

Sharing Clinical Trial Data

Maximizing Benefits, Minimizing Risk

Recommendations



RECOMMENDATION 1: Stakeholders in clinical trials should foster a culture in which data sharing is the expected norm, and should commit to responsible strategies aimed at maximizing the benefits, minimizing the risks, and overcoming the challenges of sharing clinical trial data for all parties.

Funders and sponsors should

- promote the development of a sustainable infrastructure and mechanism by which data can be shared, in accordance with the terms and conditions of grants and contracts;
- provide funding to investigators for sharing of clinical trial data as a line item in grants and contracts
- include prior data sharing as a measure of impact when deciding about future funding;
- include and enforce requirements in the terms and conditions of grants and contracts that investigators will make clinical trial data available for sharing under the conditions recommended in this report; and
- fund and promote the development and adoption of common data elements.

Disease advocacy organizations should

- require data sharing plans as part of protocol reviews and criteria for funding grants;
- provide guidance and educational programs on data sharing for clinical trial participants;
- require data sharing plans as a condition for promoting clinical trials to their constituents; and
- contribute funding to enable data sharing.

Regulatory and research oversight bodies should

- work with industry and other stakeholders to develop and harmonize new clinical study report (CSR) templates that do not include commercially confidential information or personally identifiable data;
- work with regulatory authorities around the world to harmonize requirements and practices to support the responsible sharing of clinical trial data; and

- issue clear guidance that the sharing of clinical trial data is expected, and that the role of Research Ethics Committees or Institutional Review Boards (IRBs) is to encourage and facilitate the responsible and ethical conduct of data sharing through the adoption of protections such as those recommended by this committee and the emerging best practices of clinical trial data sharing initiatives.

Research Ethics Committees or IRBs should

- provide guidance for clinical trialists and templates for informed consent for participants that enable responsible data sharing;
- consider data sharing plans when assessing the benefits and risks of clinical trials; and
- adopt protections for participants as recommended by this committee and the emerging best practices of clinical trial data sharing initiatives.

Investigators and sponsors should

- design clinical trials and manage trial data with the expectation that data will be shared;
- adopt common data elements in new clinical trial protocols unless there is a compelling scientific reason not to do so;
- explain to participants during the informed consent process
 - what data will (and will not) be shared with the individual participants during and after the trial,
 - the potential risks to privacy associated with the collection and sharing of data during and after the trial and a summary of the types of protections employed to mitigate this risk, and
 - under what conditions the trial data may be shared (with regulators, investigators, etc.) beyond the trial team; and
- make clinical trial data available at the times and under the conditions recommended in this report.

Research institutions and universities should

- ensure that investigators from their institutions share data from clinical trials in accordance with the recommendations in this report and the terms and conditions of grants and contracts;
- promote the development of a sustainable infrastructure and mechanisms for data sharing;
- make sharing of clinical trial data a consideration in promotion of faculty members and assessment of programs; and
- provide training for data science and quantitative scientists to facilitate sharing and analysis of clinical trial data.

Journals should

- require authors of both primary and secondary analyses of clinical trial data to
 - document that they have submitted a data sharing plan at a site that shares data with and meets the data requirements of the World Health Organization’s International Clinical Trials Registry Platform before enrolling participants, and
 - commit to releasing the analytic data set underlying published analyses, tables, figures, and results no later than the times specified in this report;
- require that submitted manuscripts using existing data sets from clinical trials, in whole or in part, cite these data appropriately; and
- require that any published secondary analyses provide the data and metadata at the same level as in the original publication.

Membership and professional societies should

- establish policies that members should participate in sharing clinical trial data as part of their professional responsibilities;
- require as a condition of submitting abstracts to a meeting of the society and manuscripts to the journal of the society that clinical trial data will be shared in accordance with the recommendations in this report; and
- collaborate on and promote the development and use of common data elements relevant to their members.

RECOMMENDATION 2: Sponsors and investigators should share the various types of clinical trial data no later than the times specified below. Sponsors and investigators who decide to make data available for sharing before these times are encouraged to do so.

Trial registration:

- The data sharing plan for a clinical trial (i.e., what data will be shared when and under what conditions) should be publicly available at a third-party site that shares data with and meets the data requirements of WHO's International Clinical Trials Registry Platform; this should occur before the first participant is enrolled.

Study completion:

- Summary-level results of clinical trials (including adverse event summaries) should be made publicly available no later than 12 months after study completion.
- Lay summaries of results should be made available to trial participants concurrently with the sharing of summary-level results, no later than 12 months after study completion.
- The full data package (including the full analyzable data set, the full protocol,¹ the full statistical analysis plan, and the analytic code) should be shared no later than 18 months after study completion (unless the trial is in support of a regulatory application).

Publication:

- The post-publication data package (including the subset of the analyzable data set supporting the findings, tables, and figures in the publication and the full protocol, full statistical analysis plan, and analytic code that supports the published results) should be shared no later than 6 months after publication.

Regulatory application:

- For studies of products or new indications that are approved, the post-regulatory data package (including the full analyzable data set and clinical study report redacted for commercially or personal confidential information, together with the full protocol, full statistical analysis plan, and analytic code) should be shared 30 days after regulatory approval or 18 months after study completion, whichever occurs later.

¹ Includes the protocol in place at the start of the trial, any modifications, and the final protocol.

- For studies of new products or new indications for a marketed product that are abandoned, the post-regulatory data package should be shared no later than 18 months after abandonment. However, if the product is licensed to another party for further development, these data need be shared only after publication, approval, or final abandonment.

RECOMMENDATION 3: Holders of clinical trial data should mitigate the risks and enhance the benefits of sharing sensitive clinical trial data by implementing operational strategies that include employing data use agreements, designating an independent review panel, including members of the lay public in governance, and making access to clinical trial data transparent. Specifically, they should take the following actions:

- Employ data use agreements that include provisions aimed at protecting clinical trial participants, advancing the goal of producing scientifically valid secondary analyses, giving credit to the investigators who collected the clinical trial data, protecting the intellectual property interests of sponsors, and ultimately improving patient care.
- Employ other appropriate techniques for protecting privacy, in addition to de-identification and data security.
- Designate an independent review panel—in lieu of the sponsor or investigator of a clinical trial—if requests for access to clinical trial data will be reviewed for approval.
- Include lay representatives (e.g., patients, members of the public, and/or representatives of disease advocacy groups) on the independent review panel that reviews and approves data access requests.
- Make access to clinical trial data transparent by publicly reporting
 - the organizational structure, policies, procedures (e.g., criteria for determining access and conditions of use), and membership of the independent review panel that makes decisions about access to clinical trial data; and
 - a summary of the decisions regarding requests for data access, including the number of requests and approvals and the reasons for disapprovals.
- Learn from experience by collecting data on the outcomes of data sharing policies, procedures, and technical approaches (including the benefits, risks, and costs), and share information and lessons learned with clinical trial sponsors, the public, and other organizations sharing clinical trial data.

RECOMMENDATION 4: The sponsors of this study should take the lead, together with or via a trusted impartial organization(s), to convene a multistakeholder body with global reach and broad representation to address, in an ongoing process, the key infrastructure, technological, sustainability, and workforce challenges associated with the sharing of clinical trial data. 6