American Course on Drug Development and Regulatory Sciences (ACDRS) Special Workshop:
Substantial Evidence in 21st Century Regulatory Science -
Borrowing Strength from Accumulating Data *draft as of 3/21/16*
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	20	**Introduction to Workshop** *Carl C. Peck, MD, Adjunct Professor, University of California, San Francisco*

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

8:05 am	25	**Keynote Address** *Mark McClellan, MD, PhD, Professor of Business, Medicine and Health Policy and Director, Duke-Robert J. Margolis, MD, Center for Health Policy*
8:30 am	10	**Legislative History of Requirement for Substantial Evidence** *Carl Peck*
8:40 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*
9:00 am	15	**Empirical vs Causal Evidence and the Intrusion of Bayesian Inference** *Donald Rubin*
9:15 am	15	**Substantial Evidence in CDER and CBER today** *Lisa LaVange, PhD, Director, Office of Biostatistics, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)*
9:30 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*
9:45 am	30	**Panel Discussion** *Session 1 speakers*
10:15 am	15	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*

University of California
San Francisco
UCSF
Schools of Pharmacy and Medicine
Department of Bioengineering
and Therapeutic Sciences

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	**TBC** *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, Lisa LaVange,Telba Irony and David Ohlssen*
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, MD, Director, CDER, FDA; Robert J. Temple, MD, Deputy Director for Clinical Science, CDER, FDA; Lisa LaVange; Steven Goodman; and David W. Feigal Jr., MD, MPH, Partner, NDA Partners*
4:15 pm	15	**Next Steps** *Steve Ruberg and Carl Peck*
4:30 pm		Adjourn