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EDITORIAL

Open Data

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Article

In the fall of 2013, the Institute of Medicine (IOM) convened a committee, on which I serve, to examine the sharing of data in the setting of clinical trials. The committee is charged with reviewing current practices on data sharing in the context of randomized, controlled trials and with making recommendations for future data-sharing standards. Over the past few months, the committee has prepared a draft report that reviews current practices on data sharing and lays out a number of potential data-sharing models. Full details regarding the committee's charge and the interim report are available at www.iom.edu/activities/research/sharingclinicaltrialdata.aspx.

The committee has not yet made any recommendations on any aspect of data sharing. Rather, we ask members of the research community and the public at large to read the draft report and to provide comments on it and on our data-sharing models. We plan to issue a report with final recommendations late in 2014.

Since data sharing affects everyone who participates in randomized, controlled trials or who benefits from the information gathered in such trials, I urge you to read the report and provide comment for us. I am especially eager to receive feedback from the biomedical community about one issue in particular of the many considered in the report. At the completion of a research study or clinical trial, a first report is often published. Usually, this report contains the key findings of the study but only a small fraction of the data that were gathered to answer the scientific or clinical question at hand. To what extent and for how long should the investigators who performed the research have exclusive access to the data that directly support the published material? And should the full study data set be subject to the same timetable?

Open-data advocates argue that all the study data should be available to anyone at the time the first report is published or even earlier. Others argue that to maintain an incentive for researchers to pursue clinical investigations and to give those who gathered the data a chance to prepare and publish further reports, there should be a period of some specified length during which the data gatherers would have exclusive access to the information. Since these researchers could always agree to collaborate with others who were not involved in the study in order to use the data to help answer a scientific question, the period of exclusivity would really apply only to noncollaborative use of the data. That is, there would be a defined period during which the data would not be available to those who wanted to perform their own analyses and draw conclusions that could, for example, provide them with a scientific or commercial competitive advantage over the researchers who had originally gathered the data or allow them to derive conclusions that are potentially at odds with those drawn in the original publication.

As members of a community that either produces or uses data, what approach do you think serves our community best? There is no need to reply to the *Journal,* but please read the interim report and let the IOM know how you feel about this and the many other critical issues related to data sharing that are reviewed in the document. The IOM is collecting comments until March 24, 2014, at www8.nationalacademies.org/cp/projectview.aspx?key=49578.

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

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