

International Partnership for

CRITICAL MARKERS OF DISEASE

CMOD

9TH ANNUAL

Biomarkers Meeting

September 12-13, 2011

FDA Campus

10903 New Hampshire Ave

White Oak, MD

Meeting Overview

The program will provide colleagues with the opportunity to learn of clinical challenges in cardiovascular and related diseases that may be addressed with the development of biomarkers and emerging sciences such as genomics, proteomics, and imaging. Particular emphasis will be placed on biomarker development, qualification, incorporation into clinical trials, analysis, and interpretation. Included will be a number of case studies from leaders in the field, including medical and regulatory science experts from the United States, Canada and Europe.

There is no registration fee for full-time FDA and NIH, but registration is required to attend. CME credits provided.

Please contact Therese.Heinonen@mhicc.org if you are interested in attending.

CMOD Agenda

September 12, 2011 - 9:00 a.m. to 4:30 p.m.

INTRODUCTION

Welcome and Introduction

SESSION ONE - Biomarkers and Imaging Technologies: Current Needs and Priorities (Chairs: P. Libby and N. Stockbridge)

Biomarkers 101

Robert Temple, US FDA

Common Threads, Common Targets?

Peter Libby, Brigham and Women's Hospital

That Status of PM Regulations in Canada

Agnes Klein, Health Canada

Biomarker Utility in Cellular, Tissue, and Gene Therapy Product Dvpt

Steven Bauer, OCTGT/CBER, FDA

European Medicines Agency Biomarker Priorities

Pat O'Mahony, European Medicines Agency

Molecular Medicine in Ireland

Suzanne Bracken, Molecular Medicine Ireland

Application of Advanced Imaging

Robert Balaban, NHLBI, NIH

Roundtable Discussions - FACULTY

LUNCH - PROVIDED

SESSION TWO - Developing Biomarkers for Generation X, Y and Z (Chairs: S. Skarlatos and J-C Tardif)

Molecular Imaging at NIH

Simhan Danthi, NHLBI, NIH

Biomarkers for Heart Failure

Peter Liu, University of Toronto

Stem Cells, Genes and Devices in Cardiac Repair

Doris Taylor, University of Minnesota

Protein-Based Technologies in Cancer Research

Lance Liotta, George Mason University

Integrating Blood-Based and Imaging Markers in Clinical Trials

Jean-Claude Tardif, Montreal Heart Institute

Standardizing Imaging in Clinical Trials

Allen J. Taylor, Georgetown University

Roundtable Discussions - FACULTY

September 13, 2011 - 9:00 a.m. to 4:30 p.m.

SESSION THREE - Regulatory Innovation and Collaboration (Chairs: Doug Throckmorton and Agnes Klein)

Biomarker Qualification Project

Marc Walton, US FDA

Renal Biomarkers

Melanie Blank, US FDA

Cystatin C for Measuring GFR

Andrew Levey, Tufts Med Center

Thorough BP Project

Robert Fiorentino, US FDA

Pharmacogenomics

Issam Zineh, US FDA

The Critical Path

Douglas Throckmorton, US FDA

Roundtable Discussions - FACULTY

LUNCH - PROVIDED

SESSION FOUR - Emerging Biomarker Challenges Case Study: HDL-Targeted Therapies (Chairs: Jean-Claude Tardif and Alan Remaley)

A Mechanistic Understanding of HDL Properties

Alan Remaley, NHLBI, NIH

HDL-Targeted Therapies

Bryan Brewer, Medstar Research

Completed and Ongoing Clinical Trials - CETP, HDL Infusion

Jean-Claude Tardif, Montreal Heart Institute

ACCORD and AIM-HIGH

Yves Rosenberg, NHLBI, NIH

HDL as Marker of Disease

Robert Rosenson, Mt. Sinai Medical Center

Regulatory Decision Making

Eric Colman, US FDA

Roundtable Discussions - FACULTY

Faculty

Robert Balaban, PhD, Director, Laboratory of Cardiac Energetics, NHLBI, NIH

Steven R. Bauer, PhD, FDA, Center for Biologics Evaluation & Research, OCTGT

Melanie Blank, MD, Medical Reviewer, Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research, United States Food and Drug Administration (FDA)

Suzanne Bracken, PhD, Program Officer in Translational Research, Molecular Medicine Ireland

H Bryan Brewer, MD, Medstar Research Institute

Eric Colman, MD, Deputy Director, Division of Metabolism and Endocrine, Center for Drug Evaluation and Research, FDA

Simhan Danthi, PhD, , NHLBI, NIH

Robert Fiorentino, MD, Medical Reviewer, Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research, United States FDA

Agnes Klein, MD, Director, Center for Evaluation of Radiopharmaceuticals and Biotherapeutics, Health Canada

Andrew Levey, MD, Chief, Division of Nephrology, Tufts Medical Center

Peter Libby, MD, Mallinckrodt Professor of Medicine, Harvard Medical School, Chief of Cardiovascular Medicine, Brigham & Women's Hospital

Lance Liotta, MD, PhD, The Center for Applied Proteomics and Molecular Medicine, George Mason University

Peter Liu, MD, PhD, Professor of Medicine, University of Toronto

Pat O'Mahony, DMV, European Medicines Agency Management Board & Irish Medicines Board

Alan Remaley, MD, PhD, Laboratory of Lipoprotein Metabolism, NHLBI, NIH

Yves Rosenberg, MD, MPH, Acting Branch Chief, Atherothrombosis and Coronary Artery Disease Branch, NHLBI, NIH

Robert Rosenson, MD, Professor of Medicine, Mt. Sinai School of Medicine

Sonia Skarlatos, MD, Deputy Director, Division of Cardiovascular Sciences, National Heart Lung and Blood Institute, National Institutes of Health

Norman Stockbridge, MD, Director, Division of Cardiovascular and Renal Products, Center for Drug Evaluation and Research, FDA

Jean-Claude Tardif, MD, Director, Research Center Montreal Heart Institute, Professor of Medicine, University of Montreal

Allen J. Taylor MD, Professor of Medicine, Georgetown University, Department of Medicine, Washington Hospital Center

Doris Taylor, PhD, Director of the Center for Cardiovascular Repair, Stem Cell Institute, University of Minnesota

Robert Temple, MD, Deputy Director of Clinical Science, Center for Drug Evaluation and Research, United States FDA

Douglas Throckmorton, MD, Deputy Center Director, Center for Drug Evaluation and Research, United States FDA

Marc Walton, MD, PhD, Associate Director, Office of Translational Sciences, Center for Drug Evaluation and Research, United States FDA

Issam Zineh, PharmD, MPH, Associate Director for Genomics, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, United States FDA

Important Information

Address

10903 New Hampshire Avenue
Silver Spring, MD 20993

Driving Directions, Parking and Public Transportation

*Carpooling or use of public transportation is strongly suggested

Driving Directions

From the Capital Beltway I-495, take Exit 28A (New Hampshire Avenue North). Enter the campus by turning right onto Michelson Road. (Michelson road is located at the intersection of New Hampshire Avenue and Northwest Drive).

Visitor Parking

Proceed and make the first right turn. Make another right at the stop sign and enter the visitor parking lot on your left (you will be required to show government-issued identification to enter). Building 21 is directly in front of the North parking lot. Building 22 is the main entrance building on the left side of building 21, and directly in front of the garage.

Metro Rail Directions

Travelers from the Reagan National Airport have the option of using the D.C. area's Metro Rail System (see the Metro System Map). Please refer to the Washington Metropolitan Area Transit Authority's web site for public transportation information: www.wmata.com. The closest Metro Rail station is Silver Spring (www.wmata.com/rail/station_detail.cfm?station_id=31) which is on the Red Line. This Metro station is approximately eight miles from the White Oak Campus. From National Airport, riders may take the Blue Line to the Red Line (transfer at Metro Center) or the Yellow Line to the Red Line (transfer at Gallery Place). From the Silver Spring Station, take a taxi to the building or see information below for "Ride-On Bus" (operated by Montgomery County).

Ride-On Bus

Ride-On Bus route 22 operates between the Silver Spring Metro Station and the White Oak Campus: <http://www.montgomerycountymd.gov/tsvtmpl.asp?url=/content/dot/transit/routesandschedules/allroutes/route022.asp>

Security

All participants should enter Building 22 and go through the routine security check procedures for building entrance. Government issued identification (i.e., drivers license, passport) will be required.

Cameras or other recording equipment are not permitted through security. FDA personnel will be available to escort you from the security checkpoint to the workshop.

Nearby Hotels

Hilton Washington D.C. / Silver Spring

Phone: (301) 589-5200

Silver Spring Courtyard North (Marriott)

Phone: (301) 680-8500

Silver Spring Residence Inn (Marriott)

Phone: (301) 572-2322