The Need to Accelerate Therapeutic Development — Must Randomized Controlled Trials Give Way?

Presented by NYU School of Medicine and the New York Academy of Sciences

June 21 – 22, 2017

The New York Academy of Sciences Conference Center, New York, NY

AGENDA

This Bioethics Conference is supported by funding from

Johnson & Johnson

The program is not certified for continuing education

Day 1: Wednesday, June 21, 2017

8:00 AM **Registration and Breakfast**

8:40 AM **Welcoming Remarks**

Melanie Brickman Borchard, PhD, MSc, The New York Academy of Sciences
Arthur Caplan, PhD, NYU School of Medicine
Joanne Waldstreicher, MD, Johnson & Johnson

9:00 AM ***Setting the Stage***
Arthur Caplan, PhD, NYU School of Medicine

Session I: The History and Contribution of Randomized Controlled Trials to Public Health

9:30 AM **Panel Discussion**

Moderator: **Arthur Caplan**, PhD, NYU School of Medicine
Panelists: **Susan S. Ellenberg**, PhD, Perelman School of Medicine, University of Pennsylvania
Howard Fingert, MD, FACP, Takeda Pharmaceuticals
Susan E. Lederer, PhD, University of Wisconsin School of Medicine and Public Health
Jane Perlmutter, PhD, Gemini Group

10:45 AM **Networking Coffee Break**

Session II: Beyond RCTS – Assessing the Need for Alternatives

11:15 AM **Panel Discussion**

Moderator: **Charles Weijer**, MD, PhD, Western University
Panelists: **Luciana Lopes Borio**, MD, U.S. Food and Drug Administration
Barry J. Gertz, MD, PhD, Clarus Ventures
Andrea Troxel, ScD, NYU School of Medicine

12:30 PM **Networking Luncheon**

1:45 PM **Keynote Lecture**
Finding the Right Balance in Learning about Therapies
Robert Califf, MD, Duke University

Session III: Weighing the Risks of Randomized Controlled Trials and Alternatives

2:25 PM **Panel Discussion**

Moderator: **Steve Usdin**, *BioCentury*
Panelists: **Holly Fernandez Lynch**, JD, MBioethics, Harvard Law School
Amrit Ray, MD, Johnson & Johnson
Matthew Rotelli, PhD, Eli Lilly and Company
Robert Walker, MD, U.S. Department of Health and Human Services

3:40 PM **Networking Coffee Break**

Session IV: Ethics and Patient Advocacy in Clinical Trial Design

4:10 PM **Panel Discussion**

Moderator: **Alison Bateman-House**, PhD, MPH, MA, NYU School of Medicine
Panelists: **Rebecca Susan Dresser**, JD, Washington University in St. Louis
Andrew McFadyen, The Isaac Foundation
Jane Reese-Coulbourne, MS, ChE, MK&A
Peter Saltonstall, National Organization for Rare Disorders
J. Russell Teagarden, DMH, MA, NYU School of Medicine Working Group on Compassionate Use and Pre-Approval Access

5:25 PM **Closing Remarks**

5:30 PM **Networking Reception**

7:00 PM **Day 1 Adjourns**

Day 2: Thursday, June 22, 2017

8:00 AM **Registration and Breakfast**

8:45 AM **Keynote Lecture**
Modern Trends in Clinical Drug Development
Janet Woodcock, MD, U.S. Food and Drug Administration

Session V: Lessons from the Eteplirsen Drug Trial for Duchenne Muscular Dystrophy

9:30 AM **Panel Discussion**

Moderator: **Meg Tirrell**, CNBC
Panelists: **Pat Furlong**, Parent Project Muscular Dystrophy
Edward M. Kaye, MD, Sarepta Therapeutics
David Scheer, Sheer & Company, Inc.
Ellis Unger, MD, U.S. Food and Drug Administration

10:45 AM **Networking Coffee Break**

Session VI: A Way Forward: Shaping Clinical Trial Innovation

11:15 AM **Panel Discussion**

Moderator: **Donald Berry**, PhD, MD Anderson Cancer Center
Panelists: **Anne Cropp**, PharmD, BCAP, Early Access Care, LLC
George Demetri, MD, Dana-Farber Cancer Institute
Clifton Leaf, *Fortune*
Christopher Robertson, PhD, JD, University of Arizona
John (L.P.) Thompson, PhD, Columbia University

12:30 PM **Networking Luncheon**

Session VII: Ethics Panel Wrap-up: What is the Future of Accelerated Development and the Randomized Controlled Trial Standards?

1:45 PM **Panel Discussion**

Moderator: **Timothy Caulfield**, LLB, LLM, University of Alberta
Panelists: **Nancy M.P. King**, JD, Wake Forest School of Medicine
Vinay Prasad, MD, MPH, Oregon Health and Science University
Eric Rubin, MD, Merck & Co. Inc.
Jeffrey S. Weber, MD, NYU Langone Medical Center

3:00 PM **Closing Remarks**

3:20 PM **Colloquium Concludes**

**** Note:*** *Included in all panels will be approximately 10-15 minutes for Q&A with attendees of the Colloquium.*