CASE STUDY · ONCOLOGY

Lymphoma Trial Using Lugano Classification

45 sites · FDG PET/CT · Lugano 2014 and Deauville scoring

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. In lymphoma trials, treatment decisions and endpoint determinations rest on metabolic response classification, yet Deauville scoring varies materially when performed independently at individual sites. Across 45 sites, wide divergence in site-level scoring had made complete metabolic response classifications difficult to trust, threatening the integrity of the trial's response-based endpoints and complicating the planned interim analysis. The sponsor required a central review process capable of standardizing interpretive conventions and documenting the resolution of discordant assessments.

Technical variation added to the interpretive difficulty. FDG uptake measurements are influenced by scanner calibration, uptake time, patient preparation and reconstruction method, all of which differed across sites, and because Deauville scoring compares lesion uptake with reference regions, inconsistencies in acquisition or processing could shift a patient's apparent response category. The sponsor needed nuclear medicine expertise, acquisition-sensitive quantitative quality control and a predefined adjudication process that would serve both the interim dataset and subsequent assessments without any change in scoring convention, with every determination traceable to its examinations, reference-region comparisons and documented reader decisions. A persistent anatomical mass does not necessarily imply persistent metabolic disease. Reference-region comparisons preserve the interpretive basis of Deauville scoring, particularly where modest differences in uptake can change the assigned response category.

Intrinsic Imaging's Solution

Intrinsic Imaging supported sites with acquisition guidance covering patient preparation, uptake timing and reconstruction parameters, and reviewed each submission for completeness and technical adequacy before central assessment. SUV calibration was verified for every submission to ensure quantitative comparability across scanners, and where technical issues affected quantitative reliability, sites were contacted promptly for clarification or correction.

Nuclear medicine physicians performed blinded dual assessments of every FDG PET/CT examination under the Lugano 2014 classification. Readers were trained on the classification and Deauville scoring conventions using reference cases before reading began, and reference-region measurements and quantitative values were reviewed for plausibility before final scoring. Readers documented technical limitations whenever they affected interpretation, so that the sponsor understood not only each patient's response category but the factors that informed it.

Any disagreement in Deauville scoring between the two primary readers was resolved through formal adjudication. Adjudication decisions were documented, and adjudication rates and reader performance were monitored throughout the study so that emerging patterns of discordance could be addressed before they affected the interim dataset. The structure placed an inherently interpretive assessment within a standardized, documented process that supported consistency while preserving a complete record of reader disagreement and its resolution for data review and regulatory inspection.

Intrinsic Imaging’s Results

- Below 12% adjudication rate for Deauville scoring between blinded primary readers, sustained across all 45 sites from the interim dataset through subsequent response assessments
- Consistent metabolic response classification across participating sites, with each determination traceable to its examinations, reference-region comparisons and documented reader decisions
- Reconciled central review dataset delivered on schedule for the planned interim analysis, with SUV calibration verified on every FDG PET/CT submission before Deauville scoring
- Acquisition guidance, reader training materials and adjudication procedures retained by the sponsor as a tested framework for later-phase lymphoma studies and registration

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

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.

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