IOM report proposes standards for sharing clinical trial data

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Stakeholders in clinical trials should foster a culture in which data sharing is the expected norm and commit to responsible strategies aimed at maximizing the benefits, minimizing the risks, and overcoming the challenges of sharing data, says a new report from the Institute of Medicine. The report lays out recommended guidelines about which data from a clinical trial should be shared and when, such as the analytic data set that supports publication of results should be shared no later than six months after publication and the full analyzable data set should be shared no later than 18 months after study completion or 30 days after regulatory approval.

Clinical trials are studies that help determine whether new health interventions—such as drugs, therapies, and vaccines—are safe and effective for patients and the public. Vast amounts of data are generated over the course of a clinical trial; however, a large portion is never published in peer-reviewed journals. The committee that wrote the report concluded that responsible sharing of clinical trial data is in the public interest. Data sharing can advance new discoveries and improve clinical care by maximizing the knowledge gained from data collected in trials, stimulating new ideas for research, and avoiding unnecessarily duplicative trials. At the same time, sharing clinical trial data presents risks, burdens, and challenges, including protecting the privacy and consent of clinical trial participants, providing researchers adequate time to analyze and publish the data they collected, safeguarding commercially confidential information of sponsors, guarding against invalid secondary analyses, and assuring research institutes that

requirements for sharing clinical trial data will not be unfunded mandates.

"The sharing of clinical trial data needs to be carried out in a way that maintains incentives for sponsors and researchers to develop new clinical trials and therapies and that sustains patients' willingness to participate in them," said committee chair Bernard Lo, president of the Greenwall Foundation. "Our recommendations attempt to balance the interests of different stakeholders with the public interest in having the best information possible regarding the effectiveness and safety of therapies."

The challenge is to set clear expectations that clinical trial data should be shared and to agree on how to do so in a responsible manner that mitigates the risks involved, the committee said. All stakeholders in clinical trials—including participants, sponsors, regulators, investigators, research institutions, journals, and professional societies—have roles and responsibilities in sharing data. The report's recommendations for which specific data should be shared after key times in a clinical trial are:

- At the time of trial registration before the first participant is enrolled, sponsors and investigators should have a plan for which data will be shared, when it will be shared, and under what conditions, making it available publicly at a third-party site that shares data with and meets the data requirements of the World Health Organization's International Clinical Trials Registry Platform.
- At the completion of a study, sponsors and investigators should make summary-level results of clinical trials, including adverse event summaries, publicly available no later than 12 months after study completion. Lay summaries of results should be made available to trial participants concurrently with the sharing of summary-level results no later than 12 months after study

completion. The "full data package"—which is the full analyzable data set, full protocol, statistical analysis plan, and analytic code—should be shared no later than 18 months after study completion, unless the trial is in support of a regulatory application.

- After a publication reports the results of a clinical trial, the "post-publication data package"—which consists of the analytic data set supporting the results and metadata, including the protocol, statistical analysis plan, and analytic code supporting published results—should be shared no later than six months after publication.
- For studies of products or new indications that are approved, the "post-regulatory data package"—consisting of the clinical study report that is redacted for commercially or personal confidential information, the full analyzable data set, full protocol, statistical analysis plan, and analytic code—should be shared 30 days after regulatory approval or 18 months after study completion, whichever occurs later.
- For studies of new products or new indications for a marketed product that are abandoned, the "post-regulatory data package" should be shared no later than 18 months after abandonment. However, if the product is licensed to another party for further development, these data should be shared only after publication, approval, or final abandonment.

The committee also recommended how clinical trial data should be shared in order to mitigate risks and enhance benefits. Holders of clinical trial data should employ data use agreements, designate an independent review panel that involves members of the lay public, make access to clinical trial data a transparent process, and learn from experience by collecting and sharing data on the outcomes of data sharing policies.

"The rapidly changing landscape of clinical trials and the movement toward greater transparency create a need to establish professional standards and set expectations of how to share clinical trial data," said Victor Dzau, president of the Institute of Medicine. "Numerous approaches and models for sharing clinical trial data are being implemented across the globe, and more and more organizations are taking the initiative to share their data. The time is right to have the principles in this report serve as a guide for what specific clinical trial data to share, at what time, and under what conditions."

Given that no body or authority currently is capable of enforcing the recommendations offered in the report for all stakeholders, the committee recommended that the 23 sponsors of the study should take the lead to convene a multi-stakeholder body with global reach and broad representation to address, in an ongoing process, the key challenges associated with sharing clinical trial data.

More information: www.nap.edu/catalog/18998/shar … fits-minimizing-risk

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