



Public Workshop on COVID-19 Lessons Learned: Clinical Evaluation of Therapeutics

September 28, 2021

1-5:30pm Eastern

Agenda

1pm	Welcome and Introduction Kevin Bugin, PhD Acting Deputy Director of Operations, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration and formerly Therapeutics Chief of Staff, Federal COVID-19 Response (previously known as Operation Warp Speed) Susan C. Winckler, RPh, Esq. CEO, Reagan-Udall Foundation for the FDA
1:15pm	Opening Plenary Janet Woodcock, MD Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration Francis S. Collins, MD, PhD Director, National Institutes of Health
1:45pm	Research, Scoping, & Prioritization Panel <i>Moderated by</i> Stacey Adam, PhD Associate Vice President, Research Partnerships, Foundation for the National Institutes of Health Michael Santos, PhD Vice President, Science, Foundation for the National Institutes of Health <i>Panelists:</i> <ul style="list-style-type: none">• Janet Woodcock, MD, Acting Commissioner of Food and Drugs, U.S. Food and Drug Administration• Phyllis Arthur, MBA, Vice President, Infectious Diseases and Emerging Science Policy, BIO• Elliott Levy, MD, COVID R&D Consortium• Sarah Read, MD, Deputy Director, Division of AIDS, National Institute of Allergy and Infectious Diseases and Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Therapeutics-Clinical Work Group Co-Chair
2:45pm	Infrastructure & Resourcing Panel <i>Moderated by</i> Esther Krofah Executive Director, FasterCures and Center for Public Health, Milken Institute Kristin Schneeman Director, FasterCures <i>Panelists:</i> <ul style="list-style-type: none">• Barbara Bierer, MD, Faculty Director, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard; Professor of Medicine, Harvard Medical School and Brigham and Women's Hospital

- Michael Kurilla, MD, PhD, Director, Division of Clinical Innovation, National Center for Advancing Translational Sciences, National Institutes of Health
- James Mayne, PhD, Vice President, Science Advocacy, Pharmaceutical Research & Manufacturers of America
- Doug Peddicord, PhD, Executive Director, Association of Clinical Research Organizations and President, Washington Health Strategies Group

3:45pm

Clinical Trial Execution Panel

Moderated by

Mark McClellan, MD, PhD

Robert J. Margolis Professor of Business, Medicine, and Policy, and Founding Director of the Duke-Margolis Center for Health Policy, Duke University

Sarah Sheehan, MPA

Managing Associate, Duke Margolis Center for Health Policy

Panelists:

- Samuel Brown, MD, MS, Senior Medical Director for Clinical Trials, Intermountain Healthcare Professor of Medicine, Intermountain Medical Center and University of Utah
- Janice Chang, Chief Operating Officer, TransCelerate BioPharma Inc.
- Clark Files, MD, Associate Professor, Pulmonary, Critical Care, Allergy, and Immunologic Diseases, Wake Forest School of Medicine and Co-Chair, I-SPY COVID Clinical Operations Group
- Monica Webb Hooper, PhD, Deputy Director, National Institute on Minority Health and Health Disparities
- Kate Zenlea, MPH, CPH, Managing Director, The Global Health Initiative at Henry Ford Health System

4:45pm

Public Comment

Open to those who submitted comments; time permitting

5:15pm

Closing Plenary

Kevin Bugin, PhD

Acting Deputy Director of Operations, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration and formerly Therapeutics Chief of Staff, Federal COVID-19 Response (previously known as Operation Warp Speed)