CASE STUDY · ONCOLOGY

International Phase II Non-Hodgkin Lymphoma Trial With PET/CT and PET/MRI

International Phase II · FDG PET/CT, PET/MRI · Lugano classification and Deauville score

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 Phase II trial assessed a new treatment for non-Hodgkin lymphoma using FDG PET combined with CT or, at some sites, MRI. Metabolic response assessment under the Lugano classification depends on Deauville scoring relative to mediastinal and liver uptake, which varies with uptake time, glucose level and reconstruction, and the inclusion of PET/MRI alongside PET/CT introduced a second hybrid modality with different attenuation correction and anatomical reference.

The sponsor needed consistent Deauville scoring and Lugano response classification across both modalities and all sites, with documented handling of the cases where PET and anatomical findings disagreed. A residual mass and persistent metabolic activity do not carry interchangeable implications, making disagreement between anatomical and functional findings a substantive interpretive issue rather than merely a reporting discrepancy. Differences between hybrid modalities also complicate longitudinal comparisons because an apparent change in uptake must be interpreted in the context of how the examination was acquired and corrected.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the protocol imaging section and charter with quantitative PET acquisition requirements for both PET/CT and PET/MRI, including fasting, uptake time and reconstruction, and qualified each site's hybrid system. Sites were trained on the protocol and on complete submission of anatomical and metabolic series. The acquisition requirements address sources of variability that can alter lesion uptake relative to reference tissues without reflecting a biological change in lymphoma. Qualification of each hybrid system is particularly relevant when anatomical imaging and attenuation correction differ across platforms. Complete anatomical and metabolic submissions provide the complementary information needed to interpret uptake within its structural context.

Nuclear medicine and oncology radiologists performed blinded independent reads applying Deauville scoring and Lugano response classification, with the charter defining reference region placement, the handling of residual masses with low uptake, and the reconciliation of metabolic and anatomical findings. Discordant Deauville scores affecting the response category were adjudicated. Explicit reference region conventions make the basis of a Deauville judgment more reproducible when uptake lies near a category boundary. Rules for residual masses distinguish persistent anatomical abnormality from metabolically active disease without assuming that lesion size alone establishes response. Adjudication addresses disagreements consequential to classification, although consensus cannot eliminate uncertainty inherent in borderline uptake or discordant imaging findings.

Image transfer, blinding and processing were centralized, with uptake-time compliance verified at receipt, and the response dataset was delivered with modality identified for each timepoint. Recording modality at each assessment preserves an important contextual variable for interpreting longitudinal response. Receipt checks on uptake timing address a known acquisition dependency rather than establishing that all remaining measurements are interchangeable. Together, these records help distinguish the documented assessment pathway from the broader question of whether observed metabolic change represents treatment effect.

Intrinsic Imaging’s Results

- Approximately 95 patients at 21 sites in 8 countries assessed under blinded Deauville and Lugano double reads with adjudication
- Quantitative PET protocol applied across PET/CT and PET/MRI with uptake-time compliance above 90%
- Discordant Deauville scores affecting response category resolved by adjudication in roughly 12% of timepoints with documented rationale
- Metabolic and anatomical findings reconciled under charter rules with modality recorded for every assessment

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

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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