

*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

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**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.

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**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*

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## **SESSION I: THE CURRENT LANDSCAPE OF CLINICAL TRIAL DATA SHARING AND REUSE**

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### **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)

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## SESSION II: KEY CHALLENGES IN CLINICAL TRIAL DATA SHARING AND REUSE

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### 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*

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**DAY 1: REFLECTIONS**

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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*

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### **SESSION III: FINDING VALUE IN SHARING CLINICAL TRIAL DATA**

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#### 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**