CASE STUDY · MEDICAL DEVICE

Rescuing a Stalled Peripheral Vascular Trial

35 sites · Duplex ultrasound, angiography · Patency and restenosis

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 peripheral vascular device trial encountered substantial delays attributable to inadequate imaging quality. Substandard duplex ultrasound submissions and incomplete angiographic series had rendered nearly a quarter of follow-up timepoints unevaluable across 35 sites, placing the longitudinal patency and restenosis dataset, and with it the trial's 12-month endpoint, at serious risk. Restoring endpoint evaluability required correction of site acquisition practice as much as improvement in central interpretation.

The deficiencies varied by site and modality. Some duplex examinations omitted required segments or velocity measurements, others lacked appropriate angle correction or labeling, and certain angiographic series failed to provide the projections needed to evaluate the treated segment. Because follow-up visits occurred within defined windows, inadequate imaging could not always be recovered later, and every month of delay meant further loss of endpoint data. The sponsor required a site-specific assessment of acquisition deficiencies, corrective training and timely recovery of evaluable follow-up examinations, together with documented handling of limited studies so that the imaging evidence available for the endpoint and submission could be characterized precisely. Patency and restenosis remain distinct endpoint concepts, and technically limited imaging may support some observations without supporting every planned measurement. Explicit evaluability definitions preserve those distinctions within the recovered follow-up record.

Intrinsic Imaging’s Solution

Intrinsic Imaging analyzed previous submissions to identify the recurring problems at each site, then revised the acquisition guidance for both duplex ultrasound and angiography and delivered targeted retraining addressing each center's specific gaps. The revised guidance used clear checklists and worked examples, so that sonographers and interventional teams understood exactly what a complete, evaluable examination required.

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 within their follow-up windows. Our project managers tracked site performance over time, offering additional support wherever problems persisted and keeping the sponsor informed as evaluability improved.

Central readers assessed patency and restenosis under a clarified charter with explicit definitions for evaluability, velocity criteria and angiographic findings. Where examinations were technically limited but still partially evaluable, readers documented the limitations consistently, giving the sponsor a transparent account of how each timepoint contributed to the endpoint analysis. Sites that had struggled with acquisition gained clear standards and practical feedback, reducing the need for repeat imaging, easing the burden on participants and site staff, and improving the consistency of submissions for the remainder of the trial.

Intrinsic Imaging’s Results

- 23% to below 5%: the reduction in unevaluable follow-up timepoints after targeted site retraining and same-week feedback on every duplex ultrasound and angiographic submission
- 12-month endpoint data recovered through evaluable duplex ultrasound and angiographic imaging of patency and restenosis obtained while patients remained within their protocol-defined follow-up windows
- Core laboratory report delivered for the PMA submission, with technical limitations documented consistently for every partially evaluable examination contributing to the endpoint
- 35 sites brought to a common acquisition standard, reducing repeat examinations for participants and sustaining evaluability through the remainder of the trial

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

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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