

Sharing Your Thoughts About Sharing Clinical Trial Data

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THE INSTITUTE OF MEDICINE (IOM) is looking for your opinion on sharing clinical trial data.

The IOM has convened an ad hoc committee to conduct a consensus study to develop recommendations for sharing clinical trial data. This committee, chaired by Bernard Lo, executive director of the Greenwall Foundation, came together in October 2013 and will deliver a final report by December 2014. As an early step, the committee created a framework for discussion that describes the committee's early thoughts on guiding principles, defines key elements of data and data-sharing activities, and describes a select set of data-sharing activities. This framework is meant to set the stage for the identification of the numerous opportunities and challenges for which clinical data sharing may need to account. True clinical data sharing will require a culture shift, and, as such, potential effects on the broad ecosystem of biomedical research and the development of interventions must be assessed. It is often remarked that incentives are not aligned for deep collaboration and sharing, and so these must be considered across various stakeholder groups. Thus, guiding principles are not objective statements in a vacuum and could be perceived different ways by different stakeholders.

Clinical trials are critical to evaluating interventions, and they are a significant investment on the part of many stakeholders: the participants in the trials, investigators who conduct the trials and analyze the data, and the sponsors of the trials. An IOM October 2012 workshop, chaired by this author, concluded that sharing clinical trial data has fairly wide acceptance as an important activity to accelerate treatment development. The workshop also concluded that much of the data generated by clinical trials is not shared, and sharing data is often difficult. An IOM workshop is an excellent vehicle for hearing from many stakeholders and defining an issue. It does not, however, make recommendations. The IOM process for creating recommendation is much more rigorous. This requires a consensus study, which in this case will recommend guiding principles and a framework, including strategies and activities, for the responsible sharing of clinical trial data. A final report will be released in December 2014.

The framework document released in January 2014 did not include any recommendations, as will the final report, but instead laid out key issues so “that the public can point out omissions and begin to suggest benefits, interests, risks, and burdens of options that should be considered” (Institute of Medicine 2014).

The committee's charge includes articulating guiding principles and describing a selected set of data and data-sharing activities. This must include the types of data that might be shared (from summary-level to individual-level data), the provider and the recipient of the data, and what kind of sharing (open, closed, semi-restricted, gate-kept, privately exchanged).

The committee would like your thoughts about the following principles, strategies, and activities. Share with us what resonates, what is missing, what you disagree with, and what implications or ramifications you see. Do you know good data-sharing models? Have you experienced data sharing that led to problems? If so, what were they, and how could the challenges have been better addressed? Your contributions will help the committee refine this conceptual framework to organize the ongoing work of the committee; guide future analysis of benefits, risks, burdens, and challenges; and help shape the recommendations in final report.

Summary of the Framework Report

Provisional guiding principles of data sharing

- 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 strategies resulting from the principles

- 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, with all of the ensuing ramifications
- Need to be globally applicable and practically achievable

Data-sharing elements and 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?

These are conceptual categories rather than actual proposals and for each model several features must be considered:

- Types of data
- Providers of data
- Recipients of data
- Timing of sharing
- Conditions or qualifications for access
- Conditions of use

Four approaches or models of how clinical trial data might be shared:

- Open access
- Controlled access to individual company, institution, or researcher data
- Controlled access to pooled or multiple data sources
- Closed partnership/consortium

Topics in need of public feedback

- Global impact and practical considerations
- Timing and prioritization
- Mitigating risks
- Enhancing incentives
- Measuring impact

It is important that all stakeholders contribute to this process. From where you stand, and what you do, and your vision for the future of the discovery of interventions to improve human health, what should this report recommend?

I am so often reminded that each of us plays a small role; we each have a piece of an enormous puzzle. Most of us cannot see the edges and corners. And, despite our small part, we have a great deal to add to the whole. Please come forward with your thoughts and ideas—you can simply email them to

the committee, or place them in the portal created for this purpose at: <http://www8.nationalacademies.org/cp/feedback.aspx?key=49578&type=project>.

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Members of the Committee are as follow:

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Reference

Institute of Medicine. Strategies for responsible sharing of clinical trial data. 2014. Available at: www.iom.edu/Activities/Research/SharingClinicalTrialData.aspx, accessed March 14, 2014.

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