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A Historic Moment for Open Science: The Yale University Open Data Access Project and Medtronic

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This issue of *Annals* heralds a historic moment in the emerging era of open science. It features 2 systematic reviews on recombinant human bone morphogenetic protein-2 (rhBMP-2) (1, 2), an orthobiologic agent used in certain surgeries to promote bone growth that once achieved close to $1 billion in annual sales for Medtronic (Minneapolis, Minnesota). The reviews are based on patient-level data from all clinical trials conducted by Medtronic, which were shared through the Yale University Open Data Access (YODA) Project (3). With the publication of these reviews and the public release of its comprehensive reports, all of the clinical trial data for this product will now be made available by the YODA Project to other investigators for further analysis and examination.

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The YODA Project seeks to address the problem of unpublished and selectively published clinical evidence (4, 5). Nearly half of clinical trials are never published, and many that are have long delays in publication. Among those published, the information is often incomplete. Evidence suggests that some data are not missing at random and that the sharing of data, particularly patient-level data, often provides new insights that are consequential to patients.

Currently, even the most conscientious physicians—those committed to knowing the latest literature— cannot fully understand the true risks and benefits of many treatments. Patients, therefore, are hampered in their ability to make truly informed decisions. In addition, missing data undermine evidence-based medicine, as recommendations based on the published literature, whether in systematic reviews, guidelines, book chapters, or online resources, are not based on the totality of the evidence. To improve the care of patients, clinical trial data, protocols, and results need to be made more widely available and shared for public benefit (6).

Amid the current dialogue about open science in medicine, few imagined that such a prominent company would voluntarily make available all of its internal patient-level clinical research data on one of its major products. At a time when many companies express verbal support of open science, Medtronic joined the YODA Project and demonstrated what is possible. It is true that Medtronic was embroiled in a controversy about rhBMP-2 when it decided to share data (7). However, among the other companies that also encountered concerns about their products or the transparency of their research, Medtronic was unique in its response. Will the company’s decision to release its data through the YODA Project be a footnote or a headline in the history of open clinical science? We hope that the action will reset expectations about the social contract between scientists and society.

The YODA Project evolved as a collaborative endeavor guided by aspirations to promote open science, ensure good stewardship of clinical trial data, serve society and patients, and respect industry concerns. The YODA team approached Medtronic with a proposal to provide us with all of its relevant and de-identified rhBMP-2 patient-level clinical trial data. The agreement included 2 parts. First, the YODA team would contract with 2 independent research groups, selected through a competitive and open process, to perform comprehensive analyses of the data to evaluate the quality of the studies and synthesize evidence about the effectiveness and safety of rhBMP-2. The reviews in this issue are the result of those efforts. Second, after these reviews, the YODA team would make the data available to others to address additional potential scientific questions.

Cooperation was the key to addressing the challenges of data sharing. We engaged a steering committee that included representation from academia, government, and industry. We convened an additional group of experts for a consensus meeting to develop appropriate methods and best practices. We also held a public comment period on our proposed approach. Although our contract with Medtronic gave us jurisdiction over the data, we sought a path that would navigate Medtronic’s concerns about data misuse, false-positive inferences from data mining, legal ramifications, privacy issues, and commercial advantage

for competitors. Among the results of these efforts was the development of a data release policy, available at http://medicine.yale.edu/core/projects/yodap/index.aspx.

To be worthy of replication, the YODA Project needs to serve society and patients but should also produce benefits for the companies that fund the vast majority of research on medical products. One premise of the project is that companies can address their declining public perception by committing to data transparency and benefit from a culture of open science. Moreover, the open sharing of these data will ensure that conclusions drawn by any group can be checked by other individuals, mitigating concerns that competitors will seek to misuse the data.

Will other companies follow suit? It is too early to say, but a recent announcement from GlaxoSmithKline (London, United Kingdom) about plans to share detailed clinical trial data is promising (8). Will clinicians be willing to show a preference for products from companies that share data? Will patients clamor for companies to be forthcoming with data? Will society reject claims that data are proprietary when they relate directly to decisions that people are making about products that are on the market?

Our aspiration is for the YODA Project to provide a framework for the release of patient-level data and for the Medtronic release of data not to be an anomaly but a critical step forward in the rapidly changing culture of science. Ultimately, those of us who practice evidence-based medicine or conduct clinical research are the beneficiaries of the generosity of research participants. Participants expect that we will learn from their contributions and use the knowledge to help others. To do so requires that the data and findings from the research be widely and fully disseminated.

The concerns about data sharing are relevant to the entire clinical research enterprise, far beyond industry (9, 10). Academia needs to reflect on and change its own culture, which is similarly reluctant to share data. We need to ensure that the current regulatory environment facilitates sharing of de-identified data while developing the technical solutions and the will to promote open science. We also need to find ways to reward those who share data, providing them a piece of the academic credit from the dividends of their work. Here we have a case in which the actions of industry should inspire academia to follow.

The process that produced the reviews in this issue ensured that they were based on the totality of the evidence. That we have established a new standard should be a headline. Let us resolve to have this effort be the first step in the next era of cooperation among industry, academia, clinicians, and the public— one that rewards data sharing, promotes open science, and ultimately makes it untenable to obscure data relevant to the risks and benefits of approved medical products.

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