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NEWS

Johnson & Johnson appoints Yale project team to run data sharing scheme

Zosia Kmietowicz

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Johnson & Johnson has appointed an independent US body to field requests from researchers for access to its clinical trials data.

Janssen, the pharmaceutical arm of Johnson & Johnson, has entered into an agreement with the Yale University Open Data Access (YODA) project at the Yale School of Medicine in New Haven, Connecticut. The YODA team will make final decisions about all requests for sharing data, including clinical study reports and de-identified patient level data.

Joanne Waldstreicher, chief medical officer at Johnson & Johnson, said in a statement, "We are pleased to collaborate with YODA to ensure that each and every request for access to our pharmaceutical clinical data is reviewed objectively and independently. This represents a new standard for responsible, independent clinical data sharing."

Under the agreement members of the YODA team will select and appoint an independent external panel of non-Janssen experts to help to assess some requests.

Harlan Krumholz, a professor of cardiology and public health at the Yale School of Medicine, told the *New York Times*, "This is an extraordinary donation to society, and a reversal of the industry's traditional tendency to treat data as an asset that would lose value if exposed to public scrutiny."[1]

He said that more than half of clinical trials carried out in the United States were not published within two years of their completion and that many were never published, with the result that "evidence based medicine is, at best, based on only some of the evidence."

The decision by drug companies to share data was not easy, said Krumholz, because "companies worry that their competitors will benefit, that lawyers will take advantage, that incompetent scientists will misconstrue the data and come to mistaken conclusions."

However, he added, "The more we share data, the more we find that many of these problems fail to materialise."

Last June researchers heralded "a historic moment for open science" when the medical device company Medtronic allowed YODA researchers access to all of its data on a product that promotes bone growth.[2]

The reviews of the data produced conflicting results: one found that the agent was no better than a bone graft and might be associated with a slight increase in cancer, while the other found that the agent was effective and the cancer risk inconclusive. Krumholz said, "To us these differences reinforce the value of open science: now the data are out there for further study."

The list of drug companies that have signed up to clinical trial transparency has grown steadily. In January 2013 the UK based GlaxoSmithKline launched an online system to enable researchers to access anonymised data from its clinical trials,[3] and Roche and Pfizer followed soon afterwards.

However, those three companies have all set up "independent review panels," which have the option to deny access. Pfizer's commitment to transparency was also criticised for excluding studies of unlicensed uses of its drugs and for promising to publish only synopses of clinical study reports rather than the full documents.[4]

Krumholz said that the deal with Johnson & Johnson would require people who wanted data to submit a proposal and identify their research team, funding, and any conflicts of interest. He added, "They have to complete a short course on responsible conduct and sign an agreement that restricts them to their proposed research question. Most important, they must agree to share whatever they find. And we exclude applicants who seek data for commercial or legal purposes."

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2 Kmietowicz Z. First reviews are published that are based on the "totality of the evidence." *BMJ* 2013;346:f3909.
3 Coombes R. GlaxoSmithKline grants researchers access to clinical trial data. *BMJ* 2012;345:e6909.
4 Kmietowicz Z. Pfizer's open data policy should include trials of off-label uses, say critics. *BMJ* 2013;347:f7327.

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