Discussion Framework for Clinical Trial Data Sharing:
Guiding Principles, Elements, and Activities

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IOM Committee on Responsible Sharing of Clinical Trial Data
Study Sponsors

- National Institutes of Health
- U.S. Food and Drug Administration
- AbbVie Inc.
- Amgen Inc
- AstraZeneca Pharmaceuticals
- Bayer, Biogen Idec
- Bristol-Myers Squibb
- Burroughs Wellcome Fund
- Doris Duke Charitable Foundation
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- Medical Research Council (UK)
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- Sanofi-Aventis
- Takeda
- Wellcome Trust
Committee members

**Bernard Lo, M.D.** (Chair), The Greenwall Foundation

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**Sharon Terry, M.A.,** Genetic Alliance

**Joanne Waldstreicher, M.D.,** Johnson & Johnson
Charge to the Committee

An ad hoc committee of the Institute of Medicine will conduct a study to develop guiding principles and a framework (activities and strategies) for the responsible sharing of clinical trial data...
Charge to the Committee: Framework Document

- Articulate guiding principles …
- Describe a selected set of data and data sharing activities …
  - Types of data (e.g., summary, participant)
  - Provider(s) and recipient(s) of shared data
  - Whether and when data are disclosed publicly, with or without restrictions, or exchanged privately among parties
- No findings or recommendations
Charge to the Committee: final report

• For each data sharing activity:
  • Identify key benefits of sharing and risks of not sharing to research sponsors and investigators, study participants, regulatory agencies, patient groups, and the public.
  • Address key challenges and risks of sharing
  • Outline strategies and suggest practical approaches to facilitate responsible data sharing
• Make recommendations to enhance responsible sharing of clinical trial data.
Committee Study Process

- Committee formation
- **1st Committee Mtg** Open Session (Oct 22-23)
- **2nd Committee Mtg** Open Session (Feb 3-4)
- **3rd Committee Mtg** Open Session (May 5)
- **4th Committee Mtg** Closed
- **5th Committee Mtg** Closed
- Release Framework for public comment (January 22)
- Sponsor Briefing (TBD)
- Report Release (TBD)

***Dates***
- 2013
- 2014
Peer Review of Document

• The review of this report was overseen by Enriqueta Bond at The Burroughs Wellcome Fund who served as Coordinator, while Stephen E. Fienberg at Carnegie Mellon University served as Monitor.

• They were responsible for making certain the independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered.

• There were 11 reviewers:

  • Peter S. Kim, Stanford University School of Medicine
  • Christine Laine, Annals of Internal Medicine
  • Bartha Knoppers, McGill University
  • Marc Boutin, National Health Council
  • Jerome P. Reiter, Duke University
  • Harlan M. Krumholz, Yale University School of Medicine
  • Lawrence J Appel, Johns Hopkins Medical Institutions
  • David Korn, Harvard University
  • Kay Dickersin, Johns Hopkins Bloomberg School of Public Health
  • Donald M Steinwachs, Johns Hopkins University
  • Alan M. Zaslavsky, Harvard Medical School
  • David Harrington, Harvard School of Public Health
  • Sir Michael Rawlins, Royal Society of Medicine
Provisional Guiding Principles

• Respect individual participants whose data are shared.

• Maximize benefits to participants in clinical trials and to society, while minimizing harms.

• Increase public trust in clinical trials.

• Carry out sharing of clinical trial data in a manner that enhances fairness.
Operational Considerations

• Timing of when data are shared.
• Proportional consideration of benefits, burdens, and risks to various parties…
• Opportunities to embed “learning” in a clinical trial data sharing system.
  • Benefits
  • Adverse consequences
  • Best practices
  • Ongoing quality improvement
• Need to be globally applicable and practically achievable.
To whom do benefits of clinical trials data belong?

- Property interest in clinical trial data?
  - Research institutions?
  - Funders of research?
- Do benefits primarily belong to:
  - Public?
  - Institutions and individuals who invested time and resources in trial?
  - Implications for obligation to share data
  - Need to balance perspectives and guiding principles and legal requirements
Data sharing elements and activities

- Conceptual framework to organize the ongoing work of the committee
- Guide future analysis of benefits, risks, burdens challenges
- Recommendations in final report
Metadata and additional documentation

• Without metadata, it is difficult to use or interpret other data

• Some metadata and related documents might be needed to facilitate full use of shared data, e.g.:
  • Full protocol and amendments
  • Manual of operations and standard operating procedures
  • Statistical Analysis Plan (SAP) and amendments, codes, software
Data sharing elements / activities

- **Who** Are the Providers of Shared Data?
- **Who** Are the Recipients of Shared Data?
- **When** Might Clinical Trial Data Be Shared?
- **How** Might Data be Shared?
  - Models range from *Open* to *Controlled Access*
Models for data sharing

• Four approaches or models of how clinical trial data might be shared
  • Conceptual categories rather than actual proposals
• For each model, several features considered:
  • Types of data
  • Providers of data
  • Recipients of data
  • Timing of sharing
  • Conditions or qualifications for access
  • Conditions of use
Models for data sharing

• Open Access
• Controlled Access to Individual Company, Institution, or Researcher Data
  • Conditions or qualifications for access
  • Conditions for data use
• Controlled Access to Pooled or Multiple Data Sources
• Closed Partnership/Consortium
Topics for public feedback to assist in second phase of study

- Global impact and Practical Considerations
- Timing and Prioritization
- Mitigating Risks
- Enhancing Incentives
- Measuring Impact
Project Website:

www.iom.edu/Activities/Research/SharingClinicalTrialData.aspx


Submit Direct Feedback:

- Comments may be submitted to the committee via the committee’s project website, http://www8.nationalacademies.org/cp/projectview.aspx?key=49578.
www.iom.edu/Activities/Research/SharingClinicalTrialData.aspx and on the National Academies Press website: www.nap.edu

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An ad hoc committee of the Institute of Medicine will conduct a study to develop **guiding principles and a framework (activities and strategies) for the responsible sharing of clinical trial data**. For the purposes of the study, the scope will be limited to interventional clinical trials and “data sharing” will include the responsible entity (data generator) making the data available via open or restricted access, or exchanged among parties. For the purposes of this study, “data generator” will include industry sponsors, data repositories, and researchers conducting clinical trials.

Specifically, the committee will

- Articulate guiding principles that underpin the responsible sharing of clinical trial data.
- Describe a selected set of data and data sharing activities, including, but not limited to
  - types of data (e.g., summary, participant);
  - provider(s) and recipient(s) of shared data; and
  - whether and when data are disclosed publicly, with or without restrictions, or exchanged privately among parties.
- For each data sharing activity, the committee will
  - identify key benefits of sharing and risks of not sharing to research sponsors and investigators, study participants, regulatory agencies, patient groups, and the public.
  - address key challenges and risks of sharing (e.g., resource constraints, implementation, disincentives in the academic research model, changing norms, protection of human subjects and patient privacy, intellectual property/legal issues, preservation of scientific standards, and data quality).
  - outline strategies and suggest practical approaches to facilitate responsible data sharing.

Make recommendations to enhance responsible sharing of clinical trial data. The committee will identify guiding principles and characteristics for the optimal infrastructure and governance for sharing clinical trial data, taking into consideration a variety of approaches (e.g., a distributed/federated data system).

In developing the principles and framework and in defining the rights, responsibilities, and limitations underpinning the responsible sharing of clinical trial data, the committee will take into account the benefits of data sharing, the potential adverse consequences of both sharing and not sharing data, and the landscape of regulations and policies under which data sharing occurs. Focused consideration will also be given to the ethical standards and to integrating core principles and values, including privacy. The committee is not expected to develop or define specific technical data standards.

A framework for discussion will be released for public comment, which will include tentative findings regarding (a) guiding principles and (b) a selected set of data sharing activities. Based on the public comments received and further deliberations, the committee will prepare a final report with its findings and recommendations.