CASE STUDY · CARDIOVASCULAR

Global Cardiovascular Trial With CCTA and MRI

60 sites · CCTA, cardiac MRI · Plaque, stenosis and LVEF

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. This global cardiovascular outcomes trial required reproducible quantification of coronary plaque burden, stenosis grade and left ventricular ejection fraction across 60 sites operating a heterogeneous mix of scanner models. Each measurement contributed to endpoint assessment, and even modest inter-reader or inter-site variability could obscure a treatment effect. The sponsor required acquisition and interpretation methods that preserved comparability across sites and platforms, with technical limitations identified and documented throughout.

The trial's scale and duration added a second order of difficulty. Imaging would be acquired over an extended period during which staff turnover, protocol interpretation and equipment changes could gradually erode consistency. Coronary CT angiography in particular depends on heart-rate control, contrast timing and reconstruction choices, and small deviations can render plaque or stenosis assessment unreliable. The sponsor needed a system that would sustain quality across thousands of patients, not merely at study startup, and a measurement framework that limited both technical and interpretive drift. Plaque burden, stenosis and ventricular function describe distinct cardiovascular properties; agreement within each measurement domain is therefore more informative than assuming that consistency in a single variable demonstrates consistency throughout the imaging endpoint framework.

Intrinsic Imaging's Solution

Intrinsic Imaging established acquisition guidelines tailored to each scanner platform and worked with every site to align its practice, providing training before activation and refresher guidance whenever quality trends indicated drift. A dedicated quality control gateway assessed each submission against defined acceptance criteria and intercepted unusable or non-conformant scans before they reached central review, returning specific, actionable feedback rather than general requests for repeat imaging.

Central readers followed a detailed charter defining plaque quantification, stenosis grading and ventricular function measurement. Structured training preceded reading, and calibration exercises were repeated throughout the trial so that measurement remained uniform from the first patient enrolled to the last. Reader performance was monitored continuously to identify emerging variability and guide corrective action before it could affect endpoint data.

Site performance metrics, including first-pass acceptance rates and the most common reasons for non-conformance, were reviewed regularly with the sponsor. These reviews directed targeted retraining where it would have the greatest effect, without imposing additional burden on sites already performing well, and gave the sponsor's clinical team a clear view of imaging status throughout enrollment and follow-up. Equipment and software changes at sites were tracked so that requalification could be required where a change threatened comparability.

Intrinsic Imaging’s Results

- 99.1% evaluable scan rate across more than 3,400 patients, achieved by intercepting non-conformant acquisitions at the quality control gateway before they reached central review
- Inter-reader variability held below 4% for plaque burden, stenosis grade and ejection fraction measurements throughout the full course of enrollment and follow-up
- 60 sites operating heterogeneous scanner platforms produced coronary plaque, stenosis and ventricular measurements comparable enough to support pooled endpoint analysis in the outcomes trial
- Continuous reader calibration and transparent site-performance reporting allowed the sponsor to address emerging quality issues before they could affect trial timelines

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

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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