CASE STUDY · CARDIOVASCULAR & THORACIC

Cardiovascular Clinical Trial With 1,500 Multimodality Reviews

1,500 radiological reviews · Echocardiography, cardiac MRI, CT · Safety and effectiveness endpoints

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 cardiovascular clinical trial required 1,500 central reviews to evaluate the clinical safety and effectiveness of a new product. Cardiovascular endpoints span modalities, and the trial collected echocardiography, cardiac MRI and CT at different timepoints, each with its own acquisition variability and measurement conventions for cardiac function and structure.

The sponsor needed a single core lab able to manage all three modalities with consistent conventions, so that ejection fraction and chamber dimensions measured on echocardiography could be interpreted alongside cardiac MRI and CT findings, and a review process whose documentation would support both the safety and effectiveness analyses. These modalities characterize related aspects of cardiovascular anatomy and physiology, but their measurements are not inherently interchangeable. Differences in temporal sampling, imaging planes and boundary definition can create apparent discrepancies without corresponding biological change. Interpretation therefore depends on preserving modality-specific meaning while establishing a coherent framework for evaluating findings across the longitudinal record.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with acquisition standards for each modality, including echocardiographic view and Doppler requirements, cine cardiac MRI parameters and gated CT protocols, and qualified sites on test submissions for each modality in use. Acquisition requirements address the sources of variability before interpretation begins, when missing views or inadequate cardiac coverage may still be preventable. Test submissions provide a practical basis for assessing whether a site can implement the intended protocol. Their relevance is specific to acquisition quality and does not imply that all residual differences between imaging techniques have been eliminated.

Cardiovascular-trained radiologists and cardiologists reviewed examinations under modality-specific reading charters with harmonized measurement conventions, so that functional measurements were comparable across modalities within the limits of each technique. Primary effectiveness measurements were double-read with adjudication, and safety findings were captured under predefined definitions. Harmonized conventions make explicit how readers identify structures and derive measurements, reducing ambiguity when results are considered together. Adjudication provides a defined resolution pathway for discrepant effectiveness assessments rather than allowing informal reconciliation. Agreement remains a measure of consistency within the reading framework, not an independent demonstration that measurements are accurate against an external biological standard.

Image transfer, quality control and processing were managed from the San Antonio office, with modality-specific quality checks at receipt and consolidated reporting of safety findings to the sponsor. Modality-specific checks are important because an examination suitable for anatomical review may still be insufficient for a particular functional measurement. Consolidated safety reporting places observations from different techniques into a common reporting process, while interpretation must still distinguish imaging findings from conclusions about clinical causality. The imaging evidence contributes to safety assessment without independently establishing whether an observed abnormality is attributable to treatment.

Intrinsic Imaging’s Results

- 1,500 multimodality cardiovascular reviews completed across echocardiography, cardiac MRI and CT under harmonized measurement conventions
- Modality-specific acquisition standards adopted at 22 sites with unevaluable examinations under 5%
- Primary effectiveness measurements double-read with reader agreement above 90% and adjudication documented
- Consolidated imaging safety reporting delivered to the sponsor on a defined schedule throughout follow-up

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Read the full study online: https://intrinsicimaging.com/case-studies/cardiology-cardiovascular-1500-reviews

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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