-brain-mets-2016

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