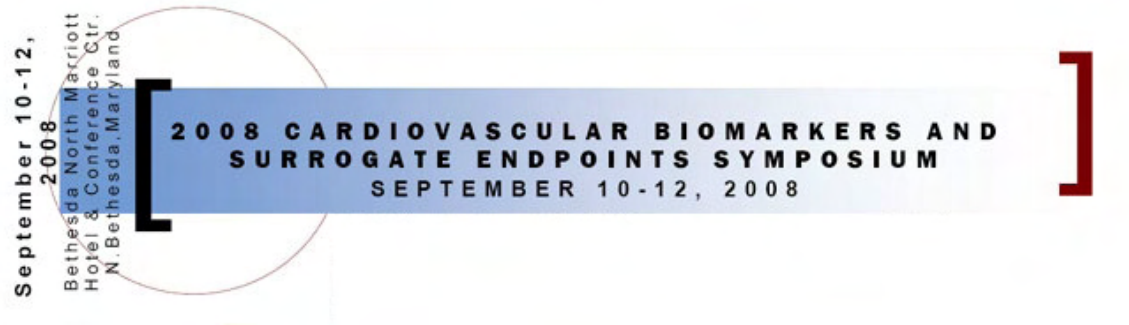
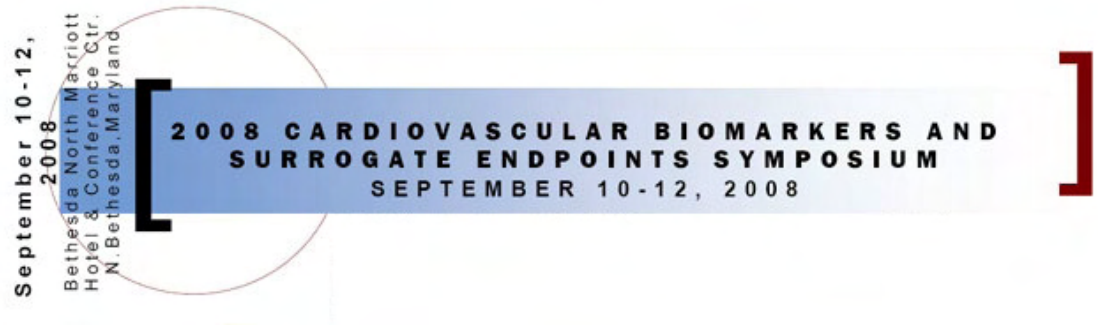


AGENDA

September 10, 2008

Dinner 6:00-6:30	**INTRODUCTION – Jean-Claude Tardif/Peter Libby**
6:30pm – 9:30pm	**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
Speakers:	**Phil Barter** (30 min) "HDL Overview and Recent Trials" **H. Bryan Brewer** (30 min) "HDL Mimetics" **Kerry-Anne Rye** (30 min) "Anti-inflammatory properties of HDL" **Jay Heinecke** (30 min) "When Good Cholesterol Goes Bad" **Alan Tall** (30 min) "A Mechanistic Understanding of the Anti-atherogenic Properties of HDL: Occam's razor revisited"
Panel Discussion	(30 minutes)
Panelists:	**Jean-Claude Tardif** **Peter Libby** **David Orloff** **Christie Ballantyne** **Alan Tall** **Phil Barter** **H. Bryan Brewer** **Jay Heinecke** **Kerry-Anne Rye**



September 11, 2008 **INTRODUCTION – Jean-Claude Tardif/Peter Libby**

8:00am – 11:30am **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, MD, NIH, NHLBI

Speakers:

Discovery

Robert Balaban (30 min)"Systems Biology Approaches to ID New Targets and Markers"
Jacques Mizrahi "Case Study (30 min)– Type II Diabetes"

Product Development

Jean-Jacques Garaud (30 min)"Markers in Drug Development – Balancing Evidence and Risk in Decision-Making"

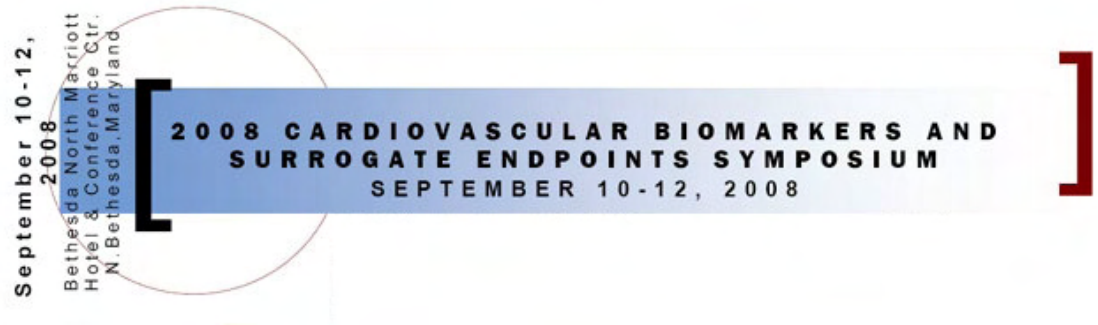
BREAK (20 min)

Bram Zuckerman (15 min)"Biomarkers in Device Development and Evaluations"
David Orloff (15 min) "Biomarkers in Drug Development"
Wolfgang Koenig (20 min) Case Studies
Jean-Claude Tardif (20 min) Case Studies

Panel Discussion (30 min)

Panelists:

Wolfgang Koenig
Bram Zuckerman
Jean-Jacques Garaud
Jacques Mizrahi
Robert Balaban
Jean-Claude Tardif
Peter Libby
Elizabeth Mansfield
Michael Perelman
Joel Raichlen
Ben Eloff



September 11, 2008 **SPECIAL IMAGING WORKSHOP**

12:00pm – 3:00pm **CENTRAL IMAGE ANALYSIS – OPTIMIZING PRACTICES AND PROCEDURES**

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

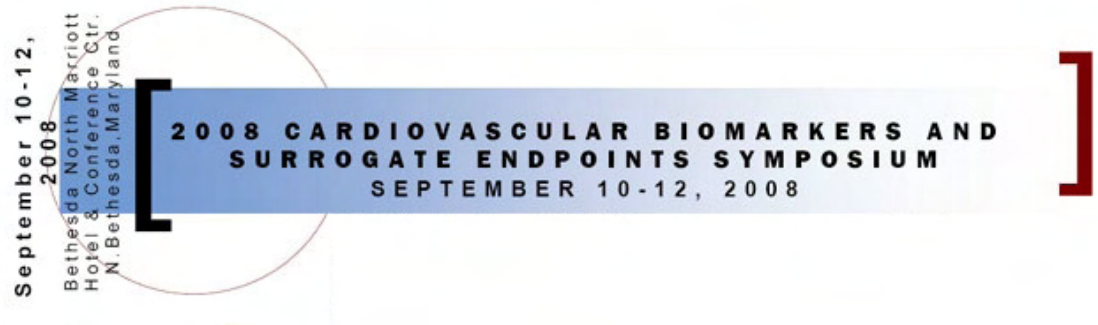
Speakers:

Regulatory Considerations in Central Image Analysis
- **Dwaine Rieves, M.D.** (30 min)
- **Brandon Gallas, M.D**. (30 min)

Central Image Analysis for Research and Product Development
- **Jean-Claude Tardif, M.D**. (15 min)
- **Jonathan Allis, M.D.** (15 min)
- **George Mills, M.D.** (30 min)

Roundtable Discussions (60 min)

Panelists:
Douglas Throckmorton
Dwaine Rieves
Norman Stockbridge
Robert Balaban
Jean-Claude Tardif
Joao Lima
Don Black
Brandon Gallas
David Brown
Joel Raichlen
George Mills



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

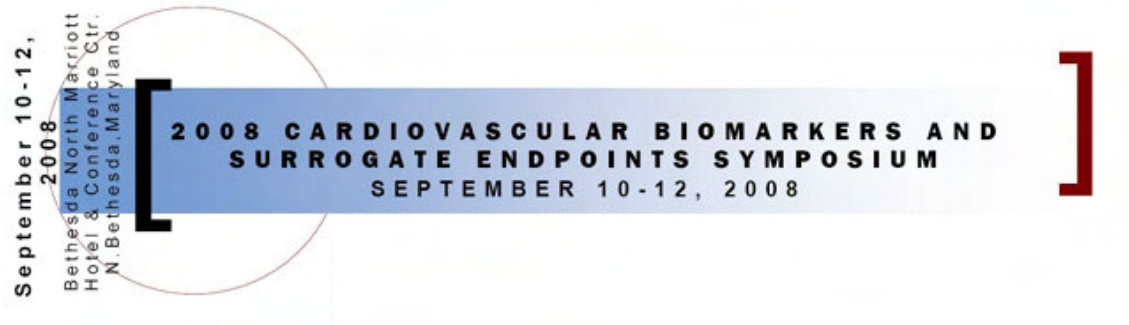
Speakers:
Eric Brass (30 min)"Proteomics/RNA expression profiling for skeletal muscle"
Roger Ulrich (30 min) "Differentiating Biomarkers for Drug-Induced Liver Injury"
Federico Goodsaid (30 min) "markers of renal toxicity"

BREAK (30 min)

James DeLemos (30 min) "Biomarkers and Thrombosis"
Jeff Leiden (30 min)"Educating People About the Risk/Benefit Decisions"

Panelists:
Panel Discussion (30 min)

Jean Rouleau
Norman Stockbridge
Eric Brass
Peter Libby
Jean-Claude Tardif
Roger Ulrich
Federico Goodsaid
Jeff Leiden
Amy Rudolph
Bram Zuckerman
James DeLemos
Philip Sager



Dinner 6:30 - 7:00

7:00pm – 10:00pm **SURROGATES FOR REGULATORY APROVAL – A 360 degree Perspective**

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

Speakers:
David Waters, M.D. (10 min) Introduction

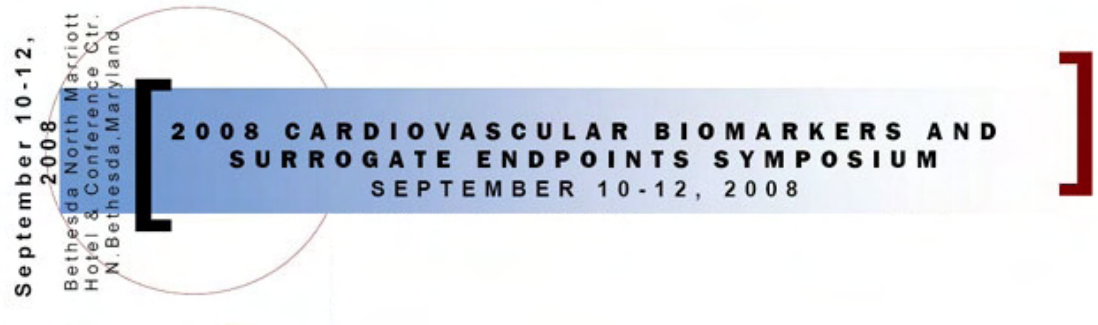
FDA Case Studies:
LDL - **Mary Parks, M.D.** (20 min)
Glucose - **Hylton Joffe, M.D.** (20 min)
HDL/Imaging - **Eric Colman, M.D.** (20 min)

Clinician's Perspective
Clinician #1 **Allen Taylor, M.D. (15 min)**
Clinician #2 **Lawrence Leiter, M.D. (15 min)**
Clinician #3 **Paul Ridker, M.D. (15 min)**

Panel Discussion:
Regulatory Perspective
US FDA - **Robert Temple, M.D**. (20 min)
Health Canada - **Agnes Klein, M.D.** (20 min)

Panelists:
Surrogates versus Outcome Studies? (30 min)

Mary Parks
David Waters
Allen Taylor
Peter Libby
Jean-Claude Tardif
Robert Temple
Agnes Klein
Paul Ridker
Lawrence Leiter
Eric Coleman
Hylton Jaffe
Michele Mercuri
Russell Basser



September 12, 2008

8:00am – 11:30pm **EVIDENTIARY STANDARDS FOR BIOMARKER 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

Technical, Validation and Standardization Issues

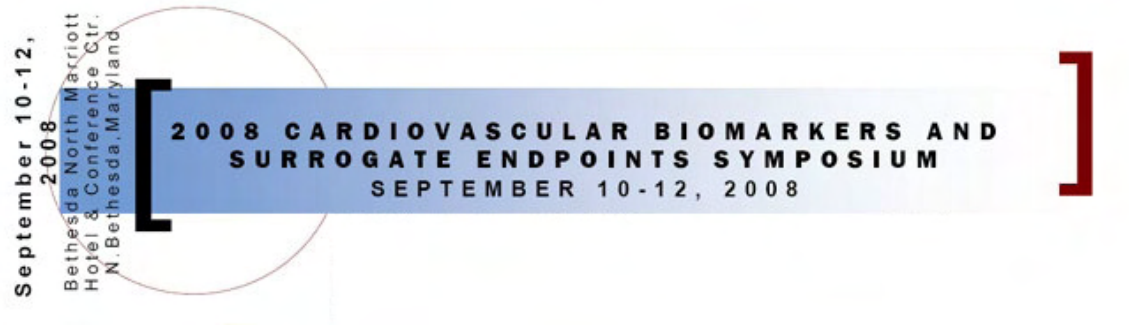
Elizabeth Mansfield, M.D, (20 min)– Getting Biomarkers There from Here: Understanding Test Performance"
Carolyn Compton M.D., Ph.D. (20 min) – Biospecimens Best Practices – What are they and why do we need them?
David Brown, Ph.D. (20 min) Imaging and Analysis methods
Gregory Campbell, Ph.D. (20 min) - Statistical Considerations

BREAK (20 min)

Non-Clinical Evidentiary Standards (20 min) **Patricia Harlow**
Biomarkers in Global Risk Assessment (20 min) **Christopher O'Donnell**
Biomarker Qualification Project (20 min) **Federico Goodsaid**

Panel Discussion (30 min)

Panelists:
Chris Cannon
Federico Goodsaid
Christopher O'Donnell
Peter Libby
Jean-Claude Tardif
Elizabeth Mansfield
Carolyn Compton
David Brown
Greg Campbell
Paula Trumbo
Patricia Harlow
Michael Davidson



Lunch 11:30 – 12:00

12:00pm – 3:30pm **BIOMARKERS IN CLINICAL PRACTICE AND PUBLIC HEALTH**

Session Leaders: **George Mensah, M.D.**, Center for Disease Control and Prevention
James De Lemos, M.D., University of Texas-Southwestern Medical School
Gurvaneet Randhawa, M.D., US Agency for Healthcare Res. and Quality

Speakers:

"Mapping the Translation Process" (20 min) – **Gurvaneet Randhawa**
"Challenges in Translating the Science" (20 min) – **George Mensah**
"Biomarkers in Population Screening and Surveillance" (20 min) – **James DeLemos**

Panel Discussion (20 min)

Panelists:

George Mensah
James De Lemos
Gurvaneet Randhawa
Peter Libby
Jean-Claude Tardif
Christie Ballantyne
David Waters
Michael Perelman
Colin Berry

Break (20 min)

Individualized and Personalized Healthcare (20 min) – **Felix Frueh**
Role of Government and Professional Societies in Clinical Guideline Development" (20 min) – TBD
"Economic/Reimbursement Considerations" (20 min) – TBD

Panel Discussion (20 min)

Panel:

Jean Rouleau
George Mensah
James De Lemos
Gurvaneet Randhawa
Mark Grant
Peter Libby
Jean-Claude Tardif
Wolfgang Koenig
Felix Frueh