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

Public Meeting
June 14, 2022
Welcome and Overview

John Halamka, Mayo Clinic
Trevan Locke, Duke-Margolis Center for Health Policy
Coalition Members

• Ascension Health
• The Broad Institute
• CURE Drug Repurposing Collaboratory (C-Path + NCATS + FDA)
• CVS Health
• Duke-Margolis Center for Health Policy
• Duke University Health System
• Emory-Morningside Center for Innovative and Affordable Medicine
• Intermountain Healthcare
• Mayo Clinic
• Medable
• MITRE
• University of California, Irvine
• Umass Memorial Health
• Vanderbilt University Medical Center
ACT@POC Objectives

I. Engage clinicians in a broader range of care settings
II. Develop and adopt effective data collection tools
III. Collaborate with experts in trial conduct
IV. Enroll diverse participants in clinical trials
V. Address unmet medical needs
VI. Improve technology supports and capabilities for trial sites in communities
Virtual Meeting Reminders

• Attendees are encouraged to contribute throughout the meeting with questions in the Zoom Q&A function.
• This meeting is being recorded, and the recording and slide deck will be posted on the Duke-Margolis event page in the weeks following the meeting.
Agenda

2:00 pm  Welcome and Overview
2:10 pm  Keynote Discussion
2:35 pm  Session 1: Why This Matters for Health Systems
3:10 pm  Session 2: Promising Areas for Progress
3:55 pm  Session 3: Utilizing Digital Tools to Increase Efficiency
4:30 pm  Session 4: Policy Considerations for Broadening Participation
5:10 pm  Closing Remarks and Adjournment

All times are listed in Eastern Time
Keynote Discussion

Janet Woodcock, U.S. Food & Drug Administration
Mark McClellan, Duke-Margolis Center for Health Policy
Session 1: Why This Matters for Health Systems

2:35 pm – 3:10 pm
Session 1 Panelists

- Kent Thielen, Mayo Clinic
- JP Valin, Intermountain Healthcare
- Tom Owens, Duke University Health System
Session 2: Promising Areas for Progress

3:10 pm – 3:55 pm
Session 2 Panelists

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

*Moderator: Adrian Hernandez, Duke Clinical Research Institute*
Session 3: Utilizing Digital Tools to Increase Efficiency

3:55 pm – 4:30 pm
Digital Tools Across the Clinical Trial Lifecycle

Pre-study Planning
Study set up
Recruitment
Study conduct
Regulatory reporting & approval
Evaluation, Post market surveillance

Cohort selection and recruitment
Data Collection
Data Analysis
Site Activation/Compliance, Regulatory, and Trial Operations
Decentralized/Hybrid Trials

Learning and Feedback
Session 3 Panelists

- John Halamka, Mayo Clinic
- Sally Okun, Clinical Trials Transformation Initiative
- Marco Schito, Critical Path Institute
- Pamela Tenaerts, Medable

Moderator: Brian Anderson, MITRE
Session 4: Policy Considerations for Broadening Participation

4:30 pm – 5:10 pm
Session 4 Panelists

- Daniela Bota, University of California, Irvine
- Frederick Masoudi, Ascension Health
- John Concato, U.S. Food & Drug Administration
- Lee Fleisher, Center for Medicare and Medicaid Services

Moderator: Rachele Hendricks-Sturrup, Duke-Margolis Center for Health Policy
Closing Remarks and Adjournment

Mark McClellan, Duke-Margolis Center for Health Policy
Thank you!

Interested in learning more about ACT@POC? Contact:
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https://actpoc.org/