

University of Nebraska - Lincoln  
**DigitalCommons@University of Nebraska - Lincoln**

---

Copyright, Fair Use, Scholarly Communication, etc.

Libraries at University of Nebraska-Lincoln


---

2016

# Strengthening Research through Data Sharing

Elizabeth Warren  
*United States Senate*

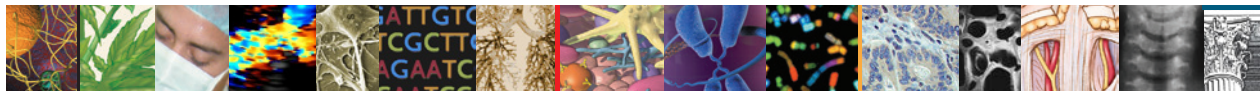
Follow this and additional works at: <http://digitalcommons.unl.edu/scholcom>

 Part of the [Intellectual Property Law Commons](#), [Scholarly Communication Commons](#), and the [Scholarly Publishing Commons](#)

---

Warren, Elizabeth, "Strengthening Research through Data Sharing" (2016). *Copyright, Fair Use, Scholarly Communication, etc.*. 26.  
<http://digitalcommons.unl.edu/scholcom/26>

This Article is brought to you for free and open access by the Libraries at University of Nebraska-Lincoln at DigitalCommons@University of Nebraska - Lincoln. It has been accepted for inclusion in Copyright, Fair Use, Scholarly Communication, etc. by an authorized administrator of DigitalCommons@University of Nebraska - Lincoln.



## Strengthening Research through Data Sharing

Elizabeth Warren, J.D.

Data sharing has incredible potential to strengthen academic research, the practice of medicine, and the integrity of the clinical trial system. Some benefits are obvious: when

researchers have access to complete data, they can answer new questions, explore different lines of analysis, and more efficiently conduct large-scale analyses across trials. Other advantages, such as providing a guardrail against conflicts of interest in a clinical trial system in which external sponsorship of research is common and necessary, are less visible yet just as critical.

I appreciate that there are many policy, privacy, and practical issues that need to be addressed in order to make data sharing practical and useful for the research community, but the stakes are too high to step back in the face of that challenge.

One policy proposal that I am

particularly enthusiastic about is making data sharing a condition of publication in major medical journals. In a recent letter to the International Committee of Medical Journal Editors (ICMJE), I applauded the committee's work in developing a framework for data sharing.<sup>1</sup> The ICMJE's proposal would require that, as a condition of having their research manuscripts considered for publication, authors share the deidentified patient data on which their results are based. This requirement would be a significant step forward in improving the transparency of clinical trials for consumers and the academic medical community. Although the privacy of participants must be protected, access

to the data underlying trial results can provide an avenue for independent confirmation of results and further analyses of the data set, raising the bar for academic rigor and integrity and speeding the progress of medical research.

As I told the members of the ICMJE, I believe that linking data sharing with publication can also help address the patchwork landscape of current regulations related to the sharing of clinical trial data. Because regulatory agencies have different protocols and requirements for sharing data related to the drugs and devices they approve, access to data about a clinical trial often hinges on which agency handles a regulatory submission rather than on the value of these data to consumers and researchers. By requiring data sharing as a condition of publication, journals can help synchronize and expand existing data-sharing practices.

I am also encouraged by the potential of such proposals to improve compliance with existing laws and regulations related to the reporting of clinical trial results. Each of the several ongoing efforts to increase data sharing through other routes has faced unique challenges. U.S. law has required the posting of summary clinical trial research results to the ClinicalTrials.gov database since the adoption of the Food and Drug Administration Amendment Act (FDAAA) in 2007. However, recent analyses have highlighted variation across sectors when it comes to trial sponsors' compliance with this law, in part due to a lack of final regulations, which leaves uncertainty about standards and impedes the ability of federal agencies to enforce requirements.<sup>2-4</sup> The European Medicines Agency has developed a policy that would require patient-level data to be disclosed after a drug has been approved. This plan has been delayed because of disagreement among stakeholders about how to share these data. Compliance with the more rigorous ICMJE requirements, though it will not automatically harmonize existing regulations, could nonetheless create a baseline expectation that data will be shared and prepare researchers to comply with other mandates.

Requiring researchers to file a data-sharing plan for patient-level data when they initially register a trial could increase pressure on trial sponsors to post results in a timely fashion, regardless of the type of trial, the country of origin of the research, and whether or not the research is being performed to support approval of a new medical product.

The costs associated with pre-

paring data for sharing can and should be built into the grants, cooperative agreements, and contracts that researchers negotiate with trial sponsors; in other words, expenses associated with administering data-sharing protocols must be treated as a standard, necessary aspect of the costs of carrying out a clinical trial. And over the long run, data sharing may help reduce costs by allowing researchers to avoid duplicating trials or to answer questions without undertaking a separate data-collection effort.

Widespread practices of data sharing can also help to address concerns about conflicts of interest that may arise when clinical trials are funded by industry sponsors that stand to profit from favorable research results. By making trial results available for independent scrutiny by outside reviewers, data sharing makes it less likely that trial sponsors can buy the analysis and results they want. Expanding opportunities for scrutiny through data transparency raises the bar for integrity in analysis and interpretation of results, helping to improve the reproducibility and rigor of our clinical trial system.

As the research community and policymakers develop and implement data-sharing requirements, I urge them to craft clear standards for granting qualified researchers access to the data underlying published results in cases in which the data cannot be made public. I recognize that some types of data may necessitate additional protections to preserve the rights and privacy of trial participants and researchers. However, these protections should not place undue burdens on researchers or restrict data access

to an overly narrow pool of researchers, nor should they be used to shield data from public view when no legitimate justification exists for restricting public access.

I understand the trepidation that some academics in medical research feel when they contemplate publicly sharing data. As an academic myself, I know the professional stakes attached to credit for original research. I expect that the field will engage in vigorous debate over what length of delay is appropriate before individual-level patient data are released publicly. However, I urge researchers with concerns about academic credit or a new way of doing things not to lose sight of the bigger picture: transparency and reanalysis of data are core practices of rigorous, peer-reviewed research, and increasing access to data will ultimately strengthen — rather than erode — these practices.

Finally, in considering how to encourage data sharing, I urge members of the medical research community to also consider ways to improve the public sharing of information from trials that have produced null, inconclusive, or negative results. As a recent study emphasized, negative trial results have a “sizeable scientific impact,” yet they are less likely to find their way into the pages of major medical journals.<sup>5</sup> Encouraging the publication of such trials and the release of their underlying data will help to further accelerate medical progress, uphold the ethical standards of human-subjects research, and help in holding industry sponsors accountable.

Data sharing holds incredible promise for strengthening the

practice of medical research and the integrity of our clinical trial system. I look forward to following these proposals as they continue to develop and urging their implementation.

Disclosure forms provided by the author are available at NEJM.org.

Elizabeth Warren (D-MA) is a U.S. senator.

1. Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data — a proposal from the International Committee of Medical Journal Editors. *N Engl J Med* 2016;374:384-6.
2. Anderson ML, Chiswell K, Peterson ED, Tasneem A, Topping J, Califf RM. Compliance with results reporting at ClinicalTrials.gov. *N Engl J Med* 2015;372:1031-9.
3. Piller C. Failure to report: a STAT investigation. Boston: STAT, December 13, 2015 (<https://www.statnews.com/2015/12/13/clinical-trials-investigation/>).
4. Miller JE, Korn D, Ross JS. Clinical trial registration, reporting, publication and FDAAA compliance: a cross-sectional analysis and ranking of new drugs approved by the FDA in 2012. *BMJ Open* 2015;5(11):e009758.
5. Unger JM, Barlow WE, Ramsey SD, LeBlanc M, Blanke CD, Hershman DL. The scientific impact of positive and negative phase 3 cancer clinical trials. *JAMA Oncol* 2016 March 10 (Epub ahead of print).

DOI: 10.1056/NEJMp1607282

Copyright © 2016 Massachusetts Medical Society.

This document is a U.S. government work and is not subject to copyright in the United States.