



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

September 28, 2021

1-5:30pm Eastern

Agenda

1pm	Welcome and Introduction
	<p>Kevin Bugin, PhD, Acting Deputy Director of Operations, Office of New Drugs, Center for Drug Evaluation and Research, FDA; Former Therapeutics Chief of Staff, Federal COVID-19 Response or Countermeasures Acceleration Groups (formerly known as Operation Warp Speed)</p> <p>Susan C. Winckler, RPh, Esq., CEO, Reagan-Udall Foundation for the FDA</p>
1:15pm	Opening Plenary
	<p>Janet Woodcock, MD, Acting Commissioner of Food and Drugs, FDA</p> <p>Francis S. Collins, MD, PhD, Director, National Institutes of Health</p>
1:45pm	Research, Scoping, & Prioritization Panel
	<p>Moderated by</p> <p>Stacey Adam, PhD, Associate Vice President, Research Partnerships, Foundation for the National Institutes of Health</p> <p>Michael Santos, PhD, Vice President, Science, Foundation for the National Institutes of Health</p> <p><i>Panelists:</i></p> <ul style="list-style-type: none"> • Janet Woodcock, MD, Acting Commissioner of Food and Drugs, FDA • Phyllis Arthur, MBA, Vice President, Infectious Diseases & Diagnostics 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
	<p>Moderated by</p> <p>Esther Krofah, Executive Director, FasterCures and Center for Public Health, Milken Institute</p> <p>Kristin Schneeman, Director, FasterCures, Milken Institute</p> <p><i>Panelists:</i></p> <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, Vice President, Science Advocacy, PhRMA • Doug Peddicord, PhD, Executive Director, Association of Clinical Research Organizations
3:45pm	Clinical Trial Execution Panel
	<p>Moderated by</p> <p>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</p> <p>Sarah Sheehan, MPA, Managing Associate, Duke Margolis Center for Health Policy</p>

Panelists:

- Samuel Brown, MD, MS, Attending Physician, Intermountain Medical Center and Assistant Professor of Pulmonary and Critical Care, University of Utah School of Medicine Intermountain
- Janice Chang, Chief Operating Officer, TransCelerate BioPharma Inc.
- 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 in Docket; time permitting

5:15pm

Closing Plenary

Kevin Bugin, PhD, Acting Deputy Director of Operations, Office of New Drugs, Center for Drug Evaluation and Research, FDA; Former Therapeutics Chief of Staff, Federal COVID-19 Response or Countermeasures Acceleration Groups (formerly known as Operation Warp Speed)