Public Workshop: Strategies for Responsible Sharing of Clinical Trial Data

WEBCAST LINK
http://www.iom.edu/Activities/Research/SharingClinicalTrialData/2014-FEB-03.aspx

February 3–4, 2014 – Open Session
The National Academies
Keck Center, Room 208
500 5th Street, NW
Washington, D.C. 20001

Workshop Objectives:
- Seek public comment on the discussion framework document released in January 2014.
- Discuss the elements and activities of data sharing outlined in the discussion framework document and review the completeness of the set of selected models as an heuristic framework for the committee’s analytic process to be undertaken as part of the study.
- Identify key benefits of sharing and risks of not sharing clinical trial data; and key challenges and risks of sharing clinical trial data.
- Discuss the landscape of laws, regulations, and policies under which data sharing occurs, focusing on competition and intellectual property laws and protection of clinical trial research participants.
- Discuss incentives for data sharing and challenges in the implementation and ongoing conduct of data sharing activities.
- Seek public comment on potential strategies and approaches to facilitate responsible data sharing.

February 3 (Day 1) – OPEN SESSION 1:00–5:00p.m.

1:00 p.m. Welcome and Introductory Remarks (begin open session)
Bernard Lo, Committee Chair, The Greenwall Foundation

1:05 p.m. Overview of the Framework for Discussion
Bernard Lo, Committee Chair, The Greenwall Foundation
- Overview of the process for development of the framework for discussion and the purpose of the discussion framework work product
- Overview of major points made in the document
- Overview of the key issues for feedback identified by the committee
SESSION 1: CLINICAL TRIAL DATA ELEMENTS AND SHARING ACTIVITIES: PUBLIC FEEDBACK

Session Objectives:
• Identify the key purposes, benefits, risks, and challenges of each model described in the discussion framework. Where relevant, explore how each model's benefits and burdens are differentially experienced by research sponsors and investigators, study participants, regulatory agencies, patient groups, and the public.
• Consider whether other models of sharing might be included in the analytic framework.

Series of Panel Discussions

1:20 p.m.  Model 1 – Open Access (25 mins)

Moderator: Ida Sim, UCSF School of Medicine

Discussants:
John Wilbanks, Sage Bionetworks
Atul Butte, Stanford University School of Medicine

1:45 p.m.  Model 2 – Controlled Access to Individual Company, Institution, or Researcher Data (25 mins)

Moderator: Steve Goodman, Stanford University School of Medicine

Discussants:
Joe Ross, Yale University School of Medicine
Ira Shoulson, Georgetown University

2:10 p.m.  Model 3 – Controlled Access to Pooled or Multiple Data Sources (25 mins)

Moderator: Steve Goodman, Stanford University School of Medicine

Discussants:
Jessica Scott, GlaxoSmithKline
Laurie Ryan, Alzheimer’s Disease Neuroimaging Initiative

2:35 p.m.  Model 4 – Closed Partnership/Consortium (25 mins)

Moderator: Ida Sim, UCSF School of Medicine

Discussant:
Lynn D. Hudson, Critical Path Institute
3:00 p.m.  **Moderated Discussion and Public Response (25 mins)**

**Moderator:** Steve Goodman, Stanford University School of Medicine

**Discussion Questions:**
- Invited panelists have the opportunity to present benefits, risks, and challenges of other models from their perspective.
- What, if any, changes or additions to the descriptions of the models might be considered?
- Are there other models substantially different from those the committee has proposed that could be included?

3:25 p.m.  **BREAK (15 mins)**

3:40 p.m.  **Guiding Principles for Clinical Trial Data Sharing (65 mins)**

- Invited discussants to consider the suggested guiding principles for data sharing.
- Discuss how the principles can be operationalized to balance the benefits and risks of data sharing.

**Moderator:** Patricia A. King, Georgetown University Law Center

**Discussants:**
Susan Bull, The Ethox Centre, University of Oxford
Barbara Bierer, Brigham and Women’s Hospital
Phil Fontanarosa, *JAMA*

4:45 p.m.  **Brief Preliminary Public Comment Period**

5:00 p.m.  **Closing Remarks *(adjourn open session)***

*Bernard Lo, Committee Chair*
February 4 (Day 2) – OPEN SESSION 9:00 a.m.–5:30 p.m.

9:00 a.m. Welcome and Introductory Remarks (begin open session)
Bernard Lo, Committee Chair

SESSION 2: LEGAL, REGULATORY, AND POLICY CONTEXT

Session Objective: Discuss the landscape of laws, regulations, and policies under which data sharing occurs, focusing on protection of clinical trial research participants and competition and intellectual property laws.

Legal, Regulatory, and Policy Context: Protection of Research Participants

9:10 a.m. International Legal and Policy Context
Mark Barnes, Ropes & Gray LLP and Harvard Multi-Regional Clinical Trials (MRCT) Network

9:45 a.m. Discussion Panel: Informed Consent (45 mins)

Panelists to discuss:
- Issues and barriers for retrospective data sharing (trials already conducted or under way)
  - Current legal framework – U.S. (Common Rule and FDA) and international
- Suggestions to facilitate sharing while guarding principles and requirements for informed consent for prospective data sharing (trials not yet conducted or initiated)
  - Legal and policy framework needed to facilitate prospective data sharing
  - Principles and elements of the consent document and process
  - Operational and institutional issues, especially IRB/ethics committee review

Moderator: Elizabeth G. Nabel, Harvard Medical School, Brigham and Women’s Hospital

Discussants:
Pearl O’Rourke, Harvard University
David Forster, Western IRB

10:30 a.m. BREAK (15 mins)
10:45 a.m.  Discussion Panel: **Privacy** *(60 mins)*

Panelists to discuss:
- Current legal framework of privacy protections – global legal/regulatory structure, with an emphasis on EU and U.S. and high-level description of other non-EU/U.S. jurisdictions
  - How can a global infrastructure or common global approach to data sharing address or take into account disparate data privacy protection requirements and different cultural standards?
- Privacy risks presented by data sharing (including to patients, researchers, and institutions)
- Current deidentification and reidentification technology and standards
- Defining “deidentified” and “anonymized” data; purposes and uses of identifiable/non-anonymized data – when/for what scientific or other purposes are identifiable data required?
- Fair information practices and approaches to privacy protection

**Moderator:** Deven McGraw, Center for Democracy & Technology

**Panelists:**
- Robert Gellman, Privacy and Information Policy Consultant
- Barbara Evans, University of Houston Law School
- Bradley Malin, Vanderbilt University
- Mark Barnes, Ropes & Gray LLP

11:45 p.m.  **LUNCH** *(45 mins)*

**Legal, Regulatory, and Policy Context: Intellectual Property and Competition Law** *(60 mins)*

12:30 p.m.  Series of Speakers: **Intellectual Property and Competition Law**

Speakers to address:
- Intellectual Property Law; Patent Issues
- Data Exclusivity Rules and Regulatory Landscape
- Definition of “Commercial Confidential Information”
- Antitrust Considerations for Data Sharing

**Moderator:** Arti Rai, Duke University School of Law

**Speakers:**
- Benjamin Roin, Petrie-Flom Center, Harvard Law School
- Trevor Cook, WilmerHale
- Jorge Contreras, American University, Washington College of Law
- Aliza Y. Glasner, Georgetown University
SESSION 3: INCENTIVES FOR SHARING AND IMPLEMENTATION OF DATA SHARING ACTIVITIES

**Session Objectives:**

- Discuss how recognition and promotion structures and processes can provide incentives or disincentives to share data. Identify these incentives and norms in academia, industry, government, and other sectors as relevant. Explore potential strategies to lower disincentives or other barriers to data sharing.
- Discuss potential negative or unintended consequences of sharing data and explore potential strategies to mitigate these consequences or challenges.

1:30 p.m. Discussion Panel: **Scientific Standards and Data Integrity/Quality** (45 mins)

Panelists to discuss:

- The impact of secondary analyses of data. What methods should be in place to ensure that potential consequences are balanced?
- Strategies to provide an understanding of how different analyses may lead to different conclusions. Approaches to address potential negative consequences and support the scientific integrity of the original and derivative works.
- Standards and expectations for secondary use. Provide examples where data sharing made a positive difference in understanding and where data sharing led to detrimental outcomes or analyses that did not meet scientific standards.

**Moderator:** Jeffrey Drazen, New England Journal of Medicine

**Discussants:**

- Peter Doshi, Johns Hopkins University
- John Ioannidis, Stanford University School of Medicine
- Erika Von Mutius, University of Munich

2:15 p.m. Discussion Panel: **Cultural and Financial Incentives for Data Sharing – Recognition and Promotion** (45 mins)

Panelists to discuss:

- Recognition and promotion norms in academia – including academic promotion/tenure structures; approaches to academic credit for clinical trialists – and their impact on incentives to share data
- Industry staffing/promotion structures; cultural issues relating to data sharing
Moderator: Joanne Waldstreicher, Johnson & Johnson

Discussants:
  Ira Shoulson, Georgetown University
  Ann Bonham, Association of American Medical Colleges (AAMC)
  Michael Rosenblatt, Merck

3:00 p.m. BREAK (15 mins)

3:15 p.m. Discussion Panel: Resource Considerations and Implementation Barriers (45 mins)

Panelists to discuss:
- Benefits, risks, and challenges associated with having staff to answer inquiries and questions from secondary users of data.
- Handling of data queries/requests; allocation of responsibilities for housing data and maintaining needed records
- Issues pertaining to sharing of data in settings of limited resources (e.g., developing or resource-poor countries or small companies/biotech)

Moderator: Tim Coetzee, National MS Society

Discussants:
  Atul Butte, Stanford University School of Medicine
  Janet Wittes, Statistics Collaborative
  Matt Gross, SAS
  Kenneth I. Moch, Chimerix

SESSION 4: OVERARCHING AND CROSS-CUTTING ISSUES

Session Objectives:
- Discuss and explore the practical implications of the proposed guiding principles in light of the panel discussions held during this public workshop.
- Discuss selected cross-cutting questions and issues posed by the committee in the discussion framework.
- Suggest strategies and practical approaches to facilitate responsible data sharing.

4:00 p.m. Discussion Panel: Cross-Cutting Proposed Guiding Principles and Discussion Framework Questions (45 mins)

Panelists to discuss:
- Because most large clinical trials are global in nature, how can clinical trial data be shared in that global context? How can different national regulations for research participants’ privacy protections, approval of drugs and devices, data exclusivity and intellectual property laws, resources, and health priorities be taken into account?
- How might strategies and approaches regarding data sharing take into account clinical trials conducted in resource-poor settings; trials designed by citizen-
scientists using data they contribute directly; and trials designed through participatory research?

- How might different types of clinical trial data, and different uses of shared data, be prioritized for sharing? What would be the rationale for placing a higher priority on certain types of data or analyses? What might be the advantages and disadvantages of distinguishing highest priority sharing of clinical trial data from subsequent sharing activities?

- What might be the advantages and disadvantages to various stakeholders of sharing different types of datasets, at different points in time after the completion of a clinical trial?

- Should programs or approaches calling for or requiring new data sharing apply only to new trials undertaken from the date of a new program forward, or retroactively apply to clinical trials started before the data sharing program was initiated?

- What might be done to minimize the risks to patients and to public health from the dissemination of findings from invalid analyses of shared clinical trial data?

- What measures should be deployed to minimize the privacy and confidentiality risks to trial participants? For example, are current anonymization or de-identification methodologies sufficient?

- Under what circumstances are identifiable data needed to fulfill articulated purposes of a data sharing activity? Under what circumstances might re-identification of trial participants be beneficial (for the participants or the public)? Have there been there examples of instances of re-identification of trial participants (e.g., for safety reasons to warn a patient of a potential risk, or for questionable and potentially unethical reasons) and what were the impacts?

- What incentives and protections might be established to encourage clinical trial sponsors and clinical investigators to continue to conduct clinical trials in the future, without unduly restricting the sharing of certain types of data? How do we protect or provide incentives for researchers to share data?

- What is the appropriate responsibility of the primary investigator(s) or research institution(s) to support secondary users in their interpretation of shared data, and what infrastructure or resources are needed to enable such ongoing support? For those with experience in data sharing, what is the burden of providing such support to help others understand and use the provided information?

- What would be appropriate outcome measures to assess the usefulness of different models of clinical trial data sharing, and how can they be used to guide improvements in data sharing practices?

**Moderator:** Bernard Lo, Committee Chair, The Greenwall Foundation

**Discussants:**
- Susan Bull, The Ethox Centre, University of Oxford
- John Ioannidis, Stanford University School of Medicine
- Erica VonMutius, University of Munich
- Ira Shoulson, Georgetown University

4:45 p.m. **Public Comment Period**

5:15 p.m. **Closing Comments (End Open Session)**
_Bernard Lo, Committee Chair, The Greenwall Foundation_