Scientists report problems with big pharma's clinical trial data used to support FDA-approved anti-cancer medicine

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A group of international scientists say they have encountered many hurdles in accessing information for a study to examine clinical trial data

used to support FDA-approved anticancer medicines even when the data was classified as eligible for access and transparent sharing.

In an article in *JAMA Oncology*, scholars from Flinders University in Australia, the University of Sharjah in the United Arab Emirates and other international institutions, collaborated to vet clinical trial data on which the U.S. Food and Drug Administration leans to approve anticancer medicine. The data analysis, the scientists maintain, has helped them come up with important implications for the public and those interested in health care transparency.

Initially, the researchers requested data from 91 clinical trials approved by FDA. "We received data from 70 trials, which represents a success rate of 77%. This is a significant improvement in data sharing compared to a decade ago," says Dr. Ahmad Abuhelwa, an assistant professor from the University of Sharjah, and one of the study's senior co-authors.

The pharmaceutical industry has been sharing data from clinical trials, allowing independent researchers to access and analyze the information. The transparency has been crucial for validating results, generating new hypotheses, and improving clinical practices and patients' care.

However, not all the data from the 70 clinical trials was comprehensively, transparently, and easily accessed and shared as the scientists cite issues related to transparency, denial of access, redactions, and lack of supporting documents.

"Transparency in the pharmaceutical industry isn't just a buzzword; it's an imperative for patient safety and research quality. Our research underscores the need for comprehensive data sharing, creating a win-win for all stakeholders," confirms the study's lead author, Dr. Ashley Hopkins, of Flinders University's College of Medicine and Public Health, Flinders Health and Medical Research Institute, Australia.

The scientists were presented with several challenges to secure access to the clinical trials selected for analysis. "Twenty-one trials (23%) were denied access for various reasons, including ongoing regulatory activities, data co-development issues, and concerns about the proposed statistical analyses. This suggests that there are hurdles in accessing data even when trials are deemed eligible for sharing," notes Dr. Abuhelwa.

Other challenges the scientists grabbled with were related to lengthy access time and redactions. "Among the 70 trials that shared data, we faced lengthy access time (up to one year) and a significant number had redactions in key data domains. For instance, data on adverse events, survival, and assessment variables were partially or fully redacted in some cases. Redactions can complicate the analysis of data and limit its usability," Dr. Abuhelwa adds.

The scientists faced problems when searching for documentation. The researchers, says Dr. Ashley, found that a substantial number of trials did not include supporting documents like clinical study reports, data dictionaries, and anonymization guides, which are crucial for understanding and validating the data in research.

Lack of standardization is another hurdle the scientists dwell on in their study. They reveal that the clinical trial data they investigate "leads to heterogeneity" as different companies use different methods in providing their data. "This quality improvement study sheds light on the complexities and nuances of sharing individual-participant data (IPD) from pharmaceutical industry-sponsored clinical trials," Dr. Ashley adds.

The scientists commend pharmaceutical companies for making their clinical trials more transparently accessible. However, they say there is still more work to be done, and urge exerted efforts to address the issues they raise in their research. Thus, they recommend the pharmaceutical industry to furnish full access to complete and unredacted data,

emphasizing the need for transparency and standardization to make it easier for future researcher to work with the data.

Of the importance of the findings, Dr. Abuhelwa says the scientists have carved a path on what big pharma need to do in order to share their clinical trial data and make it accessible for research. "Transparency in data sharing is the foundation of better patient care. Our study sheds light on the progress and challenges in sharing clinical trial data, and it's a call to action for improving data accessibility and quality.

"The road ahead involves advocating for change. We're championing data sharing that's both accessible and reliable. With standardization and increased transparency, we can elevate health care research and improve patient outcomes."

Dr. Ashley hopes the pharmaceutical industry will make note of the implications and findings he and his co-authors have arrived at because "data is the lifeblood of patient-centered care, and our study shows that there's room for improvement in ensuring this data is complete and unredacted. We're pushing for standardized data sharing practices to empower researchers and health care providers."

Dr. Abuhelwa is upbeat about what he sees as groundbreaking research in big pharma's efforts to share clinical trial data. "Patients, doctors, and researchers all stand to benefit from transparent and standardized data sharing. Our research highlights the path to a data-sharing ecosystem where data accessibility and quality are paramount."

More information: Ashley M. Hopkins et al, Heterogeneity and Utility of Pharmaceutical Company Sharing of Individual-Participant Data Packages, *JAMA Oncology* (2023). DOI: 10.1001/jamaoncol.2023.3996

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