

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

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

Sharing Clinical Trial Data: Challenges and a Way Forward

A Workshop

November 18 – 19, 2019

National Academy of Sciences Building, Great Hall
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 in the Great Hall

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

DEBORAH ZARIN
Director, Program for the Advancement of the Clinical Trials Enterprise
Multi-Regional Clinical Trials Center,
Brigham and Women's Hospital and Harvard

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 funder perspective

LYRIC JORGENSEN
Deputy Director
Office of Science Policy, National Institutes of Health

An independent review panel perspective

SONALI KOCHHAR
Medical Director
Global Healthcare Consulting

A patient perspective

MOSES TAYLOR JR.
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
Chair
ClinicalStudyDataRequest.com
- 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 publisher perspective***
JEFFREY DRAZEN
Group Editor
New England Journal of Medicine
- A patient perspective***
DEBORAH C. PEEL
Founder and President
Patient Privacy Rights
- 12:35 p.m. *Moderated audience discussion with the panel (25 mins)*
- 1:00 p.m. **BREAK** (Lunch available in the Great Hall)

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**

TIMOTHY COETZEE
Chief Advocacy, Services, and Research Officer
National Multiple Sclerosis Society

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

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

TIANJING LI
Associate Professor
University of Colorado Denver

A platform perspective

BILL LOUV
President
Project Data Sphere

2:15 p.m. *Moderated audience 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 audience 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

MATTHEW SYDES
Professor of Clinical Trials and Methodology
MRC Clinical Trials Unit at UCL
University College London

A sponsor perspective

RAMIN DARON
Vice President, Data Architecture and Technology
Takeda Pharmaceuticals

A patient perspective

SHARON TERRY
President and CEO
Genetic Alliance

4:45 p.m. *Moderated audience discussion with the panel*

DAY 1: REFLECTIONS

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

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

JEFFREY DRAZEN, *Workshop Co-Chair*
Group Editor
New England Journal of Medicine

5:30 p.m. **ADJOURN WORKSHOP DAY 1**

DAY 2: November 19, 2019

8:00 a.m. Breakfast Available in the Great Hall

8:30 a.m. **Welcome and overview of Day 1**
JOANNE WALDSTREICHER, *Workshop Co-Chair*
Chief Medical Officer
Johnson & Johnson

JEFFREY DRAZEN, *Workshop Co-Chair*
Group Editor
New England Journal of Medicine

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 of Medicine
UCSF 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

9:30 a.m. *Moderated audience discussion with the panel*

10:00 a.m. **BREAK**

10:30 a.m. **Panel discussion: Looking forward: incentivizing data sharing and reuse**

Moderator and sponsor perspective

LIZ ROBERTS
Senior Director and Global Public Policy Lead
UCB Biosciences

A researcher perspective

MARTIN HO
Associate Director for Quantitative Patient Inputs & RWE
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

A researcher perspective

COLIN BAIGENT
Deputy Director, Clinical Trial Service Unit and Epidemiological Studies Unit
Oxford University

An institutional perspective

AMY NURNBERGER
Program Head, Data Management Services
Massachusetts Institute of Technology

A funder perspective

GEORGINA HUMPHREYS
Clinical Data Sharing Manager
Wellcome Trust

11:45 a.m. *Moderated audience discussion with the panel*

12:15 p.m. **Next Steps**

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

JEFFREY DRAZEN, *Workshop Co-Chair*
Group Editor
New England Journal of Medicine

12:30 p.m. **ADJOURN WORKSHOP DAY 2**