

The push for more clinical research data sharing is paying off

August 3 2016

In an ideal medical research landscape, clinical data would quickly be made available to all public and private researchers in the quest to speed up medical advances. The research community is getting closer to that ideal thanks, in part, to the work of the Yale Open Data Access (YODA) Project, but more work needs to be done, according to an article in the Aug. 4 *New England Journal of Medicine*.

The article on the current state of clinical trial data sharing is co-authored by Yale YODA Project leader Harlan Krumholz, M.D., and Johnson & Johnson chief medical officer Joanne Waldstreicher, M.D.

The YODA Project performs independent scientific reviews of requests for data access by non-study investigators. This complete decision-making authority over the release of the data allows all requests for [clinical data](#) to be fairly judged and decided upon by an independent academic partner.

Krumholz and Waldstreicher examined the data sharing environment, including YODA and the recent International Committee of Medical Journal Editors' (ICMJE) proposal for sharing clinical trial data. They found that the [research community](#) has made great progress in data sharing, but the transformation is just beginning.

"The medical editors of research journals are reminding us that we scientists have a principal responsibility to society and to patients who agreed to participate in our studies," said Krumholz, professor of

medicine at Yale School of Medicine. "The YODA Project demonstrates that, by having researchers quickly share information with those at other organizations, the sky hasn't fallen and worthwhile independent research projects that could not have been done otherwise are proceeding."

In their article, Krumholz and Waldstreicher take stock of the progress to date by pointing to several key examples: ICMJE has proposed to accelerate the transformation to a culture of open science. The pharmaceutical industry has articulated principles that support data sharing, and many companies, including Johnson & Johnson, have implemented programs to make their data assets available. Regulatory agencies, including the European Medicines Agency, are requiring greater sharing by companies seeking to market drugs and devices. Krumholz and Waldstreicher also point to efforts by influential organizations like the Gates Foundation policy requiring that data underlying published results be made available and open immediately.

"At Johnson & Johnson, we believe sharing clinical trial data advances the science that is the foundation of medicine," said Waldstreicher. "As our environment continues to evolve, we are encouraged that more and more stakeholders are adopting policies to allow for greater access to clinical trial data. We believe collaboration among all stakeholders—including industry, academia, patient groups and government—is essential to developing a solution that truly advances science, medicine and ultimately public health."

Krumholz and Waldstreicher added, "The ultimate measure of our success will be whether this approach creates a culture of openness on par with those of other scientific disciplines and increases the volume of high-quality medical science."

Provided by Yale University

Citation: The push for more clinical research data sharing is paying off (2016, August 3)
retrieved 25 April 2024 from <https://medicalxpress.com/news/2016-08-clinical.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.