CASE STUDY · GASTROENTEROLOGY & METABOLIC

Five-Year International Phase II Iron Overload Trial With 4,500 MRI Scans

4,500+ MRI scans over five years · 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 large five-year international Phase II trial of a new therapy for chronic iron overload in transfusion-dependent and hereditary populations involved more than 4,500 MRI examinations for liver and cardiac iron quantification. Over five years, scanner upgrades, software changes and staff turnover at sites threaten the stability of quantitative T2* measurement, and drift of even a few percent would be comparable to the treatment effect being measured.

The sponsor needed a core lab able to hold acquisition and analysis constant across a long duration, manage a large and continuous read volume, and provide expert radiologist consultation on protocol questions as the trial evolved. A long observation period makes technical continuity part of the endpoint's scientific validity, not simply an operational concern. Liver and myocardial measurements also represent different tissue compartments and should retain their separate interpretations. Apparent improvement or deterioration requires particular caution when a scanner change coincides with a patient's imaging trajectory, because technical and biological explanations may overlap.

Intrinsic Imaging's Solution

Intrinsic Imaging provided expert radiologist consultation during protocol and charter development, specifying multi-echo T2* acquisition for liver and heart on each vendor platform and establishing a phantom-based qualification and requalification program to detect scanner changes over the trial's duration. Platform-specific acquisition specifications define how the intended quantitative measurement is implemented across different scanners. Phantom-based qualification supplies a reference for technical consistency that is separate from changes in patient biology. Its role is to identify potential acquisition instability; satisfactory phantom behavior does not by itself establish that every patient examination is free from motion or other measurement limitations.

Gastrointestinal and cardiovascular radiologists experienced in liver and cardiac MRI analyzed T2* under a fixed reading charter, with longitudinal analyst assignment, a standing reproducibility sample and periodic recalibration. Quality control at receipt verified sequence parameters against the charter on every examination. Fixed analysis conventions reduce the opportunity for changing interpretation rules to imitate a longitudinal treatment signal. Maintaining analyst continuity addresses reader-related variability, while reproducibility sampling and recalibration examine consistency over the extended reading period. Receipt-level parameter checks complement these analytical controls by evaluating whether the incoming acquisition matches the conditions under which the quantitative interpretation was defined.

Project management tracked more than 4,500 scheduled examinations against protocol windows across five years, requalifying sites after scanner upgrades and maintaining the analysis conventions without change through database lock. Tracking examinations against scheduled windows preserves the temporal context needed to interpret serial iron measurements. Requalification after equipment changes addresses identifiable technical transitions, whereas unchanged analysis conventions maintain continuity in the interpretation of the acquired data. The resulting measurement stability supports longitudinal comparison, but neither reproducibility nor a low unevaluable rate independently demonstrates treatment efficacy or equivalence between hepatic and myocardial responses.

Intrinsic Imaging’s Results

- More than 4,500 liver and cardiac MRI examinations quantified over five years under unchanged analysis conventions
- Phantom-based requalification performed after each of 19 scanner upgrades or software changes at participating sites
- Longitudinal analyst reproducibility maintained within 5% for liver iron concentration across annual reproducibility samples
- Fewer than 3% of scheduled examinations unevaluable across 34 sites in 12 countries

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