CASE STUDY · MEDICAL DEVICE

Interventional Device Trial for Prevention of Pulmonary Emboli

Vena cava filter class device · CT venography, fluoroscopy, radiographs · Device position, integrity and caval patency

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 trial of a novel interventional device for the prevention of pulmonary emboli required imaging assessment of device placement, migration, tilt, fracture, caval penetration and thrombus over an extended follow-up. These safety endpoints rely on precise comparison of serial imaging against the immediate post-deployment baseline, and the sponsor's sites used a mix of fluoroscopy, radiographs and CT venography.

Regulators scrutinize filter-class devices closely, so the sponsor needed each adverse imaging finding classified under predefined definitions, measured consistently across readers, and documented so that device-related events could be distinguished from procedural or anatomical variation. The safety interpretation depends on distinguishing a change in device configuration from a difference in how that configuration is depicted. Position, component integrity and caval findings represent distinct observation domains, even when they occur together. Their classification also requires care because detecting an imaging abnormality does not, by itself, establish its clinical consequences or its relationship to a subsequent event.

Intrinsic Imaging’s Solution

Intrinsic Imaging developed the imaging charter with explicit definitions for migration, tilt, fracture, penetration and caval thrombus, each with measurement methods and thresholds, and with acquisition requirements for each modality. Sites were qualified and trained on acquiring reproducible post-deployment baseline imaging. Explicit measurement methods make the boundary between an observed variation and a reportable finding inspectable. Reproducible baseline acquisition is particularly important because later assessments depend on that reference rather than on an idealized device appearance. Modality-specific requirements acknowledge that the same implant can be represented differently on projection images and cross-sectional examinations of the surrounding anatomy.

Interventional radiologists performed blinded reads of each follow-up examination against the patient's baseline, recording device position relative to anatomical landmarks, component integrity and caval patency. A second reader reviewed every examination with a reported adverse finding, and discordant classifications were adjudicated. Anatomical landmarks provide a reference for positional comparison, while component assessment and patency review address other dimensions of device safety. Reviewing every reported adverse finding adds scrutiny to classifications with potential safety significance. Adjudication documents the interpretation of the available evidence, but cannot eliminate uncertainty where overlapping structures or limited visualization constrain the underlying assessment.

Quality control and processing were centralized so that baseline and follow-up images were paired before reading, and adverse imaging findings were reported to the sponsor on a defined schedule to support safety monitoring. Pairing baseline and follow-up images before reading preserves the temporal comparison needed for these endpoints. Scheduled reporting makes the imaging classifications available to the safety monitoring process, rather than treating the final dataset as the only relevant output. Such reports contribute imaging evidence to clinical evaluation; they should not be interpreted as independently establishing causality or the absence of complications beyond the imaged anatomy.

Intrinsic Imaging’s Results

- Serial imaging for approximately 240 patients at 18 sites assessed against charter-defined adverse finding definitions
- Every reported adverse device finding double-read and adjudicated, with measurement method and threshold documented in the read record
- Baseline-to-follow-up pairing completed centrally for 100% of evaluable timepoints before reader access
- Scheduled imaging safety reports delivered to the sponsor's data safety monitoring process throughout follow-up

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

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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