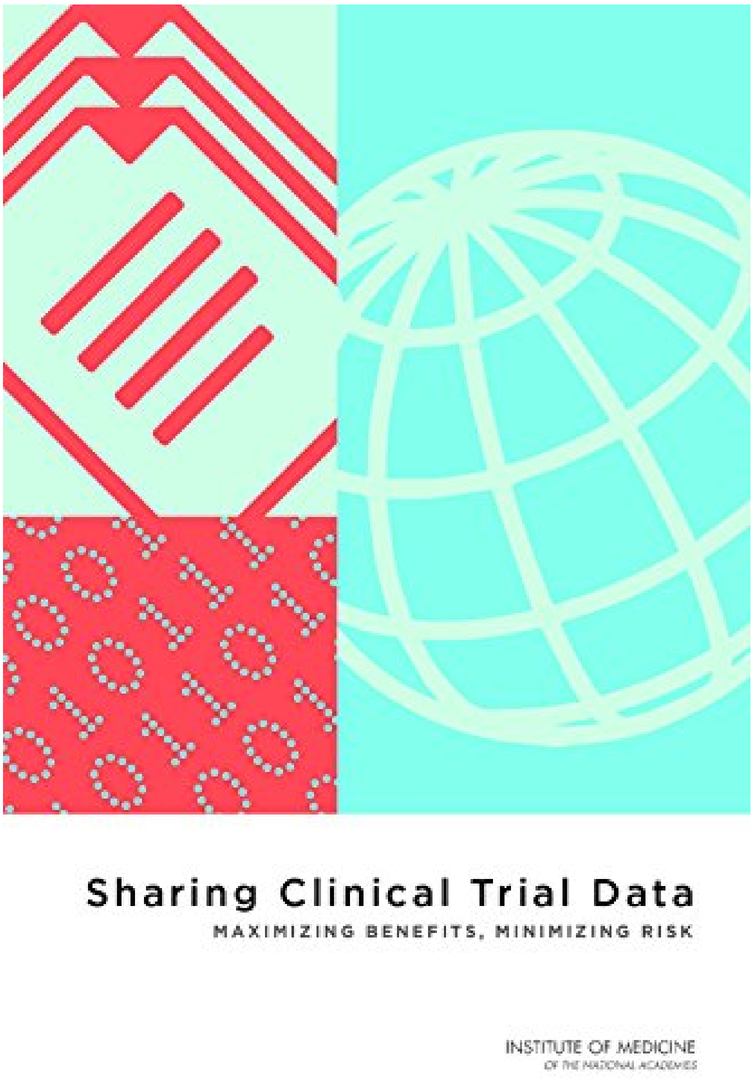
Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk

Institute of Medicine, Board on Health Sciences Policy, Committee on Strategies for Responsible Sharing of Clinical Trial Data



#3989524 in Books 2015-05-20Original language:EnglishPDF # 1 8.75 x 6.00 x .75l, .0 #File Name: 0309316294304 pages | File size: 47.Mb

Institute of Medicine, Board on Health Sciences Policy, Committee on Strategies for Responsible Sharing of Clinical Trial Data : Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk before purchasing it in order to gage whether or not it would be worth my time, and all praised Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk:

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concept?By Arete-ZoeAccording to Bernard Lo, M.D., Chair of the Committee on Strategies for Responsible Sharing of Clinical Trial Data, both patients and their physicians depend on clinical trials for evidence of efficacy and safety of therapies. Responsible sharing clinical trial data raises complex issues and challenges with regards to jurisdictional differences, privacy concerns, and variety of designs utilizing different kind of data (p x).The Committee was formed to develop guiding principles and a framework (activities and strategies) for the responsible sharing of clinical trial data (p xiii). The report assesses how key stakeholders including participants, sponsors, regulators, investigators, research institutions, journals, and professional societies assess the benefits, risks, and challenges of data sharing. The recommendations include fostering culture of data sharing in reasonable timeframe in a transparent way. The Committee suggests creation of a multi-stakeholder body with global reach and broad representation to address the key infrastructure, technological, sustainability, and workforce challenges associated with the sharing of clinical trial data (p xiv).Data sharing means that data from scientific studies is made available for secondary uses, namely reanalysis to check replicability and validity, meta-analyses and de-novo analyses (p 24).Chapter 2 presents the major potential benefits and risks of sharing clinical trial data and sets forth the guiding principles. In Chapter 3, stakeholders are identified, including their roles and responsibilities, and the benefits and risks of data sharing from their perspectives. Chapters 4 and 5 discuss type of data and timelines and methods of data sharing. Visions for data sharing are presented in Chapter 6 (p 27).Sharing of clinical trial data has great potential to accelerate scientific progress and improve public health. Data sharing increases contributions of trial participants to beyond narrow interests of the sponsor. The potential benefits need to be weighed against any potential harm, namely legitimate protection of intellectual property and privacy concerns which could potentially deter people from participating in trials. Distorted and invalid analyses may lead to lawsuits for negligence and burdensome responses. Additionally, qui tam lawsuits create a conflict of interest in the U.S. (p 34). The most important benefit of data sharing in intangible, though:Public trust is an intrinsic value undergirding the biomedical science and health research enterprise, which is fundamentally aimed at improving human health. At a more instrumental level, trust also is essential for ensuring continued public support for clinical research and for fostering participation in clinical trials (p 38).Key stakeholders in clinical trials include participants, research Ethics Committees, Data Monitoring Committees (DMCs/DSMBs), disease advocacy organizations, funders and sponsors of trials both non-profit and the industry, regulatory agencies, investigators including secondary analysts, research institutions and universities, journals and professional societies (p 48). Jurisdictional differences in protection of personal data can also be a concern, especially in Europe (p 52). Funders and sponsors have significant leverage to set standards and to encourage data sharing for the trials they fund (p 58). Specific examples of effects of secondary analyses are discussed in the context of conflict of interest of different stakeholders (pp 65-67).U.S. regulatory agencies have to maneuver within the constraints of the Freedom of Information Act (FOIA), the Trade Secrets Act (TSA), and 21 CFR 20.61(c) which makes information submitted or divulged to the FDA unavailable for public disclosure (p 70). Some legal scholars have argued that the FDA potentially has the power to disclose trade secrets for public health reasons, citing the Hatch-Waxman Act (p 71). The first recommendation of the Committee says: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 (p 80).Publication in scientific journals is the primary method for sharing clinical trial data with the scientific and medical communities. These publications, however, contain only a small subset of the data. In trials that are not part of a regulatory submission, detailed clinical study reports may or may not be prepared (p 91). The committee acknowledges that no single body or authority in the global clinical trials ecosystem has the power to enforce clinical trial data sharing (p 92).Chapter 4 scrutinizes in thorough detail what kind of data is produced in different type of trials, and how practical (or impractical) it is to share raw data, analyzable data set, clinical trial registration number and data set, full trial protocol, manual of operations, standard operating procedures, names of members of the team, Steering Committee, Clinical Events Committee, Data and Safety Monitoring Board, Data Monitoring Committee, committee charters, details of study execution, informed consent templates, included hypotheses, full statistical analysis plan (SAP), and analytic code (pp 91-105). Additional data for sharing include publications, summaries of results for registries, lay-language summaries, and clinical study reports, either in full or abbreviated form (p 105-111).The main argument for sharing data from legacy trials is that many current treatment decisions are based on clinical trials done in the past (p 111). The second Committee recommendation states: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 (p 132-133).Chapter 5 examines with whom the data are shared and under what conditions. Potential data recipients may seek access to data for a variety of purposes, which may present different potential benefits and risks: researchers, attorneys, competitors, consultants, whose clients may include investment and financing companies and research organizations, participants in the trial, journalists, disease advocacy groups, members of the public, research ethics committees, peer-review committees, data monitoring committees or educators (p 140).The key argument in favor of open access is that removing barriers facilitates reproducibility and more rapid advancement of new knowledge and discovery, and that the accompanying risk of invalid analyses is acceptable (p

141). Main concerns are participant privacy, unfair commercial use, invalid secondary analyses, and credit for clinical trialists and sponsors (p 145). The authors also mention already existing multi-sponsor web system ClinicalStudyDataRequest for requesting clinical trial data launched in January 2014 (p 149). Committee recommendation No 3 suggests:Holders of clinical trial data implement 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 (p 157).There are more platforms for sharing clinical trial data, with different data access models and sufficient total capacity to meet demand. The Committee shared its vision of culture of data sharing, articulated best practices, and called for allocating the cost of data sharing among stakeholders and protections to minimize the risks (p 164). Recommendation 4 says: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 (p 177).Appendices include details on study approach, concepts and methods of study data de-identification and legal discussions of risks to industry sponsors.The report is an essential reading for those who need to understand industry perspective. Industry generates vast majority of clinical trial data, and its primary purpose is to generate data for approval of new drugs and return on investment. A business case has to support public health perspective to incentivize data sharing.

Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients.