CLINICAL EFFECTIVENESS RESEARCH INNOVATION COLLABORATIVE

NOVEMBER 3, 2016
NATIONAL ACADEMY OF SCIENCES BUILDING
LECTURE ROOM
2101 CONSTITUTION AVE NW
WASHINGTON, DC 20418

Meeting focus: The characteristics and operationalization of open science
Core questions:
- **Purpose and use**: What are the primary opportunities and applications of secondary use of data?
- **Potential benefits**: How much might open science accelerate discovery and evidence development?
- **Governance**: What are current “ownership” profiles for health data?
- **Leadership**: What decision makers are most important in advancing open science?
- **Associated costs**: What are the cost of data de-identification, annotation, and maintenance?
- **Competition**: What are the potential downsides, and for whom, in an open science framework?
- **Vision**: What three actions are most important to advancing progress toward truly open science?

Anticipated outcome: Identification of ways in which CERIC participants can accelerate progress

8:30 am  Coffee and light breakfast available

9:00 am  Welcome, introductions, and meeting overview

Welcome from the National Academy of Medicine
*Michael McGinnis, National Academy of Medicine*

Opening remarks and meeting overview by Collaborative Chairs
*Rick Kuntz, Medtronic*
*Richard Platt, Harvard Medical School*

9:15 am  Open Science: Sharing clinical data for continuous learning

Participants will discuss benefits, barriers, associated costs, and priorities for sharing research data collected from clinical trials and the point of care. Participants will also consider possible elements of an NAM Discussion Paper on the topic.

*Rick Kuntz, Medtronic, moderator*
*Robert M. Califf, US Food and Drug Administration*
*Joe Kiani, Masimo*
*Joseph Solomon Ross, Yale University*
*Joanne Waldstreicher, Johnson & Johnson*

Q&A and Open Discussion
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<td>11:00 am</td>
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| 11:15 am | **Open Science: Sharing delivery system data for continuous learning**      | This session will continue to explore the sharing of data generated at the health system level, specifically the potential issues associated with open science and pragmatic research embedded in delivery systems. Participants will also consider possible elements of an NIH Collaboratory paper on the topic.  

*Richard Platt,* Harvard Medical School  
*Adrian Hernandez,* Duke University  
*Q&A and Open Discussion* |
| 12:00 pm | **Luncheon discussion: who owns the data?**                                   | This session will focus on data ownership, the impact of data sharing on competition and academic advancement, data requests from the public; and third party data management.                                        

*Rick Kuntz,* Medtronic, moderator  
*Julie R. Ingelfinger,* The New England Journal of Medicine  
*Alexander Ommaya,* Association of American Medical Colleges  
*Q&A and Open Discussion* |
| 1:00 pm  | **The future of open science in a continuously learning health system**      | This session will consider a vision and strategy for executing and operationalizing open science as a contributor of knowledge generation.                                                                       

*Richard Platt,* Harvard Medical School, moderator  
*Elliott Marshall Antman,* Harvard University  
*Eric Peterson,* Duke Clinical Research Institute  
*Deborah Zarin,* National Institutes of Health  
*Q&A and Open Discussion* |
| 2:30 pm  | **CERIC action: Issues and opportunities for collaborative action**          | Participants will reflect on emerging opportunities for CERIC projects.                                                                                                                                        |
| 3:00 pm  | **Summary of ongoing projects and next steps**                              |                                                                                                                                                                                                              |
|         | **Comments from the Chairs**                                                 |                                                                                                                                                                                                              |
|         | *Rick Kuntz,* Medtronic                                                      |                                                                                                                                                                                                              |
|         | *Richard Platt,* Harvard Medical School                                      |                                                                                                                                                                                                              |
|         | **Comments and thanks from the NAM**                                        |                                                                                                                                                                                                              |
|         | *Michael McGinnis,* National Academy of Medicine                            |                                                                                                                                                                                                              |
| 3:30 pm  | **Adjourn**                                                                   |                                                                                                                                                                                                              |