

**Second Annual CTSA Clinical Research Management Workshop  
Natcher Conference Center - NIH Main Campus - Bethesda, MD  
June 22-23, 2009**

**Monday, June 22, 2009**

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| 7:30 AM - 8:00 AM (30 min)   | Coffee & Continental Breakfast   |
| 8:00 AM - 8:10 AM (10 min)   | The CTSA Consortium and Clinical Research Management<br><i>Barbara Alving, Director, NCCR</i>  |
| 8:10 AM - 8:15 AM (5 min)    | Purpose and Organization of Meeting<br><i>Michael Joyner, Professor of Anesthesiology, Associate Director of CTSA, Deputy Director of Research, Mayo Clinic</i>  |
| 8:15 AM - 8:35 AM (20 min)   | Keynote Address – Use of Metrics in Process Improvement – “A Norse Saga in Rochester, MN”<br><i>Michael Joyner, Professor of Anesthesiology, Associate Director of CTSA, Deputy Director of Research, Mayo Clinic</i>  |
| 8:35 AM - 8:55 AM (20 min)   | Sponsored Trials at Academic Medical Centers: Goals and Requirements<br><i>Briggs W. Morrison, Senior Vice President, Pfizer</i>   |
| 8:55 AM - 9:15 AM (20 min)   | Draft title: Industry’s Response to Concerns of Academic Centers<br><i>Joseph Camardo, Senior Vice President, Wyeth</i>  |
| 9:15 AM - 9:35 AM (20 min)   | Draft title: Time-Based Process Analysis for NIAID Extramural HIV/AIDS Network Trials<br><i>Jonathan Kagan, Associate Director, Division of Clinical Research, NIAID</i>   |
| 9:35 AM - 9:55 AM (20 min)   | Draft title: NCI View of Clinical Research at Academic Centers<br><i>Sheila Prindiville, Director, Coordinating Center for Clinical Trials, NCI</i>  |
| 9:55 AM - 10:10 AM (10 min)  | BREAK  |
| 10:10 AM - 10:55 AM (45 min) | Panel Discussion: The Stakeholders’ Perspective<br><i>Joseph Camardo, Senior Vice President, Wyeth</i><br><i>Jonathan Kagan, Associate Director, Division of Clinical Research, NIAID</i><br><i>Susan Kelley, Chief Medical Officer, Multiple Myeloma Research Foundation</i><br><i>Briggs W. Morrison, Senior Vice President, Pfizer</i><br><i>Sheila Prindiville, Director, Coordinating Center for Clinical Trials, NCI</i><br><i>Wendy R. Sanhai, Senior Scientific Advisor, FDA</i><br><i>Alison Urkowitz, Associate Director, Research Programs, The Michael J. Fox Foundation for Parkinson's Research</i><br><b>Moderator: Tesheia Johnson, Chief Operations Officer for Clinical Investigation, Yale University</b> |

- 10:55 AM - 11:20 AM (25 min) Draft title: Stages in Clinical Research and R&D for Medical Product Development  
*Wendy R. Sanhaj, Senior Scientific Advisor, FDA*
- 11:20 AM - 11:40 AM (20 min) ClinicalTrials.gov Update on Clinical Trial Registration and Results Reporting Requirements  
*Rebecca J. Williams, Assistant Director, ClinicalTrials.gov*
- 11:40 AM - 11:50 AM (10 min) Vignette: Harvard Catalyst - Best Practice Presentation  
Draft title: IRB Reciprocity at Harvard: A Culture Shift Under the CTSA Umbrella  
*Barbara Bierer, Senior Vice President for Research, Brigham and Women's Hospital*
- 11:50 AM - 12:00 PM (10 min) Vignette: Weill Cornell - Best Practice Presentation  
*Juan Cordero, Regulatory Knowledge and Support Core Facilitator, Weill Cornell*
- 12:00 PM - 12:20 PM (15 min) Vignettes Q&A Session
- 12:20 PM - 12:40 PM (20 min) BREAK/Working Lunch
- 12:40 PM - 1:20 PM (40 min) Breakout Session 1  
- Electronic Systems for IRB and Research Management  
- Re-engineering Contracting Offices  
- IND/IDE Topics
- 1:20 PM - 2:00 PM (40 min) Breakout Session 2  
- Central Model of Clinical Trials Support  
- IRB Review for Multicenter Studies  
- Educational Resource Sharing
- 2:00 PM - 2:20 PM (20 min) IRB Pilot Data Presentation  
*Ray Hutchinson, Co-Director, Michigan Institute for Clinical and Health Research, University of Michigan*  
*Kathleen Uscinski, Deputy Director, Human Investigation Committee, Yale University*
- 2:20 PM - 2:45 PM (25 min) Q&A: IRB Pilot Data Presentation  
*Pls from Pilot (Ray Hutchinson & Kathleen Uscinski)*
- 2:45 PM - 3:05 PM (20 min) Contract Pilot Data Presentation  
*Adam Rifkind, Associate Director, Corporate Contracts, University of Pennsylvania*  
*Libby Salberg, Director, Office of Grants & Contracts Management, Vanderbilt University*
- 3:05 PM - 3:30 PM (25 min) Q&A: Contract Pilot Data Presentation  
*Pls from Pilot (Adam Rifkind & Libby Salberg)*
- 3:30 PM - 3:50 PM (20 min) Next Steps – Plan for Larger Future Study  
*Daniel Ford, Vice Dean for Clinical Investigation and CTSA Principal Investigator, Johns Hopkins University*

- 3:50 PM - 4:00 PM (10 min) BREAK
- 4:00 PM - 5:30 PM (90 min) Poster Presentations

## Tuesday, June 23, 2009

- 7:00 AM - 7:30 AM (30 min) Coffee & Continental Breakfast
- 7:30 AM - 7:35 AM (5 min) Purpose and Plan for Day 2  
*Michael Joyner, Professor of Anesthesiology, Associate Director of CTSA, Deputy Director of Research, Mayo Clinic*  
*Tesheia Johnson, Chief Operations Officer for Clinical Investigation, Yale University*
- 7:35 AM - 8:05 AM (30 min) Private Sector: The Imperative of Metrics  
*Tracy Blumenfeld, Co-Founder, President and CEO, RapidTrials*
- 8:05 AM - 8:35 AM (30 min) The Multi Site IRB Dilemma - Suggested Strategies  
*Jerry Menikoff, Director, OHRP*
- 8:35 AM - 9:05 AM (30 min) Benefits: Discussion on Consortium Sharing Issues – The Unified Consortium-Wide Approach  
*Rob Califf, Vice Chancellor for Clinical Research and CTSA Principal Investigator, Duke University*
- 9:05 AM - 9:35 AM (30 min) The CTSA Consortium in the Changing World of Drug Discovery and Development  
*Garret FitzGerald, McNeil Professor of Translational Medicine and Therapeutics, Chair, Department of Pharmacology, Director, Institute for Translational Medicine and Therapeutics, and CTSA Principal Investigator, University of Pennsylvania*
- 9:35 AM - 9:45 AM (10 min) BREAK
- 9:45 AM - 10:15 AM (30 min) Moving Forward as a Consortium  
*Anthony Hayward, Director, Division of Clinical Research Resources, NCRR*
- 10:15 AM - 10:25 AM (10 min) Vignette: Scripps Experience  
*Barbara Bigby, Director of Regulatory Services, Scripps Office of Protections of Research Subjects*
- 10:25 AM - 10:35 AM (10 min) Vignette: Facilitating the Regulatory Process in the Community Setting  
*Kathleen Uscinski, Deputy Director, Human Investigation Committee, Yale University*
- 10:35 AM - 10:45 AM (10 min) Vignette: Developing Teamwork and Sharing Best Practices Across Sites and Beyond  
*Deborah Roth, Chief Operations Officer, Duke Clinical Research Center*
- 10:45 AM - 10:55 AM (10 min) Vignettes Q&A Session

- 10:50 AM - 11:35 AM (45 min) Participant Concurrence on Process Goals  
*Michael Joyner , Professor of Anesthesiology, Associate Director of CTSA,  
Deputy Director of Research, Mayo Clinic  
Teshia Johnson, Chief Operations Officer for Clinical Investigation, Yale  
University*
- 11:35 AM - 11:55 AM (20 min) Participant Concurrence on Proposed Action Plan  
*Libby Salberg, Director, Office of Grants & Contracts Management, Vanderbilt  
University*