

PUBLICATIONS

C.G. Miller & D. Reid (2008) "Clinical Trials in Rheumatoid Arthritis and Osteoarthritis." London: Springer.

C.G. Miller & D. Pearson (2007) "Clinical Trials in Osteoporosis." London: Springer.

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K. Briot, S. Horlait, C. Roux, et. al. "Assessment of non-vertebral fracture risk in postmenopausal women." *Annals of the Rheumatic Diseases*. 66(7):931-5, 2007 Jul.

S. Bonnick, D. Kiel, K. Saag, et. al. "Comparison of Weekly Treatment of Postmenopausal Osteoporosis with Alendronate Versus Risedronate Over Two Years." *Journal of Clinical Endocrinology & Metabolism*. 91(7):2631-3637, July 2006.

S. Cohen, E. Lewiecki MD., M. McClung MD., et. al. "Denosumab in Postmenopausal Women with Low Bone Mineral Density." *The New England Journal of Medicine*. V. 345:821-831, February 2006

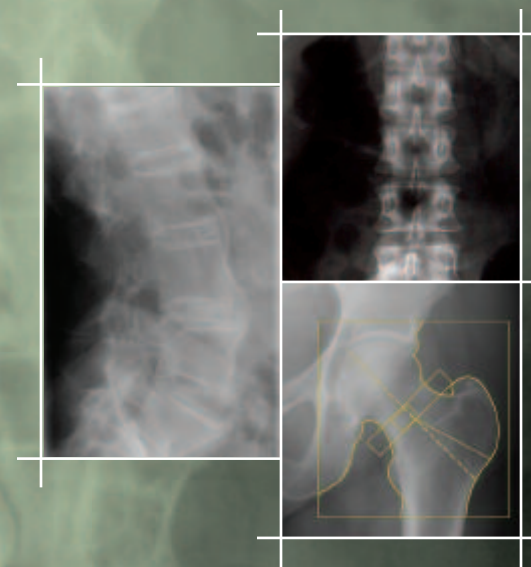
I. Mackay, C.G. Miller, DM. Reid, S. Wilkinson, et. al. "Cross-calibration of Dual Energy X-Ray Densitometers for a Large Multi-centre Genetic Study of Osteoporosis." *Osteoporosis International*. 2005

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Bona Fide Phantom (BFP)

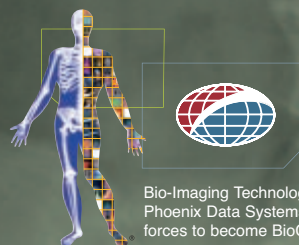
Osteoporosis Expertise



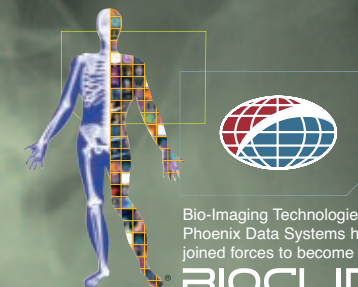
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MUSCULOSKELETAL

Osteoporosis Expertise

BioClinica has extensive experience involving the management and analysis of images for musculoskeletal clinical trials. We have completed over 200 trials in a number of specialties including:

Ankylosing Spondylitis (AS)	Osteogenesis Imperfecta
Bone Density	Osteoporosis
Bone Growth Factor	Paget's Disease
Bone Repair	Pediatric Bone Age
Fracture Studies	Psoriatic Arthritis (PsA)
Osteoarthritis	Rheumatoid Arthritis (RA)

OSTEOPOROSIS EXPERTISE

Clinical trials using Dual Energy X-Ray Absorptiometry (DXA) instruments and vertebral assessment are unique and challenging. BioClinica provides expertise in centralized image analysis in all the necessary modalities and techniques.

Our expertise supports:

- Medical Imaging Consulting Services
- Site Standardization and Technical Support
- Cross-Calibration using the Bona Fide Phantom (BFP)
- Image Management Services for X-Ray
- Image Management Services for DXA
- Image Management Services for QCT
- Eligibility Assessment Services
- Technologist Training Program with ASRT Certification

X-RAY

BioClinica has an extensive track-record conducting multi-center studies involving radiographs. As vertebral deformity is a critical and challenging end point, all the radiographs must be thoroughly prepared for evaluation. The radiographs are then carefully checked for correct acquisition and pre-quantified for the radiologists to determine the level of deformity. We have experience with both six-point quantitative morphometry and semi-quantitative techniques. Our Bio-READ™ system is programmed to conduct the independent reads using its powerful logic and automatic image retrieval system.

DXA

DXA is the standard technology to measure BMD; however it requires thorough quality control to ensure optimal data. By using the Bio-DXA™ system, BioClinica provides support for all main-stream axial densitometers (GE –Lunar and Hologic). From the optimum methodologies for cross-calibration and instrument quality control (IQC) for the technical aspects of the instrumentation, to careful assessment of patient acquisition, we ensure all patient data is analyzed precisely and accurately.

Bio-DXA™ ensures that all calibration shifts and instrument changes are automatically tracked and applied automatically to the patient data. Our certified DXA technologists have clinical DXA experience to ensure full support on all aspects of the trial. Furthermore, Hip Structural Analysis (HSA), developed by Dr. Tom Beck is also available as an analysis.

Bona Fide Phantom Calibration for DXA

BioClinica's "Bona Fide Phantom" (BFP) was specifically designed for DXA cross-calibration in clinical trials. The BFP features a calcium hydroxyapatite step-wedge embedded in a physiologically normal soft-tissue equivalent acrylic. The BFP offers a range of densities to verify instrument function over the clinically relevant range which is critical for full instrument evaluation.

QUANTITATIVE COMPUTED TOMOGRAPHY

Quantitative Computed Tomography (QCT) is used to measure true three-dimensional bone mineral density and the higher metabolically-active trabecular bone can be isolated for analysis. BioClinica has experience in many different studies using the QCT PRO™ software by Mindways. In many studies, this data is then sent to a specialist for the latest in finite element analysis for vertebral strength assessment.

PEDIATRIC EXPERTISE

BioClinica has developed expertise in pediatric bone disease studies to help obtain "pediatric exclusivity labels" for clients. These include osteogenesis imperfecta, steroid induced bone loss and bone aging. The challenge of correctly assessing bone mineral density (BMD) and evaluating vertebrae in this specialized population has set BioClinica apart in the area of bone disease. It has provided us with a network of pediatric specialists around the world with whom to collaborate. We have also conducted the first multi-center clinical trials utilizing the distal femur measurement in children, developed out of the DuPont Children's Hospital.

