



Sharing Clinical Trial Data

STATE OF THE FIELD: GOVERNANCE, TECHNICAL INFRASTRUCTURE, AND SUSTAINABILITY

Data sharing could advance scientific discovery by preventing unnecessary duplicative trials, inspiring new ideas for research, and ensuring maximum use of knowledge gained to improve clinical care. But data sharing also entails significant risks, burdens, and challenges. In the Institute of Medicine report *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*,

an expert committee provides guiding principles and a framework for the responsible sharing of clinical trial data. This action guide lays out the current challenges that will need to be addressed to fulfill the promise of data sharing, focusing on the issues of **governance, technical infrastructure, and sustainability**.

Today's Reality

- There are insufficient platforms to store and manage clinical trial data, and current platforms are not consistently discoverable, searchable, and interoperable.
- There is a shortage of skills and knowledge to manage the operational and technical aspects of data sharing.
- The costs of data sharing are borne by a small subset of sponsors, funders, and clinical trialists and are not equitably distributed.

A Vision for Data Sharing

- A culture of sharing with effective incentives and protections is in place to minimize the risks.
- There are multiple interoperable platforms for sharing clinical trial data, with different access models and sufficient capacity to meet demand.
- Stakeholders are able to identify the platform that is most appropriate for their needs.
- Best practices for sharing are identified and modified in response to ongoing experience and feedback.
- There is adequate financial support for sharing clinical trial data, and costs are fairly allocated among stakeholders.



Governance

Governance models for determining access to clinical trial data need to balance several goals: protecting the privacy of research participants, avoiding undue burdens on secondary users seeking access, avoiding undue harms to investigators and sponsors that share data, and enhancing public trust in the data sharing process. The committee endorses open access (to the public with no controls or conditions) for sharing summary-level clinical trial results (e.g., from ClinicalTrials.gov). In some cases, no or few controls on sharing other types of clinical trial data may be preferred when acceptable to all stakeholders involved, including trial participants, sponsors, and investigators. The committee recommends implementing a number of operational strategies for mitigating the risks and enhancing the benefits of sharing sensitive clinical trial data (e.g., individual participant data).

Committee Recommendation on Data Access

Holders of clinical trial data should mitigate the risks and enhance the benefits of sharing sensitive clinical trial data by using the following operational strategies:

- *Employing data use agreements*
- *Employing appropriate techniques for protecting privacy, in addition to de-identification and data security*
- *Designating an independent panel, including members of the lay public, to review data requests, where applicable*
- *Making the process of gaining access to clinical trial data transparent*
- *Learning by experience by collecting outcomes of data sharing policies, procedures, and technical approaches*

To read the full report and to view additional report resources, please visit:

nas.edu/datasharing



Technical Infrastructure

Many investigators are not in a place to store and manage data from their trials for an extended period of time, while other data holders want to maintain physical ownership of their data. To encourage data sharing, there need to be both places where investigators can easily store data after a trial has been completed, as well as a data-sharing infrastructure, able to manage data access, under a variety of access models.

Further, just because data are accessible does not mean they are usable. Data are usable only if an investigator can search and retrieve them, can make sense of them, and can analyze them within a single trial or can combine them across multiple trials. The technical infrastructure for data sharing needs to accommodate these aims.

Workforce Needs

An adequate workforce trained in the operational and technical aspects of data sharing needs to be developed. There is a growing gap between the supply of trained quantitative research scientists and people knowledgeable about biomedical informatics—including data models, ontologies, and standard vocabularies—and the growing demand for those skills. Training for the sharing of data needs to be part of the overall mission of funders of research training programs.



Sustainability

Data sharing costs include

- Infrastructure and administration costs (e.g., storage and curation, informed consent review).
- Standardization costs, including de-identification and making data understandable to others.
- Human resources to build and maintain the infrastructure, provide access, and respond to queries.
- Opportunity costs with not carrying out new research.

For data sharing to be sustainable, its costs will need to be equitably distributed across both data generators and users.