

**POST-APPROVAL
SUMMIT®**  **MAY 10-11, 2011**
Conference Center at Harvard Medical School

Day One: May 10, 2011

- 8:00 - 8:15 **Chairperson's Opening Remarks**
Richard Gliklich, MD, *Harvard Medical School, Outcome*
- A NEW ERA IN POST-APPROVAL RESEARCH**
- 8:15 - 9:00 **Keynote: Impact of Recent FDA Post-Approval Initiatives and New Approaches to Evidence Synthesis for Safety and Effectiveness**
Janet Woodcock, MD, *Director, Center for Drug Evaluation and Research, Food and Drug Administration (FDA)*
- 9:00 - 9:45 **Post-Approval Considerations in Product Development**
David Recker, MD, FACR, FACP, *Senior Vice President, Clinical Science, Takeda Global Research and Development Center*
- 9:45 - 10:00 **Break**
- BENEFIT RISK MANAGEMENT AND UPDATES ON SAFETY**
- 10:00 - 10:45 **New European Risk Management Guidelines**
Stella Blackburn, MA, MSc, FRCP(ed), FFPM, *Risk Management Development and Scientific Lead, European Medicines Agency*
- 10:45 - 11:30 **Approaches to Device Safety**
Richard E. Kuntz, MD, *Senior Vice President, Chief Scientific, Clinical and Regulatory Officer, Medtronic*
- 11:30 - 12:00 **Public-Private Partnerships in Medical Device Safety and Effectiveness Research**
Steve E. Phurrough, MD, MPA, *Chief Operating Officer and Senior Clinical Director, Center for Medical Technology Policy*
- 12:00 - 1:15 **Lunch**
- 1:15 - 3:30 **Progress Report on Safety Initiatives**
Sentinel Initiative: Richard Platt, MD, *Professor of Ambulatory Care and Prevention, Professor of Medicine, Harvard Medical School*
PROTECT-EU: Nancy Dreyer, MPH, PhD, *Chief of Scientific Affairs, Senior Vice President, Outcome*
ENCePP: Stella Blackburn, MA, MSc, FRCP(ed), FFPM, *Risk Management Development and Scientific Lead, European Medicines Agency*
DSEN: Diane Forbes, *Associate Director, Drug Safety and Effectiveness Network, Canadian Institutes of Health Research*
- 3:30 - 3:45 **Break**
- 3:45 - 4:15 **Case Study: Conducting Patient and Physician Surveys to Meet REMS Requirements**
Eric T. Smith, PharmD, *Senior Director Risk Management and Safety Evaluation, King Pharmaceuticals*
- 4:15 - 5:00 **Methodological and Statistical Considerations in Drug Safety**
Robert Glynn, ScD, *Associate Professor of Biostatistics, Harvard University, Brigham and Women's Hospital*
- 5:00 - 5:30 **Workforce and Training Needs for Real-World Research: Report of the DIA Real-World Outcomes Task Force**
Judith Glennie, PharmD, MSc, FCSHP, *Co-Chair, DIA Real-World Taskforce, Director, Strategic Health Assessment, Janssen-Ortho, Inc.*

OPENING NIGHT RECEPTION—SKYWALK OBSERVATORY AT THE PRUDENTIAL CENTER

The listed program and speakers are subject to change without notice. Visit www.postapproval.org for more details.

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Day Two: May 11, 2011

7:50 - 8:00 **Chairperson's Opening Remarks**
Richard Gliklich, MD, *Harvard Medical School, Outcome*

COMPARATIVE EFFECTIVENESS AND EVIDENCE FOR REIMBURSEMENT

8:00 - 9:45 **Panel: Using CER Data**
Pharmacy Benefits Management Perspective: Troyen A. Brennan, MD, MPH, *Executive Vice President and Chief Medical Officer, CVS Caremark Corporation*
Industry Perspective: Newell McElwee, PharmD, MSPH, *Executive Director, U.S. Outcomes Research Merck & Co*
Consumer Health Perspective: John Santa, MD, MPH, *Director, Consumer Reports Health Ratings Center, Consumers Union*

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

10:00 - 10:45 **NICE Guidance on New Technologies and Procedures**
Professor Bruce Campbell, MS, FRCP, FRCS, *Chairman Medical Technologies Advisory Committee, National Institute of Health and Clinical Excellence (NICE)*

10:45 - 11:30 **Evolution of CER at the National Institutes of Health**
Michael Lauer, MD, FACC, FAHA, *Director, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)*

11:30 - 12:30 **Lunch**

BUILDING REGISTRIES AND OBSERVATIONAL STUDIES TO MEET MULTIPLE NEEDS

12:30 - 1:30 **Designing, Operating, and Evaluating Patient Registries: The 2nd Edition AHRQ Guide "Registries for Evaluating Patient Outcomes: A User's Guide"**
Richard Gliklich, MD, *Professor, Harvard Medical School and President, Outcome*
Elise Berliner, PhD, *Director, Technology Assessment Program, Center for Outcomes and Evidence, Agency for Healthcare Research and Quality (AHRQ)*

1:30 - 2:00 **The Ophthalmic Outcomes Database: A Registry Serving Multi-Stakeholder Quality, Comparative Effectiveness and Safety Surveillance Goals**
Flora Lum, MD, *Executive Director, The H. Dunbar Hoskins Jr., M.D. Center for Quality Eye Care, American Academy of Ophthalmology*

2:00 - 2:15 **Break**

SPECIAL WORKSHOP: MEDICAL SPECIALTY ORGANIZATIONS AND PATIENT REGISTRIES

2:15 - 3:45 **Case Presentations: Specialty Society Driven Multi-Purpose Registries**
American Society of Clinical Oncology: Deborah Kamin, RN, PhD, *Senior Director, Cancer Policy and Clinical Affairs, American Society of Clinical Oncology*
American Society of Plastic Surgeons: Keith Hume, MA, *Vice President Research and Development, American Society of Plastic Surgeons and Plastic Surgery Educational Foundation*
American College of Cardiology: Barbara Christensen, MSHA, RN, *Senior Director of Registry Services, American College of Cardiology*

Note: An invitation only satellite workshop will continue on the morning of May 12.