

# PUBLICATIONS

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

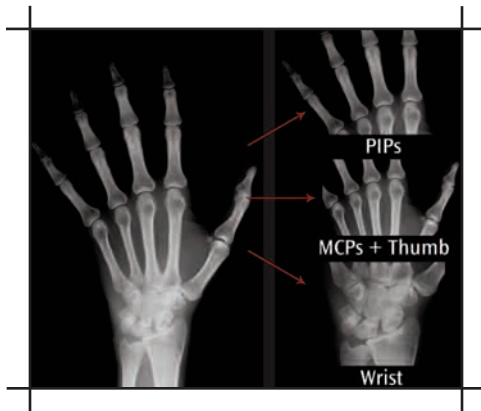
J. Davis, R. Landewé, D. van der Heijde, et. al. "Use of MSASSS Data from the OASIS Cohort as a Comparator for Radiographic Progressions Studies in Subjects with Ankyloing Spondylitis" EULAR presentation, June 2006.

CE. Antoni, D. Gladman, A. Kavanaugh, et. al. "The Infliximab Multinational Psoriatic Arthritis Controlled Trial (IMPACT): results of radiographic analyses after 1 year." Annals of the Rheumatic Diseases. 65(8):1038-43, August 2006.

L. Klareskog, R. Landewé, D. van der Heijde, et. al. "Presentation and Analysis of Data on Radiographic Outcome in Clinical Trials, Experience From the TEMPO study" Arthritis & Rheumatism Volume 52, No. 1, January 2005. pp 49-60.

R. Landewé, D. van der Heijde, C. Winalski, et. al. "Erosion Repair in Rheumatoid Arthritis in Recognized by Expert Readers but Cannot be Distinguished from Progression by Specific Features" ACR Poster Presentation, October 2004.

A. Boonen, R. Landewé, D. van der Heijde, et. al. "Providing Readers with Films of the Entire Hand or Foot Compared to Single Joints Does not Improve the Ability to Discriminate Between Progression or Repair of Radiographic Damage in RA" ACR Poster Presentation. October 2004.



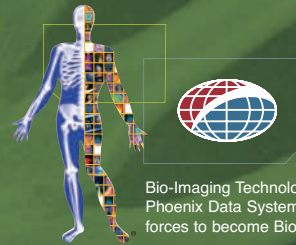
# Rheumatoid Arthritis Expertise



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# Rheumatoid Arthritis 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)

## RHEUMATOLOGY EXPERTISE

Clinical trials involving rheumatology present a number of challenges. With a wealth of experience utilizing validated scoring methods, BioClinica provides proven expertise in centralized image analysis in all necessary modalities and techniques.

Our expertise supports:

- Medical Imaging Consulting Services
- Site Standardization and Technical Support
- Image Management Services for X-ray
- Image Management Services for MRI
- Eligibility Assessment Services
- Independent Blinded Reads

## X-RAY

All phase III studies in rheumatology have relied on radiographs for determining the imaging end-points. We are experienced in reading X-rays of the hands and feet utilizing the Sharp/van der Heijde methods and are also very familiar with their modifications for PsA. BioClinica has an extensive track-record for handling multi-center studies involving radiographs, ensuring the critical level of detail required for trial accuracy is employed.

The independent blinded interpretation of imaging studies is of paramount importance in every clinical trial. BioClinica's Bio-READ™ system provides the platform for "state of the art" radiological evaluation of the clinical trial data. The radiologists selected for these reads are all licensed, board certified musculoskeletal or rheumatologic experts and meet all FDA requirements as independent readers. BioClinica also has a dedicated team of professionals (Read Management Services) who manage the review process to ensure the success of the read.

## MAGNETIC RESONANCE IMAGING (MRI)

The use of Magnetic Resonance Imaging (MRI) in rheumatology clinical trials is becoming more common and BioClinica has the experience and expertise to successfully manage studies in this modality. At BioClinica, we combine the latest software

technology with our imaging expertise, process knowledge and regulatory experience to implement projects in the most time and cost-efficient manner possible. BioClinica utilizes the MRI scoring systems recommended by OMERACT for both RA and PsA. MRI images in AS can be read utilizing methods developed by Spondyloarthritis Research Consortium of Canada (SPARCC). These scoring methods are used in conjunction with our computerized blinded read system Bio-READ™.

## GLOBAL RADIOLOGICAL EVALUATIONS

Due to the demanding nature of the reads and the length of time required to conduct a major phase III read for RA, BioClinica has developed a unique process using read stations placed with world renowned opinion leaders. Initiated in 1997, BioClinica has allowed readers to evaluate the images in their home or office on a secure and FDA compliant system. BioClinica continues to refine this process which ensures our leadership of managing RA, AS and PsA clinical trials. This process provides secure data able to be read in a timely fashion while minimizing reader fatigue and error.

## INDUSTRY LEADERS

BioClinica has led the way in handling medical images in Phase II and III Rheumatoid Arthritis trials. All of the anti-TNFalpha therapy trials were conducted using BioClinica's expertise. BioClinica supports the work of OMERACT, the international network committed to achieving data guideline consensus and improving outcome easurement in rheumatoid arthritis clinical trials. BioClinica has sponsored an OMERACT Healing and Erosion sub-committee meeting which resulted in work that was published at an ACR meeting in October 2004. Additionally we have significant experience working with the Sharp scoring methodology. We continue to work closely with Prof. Dr. Désirée van de Heijde in the development of read standards.

