Imaging Biomarkers in Clinical Trials
Current Practice & Future Trends

Keynote Speakers—
Bruce Chabner, MD, Director of Clinical Research, MGH Cancer Center
Dwaine Rieves, MD, Director, Division of Medical Imaging Products, FDA
Robert Tepper, MD, Partner, Third Rock Ventures, Boston, MA

Traditional criteria: RECIST, WHO, Cheson
Novel imaging biomarkers in drug development
Emerging modalities: PET/MR, elastography, DCE, perfusion
38 lectures with up to 12.25 AMA PRA Category 1 Credits™

Course Directors:
Sanjay Saini, MD
Professor of Radiology, Harvard Medical School

Giles Boland, MD
Associate Professor of Radiology, Harvard Medical School

Sheela Agarwal, MD
Clinical Fellow in Radiology, Harvard Medical School

In cooperation with:
Drug Information Association

Massachusetts General Hospital
Department of Radiology

Harvard Medical School
Department of Continuing Education

O’Keeffe Auditorium
Massachusetts General Hospital, Boston
Who Should Attend This Course

This course is geared towards individuals from academic medical centers, pharmaceutical companies, contract research organizations, and biotechnology companies that design and manage clinical trials. These individuals include Medical Directors, Physicians, and PhD Scientists. In addition, this course will benefit radiologists who interpret images and non-radiologists involved in imaging clinical trials. Participants will learn appropriate analysis methodology.

Course Overview

Imaging biomarkers serve as important endpoints for clinical trials in the approval process for therapeutic drugs. Various criteria have been developed for objective interpretation of imaging studies. Additionally, there are emerging imaging techniques that have the potential for applications as surrogate endpoints for clinical trials.

In this program, we will review the current practice of imaging biomarkers in clinical trials in oncology, cardiovascular, metabolic, bone and joint diseases. Additionally, we will highlight advanced imaging techniques that have potential as surrogate biomarkers.

The educational need addresses a combination of knowledge, competence, and performance gaps. Imaging techniques and read criteria continue to evolve, and it is important for investigators to keep current with the best practices. Also, these are not used in daily clinical practice so knowledge can only be obtained from courses such as this or by reading medical literature.

We believe that didactic lectures from leading experts on topics with Q&A sessions will most efficiently disseminate the knowledge regarding imaging biomarkers and advanced imaging techniques. The lectures will include case studies of previous clinical trials, discussing their successes and failures.

Learning Objectives

Upon completion of this course, participants will be able to:

• Discuss and implement the latest imaging criteria such as RECIST and WHO
• Identify new imaging modalities that may be used in clinical trials
• Differentiate types of imaging modalities that can be used for different disease types
• Improve their knowledge and competence

ACGME Competencies

This course is designed to meet one or more of the following Accreditation Council of Graduate Medical Education competencies:

This course has been designed to enhance medical knowledge and patient care through better design of clinical trials and interpretation of imaging data.
GUEST FACULTY

Dwaine Rieves, MD - KEYNOTE Speaker
Director, Division of Medical Imaging Products, U.S. Food and Drug Administration

Robert Tepper, MD - KEYNOTE Speaker
Partner, Third Rock Ventures, Boston, MA

HARVARD MEDICAL SCHOOL FACULTY

Sheela Agarwal, MD
Clinical Fellow in Radiology, MGH / HMS

Michael Blake, MD
Assistant Professor of Radiology, MGH / HMS

Giles Boland, MD
Associate Professor of Radiology, MGH / HMS

Miriam Bredella, MD
Assistant Professor of Radiology, MGH / HMS

Jonathan Carlson, MD
Clinical Fellow in Medicine, MGH / HMS

Cesar Castro, MD
Instructor in Medicine, MGH / HMS

Bruce Chabner, MD - KEYNOTE Speaker
Professor of Medicine, MGH / HMS

John Chen, MD
Assistant Professor of Radiology, MGH / HMS

William Copen, MD
Instructor in Radiology, MGH / HMS

Subba Digumarthy, MD
Instructor of Radiology, MGH / HMS

Georges El-Fakhri, PhD
Associate Professor of Radiology, MGH / HMS

Jason Gaglia, MD
Instructor in Medicine, Joslin Diabetes Center / HMS

Brian Ghoshhajra, MD
Instructor of Radiology, MGH / HMS

Alexander Guimaraes, MD
Assistant Professor of Radiology, MGH / HMS

Rajiv Gupta, MD
Instructor of Radiology, MGH / HMS

Mukesh Harisinghani, MD
Associate Professor of Radiology, MGH / HMS

Gordon Harris, PhD
Professor of Radiology, MGH / HMS

Udo Hoffmann, MD
Associate Professor of Radiology, MGH / HMS

Jacob Hooker, PhD
Assistant Professor of Radiology, MGH / HMS

Mannudeep Kalra, MD
Assistant Professor Radiology, MGH / HMS

Jayashree Kalpathy-Cramer, PhD
Instructor in Radiology, MGH / HMS

Mykol Larvie, MD
Instructor in Radiology, MGH / HMS

Umar Mahmood, PhD, MD
Associate Professor of Radiology, MGH / HMS

Victorine Muse, MD
Instructor in Radiology, MGH / HMS

William Palmer, MD
Assistant Professor of Radiology, MGH / HMS

Stuart Pomerantz, MD
Instructor in Radiology, MGH / HMS

Otto Rapalino, MD
Instructor in Radiology, MGH / HMS

Javier Romero, MD
Instructor in Radiology, MGH / HMS

Bruce Rosen, PhD, MD
Professor of Radiology, MGH / HMS

Daniel Rosenthal, MD
Professor in Radiology, MGH / HMS

Martin Reuter, PhD
Instructor in Neurology, MGH / HMS

Dushyant Sahani, MD
Associate Professor of Radiology, MGH / HMS

Sanjay Saini, MD
Professor of Radiology, MGH / HMS

Anthony Samir, MD
Instructor in Radiology, MGH / HMS

Martin Torriani, MD
Assistant Professor of Radiology, MGH / HMS

Ahmed Tawakol, MD
Assistant Professor of Medicine; MGH / HMS

Lawrence Wald, MD
Associate Professor of Radiology, MGH / HMS

Ralph Weissleder, PhD, MD
Professor of Radiology, MGH / HMS
Friday April 27

**Session 1: Emerging Technologies**

12:55-1:00PM Welcome

1:00-1:25 **KEYNOTE:** Regulatory Perspective of Imaging Biomarkers as Surrogate Endpoints

- **Dwaine Rieves**
  Director, Division of MIP, U.S. FDA

1:25-1:30 Discussion and Q&A

**Martinos Center Symposium**

1:30-1:50 Multimodal Functional Brain Imaging

- **Bruce Rosen**
  Professor of Radiology HMS

1:50-2:10 Role of PET/MR in Drug Development

- **Alex Guimaraes**
  Assistant Professor of Radiology HMS

2:10-2:30 PET Radiotracers in Drug Development & Clinical Trials

- **Jacob Hooker**
  Assistant Professor of Radiology HMS

2:30-2:50 Quantitative Imaging to Assess Therapeutic Response in Tumors

- **Jayashree Kalpathy-Cramer**
  Instructor in Radiology HMS

2:50-3:10 Advanced MR Technologies

- **Larry Wald**
  Associate Professor of Radiology HMS

3:10-3:20 Discussion and Q&A

3:20-3:30 Break

**CMIR Symposium**

3:30-3:50 Overview of New Molecular Technologies

- **Ralph Weissleder**
  Professor of Radiology HMS

3:50-4:10 Signaling Inhibition in Cancer

- **Jonathan Carlson**
  Clinical Fellow in Radiology HMS

4:10-4:30 Micro-NMR in Cancer and Infectious Disease

- **Cesar Castro**
  Instructor in Radiology HMS

4:30-4:50 Imaging in Diabetes

- **Jason Gaglia**
  Instructor in Radiology HMS

4:50-5:10 Quantitative Oncologic PET-CT and PET-MR

- **Georges El Fakhri**
  Associate Professor of Radiology HMS

5:10-5:15 Discussion and Q&A

5:15-5:40 **KEYNOTE:** Imaging Biomarkers: Pharmaceutical Industry Perspective

- **Bob Tepper**
  Third Rock Ventures - Boston, MA

5:40-5:50 Discussion and Q&A

5:50 Adjourn

Saturday April 28

**Session 2: Current Practice**

8:00-8:15AM Oncology: WHO, RECIST

- **Giles Boland**
  Associate Professor of Radiology HMS

8:15-8:30 Revised Response Criteria for Malignant Lymphoma (Cheson)

- **Victorine Muse**
  Instructor in Radiology HMS

8:30-8:45 Response Assessment using PET FDG in Oncology

- **Michael Blake**
  Assistant Professor of Radiology HMS

8:45-9:00 Assessment of Advanced Cardiac Imaging in the Era of Comparative Effectiveness

- **Udo Hoffmann**
  Associate Professor of Radiology HMS

9:00-9:15 Cardiovascular Imaging Markers with Advanced Cross-sectional Imaging

- **Brian Ghoshhajra**
  Instructor in Radiology HMS
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<thead>
<tr>
<th>Time</th>
<th>Session/Activity</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>9:15-9:40</td>
<td>KEYNOTE: Imaging Biomarkers in Trials of New Targeted Therapies</td>
<td>Bruce Chabner, Professor of Medicine, HMS</td>
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<td>9:40-9:50</td>
<td>Discussion and Q&amp;A</td>
<td>John Chen, Assistant Professor of Radiology, HMS</td>
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<td>9:50-10:00</td>
<td>Break</td>
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<tr>
<td>10:00-10:15</td>
<td>Oncology: Brain Tumor Volumetrics</td>
<td>Stuart Pomerantz, Instructor in Radiology, HMS</td>
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<td>10:15-10:30</td>
<td>MR Imaging Outcome Measures in Multiple Sclerosis</td>
<td>William Copen, Instructor in Radiology, HMS</td>
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<td>10:30-10:45</td>
<td>Imaging Biomarkers in Stroke</td>
<td>Rajiv Gupta, Instructor in Radiology, HMS</td>
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<td>10:45-11:00</td>
<td>Neuroimaging in Vasospasm</td>
<td>Daniel Rosenthal, Professor of Radiology, HMS</td>
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<td>11:00-11:15</td>
<td>Non-invasive Measurement of Bone Strength</td>
<td>William Palmer, Assistant Professor of Radiology, HMS</td>
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<td>11:15-11:30</td>
<td>Imaging Biomarkers for Arthropathy</td>
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<td>11:30-11:45</td>
<td>Quantifying Fat Distribution</td>
<td>Martin Torriani, Assistant Professor of Radiology, HMS</td>
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<td>11:45-12:00</td>
<td>Discussion and Q&amp;A</td>
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<td>12:00-1:00</td>
<td>Lunch on your own</td>
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<td>1:00-1:15</td>
<td>Session 3: Advanced Imaging Techniques</td>
<td>Sanjay Saini, Moderator</td>
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<td>1:15-1:30</td>
<td>New PET Radiotracers in Oncology</td>
<td>Umar Mahmood, Associate Professor of Radiology, HMS</td>
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<td>1:30-1:45</td>
<td>PET Imaging in Neurodegenerative Disease</td>
<td>Mykol Larvie, Instructor in Radiology, HMS</td>
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<td>1:45-2:00</td>
<td>Total Radiosynthesis: A Paradigm Shift in Molecular Imaging</td>
<td>Neil Vasdev, Lecturer in Radiology, HMS</td>
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<td>2:00-2:15</td>
<td>Advanced MR Imaging Techniques in CNS Drug Development</td>
<td>Otto Rapalino, Instructor in Radiology, HMS</td>
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<td>2:15-2:30</td>
<td>Multi-modal Imaging of Atherosclerosis for Assessment of Therapeutic Efficacy</td>
<td>Ahmed Tawakol, Assistant Professor of Radiology, HMS</td>
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<td>2:30-2:45</td>
<td>MR Lymphography for Nodal Staging</td>
<td>Mukesh Harisinghani, Associate Professor of Radiology, HMS</td>
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<td>2:45-2:50</td>
<td>Functional Lung Imaging</td>
<td>Subba Digumarthy, Instructor in Radiology, HMS</td>
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<td>2:50-3:00</td>
<td>Break</td>
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<td>3:00-3:15</td>
<td>Novel MR Imaging Biomarkers for NAFLD</td>
<td>Sheela Agarwal, Clinical Fellow in Radiology, HMS</td>
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<td>3:15-3:30</td>
<td>US Elastography as an Imaging Biomarker in Chronic Liver Disease</td>
<td>Anthony Samir, Instructor in Radiology, HMS</td>
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<td>3:30-3:45</td>
<td>CT Perfusion Imaging as a Biomarker in Oncology Clinical Trials</td>
<td>Dushyant Sahani, Associate Professor of Radiology, HMS</td>
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<td>3:45-4:00</td>
<td>Dual Energy CT as a New Imaging Biomarker: Applications and Limitations</td>
<td>Mannudeep Kalra, Assistant Professor of Radiology, HMS</td>
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<td>4:00-4:15</td>
<td>Advanced Imaging Techniques in MSK</td>
<td>Miriam Bredella, Assistant Professor of Radiology, HMS</td>
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<td>4:15-4:30</td>
<td>The Spot Sign: A Novel Imaging Biomarker for Intracerebral Hemorrhage</td>
<td>Javier Romero, Instructor in Radiology, HMS</td>
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<td>4:30-4:45</td>
<td>Longitudinal Image Processing to Establish Imaging Biomarkers</td>
<td>Martin Reuter, Instructor in Radiology, HMS</td>
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<td>4:45-5:00</td>
<td>Tumor Metrix</td>
<td>Gordon Harris, Professor of Radiology, HMS</td>
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<td>5:00-5:15</td>
<td>Discussion, Q&amp;A and Wrap-Up</td>
<td>Sanjay Saini, Professor of Radiology, HMS</td>
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<td>5:15 PM</td>
<td>Adjourn</td>
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*Program changes/substitutions may be made without notice.*
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REGISTRATION INFORMATION
Physician: $500.00 (USD)
Reduced Fee for Residents, Fellows in Training, and Allied Health Professionals: $250.00 (USD)
Registration by credit card (VISA or MasterCard) can be made at: www.cme.hms.harvard.edu/courses/biomarkers. Registration by check (draft on a United States bank), please make payable to Harvard Medical School and mail with registration form to Harvard Medical School–Department of Continuing Education, PO Box 825, Boston, MA 02117-0825. Telephone or fax registration is not accepted. Registration with cash payment is not permitted. Upon receipt of your paid registration an email confirmation from the HMS-DCE office will be sent to you. Be sure to include an email address that you check frequently. Your email address is used for critical information including: registration confirmation, evaluation and certificate.

INQUIRIES
By phone 617-384-8600, Monday-Friday, 10 AM to 4 PM (EST) or by email at: hms-cme@hms.harvard.edu.

ONLINE INFORMATION
To register or view activity information online, visit: www.cme.hms.harvard.edu/courses/biomarkers. To ensure proper registration, please add the first three characters of the source code found at the bottom of this registration form.

DISCLOSURE POLICY
Harvard Medical School (HMS) adheres to all ACCME Essential Areas, Standards, and Policies. It is HMS’s policy that those who have influenced the content of a CME activity (e.g. planners, faculty, authors, reviewers and others) disclose all relevant financial relationships with commercial entities so that HMS may identify and resolve any conflicts of interest prior to the activity. These disclosures will be provided in the activity materials along with disclosure of any commercial support received for the activity. Additionally, faculty members have been instructed to disclose any limitations of data and unlabeled or investigational uses of products during their presentations.

REFUND POLICY
A handling fee of $60 is deducted for cancellation. Refund requests must be received by postal mail, email or fax one week prior to this activity. No refunds will be made thereafter.

COURSE LOCATION
All sessions for this activity will be held at Massachusetts General Hospital, O’Keeffe Auditorium, Blake 1, 55 Fruit Street, Boston, MA.

ACCOMMODATIONS /TRAVEL
Hotels within five minutes walking distance of the course are:
The Holiday Inn Boston at Beacon Hill offers preferred rates. To check availability and book a room at the special preferred rate, please visit the MGH rate website at www.hisboston.com/mgh or you may call 617-742-0461 (Mon – Fri, 8AM – 3 PM) or 800-465-4329 and ask for the Mass General Hospital rate. The current special preferred rate during the Imaging Biomarkers and Clinical Trials course dates is $189 + tax.
The Liberty Hotel also offers a “Partners Healthcare/MGH rate” based on availability. Please contact the Reservations Department at 617-224-4019.
Please do not purchase non-refundable airline ticket(s) until you have received an email from our office confirming your paid registration. For airline reservations contact the HMS Travel Desk toll free 1-877-4-HARVMD (1-877-442-7863) Monday - Friday 9 AM - 8 PM (EST). From outside the U.S., Canada and Virgin Islands, please call 617-559-3764.
Imaging Biomarkers in Clinical Trials

Current Practice & Future Trends

April 27-28, 2012

TUITION FEES

Physicians $500 (USD)

Technologists $250 (USD)

Residents/Fellows in Training $250 (USD)

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U.S. Medical School

International Medical School

Year of Graduation

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