

**2007 CARDIOVASCULAR BIOMARKERS AND SURROGATE ENDPOINTS
SYMPOSIUM
BETHESDA, MARYLAND, USA**

**AGENDA
October 17, 2007**

7:00am – Registration open – Salon D Foyer

7:30am – 8:30am Complimentary Continental Breakfast – Salon D Foyer

8:00am – 8:20am

Introduction

Dr. Jean-Claude Tardif and Dr. Therese Heinonen, Montreal Heart Institute

8:20am – 8:40am

Pathogenesis of Atherothrombotic Disease and Biomarker Identification

Dr. Peter Libby, Brigham and Women's Hospital

8:40am – 9:00am

Applications of Systems Biology to Biomarkers

Dr. Robert Balaban, National Heart, Lung, and Blood Institute (NHLBI), National Institute of Health (NIH)

9:00am – 9:20am

Indicators of Risk in Patients with Type 2 Diabetes

Dr. Alan Garber, Baylor College of Medicine

9:20am – 9:40am

Novel Biomarkers of Arrhythmia and Sudden Death

Dr. Christine Albert, Brigham and Women's Hospital

9:40am – 10:00am

Novel Biomarkers in Heart Failure

Dr. James DeLemos, University of Texas Southwestern Medical School

10:00am – 10:30am **BREAK**

10:30am – 10:50am

The Genomics of Inflammation

Dr. John Rioux, Montreal Heart Institute

10:50am – 11:10am

Is CRP a Validated Biomarker of CV Disease?

Dr. Paul Ridker, Brigham and Women's Hospital

11:10am – 11:30am

Novel Biomarker Approaches for CAD

Dr. Jean-Claude Tardif, Montreal Heart Institute

11:30am – 11:50am

The Development of Novel In Vitro Diagnostics

Dr. Elizabeth Mansfield, Office of In Vitro Diagnostic Device Evaluation, CDRF, US FDA

11:50am - 12:10pm

The Critical Path Initiative and Priority List

Dr. Douglas Throckmorton, Center for Drug Evaluation and Research (CDER), US FDA

12:10pm – 1:00pm

Questions and Answers – Faculty and PANEL DISCUSSIONS

1:00pm – 2:00pm

COMPLIMENTARY LUNCH BUFFET – SALON B/C

1:30pm – 5:00pm PARALLEL BREAKOUT SESSIONS

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1:30pm – 5:00PM
Parallel Breakout Sessions**

<p>Session 1 – Cardiovascular Imaging – Salon D 1:30pm – 5:00pm</p> <p>Co-chairs: Dr. Jean-Claude Tardif, Montreal Heart Institute Dr. Zahi Fayad, Mount Sinai School of Medicine</p>	<p>Session 2 – Lipids and Inflammation – Salon A 1:30pm – 5:00pm</p> <p>Co-chairs: Dr. Peter Libby, Brigham and Women’s Hospital Dr. Ernst Schaefer, Tufts University</p>
<p>PRESENTATIONS</p> <p>Imaging Overview Dr. Jean-Claude Tardif, Montreal Heart Institute</p> <p>Magnetic Resonance Imaging and Computed Tomography Dr. Zahi Fayad, Mount Sinai School of Medicine</p> <p>Ultrasonography Dr. Allen Taylor, Walter Reed Army Medical Center</p> <p>Arterial Tonometry Dr. Gary Mitchell, Cardiovascular Engineering Inc.</p> <p>3-D Carotid Ultrasound Dr. J. David Spence, Robarts Research Institute</p> <p>Nuclear Imaging Dr. Rory Hachamovitch, University of Southern California</p> <p>Micro-Ultrasound Dr. Tom Little, VisualSonics</p>	<p>PRESENTATIONS</p> <p>HDL Overview Dr. Ernst Schaefer, Tufts University</p> <p>Novartis-Framingham HDL Projects Dr. Seigo Izumo, Cardiovascular Research, Novartis</p> <p>Traditional Lipid Biomarkers Dr. Jean Davignon, University of Montreal</p> <p>Change in Inflammation Markers in the Postprandial State Dr. W. Virgil Brown, Emory University</p> <p>Endothelial Progenitor Cells Dr. Colin Berry, National Heart, Lung and Blood Institute, NIH</p> <p>ApoB, LDL, and Particle Size Dr. Russell Warnick, Berkeley Heart Lab</p>
<p>Expert Panel:</p> <p>Dr. Norman Stockbridge, Division of Cardio-Renal, CDER, US FDA</p> <p>Dr. Robert Balaban, National Heart, Lung, and Blood Institute, NIH</p> <p>Dr. Douglas Throckmorton, CDER, US FDA</p> <p>Dr. Bram Zuckerman, Division of CV Devices, CDRH, US FDA</p> <p>Dr. Michael Klimas, Imaging, Merck & Co.</p> <p>Dr. James Zhang, Siemens Molecular Imaging</p> <p>Dr. Donald Black, Research and Development, GE Healthcare</p> <p>Dr. Joel Raichlen, Clinical Research, AstraZeneca</p>	<p>Expert Panel:</p> <p>Dr. Mary Parks, Division of Metabolism and Endocrine, CDER, US FDA</p> <p>Dr. Alan Garber, Baylor College of Medicine</p> <p>Dr. James De Lemos, University of Texas-Southwestern Medical School</p> <p>Dr. Paul Ridker, Brigham and Women’s Hospital</p> <p>Dr. Michael Perelman, Schering-Plough Research Institute</p> <p>Dr. Bill Sasiela, Aegerion Pharmaceuticals</p>

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8:00am – 8:20am

Cardiovascular Molecular Imaging

Dr. Ralph Weissleder, Harvard School of Medicine

8:20am – 8:40am

Biomarker Qualification for Specific Applications

Dr. John Wagner, Clinical Pharmacology, Merck & Co.

8:40am – 9:00am

Markers of CV Disease: Biomarkers in Clinical Practice and Public Health

Dr. George Mensah, Centers for Disease Control and Prevention

9:00am – 9:20am

Biomarkers in Model-Based Drug Development

Dr. Robert Powell, Office of Clinical Pharmacology, CDER, US FDA

9:20am – 9:40am

The Balance Between Safety and Efficacy: Biomarkers and Drug Safety

Dr. Eric Brass, Harbor-UCLA Medical Center

9:40am – 10:00am

The Cardiac Safety Research Consortium and Markers in Cardio-Renal

Dr. Norman Stockbridge, Division of Cardio-Renal Drug Products, CDER, US FDA

10:00am – 10:30am **BREAK**

10:30am – 10:50am

NIH Cardiovascular Genomic Initiatives

Dr. Christopher O'Donnell, Framingham Heart Study, NHLBI, NIH

10:50am – 11:10am

NHLBI Biomarker Initiatives

Dr. Daniel Levy, Framingham Heart Study, Center for Population Studies, NHLBI, NIH

11:10am – 11:30am

Biomarker Challenges and Opportunities

Dr. Steven Gutman, Office of In Vitro Diagnostic Devices Eval. and Safety, CDER, US FDA

11:30am – 11:50am

Diagnostic Challenges and New Directions

Dr. Jonathan Allis, Imaging Technology, GE Healthcare

11:50am – 12:10pm

Economic Evaluation of Biomarkers

Dr. David Meltzer, University of Chicago

12:10pm – 1:00pm

Questions and Answers – Faculty and PANEL DISCUSSIONS

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<p>Session 1 – Genomics, Proteomics, and Metabolomics – Salon A</p> <p>1:30pm – 5:00pm</p> <p>Co-chairs: Dr. Christopher O'Donnell, NHLBI,NIH Dr. Felix Frueh, Office of Clinical Pharmacology, CDER, US FDA</p>	<p>Session 1 – Trial Design, Drug/Diagnostic Development, Case Studies – Salon D</p> <p>1:30pm – 5:00pm</p> <p>Co-chairs: Dr. Peter Libby, Brigham and Women's Hospital Dr. Jean-Claude Tardif, Montreal Heart Institute</p>
<p>PRESENTATIONS</p> <p>Pharmacogenomics Dr. Michael Phillips, Genome Quebec</p> <p>Collaborative Models for Biomarker Development Dr. Vincent Mooser, Clinical Pharmacology and Disc. Med, GSK</p> <p>Examining the Plasma Microparticle Proteome for Biomarker Disc. Dr. David Smalley, University of Virginia</p> <p>Biomarker Development Dr. Bruce McManus, University of British Columbia</p>	<p>PRESENTATIONS</p> <p>Advanced Trial Design Dr. Robert Califf, Duke Translational Medicine Institute</p> <p>Drug/Diagnostic Development Strategies Dr. Donald Black, Research and Development, GE Healthcare</p> <p>Collaborative Model for Enhanced Drug Discovery and Dvpt. Dr. Giora Feuerstein, Translational Medicine, Wyeth</p> <p>Case Studies Dr. Marc Pfeffer, Brigham and Women's Hospital</p>
<p>Expert Panel:</p> <p>Dr. John Rioux, Montreal Heart Institute</p> <p>Dr. Federico Goodsaid, Office of Clinical Pharmacology, CDER, US FDA</p> <p>Dr. George Mensah, Centers for Disease Control and Prevention</p> <p>Dr. Daniel Levy, NHLBI, NIH</p> <p>Dr. Eric Brass, Harbor-UCLA Medical Center</p> <p>Dr. Jean-Jacques Garaud, Drug Development, Hoffmann-La Roche</p> <p>Dr. Seigo Izumo, Cardiovascular Research, Novartis</p>	<p>Expert Panel:</p> <p>Dr. Mary Parks, Division of Met. and Endocrine, CDER, US FDA</p> <p>Dr. David Waters, University of California</p> <p>Dr. Douglas Throckmorton, CDER, US FDA</p> <p>Dr. David Orloff, Medpace</p> <p>Dr. Michele Mercuri, Novartis</p> <p>Dr. Amy Rudolph, Pfizer</p> <p>Dr. Gurvaneet Randhawa, Agency of Healthcare Res. and Quality</p> <p>Dr. Joao Lima, Johns Hopkins University</p>

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October 19, 2007**

7:00am – Registration open – Salon D Foyer

7:30am – 8:30am Complimentary Continental Breakfast – Salon D Foyer

8:00am – 8:20

Cardiovascular Biomarkers – Defining the Need

Dr. David Waters, University of California

8:20am – 8:40am

The Biomarker Consortium Update

Dr. Daniel Schultz, Center for Devices and Radiological Health, US FDA

8:40am – 9:00am

Drug Development Challenges

Dr. Jean-Jacques Garaud, Drug Development, F. Hoffmann-La Roche

9:00am – 9:20am

Challenges for Co-development of New Medical Products: A Regulatory Perspective

Dr. Felix Frueh, Office of Clinical Pharmacology, CDER, US FDA

9:20am – 9:40am

Regulatory Considerations and Nutritional Labeling

Dr. Paula Trumbo, Center for Food Safety and Applied Nutrition, US FDA

9:40am – 10:00am

Biomarkers in Cardiovascular Device Development

Dr. Bram Zuckerman, Office of Device Evaluation, Center for Devices and Rad. Health, US FDA

10:00am – 10:20am

Biomarkers in FDA Regulatory Science – Metabolism and Endocrine

Dr. Mary Parks, Division of Metabolism and Endocrine Products, CDER, US FDA

10:20am – 10:40am

Biomarker Applications in Health Canada – Radiopharmaceuticals and Biotherapeutics

Dr. Agnes Klein, Center for Eval. of Radiopharmaceuticals and Biotherapeutics, Health Canada

10:40am – 11:00am

Biomarkers - A Third Party Payer's Considerations

Dr. Naomi Aronson, Technology Evaluation Center, Blue Cross and Blue Shield Association

11:00am – 11:20am

The European Perspective on Biomarkers and Surrogates

Dr. Eric Abadie, Therapeutics Evaluation, AFSSAPS, European Medicines Agency (EMA)

11:20am – 11:40am

Biomarker Qualification in FDA Regulatory Science

Dr. Federico Goodsaid, Office of Clinical Pharmacology, CDER, US FDA

11:40am – 12:10pm

FDA Pilot Process for Biomarker Qualification

Dr. Federico Goodsaid

12:10pm – 1:00pm

Questions and Answers/Prioritizing Biomarker Needs and Future Collaborations

Faculty

PROGRAM ADJOURNS