

Global Cardiovascular Trial With CCTA and MRI

60 sites

CCTA, cardiac MRI

Plaque, stenosis and LVEF

Challenge

This global cardiovascular outcomes trial required reproducible quantification of coronary plaque burden, stenosis grading, and left ventricular ejection fraction across 60 sites operating a heterogeneous mix of scanner models. Each measurement carried endpoint-level significance, and even modest inter-reader or inter-site variability risked obscuring treatment effects. The sponsor needed assurance that a scan acquired at any site, on any supported scanner, would yield measurements directly comparable to those from every other site in the program.

Our Solution

Intrinsic Imaging established standardized acquisition guidelines tailored to each scanner platform and enforced them through a dedicated quality control gateway that intercepted unusable or non-conformant scans before they reached central review, with prompt feedback enabling sites to correct deficiencies. Central readers underwent structured training and continuous calibration throughout the trial, so that plaque quantification, stenosis grading, and ejection fraction measurement remained uniform from the first patient enrolled to the last.

Results

- 99.1% evaluable scan rate across 3400+ patients
- Inter-reader variability maintained below 4%
- Ongoing reader calibration throughout the trial

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

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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.

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