

# Sharing Clinical Trial Data

## Maximizing Benefits, Minimizing Risk



**Although clinical trials generate vast amounts of data**, a large portion is never published or made available to other researchers. Data sharing could advance scientific discovery and improve clinical care by maximizing the knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials. But data sharing also entails significant risks, burdens, and challenges. Policies are needed to protect the privacy of participants, the investment of funders and sponsors, the academic recognition of investigators, and the validity of analyses, among other concerns.

With support from 23 public- and private-sector sponsors in the United States and abroad, the Institute of Medicine (IOM) assembled a committee to develop guiding principles and a practical framework for the responsible sharing of clinical trial data. In its report, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*, the committee concludes that sharing data is in the public interest, but a multi-stakeholder effort is needed to develop a culture, infrastructure, and policies that will foster responsible sharing—now and in the future.

**Data sharing could advance scientific discovery and improve clinical care by maximizing the knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials.**

### Guiding Principles for Sharing Clinical Trial Data

The ultimate goal of data sharing should be to increase scientific knowledge, leading to better therapies for patients. With this goal in mind, the IOM committee presents the following guiding principles for responsible sharing of clinical trial data:

- Maximize the benefits of clinical trials while minimizing the risks of data sharing.
- Respect individual participants whose data are shared.

- Increase public trust in clinical trials and the sharing of trial data.
- Conduct the sharing of trial data in a fair manner.

These principles should be balanced in the context of specific trials and stakeholder needs, including concerns about the potential harms and costs of data sharing.

Collaboration among a broad set of stakeholders is needed to create a culture in which responsible data sharing is incentivized and best practices are disseminated widely. To foster such a culture, including strategies to develop infrastructure, oversight, and sustainability, the IOM report details specific actions for funders and sponsors of clinical trials; disease advocacy organizations; regulatory and research oversight agencies; research ethics committees or institutional review boards; investigators; research institutions and universities; academic journals; and membership and professional societies.

### Optimal Timing for Data Sharing

There are many different types of data generated during the course of a clinical trial, including individual participant data (including raw data or the analyzable dataset); metadata (for example, trial protocol, statistical analysis plan, analytic code); and summary-level data (for example, lay summaries and clinical study reports). Sharing each type carries different benefits, risks, and challenges. For example, making the analyzable dataset available to researchers allows reanalysis and replication of trial results, but could lead to privacy concerns and inappropriate use. Furthermore, the analyzable dataset must be accompanied by metadata to ensure that secondary analyses are rigorous and efficient. Taking into account these and other considerations, the IOM committee identifies the optimal stage in the clinical trial lifecycle at which each data type should be shared, and under what conditions.

Decisions about the timing of data sharing should balance several goals:

1. allow a fair opportunity for clinical trialists to publish results before secondary investigators gain access to the data;
2. allow secondary investigators to access unpublished trial data after a fair period has passed or reproduce the findings of a published analysis; and
3. protect the commercial interests of sponsors in gaining regulatory approval for a product so that they receive fair financial rewards for their investment.

The IOM committee acknowledges the importance of allowing ample time after the completion of a trial for original investigators to complete their analyses; however, the committee concludes that this period should extend no longer than 18 months. When that period has passed—regardless of whether the trial results have been published—the IOM committee finds that the scientific process is best served by allowing other investigators to access the data. However, if the trial is part of a submission to a regulatory agency for approval, an exception should be made, and the data should be shared no later than 30 days after regulatory approval or 18 months after product abandonment.

When trial findings are published before the 18-month period has passed, the committee recommends that the supporting analytic dataset be shared within 6 months of publication. Although many practical constraints currently prevent the release of the analytic dataset simultaneously with publication, the committee expresses its hope that, as systems for responsible data sharing evolve, simultaneous sharing will become the standard.

Due to the wide variation in clinical trial types, the IOM committee recognizes that there will be necessary exceptions to its timing recommendations. These recommendations are meant to be professional standards rather than inflexible rules. In some cases, it may be appropriate to share data later than recommended; in others—particu-

**Collaboration among a broad set of stakeholders is needed to create a culture in which responsible data sharing is incentivized and best practices are disseminated widely.**

larly for trials likely to have major clinical, public health, or policy implications—it may be best to share data sooner. It is important to note that the committee’s data sharing recommendations do not apply to trials that are already complete, or “legacy” trials. Decisions to share legacy data should be made on a case by case basis, although the committee urges sponsors and investigators to prioritize the sharing of data from legacy trials whose findings influence decisions about clinical care.

### **Access to Clinical Trial Data**

Many of the risks associated with sharing clinical trial data may be mitigated by controlling which parties can access data and under what conditions. Policies for granting access to data should be in the service of several goals—protecting the privacy of participants; reducing risk of invalid analyses or misuse; avoiding undue burdens on data users and harm to investigators and sponsors; and enhancing public trust in clinical trial data sharing.

The committee believes that open, public access to clinical trial data is appropriate for sharing clinical trial results and may be desirable for sharing other types of data when all stakeholders—sponsors, investigators, and participants—are comfortable and believe the benefits outweigh the risks. But in many cases, stakeholders may have concerns about granting open access, including risks to privacy and security. A number of provisions could help assuage such concerns, including de-identification and data use agreements. Case-by-case reviews of data access requests could mit-

igate risks but may inhibit valid secondary analyses and stifle innovation if too restrictive. Reviews should be conducted by independent panels that include representatives from community, patient, and disease advocacy groups and should ensure transparent policies and procedures. Finally, the committee urges stakeholders to share lessons and best practices for data access policies as data sharing practices evolve.

### **The Future of Clinical Trial Data Sharing**

Although increased data sharing holds promise for scientific advancement, significant barriers remain. The IOM committee identifies several key challenge areas:

- *Infrastructure:* Currently, there are insufficient platforms to efficiently store and manage the breadth of trial data.
- *Technology:* At present, data sharing platforms are not consistently discoverable, searchable, or interoperable.
- *Workforce:* The clinical trials ecosystem lacks an adequate workforce to manage the operational and technical aspects of data sharing.
- *Sustainability:* For a system of data sharing to be sustainable, costs will need to be distributed equitably across both generators and users of data.

The committee outlines a conceptual business model for sustainable and equitable data sharing.



## Committee on Strategies for Responsible Sharing of Clinical Trial Data

**Bernard Lo** (Chair)  
President, The Greenwall Foundation

**Tim Coetzee**  
Chief Research Officer, National Multiple Sclerosis Society

**Jeffrey Drazen**  
Editor-in-Chief, *New England Journal of Medicine*

**Steve Goodman**  
Professor, Medicine & Health Research & Policy, Stanford University School of Medicine

**Patricia King**  
Carmack Waterhouse Professor of Law, Medicine, Ethics and Public Policy, Georgetown University Law Center

**Trudie Lang**  
Principal Investigator, Global Health Network, Nuffield Department of Medicine, University of Oxford

**Deven McGraw**  
Partner, Healthcare Practice, Manatt, Phelps & Phillips, LLP

**Elizabeth Nabel**  
President, Brigham and Women's Hospital

**Arti Rai**  
Elvin R. Latty Professor of Law, Duke University School of Law

**Iida Sim**  
Professor of Medicine and Co-Director of Biomedical Informatics of the Clinical and Translational Science Institute, University of California, San Francisco

**Sharon Terry**  
Chief Medical Officer, Genetic Alliance

**Joanne Waldstreicher**  
Chief Medical Officer, Johnson & Johnson

### Study Staff

**Anne B. Claiborne**  
Senior Program Officer

**India Hook-Barnard**  
Study Director (from July 2014)

**LeighAnne Olsen**  
Study Director (until November 2013)

**Rebecca N. Lenzi**  
Study Director (November 2013 to April 2014)

**Michelle Mancher**  
Associate Program Officer

**Elizabeth Cornett**  
Research Assistant (from October 2014)

**Rachel Kirkland**  
Senior Program Assistant (until October 2013)

**Barret Zimmermann**  
Senior Program Assistant (October 2013 to July 2014)

**Michael Berrios**  
Senior Program Assistant (from September 2014)

**Scott Halpern**  
IOM Anniversary Fellow

**Andrew M. Pope**  
Director, Board on Health Sciences Policy

### Study Sponsors

AbbVie Inc.

Amgen Inc.

AstraZeneca Pharmaceuticals

Bayer

Biogen Idec

Bristol-Myers Squibb

Burroughs Wellcome Fund

Doris Duke Charitable Foundation

Eli Lilly and Company

EMD Serono

Food and Drug Administration

Genentech

GlaxoSmithKline

Johnson & Johnson

Medical Research Council (UK)

Merck & Co., Inc.

National Institutes of Health

Novartis Pharmaceuticals Corporation

Novo Nordisk

Pfizer Inc.

Sanofi-Aventis


Takeda

The Wellcome Trust

Because data sharing benefits multiple stakeholders—including the public, insurers, health care providers, and researchers—all of these stakeholders should also bear some of the costs of the data sharing enterprise. Additional sources of funding, such as philanthropy, should be explored. Finally, the committee notes an ongoing need for accurate measurements of the costs of data sharing.

In order for responsible data sharing to become pervasive, sustained, and rooted as a professional norm, these and other challenges will have to be addressed collaboratively by diverse institutions and stakeholders. To promote discussion and exchange of ideas among these groups and to foster agreement around best practices, standards, and incentives, the committee recommends the formation of a global, multi-stakeholder body to address current and future challenges.

## Conclusion

Clinical trials are essential to determining the safety and efficacy of new health treatments, but limited data sharing prevents maximum utilization of knowledge gained. In short, the current system fails to provide an adequate return on the investments of trial participants, investigators, and sponsors. Greater data sharing could enhance public well-being by accelerating the drug discovery and development process, reducing redundant research, and facilitating scientific innovation. Before these benefits can be realized, however, stakeholders must confront significant risks and challenges. In *Sharing Clinical Trial Data*, the IOM committee provides a practical and ethical framework to help stakeholders navigate this complex terrain. 



**INSTITUTE OF MEDICINE**

OF THE NATIONAL ACADEMIES

**Advising the nation • Improving health**

500 Fifth Street, NW  
Washington, DC 20001

TEL 202.334.2352

FAX 202.334.1412

[www.iom.edu](http://www.iom.edu)

**The Institute of Medicine serves as adviser to the nation to improve health.**

Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policy makers, health professionals, the private sector, and the public.

Copyright 2015 by the National Academy of Sciences. All rights reserved.