CASE STUDY · ONCOLOGY

Glioblastoma Trial With RANO Criteria

30 sites · Brain MRI with perfusion · RANO and mRANO

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. Following chemoradiation, glioblastoma patients frequently exhibit treatment-related imaging changes that mimic tumor progression. Distinguishing pseudoprogression from true progression is among the most difficult judgments in neuro-oncology imaging, and premature or inconsistent progression determinations distort progression-free survival analyses and prompt inappropriate treatment changes. The trial required central application of RANO and modified RANO criteria rigorous enough to manage this ambiguity uniformly across all 30 sites.

Imaging variability compounded the challenge. Brain MRI protocols differed in sequence selection, slice thickness, contrast timing and perfusion technique, complicating comparison across timepoints. RANO assessments also depend on clinical information such as corticosteroid use and neurological status, which had to be integrated into central review without compromising reader blinding to treatment assignment. The sponsor required consistent application of both frameworks, appropriate integration of perfusion findings and clinical context, and a review process that distinguished response classification from uncertainty requiring follow-up, documented the basis and timing of every progression determination, and preserved traceability across the complete imaging history. Perfusion findings supply physiological context but do not independently resolve every ambiguous post-treatment abnormality. Their interpretation remains anchored to the response framework and the longitudinal evidence available at each assessment.

Intrinsic Imaging's Solution

Intrinsic Imaging provided sites with a standardized brain tumor imaging protocol, including guidance for perfusion acquisition where available. Submissions were checked for sequence completeness and technical consistency, and sites received prompt feedback when examinations could not support reliable assessment.

Our neuroradiologists applied RANO and modified RANO criteria under a reading charter that defined how imaging findings and relevant clinical information would be combined, how measurable and non-measurable disease would be followed, and when confirmatory imaging was required. Perfusion assessments were incorporated into the interpretation of suspected pseudoprogression, adding a physiological dimension to conventional morphological review. A standardized confirmation workflow governed every ambiguous case, reducing the risk of classifying transient treatment-related change as progression, and project managers tracked confirmatory scans so they were acquired and reviewed promptly.

Readers were trained on these rules using reference cases before reading began. Adjudication was invoked when primary readers disagreed on progression status, response category or event timing; adjudicators reviewed the complete imaging history and clinical context under the same charter, and their decisions were documented in detail. Findings initially attributed to treatment effect may resolve, stabilize or subsequently meet progression criteria, and structured confirmation allowed these trajectories to be interpreted consistently across sites while retaining the rationale for every complex case.

Intrinsic Imaging’s Results

- 30 sites assessed under a single standardized confirmation workflow, reducing the incidence of premature progression determinations that would otherwise have distorted the progression-free survival analysis
- Perfusion findings and clinical context, including corticosteroid use, integrated into RANO and mRANO review without compromising reader blinding to treatment assignment
- Inspection-ready audit trail documenting the imaging basis, clinical context, timing and adjudication of every progression determination across each patient's complete imaging history
- Standardized brain tumor imaging protocol improved cross-timepoint comparability despite heterogeneous site practice in sequence selection, slice thickness, contrast timing and perfusion technique

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

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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