

CASE STUDY · CARDIOVASCULAR & THORACIC

International Phase II Cardiac Safety Trial With Cardiac MRI

30 sites in 7 countries · Cardiac MRI · LVEF, LV volumes and mass

Challenge

An international Phase II trial required cardiac MRI to assess the cardiac safety and tolerability of a novel drug. The endpoint depended on detecting small changes in left ventricular ejection fraction, volumes and mass over the treatment period, measurements that vary with scanner vendor, sequence parameters, slice planning and contouring convention.

Across 30 sites with differing cardiac MRI experience, the sponsor needed acquisition standardized enough to make serial measurements comparable, contouring consistent enough that a change of a few percentage points in ejection fraction would be meaningful, and reporting fast enough to feed the trial's safety monitoring.

Intrinsic Imaging's Solution

Intrinsic Imaging's cardiovascular team designed the imaging charter around a standardized cine cardiac MRI protocol with defined short-axis coverage, slice thickness, temporal resolution and breath-hold technique, and provided site-specific guidance for each vendor platform. Sites were qualified on test acquisitions reviewed for slice planning and image quality.

Cardiologists and radiologists with cardiac MRI expertise performed quantitative analysis under a reading charter that fixed contouring conventions for endocardial and epicardial borders, papillary muscle handling and phase selection. Each patient was followed by the same primary analyst, with a second analyst on a prespecified sample to document reproducibility, and qualitative review captured pericardial, valvular and myocardial findings.

Image transfer and quality control were centralized with acquisition feedback to sites, and safety-relevant changes in ventricular function were reported to the sponsor on a defined schedule.

Intrinsic Imaging's Results

- Cardiac MRI standardized across 30 sites in 7 countries with vendor-specific acquisition guidance
- Approximately 620 examinations quantified for LVEF, volumes and mass under fixed contouring conventions
- Inter-analyst reproducibility of LVEF within 3 percentage points documented on a 15% double-analysis sample
- Unevaluable examinations held under 4% through site qualification and rapid acquisition feedback

Read the full study online: <https://intrinsicimaging.com/case-studies/cardiology-cardiac-mri-safety>

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.

Contact:

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