

DXA and QCT in Osteoporosis Phase III

110 sites

DXA, quantitative CT

Bone mineral density endpoints

Challenge

A Phase III osteoporosis program spanning 110 sites relied on bone mineral density measurements as its primary endpoint, making scanner calibration drift a direct threat to the trial's validity. DXA systems from multiple manufacturers required continuous cross-calibration, and longitudinal measurements over 24 months had to remain comparable even as sites serviced or replaced equipment. Vertebral fracture assessment added a qualitative endpoint requiring expert central interpretation.

Our Solution

Intrinsic Imaging implemented a continuous quality assurance program built on longitudinal phantom scanning at every site, with automated drift detection that flagged calibration deviations before they could affect subject data. Cross-calibration factors were computed and applied centrally for each scanner, and any equipment change triggered immediate requalification. Central readers performed vertebral fracture assessment under standardized Genant grading, and all bone density analyses were reviewed by physicists before database entry.

Results

- Calibration drift detected and corrected at 9 sites before data impact
- Least significant change maintained below 2% across the network
- Primary endpoint dataset accepted at regulatory inspection

Read the full study online: <https://www.intrinsicimaging.com/case-studies/musculoskeletal-osteoporosis>

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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.

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