CASE STUDY · GASTROENTEROLOGY & METABOLIC

Three-Year International Phase II Trial in Chronic Iron Overload

Sites in Asia, Europe, North America and the Middle East · Liver and cardiac T2* MRI · Liver iron concentration and myocardial T2*

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. A three-year international Phase II trial evaluated a new therapy for chronic iron overload using MRI measurement of liver and myocardial iron. T2* relaxometry is quantitative but vendor- and sequence-dependent, and the participating sites spanned Asia, Europe, North America and the Middle East with a wide range of scanner platforms and relaxometry experience.

The sponsor needed liver iron concentration and myocardial T2* measured consistently enough to detect treatment-related change over three years, with calibration across platforms, stable analysis conventions and a quality process that kept sites compliant with a demanding protocol. The quantitative appearance of a relaxometry result can obscure its dependence on acquisition and fitting choices. Liver and myocardial measurements require tissue-specific interpretation, and their trajectories need not be assumed to coincide. Across geographically dispersed sites, the scientific challenge is therefore to preserve the meaning of each measurement rather than merely produce values in a common format.

Intrinsic Imaging's Solution

Intrinsic Imaging developed image acquisition guidelines for multi-echo gradient echo T2* sequences on each vendor platform, qualified every site with phantom and volunteer acquisitions, and trained site technologists on breath-hold technique, echo spacing and slice positioning for the liver and interventricular septum. Echo spacing and breath-hold execution affect the information available for characterizing signal decay, while consistent slice positioning supports comparison of the intended tissue region. Phantom acquisitions address technical implementation, and volunteer acquisitions place the protocol in a practical scanning context. Together, these qualification elements examine complementary aspects of readiness without establishing that subsequent patient examinations will be uniformly evaluable.

Radiologists with experience in iron quantification analyzed liver and myocardial T2* under a reading charter fixing region-of-interest placement, curve-fitting method and the conversion to liver iron concentration. Each patient was followed by the same analyst where possible, with a second analyst on a prespecified sample for reproducibility. Prespecified region placement and curve fitting limit discretionary analytical choices that could otherwise create apparent longitudinal change. The conversion to liver iron concentration introduces an additional interpretive step beyond the measured relaxation behavior and therefore benefits from a fixed convention. Analyst continuity reduces reader switching, while the sampled independent analysis characterizes reproducibility rather than providing an external validation of tissue iron content.

Images were processed and quality-controlled centrally, with sequence parameter deviations identified at receipt and returned to sites for correction within protocol windows. Early identification of sequence deviations matters because quantitative analysis cannot necessarily compensate for acquisition outside the intended specification. Correction within the permitted windows supports consistency of the longitudinal record while retaining the protocol's timing requirements. A low proportion of unevaluable visits indicates usable imaging availability, but it does not establish that missing measurements are unrelated to disease severity or that observed changes demonstrate clinical benefit.

Intrinsic Imaging’s Results

- T2* relaxometry standardized across 26 sites on four continents with vendor-specific sequence guidance and phantom qualification
- Approximately 900 liver and cardiac examinations quantified over three years under fixed analysis conventions
- Analyst reproducibility of liver iron concentration within 5% documented on a double-analysis sample
- Sequence parameter deviations caught at central quality control and corrected, with fewer than 3% of visits unevaluable

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Read the full study online: https://intrinsicimaging.com/case-studies/metabolic-iron-overload-three-year

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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