The National Academies of
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Forum on Drug Discovery, Development, and Translation
Forum on Neuroscience and Nervous System Disorders
National Cancer Policy Forum
Roundtable on Genomics and Precision Health

AGENDA

Sharing Clinical Trial Data Action Collaborative:
Data Sharing Goals for Nonprofit Funders of Clinical Trials
Thursday, November 30, 2017
National Academy of Sciences Building, Room 125
2101 Constitution Avenue, NW
Washington, DC 20418

Meeting Objectives:

- Discuss draft *Statement of Data Sharing Goals for Nonprofit Funders of Clinical Trials* and agree upon goals which will be brought back to organizations' research boards and, ideally, incorporated into funding policies.
- Share risks and challenges to reaching these goals and strategies for overcoming them
- Plan next steps—how can these goals be adopted by a wider range of nonprofit groups and serve as a launching point for engagement of other stakeholders?

Meeting Background:

The Sharing Clinical Trial Data Action Collaborative is a follow up activity to the 2015 IOM consensus study report, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk.* The report calls upon stakeholders to foster a culture of sharing and offers a blueprint for action within and across sectors. Four Forums and Roundtables[1] of The National Academies of Sciences, Engineering, and Medicine (The Academies) provided, through their convening activities, momentum and a framework for initiating the consensus study. Those Forums and Roundtables now serve as a platform to help support coordination and collaboration among the various stakeholders and to help address barriers and challenges to enabling the responsible sharing of data.

Data Sharing Goals for Nonprofit Funders of Clinical Trials
A working group of the action collaborative, co-chaired by Sharon Terry (Genetic Alliance) and Timothy Coetzee (National Multiple Sclerosis Society), met in 2016 to discuss the development of a draft "statement" to convey both aspirational and practical clinical trial data sharing goals and strategies for the nonprofit community to consider. A priority of the working group has been to develop actionable goals that could be brought to organizations' research boards and be incorporated into funding policies. The meeting today aims to: (1) bring together a larger group of nonprofit funders to discuss and improve upon the draft statement of data sharing goals and, (2) provide a launching point for the prioritization and uptake of data sharing activities among an ever-increasing number of nonprofits engaged in clinical research.

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[1] Forum on Drug Discovery, Development, and Translation; Forum on Neuroscience and Nervous System Disorders; National Cancer Policy Forum; and Roundtable on Genomics and Precision Health.

8:30 a.m.   Breakfast Available

SESSION I: WELCOME AND MEETING OVERVIEW

9:00 a.m.   **Welcoming Remarks**

CAROLYN SHORE
Director, Forum on Drug Discovery, Development, and Translation
National Academies of Sciences, Engineering, and Medicine

SARAH BEACHY
Director, Roundtable on Genomics and Precision Health
National Academies of Sciences, Engineering, and Medicine

9:05 a.m.   **Overview of Meeting Objectives**

SHARON TERRY, *Collaborative Co-Chair*
President and Chief Executive Officer
Genetic Alliance

TIM COETZEE, *Collaborative Co-Chair*
Chief Advocacy, Services, and Research Officer
National Multiple Sclerosis Society

SESSION II: DATA SHARING POLICIES AT THE ORGANIZATIONAL AND CROSS-ORGANIZATIONAL LEVELS

9:15 a.m.   **Goal #1: Encourage co-development of data sharing policies with prospective research participants**

Discussion Leader: *Sharon Terry, Genetic Alliance*
- How can nonprofit funders of clinical trials encourage/require/enforce grantees to work directly with patients and the lay public – making them full partners/co-developers in the research program?
- Is the incentivizing data sharing limited to funding scenarios or could/should nonprofit organizations withhold access to patient networks if a particular clinical trial is not designed from the beginning to share the resulting data?
- What role could/should nonprofit funders have in educating patients and the lay public on the importance of data sharing for biomedical research, as well as the risks?
- What role could/should nonprofit funders have in ensuring data is shared directly with the research participant from which it came?

10:00 a.m.	**Goal #2: Develop or adopt transparent and fair approval processes for data use**

Discussion Leader: *Kathy Giusti, Multiple Myeloma Research Foundation (invited)*
- How could/should nonprofit organizations inform the data use policies applied to data generated from the clinical trials they fund?
- Discuss some of the reasons why data from a trial might not be shared.
- Is the approach of third-party vetting of data access requests fiscally or philosophically desirable for individual disease/patient advocacy organizations?

10:45 a.m.	**Goal #3: Promote the development of a sustainable and feasible data sharing infrastructure**

Discussion Leader: *Sharon Terry, Genetic Alliance*
- How should nonprofit funders identify the appropriate platform for storing and sharing data generating through the clinical trials they fund?
- Is it necessary for nonprofit funders to select just one platform for housing data and require that it be used for data generating from clinical trials?

11:30 a.m.	**Synthesis** – identify themes emerging from discussion and potential areas of agreement

Discussion Leaders: *Tim Coetzee and Sharon Terry*

12:00 p.m.	**Working Lunch**

12:30 p.m.	**Goal #4: Promote and support the development and adoption of standards, standard language, and common data elements**

Discussion Leader: *Tim Coetzee, National Multiple Sclerosis Society*
- How can nonprofit funders best spend their time, money, influence in the busy world of standards, standard language, and common data elements to facilitate data sharing?
- Are there best practices for nonprofit funders engaging in the development of standards for data sharing?

SESSION III: DATA SHARING POLICIES IN CONTRACTS AND GRANTS

1:15 p.m.	**Goal #5: Include incentives and enforce requirements in grants, contracts, and other funding structures, that will both promote and provide accountability for investigators to share and use shared data**

Discussion Leader: *Tim Coetzee, National Multiple Sclerosis Society*
- What are the potential benefits and risks of requiring and enforcing data sharing policies from the perspective on nonprofit funders of clinical trials?
- How can nonprofit funders of clinical trials best leverage their influence to incentive investigators to share and use shared data?

- How can nonprofit funders enforce data sharing among grantees?
- If a data sharing plan is required by a nonprofit funder of a clinical trial, is an acceptable response to that requirement that the plan is to *not* share the data?

2:00 p.m.   **Goal #6: Provide funding and include data sharing as a line item in grants and contracts**

Discussion Leader: *Sharon Terry, Genetic Alliance*
- How should nonprofit funders prioritize the resource-intensive activity of data sharing over other spending needs?
- What are the risks and benefits of setting aside nonprofit resources for data sharing? Will the organization's patient community be supportive?
- Should every grant and contract for a clinical trial include data sharing or is there a way to prioritize among projects?

2:45 p.m.   **Goal #7: Include prior data sharing as a measure of impact when making decisions on whether to fund or support clinical trials**

Discussion Leader: *Marc Boutin, National Health Council*
- How could nonprofits effectively use an investigator's history of data sharing in their evaluations of whether or not to fund a clinical trial or grant access to their patient network?
- Discuss the pros and cons of different options along the continuum of data sharing (i.e., from sharing very little or no data to full transparency/no secrecy). For instance, if a culture of data sharing becomes truly pervasive, innovation could be predicated on something other than intellectual property (e.g., exclusivity). What would be the potential benefits and risks of such a shift for nonprofit funders?

3:30 p.m.   **Synthesis** – identify themes emerging from discussion and potential areas of agreement

Discussion Leaders: *Tim Coetzee and Sharon Terry*

3:50 p.m.   **Next Steps**

Discussion Leaders: *Tim Coetzee and Sharon Terry*
- Discuss and resolve any remaining concerns on the content/language of goals
- Discuss plans for promoting goals to our institutions and the broader community
- Plan immediate next steps

4:00 p.m.   ADJOURN