CASE STUDY · GASTROENTEROLOGY & METABOLIC

Obesity Trial With DXA Body Composition and MRI Fat Quantification

90 sites in 14 countries · DXA, abdominal MRI, MRI-PDFF · Lean mass, visceral fat and liver fat

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. Weight loss alone no longer satisfies regulators, payers or clinicians evaluating an incretin-based obesity therapy. The sponsor of this Phase III program needed to demonstrate not merely how much weight participants lost but what that weight consisted of: whether fat mass declined while lean mass was preserved, and whether visceral adipose tissue and liver fat, the depots most closely tied to cardiometabolic risk, changed in parallel. Those questions placed dual-energy X-ray absorptiometry and quantitative MRI at the center of the trial's key secondary endpoints.

The difficulty was comparability. Ninety sites in 14 countries operated DXA systems from two manufacturers, each with its own calibration, software version and analysis conventions, and body-composition results from different systems are not interchangeable without correction. In a population with high body mass, scan-table weight limits, truncated fields of view and positioning errors threatened to render a meaningful share of examinations unevaluable. The MRI sub-study introduced a further layer of variability: visceral fat segmentation and proton density fat fraction measurements were to be acquired on scanners from three vendors, and the sponsor required a single, defensible measurement chain from acquisition to database.

Intrinsic Imaging's Solution

Intrinsic Imaging began with a site-qualification program designed specifically for body-composition imaging. Every site submitted phantom scans and a test-subject acquisition before activation, and we built a cross-calibration model for the two DXA manufacturers from a phantom series circulated to every system in the study. The acquisition manual specified positioning for high-BMI participants, including half-body acquisition with mirroring where table width was exceeded, so that lean and fat mass estimates remained consistent across visits.

All DXA analyses were performed centrally by trained analysts using one software platform and standardized regions of interest, with each participant's follow-up scans analyzed by the same analyst against baseline to minimize longitudinal drift. For the MRI sub-study, we issued vendor-specific protocols for the abdominal fat and PDFF sequences, qualified each scanner with a fat-fraction phantom and performed visceral and subcutaneous adipose tissue segmentation centrally under physician oversight.

Quality control reviewed every incoming examination within two business days, so that sites could repeat a scan within the protocol window rather than lose the timepoint. Body-composition and MRI results were delivered to the sponsor on an agreed monthly transfer schedule, formatted to join directly with the weight and laboratory data in the sponsor's clinical database, so that the compositional endpoints could be analyzed alongside the primary weight outcome without further reconciliation.

Intrinsic Imaging’s Results

- 97.2% of DXA examinations evaluable at first submission, with repeat acquisition recovering most of the remainder within the visit window despite high-BMI positioning constraints
- Below 1.5% inter-manufacturer bias in fat mass after phantom-based cross-calibration, permitting pooled body-composition analysis across all 90 sites in 14 countries
- Three weeks from the last participant's final visit to delivery of the visceral adipose tissue and MRI-PDFF datasets, supporting the sponsor's topline timeline
- Two DXA platforms and three MRI vendors reconciled into a single measurement chain, delivered in a format that joined directly with weight and laboratory data

Read the full study online: https://intrinsicimaging.com/case-studies/metabolic-obesity

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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