American Course on Drug Development and Regulatory Sciences (ACDRS) Special Workshop:
Substantial Evidence in 21st Century Regulatory Science -
Borrowing Strength from Accumulating Data
University of California Washington Center • 1608 Rhode Island Ave NW, Washington DC

April 21, 2016

Time	*Duration*	*Topic*
7:30 am	30	**Continental Breakfast**
8:00 am	10	**Introduction to Workshop** *Carl C. Peck, MD, Adjunct Professor, University of California, San Francisco*

Session 1: Introduction and Motivations
Co-Chairs: Carl C. Peck and Donald B. Rubin, PhD, John L. Loeb Professor of Statistics, Harvard University

8:10 am	15	**Keynote Address** *Janet Woodcock, MD, Director, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)*
8:25 am	20	**Featured Speaker** *Mark McClellan, MD, PhD, Director, Duke-Robert J. Margolis, MD Center for Health Policy, Duke University*
8:45 am	20	**Tutorial Frequentist/Bayesian - Statistical Frameworks for Substantial Evidence** *Stephen J. Ruberg, PhD, Distinguished Research Fellow & Scientific Leader, Advanced Analytics, Eli Lilly and Company*
9:05 am	20	**Empirical vs Causal Evidence and the Intrusion of Bayesian Inference** *Donald B. Rubin*
9:25 am	15	**Substantial Evidence in CDER and CBER today** *Lisa LaVange, PhD, Director, Office of Biostatistics, CDER, Food and Drug Administration*
9:40 am	15	**Bayesian Submissions to FDA and the Evidentiary Standard for Effectiveness—the CDRH Experience** *Gregory Campbell, PhD, former Director, Division of Biostatistics, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, FDA*
9:55 am	25	**Panel Discussion** *Session 1 speakers*
10:20 am	10	Break

Session 2: Stakeholder Perspectives on the Use of Bayesian Methods in Drug Development and Regulatory Science (DD&R)
Co-chairs: Karen L. Price, PhD, Research Advisor, Eli Lilly and Company; and John Scott, PhD, Deputy Director, Division of Biostatistics, Center for Biologics Evaluation and Research, FDA

10:30 am	15	**Overview of DIA Bayesian Scientific Working Group** *Karen Price*
10:45 am	20	**The Value of Bayesian Methods for Evidence-Based Medicine** *Steven Goodman, MD, MHS, PhD, Professor of Medicine and Epidemiology, Co-Director, METRICS, Stanford School of Medicine*

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11:05 am	20	**Industry Perspective of the Value of Bayesian Methods** *David Ohlssen, PhD, Biometrical Fellow, Statistical Methodology & Consulting Center, Novartis*
11:25 am	20	**Regulatory Perspective of the Value of Bayesian Methods** *Telba Irony, PhD, Deputy Director, Office of Biostatistics and Epidemiology, CBER, FDA*
11:45 am	15	Box lunch pick-up
Noon	45	**Luncheon talk: Reverend Bayes Goes to Washington** *Sharon Bertsch McGrayne, Author of "The Theory that Would Not Die, How Bayes' Rule Cracked the Enigma Code, Hunted Down Russian Submarines & Emerged Triumphant from Two Centuries of Controversy"*

Session 3: Opportunities to Advance the Use of Bayesian Methods for DD&R
Co-chairs: Lisa LaVange and Karen L. Price

12:45 pm	20	**What a Bayesian Owes a Frequentist** *Frank E. Harrell Jr., PhD, Professor and Chair, Department of Biostatistics, Vanderbilt University*
1:05 pm	20	**The Role of Simulations for Bayesian Analyses and Regulatory Approval** *Scott Berry, PhD, President & Senior Statistical Scientist, Berry Consultants*
1:25 pm	20	**Bayesian Methods in Regulatory Science: Identifying Patient Subgroups with Positive Treatment Effects** *Bradley Carlin, PhD, Professor & Division Head, Biostatistics, University of Minnesota*
1:45 pm	45	**Panel Discussion** *Scott Berry, Bradley Carlin, Frank Harrell, Steven Goodman,Telba Irony, David Ohlssen and John Scott*
2:30 pm	15	Break

Session 4: Substantial Evidence through a Bayesian Lens
Co-chairs: Stephen Ruberg and Gregory Campbell

2:45 pm	30	**Hypothetical Drug Development Program using a Bayesian Paradigm** *Stephen Ruberg*
3:15 pm	60	**Points to Consider (panel)** *Janet Woodcock; Robert J. Temple, MD, Deputy Director for Clinical Science, CDER, FDA; Lisa LaVange; Steven Goodman; David W. Feigal Jr., MD, MPH, Partner, NDA Partners; and Carl C. Peck*
4:15 pm	15	**Next Steps** *Stephen Ruberg and Carl C. Peck*
4:30 pm		Adjourn

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