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

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.

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.

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.

Images were processed and quality-controlled centrally, with sequence parameter deviations identified at receipt and returned to sites for correction within protocol windows.

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

---

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 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 andOphthalmology. 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.

Contact:
Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com