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 KRUNHOLZ**  
Harold H. Hines, Jr. Professor of Medicine  
Yale School of Medicine

**A funder perspective**  
**LYRIC JORGENSON**  
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
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**