

BOSTON, MA **APRIL 7-8, 2003**

5TH ANNUAL WORKSHOP IN COLLABORATION WITH
THE MASSACHUSETTS GENERAL HOSPITAL
CENTER FOR BIOMARKERS IN IMAGING



MEDICAL IMAGING IN CLINICAL TRIALS

TARGET AUDIENCE

Program participants should include decision-makers in drug development, clinical researchers, and regulatory specialists as well as those with an interest in surrogate endpoints in clinical trials and strategic drug development program acceleration.

OVERVIEW

This workshop will address the increasing role of medical imaging in clinical trials. Imaging is increasingly being used to make go/no-go decisions and to provide surrogate endpoints in clinical trials. The Food and Drug Administration has demonstrated increasing willingness to rely on surrogate endpoints such as imaging.

PROGRAM CHAIRPERSONS

A. Gregory Sorensen, MD

Associate Director, MGH-NMR
Center, Massachusetts General Hospital
and Harvard Medical School
Vice President, Clinical Development and
Medical Director, EPIX Medical

Liqun Wang, PhD

Director and Global Head, MR Imaging,
Translational Medicine and Technology
GlaxoSmithKline R&D, UK

Mostafa Analoui, PhD

Senior Director and Global Head,
Computational Medicine,
Clinical Technology,
Pfizer Global Research and Development

Accreditation and Credit Designation

The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 12.5 category 1 credits toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.



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Learning Objectives – At the conclusion of this meeting, participants should be able to:

- ▶ Identify current issues in using imaging as endpoints in clinical trials
- ▶ Discuss the strengths and weaknesses of imaging endpoints in oncology, neuroscience, osteoarthritis, and cardiology applications
- ▶ Recognize the complexities and challenges of using imaging in a practical way in trials involving imaging
- ▶ Discuss new and evolving biomarkers in imaging

SUNDAY • APRIL 6

6:00-8:00 PM REGISTRATION

MONDAY • APRIL 7

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:15-8:30 AM **WELCOME AND OPENING REMARKS**
A. Gregory Sorensen, MD
*Associate Director, MGH-NMR CENTER, MASSACHUSETTS GENERAL HOSPITAL AND HARVARD MEDICAL SCHOOL
 Vice President, Clinical Development and Medical Director, EPIX MEDICAL*

8:30-10:00 AM **SESSION I**

GENERAL ISSUES

CHAIRPERSON

A. Gregory Sorensen, MD

The use of medical imaging in clinical trials has become commonplace in some areas and is still novel in other areas. This session will discuss some of the successes and failures of imaging in drug development, with particular attention to the issues around scientific validation.

REALITIES OF USING MEDICAL IMAGING IN CLINICAL TRIALS

Stephen Williams, MD, PhD

Worldwide Head, Clinical Technology, PFIZER GLOBAL RESEARCH AND DEVELOPMENT, PFIZER INC

IMAGING AS AN ENDPOINT FOR CLINICAL TRIALS: STRENGTHS AND WEAKNESSES
Representative Invited
 FDA

IMAGING IN THERAPEUTIC SUBMISSIONS
Lydia Martynec, MD
Medical Reviewer, CBER, FOOD AND DRUG ADMINISTRATION

10:00-10:30 AM **REFRESHMENT BREAK**

10:30 AM-12:30 PM **SESSION II**

ONCOLOGY

CHAIRPERSON

Mostafa Analoui, PhD

Imaging plays an important role in oncology from early development to surrogate endpoints in pivotal trials. PET scanning allows for assessing biodistribution in early phases. Phase III trials typically require anatomical imaging with recent migration from WHO and SWOG criteria to RECIST. This session will focus on the use of imaging in early and late phase oncology clinical trials.

IMAGING THERAPEUTIC RESPONSE IN ONCOLOGY: FROM CONVENTIONAL TO NOVEL TECHNIQUES
Lawrence Schwartz, MD

Associate Professor of Radiology, Director of MRI, MEMORIAL SLOAN KETTERING CANCER CENTER

PET/CT: APPLICATIONS IN ONCOLOGICAL IMAGING
Richard Wahl, MD

Professor of Radiology and Oncology, Director of Nuclear Medicine and PET, JOHN HOPKINS UNIVERSITY

ADVANCES IN PET CHEMISTRY AND TARGET SELECTION
Michael T. Klimas, PhD

Manager, Pharmaceutical Programs, GE MEDICAL SYSTEMS, GENOMICS AND MOLECULAR IMAGING

IMPLEMENTING RESPONSE EVALUATION CRITERIA IN SOLID TUMOR (RECIST) IN CLINICAL TRIALS

Mark A. Goldberg, MD

President, PERCEPTIVE INFORMATICS, INC.

12:30-1:30 PM LUNCHEON

1:30-3:00 PM SESSION III

NEUROIMAGING

CHAIRPERSON

Liqun Wang, PhD

The neurosciences have been a particular focus of imaging technologies, and this session will review some of the newest techniques focused on understanding two key areas: pain and Alzheimer's disease. Both of these problems have challenging traditional endpoints and imaging continues to hold out promise of more rational development.

IMAGING NORMAL AND NEUROPATHIC PAIN

Kenneth L. Casey, MD

*Professor of Neurology and Physiology, UNIVERSITY OF MICHIGAN
Consultant in Neurology, VA MEDICAL CENTER*

UNDERSTANDING PAIN MECHANISM WITH fMRI

David Borsook, MD, PhD

Vice President, Chief Scientific Officer, DESCARTES THERAPEUTICS, INC.

DEVELOPING IMAGING BIOMARKERS FOR DISEASES: NIA IMAGING INITIATIVE FOR ALZHEIMER'S DISEASE

Susan Molchan, MD

Program Director, Alzheimer's Disease Clinical Trials, Neuroscience and Neuropsychology of Aging Program, NATIONAL INSTITUTE ON AGING, NATIONAL INSTITUTES OF HEALTH

3:00-3:30 PM REFRESHMENT BREAK

3:30-5:30 PM SESSION IV

CHALLENGES IN DEVELOPING IMAGING TOOLS FOR DRUG DEVELOPMENT

CHAIRPERSON

Mostafa Analoui, PhD

After years of experience, certain pitfalls have arisen for medical imaging. Newer approaches to standardization and combinations of imaging tools to fill out a complete picture are increasingly employed to overcome traditional shortfalls. This session will highlight some of the pitfalls and newer approaches to overcoming them.

QUANTITATIVE CLINICAL IMAGING: CHALLENGES AND STRATEGIES

Mostafa Analoui, PhD

Senior Director and Global Head, Computational Medicine, Clinical Technology, PFIZER GLOBAL RESEARCH AND DEVELOPMENT

QUANTITATIVE VARIANCE REDUCTION IN BRAIN MRI

Anders Dale, PhD

*Associate Director, A.A. MARTINOS CENTER, MASSACHUSETTS GENERAL HOSPITAL, Health Sciences and Technology Associate
Professor of Radiology, HARVARD MEDICAL SCHOOL*

THE USE OF IMAGING TO ENHANCE THE TRANSITION FROM PRECLINICAL TO CLINICAL DEVELOPMENT

David S. Lester, PhD

Director, Clinical Technologies, PHARMACIA CORPORATION

APPLICATION OF MEDICAL IMAGING IN ONCOLOGY

Sanjay Saini, MD

*Professor of Radiology, HARVARD MEDICAL SCHOOL,
MASSACHUSETTS GENERAL HOSPITAL*

5:30-6:30 PM RECEPTION

TUESDAY • APRIL 8

7:00-8:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00-10:00 AM SESSION V

GETTING THE WORK DONE : PRACTICAL ISSUES

CHAIRPERSON

A. Gregory Sorensen, MD

A critical part of imaging in clinical trials is around the logistical issues. This special session will highlight "best practices" from a range of highly experienced contract research organizations. Each speaker will briefly summarize the challenges and current solutions, and the session will end with an interactive discussion.

QUANTITATIVE IMAGING: PROTOCOL DEVELOPMENT AND QUALITY ASSURANCE FOR MEDICAL IMAGING IN CLINICAL TRIALS

Cecil Charles, PhD

Director, Duke Image Analysis Laboratory, DUKE UNIVERSITY MEDICAL CENTER

BLINDED READER TRAINING

Subba Rao Digumarthy, MD

Radiology Research Fellow, WORLDCARE CLINICAL, INC.

IMAGE MANAGEMENT FROM A REGULATORY PERSPECTIVE

Ted Gastineau

Chief Executive Officer, BEACON BIOSCIENCE

CFR(11) COMPLIANCE IN CUSTOMIZED ANALYSES

Manish Kothari

Vice President of Medical Imaging Technologies, SYNARC, INC.

IMAGING DATA INTEGRATION

Jay B. Zimmerman

Vice President, Operations Medical Diagnostics, PERCEPTIVE INFORMATICS, INC.

MANAGING EXPECTATIONS IN CLINICAL TRIALS:

SPONSOR AND VENDOR

Mark L. Weinstein

President and CEO, BIO-IMAGING TECHNOLOGIES, INC.

**AUTOMATING DATA COLLECTION, TRANSMISSION, AND ANALYSIS:
DOS AND DON'TS OF MULTICENTER STUDIES**
Alex P. Zijdenbos, PhD
Chief Science Officer, NEURALYSE INC.

10:00-10:30 AM REFRESHMENT BREAK

10:30 AM-12:00 PM SESSION VI

CARDIOLOGY/ATHEROMA

CHAIRPERSON

Liqun Wang, PhD

While imaging has long been used in cardiology, there has been recent strong interest in using imaging to identify the vulnerable plaque and attempt to improve our understanding of its role and therapeutic targeting possibilities. Speakers in this session will describe cross-sectional approaches to imaging plaque and highlight recent insights such techniques have provided.

**MR IMAGING OF ATHEROSCLEROSIS: LATEST DEVELOPMENT AND
FUTURE DIRECTIONS**

Chun Yuan, PhD

*Professor, Department of Radiology, UNIVERSITY OF
WASHINGTON*

CORONARY PLAQUE IMAGING WITH CT

Stephan Achenbach, MD

*Assistant Professor of Medicine, Department of Cardiology,
UNIVERSITY OF ERLANGEN, GERMANY
Research Fellow, Department of Radiology, MASSACHUSETTS
GENERAL HOSPITAL*

CORONARY IMAGING WITH MRA: A MULTICENTER EXPERIENCE

Warren Manning, MD

*Associate Chief Noninvasive Cardiac Imaging, Associate Professor
of Medicine and Radiology, HARVARD MEDICAL SCHOOL*

12:00-1:30 PM LUNCHEON

1:30-3:00 PM SESSION VII

OSTEOARTHRITIS IMAGING

CHAIRPERSON

Charles Peterfy, MD, PhD

Chief Medical Officer, Executive Vice President, SYNARC, INC.

The Osteoarthritis Initiative has provided a platform to begin to understand how some of the newer imaging techniques such as MRI compare with both older imaging techniques such as x-ray and non-imaging biomarkers. This session will focus on the role of imaging in the evaluation of osteoarthritis and its treatment, especially with novel agents.

**FACTORS ASSOCIATED WITH OSTEOARTHRITIS PROGRESSION AND
WITH PAIN**

David T. Felson, MD, MPH

*Professor of Medicine and Public Health, BOSTON UNIVERSITY
SCHOOL OF MEDICINE, CLINICAL EPIDEMIOLOGY RESEARCH AND
TRAINING UNIT*

REPEATABILITY IN MR OA IMAGING

Saara MS Totterman, MD, PhD

Chief Medical Officer, VIRTUALSCOPICS, LLC

**IMAGING STRUCTURAL CHANGES IN OSTEOARTHRITIS:
ASSESSING THE JOINT AS A WHOLE-ORGAN?**

Charles Peterfy, MD, PhD

*Chief Medical Officer, Executive Vice President,
SYNARC, INC.*

3:00-3:15 PM

CLOSING REMARKS

Mostafa Analoui, PhD

*Senior Director and Global Head, Computational
Medicine, Clinical Technology, PFIZER GLOBAL
RESEARCH AND DEVELOPMENT*

3:15 PM

WORKSHOP ADJOURNED

Statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Audio/visual taping of any DIA workshop is prohibited without prior written consent from DIA.

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TRAVEL AND HOTEL: The most convenient airport is Logan International Airport and attendees should make airline reservations as early as possible to ensure availability. The Boston Marriott Long Wharf is holding a block of rooms at the reduced rate below until March 17, 2003, for the DIA meeting attendees.

Single \$199 Double \$199

To reserve your room, please contact the Boston Marriott Long Wharf by telephone at +1 617 227 0800, or by fax at +1 617 227 2867 and mention the DIA meeting. The Boston Marriott Long Wharf is located at 296 State Street, Boston, MA 02109, USA.

CONTACT & TABLETOP EXHIBIT INFORMATION: Attendees are welcome to visit the limited tabletop exhibits during the meeting and receptions. For meeting and tabletop exhibit information, contact Cheresse Verdi, Meeting Manager at the DIA office in Horsham, PA by telephone +1 215 442 6131, fax +1 215 442 6199 or email Cheresse.Verdi@diahome.org. Should you be interested in obtaining space for a tabletop exhibit, please check the box in the REGISTRATION FEE area below.

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CANCELLATION POLICY: On or before APRIL 1, 2003 Administrative fee that will be withheld from refund amount: Member/Nonmember = \$200 Gov't/Academia (Member/Nonmember) = \$100 Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

PLEASE CONSIDER THIS FORM AN INVOICE
Medical Imaging in Clinical Trials

Meeting I.D. # 03022 - April 7-8, 2003
Boston Marriott Long Wharf, Boston, MA, USA

Registration Fees: Please check all applicable fees.

If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee.

Registration fee includes refreshment breaks, luncheons and reception and will be accepted by mail, fax, or email.

- Member US \$ 790
Nonmember US \$1040
Government & Academia (Full-Time), Member US \$ 375
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GROUP DISCOUNTS AVAILABLE

Register 3 individuals from the same company location and receive complimentary registration for a 4th! All 4 individuals must register and prepay at the same time. DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute enrolled delegates of similar membership status at any time.

Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company location and return them together to DIA.

Please indicate that this form is part of a group registration by checking this box.

Please list below the names of the other three registrants from your company location.

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