

New Approaches to Clinical Trials: Implications for Comparative Effectiveness
 An Invitational Forum
 Wednesday, May 6 2009 St. Regis Hotel Washington, DC

AGENDA

7:00 a.m. to 8:00 a.m.	Continental Breakfast
8:00 a.m. to 8:20 a.m.	Welcome & Introduction: Bryan R. Luce, PhD, MBA, The PACE Initiative and United BioSource Corporation (UBC)
8:20 a.m. to 9:00 a.m.	Keynote: Robert J. Temple, MD, FDA Topic: “The Case for Comparative Trials in the Comparative Effectiveness Research Agenda”
9:00 a.m. to 10:00 a.m.	Session 1: Pragmatic Clinical Trials: Finding Common Ground. Sean Tunis, MD, CMTP; Jodi B. Segal, MD, MPH, Johns Hopkins University School of Medicine
10:00 a.m. to 10:20 a.m.	Break
10:20 a.m. to 11:20 a.m.	Session 2: Operational Efficiency: CTTI and Critical Path Initiative (CPI). Judith Kramer, MD, MS, Duke Clinical Research Institute, CTTI and Rachel Behrman, MD, FDA
11:20 a.m. to 12:20 p.m.	Session 3: PACE Initiative & Analytical Efficiency: The Potential Role of Bayesian Adaptive Techniques in CER. B. Luce; Steven Goodman, MD, MHS, PhD, Johns Hopkins School of Medicine; Jason Connor, PhD, Berry Consultants
12:20 p.m. to 1:30 p.m.	Luncheon Speaker: Gail Wilensky, PhD, Project Hope Topic: “Comparative Effectiveness Research and the Public Policy Debate”

1:30 p.m. to 3:15 p.m.	<p>Reactor Panel and General Discussion: Clifford Goodman, PhD, The Lewin Group (Facilitator)</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Marc Berger, MD, VP, Global Health Outcomes, Eli Lilly and Company • Mark Carlson, MD, Chief Medical Officer and SVP, Research and Clinical Affairs, Cardiac Rhythm Management Division, St. Jude Medical • James J. Ferguson, MD, VP, Global Medical, Surgical and Critical Care Business Unit, The Medicines Company • Susan Gardner, PhD, Director, Office of Surveillance and Biometrics, CDRH, FDA • Michael S. Lauer, MD, FACC, FAHA, Director, Division of Prevention and Population Sciences (DPPS), NHLBI, NIH • Murray Ross, PhD, VP, Kaiser Foundation Health Plan, Inc.; Director, Kaiser Permanente Institute for Health Policy • Jean Slutsky, P.A., M.S.P.H., Director, Center for Outcomes and Evidence, AHRQ • Steven Snapinn, PhD, VP, Global Biostatistics & Epidemiology, Amgen, Inc.
3:15 p.m. to 3:30 p.m.	Break
3:30 p.m. to 3:50 p.m.	Commentary by J. Sanford (Sandy) Schwartz, MD, University of Pennsylvania
3:50 p.m. to 4:40 p.m.	Discussion: What Needs to Change? C. Goodman
4:40 p.m. to 5:00 p.m.	Wrap up: B. Luce

Sponsorship: Eli Lilly; Kaiser Permanente Institute for Health Policy; Shire Pharmaceuticals; St. Jude Medical; United BioSource Corporation; The PACE (Pragmatic Approaches to Comparative Effectiveness) Initiative* (**The PACE Initiative sponsorship includes: Amgen Inc.; Eli Lilly and Company; Forest Laboratories, Inc.; MedImmune, Inc.; National Pharmaceutical Council, and United BioSource Corporation.*)