



## Sharing Individual Patient Data from Clinical Trials

Jeffrey M. Drazen, M.D.

Two years ago, you finished a trial that took 5 years of your life. You'd had an idea for a new indication for a marketed drug. After cajoling the drug maker and pleading with your colleagues around

the world, you put together, on a shoestring budget, an active-comparator-controlled trial with more than 1000 patients, with each followed for more than 2 years. The results were positive but not stunning; people with the condition under study now had another option for treatment that was equally effective but a little less toxic than existing therapies. You were able to get the work published in a major medical journal. With the primary work published, you had hoped to analyze the data further and prepare additional reports. But another year has gone by with no more publications. Your data lie dormant, providing no benefit for anyone.

You are not the only one in this position; there are many data

sets from clinical trials that are either never published or from which only a single report is ever produced. Can these data provide value to others?

In October 2013, the Institute of Medicine (IOM) convened a committee to examine the current and future practice of sharing individual patient data gathered in the performance of controlled clinical trials. An interim assessment was issued for public comment in January 2014,<sup>1</sup> and the full report and an executive summary are now available. I served as a member of that committee. Here, I will summarize the report's major findings, but this article is not a policy statement from the *Journal*. We will articulate our policy after we have had a chance to share

the report with our readers, editors, and editorial board; we anticipate that the International Committee of Medical Journal Editors will also formulate policy on this matter. We urge you to contact us with your thoughts and concerns by commenting on this Perspective article at [NEJM.org](http://NEJM.org).

The guiding principle of the committee's discussions and the report is that participants put themselves at risk to participate in clinical trials. The clinical trial community therefore has the responsibility to reward that altruistic behavior by widely sharing the information gathered so that as much useful knowledge as possible can be wrought from the data. Data sharing was not thought to be without risk; two major risks the committee weighed were the possibilities that individual trial participants might be identified and that persons bent on discrediting the published work would perform rogue analyses based on fallacious assumptions or ap-

proaches. Overall, however, when the ecosystem of data gathering, interpretation, and sharing was broadly examined, the committee concluded that the benefits of sharing outweighed the risks. The IOM report provides a high-level overview of how to proceed.

The IOM committee proposes that investigators, regardless of the entity supporting their work, register a data-sharing plan as part of the trial-registration package required for all randomized trials. The information added to the registration would indicate what data the investigators plan to share, with whom, and under what terms. It was the committee's intention that extant trial registries — that is, those that contribute to or share data with the World Health Organization's International Clinical Trials Registry Platform — would expand the minimally acceptable registration data set to include a field where the investigators could articulate their data-sharing plan. At

 An audio interview with Dr. Drazen is available at NEJM.org

this time, no clinical trial registries have added such a field to the registration package, but it is likely that they will do so soon.

The committee recommends that, at a minimum, investigators share the data underlying the results reported in a journal article within 6 months after publication. Because not all studies are reported in journal articles in a timely manner, the committee also recommends that data be made public no less than 18 months after the “last-patient-last-visit” landmark has been passed, regardless of publication status. There are exceptions to these recommendations, but they do not lend themselves to simple summary, and interested readers are referred to the full report.

With whom will data be shared? When they register a trial, investigators will need to indicate whether their data can be shared with any interested party without a formal agreement regarding the use of the data, only with interested parties willing to enter into a data-sharing agreement, or only with interested parties who bring a specific analysis proposal to a third party for approval. It is possible that investigators could choose to share their data with different groups at various times. For example, data might be shared for the first year of availability only with parties who specify their analysis plan but be shared more widely thereafter.

The committee assumed that, going forward, clinical trial data will be gathered under an informed-consent agreement that conforms to the registered data-sharing plan. When a trial has been completed, the database cleaned and locked, and analyses for the primary and secondary outcomes finalized, the data would be deidentified and transferred, along with the needed metadata (i.e., a detailed description of the data structure and a delineation of the detailed methods used to complete the preplanned analyses), to a third party to hold. The third party would release the data and the metadata to the agreed-upon users on request. Currently, there are some functioning data repositories, but much greater capacity for data archiving is needed.

Users of the data that are obtained in this fashion would have a number of obligations. These include, but are not limited to, providing credit to the source of the data used in their analyses and clearly articulating in any publication how their own analyses differed from those previously

reported by the data-gathering authors. This information should include the specific computer codes used to analyze the data and obtain the reported outcomes. If the results differ from previously published results, the authors need to include a detailed description clarifying why the conclusion of their analysis differs from that in the past analysis.

There are many hurdles ahead to an effective data-sharing culture. We need to modify trial registries to hold additional information. We need to gather and store our data carefully so that they can be understood and shared by others. Ideally, a series of third-party data warehouses will spring up to facilitate data sharing; we need to be sure that these warehouses can hold the data securely while parceling it out to qualified parties.

Although there are technical hurdles, we need to change how we think about data. We need to view it as a community resource, much like a shared park, rather than as personal property. We need to recall every day that selfless volunteers put themselves at risk to advance medical science by enabling the data to be gathered. To honor that sacrifice, we need to turn those data into applicable knowledge; somebody else may well find something useful in your trial data that have been sitting idle for years. Let's share and find out.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

1. Institute of Medicine. Discussion framework for clinical trial data sharing: guiding principles, elements, and activities. January 22, 2014 (<http://www.iom.edu/Reports/2014/Discussion-Framework-for-Clinical-Trial-Data-Sharing.aspx>).

DOI: 10.1056/NEJMp1415160

Copyright © 2015 Massachusetts Medical Society.