NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Drug Discovery, Development, and Translation
National Cancer Policy Forum

Toward a Framework to Improve Diversity and Inclusion in Clinical Trials – A Workshop

May 20, 2024, 8:30 am – 5:00 pm (ET)

National Academy of Sciences Building
2101 Constitution Avenue NW Washington, DC 20418

To watch an event livestream, please visit the workshop page here.

PURPOSE

This workshop, convened by the National Academies' Forum on Drug Discovery, Development, and Translation; and National Cancer Policy Forum; will provide a venue for stakeholders to explore opportunities to improve racial and ethnic diversity in clinical trials with a focus on system-level change and collective efforts across organizations and sectors that no one entity can effectively take on alone. This workshop builds upon previous meetings hosted by the Clinical Trials Transformation Initiative (CTTI) in June 2023, the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard (MRCT) in September 2023, and FasterCures, Milken Institute in November 2023.

The public workshop will feature invited presentations and discussions to:

- Explore strategies for equitable participation, including innovative trial designs and partnerships to support community investment, engagement, and workforce development.
- Highlight ways that stakeholders can contribute to sustainable and scalable public awareness campaigns.
- Discuss business plans and funding mechanisms to allocate financial resources to improve clinical trial diversity.
- Consider ways to enable established and developing sites to increase capacity to conduct more equitable and representative clinical trials.
- Examine components of national, interoperable, and accountable systems for collecting and sharing condition-specific demographic data.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

May 20, 2024

8:30 am WELCOME AND OPENING REMARKS

FREDA LEWIS-HALL, *Workshop Chair*
Former Executive Vice President and Chief Medical Officer (Retired)
Pfizer

VICTOR DZAU
President
National Academy of Medicine

8:40 am NATIONAL ACTION PLAN OVERVIEW

BARBARA BIERER
Faculty Director, Multi-Regional Clinical Trials Center
Professor of Medicine
Harvard Medical School and Bringham and Women's Hospital

MORGAN HANGER
Executive Director
Clinical Trials Transformation Initiative

9:00 am PANEL 1: STRATEGIES FOR EQUITABLE PARTICIPATION IN CLINICAL TRIALS

Session Objectives:

- Highlight strategies for equitable participation in clinical trials, including innovative trial designs and methodologies, nontraditional clinical trial sites, and community-based partnerships.
- Discuss collaborative approaches to increase relevance, impact, and ease of enrollment for clinical trial participants, while also minimizing the burden of engagement for those conducting the trials.
- Explore collective approaches to overcome barriers to equitable and representative clinical trial participation.

Panel Discussion with Audience Q&A

Moderator: Martin Mendoza, Centers for Medicare and Medicaid Services

RALPH CAMMACK
Director of Research
Wabanaki Public Health and Wellness

QUITA HIGHSMITH
Vice President and Chief Diversity Officer
Genentech

BRIAN RIVERS
Director, Cancer Health Equity Institute
Morehouse School of Medicine

MATTHEW WATLEY
Senior Pastor
Kingdom Fellowship AME Church

KARRIEM WATSON
Chief Engagement Officer
All of Us Research Program
National Institutes of Health

10:00 am **COFFEE BREAK (15 mins)**

10:15 am FIRESIDE CHAT: CENTERS FOR MEDICARE AND MEDICAID SERVICES

SHARI LING
Deputy Chief Medical Officer
Centers for Medicare and Medicaid Services

ESTHER KROFAH, *Moderator*
Executive Vice President, Health
Milken Institute

11:00 am PANEL 2: DEFINING, COLLECTING, AND SHARING DATA ON TRIAL DIVERSITY

Session Objectives:

- Highlight key components of national, interoperable, and accountable systems for collecting and sharing condition-specific demographic data.
- Explore collaborative approaches to collect and share clinical trial data across organizations and sectors to enable continuous learning and improvement in trial diversity.

Panel Discussion with Audience Q&A

Moderator: Carla Rodriguez-Watson, Reagan-Udall Foundation for the FDA

JAMIE BREWER
Medical Oncologist and Clinical Team Lead
Office of Oncologic Diseases
Food and Drug Administration

U. MICHAEL CURRIE
Healthcare Consultant

STEPHEN KONYA
Senior Advisor to the Deputy National Coordinator
Innovation Portfolio Lead
Office of the National Coordinator for Health Information Technology

SARAH HUDSON SCHOLLE
Principal
Leavitt Partners

VINDELL WASHINGTON
Chief Clinical Officer
Director of Health Equity Center of Excellence
Verily

12:00 pm **LUNCH (45 mins)**

12:45 pm PANEL 3: CLINICAL TRIAL SITE ENABLEMENT

Session Objectives:

- Consider ways to enable established and developing sites – including community-based practices – to increase capacity to conduct more equitable and representative clinical trials.
- Explore business plans and funding mechanisms that promote site enablement and advance equity in clinical trials.
- Discuss cross-sector opportunities for workforce development to support clinical trial site development.

Panel Discussion with Audience Q&A

Moderator: Kathy Mickel, Society for Clinical Research Sites

MEGAN COYLEWRIGHT
Vice Chief of Cardiology
Erlanger Health System

AMY FLOWERS
Director of Policy Research
National Association of Community Health Centers

KRISTEN NWANYANWU
Associate Professor of Ophthalmology and Visual Science
Yale School of Medicine

JONI RUTTER
Director, National Center for Advancing Translational Sciences
National Institutes of Health

CHERYL WILLMAN
Executive Director, Cancer Programs
Director, Mayo Clinic Comprehensive Cancer Center
Mayo Clinic

1:45 pm FIRESIDE CHAT: FOOD AND DRUG ADMINISTRATION & NATIONAL INSTITUTES OF HEALTH

MONICA BERTAGNOLLI
Director
National Institutes of Health

ROBERT CALIFF
Commissioner of Food and Drugs
Food and Drug Administration

NAMANDJÉ BUMPUS
Principal Deputy Commissioner
Food and Drug Administration

FREDA LEWIS-HALL, *Workshop Chair*

2:45 pm COFFEE BREAK (35 mins)

3:20 pm PANEL 4: CHALLENGING THE CLINICAL TRIAL ECOSYSTEM

Session objectives:

- Explore practical and implementable approaches for collaboration across organizations and sectors to advance more equitable and representative participation in clinical trials.
- Consider collective strategies for scaling and sustaining proven approaches for enabling more diverse and inclusive clinical trials.
- Discuss collaborative opportunities for improving public awareness about the risks, benefits, and value of clinical trial participation.

Panel Discussion with Audience Q&A

Moderator: Michelle McMurry-Heath, BioTechquity Clinical

STACEY ADAM
Vice President, Science Partnerships
Foundation for the National Institutes of Health

MARY NWOKEDI-NWANERI
Director, Diversity in Clinical Trials
PhRMA

NATALIA CHALMERS
Chief Dental Officer
Centers for Medicare and Medicaid Services

GWEN DARIEN
Executive Vice President, Patient Advocacy, Engagement, and Education
National Patient Advocate Foundation

DECHANE DORSEY
Executive Director, AdvaMed Accel
AdvaMed

MARY THANH HAI
Deputy Director for Clinical, Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

4:40 pm CLOSING REMARKS

FREDA LEWIS-HALL, *Workshop Chair*

5:00 pm ADJOURN WORKSHOP

RECEPTION TO IMMEDIATELY FOLLOW (90 minutes)