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

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.

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.

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.

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.

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 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 andOphthalmology. 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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