

## Achieving Broad Participation in Meaningful Clinical Research at the Point of Care

Public Meeting  
June 14, 2022

**Meeting Objective:** The costs of clinical trials are high and rising, resulting in slow innovation in many areas and limiting the types of sites that can run clinical trials. The Coalition for Advancing Clinical Trials at the Point of Care is convening this meeting to explore the barriers to broader clinical trial participation by clinicians at the point of care as well as new opportunities to overcome these barriers. Enabling more meaningful clinical research at the point of care will help close major gaps in clinical trial evidence generation, improve patient care, and move us towards a learning health system.

**2:00 p.m. Welcome and Overview**

**John Halamka**, Mayo Clinic  
**Trevan Locke**, Duke-Robert J. Margolis, MD, Center for Health Policy

**2:10 p.m. Keynote Discussion**

**Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy  
**Janet Woodcock**, U.S. Food and Drug Administration

**2:35 p.m. Session 1: Why This Matters for Health Systems**

*Objective:* This session will feature representatives from health systems leadership to discuss their interest in generating more practically relevant evidence faster. Panelists will share their experiences working to close evidence gaps and improve care quality.

*Moderator:* **Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy

*Panelists:*

**Kent Thielen**, Mayo Clinic  
**Tom Owens**, Duke Health  
**JP Valin**, Intermountain Healthcare

**3:10 p.m. Session 2: Promising Areas for Progress**

*Objective:* This forward-looking session will provide an overview of two areas of work planned by The Coalition for Advancing Clinical Trials at the Point of Care for 2022 and highlight promising priority disease areas for implementation of point-of-care research.

*Moderator:* **Adrian Hernandez**, Duke Clinical Research Institute

*Panel Discussion:*

**Carrie Wolinetz**, Office of Science and Technology Policy  
**Kimberly Sciarretta**, Biomedical Advanced Research and Development Authority  
**Owen Garrick**, CVS Health  
**David Soergel**, Novartis  
**Samuel Brown**, Intermountain Healthcare



**3:55 p.m.**

### **Session 3: Utilizing Digital Tools to Increase Efficiency**

*Objective:* Panelists in this session will explore how progress can be accelerated in digital tool validation and adoption. Participants will highlight promising existing examples of tools, consider how such tools might be applied to clinical trials across product and disease classes, and discuss opportunities to improve data linkage and data interoperability by leveraging existing standards to collect higher quality data on outcomes for patients.

*Moderator:* **Brian Anderson**, MITRE

*Panelists:*

**John Halamka**, Mayo Clinic

**Sally Okun**, Clinical Trials Transformation Initiative

**Marco Schito**, Critical Path Institute

**Pamela Tenaerts**, Medable

*Discussion and Q&A*

**4:30 p.m.**

### **Session 4: Policy Considerations for Broadening Participation**

*Objective:* Participants in this session will consider regulatory and reimbursement strategies for broadening clinician participation in clinical trials and clinical trial representativeness. Discussion will include approaches for incentivizing patient and provider participation, training requirements, potential liability concerns, areas for better stakeholder coordination, and where funding might be needed for new infrastructure.

*Moderator:* **Rachele Hendricks-Sturup**, Duke-Robert J. Margolis, MD, Center for Health Policy

*Panelists:*

**Daniela Bota**, University of California, Irvine

**Frederick Masoudi**, Ascension Health

**John Concato**, U.S. Food and Drug Administration

**Lee Fleisher**, Center for Medicare and Medicaid Services

*Discussion and Q&A*

**5:10 p.m.**

### **Closing Remarks and Adjournment**

**Mark McClellan**, Duke-Robert J. Margolis, MD, Center for Health Policy