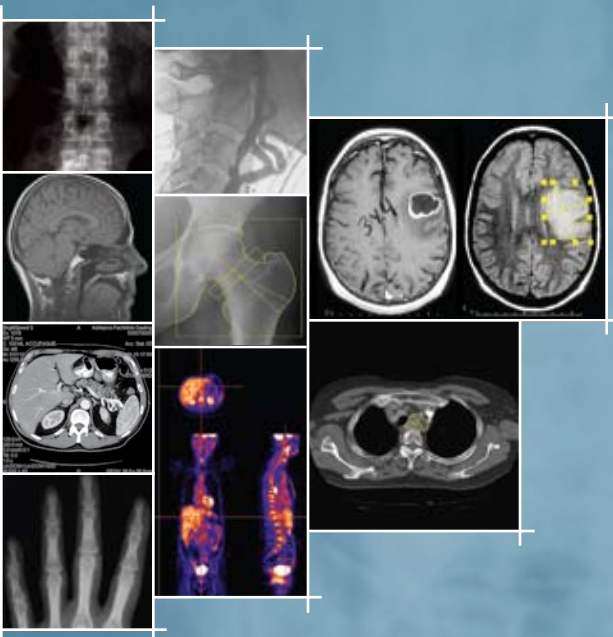
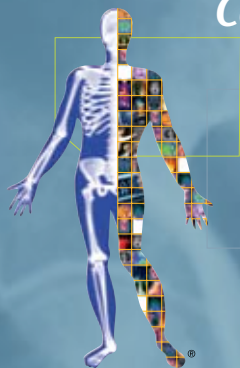


Course

Curricula



*Optimizing Medical Imaging in Clinical Trials
Complimentary Educational Symposia*



BIOCLINICA™



BioClinica's Course Curricula

BioClinica is pleased to present new symposiums on medical imaging in various therapeutic areas. Distinguished faculty, including BioClinica scientific staff, will educate Pharmaceutical and Biotech personnel of the vital role of imaging in the development of therapeutic specific compounds.

These symposiums are designed to provide Pharmaceutical and Biotech personnel the understanding and background in specific areas of clinical trials based around imaging. These didactic style lectures can be tailored to your needs and can provide participants the opportunities to ask questions.

The recommended staff that should attend these courses includes, but is not limited to: Medical Directors, Program Managers, Project Managers, Statisticians, Data Management Teams, Outsourcing/ Procurement Teams and Clinical Research Associates.

Our complimentary course curricula are tailored to fit your company's need. They can be offered on-site at your facilities or hosted by BioClinica. Alternatively an off-site location of your choosing may provide the perfect setting to start team building and provide education for a new protocol or to develop the team's understanding of a disease state, its end points and the challenges of imaging.

To plan your next symposium, please call Dr. Harris Ahmad at (267) 757 – 3030 or email at courses@bioclinica.com

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Core Labs 101 and Charter Development

Course Description:

If your trial has an imaging component then an Imaging Core Lab (ICL) is the essential key to a successful clinical trial as it serves as the logistical hub for medical imaging. The blueprint for an ICL often revolves around the imaging review charter, an FDA required document that entails the physical movement of imaging and read design.

BioClinica's course will introduce the role of the ICLs and how sponsors successfully work with ICLs in a clinical trial. Topics include standardizing image acquisition and sites, as well as imaging review charter development. The course will also detail quality control by technologists, pre-quantification and how images are prepared for an independent efficacy and eligibility read. Finally, our speakers will explain how the blinded read is performed and how the results are compiled and prepared for export. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to clinical trials.

Course Agenda:

- An Introduction to Imaging Core labs
- Study Start-up and Read Design
- The Purpose and Components of Imaging Review Charters
- Site Standardization – Guidelines, Start up and Quality Control
- Blinded Independent Reviews – Read Designs and Reader Training
- Project Management – Reporting, Data Export and Communication
- FDA Trends – An Update on Adjudication

Potential Faculty:

Harris Ahmad, M.D., Medical Liaison, Medical Affairs, BioClinica
Danielle Heller, RT, Read Support Analyst, BioClinica
Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica
Jennifer Minko, Director, Clinical Operations, BioClinica
Lenore Noonan, Director, Clinical Operations, BioClinica
Jennifer Schick, Project Director - Oncology, BioClinica

**Core Labs and Charters 101 can be divided into two half day symposiums or one full day.

Medical Imaging in Oncology



Course Description:

Oncology continues to be one of the leading areas of drug development focus in the pharmaceutical industry. BioClinica's, "Medical Imaging in Oncology", will provide a comprehensive review of topics which include the measurement methodologies which will encompass the historic perspective. The evaluation of these measurement techniques will be presented along with, how to consider these methodologies in protocol development. Discussion of the FDA guidelines with case examples will be provided. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to oncology clinical trials.

Course Agenda:

- Imaging Modalities and Acquisition in Oncology
- The Use of Contrast Agents in CT and MRI
- Read Methodologies in Oncology Clinical Trials
- A Brief Overview of Medical Imaging Charters in Oncology Clinical Trials
- Response Assessment Criteria and Guidelines
- RECIST 1.0 and 1.1 Compared
- Cheson 1999 Guidelines with 2007 update
- Regulatory Topics in Oncology Clinical Trials: Reader Pitfalls and Adjudication
- Updates from Presentations to the FDA

Potential Faculty:

Harris Ahmad, M.D., Medical Liaison, Medical Affairs, BioClinica

Danielle Heller, RT, Read Support Analyst, BioClinica

Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica

Jennifer Minko, Director, Clinical Operations, BioClinica

Lenore Noonan, Director, Clinical Operations, BioClinica

Andrea Perrone, M.D., VP and Medical Director, Clinical Operations, BioClinica

Jennifer Schick, Project Director - Oncology, BioClinica

** All attendees will receive a complimentary training CD on the Cheson and RECIST criteria developed for categorizing response in the Oncology drug development.



Medical Imaging in Neurologic Diseases

Course Description:

Over the past few decades, pharmaceutical development in neurology has become more vital to the health of our aging adult patient population. BioClinica's, "Medical Imaging in Neurologic Diseases", will provide a comprehensive review of recent advances in imaging research and its application in drug development.

Participants will have the opportunity to expand their knowledge of the latest measurement techniques in medical imaging for evaluating drug development in diseases involving the central nervous system. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to neurology clinical trials.

Course Agenda:

- Stroke Imaging in Clinical Trials
- Methodology, Analysis, and Imaging Sequences in CNS Clinical Trials
- Quality Assurance (QA) and Quality Control (QC) of Imaging in CNS Clinical Trials
- Clinical Imaging Biomarkers in CNS Drug Development
- Total Brain Volume and Hippocampal Brain Volume
- End Points in Multiple Sclerosis

Potential Faculty:

Harris Ahmad, M.D., Medical Liaison, Medical Affairs, BioClinica
Marc Fisher, M.D., Vice Chair, Neurology, UMass Memorial Medical Center
Igor Grachev M.D., PhD, VP, Clinical Affairs & Business Development, BioClinica
Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica
Chahin Pachai, PhD, Vice President & Executive Director, BioClinica
Andrea Perrone, M.D., VP and Medical Director, Clinical Operations, BioClinica



Cardiovascular Imaging in Clinical Trials

Course Description:

Imaging has become increasingly important as a biomarker in the development of drugs in the cardiovascular area. BioClinica's, "Cardiovascular Imaging in Clinical Trials", will provide a comprehensive review of recent advances in imaging for this therapeutic area. Principles and standardization of image acquisition, guidelines for variability and validation of core lab analysis in clinical trials will be discussed.

Participants will have the opportunity to expand their knowledge of the latest measurement techniques for evaluating vascular disease. In addition, the current cutting-edge tools for quantitative image analysis in coronary and peripheral angiography will be presented. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to cardiovascular clinical trials.

Course Agenda:

- Overview of CT and MR Coronary Angiography
- Overview of CT and MR Vascular Angiography
- Site Challenges in Cardiovascular Clinical Trials
- An Introduction to MRI and CT in Cardiovascular Imaging
- X-ray Angiography 101

Potential Faculty:

George Heyrich, M.D., FACR, Cardiologist & BioClinica Scientific Advisory Board
Rudy Meijer, MSc, Manager Scientific Services, BioClinica
Marion Pearson, PhD Director Core Lab, BioClinica
Andrea Perrone, M.D., VP and Medical Director, Clinical Operations, BioClinica



Cutting Edge Methodologies in Osteoporosis Clinical Trials

Course Description:

This symposium, will provide a comprehensive review of recent advances in medical imaging for the evaluation of osteoporosis. Participants will have the opportunity to expand their knowledge of the latest measurement techniques for evaluating bone quality and fracture prediction. In addition, several imaging modalities that accurately assess osteoporosis will be explained on an understandable, industry relevant level. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to osteoporosis clinical trials.

Course Agenda:

- Vertebral Morphometry Techniques Complexities and Differentials
- Statistical Modeling for the Assessment of Vertebral Shape Assessment of Osteoporotic Vertebral Fractures: Quantitative and Semi-quantitative Techniques
- Implementation of QCT and pQCT as a Complimentary Tool for the Evaluation of Drug Effect in Bone Density
- Quantitative CT (QCT) and its Use in Determining Volumetric BMD
- The Development of Micro Architecture In-vivo using MRI
- Clinical Non-Invasive Bone Strength Assessment Using Finite Element Modeling – Biomechanical CT
- Prediction of Hip Fractures Using X-ray

Potential Faculty:

Harris Ahmad, M.D., Medical Liaison, Medical Affairs, BioClinica

Claude Arnaud, M.D., FACE, Chief Medical Officer, Imaging Therapeutics, Inc.

Alan Brett, PhD., Chief Technology Officer, Optasia Medical Ltd.

Keenan Brown, PhD., President, Mindways Software, Inc.

Curtis Hayes, M.D., Professor MSK Radiology, Virginia Commonwealth University

Michael Kleerekoper, M.D., Chief Medical Officer, MicroMRI

Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica

** We will provide complimentary copies of the book “Clinical Trials in Osteoporosis” upon request and availability.



Rheumatoid Arthritis

Imaging and Methodologies

Course Description:

This symposium, will provide a comprehensive review of the imaging component for inflammatory rheumatic disease and related conditions in clinical trial research. Principles and standardization of image acquisition, interpretation of the images and the analysis of imaging results will be described. Considerable time will also be devoted to MRI scoring systems in rheumatoid arthritis such as RAMRIS and OMERACT, WOMMS.

Participants will have the opportunity to expand their knowledge of the importance of imaging as it pertains to rheumatological assessment in clinical trials.

Course Agenda:

- Comparison of X-Ray Scoring Systems
- Radiographic and MRI Scoring Systems in Rheumatoid Arthritis
- Image Data Acquisition in Rheumatoid Arthritis
- Quality Control in Rheumatoid Arthritis
- Blinded Reads - Challenges and Complexities
- Radiographic and MRI Scoring systems in Ankylosing Spondylitis
- Radiographic Scoring Methods in Psoriatic Arthritis
- Example From Successful NDA's

Potential Faculty:

Harris Ahmad, M.D., Medical Liaison, Medical Affairs, BioClinica

Mark Endres, Senior VP of Global Business Development, BioClinica

Desiree van Der Heijde M.D., PhD, Rheumatology, Leiden University Med Center

Cornelis Van Kuijk, VU University Medical Center, Amsterdam, Netherlands

Lenore Noonan, Director, Clinical Operations, BioClinica

Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica

Andrea Perrone, M.D., VP and Medical Director, Clinical Operations, BioClinica

** We will provide complimentary copies of the book, "Clinical Trials in Rheumatoid Arthritis and Osteoarthritis" upon request and availability.



Imaging in Osteoarthritis Clinical Trials

Course Description:

BioClinica's, "Medical Imaging in Osteoarthritis", will provide a comprehensive review of the X-ray and MRI components required for the efficacy assessment of Osteoarthritis (OA) clinical trials. These in depth lectures have been designed to focus on specific topics that are relevant to professionals in the clinical trial industry. Principles and standardization of image acquisition, interpretation of the images and the analysis of imaging results will be described. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to osteoarthritis clinical trials.

Course Agenda:

- The Challenge of Image Acquisition of X-rays in Knee OA
- Anatomic Basis for Radiographic Technique, Description of the Acquisition Techniques, Reproducibility and Recommendations
- Kellgren-Lawrence Scoring
- The Evaluation of Joint Space Width (JSW) of X-rays in Clinical Trials
- Comparison of Osteoarthritis Scoring Systems, Radiographic Parameters, and Joint Space Evaluation
- Potential New Developments: Active Shape Modeling in OA for Reproducible Assessment of JSW
- Regulatory Requirements

Potential Faculty:

Alan Brett PhD, Chief Technology Officer, Optasia Medical Ltd.

Eric Bogner, M.D. Attending Radiologist, Hospital for Special Surgery, New York

Felix Eckstein M.D., Director, Anatomy & MSK Research, Paracelsus University

Curtis Hayes, M.D., Professor, MSK Radiology, Virginia Commonwealth University

Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica

** We will provide complimentary copies of the book, "Clinical Trials in Rheumatoid Arthritis and Osteoarthritis" upon request and availability.



Bone Densitometry in Clinical Trials

Course Description:

BioClinica's, "Bone Densitometry in Clinical Trials", will introduce the imaging modalities of Dual Energy Absorptometry (DXA) and Quantitative Computed Tomography (QCT) and the role in osteoporosis clinical trials. DXA is a unique imaging technique in which attendees will gain a clear understanding of the acquisition requirements and aspects surrounding quality control and the challenges with analysis. The underlying principles of the assessment of Bone Mineral Density (BMD) will be discussed along with fracture assessment and how this should be applied in a clinical trial. Participants will have the opportunity to expand their knowledge of the challenges of imaging as it pertains to bone densitometry in clinical trials.

Course Agenda:

- DXA Methodology and Instrument Requirements in Clinical Trials
- DXA Quality Assurance and Quality Control (QA/QC)
- DXA Methodology and Instrument Requirements in Clinical Trials
- T-Scores and Z-Scores
- K or R Values; The Basis Behind a DXA Scan
- Metrics for Instrumentation in Clinical Trials and Specifically for DXA.
- Differences Between Hologic & GE-Lunar Densitometer
- Pediatric Densitometry
- Bone Densitometry which Anatomical Sites to Select

Potential Faculty:

Harris Ahmad, M.D., Medical Liaison, Medical Affairs, BioClinica
Stuart Jackson, PhD, Professor of Radiology, University of Alberta
Colin Miller, PhD FICR CSci, Senior Vice President, Medical Affairs, BioClinica
Debby Petersen, BS, RT(R), CDT, Imaging Analysis Technologist, BioClinica

** We will provide complimentary copies of the book "Clinical Trials in Osteoporosis" upon request and availability.

A Sample of the Scientific Contributions Made by the Faculty

- Pain fMRI in rat cervical spinal cord: An echo planar imaging evaluation of sensitivity of BOLD and blood volume-weighted fMRI. F. Zhao, M. Williams, X. Meng, DC. Welsh, ID. Grachev, R. Hargreaves, DS. Williams. Neuroimage. 2008 Sept 16 [Epub ahead of print]
- Effect of Carotid Angioplasty and Stenting on Duplex Velocity Measurements in Porcine Model. Gert J. de Borst, MD, PhD., Rudy Meijer, MSc., Rob Lo, MD., Hans W. G. Vosmeer., Rob G. A. Ackerstaff, MD, PhD., Frans L. Moll, MD, PhD. J Endovasc Ther 2008 Sept;15

- Magnetization transfer imaging shows tissue abnormalities in the reversible penumbra. T. Tourdias, V. Douset, I. Sibon, E. Pelé, P. Ménégon, J. Asselineau, C. Pachai, F. Rouanet, P. Robinson, G. Chêne, and JM. Orgogozo Stroke. 2007 Oct.; 107.483925

Education Alternatives for imaging techniques in clinical trials. CG. Miller, K. Wertz. World Pharma Network. July 2007; 42-43

- Cross-calibration of Dual Energy X-Ray densitometers for a large multi-centre genetic study of osteoporosis. DM. Reid, I. Mackay, S. Wilkinson, C. Miller, et al. Osteoporosis International 2005

- Hippocampal Diffusion Tensor Measurements in Temporal Lobe Epilepsy. FB. Mohamed, KA. Khaled, SH. Faro, A. Pinus, H. Ahmad, M. Williams, J. Haselgrove, B. Assaf. 11th Scientific Meeting of the International Society of Magnetic Resonance in Medicine, 2003 p.: 2227

- Scanning data for clinical information. C. Miller, K. Noever. Good Clinical Practices Journal. 2003. 10; 9: 21-24

- Image Management in Clinical Trials. CG. Miller. Business Briefing: Pharmatech 2002

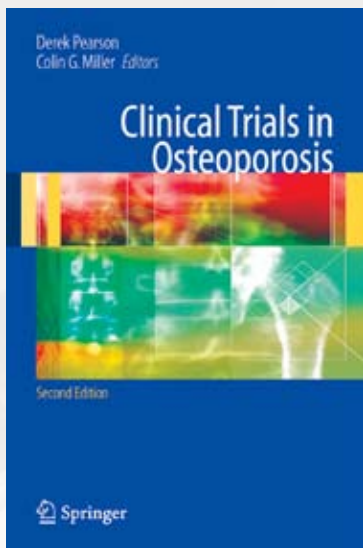
- The use of medical imaging in clinical trials. CG. Miller. SoCRA Source November 2001; 30; 26-28

- Integrative Processes: Neuroscience clinical imaging biomarkers. ID. Grachev, R. Hargreaves. In Book "CNS Imaging in Drug Development". Springer, in press.

- Quantitative MRI markers in Stroke and MS trials C. Pachai Conducting successful implementation and evaluation of imaging informatics - Pre-conference workshop, January 23rd, 2006

- Multimedia Interactive Training Programs for RECIST 1.0, 1.1 and Cheson Response Criteria. Developed by Harris Ahmad M.D., Danielle Heller RT, Stuart Jackson PhD, Jill Langer MD, Lenore Noonan, Andrea Perrone MD, Ryan Price ; BioClinica 2009

Books Co-Edited by Dr. Colin G. Miller
Senior VP, Medical Affairs, BioClinica



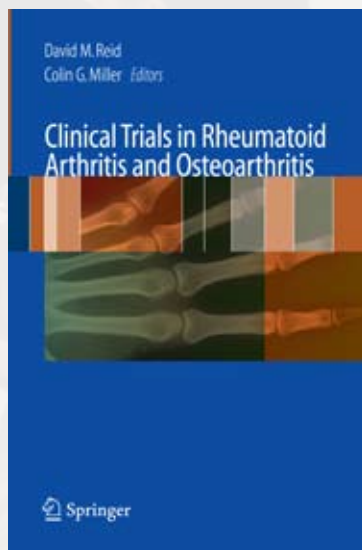
Clinical Trials in Osteoporosis written by: Derek Pearson and Colin Miller. Published by Springer London Ltd. 2002. (ISBN 1852332298) (2nd Edition 2007)

The second revised and updated edition of “Clinical Trials in Osteoporosis” is a practical handbook on clinical trials in the growing field of osteoporosis. Topics covered include study design, technical issues, data collection, quality assurance, data analysis and presentation. It takes the user through the process step-by-step from start to finish, also providing a background on regulatory guidelines, ethical implications, endpoints, current therapies and the ideal drug to use.

Clinical Trials in Rheumatoid and Osteoarthritis written by: David Reid and Colin Miller. Published by Springer London Ltd. 2008 (ISBN 97811852338749).

Designed to be a practical handbook on clinical trial management in these key therapeutic areas, ‘Clinical Trials in Rheumatoid Arthritis and Osteoarthritis’ is aimed at principal investigators pharmaceutical physicians and other pharmaceutical staff involved in the design, conduct and monitoring of these increasingly complex diseases.

Topics covered in this title will therefore include study design, clinical endpoints, technical issues, data collection, use of centralized medical image reading facilities and biochemical marker laboratories, as well as data analysis and future therapies. This book takes the user through the process step-by-step from start to finish, also providing a background on the regulatory guidelines, ethical implications, endpoints, and current therapies.

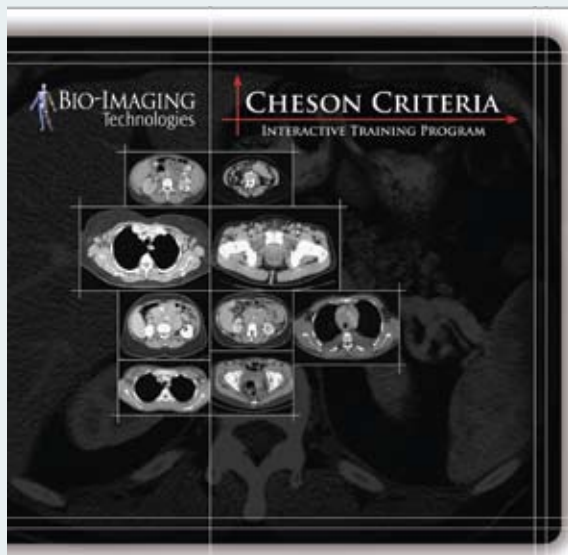




RECIST (Response Evaluation Criteria in Solid Tumors) was originally published in 2000 as version 1.0 with an update 1.1 released in January 2009 by an international collaborative group involved in cancer research. Numerous clinical trials, both past and present, use this criteria to evaluate solid tumor response in the drug development process. BioClinica's "Interactive RECIST Training

Program" is an excellent learning technique that will guide the user through the criteria and its classifications on response for solid tumors.

Based on the 1999 and 2007 Cheson publications, our interactive training program CD guides the user through the Cheson lymphoma response criteria. The program provides the opportunity to learn the response criteria in depth for clinicians and industry professionals on all levels participating in lymphoma clinical trials. The program emphasizes the need for reproducibility and



standardization of response for trials in which imaging is an endpoint for therapeutic efficacy. This complimentary CD is currently available upon request.

Locations



ACE Conference Center
800 Ridge Pike
Lafayette Hill, PA 19444

ACE Conference Center is an outstanding venue on 311 retreat like acreage with 38 specially-equipped meeting rooms, 120 deluxe guest rooms, recreation center, two lounges and golf. Business center services are available including wireless internet access. Dining room provides outstanding cuisine for breakfast, lunch and dinner.

The Doubletree Hotel Philadelphia is centrally located in the heart of Philadelphia's cultural district on the Avenue of the Arts. Across from the Academy of Music, this comfortable high-rise is within walking distance of many of Philadelphia's attractions including the Pennsylvania Convention Center, City Hall, and the Liberty Bell.

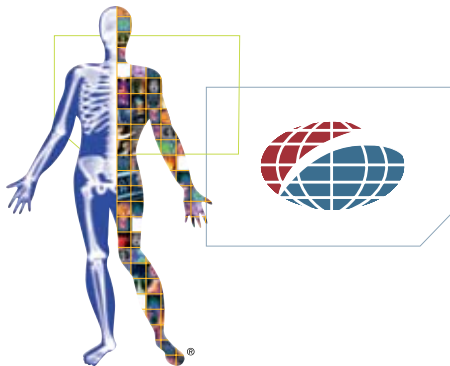


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