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"Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk"

Committee on Strategies for Responsible Sharing of Clinical Trial Data, 2015, 235 pages, National Academies Press, $65.00

Review by Norman M. Goldfarb

"Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk" is a fine addition to the influential series of reports by the Institute of Medicine. This book is a valuable contribution to an idea — transparency in clinical trial results — that is rapidly gaining acceptance. Data from clinical trials, even those that are unsuccessful, can be very valuable, e.g., in meta-analyses or in preventing other researchers from wasting their time — and risking the health of study participants — testing hypotheses that have already been disproven. Patients are more likely to participate in clinical trials if they know their data will not be locked away in some vault of corporate (or academic) secrets. The report makes numerous recommendations for creating a sharing culture for the responsible release of information, while protecting the proprietary rights of the researchers.

The following excerpt illustrates the committee's thorough analysis:

> **Abandonment**
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> In some cases, a clinical trial (whether terminated early or completed) may be part of a product development program that is abandoned. Products and indications may be abandoned either before or after regulatory submission and for a variety of reasons. Sponsors may decide to abandon products and indications undergoing development for regulatory application for scientific or medical reasons (e.g., a lack of efficacy for the indication of interest or a serious safety issue) or for administrative reasons (e.g., business considerations, drug supply). If a product development program is abandoned,
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> - the sponsor may continue to seek or already have regulatory approval for the product for a different indication, using other clinical trial data; or
> - the sponsor may abandon the new product under development for all indications, in which case the sponsor may or may not decide to transfer intellectual property rights to another sponsor, either for-profit or nonprofit, that wants to develop the product.
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> If the sponsor transfers intellectual property rights to another sponsor, the new sponsor has an interest in having an exclusive period in which to conduct additional trials, seek additional patents, and prepare a regulatory submission. Lack of such an exclusive period would be a disincentive for another sponsor to develop the product and seek regulatory approval. Indeed, because of the potential importance of this approach to developing new therapies, the committee encourages making such decisions to transition abandoned products to other interested parties as expeditiously as possible.
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> The committee also considered the case in which a sponsor abandons a product or indication and does not transfer the intellectual property rights to develop the product to another sponsor. In such cases, sharing clinical trial data may help other researchers studying and other sponsors developing similar products. The design of trials on these other products may be modified by the results of the abandoned trial, for example, if the results suggest safety or efficacy endpoints. If a sponsor

abandons a new indication for a marketed product, sharing the clinical trial data can benefit other researchers, clinicians and the public. Sharing data on a product approved for other uses will increase general knowledge of the product, including its efficacy and safety profile.

Taking the above considerations into account, the committee reached the following conclusions regarding abandoned trials (whether terminated early or completed) conducted for products or indications intended for regulatory application.

Conclusion: *If a clinical trial has ended and the sponsor abandons development of a new product (and does not transfer rights to develop the product to another sponsor), it is appropriate to share the post-regulatory data package 18 months after the decision has been made definitively to abandon the product and not pursue further development.*

In this case, the 18-month moratorium will allow the trial investigators to analyze the data from the trial and publish their findings. This 18-month moratorium is similar to the moratorium for completed trials, allowing investigators to analyze and publish their work. As with all trial data, the analytic data set supporting a publication should be available no later than six months after publication.

Conclusion: *If a product will continue to be developed by the sponsor or if it is transitioned or licensed to a new sponsor that is pursuing development and approval, it is appropriate to share the post-regulatory data package 30 days after regulatory approval of the product or 18 months after study completion, whichever occurs later*.

Conclusion: *If a sponsor will not be seeking regulatory approval of the new indication for a marketed product for which a trial was intended to be part of a regulatory submission, it is appropriate to share the post-regulatory data package 18 months after the decision has been made definitively to abandon the indication.*

The book consists of seven chapters:

- Introduction
- Guiding Principles for Sharing Clinical Trial Data
- The Committee's Approach to Applying the Principles
- The Roles and Responsibilities of Stakeholders in the Sharing of
- The Clinical Trial Life Cycle and When to Share Data
- Access to Clinical Trial Data: Governance
- The Future of Data Sharing in a Changing Landscape

The book is available in bookstores.

Reviewer

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