CASE STUDY · ONCOLOGY

Phase II Glioblastoma Multiforme Trial With Central Neuroradiology Review

Phase II · Brain MRI · RANO response assessment

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 Phase II trial evaluated a novel treatment for glioblastoma multiforme, the most common and aggressive primary brain tumor in adults. Response assessment in glioblastoma is complicated by pseudoprogression after chemoradiation, by the effect of corticosteroids on enhancement, and by variability in MRI acquisition across sites, all of which can produce apparent progression that is not tumor growth.

The sponsor needed a standardized MRI protocol, blinded neuroradiology review under RANO criteria, and a process that integrated clinical information such as steroid dose into the assessment while preserving blinding to treatment, so that progression-free survival would be measured consistently. In this setting, a change in enhancement is not a direct measurement of viable tumor burden, particularly when treatment and corticosteroid exposure can alter its appearance. The timing and clinical context of an examination are therefore integral to interpretation. An imaging progression event must remain distinguishable from a provisional concern that requires confirmation under the specified assessment framework.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the protocol imaging section and charter with a standardized brain tumor MRI protocol, qualified sites against it and trained site staff on timepoint scheduling and submission of the clinical data elements RANO requires. Image transfer, blinding and processing were centralized with quality control at receipt. A standardized acquisition framework makes serial examinations more comparable when subtle changes in enhancement or non-enhancing abnormality influence response classification. The required clinical data provide context that images alone cannot supply, while treatment blinding separates that necessary context from knowledge that could bias efficacy judgments. Quality control at receipt addresses whether the submitted examination supports the planned assessment, not whether its findings are biologically specific.

Board-certified, fellowship-trained neuroradiologists performed blinded independent reads under RANO criteria, with the charter governing measurable disease definition, handling of enhancing and non-enhancing components, the pseudoprogression window and confirmation requirements. Discordant response assessments were adjudicated. Separating enhancing and non-enhancing disease acknowledges that relevant tumor-associated changes may not follow a uniform imaging pattern. Defined confirmation requirements constrain how early ambiguous findings contribute to progression determinations. Adjudication provides a documented resolution of discordant assessments, but cannot by itself establish whether an equivocal abnormality represents viable tumor, treatment effect or a mixture of processes.

Reader calibration used reference cases spanning true progression, pseudoprogression and treatment effect, and reader agreement was monitored during the trial. Reference cases make the interpretive boundaries of the charter concrete, especially where pseudoprogression resembles worsening disease. Monitoring agreement addresses consistency of application over time rather than proving diagnostic truth. In a progression-free survival analysis, that distinction is important because reproducible assessment and biological certainty are related but separate objectives, and a consistent decision rule still operates within the limitations of MRI.

Intrinsic Imaging’s Results

- Approximately 110 patients at 18 sites assessed under blinded RANO double reads with adjudication
- Standardized brain tumor MRI protocol adopted at all sites with unevaluable timepoints under 3%
- Suspected pseudoprogression managed under a documented confirmation workflow, with rationale recorded for every progression determination
- Corticosteroid and clinical data integrated into RANO assessment without compromising reader blinding to treatment arm

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Read the full study online: https://intrinsicimaging.com/case-studies/oncology-gbm-phase-ii-2015

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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