J&J Partners with Yale to Share Trial Data

Johnson & Johnson’s collaboration with medical school sets it apart from other initiatives

Johnson & Johnson’s (J&J) Janssen is among the latest pharmaceutical companies to make clinical trial data available to outside researchers. The move comes at a time of increasing momentum for open science, with a growing number of drug companies allowing unprecedented access to confidential data.

J&J announced in January that it has partnered with the Yale University Open Data Access (YODA) Project in New Haven, CT, to share clinical study reports and deidentified patient-level data from all J&J drugs approved in the United States and Europe. Yale will review proposals from researchers and make final decisions on which researchers are granted access to the data, without input from J&J. This is the first time industry has enlisted a completely independent third party to broker every request for its data.

“Having a whole world of scientists be able to access our data and to do important analyses really expands the ability of science and medicine to improve public health, and adds to what we’ve already done with our studies,” says J&J’s chief medical officer Joanne Waldstreicher, MD, who convinced the company’s top executives to team up with Yale.

Researchers, for instance, might comb the data for new classes of adverse events among drugs that share the same therapeutic target or conduct subgroup analyses to determine which patients benefit most from a drug. An undergraduate or graduate student pursuing a thesis to test a new hypothesis or replicate a study might also use the data.

Within 3 weeks of J&J announcing its initiative, Yale had received nearly 30 preliminary requests through www.clinicaltrialstrudytransparency.com, a site that will house a catalog of hundreds of Janssen studies. Formal requests for pharmaceutical data will be accepted starting in early April. J&J will eventually make clinical trial data available from its medical devices and over-the-counter products.

Beyond advancing data-driven science, new efforts by the drug industry to open up its clinical research vaults aim to build public trust in the benefits and risks of approved drugs, says cardiologist Harlan Krumholz, MD, director of the YODA Project and professor of medicine at Yale School of Medicine. “With much data out of public view and many trials never published or selectively published, patients and doctors were in a position of not being able to make informed choices. Evidence-based medicine was being undermined,” he says.

Industry has begun to appreciate the reputational cost of continuing the old model of keeping valuable knowledge locked away, Krumholz says. The threat of regulation may have also prompted industry’s shift toward data openness, he adds. The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) last year released proposals to expand access to data submitted as part of regulatory applications.

“The time was right for more responsible sharing of clinical trial data,” says Jeffrey Fraser, vice president and senior counsel for Pharmaceutical Research and Manufacturers of America (PhRMA), the trade group for U.S. drugmakers. To that end, in July 2013, PhRMA and its European counterpart, the European Federation of Pharmaceutical Industries and Associations (EFPIA), released “Principles for Responsible Clinical Trial Data Sharing,” a set of standards for biopharmaceutical companies in the U.S. and Europe that took effect on January 1.

Although the new principles are voluntary, Fraser expects all of PhRMA’s 53 U.S.-based member companies to soon comply. PhRMA and EFPIA will release a progress report in late 2014.

Alongside J&J, GlaxoSmithKline (GSK), Novartis, Pfizer, Roche, and Sanofi have implemented their own data-sharing initiatives in accordance with the new industry principles. Sanofi, for instance, will make available data from studies submitted to the FDA and EMA for drugs approved by both agencies on or after January 1, 2014. GSK now provides access to more than 450 studies of approved drugs and failed investigational agents.

It is the data on failed drugs that Warren Kibbe, PhD, director of the National Cancer Institute’s Center for Biomedical Informatics and Information Technology, expects will generate a slew of new hypotheses. “Getting that data out to folks in the research community allows them to ask, ‘Can I improve on the agent?’ or ‘Is this agent better in another disease?’” he says.

The next challenge, Krumholz says, is getting academic institutions to share their data troves, which they might soon do.

The Institute of Medicine (IOM) is expected to publish its final recommendations on the responsible sharing of clinical trial data in late 2014. Its draft report, released for public comment in January, outlines a preliminary framework on what types of data might be shared, who provides and receives shared data, and whether access to data will be controlled.

Even so, Krumholz isn’t confident the IOM report will persuade data-sharing stragglers to fall in line. “This acceleration of data sharing is a wake-up call for everyone, not just industry,” he says. “Academic institutions need to get on the ball.” —Melissa Weber
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