



CORRESPONDENCE

Preparing for Responsible Sharing of Clinical Trial Data

N Engl J Med 2014; 370:484-485 | January 30, 2014 | DOI: 10.1056/NEJMc1314515

Share:     

Article

To the Editor:

Mello et al. (Oct. 24 issue)¹ identify ensuring the responsible use of data as a key aspect of any system for expanded access to participant-level data. In their careful framework for considering the legal, ethical, and policy implications of such sharing, however, they omit a powerful mechanism to meet this aim. Open computer code facilitates replication, which both advances knowledge² and holds powerful interests accountable.³

Regardless of which of the four proposed models are adopted, data-use agreements should require data requesters to publish their computer code alongside any analysis. The program should be complete, in that it takes as its input the provided trial data and finishes by providing every table, figure, and summary statistic reported in the final paper.

Just as proposals for an increase in the level of shared clinical trial data use openness as a mechanism to hold data generators accountable, openness can hold data requesters accountable. If scientists can make progress in ensuring the replicability of studies that include the use of genetically modified mice,⁴ surely the far easier task of ensuring replicable reanalyses can be achieved.

Ari B. Friedman, M.S.
Leonard Davis Institute of Health Economics, Philadelphia, PA
arib@alumni.upenn.edu

No potential conflict of interest relevant to this letter was reported.

4 References >

- 1 Mello MM, Francer JK, Wilenzick M, Teden P, Bierer BE, Barnes M. Preparing for responsible sharing of clinical trial data. *N Engl J Med* 2013;369:1651-1658
[Free Full Text](#) | [Web of Science](#) | [Medline](#)
- 2 King G. Replication, replication. *PS: Political Science and Politics* 1995;28:443-99
(<http://gking.harvard.edu/files/replication.pdf>).
- 3 Herndon T, Ash M, Pollin R. Does high public debt consistently stifle economic growth? A critique of Reinhart and Rogoff. PERI Working Paper Series. April 15, 2013
(http://www.peri.umass.edu/fileadmin/pdf/working_papers/working_papers_301-350/WP322.pdf).
- 4 The sharing principle. *Nature* 2009;459:752-752
[CrossRef](#) | [Web of Science](#) | [Medline](#)

To the Editor:

Mello and colleagues outline the potential benefits and risks of participant-level data sharing. They highlight technical and ethical concerns as sponsors and investigators move these initiatives forward. However, insofar as innovations overcome important limitations such as intellectual property and privacy, two points remain relevant.

First, implementing responsible participant-level data sharing is a moral imperative to accelerate discovery with limited resources and to address the ominous quality of scientific output. Current siloed and fragmented science fails to answer important questions in an increasingly complex world.¹ Conversely, participant-level data sharing shifts the paradigm to collaboration, which enables the pooling of skills, insights, and resources from different teams.²

Second, concurrently with this wave of data availability, computational tools can now tackle big data opportunities. It is possible to manage large-scale data sets, reformat them to link and integrate, and construct analytic algorithms in an effective and timely fashion.³ A perfect storm is exposing a large volume of data to new tools, paving the way to groundbreaking collaboration across networks to increase productivity and boost the quality of medical science.

Mauricio Ferri, M.D.
University of Calgary, Calgary, AB, Canada
mbellerferri@gmail.com

Kald Abdallah, M.D., Ph.D.
Sanofi, Bridgewater, NJ

Dr. Abdallah reports being an employee of and holding equity in Sanofi. No other potential conflict of interest relevant to this letter was reported.

3 References >

- 1 Unreliable research: trouble at the lab. *The Economist*. October 18, 2013 (<http://www.economist.com/news/briefing/21588057-scientists-think-science-self-correcting-alarming-degree-it-not-trouble>).
- 2 Eichler HG, Petavy F, Pignatti F, Rasi G. Access to patient-level trial data – a boon to drug developers. *N Engl J Med* 2013;369:1577-1579
[Free Full Text](#) | [Web of Science](#) | [Medline](#)
- 3 Schadt EE, Linderman MD, Sorenson J, Lee L, Nolan GP. Computational solutions to large-scale data management and analysis. *Nat Rev Genet* 2010;11:647-657
[CrossRef](#) | [Web of Science](#) | [Medline](#)

Citing Articles (1)

- 1 Jongoh Kim, Susan L. Samson. (2014) Cardiovascular Effects of Incretin Therapy in Diabetes Care. *Metabolic Syndrome and Related Disorders* 12:6, 303-310
[CrossRef](#)