CASE STUDY · MEDICAL DEVICE

International Phase II Study of a Novel Vascular Device

International Phase II device study · Angiography, duplex ultrasound, CT angiography · Patency and device integrity

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. An international Phase II study evaluated a novel vascular medical device, with imaging endpoints covering deployment success, patency and device integrity over follow-up. Sites across several countries used different combinations of procedural angiography, duplex ultrasound and CT angiography, and duplex technique in particular varies widely between vascular laboratories.

The sponsor needed interventional radiologists experienced with the device class to define reproducible endpoints, standardize acquisition across countries, and assess every device image consistently so that Phase II results would support the design of a pivotal trial. For an exploratory device study, the usefulness of an endpoint depends partly on whether its meaning remains stable across participating vascular laboratories. A deployment assessment, a patency classification and an integrity finding answer different questions. Variation in acquisition can obscure those distinctions, making it difficult to determine whether an observed difference reflects device behavior or the way that behavior was measured.

Intrinsic Imaging’s Solution

Intrinsic Imaging's interventional radiology-led device team developed the imaging charter with acquisition requirements for each modality, including a standardized duplex protocol with defined velocity criteria, and endpoint definitions for deployment success, patency and device integrity. Sites were qualified and trained in each country. The standardized duplex criteria provide an explicit connection between the acquired flow information and the endpoint assigned from it. Defining the other modalities within the same charter creates a shared interpretive framework without assuming that anatomical and hemodynamic measurements are interchangeable. Qualification and training address the acquisition conditions under which those endpoint definitions can be applied meaningfully across participating countries.

Full-time, fellowship-trained interventional radiologists performed blinded reads of all device images against each patient's post-deployment baseline, with double reads on primary endpoints and adjudication of discordant findings. The post-deployment baseline establishes the reference appearance for subsequent assessment of the implanted device. Comparison with that baseline is conceptually different from judging whether deployment itself met the specified success criteria. Independent primary endpoint reads and adjudication address interpretive consistency, while leaving the underlying limitations of image quality and modality-specific visibility relevant to each individual assessment.

Image transfer, quality control and processing were centralized, with inadequate duplex studies returned for re-acquisition, and the dataset was delivered with modality identified for every measurement to inform pivotal trial design. Returning inadequate duplex examinations addresses deficiencies in the evidence before measurements enter the endpoint dataset. Retaining modality identity makes the provenance of those measurements visible when considering later trial design. The resulting definitions and acquisition standards can inform that design, but their transfer does not by itself establish performance in a larger population or resolve uncertainty about longer-term device behavior.

Intrinsic Imaging’s Results

- Approximately 150 patients at 14 sites in 6 countries assessed across angiography, duplex ultrasound and CT angiography
- Standardized duplex protocol with defined velocity criteria adopted at all sites, with inadequate studies reduced to under 6% after training
- Primary endpoint double reads with reader agreement above 90% and documented adjudication
- Endpoint definitions and acquisition standards carried forward by the sponsor into pivotal trial design

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Read the full study online: https://intrinsicimaging.com/case-studies/device-vascular-phase-ii-2014

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 50 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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