

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

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.

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.

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.

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.

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

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 750 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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