FDA-University of Maryland CERSI Public Workshop:
ADEPT 9: Enhancing Diversity in Therapeutics Development for Pediatric Patients
Friday, September 6, 2024 (9:00 AM-5:00 PM)

Welcome & Introduction

9:00 AM – 9:05 AM **Welcome and Overview**
Lily Mulugeta
Associate Director, Division of Pediatrics and Maternal Health (DPMH)
US Food and Drug Administration (FDA)

9:05 AM – 9:10 AM **Introductory Remarks**
Hilary Marston
Chief Medical Officer
US FDA

9:10 AM – 9:25 AM **Opening Presentation**
Mathilda Fienkeng
Director of Division of Medical Policy Development, Office of Medical Policy
US FDA

9:25 AM – 9:40 AM **Keynote Talk**
Michelle and Michael Burgess
International Children's Advisory Network" (iCAN) Patient/Parent

Session 1: Current Status of Pediatric Trial Participation and Lessons Learned

9:40 AM – 10:00 AM **FDA Perspective**
Christine Lee
Acting Associate Commissioner and Director
Office of Minority Health and Health Equity (OMHHE), US FDA

10:00 AM – 10:20 AM **Diversity in Pediatric Research: Academic Perspective**
Sue Rahman
Chief Scientific Officer
Health Data Synthesis Institute

10:20 AM – 10:30 AM **BREAK**

10:30 AM – 10:50 AM **Landscape of Industry Sponsored Pediatric Trials**
Pam Simpkins
Managing Partner, Mezzopointe, LLC

10:50 AM – 11:30 AM **Panel Discussion**

Moderators:

Dionna Green
Director, Office of Pediatric Therapeutics, US FDA

Lois K Lee
Senior Associate in Pediatrics, Division of Emergency Medicine
Boston Children's Hospital

Panelists:

Sneha Dave
Executive Director, Generation Patient

Florence Bourgeois
Associate Professor, Pediatrics, Harvard Medical School

Ann McMahon
Regulatory Scientist, Office of Pediatric Therapeutics, US FDA

Pam Simpkins
Managing Partner, Mezzopointe, LLC

Sue Rahman
Chief Scientific Officer, Health Data Synthesis Institute

Christine Lee
Acting Associate Commissioner and Director, OMHHE, US FDA

11:30 AM – 12:30 PM **LUNCH**

Session 2: Inclusion Strategies

12:30 PM – 1:05 PM **Inclusive Trial Designs and Methodological Considerations (Case Examples)**

Recruitment and Retention/Decentralized Trials
Rachel Randell
Assistant Professor of Pediatrics
Duke University and Duke Clinical Research Institute (DCRI)

Addressing Diversity in Clinical Trials and Diversity Plans
Ted Love
Chair of Board of Directors, Biotechnology Innovation Organization

Bella Oguno
Vice President, Development Operations, Nuvig Therapeutics

1:05 PM – 1:20 PM **Diversity in Pediatric Type 2 Diabetes Trials**
Lauren Wood Heickman
Clinical Reviewer

Division of Diabetes, Lipid Disorders, and Obesity (DDLO), US FDA

1:20 PM – 2:00 PM **Panel Discussion**

Moderators:

Lily Mulugeta
Associate Director, DPMH US FDA

Sue Rahman
Chief Scientific Officer, Health Data Synthesis Institute

Panelists:

Anvita Ambardekar
High School Student, Pediatric Perspective iCAN

Lauren Wood Heickman
Clinical Reviewer, DDLO US FDA

Martha Donoghue
Acting Associate Director, Pediatric Oncology, Office of Oncologic Diseases, US FDA

LaShell Robinson
Head of Diversity, Equity & Inclusion, Clinical Research Department, Takeda

Ki Lee Milligan
Executive Director, Pediatric Center for Excellence, Global Drug Development, Novartis

Ted Love (Virtual)
Chair of Board of Directors, Biotechnology Innovation Organization

Stephen Balevic (Virtual)
Associate Professor of Medicine and Pediatrics, Duke University and DCRI

Rachel Randell
Assistant Professor of Pediatrics, Duke University and DCRI

Christina Edwards
Director of Clinical Trials, National Minority Quality Forum

2:00 PM – 2:15 PM **BREAK**

2:15 PM – 3:00 PM **Panel Discussion: Community Engagement and Trust Building**

Moderator:

Carla Epps
Senior Physician, DPMH US FDA

Panelists:

Billie Jo Kipp
Clinical Psychologist, Indigenous Innovators Collaborative

Nasrin Sari
Patient/Community Representative

Sneha Dave
Executive Director, Generation Patient

LaToya Williams
Community Clinical Director, Inside Edge Consulting Group

Anvita Ambardekar
High School Student, Pediatric Perspective iCAN

3:00 PM – 3:45 PM **Best Practices That Help Children and Families to Stay in Clinical Trials**

Tamorah Lewis
Sellers Chair, Pharmacology and Pharmacogenetics
Division Head, Clinical Pharmacology & Toxicology
Staff Neonatologist, The Hospital for SickKids

Christina Edwards
Director of Clinical Trials, National Minority Quality Forum

Puja Umaretiya
Assistant Professor, Division of Pediatric Hematology/Oncology
UT Southwestern, Children's Medical Center

3:45 PM – 4:55 PM **Panel Discussion**

Moderators:
Carla Epps
Senior Physician, DPMH US FDA

Billie Jo Kipp
Clinical Psychologist, Indigenous Innovators Collaborative

Panelists:
Lynne Yao
Director, DPMH US FDA

Tamorah Lewis
The Hospital for SickKids

LaToya Williams
Community Clinical Director, Inside Edge Consulting Group

Florence Bourgeois
Associate Professor, Pediatrics, Harvard Medical School

Bella Oguno
Vice President, Development Operations, Nuvig Therapeutics

	Melissa Penn *Director of Patient Engagement R&D, Bayer Pharmaceuticals*
	Michelle/Michael Burgess *iCAN Patient/Family Representative*
	Nasrin Sari *Patient/Community Representative*
	Puja Umaretiya *Assistant Professor, UT Southwestern, Children's Medical Center*
	Christina Edwards *Director of Clinical Trials, National Minority Quality Forum*
4:55 PM – 5:00 PM	**Closing Remarks** *Lynne Yao* *Director, DPMH US FDA*