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Discussion Framework for Clinical Trial Data Sharing

Specific Topics for Public Feedback

As required in the charge to the committee, *Discussion Framework for Clinical Trial Data Sharing: Guiding Principles, Elements, and Activities* is being released for public comment. The committee welcomes comments from interested parties to help ensure that major concerns and areas are not overlooked, and particularly invites comments on the difficult or complex topics outlined in Box 1 of the framework.

Comments may be submitted to the committee at either of two forthcoming public workshops, or via the committee's project website, **http://www8.nationalacademies.org/cp/projectview.aspx?key=49578**. The specific topics for public feedback are below.

Global Implementation and Practical Consideration

- Because most large clinical trials are global in nature, how can clinical trial data be shared in that global context? How can different national regulations for research participants' privacy protections, approval of drugs and devices, data exclusivity and intellectual property laws, resources, and health priorities be taken into account?
- How might strategies and approaches regarding data sharing take into account clinical trials conducted in resource-poor settings; trials designed by citizen-scientists using data they contribute directly; and trials designed through participatory research?

Timing and Prioritization

- How might different types of clinical trial data, and different uses of shared data, be prioritized for sharing? What would be the rationale for placing a higher priority on certain types of data or analyses? What might be the advantages and disadvantages of distinguishing highest priority sharing of clinical trial data from other sharing activities?
- What might be the advantages and disadvantages to various stakeholders of sharing different types of datasets, at different points in time after the completion of a clinical trial?
- Should programs or approaches calling for or requiring new data sharing apply only to new trials undertaken from the date of a new program forward, or retroactively apply to clinical trials started before the data sharing program was initiated?

Mitigating Risks

- What might be done to minimize the risks to patients and to public health from the dissemination of findings from invalid analyses of shared clinical trial data?
- What measures should be deployed to minimize the privacy and confidentiality risks to trial participants? For example, are current anonymization or de-identification methodologies sufficient?
- Under what circumstances are identifiable data needed to fulfill articulated purposes of a data sharing activity? Under what circumstances might re-identification of trial participants be beneficial (for the participants or the public)? Have there been there examples of instances of re-identification of trial participants (e.g., for safety reasons to warn a patient of a potential risk, or for questionable and potentially unethical reasons) and what were the impacts?

Committee on Strategies for Responsible Sharing of Clinical Trial Data

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Enhancing Incentives

- What incentives and protections might be established to encourage clinical trial sponsors and clinical investigators to continue to conduct clinical trials in the future, without unduly restricting the sharing of certain types of data? How do we protect or provide incentives for researchers to share data?
- What is the appropriate responsibility of the primary investigator(s) or research institution(s) to support secondary users in their interpretation of shared data, and what infrastructure or resources are needed to enable such ongoing support? For those with experience in data sharing, what is the burden of providing such support to help others understand and use the provided information?

Measuring Impact

- What would be appropriate outcome measures to assess the usefulness of different models of clinical trial data sharing, and how can they be used to guide improvements in data sharing practices?

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