Challenges and a Way Forward in Sharing Clinical Trial Data

A Workshop

November 18 – 19, 2019
National Academy of Sciences Building, Lecture Room
2101 Constitution Ave. NW, Washington, DC 20418

WORKSHOP OBJECTIVES:

Following release of the 2015 Institute of Medicine report, Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk:

- Consider the value and potential risks/costs of sharing clinical trial data for key stakeholders, including clinical trialists, sponsors, primary and secondary researchers, and patients;
- Review the current landscape of clinical trial data sharing and reuse across public and private sectors (e.g. policies, platforms, collaborations, data sharing culture, published research output);
- Examine use cases and trends from across public and private sectors when it comes to success, failure, lessons learned, and value;
- Consider the perspectives and expectations of primary and secondary researchers, clinical trial participants, patient organizations, research sponsors (pharmaceutical companies and nonprofit organizations), journals, institutions, and federal agencies; and
- Discuss next step opportunities for stakeholders to better harmonize incentives, policy, data standards, and governance to encourage the sharing and reuse of clinical trial data.

DAY 1: November 18, 2019

8:00 a.m. Breakfast available outside the Lecture Room

8:30 a.m. Welcome and opening remarks

JOANNE WALDSTREICHER, Workshop Co-Chair
Chief Medical Officer
Johnson & Johnson

JEFFREY DRAZEN, Workshop Co-Chair
Group Editor
New England Journal of Medicine
SESSION I  THE CURRENT LANDSCAPE OF CLINICAL TRIAL DATA SHARING AND REUSE

Session Objectives:

- Consider the value and potential risks/costs of sharing clinical trial data for key stakeholders, including clinical trialists, sponsors, primary and secondary researchers, and patients;
- Review the current landscape of clinical trial data sharing and reuse across public and private sectors (e.g., policies, platforms, collaborations, data sharing culture);
- Examine case studies and trends from across public and private sectors when it comes to success, failure, lessons learned, and value.

9:00 a.m.  Landscape overview by session moderators

BERNARD LO
President and CEO
The Greenwall Foundation

ELIZABETH NABEL (INVITED)
President, Brigham Health,
Brigham and Women’s Hospital

9:20 a.m.  Policies in practice: Lessons learned

A researcher perspective
HARLAN KRUMHOLZ
Harold H. Hines, Jr. Professor of Medicine
Yale School of Medicine

A sponsor perspective
TBD

An independent review panel perspective
SONALI KOCHHAR
Medical Director
Global Healthcare Consulting

A patient perspective
MOSES TAYLOR
Participant
SPRINT Trial
10:20 a.m.  **Data sharing platforms: Use cases**

**Vivli**  
REBECCA LI  
Executive Director  
Vivli

**The YODA Project**  
JOSEPH ROSS  
Professor of Medicine and Public Health  
Yale School of Medicine

**SOAR**  
FRANK ROCKHOLD  
Professor of Biostatistics and Bioinformatics  
Duke University Medical Center

**ClinicalStudyDataRequest.com**  
SCOTT SHAUNESSY  
CEO- ideaPoint  
Anaqua, Inc.

11:20 a.m.  **BREAK**

11:50 a.m.  **Panel discussion: Striking a balance between benefit/value and risk/cost – is the juice worth the squeeze?**

*A data analyst perspective*  
DAVID DEMETS  
Professor Emeritus, Department of Biostatistics and Medical Informatics  
University of Wisconsin, Madison

*A data sharing perspective*  
TBD

*A patient perspective*  
DEBORAH C. PEEL  
Founder and President  
Patient Privacy Rights

12:35 p.m.  **Audience discussion with the panel (25 mins)**

1:00 p.m.  **BREAK** (Lunch available Outside the Lecture Room)
SESSION II KEY CHALLENGES IN CLINICAL TRIAL DATA SHARING AND REUSE

Session Objectives:

- Discuss key challenges to clinical trial data sharing and reuse by including use cases;
- Consider the perspectives and expectations of clinical trial participants, patients, research sponsors (pharmaceutical companies and nonprofit organizations), journals, academic researchers and institutions, institutional review boards, and federal agencies.

1:30 p.m. Opening remarks by session moderators

ISAAC KOHANE (INVITED)
Chair, Department of Biomedical Informatics
Harvard Medical School

DINA PALTOO
Assistant Director, Policy Development
National Institutes of Health, National Library of Medicine

1:45 p.m. Panel Discussion: Data interoperability and platform usability

Use case: population data
ERNEST HAWK
Vice President and Division Head, Cancer Prevention and Population Sciences
MD Anderson

Use case: meta-analysis
TIANJIING LI
Associate Professor
University of Colorado Denver

A platform perspective
BILL LOUV
President
Project Data Sphere

2:15 p.m. Moderated discussion with the panel

2:45 p.m. Panel discussion: Infrastructure sustainability

A funder perspective
GEORGINA HUMPHREYS
Clinical Data Sharing Manager
Wellcome Trust
**A business perspective**

PANDURANG KULKARNI  
Chief Analytics Officer R&D  
VP, Biometrics and Advanced Analytics  
Eli Lilly and Company

**A platform perspective**

SEAN COADY  
Program Officer  
National Heart, Lung, and Blood Institute  
National Institutes of Health

3:15 p.m.  *Moderated discussion with the panel*

3:45 p.m.  **BREAK**

4:15 p.m.  **Panel discussion: Challenges and disincentives for sharing and using data**

**Use case: Statistical replication**

**A researcher perspective**

MATT SYDES (*INVITED*)  
Reader in Clinical Trials  
MRC Clinical Trials Unit  
University College London

**A sponsor perspective**

TBD

**A patient perspective**

SHARON TERRY  
President and CEO  
Genetic Alliance

5:00 p.m.  *Audience Q&A with the panel*

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**DAY 1  REFLECTIONS**

5:15 p.m.  **Finding value as we move forward**

JOANNE WALDSTREICHER, *Workshop Co-Chair*  
Chief Medical Officer  
Johnson & Johnson
SESSION III FINDING VALUE IN SHARING CLINICAL TRIAL DATA

Session Objectives:
- Discuss next step opportunities for stakeholders to better align incentives, and implement policy, technology, and governance that encourage the sharing and reuse of clinical trial data;
  - Explore opportunities for overcoming technical barriers;
  - Explore opportunities for addressing cultural barriers; and
  - Discuss possible solutions/next steps going forward.

8:45 a.m. Panel discussion: Overcoming usability and sustainability challenges

Moderator
IDA SIM
Professor
University of California, San Francisco School of Medicine

A data user perspective
MARK HELFAND
Professor of Medicine, Medical Informatics, and Clinical Epidemiology
Oregon Health & Science University
A data generator/sharer perspective
MONICA BERTAGNOLLI
Professor of Surgery
Harvard Medical School

A platform perspective
REBECCA KUSH
Chief Scientific Officer
Elligo Health Research

9:15 a.m. Audience discussion with the panel

10:15 a.m. BREAK

10:45 a.m. Panel discussion: Looking forward: incentivizing data sharing and reuse

Moderator
TBD

A researcher perspective
COLIN Baignent
Deputy Director, Clinical Trial Service Unit and Epidemiological Studies Unit
Oxford University

An institutional perspective
AMY NURNBERGER
Program Head, Data Management Services
MIT

A sponsor perspective
LIZ ROBERTS
Senior Director and Global Public Policy Lead
UCB Biosciences

A funder perspective
GEORGINA HUMPHREYS
Clinical Data Sharing Manager
Wellcome Trust

11:45 a.m. Audience discussion with the panel

12:15 p.m. Next Steps

JOANNE WALDSTREICHER, Workshop Co-Chair
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12:30 p.m.  ADJOURN WORKSHOP DAY 2