Caring is sharing: Call for more openness on cancer drug trial results

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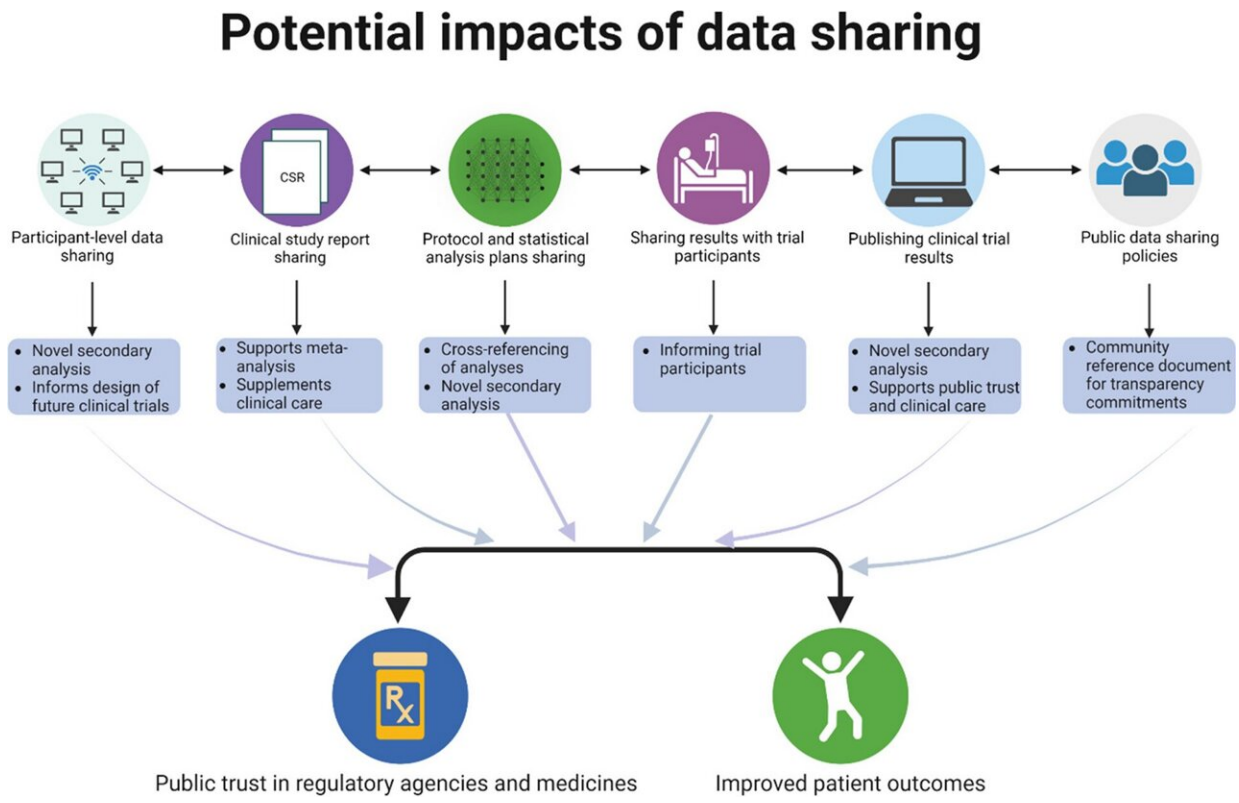

Credit: *BMC Medicine* (2023). DOI: 10.1186/s12916-023-03113-0

Development of potential or improved anti-cancer treatments is being blocked or slowed down by a lack of transparency in data sharing between pharmaceutical companies and research groups, according to cancer clinicians, researchers and consumers.

The multidisciplinary team led by Flinders University researchers Mr. Natansh Modi and Dr. Ashley Hopkins evaluates the literature and policy developments since the 2013 data-sharing commitments were struck by US and European regulators, including the commitment to publish clinical trial results.

The agreement forged by the Pharmaceutical Research and Manufacturers of America (PhRMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) included a commitment to give public access to clinical study reports from clinical trials submitted to the Food and Drug Administration (FDA), European Medicines Agency and EU member states.

However, an article entitled 'A 10-year update to the principles for clinical trial data sharing by pharmaceutical companies: perspectives based on a decade of literature and policies', published in *BMC Medicine* identifies critical areas for improvement in data sharing and collaboration within the pharmaceutical industry—as well as among all institutions involved in clinical trials.

"It will take even more commitment, time and resources to make a collective effort to enhance the accessibility and transparency of critical data in clinical trials," says NHMRC Ph.D. candidate Mr. Modi, from the Clinical Cancer Epidemiology Lab at the Flinders University College of Medicine and Public Health.

"We have identified a series of evidence-based recommendations to enhance existing principles, promote harmonized data sharing practices, and establish clearer guidelines for pharmaceutical industry data sharing."

Senior Research Fellow in Pharmacology Dr. Hopkins, adds the Clinical Cancer Epidemiology Lab research is focusing on the "substantial

opportunity to enhance the data sharing ecosystem" including ensuring that clinical trials deemed as eligible for sharing be made "truly accessible" and that individual-participant data (IPD) packages meet a "standard of utility."

In a recent study, the researchers were allowed access to 70 or 77% of IPDs from 91 trials of FDA-approved anticancer medicines against solid tumors, carried out in the 12 months to February 9 2023. Access was denied to the remaining 21 trials, and completeness of the data and supporting documentation was variable.

As a result, the *BMC Medicine* correspondence is calling for updates in sharing and accessibility of participant-level data, clinical study reports, protocols, statistical analysis plans, lay summaries and result publications from pharmaceutical industry-sponsored trials.

Some key recommendations include:

- **Immediate** eligibility for sharing participant-level data from any clinical trial underpinning a product label or submitted for drug approval.
- **Public** availability of full Clinical Study Reports from all clinical trials submitted to support medicine approvals for direct download.
- **Sharing** protocols and Statistical Analysis Plans for all published clinical trials within six months of enrolling the first participant.
- **Provide** lay summary documents to all clinical trial participants within 12 months of primary outcome completion, to comply with the European Union Clinical Trials Regulation.

- **Dissemination** of clinical trial results and result publications not dependent on clinical trial outcome or phase, covering all follow-up data.

- **Pharmaceutical** companies should have publicly available web pages detailing their data sharing policies, procedures and commitments in a standardized format.

"The proposed policy and process updates should also cover institutions such as universities, medical societies, advocacy groups, regulators, funders and journals involved in reporting and carrying out clinical trials," Mr. Modi says.

"The ultimate goal is to create a data sharing ecosystem that prioritizes science and patient-centered care, benefiting all stakeholders in the field."

Collaborators on the article include researchers from Bond University, University of South Australia, University of Toronto, Flinders Center for Innovation in Cancer, The University of Sydney, The University of Queensland, The University of Melbourne, Monash University, and other clinical trial organizations.

More information: Natansh D. Modi et al, A 10-year update to the principles for clinical trial data sharing by pharmaceutical companies: perspectives based on a decade of literature and policies, *BMC Medicine* (2023). DOI: 10.1186/s12916-023-03113-0

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