CASE STUDY · ONCOLOGY

Multiple Myeloma Trial With IMWG Imaging Criteria

120 sites in 22 countries · Whole-body low-dose CT, FDG PET/CT, MRI · IMWG response and extramedullary disease

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. Response in multiple myeloma is defined largely by laboratory measures, which can lead sponsors to underestimate the imaging work a global trial requires. In this Phase III study the imaging component was decisive at three points: documenting bone disease and extramedullary plasmacytomas at baseline, confirming progression when new bone lesions or soft-tissue masses appeared, and assessing metabolic response on FDG PET/CT in the subset of patients with imaging-evaluable disease.

The 120 sites in 22 countries did not share a common imaging practice. Some performed whole-body low-dose CT, others relied on PET/CT, and a minority still submitted skeletal surveys or regional MRI. Extramedullary lesions, which carry prognostic weight, were measured inconsistently or not at all. Without a defined modality hierarchy and central assessment, the imaging contribution to IMWG response categories would have varied by region, and the sponsor's response algorithm, which combined laboratory and imaging inputs on a fixed schedule, could not have been applied uniformly. The sponsor required a core laboratory capable of harmonizing acquisition across regions, interpreting myeloma bone disease with appropriate specialist judgment and delivering imaging variables in a form its statisticians could merge directly.

Intrinsic Imaging's Solution

Intrinsic Imaging wrote an imaging charter that set a modality hierarchy aligned to the International Myeloma Working Group criteria: whole-body low-dose CT as the required baseline skeletal examination, FDG PET/CT where available for metabolic assessment, and MRI for suspected spinal or extramedullary disease. Sites that had been submitting skeletal surveys were transitioned to low-dose CT through protocol templates and radiation-dose guidance acceptable to local ethics committees.

The reading panel paired radiologists experienced in myeloma bone disease with nuclear medicine physicians for the PET component. Readers recorded lytic lesion burden, measured extramedullary plasmacytomas bidimensionally and assessed PET response using Deauville-based criteria, with dual independent reads and adjudication for every progression call. Because myeloma bone lesions rarely heal radiographically, readers were trained to distinguish genuinely new lytic lesions from pre-existing lesions that had become more conspicuous, and to separate fracture and treatment-related change from progression, since either misreading would have advanced a progression date incorrectly.

To support sites with limited myeloma imaging experience, we held a protocol-training webinar in each region before activation and returned acquisition-quality feedback on each site's first three submissions, bringing whole-body low-dose CT coverage and reconstruction into line with the manual within the first quarter of enrollment. A data transfer specification delivered imaging-derived variables, including new-lesion flags and plasmacytoma measurements, in a structure the sponsor's statisticians could merge directly with serum and urine results.

Intrinsic Imaging’s Results

- 96.8% inter-reader concordance on progression calls after adjudication, sustained across whole-body low-dose CT, FDG PET/CT and MRI throughout the Phase III study
- 100% of patients with soft-tissue involvement at baseline had extramedullary disease measured centrally, compared with only partial site-level reporting before central review
- 120 sites in 22 countries aligned to a single IMWG modality hierarchy, with skeletal-survey sites transitioned to low-dose CT within the first quarter
- Imaging-derived response variables delivered on schedule for every interim analysis and the final IMWG response determination, merged directly with serum and urine results

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

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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