CASE STUDY · GASTROENTEROLOGY

NASH Trial With MRI-PDFF and Liver Stiffness

50 sites · MRI-PDFF, MR elastography · Liver fat and stiffness

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. Quantitative liver imaging biomarkers are only as reliable as the scanners that produce them. In this NASH program, vendor differences in MRI-PDFF and MR elastography implementation threatened the comparability of liver fat fraction and stiffness measurements across 50 sites. Because these quantitative endpoints would inform Phase IIb dose selection, even modest cross-vendor bias could influence the interpretation of biomarker differences relevant to subsequent development.

Site experience with quantitative liver MRI also varied. Accurate PDFF measurement requires appropriate sequence selection and parameter settings, while MR elastography depends on correct driver placement, wave propagation and image quality. Without consistent acquisition and analysis, measurements could reflect technical differences rather than true change in liver fat or stiffness. The sponsor required cross-vendor scanner qualification, submission-level acquisition verification and uniform quantitative analysis, controlling the complete acquisition-to-measurement process rather than standardizing reported values alone, with each measurement documented from source data through quality review and any qualification or exclusion arising from technical limitation. Fat fraction and stiffness describe different tissue properties, and changes in these measures need not coincide. Preserving separate analysis definitions avoids interpreting a technically reproducible biomarker difference as evidence of clinical benefit without the broader trial context.

Intrinsic Imaging's Solution

Intrinsic Imaging implemented phantom-based scanner qualification to characterize and calibrate each platform before enrollment. Our team provided vendor-specific acquisition guidance and trained site staff before activation, then verified sequence parameters on every submission at the point of receipt. Each submission was reviewed for sequence compliance, technical quality and analysis readiness, and sites received prompt feedback when corrections were needed.

Central quantitative review of liver fat fraction and stiffness was performed under uniform analysis protocols, with vendor-specific considerations documented and controlled. Central analysts followed standardized procedures for region-of-interest placement, quality assessment and measurement reporting, and ongoing quality monitoring identified emerging site or vendor issues early, preserving comparability across the program as enrollment expanded.

Measurements with technical limitations were reviewed under defined criteria to determine whether they could be reported reliably. Where results were excluded or qualified, the rationale was documented consistently, giving the sponsor a transparent understanding of data completeness and quality at each timepoint and site. Quantitative liver imaging was treated throughout as an integrated measurement process encompassing scanner qualification, acquisition control, standardized analysis and continuous monitoring, producing a harmonized dataset in which measurements could be compared meaningfully across sites, scanners and timepoints, and a methodology suited to the larger site networks of later-phase development.

Intrinsic Imaging’s Results

- 96%+ evaluable scan rate across 50 sites, achieved through phantom-based scanner qualification and verification of sequence parameters on every submission at receipt
- Consistent PDFF and stiffness values across scanner vendors, with vendor-specific considerations documented and controlled within uniform central quantitative analysis protocols
- Reliable quantitative liver fat fraction and stiffness data delivered as the harmonized basis for the sponsor's Phase IIb dose-selection decision in its NASH program
- Documented rationale for every qualified or excluded measurement, giving the sponsor a transparent view of data completeness and quality by timepoint, site and scanner vendor

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Read the full study online: https://intrinsicimaging.com/case-studies/gastroenterology-liver

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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