NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Drug Discovery, Development, and Translation
Roundtable on Black Men and Black Women in Science, Engineering, and Medicine

Preparing the Future Workforce in Drug Research & Development – A Workshop

October 16, 2023, 9:00 am – 5:00 pm (ET)

October 17, 2023, 8:30 am – 2:00 pm (ET)

National Academies Building, Room 120
2101 Constitution Avenue NW Washington, DC 20418

To watch a zoom livestream, please visit the workshop page here.

PURPOSE

This workshop, convened by the National Academies' Forum on Drug Discovery, Development, and Translation; and Roundtable on Black Men and Black Women in Science, Engineering, and Medicine; will provide a venue for stakeholders to consider what is needed to support the next generation drug research and development (R&D) workforce – one that is resilient, culturally aware, anti-racist and interdisciplinary. Workshop participants will identify the types of expertise and disciplines needed to achieve the aspirations for a transformed clinical trials enterprise in 2030 and enable a workforce that can better support the evolving needs of drug R&D. There will also be opportunity to explore approaches for engaging and preparing a more person-centered drug R&D workforce.

The public workshop will feature invited presentations and discussions to:

- Examine the current landscape of U.S. academic, government, industry, and professional society training programs for preparing the next generation of drug R&D researchers and clinicians.
- Identify what types of expertise are needed and what disciplines should be included (e.g., nurses, physician assistants, nurse practitioners, pharmacists, genetic counselors, research assistants, data scientists, engineers) to achieve the aspirations for a transformed clinical trials enterprise in 2030 and enable a workforce that can better support the evolving needs of drug R&D.
- Consider approaches for engaging and preparing a more diverse person-centered drug R&D workforce, particularly at the clinician/principal investigator-level.
- Explore ways that stakeholders can better prepare the next generation workforce, including opportunities to develop career paths and incentives for academics, primary care, and community-based practitioners.

DAY 1: MONDAY, OCTOBER 16, 2023

9:00 am WELCOME, OPENING REMARKS, AND OVERVIEW OF ROLES IN DRUG R&D

JONATHAN WATANABE, *Workshop Co-chair*
Professor of Clinical Pharmacy
Director, Center for Data-Driven Drugs Research and Policy
Associate Dean of Assessment and Quality
University of California Irvine School of Pharmacy and Pharmaceutical Sciences

CHERIÉ BUTTS, *Workshop Co-chair*
Medical Director
Therapeutics Development Unit
Biogen

9:30 am SESSION I – FUTURE STATE OF THE CLINICAL TRIALS WORKFORCE

Session Objectives:

- Identify what types of expertise are needed and what disciplines should be included to achieve the aspirations for a transformed clinical trials enterprise in 2030 and enable a more person-centered, culturally aware workforce that can better support the evolving needs of drug R&D.
- Consider key elements/guiding principles for establishing a more self-sustaining and inclusive workforce system.

9:30 am Panel Discussion

Moderator: Cherié Butts, Biogen

AMANDA BRYANT-FRIEDRICH
Dean, Graduate School
Professor of Pharmaceutical Sciences
Wayne State University

SUSAN MONAREZ
Deputy Director
ARPA-H

MURALI ARAVAMUDAN
Chief Executive Officer
nference

JOHN (WIG) WIGNESWARAN
Chief Medical Officer
Walmart

Discussion Questions:

- What types of existing clinical trials training and expertise will become even more critical 10 years from now?
- What new types of clinical trials expertise/disciplines/training will be needed to achieve a 2030 vision of the future?
- What are some key considerations/guiding principles for enabling a more sustainable future clinical trials workforce?

- What are some key considerations/guiding principles for enabling a more inclusive future clinical trials workforce?

10:15 am **Q&A/Audience Discussion**

10:30 am **COFFEE BREAK**

11:00 am SESSION II – CURRENT STATE OF THE CLINICAL TRIALS WORKFORCE

Session Objectives:

- Consider the traditional roles and expertise required at each stage of drug development and how these roles have changed over time.
- Examine the current landscape of U.S. academic, government, industry, and professional society training programs for preparing the next generation of clinical trials researchers and clinicians.
- Consider critical gaps and anticipated needs for the 2030 clinical trials enterprise workforce.

11:00 am **Setting the Stage**

ROBERT WINN
Director
VCU Massey Cancer Center

11:20 am **Panel Discussion**

Moderator: Lamont Terrell, GSK

RAMITA TANDON
Chief Clinical Trials Officer
Walgreens

BLAYNE CUTLER
President and Chief Executive Officer
Heluna Health

LINDA L. DEMER
Executive Co-Director, UCLA STAR
University of California Los Angeles

Discussion Questions:

- What are the traditional roles and expertise required at different stages of drug development, and how have these roles evolved over the last 10 years (e.g., in response to technological advancements and changing priorities)?
- What are the strengths and limitations of current clinical trials training programs – are they equipped to prepare the next generation of researchers and clinicians given the evolving landscape? If not, why not?
- What are the critical gaps in training/expertise and anticipated needs for the 2030 clinical trials enterprise workforce?

12:05 pm **Q&A/Audience Discussion**

12:20 pm **LUNCH BREAK**

1:20 pm SESSION III – OVERCOMING BARRIERS TO PROGRESS

Session Objectives:

- Discuss approaches to remove barriers and achieve a more person-centered, culturally aware drug R&D workforce.
- Share lessons learned based on current efforts and consider what practices/approaches can be more broadly applied.

1:20 pm Setting the Stage

AVERY AUGUST
Professor of Immunology
Deputy Provost
Cornell University

1:35 pm Presentation

TONYA FANCHER
Vice Chair, Workforce Diversity
Associate Dean, Workforce Innovation and Education Quality Improvement
University of California, Davis

1:50 pm Panel Discussion

Moderator: Perdita Taylor-Zapata, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH

NINA SCHOR
Deputy Director for Intramural Research
Office of the Director, NIH

ADRIAN HERNANDEZ
Executive Director
Duke Clinical Research Institute

Discussion Questions:

- What are the main barriers/challenges when it comes to the development of a more person-centered and culturally aware workforce, and how can these barriers be effectively dismantled?
- What practices/approaches have current efforts/programs taken to address these barriers?
- What practices/approaches could be more broadly applied?

2:30 pm Audience Q&A

2:45 pm COFFEE BREAK

3:15 pm SESSION IV – BREAKOUT DISCUSSION: ENVISIONING THE FUTURE LANDSCAPE

Session Objectives:

- Consider practical approaches for engaging and preparing a more diverse person-centered drug R&D workforce, particularly at the clinician/principal investigator-level.
- Explore ways to integrate key elements/guiding principles for establishing a more sustainable and inclusive workforce system.

3:15 pm Breakout Discussion

Breakout Session Topics (Role/Discipline):

- Investigator Physician
- Community Engagement
- Study Coordinator
- Precision Medicine
- AI/Machine Learning

Breakout Questions:

- What is the anticipated capability and capacity for this role/discipline to meet the needs of a 2030 clinical trials enterprise?
- What elements/programs/policies should be put in place to support this career path or area in a way that is more person-centered and inclusive?
- What key elements or guiding principles should be considered to sustainably support/enable this career path or area?
- What are 1-3 short-term (i.e., within the next five years), tangible, and measurable milestones for assessing progress towards that goal?

Breakout Session Leaders

Role: Investigator Physician
KEITH NORRIS
Professor of Medicine
University of California, Los Angeles

DOWIN BOATRIGHT
Vice Chair, Research, Emergency Medicine
NYU Grossman School of Medicine

Discipline: Community Engagement
ARCH MAINOUS
Professor and Vice Chair of Research, Community Health & Family Medicine
University of Florida

DAMANI PIGGOTT
Associate Vice Provost for Graduate Diversity and Partnerships
Associate Professor of Medicine and Epidemiology
Johns Hopkins University

Role: Study Coordinator
BENJAMIN WILFOND
Professor, Divisions of Bioethics & Palliative Care and Pulmonary & Sleep Medicine
Department of Pediatrics, University of Washington School of Medicine

Discipline: Precision Medicine
JONATHAN WATANABE, *Workshop Co-chair*
Professor of Clinical Pharmacy
Director, Center for Data-Driven Drugs Research and Policy
Associate Dean of Assessment and Quality
University of California Irvine School of Pharmacy and Pharmaceutical Sciences

Discipline: AI/Machine Learning
STEPHANIE KRAFT
Assistant Professor of Pediatrics, University of Washington School of Medicine
Director of Research
Treuman Katz Center for Pediatric Bioethics and Palliative Care, Seattle Children's Research Institute

4:15 pm **Full Group Discussion**

JONATHAN WATANABE, *Workshop Co-chair, Moderator*
Professor of Clinical Pharmacy
Director, Center for Data-Driven Drugs Research and Policy
Associate Dean of Assessment and Quality
University of California Irvine School of Pharmacy and Pharmaceutical Sciences

4:50 pm **DAY 1 WRAP UP**

CHERIÉ BUTTS, *Workshop Co-chair*
Medical Director
Therapeutics Development Unit
Biogen

5:00 pm **ADJOURN WORKSHOP DAY 1**

5:00 pm **WORKING RECEPTION**

DAY 2: TUESDAY, OCTOBER 17, 2023

8:30 am SESSION V – SCALING AND SUSTAINABILITY OF WORKFORCE PROGRAMS

Session Objectives:

- Explore ways that stakeholders can better prepare the next generation workforce, including opportunities to develop career paths and incentives for academics, primary care, and community-based practitioners.
- Consider opportunities/policies to accelerate and scale-up efforts to develop and support a more person-centered, culturally aware drug R&D workforce.

8:30 am Fireside Chat

MARIE A. BERNARD
Chief Officer for Scientific Workforce Diversity
Office of the Director, NIH

CHERIÉ BUTTS, *Workshop Co-chair, Moderator*
Medical Director
Therapeutics Development Unit
Biogen

9:00 am Panel Discussion

Moderator: Cherié Butts, Biogen

RDML RICHARDAE ARAOJO
Associate Commissioner for Minority Health
Director of the Office of Minority Health and Health Equity
Officer of the Commissioner, FDA

ANNE GRANGER
Head, Postdoctoral Program
Biomedical Research, Novartis

MARWAN FATHALLAH
President and Global Chief Executive
Drug Information Association, Inc.

BILL LINDSTAEDT
Consultant, STEM PhD Career Development
Co-Investigator, pd|hub Collections, Professional Development Hub
(Retired) Assistant Vice Chancellor for Career Advancement
University of California, San Francisco

Discussion Questions:

- How can academia, industry, and government better collaborate to create clear and attractive career paths for individuals interested in pursuing drug research and development, particularly for those from diverse backgrounds?
- In scaling up efforts, what types of opportunities/policies can accelerate the development and support for a more person-centered, culturally aware drug R&D workforce?

9:30 pm **Audience Q&A**

9:45 am SESSION VI – BREAKOUT DISCUSSION: WHAT NEEDS TO BE DONE AND WHO CAN DO IT?

Session Objectives:

- Consider priority areas to be addressed to support and sustain workforce programs/efforts.
- Consider who would/should benefit from initiatives and future training programs.
- Discuss roles/responsibilities for different stakeholders to support and enable a more person-centered, culturally aware workforce.

9:45 am **Breakout Discussion**

Breakout Session Topics (Stakeholder/Sector):

- Government
- Industry
- Academia
- Non-Profit

Breakout Questions:

- What are the specific roles/responsibilities for this stakeholder/sector to support and enable a more person-centered, culturally aware workforce?
- What are the essential priority areas that should be addressed by this stakeholder/sector to ensure long-term sustainability of workforce programs?
- How can this stakeholder/sector better collaborate with others to achieve these efforts?
- What are some next steps that you and your organization could do towards furthering the points above?

Breakout Session Leaders

Stakeholder/Sector: Government
ANNE ZAJICEK
Program Director, Office of Clinical Research Education and Collaboration Outreach
Office of Intramural Research, NIH

AMIR TAMIZ
Director, Division of Translational Research
National Institute of Neurological Disorders and Stroke, NIH

Stakeholder/Sector: Industry
TYRONE QUARTERMAN
Senior Manager of Health Equity, Diversity, Equity, and Inclusion, University Affairs and Relations
Myriad Genetics

Stakeholder/Sector: Academia – Undergraduate Programs
TRACIE LOCKLEAR
Clinical Research Sciences Program Leader
Research Assistant Professor
North Carolina Central University

Stakeholder/Sector: Academia – Graduate Programs
PRISCILLA PEMU
Professor of Clinical Medicine
Medical Director of the Clinical Research Center
Vice Chair for Research in the Department of Medicine
Morehouse School of Medicine

Stakeholder/Sector: Non-profit
MARY JO LAMBERTI
Research Associate Professor at Tufts University School of Medicine
Director of Sponsored Research
Tufts Center for the Study of Drug Development

HEATHER PIERCE
Senior Director for Science Policy and Regulatory Counsel
Association of American Medical Colleges

10:30 am **COFFEE BREAK**

11:00 am SESSION VII – POLICIES FOR WORKFORCE SUSTAINABILITY AND FUTURE-PROOFING

Session Objectives:

- Explore policies and procedures that could be implemented to ensure a more person-centered, culturally aware drug R&D workforce in 2030.
- Consider guiding principles for different stakeholders to support and enable a more person-centered, culturally aware drug R&D workforce.

11:00 am **Setting the Stage**

ELIZABETH OFILI
Professor of Medicine
Morehouse School of Medicine

11:15 am **Panel Discussion**

Moderator: Lola Fashoyin-Aje, U.S. Food and Drug Administration

CYNTHIA FUHRMANN
Associate Professor, RNA Therapeutics Institute
Associate Professor, Biochemistry & Molecular Biotechnology
University of Massachusetts Chan Medical School

KENNETH MAYNARD
Director, Global Program Team Effectiveness and Global Program Leader Excellence
Takeda

SUSAN LANDIS
Executive Director
Association of Clinical Research Professionals

Discussion Questions:

- What policies and procedures should different stakeholders (government/industry/academia/non-profits) consider to better support sustainable career development programs and continuous training/learning for different roles/disciplines?
- What are some lessons learned/guiding principles that different stakeholders should consider that would support a more person-centered and culturally aware clinical trials workforce?

11:50 am **Audience Q&A**

12:00 pm **WORKING LUNCH (1 hour)**

1:00 pm SESSION VIII – A PATH FORWARD

Session Objectives:

- Consider near-term and longer-term approaches to achieve a more person-centered, culturally aware drug R&D workforce.
- Discuss how success and failure could be measured.
- Consider practical next step opportunities.

1:00 pm **Presentation**

KATHERINE TUTTLE
Executive Director for Research
Providence Health Care

1:10 pm **Panel Discussion**

Moderator: Tammy Collins, Burroughs Wellcome Fund

JULIA TIERNEY
Chief of Staff
Office of the Commissioner, FDA

JOSEPH MENETSKI
Senior Vice President
Foundation for the National Institutes of Health

ANN TAYLOR
Former Chief Medical Officer
AstraZeneca

Discussion Questions:

Based on what you heard today…

- What are 2-3 key considerations/priority goals that should be met over the next 5-10 years to ensure the workforce can meet the needs of the 2030 clinical trials enterprise?
- How can different stakeholders (e.g., government, industry, non-profits) best strike a balance between filling immediate workforce needs and laying the groundwork for workforce development in the long-term?
- What is going well and what needs to change in terms of policy/investment/career development programs?
- What are some practical next steps different stakeholders should take now to support the 2030 workforce (i.e., who needs to do what by when)?

1:40 pm **Audience Q&A**

1:50 pm WRAP UP DISCUSSION AND CLOSING REMARKS

CHERIÉ BUTTS, *Workshop Co-chair*
Medical Director
Therapeutics Development Unit
Biogen

JONATHAN WATANABE, *Workshop Co-chair*
Professor of Clinical Pharmacy
Director, Center for Data-Driven Drugs Research and Policy
Associate Dean of Assessment and Quality
University of California Irvine School of Pharmacy and Pharmaceutical Sciences

2:00 pm **ADJOURN DAY 2**