Further transparency needed in cancer clinical trials

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Despite significant improvements in data sharing for cancer clinical trials over the last 10 years, further changes are still needed to ensure patient-centered care, medical advancements, and trust in the

pharmaceutical industry, say Flinders University researchers.

In an article published in the *Journal of Clinical Oncology*, the authors call for mandated data sharing policies for all industry-sponsored oncology trials to support future research, help prevent the duplication of studies, and ensure robust reviews and analyses can take place.

"Participants often enroll in clinical trials knowing that while the trial may not personally benefit them, they are contributing to advancements in care for someone else in the future," says lead author Natansh Modi, an NHMRC Ph.D. candidate at the Clinical Cancer Epidemiology Lab at Flinders University.

"This can't happen if the data that is needed to make these improvements isn't made available to other researchers."

Clinical study reports (CSRs) and individual participant data (IPD) are seen by several organizations, including the World Health Organization, as critical to building trust in the drug approval process and contributing to future drug trials.

However, despite containing detailed information on methods, results, and each participant's responses to treatments, they are not generally accessible to researchers undertaking systematic reviews and meta-analyses.

"These types of studies ensure researchers can take all the information that is out there about a particular drug and treatment, review the evidence, and create guidelines and best practices for how doctors can best treat their patients," says Mr. Modi.

"But due to the unavailability of the data, it isn't the norm to include CSRs and IPD, instead researchers must rely on summaries in published

papers which are much less detailed, introducing a substantial risk of bias and compromising the review's ability to improve patient care."

Previous research by Mr. Modi and his Flinders University colleague Associate Professor Ash Hopkins found that IPD was not available for more than half of the clinical trials that led to the United States Food and Drug Administration approval of certain anticancer medicines.

Despite an increase in the availability of CSRs and IPDS over the last 10 years or so, the authors say more needs to be done to further promote transparency.

"Pharmaceutical companies, funding bodies and journal publishers need to implement standardized data sharing policies that allow the data to be shared from the moment a drug is approved for use," says Mr. Modi.

"Furthermore, independent review panels should be established to help eliminate conflicts of interest and bias when data sharing requests are made.

"And while patient data protection is paramount, it has been found that 90% of trial participants support data sharing. As long as consent is there from the start, IPD should be shared to ensure trial data can be scrutinized.

"These changes require support from the many stakeholders involved in a drug's development, but the ultimate goal is to create a data sharing ecosystem that prioritizes scientific advancement and patient-centered care."

More information: Natansh D. Modi et al, Clinical Study Report and Individual Participant Data Transparency for US Food and Drug Administration–Approved Anticancer Drugs: A Call for Systematic Data