CASE STUDY · MEDICAL DEVICE

International Phase III Orthopedic Device Trial With 7,000 Imaging Examinations

400+ patients, ~7,000 examinations · CT, MRI, radiographs · Quantitative and qualitative orthopedic 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. An international Phase III trial of a novel orthopedic device enrolled more than 400 patients and generated approximately 7,000 CT, MRI and radiographic examinations for the assessment of device safety and effectiveness. Orthopedic device endpoints combine quantitative measurements such as alignment, migration and implant position with qualitative assessments of bone response, loosening and adjacent-segment change, each requiring consistent technique across modalities and timepoints.

The sponsor needed a core lab able to manage a large multimodal volume, apply measurement conventions reproducibly across readers over the trial's duration, and manage metal artifact that degrades CT and MRI around implants. A change in apparent implant position may reflect acquisition geometry as well as a true mechanical change, while periprosthetic abnormalities can be obscured or mimicked by artifact. Longitudinal interpretation therefore requires attention to both measurement comparability and tissue visibility. Quantitative stability and the absence of a particular qualitative finding are not interchangeable measures of device performance.

Intrinsic Imaging's Solution

Intrinsic Imaging developed the imaging charter with standardized radiographic positioning, CT metal artifact reduction parameters and MRI sequences suited to periprosthetic assessment, and qualified sites on test acquisitions. Image acquisition, transfer and quality control were centralized with acquisition feedback to sites. Standardized radiographic positioning addresses the dependence of projected measurements on patient orientation. Artifact-focused CT parameters and appropriate MRI sequences address visibility around the implant, but cannot be assumed to restore all obscured anatomy. Test acquisitions provide a basis for assessing whether site technique supports the intended measurements before serial examinations are interpreted within the trial.

Musculoskeletal radiologists performed quantitative measurements of implant position, migration and alignment and qualitative assessment of radiolucency, osteolysis, heterotopic ossification and adjacent-segment change under a reading charter with fixed landmarks and measurement methods. Primary endpoint assessments were double-read with adjudication. Fixed landmarks and measurement conventions constrain variation in how readers define implant position and alignment. Their value is greatest when a small apparent interval change could otherwise arise from inconsistent reference selection. Qualitative definitions provide a separate framework for describing bone and adjacent tissue responses. Double reading and adjudication address disagreement in primary endpoint assessment without establishing that every apparent abnormality represents clinically important device dysfunction.

Project management tracked roughly 7,000 examinations across the follow-up schedule, and reader agreement was monitored at planned intervals with recalibration as needed. Tracking examinations across follow-up supports continuity of the longitudinal imaging record, while agreement monitoring addresses consistency in applying the charter. Recalibration can reinforce shared conventions when interpretation drifts, but agreement remains distinct from measurement accuracy. The resulting observations require interpretation alongside the trial's other clinical evidence, particularly when imaging changes are subtle, artifact-limited or of uncertain symptomatic significance.

Intrinsic Imaging’s Results

- Approximately 7,000 CT, MRI and radiographic examinations from more than 400 patients processed and read across 26 sites in 9 countries
- Metal artifact reduction parameters standardized across CT and MRI, reducing unevaluable periprosthetic examinations to under 5%
- Quantitative implant measurements double-read on primary endpoints with reader agreement above 90%
- Qualitative safety findings including radiolucency, osteolysis and heterotopic ossification captured under predefined definitions at every timepoint

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Read the full study online: https://intrinsicimaging.com/case-studies/device-orthopedic-phase-iii

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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