CASE STUDY · CARDIOVASCULAR

Heart Failure Trial Echocardiography Core Lab

75 sites · Transthoracic echocardiography · LVEF, GLS and LV volumes

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. In heart failure trials, ejection fraction and myocardial strain measurements frequently determine both eligibility and efficacy, yet echocardiography is among the most operator-dependent of imaging modalities. Across 75 sites, differences in acquisition quality and measurement technique placed the LVEF, global longitudinal strain and ventricular volume endpoints at risk. The sponsor required central assessment capable of delivering consistent, reproducible quantification from imaging acquired under real-world site conditions.

Echocardiographic variability can arise at every step: probe positioning, image depth, frame rate, endocardial visibility and the selection of cardiac cycles for measurement. Strain analysis adds further sensitivity to image quality and software methodology. Because the same measurements informed eligibility and efficacy, consistency was necessary from screening through follow-up. The sponsor required coordinated sonographer training and certification, a controlled central measurement charter and ongoing oversight of acquisition quality, with traceability to the selected views and cardiac cycles so that apparent changes in function could be examined, technical limitations identified and interpretable measurements distinguished from values that could not reliably support the study's assessments. Volume, ejection fraction and strain are related but non-interchangeable measurements. A consistent acquisition framework allows their separate contributions to eligibility and efficacy to remain explicit throughout longitudinal interpretation.

Intrinsic Imaging’s Solution

Intrinsic Imaging developed a standardized acquisition protocol and trained and certified sonographers at every site before enrollment, establishing a uniform foundation of image quality before central review began. Each submitted study was reviewed for required views, image quality and suitability for quantitative analysis, and sites received specific feedback to improve subsequent examinations, sustaining acquisition standards throughout enrollment and follow-up.

Blinded central assessment of LVEF, global longitudinal strain and ventricular volumes was performed under a detailed measurement charter. Central readers were trained and calibrated on the charter, including definitions for ventricular volumes, ejection fraction and strain. Reader performance was monitored throughout the study, and quality trends were reviewed regularly so that emerging issues could be addressed promptly rather than discovered at analysis.

Studies with limited image quality were reviewed carefully to determine whether reliable measurements could still be obtained. Readers documented technical limitations consistently, and measurements were excluded only when required by the charter, ensuring transparent and uniform handling of suboptimal examinations. The upstream investment in sonographer training yielded compounding benefit: sites gained clear standards and specific feedback, improving the quality of subsequent examinations and reducing the need for queries or repeat imaging, to the advantage of both the endpoint data and the patients participating across a large, geographically diverse program.

Intrinsic Imaging’s Results

- 4,100+ echocardiographic studies assessed centrally under a single blinded measurement charter, spanning screening through follow-up across all 75 participating sites
- LVEF reader variability below 5%, achieved through sonographer certification, structured reader calibration and continuous monitoring of reader performance throughout the study
- Endpoint data delivered on time for the primary analysis, with technical limitations documented consistently for every suboptimal examination and exclusions applied only where the charter required
- Fewer queries and repeat examinations as site acquisition quality improved, benefiting both the endpoint dataset and the heart failure patients participating in the trial

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Read the full study online: https://intrinsicimaging.com/case-studies/cardiology-heart-failure

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 650 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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