CASE STUDY · MEDICAL DEVICE

# IDE Pivotal Transcatheter Valve Trial

Structural heart · CT, fluoroscopy, echocardiography · Pre- and post-implant assessment

## 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 pivotal IDE trial of a transcatheter valve replacement system required standardized imaging for anatomical assessment before implantation and longitudinal evaluation of device performance afterward. Precise annular and access-route sizing was essential to device selection and patient safety, while consistent core laboratory review of post-implant imaging over extended follow-up was needed to document positioning, function and durability. Measurements taken at different timepoints and by different readers had to remain directly comparable, and every assessment had to satisfy the evidentiary standard of a PMA submission.

Three modalities, each with its own acquisition demands, complicated the task. CT required appropriate contrast timing and coverage for annular assessment; fluoroscopy and echocardiography had to capture device position and function consistently at each follow-up visit. Implanting centers differed in equipment and experience, and the sponsor needed a core laboratory capable of bringing every site to a common standard without slowing enrollment, with traceability to source images and individual readers across the complete follow-up record. Anatomical sizing before implantation and functional assessment afterward have different evidentiary purposes. Their integration depends on preserving the measurement definitions specific to each modality and stage of follow-up.

## Intrinsic Imaging's Solution

Intrinsic Imaging assembled a dedicated team of cardiovascular radiologists and imaging engineers and developed modality-specific acquisition guidelines emphasizing the elements most critical to accurate sizing and reproducible follow-up assessment. Each implanting center was trained before enrollment, and quality control identified incomplete or suboptimal examinations before they could affect the dataset, with our project team supporting repeat acquisition where needed.

Pre-procedural CT studies were analyzed using three-dimensional multiplanar reconstruction with calibrated measurement methods, yielding reproducible anatomical sizing for every implant candidate and returned promptly so that sizing information could inform procedural planning in accordance with the protocol. Post-implant assessments followed the same calibrated methodology at every follow-up timepoint, so that longitudinal comparisons rested on a consistent measurement foundation.

Readers were trained and calibrated on the measurement charter before reading began, using reference cases to align on landmark identification, sizing conventions and post-implant assessment criteria. Periodic reviews of reader agreement confirmed that measurements remained consistent as enrollment expanded and follow-up accumulated, and the complete imaging record was maintained for the analyses the PMA submission would require. Throughout, our project team reported site compliance and reader agreement to the sponsor at regular intervals, so that any erosion in acquisition quality or measurement consistency could be addressed before it reached the longitudinal dataset.

## Intrinsic Imaging’s Results

- 100% technical protocol compliance across all implanting sites, sustained from pre-procedural CT sizing through fluoroscopy and echocardiography at every post-implant follow-up visit
- Core laboratory assessments accepted by FDA reviewers without any request for re-analysis or supplementary measurement of the pre-procedural or post-implant imaging
- Calibrated three-dimensional sizing and longitudinal post-implant measurements formed part of the clinical evidence presented in the PMA submission for the transcatheter valve replacement system
- Defined imaging methodology retained by the sponsor for post-approval studies and subsequent device iterations, preserving continuity of evidence well beyond the pivotal trial

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