

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

Welcome & Introduction

9:00 AM – 9:05 AM	Welcome and Overview <i>Lily Mulugeta (FDA)</i>
9:05 AM – 9:10 AM	Introductory remarks <i>Hilary Marston, Chief Medical Officer, FDA</i>
9:10 AM – 9:25 AM	Opening Presentation <i>Mathilda Fienkeng (FDA)</i>
9:25 AM – 9:40 AM	Keynote talk <i>TBD</i>

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

9:40 AM – 10:00 AM	FDA Perspective <i>Christine Lee (OMHHE, FDA)</i>
10:00 AM – 10:20 AM	Diversity in Pediatric Research: Academic Perspective <i>Sue Rahman (Health Data Synthesis)</i>
10:20 AM – 10:30 AM	BREAK
10:30 AM – 10:50 AM	Landscape of Industry Sponsored Pediatric Trials <i>Pam Simpkins (Mezzopointe)</i>
10: 50 AM – 11:30 AM	Panel Discussion <i>Moderators: Dionna Green (FDA)/Lois Lee (Boston Children's Hospital)</i> <i>Panelists: Patient representative, Florence Bourgeois (Boston Children's Hospital, Ann McMahon (FDA), Pam Simpkins, Sue Rahman, Christine Lee</i>
11:30 AM – 12:30 PM	LUNCH

Session 2: Strategies for Inclusion

12:30 PM – 1:05 PM	Inclusive Trial Designs and Methodological Considerations (Case Examples) Recruitment and Retention/Decentralized Trials-15min
--------------------	---

Stephen Balevic (Duke Pediatric Trials Network)

Addressing Diversity in Clinical Trials and Diversity Plans-20min

Ted Love (BIO)

1:05 PM – 1:20 PM

Data interpretation/Extrapolation of adult data for efficacy/safety findings

TBD

1:20 PM – 2:00 PM

Panel Discussion

Moderators: *Lily Mulugeta/TBD*

Panelists: *Patient representative , Ki Lee Milligan (Novartis), Ted Love, Stephen Balevic, Christina Edwards*

2:00 PM – 2:15 PM

BREAK

2:15 PM – 3:00 PM

Panel Discussion: Community Engagement and Trust Building (virtual option)

TBD

TBD

TBD

LaToya Williams

3:00 PM – 3:45 PM

Best practices that help children and families to stay in clinical trials (3 speakers)

Tamora Lewis (SickKids)-15min

Puja Umaretiya (UT Southwestern)-15min

Christina Edwards (National Minority Quality Forum)-15min

3:45 PM – 4:55 PM

Panel Discussion

Moderator: *Carla Epps (FDA)/Industry*

Panelists:

- *Lynne Yao, FDA*
- *Tamora Lewis*
- *Christina Edwards*
- *Puja Umaretiya*
- *Patient Representative*
- *Florence Bourgeois*
- *TBD*

4:55 PM – 5:00 PM

Closing Remarks

Lynne Yao, FDA