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

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. 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. The central interpretive problem is separating plausible treatment-period change from variation introduced by acquisition or analysis. Ventricular function, volume and mass describe related but distinct characteristics, so consistency in an individual measurement does not guarantee consistency across the full assessment. A safety interpretation must also distinguish a temporally observed imaging change from evidence that the investigational treatment caused it.

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. Defined ventricular coverage and temporal sampling support comparable representation of the cardiac cycle across examinations. Vendor-specific guidance translates the common protocol into practical acquisition requirements without assuming that scanner implementations are identical. Qualification review is particularly relevant to serial analysis because differences in slice planning can alter the anatomy included in subsequent volume and mass measurements.

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. Fixed border and papillary muscle conventions constrain analytical choices that can otherwise shift ventricular measurements independently of physiology. Longitudinal analyst assignment limits reader switching as a source of variability, while the reproducibility sample provides a separate view of analytical consistency. Qualitative findings add anatomical context but should not be interpreted as substitutes for the prespecified quantitative safety measures.

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. Acquisition feedback addresses technical deviations near the point of collection, when their implications for evaluability can be assessed. Scheduled communication supports the trial's monitoring process, but the reported reproducibility describes measurement behavior under the study framework rather than a universal threshold for clinically important cardiac change.

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

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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 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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