

Rescuing a Stalled Peripheral Vascular Trial

35 sites

Duplex ultrasound, angiography

Patency and restenosis

Challenge

A peripheral vascular medical device trial had stalled under the weight of poor-quality imaging. Substandard duplex ultrasound submissions and incomplete angiographic series had rendered nearly a quarter of follow-up timepoints unevaluable, placing the longitudinal patency and restenosis dataset—and with it the trial's 12-month endpoint—in genuine jeopardy. Recovering the program required not merely better review, but a fundamental correction of acquisition practices at the sites themselves.

Our Solution

Intrinsic Imaging revised the acquisition guidance for both duplex ultrasound and angiography and delivered targeted retraining to every participating site, addressing the specific deficiencies observed in prior submissions. Quality checks performed at the moment of submission, coupled with same-week feedback to sites, created a rapid correction loop that allowed acquisition problems to be identified and remedied while patients remained in follow-up. Central review of patency and restenosis then proceeded on a steadily improving foundation of evaluable imaging.

Results

- Unevaluable timepoints reduced from 23% to below 5%
- Follow-up data recovered for the 12-month endpoint
- Core lab report delivered for the PMA submission

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

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.

Contact:

Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com