Public Workshop: Strategies for Responsible Sharing of Clinical Trial Data

Agenda

Keck Center, Room 100
The National Academies
500 5th Street, NW
Washington, D.C. 20001

May 5, 2014

Overall Workshop Objectives:

− Discuss the benefits, risks, and challenges of data sharing with medical product developers outside of large pharmaceutical companies, including small biotechnology/venture capital, diagnostics and other devices, and disease and condition-specific organizations.
− Discuss incentives and disincentives in the global clinical trial landscape, particularly within research institutions, including universities, organizations that carry out data sharing, funders, journals, and other organizations involved in clinical trials.
− Discuss guiding principles and characteristics for the optimal infrastructure and governance for sharing clinical trial data.

9:30 a.m. Welcome and Introductory Remarks
Bernard Lo, Committee Chair, The Greenwall Foundation

9:40 a.m. Introductory Presentation
Vision for the Future of Clinical Trials: Implications for Data Sharing (20 minutes)

Bernard Munos, M.B.A. (confirmed), InnoThink Center for Research in Biomedical Innovation

SESSION 1: Strategies and Practical Approaches for Responsible Sharing of Clinical Trial Data:
Perspectives of Trial Sponsors and Investors

Session Objectives:

− Hear from investors and sponsors of clinical research (e.g. biotechnology, diagnostic, device, and patient supported research trials) who will discuss the benefits, risks, and challenges of sharing clinical trial data from their perspective and how those may align or differ from those associated with large drug trials.
− Identify strategies and practical approaches to overcome challenges and barriers to responsible data sharing identified by these sponsors.

10:00 a.m. Discussion Panel: (75 mins)
SESSION 2: Strategies and Practical Approaches for Incentivizing Responsible Sharing of Clinical Trial Data: Perspectives of Investigators and Leaders of Academic Medical Centers

Session Objectives:
- Understand current norms and attitudes towards clinical trials data sharing
- Identify new and current incentives that might facilitate clinical trial data sharing and practical steps within the broad clinical trial enterprise (including major research fields, international settings and limited resource settings, data coordinating centers).
- Discuss incentives and disincentives in the global clinical trial landscape and the academic research model and strategies for overcoming disincentives.

11:30 a.m. Discussion Panel
Clinical Trial Investigators and Leaders of Academic Medical Centers and Data Coordinating Centers (60 mins)

Moderator:
Bernard Lo, Committee Chair

Panelists:
- Steve Cummings, M.D. (confirmed), Professor Emeritus, Department of Medicine (General Internal Medicine), UCSF and Director, San Francisco Coordinating Center
- Clay Johnston, M.D., Ph.D. (confirmed – WebEx), Dean of School of Medicine, University of Texas at Austin, former Director of UCSF Clinical and Translational Science Institute.
Paula K. Shireman, M.D. (confirmed), Vice Dean for Research, University of Texas Health Science Center San Antonio

Quarraisha Abdool Karim, Ph.D., M.S. Associate Professor at Columbia University and Associate Scientific Director, CAPRISA (Center for the AIDS Programme of Research in South Africa) (via WebEx May 6th)

Rory Collins Ph.D., Professor of Medicine and Epidemiology, University of Oxford and Chief Executive, UK Biobank (via WebEx-May 6th)

12:30 p.m. LUNCH

SESSION 3: Strategies and Practical Approaches for Responsible Sharing of Clinical Trial Data: Governance and Infrastructure

Session Objectives
− Identify guiding principles and characteristics for the optimal infrastructure and governance for responsible sharing of clinical trial data.
− Discuss optimal and practical governance models that account for the global nature of clinical trials, in which relevant laws, policies and practices vary by jurisdiction

1:30 p.m. Discussion Panel
Operational Principles for the Governance for Sharing Clinical Trial Data (90 mins)

Moderator:
Tim Coetzee, Committee Member

Panelists:
Bartha Knoppers, Ph.D., LL.M., LL.B. (confirmed), Director, Centre of Genomics and Policy at McGill University

Philip E. Bourne, Ph.D. (confirmed), Associate Director for Data Science (ADDS), National Institutes of Health

Glenn Cohen, J.D. (confirmed) Professor of Law and Co-Director, Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics

Jane Kaye D.Phil., LL.B., (via WebEx-May 7th) Director of the Centre for Law, Health and Emerging Technologies at Oxford: (HeLEX) based in the Department of Public Health at the University of Oxford

3:00 p.m. Discussion Panel
Characteristics for the Optimal Infrastructure of Data Sharing (90 mins)

Moderator:
Ida Sim, Committee Member
Panelists:
  Harlan Krumholz, M.D. (confirmed), Director, Yale University Open Data Access (YODA) Project
  Philip E. Bourne, Ph.D. (confirmed), Associate Director, Data Science (ADDS), National Institutes of Health
  Frank Rockhold, Ph.D. (confirmed), GSK Sr. Vice President GCSP
  Paula K. Shireman, M.D. (confirmed), Vice Dean for Research, University of Texas Health Science Center San Antonio
  Rory Collins, Ph.D., Professor of Medicine and Epidemiology, University of Oxford and Chief Executive, UK Biobank (via WebEx-May 6th)

4:30 p.m. Public Comment Period (30 mins)
5:00 p.m. ADJOURN

SESSION 4: Continuation from May 5th

Via Teleconference Line: 1-866-528-2256 / Access Code: 8472522

May 6th
9:30 a.m. -10:15 a.m. Clinical Trial Investigator Perspectives
  Quarraisha Abdool Karim, Ph.D., M.S.
  Associate Professor at Columbia University and Associate Scientific Director, CAPRISA (Center for the AIDS Programme of Research in South Africa) (confirmed)

10:15 a.m. -10:30 a.m. Break

10:30 a.m.-11:30 a.m. Characteristics for the Optimal Infrastructure of Data Sharing and Incentivizing Data Sharing
  Rory Collins, Ph.D., Professor of Medicine and Epidemiology, University of Oxford and Chief Executive, UK Biobank (confirmed)

May 7th
9:00 a.m. -9:45 a.m. Operational Principles for the Governance for Sharing Clinical Trial Data
  Jane Kaye, D.Phil., LL.B., Director of the Centre for Law, Health and Emerging Technologies at Oxford: (HeLEX) based in the Department of Public Health at the University of Oxford (confirmed)