

CASE STUDY · MUSCULOSKELETAL

Global Phase II Arthritis Trial With Quantitative Joint Imaging

Global Phase II · Hand and foot radiographs, joint MRI · Structural progression scoring

Challenge

A global Phase II trial investigated the safety and efficacy of a new pharmaceutical compound for arthritis, with imaging endpoints measuring structural progression in affected joints. Radiographic scoring of erosion and joint space narrowing and MRI assessment of synovitis, bone marrow edema and erosion are reader-intensive, semi-quantitative and sensitive to positioning and acquisition technique.

The sponsor needed consistent scoring across readers and timepoints to detect a treatment effect on slow structural change within a Phase II timeframe, and a protocol that sites with varied musculoskeletal imaging experience could execute reliably.

Intrinsic Imaging's Solution

Intrinsic Imaging's musculoskeletal team developed the imaging charter with standardized radiographic positioning for hands and feet and a joint MRI protocol specifying sequences, coverage and contrast use, and qualified sites with test acquisitions reviewed for positioning and image quality.

Fellowship-trained musculoskeletal radiologists scored radiographs for erosion and joint space narrowing and MRI for synovitis, bone marrow edema and erosion under validated semi-quantitative systems, reading each patient's complete timepoint series together with chronological order known, as the scoring methods specify. Independent double reads were performed on all patients with adjudication of score discrepancies above a predefined threshold.

Calibration sessions were held before and during the trial, reader agreement was monitored, and quality control at receipt verified positioning so that re-acquisition could occur within protocol windows.

Intrinsic Imaging's Results

- Standardized radiographic and MRI acquisition implemented at 34 sites in 10 countries with site-level positioning feedback
- Approximately 1,400 radiographic and MRI examinations scored under validated semi-quantitative systems with independent double reads
- Inter-reader reliability for total structural score documented with an intraclass correlation above 0.90
- Unevaluable examinations held under 4% through central quality control and in-window re-acquisition

Read the full study online: <https://intrinsicimaging.com/case-studies/musculoskeletal-arthritis-phase-ii>

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 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.

Contact:

Intrinsic Imaging, LLC
580 Main St., Suite 210
Bolton, MA, 01740, USA
+1 978-616-4650
Contact@IntrinsicImaging.com