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Researchers find gaps in clinical trial data sharing

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Access to clinical-trial data helps doctors make informed prescribing decisions and promotes good science, but a new study co-authored by Yale researchers reveals that few pharmaceutical companies are fully transparent about the data behind the products they develop. The study also shows that large companies are far more transparent than smaller

ones.

The study, published in The *BMJ Open* (*British Medical Journal*), assessed the data-sharing practices of 42 pharmaceutical companies for clinical trials of 40 novel drugs and 22 biologics—products, such as vaccines, derived from living organisms—approved by the U.S. Food and Drug Administration in 2016 and 2017. The evaluation was performed using the Good Pharma Scorecard, a tool developed by researchers at Yale, Stanford, and Bioethics International which consists of transparency measures and a ranking system.

Overall, only seven of the 42 companies, 17%, entirely met the tool's standards for transparency and sharing data. Smaller companies are particularly opaque, according to the study.

"The non-large pharmaceutical companies are dragging down the sector, often failing to meet federal reporting requirements, much less voluntary standards," said Jennifer Miller, assistant professor at Yale School of Medicine, founder of Bioethics International—a nonprofit advocate for patient-centered medical innovation—and co-author of the study.

"The lack of transparency is a problem because access to robust clinical-trial data supports patient care and good science," she added. "Full transparency allows scientists to learn from previous work and prevents people from being exposed to unnecessary experiments."

Since the late 1990s, Congress and federal agencies have increased requirements for pharmaceutical companies to register and report results from clinical trials. Yet, some companies don't fully comply with the rules and industry guidelines vary.

In a 2019 study using the transparency scorecard, 25% of companies fully met the standards, which include registering clinical trials, sharing

data and study protocol publicly, and annually reporting requests for data. After companies received a 30-day window to improve their scores, the proportion of those meeting the standard rose to 33%.

This earlier analysis was limited to large companies and novel drugs. For the latest study, the researchers expanded their assessment to include biologics and companies that fall outside the 20 largest globally by market capitalization.

While 17% of companies achieved perfect scores, the assessment also found that 58% of the companies had publicly available results for all patient trials, 42% fully complied with federal reporting laws, and 26% fully met the scorecard's data-sharing measure. They also found that 26% of the products evaluated had publicly available results for all clinical trials supporting their FDA approval, and 67% had public results for patient trials within six months after their FDA approval.

Non-large companies were less responsive than large companies when offered the 30-day window to fix errors and improve data-sharing practices, the researchers said. Four companies used the opportunity to improve their data-sharing procedures, raising the median data-sharing score for all companies from 60% to 69%.

"It's not surprising that non-large companies lag behind large as they may have fewer resources and smaller staffs with less compliance experience," Miller said. "Our findings suggest that large companies may benefit from reviewing the transparency procedures of smaller companies before partnerships, mergers, and acquisitions so they don't inherit any deficiencies."

The researchers did notice improvements among large companies between the 2019 study and the latest evaluation. For example, the median data-sharing score for large companies increased from 80% for

drugs approved in 2015 to 100% for products approved in 2017.

Other study authors are Sydney Axson, Deborah Lincow, and Cary Gross of Yale; Michelle M. Mellow of Stanford University School of Medicine; and Catherine Yang of the University of Pennsylvania Perelman School of Medicine. This work was funded by Arnold Ventures, a U.S. philanthropy dedicated to addressing key national issues, including health care. Authors' competing interests are detailed in *The BMJ*.

More information: Clinical trial transparency and data sharing among biopharmaceutical companies and the role of company size, location and product type: a cross-sectional descriptive analysis, *BMJ Open* (2021). DOI: 10.5061/dryad.r2280gbdb , bmjopen.bmj.com/content/11/7/e053248

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