

Draft agenda

Tuesday, January 28, 2014

9:03 AM

Public Workshop: Strategies for Responsible Sharing of Clinical Trial Data

February 3–4, 2014 – Open Session

The National Academies

Keck Center, Room 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

1:05 p.m. **Overview of the Framework for Discussion**

Bernard Lo, Committee Chair

- 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)**

Panel discussion: Each panelist to briefly introduce themselves and provide up to 5 minutes/5slides of prepared comments, followed by a moderated discussion.

Moderator: Steve Goodman

Discussants:

John Wilbanks, Sage Bionetworks (*confirmed*)

Atul Butte, Immport (*confirmed*)

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

Panel discussion: Each panelist to briefly introduce themselves and provide up to 5 minutes/5slides of prepared comments, followed by a moderated discussion.

Moderator: Steve Goodman

Discussants:

Joe Ross, YODA (*confirmed*)

Ira Shoulson, Georgetown (*confirmed*)

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

Panel discussion: Each panelist to briefly introduce themselves and provide up to 5 minutes/5slides of prepared comments, followed by a moderated discussion.

Moderator: Ida Sim

Discussants:

Jessica Scott, GSK (*confirmed*)

Laurie Ryan, ADNI (*invited*)

Barbara Beirer, Brigham and Women's Hospital

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

Panel discussion: Each panelist to briefly introduce themselves and provide up to 5 minutes/5 slides of prepared comments, followed by a moderated discussion.

Moderator: Ida Sim

Discussants:

Lynn D. Hudson, CPATH, (*confirmed*)

Sally Okun, PatientsLikeMe (*invited*)

3:00 p.m. **Moderated Discussion and Public Response (25 mins)**

Moderator: Steve Goodman

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)**

Panel discussion: Each panelist to briefly introduce themselves and provide up to 8 minutes/8 slides of prepared comments, followed by a moderated discussion.

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

Moderator: Pat King

Discussants:

Susan Bull, Ethox Centre (*confirmed*)

Barbara Bierer, Brigham and Women's Hospital (*confirmed*)

Phil Fontanarosa, JAMA (*confirmed*)

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*)

Panel discussion: Each panelist to briefly introduce themselves and provide up to 8 minutes/8slides of prepared comments, followed by a moderated discussion.

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: Sharon Terry

Discussants:

Pearl O'Rourke, Harvard (*confirmed*)

David Forster, Western IRB (*confirmed*)

10:30 a.m. **BREAK** (*15 mins*)

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

Panel discussion: Each panelist to briefly introduce themselves and provide up to 8 minutes/8 slides of prepared comments, followed by a moderated discussion.

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

Panelists:

Barbara Evans, University of Houston Law School (*confirmed*)

Bradley Malin, Associate Professor of Biomedical Informatics and Computer Science, Director Health Information Privacy Laboratory, Vanderbilt University (*confirmed*)

Robert Gelman, Privacy and Information Policy Consultant (*confirmed*)

Mark Barnes, Ropes & Grey LLP (international perspective)

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

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

Series of Speakers: Each speaker to briefly introduce themselves and provide 10 minutes/10slides of prepared comments, followed by moderated discussion.

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

Speakers:

Benjamin Roin, Petrie-Flom Center, Harvard Law School *(confirmed)*

Trevor Cook, WilmerHale *(confirmed)*

Jorge Contreras, American University *(confirmed)*

Aliza Glasner, Georgetown Law *(invited)*

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)

Panel discussion: Each panelist to briefly introduce themselves and provide up to 8 minutes/8 slides of prepared comments, followed by a moderated discussion.

Panelists to discuss:

- The impact of secondary analyses of data. Findings could be shown to be more robust if secondary analyses reconfirm or extend the published outcomes-this could enhance public confidence in the data while there is the potential for inaccurate or inadequate conclusions to be drawn from shared data. What methods should be in place to ensure that these distinct potential consequences (public opinion of research, researchers or research institutions, industry, regulators; public understanding of scientific findings or clinical/therapeutic interventions) are balanced?
- Strategies to provide an understanding of how different analyses may lead to different conclusions including the address negative consequences and to guard scientific integrity of the original and derivative works
- Standards and expectations for secondary use of data-how can we learn from studies they have conducted what are the barriers to effective data sharing and what positive outcomes have derived from data sharing. We are especially interested in learning of examples where data sharing made a positive difference in understanding.

Moderator: Jeffrey Drazen

Discussants:

Peter Doshi, Johns Hopkins *(confirmed)*

John Ioannidis, Stanford *(confirmed)*

Erika Von Mutius, University of Munich *(confirmed)*

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

Panel discussion: Each panelist to briefly introduce themselves and provide up to 8 minutes/8 slides of prepared comments, followed by a moderated discussion.

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: Tim Coetzee

Discussants:

Ira Shoulson, Georgetown (*confirmed*)

Ann Bonham, AAMC (*confirmed*)

Phil Fontanarosa JAMA (*confirmed*)

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

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

Panel discussion: Each panelist to briefly introduce themselves and provide up to 8 minutes/8 slides of prepared comments, followed by a moderated discussion.

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: Joanne Waldstreicher

Discussants:

Atul Butte, Immport (*confirmed*)

Janet Wittes, Statistics Collaborative (*confirmed*)

Matt Gross, SAS (*confirmed*)

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:

- At what point should clinical trial data be released? What might be the advantages and disadvantages to various stakeholders of sharing different types of datasets, at different points in time after completion of a clinical trial?
- How might different types of clinical trial data, and different secondary uses of 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? Should the size of the trial matter in deciding priority?
- 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 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?
- How can clinical trial data be shared in the global context in which clinical trials are carried out? How can different regulations for 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?

Moderator: Bernard Lo

Discussants:

Susan Bull, Ethox Centre (*confirmed*)

John Ioannidis, Stanford University (*confirmed*)

Erica VonMutius, University of Munich (*confirmed*)

Ira Shoulson, Georgetown (*confirmed*)

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

5:15 p.m. **Closing Comments (*End Open Session*)**

Bernard Lo, Committee Chair