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On Site: Good Pharma Scorecard Results Show Continued Drive for Transparency

Some of the world's largest pharmaceutical companies have improved the transparency of their clinical trial data disclosures, according to new analysis from Bioethics International, yet many studies for approved drugs still go unreported.

Bioethics International's second Good Pharma Scorecard, published in the online medical journal BMJ Open, found that companies have made "meaningful progress" on several key metrics since the first scorecard was released in 2015. Companies are doing a better job in complying with legal requirements for reporting clinical trial results, according to the analysis, and making results publicly available for trials conducted in patients.

Two companies — Johnson & Johnson and Sanofi — both achieved scores of 100% for clinical trial transparency. In addition, AbbVie, Celgene, Merck and AstraZeneca all scored at or above the industry median of 91%.

The 2017 ranking evaluated clinical trial registration, results reporting, clinical study report synopsis sharing, and journal article publication rates for new drugs approved by the FDA in 2014 sponsored by large drug companies.

Jennifer E. Miller, Ph.D., an assistant professor at the New York University School of Medicine and founder and president of the not-for-profit Bioethics International, said the scorecard was created to help advance ethics and trustworthiness in the pharmaceutical sector by setting clear ethics standards and benchmarking the performance of companies against those standards each year. Miller believes clinical trial transparency is critical for protecting and respecting research participants and users of medicines and vaccines, while opacity can drive up the costs of both research and care.

"This year's scorecard shows clear corporate leaders in clinical trial transparency and industry improvement on several metrics. They demonstrated a dedication to high quality, patient-centric and ethical healthcare innovation and drug development, with Johnson & Johnson and Sanofi leading the pack," said Miller, a bioethicist and the lead author of the BMJ Open article. "We hope this improvement continues year after year."

Thomas Wicks, chief strategy officer of TrialScope, a company that offers clinical trial transparency and compliance solutions, said the Good Pharma Scorecard could serve as a benchmark that organizations could use to evaluate how their transparency efforts are viewed by the public and allow them to model the impact of policy changes to their future scores.

"Many pharma companies have made substantial investments in broader transparency and, for those organizations, it is helpful to have these commitments recognized. Other organizations may use disclosure assessments like the Good Pharma Scorecard as opportunities to reevaluate their transparency practices to consider broader disclosure commitments. Provided these disclosure assessments are based on sound evaluation criteria, they can help establish an independent measure of trust," he said.

Bioethics International's first scorecard investigated clinical trial disclosure practices for 15 drugs approved by the FDA in 2012. In the latest analysis, Miller and her team, which included researchers from Yale and Stanford, examined 505 clinical trials associated with 19 new drugs — sponsored by 11 large biopharmaceutical companies — approved by the agency in 2014.

The researchers evaluated data from more than 45 sources, including publicly available databases, clinical trial registries, medical journals, and personal communications with drug manufacturers. The researchers measured results reporting against both ethical standards, which hold that data from all trials should be made available, and the legal requirements of the 2007 FDA Amendments Act (FDAAA), which requires sponsors to register and report results of applicable clinical investigations, which exclude phase I trials, within certain time frames on ClinicalTrials.gov.

Among the key improvements, the proportion of new drugs with undisclosed phase II or III trials in new drug applications went down, from 50% to 33%, between 2012 and 2014. Additionally, the public availability of results for trials conducted in patients for each drug went up from a median of 87% to 96%, measured at 13 months post-FDA approval.

"The study highlights that companies are taking their legal obligations around clinical trial reporting seriously," said Michelle Mello, Ph.D., professor at Stanford Law School and the Department of Health Research and Policy at Stanford University School of Medicine, and a co-author of the paper. "We also found there are some emerging industry leaders that are going farther than the law requires in getting patients and doctors the information they need — and there are clear opportunities to do more."

During the past decade, companies have steadily improved clinical trial transparency programs after the passing of various laws, particularly FDAAA in 2007, and as part of efforts to improve public trust in the research process. Leading companies have made internal commitments to clinical trial transparency and set up clear lines of responsibility to operationalize the policies. Some companies have created divisions dedicated to data-sharing in clinical trials or have appointed a point person to ensure clinical trial results are disclosed to the public.

At Johnson & Johnson, which earned a 100% clinical trial transparency rate in both the 2015 and 2017 scorecards, its Janssen Research & Development division has established a first-of-its kind collaboration with Yale University School of Medicine to make summary and participant-level clinical trial data available to academic investigators. The company's transparency policies also include publishing the results of all company-sponsored interventional pharmaceutical clinical trials in peer-reviewed journals. This includes both positive and negative studies, those that end early, and those from discontinued research programs.

"At Johnson & Johnson, we believe sharing clinical trial data honors the patients who participated in the trial and contributes to improving patient care," said Joanne Waldstreicher, M.D., chief medical officer of Johnson & Johnson.

In subsequent versions of the scorecard, Bioethics International plans to expand its evaluation of clinical trial transparency and data-sharing performance and to also measure the integrity of clinical trial designs, the accessibility of medicines, drug marketing practices, and other ethics and human rights issues.

"Through the scorecard, we aim to help translate, specify and clarify standards for clinical trial transparency and other ethics and population health concerns in healthcare innovation. We also work to recognize best practices in companies and encourage improved behaviors, where needed, through annual benchmarks and rankings. This, in turn, creates a learning system that advances scientific knowledge and public health," said Miller.

— Karen Korieth

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