

**ANNOUNCING THE 6TH ANNUAL
CARDIOVASCULAR BIOMARKERS
AND SURROGATE ENDPOINTS SYMPOSIUM
BUILDING A FRAMEWORK FOR BIOMARKER APPLICATION**

SEPTEMBER 10-12, 2008

BETHESDA, MD

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Co-chaired by:

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Chief, Cardiovascular Medicine
Brigham and Women's Hospital

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PROGRAM SPONSORS:



Montreal Heart Institute
Coordinating Center



**This meeting has been organized in collaboration with
representatives from:**

National Institutes of Health
United States Food and Drug Administration
Centers for Disease Control and Prevention
Health Canada
European Medicines Agency
US HHS Agency for Healthcare Research and Quality
Public and private research institutions

PROGRAM FACULTY

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**6th Annual
Cardiovascular Biomarkers and Surrogate Endpoints
Symposium
September 10-12, 2008
Bethesda, Maryland**

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Abbreviated Agenda

September 10, 2008

6:00pm – 10:00pm

HDL CONTROVERSIES

Session Leaders:

Philip Barter, M.D., University of Sydney
H. Bryan Brewer, M.D., MedStar Research Institute
Jay Heinecke, M.D., University of Washington

September 11, 2008

8:00am – 11:30 am

PRODUCT DEVELOPMENT AND EVIDENTIARY STANDARDS

Session Leaders:

Wolfgang Koenig, M.D., University of Ulm Medical Center
Jean-Jacques Garaud, M.D., F. Hoffmann-La Roche Ltd.
Robert Balaban, M.D., National Institutes of Health

12:00pm—3:00pm

IMAGING WORKSHOP

Session Leaders:

Douglas Throckmorton, M.D., US Food and Drug Administration
Jean-Claude Tardif, M.D., Montreal Heart Institute

3:00pm – 6:30pm

SAFETY BIOMARKERS

Session Leaders:

Norman Stockbridge, M.D., US Food and Drug Administration
Eric P. Brass, M.D., Ph.D., Harbor-UCLA Medical Center
Jean Rouleau, M.D., University of Montreal

7:00pm – 10:00pm

SURROGATES FOR REGULATORY APPROVAL

Session Leaders:

Mary Parks, M.D., US Food and Drug Administration
David Waters, M.D., University of California, San Francisco
Allen Taylor, M.D., Walter Reed Army Medical Center

September 12, 2008

8:00am – 11:30pm

EVIDENTIARY STANDARDS FOR MARKER QUALIFICATION

Session Leaders:

Federico Goodsaid, M.D., US Food and Drug Administration
Christopher Cannon, M.D., Brigham and Women's Hospital
Christopher O'Donnell, M.D., NHLBI, National Institutes of Health

12:00pm – 3:30pm

BIOMARKERS IN CLINICAL PRACTICE AND PUBLIC HEALTH

Session Leaders:

George Mensah, M.D., Centers for Disease Control and Prevention
James De Lemos, M.D., U of Texas-Southwestern Medical School
Gurvaneet Randhawa, M.D., US HHS AHRQ

CME:

This educational activity has been approved for CME study credits by the Division of Continuing Professional Development, Faculty of Medicine, Université de Montréal (Canada) for a maximum of 20 hours. The Division of CPD of the Faculty of Medicine of the Université de Montréal is fully accredited by the Committee on Accreditation of CME (CACME), by Le Collège des médecins du Québec (CMQ) and, by substantial equivalence, by the Accreditation Council for CME (ACCME).

Objectives:

- Examine surrogate endpoints and controversies regarding their use in cardiovascular and diabetes drug approvals
- Review the latest biomarker and imaging technology data from recently completed clinical trials
- Identify best practices for biomarker assessment and validation
- Build a framework for biomarker application in research, development, clinical practice and public health

List of Topics:

Evaluating Biomarkers in Light of New Clinical Trial Data
Recent Data on HbA1c, LDL-C, HDL-C, CRP, and other markers
Translating Science into Clinical Applications
Population Screening and Risk Stratification
Biomarker – Guided Therapeutic Targets
Established and Emerging In-vitro Biomarkers and Diagnostics
Established and Emerging Imaging Technologies
Diabetes, Obesity and Metabolic Syndrome
Molecular Imaging
Proteomics and Genomics
Lipoproteins, Inflammation, and Other Related Risk Factors
Biomarker Economics
Evidentiary Standards and Validation
Drug/Diagnostic Development Strategies
Biomarkers in Risk and Therapeutic Assessment
Biomarkers as Safety Surrogates
Atherothrombosis, Hypertension and Heart Failure
Use of Biomarkers and Surrogates for Regulatory Decision-Making
Cardiovascular Markers in Food Safety and Nutrition
Biomarkers in Model-Based Drug Development
NIH/NHLBI Biomarker Initiatives
Statistical Considerations in Biomarker Evaluation
Application of Systems Biology to Biomarker Sciences
Biomarker Qualification in Regulatory Science
Application of CV Markers in Clinical Practice and Public Health
Regulatory Considerations for Soluble and Imaging Biomarker Applications
Pathogenesis of Atherothrombotic Disease and Biomarker Identification
Biospecimens — Best practices

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