

# AGENDA

SUMMIT SCHEDULE: DAY ONE, MAY 11, 2010

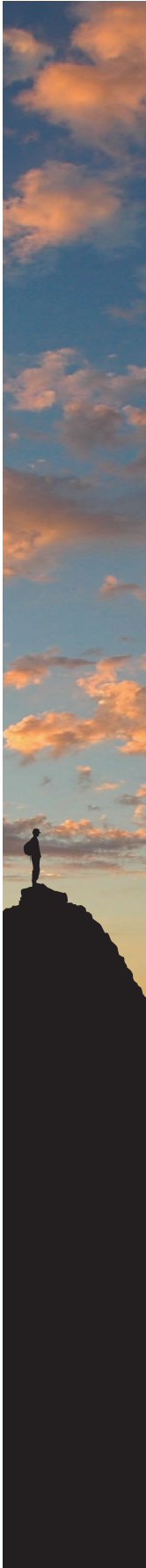
## STATE OF THE INDUSTRY—SAFETY, QUALITY, AND EFFECTIVENESS

- 8:30 - 9:00 **Chairperson's Opening Remarks and Overview of Post-Approval Landscape**  
Richard Gliklich, MD, *Harvard Medical School, Outcome*
- 9:00 - 9:45 **Perspective: The Impact of the Evolving Post-Approval Landscape**  
Michael Rosenblatt, MD, *Executive Vice President and Chief Medical Officer, Merck & Co., Inc.*
- 9:45 - 10:05 **Break**

## SAFETY AND RISK MANAGEMENT

- 10:05 - 10:50 **Evolving Role and Expectations for REMS and Safety Programs**  
Gerald Dal Pan, MD, MHS, *Director, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration (FDA)*
- 10:50 - 11:35 **European Updates to Risk Management**  
Stella Blackburn, MA, MSc, FRCP(Ed), FFPM, *Risk Management Development and Scientific Lead, European Medicines Agency*
- 11:35 - 12:05 **Case Study: Using a Registry for a REMS and PASS Requirement**  
Eleanor Segal, MD, *Vice President, Medical Safety Officer, Actelion Pharmaceuticals*
- 12:05 - 12:15 **Q&A with Speakers**
- 12:15 - 1:30 **Lunch**
- 1:30 - 2:15 **Designing Safety Studies: Interventional vs Observational**  
Sharon-Lise Normand, PhD, *Professor of Health Care Policy, Harvard Medical School and Harvard School of Public Health*
- 2:15 - 3:00 **Challenges of Device Tracking and Adverse Event Reporting**  
Richard E. Kuntz, MD, *Senior Vice President, Chief Scientific, Clinical and Regulatory Officer, Medtronic*
- 3:00 - 3:45 **Integrating Risk Management Planning into the Regulatory Decision-Making Process**  
Marc Berthiaume, MD, *Director, Marketed Pharmaceuticals and Medical Devices Bureau, Health Canada*
- 3:45 - 4:05 **Break**
- 4:05 - 5:15 **New Innovations in Safety**  
PROTECT-EU: Stella Blackburn, MA, MSc, FRCP(Ed), FFPM, *Risk Management Development and Scientific Lead, European Medicines Agency*  
Nancy Dreyer, MPH, PhD, *Chief of Scientific Affairs and Senior Vice President, Outcome*  
ASTER: Michael Ibara, PharmD, *Head of Pharmacovigilance Information Management, Pfizer, Inc.*
- 5:15 - 5:45 **Case Study: Using a Registry to Evaluate Clinical Outcomes and Monitor Safety**  
Anne Marie Conway, *Vice President Development Operations, Shire*
- 5:45 - 5:55 **Q&A with Speakers**

## OPENING NIGHT RECEPTION— ISABELLA STEWART GARDNER MUSEUM



# AGENDA

SUMMIT SCHEDULE: DAY TWO, MAY 12, 2010

8:00 - 8:15 **Chairperson's Opening Remarks**  
Richard Gliklich, MD, *Harvard Medical School, Outcome*

## COMPARATIVE EFFECTIVENESS AND EVIDENCE DEVELOPMENT

8:15 - 9:00 **Keynote: ARRA and Comparative Effectiveness Research in the New U.S. Healthcare System**  
Patrick Conway, MD, MSc, *Former Chief Medical Officer, Office of the Secretary, U.S. Department of Health and Human Services, Director of Hospital Medicine, Cincinnati Children's Hospital*

9:00 - 9:45 **Planning Across the Product Lifecycle: Addressing New Challenges for Post-Approval Data Requirements**  
Steven J. Romano, MD, *Vice President, Medical Affairs Head, Primary Care Unit, Pfizer*

9:45 - 10:00 **Break**

10:00 - 10:45 **Evolving Role of Effectiveness and Quality Performance Data**  
Barry M. Straube, MD, *Director and Chief Clinical Officer, Office of Clinical Standards and Quality, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services*

10:45 - 11:15 **Challenges and Benefits of New CE Initiatives for Industry**  
Marc Berger, MD, *Vice President, Global Health Outcomes, Eli Lilly and Company*

11:15 - 11:45 **Role of CER, Coverage Determinations, and Value-Based Reimbursement**  
Fadia Shaya, PhD, MPH, *Associate Director, Center on Drugs and Public Policy, Department of Pharmaceutical Health Services Research, University of Maryland School of Pharmacy*

11:45 - 12:15 **Comparative Effectiveness and Evidence-Based Decision-Making in the UK**  
Sarah Garner, BPharm, MRPharmS, PhD, *Associate Director, Research and Development, National Institute for Health and Clinical Excellence (NICE)*

12:15 - 1:15 **Lunch**

## MULTI-STAKEHOLDER COLLABORATION IN EVIDENCE DEVELOPMENT

1:15 - 2:00 **Collaborative Models for Priority Setting and Program Support**  
Sean Tunis, MD, MSc, *Founder and Director, Center for Medical Technology Policy*

2:00 - 2:30 **Case Study: Using a Registry for Multi-Stakeholder Needs**  
Bruce Marshall, MD, *Vice President of Clinical Affairs, Cystic Fibrosis Foundation*

2:30 - 2:45 **Break**

## REGISTRIES WORKSHOP: PLANNING, OPERATIONAL, AND ANALYTICAL CHALLENGES

2:45 - 4:15 **Designing and Operating Registries**  
Workshop Leaders:  
Nancy Dreyer, PhD, MPH, *Senior Vice President and Chief of Scientific Affairs, Outcome*  
Leanne Larson, MHA, *Vice President, Strategic Development, Outcome*  
Michelle Bulliard, RN, BScN, MICR, *Director Clinical Operations, Outcome Europe Sarl*

**Case Study: Maximizing Communications**  
David Cooper, MD, *Senior Director, Medical Affairs, Novo Nordisk*

**POST-APPROVAL  
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Conference Center at Harvard Medical School

*The listed program and speakers are subject to change without notice.*  
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