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Make clinical trials data public

Johnson & Johnson's move is a shot in the arm for transparency and better research

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Last week, Johnson & Johnson announced that it was making all of its clinical trial data available to scientists around the world. It has hired my group, Yale University Open Data Access Project, or YODA, to fully oversee the release of the data. Everything in the company's clinical research vaults, including unpublished raw data, will be available for independent review.

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.

Access denied

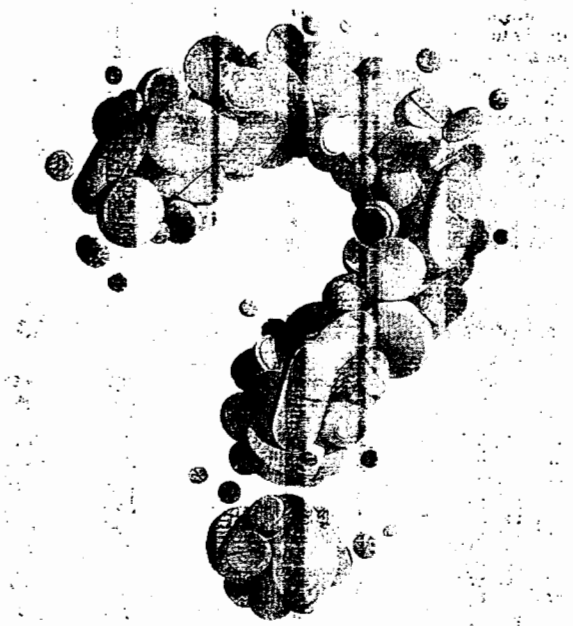
Today, more than half of the clinical trials in the US, including many sponsored by academic and governmental institutions, are not published within two years of their completion. Often they are never published at all. The unreported results, not surprisingly, are often those in which a drug failed to perform better than a placebo. As a result, evidence-based medicine is, at best, based on only some of the evidence. One of the most troubling implications is that full information on a drug's effects may never be discovered or released.

Even when studies are published, the actual data are usually not made available. End users of research — patients, doctors and policymakers — are implicitly told by a single group of researchers to "take our word for it." They are often forced to accept the report without the prospect of other independent scientists' reproducing the findings — a violation of a central tenet of the scientific method.

To be fair, the decision to share data is not easy. Companies worry that their competitors will benefit, that lawyers will take advantage, that incompetent scientists will misconstrue the data and come to mistaken conclusions. Researchers feel ownership of the data and may be reluctant to have others use it. So Johnson & Johnson, as well as companies such as GlaxoSmithKline and Medtronic that have made more cautious moves toward transparency, deserve much credit. The more we share data, however, the more we find that many of these problems fail to materialise.

Mixed results

In 2011, YODA struck a deal with Medtronic to release all the data on one of its products — a device that stimulates the production of bone. At the time, questions had been raised about the device's safety, including whether it caused cancer, and about the conflicts of interests of some of the company's researchers. Medtronic made the unusual decision to respond to the debate by releasing the device's data for independent review. We published two independent reviews of the data and now have made them globally available.



Sharing is caring But there is a question of misuse of data GOLDENARTS/SHUTTERSTOCK.COM

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

This programme doesn't mean that just anyone can gain access to the data without disclosing how they intend to use it.

We require those who want the data to submit a proposal and identify their research team, funding and any conflicts of interest. 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. Our intent is not to be tough gatekeepers, but to ensure that the data are used in a transparent way and contribute to overall scientific knowledge.

There are many benefits to this kind of sharing. It honours contributions of the subjects and scientists who participated in the research. It is proof that an organisation, whether it is part of industry or academia, wants to play a role as a good global citizen.

It shows that the organisation has nothing to hide. And it enables scientists to use the data to learn new ways to help patients. Such an approach can even teach a company like Johnson & Johnson something it didn't know about its own products.

For the good of society, this is a breakthrough that should be replicated throughout the research world. New York Times

Clinical Research