



Clinical Trials Data Sharing: Summary

Enhanced clinical trials data sharing is a policy goal with broad, bipartisan support, including consumer advocates, academia,¹ industry,² and FDA officials.³ Limited summaries of many clinical trials data are already publicly available through the FDA website, academic journals, and clinicaltrials.gov. Yet the FDA receives thousands of pages of additional detailed clinical trials data with each new drug application. This information currently remains unpublished by the FDA, representing an untapped resource for healthcare innovation.

Benefits of Full Data Sharing by the FDA

When drug companies apply for FDA approval they submit a clinical study report (CSR) that can include nearly ten thousand pages of information, including detailed descriptions of trial design and analysis, and data on how each subject responded to treatment. CSRs are not releasable under the Freedom of Information Act. Publishing these reports would allow independent researchers to make use of this data. Such “open science” helps:

- Find new information on safety and effectiveness
- Bring to light problems not detected during rapid FDA reviews
- Combine data sets to learn how rare sub-groups respond, advancing personalized medicine
- Avoid unnecessary clinical trials, saving costs and protecting human subjects from harmful experiments

Data Sharing Momentum

- The Institute of Medicine recommended that the FDA share full CSRs (redacted for commercial or personal info) for all drugs, after approval or final abandonment.^{4,5}
- The European Medicines Agency (EMA) already shares clinical trial data on drugs approved in Europe.⁶
- A White House memorandum urges agencies to maximize the public availability of information arising from federally funded research.⁷
- The National Institutes of Health requests data sharing from recipients of federal grants.⁸
- Recent legislation to promote greater data sharing includes: HR 2031 (2013) and HR 617 (2015).

Our Proposal

We support enhancing existing data sharing mechanisms through legislation to mandate publication of all CSRs (with personal info redacted) and related electronic data sets after drug is approved or rejected by the FDA.

¹ Rodwin MA, Abrahson JD, Clinical trial data as a public good. *JAMA* 2012;308(9):871-872.

² See PhRMA, Principles for responsible clinical trials data sharing, <http://onphr.ma/1NfEKkV> and Roche, Our commitment to data sharing, <http://bit.ly/1aaFXrj>.

³ Statements by Janet Woodcock. Sharing Clinical Research Data: A Workshop. Institute of Medicine. 6/13/2013. <http://tinyurl.com/oo8arop> (at 5:35)

⁴ Silverman, E. Institute of medicine urges broader sharing of clinical trial data. *The Wall Street Journal*. January 14, 2015. <http://on.wsj.com/14Cbtfq>.

⁵ Institute of Medicine. Sharing Clinical Trial Data. January 2015. <http://tinyurl.com/12dud5q>.

⁶ European Medicines Agency. European Medicines Agency agrees policy on publication of clinical trial data with more user-friendly amendments. December 6, 2014. <http://bit.ly/1lkvX1A>.

⁷ White House Office of Science and Technology Policy. Memorandum for the Heads of Executive Departments and Agencies. February 22, 2013. <http://1.usa.gov/1GtgnM>.

⁸ NIH Data Sharing Policy and Implementation Guidance. March 5, 2003. <http://tinyurl.com/9mzrc8p>