Committee on Strategies for Responsible Sharing of Clinical Trial Data

STATEMENT OF TASK

An ad hoc committee of the Institute of Medicine will conduct a study to develop guiding principles and a framework (activities and strategies) for the responsible sharing of clinical trial data. For the purposes of the study, the scope will be limited to interventional clinical trials and “data sharing” will include the responsible entity (data generator) making the data available via open or restricted access*, or exchanged among parties. For the purposes of this study, data generator will include industry sponsors, data repositories, and researchers conducting clinical trials.

Specifically, the committee will:

- Articulate guiding principles that underpin the responsible sharing of clinical trial data.
- Describe a selected set of data and data sharing activities, including, but not limited to:
  - Types of data (e.g., summary, participant)
  - Provider(s) and recipient(s) of shared data
  - Whether and when data are disclosed publicly, with or without restrictions, or exchanged privately among parties.
- For each data sharing activity, the committee will:
  - Identify key benefits of sharing and risks of not sharing to research sponsors and investigators, study participants, regulatory agencies, patient groups, and the public.
  - Address key challenges and risks of sharing (e.g., resource constraints, implementation, disincentives in the academic research model, changing norms, protection of human subjects and patient privacy, IP/legal issues, preservation of scientific standards and data quality).
  - Outline strategies and suggest practical approaches to facilitate responsible data sharing.
- Make recommendations to enhance responsible sharing of clinical trial data. The committee will identify guiding principles and characteristics for the optimal infrastructure and governance for sharing clinical trial data, taking into consideration a variety of approaches (e.g., a distributed/federated data system).

In developing the principles and framework and in defining the rights, responsibilities, and limitations underpinning the responsible sharing of clinical trial data, the committee will take into account the benefits of data sharing, the potential adverse consequences of both sharing and not sharing data, and the landscape of regulations and policies under which data-sharing occurs. Focused consideration will also be given to the ethical standards and to integrating core principles and values, including privacy. The committee is not expected to develop or define specific technical data standards.

A discussion document will be released for public comment, which will constitute a framework for discussion and will include tentative findings regarding (a) guiding principles and (b) a selected set of data sharing activities. Based on the public comments received and further deliberations, the committee will prepare a report with its findings and recommendations.

*Data generators might limit access to clinical trial data for reasons that could include intellectual property rights or legal concerns and failure to satisfy certain criteria (e.g., sufficient statistical and data management expertise).