

2008 Symposium Agenda

BUILDING A FRAMEWORK FOR BIOMARKER APPLICATION September 10—12, 2008 Bethesda, MD

Agenda:

September 10, 2008

6:00 – 6:30 PM **Dinner and Opening Remarks (Jean-Claude Tardif/Peter Libby)**

6:30 – 9:30 PM **Session 1 – 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

6:30 – 7:00 PM **HDL Overview and Recent Trials**
Philip Barter, M.D., University of Sydney

7:00 – 7:30 PM **HDL Mimetics**
H. Bryan Brewer, M.D., Medstar Research Institute

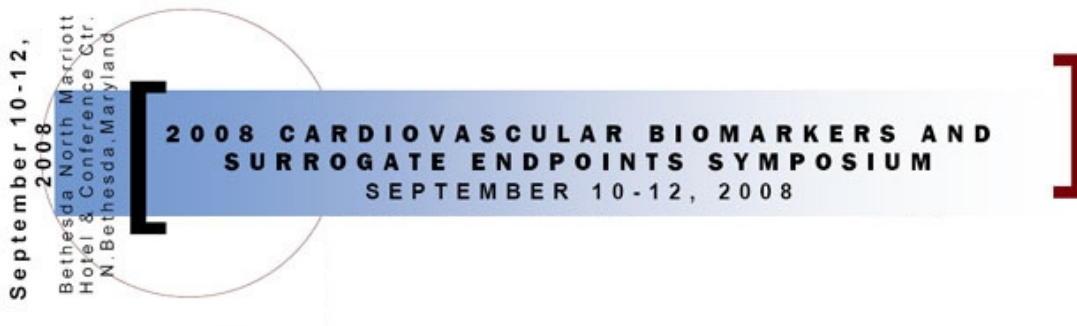
7:30 – 8:00 PM **Anti-inflammatory Properties of HDL**
Kerry-Anne Rye, Ph.D., The Heart Research Institute

8:00 – 8:30 PM **When Good Cholesterol Goes Bad**
Jay Heinecke, M.D., University of Washington

8:30 – 9:00 PM **A Mechanistic Understanding of the Anti-Atherogenic Properties of HDL: Occam's razor revisited**
Alan Tall, M.D., Columbia University

9:00 – 9:30 PM **Panel Discussion**

David Orloff, M.D., Medpace Inc.
Christie Ballantyne, M.D., Baylor College of Medicine
Carl Sparrow, Ph.D., Merck Research Laboratories
Alan Tall, M.D., Columbia University
Philip Barter, M.D., University of Sydney
H. Bryan Brewer, M.D., Medstar Research Institute
Jay Heinecke, M.D., University of Washington
Kerry-Anne Rye, M.D., The Heart Research Institute
Jean-Claude Tardif, M.D., Montreal Heart Institute
Peter Libby, M.D., Brigham and Women's Hospital



September 11, 2008

- 8:00 – 8:20 AM **Opening Remarks (Jean-Claude Tardif/Peter Libby)**
- 8:20 – 11:30 AM **Session 2 – 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., NIH, NHLBI
- 8:20 – 8:45 AM **Systems Biology Approach to ID New Targets and Markers**
Robert Balaban, M.D., NIH, NHLBI
- 8:45 – 9:10 AM **Case Studies – Type II Diabetes**
Jacques Mizrahi, M.D., F. Hoffmann-La Roche Ltd.
- 9:10 – 9:35 AM **Product Development – Balancing Evidence and Risk in Decision-Making**
Jean-Jacques Garaud, M.D., F. Hoffmann-La Roche Ltd.
- 9:35 – 10:00 AM **Biomarkers in Drug Development and Evaluation**
David Orloff, M.D., MedPace Inc.
- 10:00 – 10:20 AM **BREAK**
- 10:20 – 10:40 AM **Biomarkers in Device Development and Evaluation**
Bram Zuckerman, M.D., US FDA, CDRH
- 10:40 – 11:00 AM **Case Studies**
Wolfgang Koenig, M.D., University of Ulm Medical Center
- 11:00 – 11:30 AM **Panel Discussion**
- Elizabeth Mansfield, M.D., US FDA CDRH*
Michael Perelman, M.D., Schering-Plough
Benjamin Eloff, Ph.D., US FDA Office of the Commissioner
Jean-Claude Tardif, M.D., Montreal Heart Institute
Peter Libby, M.D., Brigham and Women's Hospital
Wolfgang Koenig, M.D., University of Ulm Medical Center
Bram Zuckerman, M.D., US FDA CDRH
Jean-Jacques Garaud, M.D., F. Hoffmann-La Roche
Jacques Mizrahi, M.D., F. Hoffmann-La Roche
Robert Balaban, M.D., NIH, NHLBI

11:30 – 12:00 PM

LUNCH

12:00 – 12:30 PM

Session 3 – SPECIAL IMAGING WORKSHOP

CENTRAL IMAGE ANALYSIS – OPTIMIZING PRACTICES AND PROCEDURES

Session Leaders:

*Jean-Claude Tardif, M.D., Montreal Heart Institute
Douglas Throckmorton, M.D., US FDA, CDER*

12:00 – 12:25 PM

Regulatory Considerations in Central Image Analysis

Dwaine Rieves, M.D., US FDA, CDER

12:25 – 12:50 PM

Regulatory Considerations in Central Image Analysis

Brandon Gallas, Ph.D., US FDA CDRH

12:50 – 1:05 PM

Central Image Analysis in An Academic Core Laboratory Setting

Jean-Claude Tardif, M.D., Montreal Heart Institute.

1:05 – 1:20 PM

Central Imaging Issues in the Development of Diagnostic Agents

Jonathan Allis, M.D., GE Healthcare.

1:20 – 1:40 PM

BREAK

1:40 – 1:50 PM

The Qualification of Imaging Surrogate Criteria

George Mills, M.D., Perceptive Informatics

1:50 – 2:15 PM

**The Quality Requirements for Successful Imaging in Clinical Trials:
Standardization of Imaging at Clinical Sites & Harmonization of Imaging
Across Multicenter Clinical Trials**

George Mills, M.D., Perceptive Informatics

2:15 – 2:45 PM

Panel Discussion

Joao Lima, M.D., Johns Hopkins University
Zahi Fayad, Ph.D., Mount Sinai
Marcelo Di Carli, M.D., Brigham and Women's Hospital
Pamela Douglas, M.D., Duke University
Eric Stroes, M.D., Academic Medical Center
Joel Raichlen, M.D., Astra-Zeneca
Norman Stockbridge, M.D., US FDA, CDER
Douglas Throckmorton, M.D., US FDA, CDER
Dwaine Rieves, M.D., US FDA, CDER
Robert Balaban, M.D., NIH, NHLBI
Jean-Claude Tardif, M.D., Montreal Heart Institute
Jonathan Allis, M.D., GE Healthcare
Brandon Gallas, Ph.D., US FDA, CDRH
George Mills, M.D., Perceptive Informatics

3:00 – 6:00 PM

Session 4 – SAFETY BIOMARKERS

Session Leaders:

*Norman Stockbridge, M.D., US FDA, CDER
Eric P. Brass, M.D., Ph.D., Harbor-UCLA Medical Center
Jean Rouleau, M.D., University of Montreal*

3:00 – 3:25 PM

Proteomics/RNA Expression Profiling for Skeletal Muscle

Eric P. Brass, M.D., Ph.D., Harbor-UCLA Medical Center

3:25 – 3:50 PM

Differentiating Biomarkers for Drug-Induced Liver Injury

Roger Ulrich, Ph.D., Calistoga Pharmaceuticals

3:50 – 4:15 PM

Markers of Renal Toxicity

Federico Goodsaid, M.D., US FDA, CDER.

4:15 – 4:30

BREAK

4:30 – 4:55 PM

Biomarkers and Thrombosis

James DeLemos, M.D., University of Texas - Southwestern Medical School

4:55 – 5:20 PM

Educating People About the Risk/Benefit Decision

Jeff Leiden, M.D., Ph.D., Clarus Ventures

5:20 – 5:50 PM

Panel Discussion

*Jean Rouleau, M.D., University of Montreal
Philip Sager, M.D., CardioDx, Inc.
Amy Rudolph, Ph.D., Pfizer, Inc.
Norman Stockbridge, M.D., US FDA, CDER
Eric Brass, M.D., Ph.D., Harbor-UCLA Medical Center
Peter Libby, M.D., Brigham and Women's Hospital
Jean-Claude Tardif, M.D., Montreal Heart Institute
Roger Ulrich, Ph.D., Calistoga Pharmaceuticals
Federico Goodsaid, M.D., US FDA, CDER
Jeff Leiden, M.D., Clarus Ventures
Bram Zuckerman, M.D., US FDA, CDRH
James DeLemos, M.D., University of Texas – Southwestern Medical School*

7:00 – 10:00 PM

**Session 5 – SURROGATES FOR REGULATORY APPROVAL
“A 360 Degree Perspective”**

Session Leaders:

*Mary Parks, M.D., US FDA, CDER
David Waters, M.D., University of California, San Francisco
Allen Taylor, M.D., Walter Reed Army Medical Center*

7:00 – 7:10 PM

Introductory Remarks

David Waters, M.D., University of California, San Francisco

7:10 – 8:10 PM

FDA Case Studies (LDL-C, HDL-C, Glucose, Imaging)

*Mary Parks, M.D., US FDA, CDER
Hylton Joffe, M.D., US FDA, CDER
Eric Colman, M.D. US FDA, CDER*

8:10 – 9:00 PM

Clinicians’ Perspectives – Biomarker Utility and Limitations

*Allen Taylor, M.D., Walter Reed Army Medical Center
Lawrence Leiter, M.D., St. Michael’s Hospital, Toronto
Paul Ridker, M.D., Brigham and Women’s Hospital*

9:00 – 9:15 PM

How Does Health Canada View the Risk/Rewards of Surrogacy?

Agnes Klein, M.D., Health Canada

9:15 – 9:30 PM

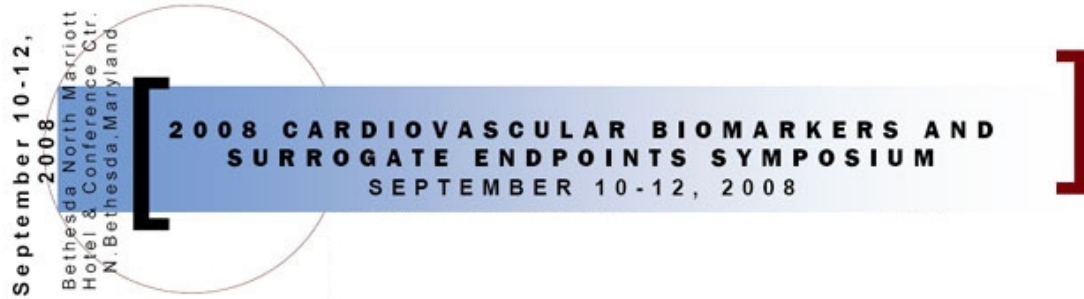
FDA Policy on Surrogates for Regulatory Approval

Robert Temple, M.D., US FDA Office of Medical Policy

9:30 – 10:00 PM

Panel Discussion

*Mary Parks, M.D., US FDA, CDER
David Waters, M.D., University of California, San Francisco
Allen Taylor, M.D., Walter Reed Army Medical Center
Peter Libby, M.D., Brigham and Women’s Hospital
Jean-Claude Tardif, M.D., Montreal Heart Institute
Robert Temple, M.D., US FDA, Office of Medical Policy
Agnes Klein, M.D., Health Canada
Paul Ridker, M.D., Brigham and Women’s Hospital
Lawrence Leiter, M.D., St. Michael’s Hospital, Toronto
Eric Coleman, M.D., US FDA, CDER
Hylton Joffe, M. D., US FDA, CDER*



September 12, 2008

- 8:00 – 8:10 AM **Opening Remarks (Jean-Claude Tardif/Peter Libby)**
- 8:10 – 11:15 AM **Session 6 – PRODUCT DEVELOPMENT AND EVIDENTIARY STANDARDS**
- Session Leaders:** *Federico Goodsaid, M.D., US FDA, CDER*
 Christopher Cannon, M.D., Brigham and Women's Hospital
 Christopher O'Donnell, M.D., NIH, NHLBI
- 8:10 – 8:30 AM **Getting Biomarkers from There to Here: Understanding Test Performance**
 Elizabeth Mansfield, M.D., US FDA, CDRH
- 8:30 – 8:50 AM **Biospecimens Best Practices – What are they and why do we need them?**
 Carolyn Compton, M.D., Ph.D., NIH, National Cancer Institute
- 8:50 – 9:10 AM **Imaging and Analysis Methods**
 David Brown, Ph.D., US FDA, CDRH
- 9:10 – 9:30 AM **Statistical Considerations**
 Gregory Campbell, Ph.D., US FDA, CDRH
- 9:30 – 9:45 AM **BREAK**
- 9:45 – 10:05 AM **Non-Clinical Evidentiary Standards**
 Patricia Harlow, Ph.D., US FDA, CDER
- 10:05 – 10:25 AM **Biomarker Data – From Observational Studies to Clinical Trials**
 Christopher O'Donnell, M.D., NIH, NHLBI
- 10:25 – 10:45 AM **Biomarker Qualification Project**
 Federico Goodsaid, M.D., US FDA, CDER
- 10:45 – 11:15 AM **Panel Discussion**
- Michael Davidson, M.D., University of Chicago*
Chris Cannon, M.D., Brigham and Women's Hospital
Giora Feuerstein, M.D., Wyeth Research
Federico Goodsaid, M.D., US FDA, CDER
Christopher O'Donnell, M.D., NIH, NHLBI
Peter Libby, M.D., Brigham and Women's Hospital
Jean-Claude Tardif, M.D., Montreal Heart Institute
Elizabeth Mansfield, M.D., US FDA, CDRH
Carolyn Compton, M.D., Ph.D., NIH, NCI
David Brown, Ph.D., US FDA, CDER

*Greg Campbell, Ph.D., US FDA, CDER
Paula Trumbo, Ph.D., US FDA, CFSAN
Patricia Harlow, Ph.D., US FDA, CDER*

10:45 – 11:15 AM

BREAK

11:15 – 2:00 PM

**Session 7 – BIOMARKERS IN CLINICAL PRACTICE AND PUBLIC HEALTH
(WITH WORKING LUNCH)**

Session Leaders:

*George Mensah, M.D., Centers for Disease Control and Prevention
James De Lemos, M.D., University of Texas – Southwestern Medical School
Gurvaneet Randhawa, M.D., US Agency for Healthcare Research and Quality*

11:15 – 11:30 AM

Mapping the Translation Process

Gurvaneet Randhawa, M.D., US AHRQ

11:30 – 11:50 AM

Challenges in Translating the Science

George Mensah, M.D., CDC

11:50 – 12:10 PM

Biomarkers in Population Screening and Surveillance

James De Lemos, M.D., University of Texas – Southwestern Medical School

12:10 – 12:30 PM

Individualized and Personalized Healthcare

Felix Frueh, Ph.D., Medco Health Solutions Inc.

12:30 – 12:50 PM

Economic Considerations

Mark Grant, M.D., Blue Cross and Blue Shield

12:50 – 1:30 PM

Panel Discussion

*Colin Berry, M.D., Ph.D., NIH, NHLBI
George Mensah, M.D., CDC
James De Lemos, M.D., University of Texas – Southwestern Medical School
Gurvaneet Randhawa, M.D., AHRQ
Peter Libby, M.D., Brigham and Women's Hospital
Jean-Claude Tardif, M.D., Montreal Heart Institute
David Waters, M.D., University of California, San Francisco
Jean Rouleau, M.D., University of Montreal
Mark Grant, M.D., Blue Cross and Blue Shield
Felix Frueh, Ph.D., Medco Health Solutions*

1:30 – 2:00 PM

Concluding Remarks – Peter Libby and Jean-Claude Tardif