U.S. FOOD & DRUG ADMINISTRATION

PEDIATRIC CLINICAL INVESTIGATOR TRAINING WORKSHOP

FDA White Oak Campus
Great Room, Bldg. 31
10903 New Hampshire Avenue
Silver Spring, MD 20993
February 28, 2019

AGENDA		
8:00 – 8:10	Welcome and Introduction	Susan McCune, MD
8:10 – 8:20	Keynote Speaker/Setting the Stage	Bridgette Jones, MD American Academy of Pediatrics (AAP)
8:20 – 8:40	Label Enabling Clinical Trials	William Smoyer, MD NationWide Children's
8:40 – 9:40	HOT TOPICS	
	Extrapolation and Innovative Trial Designs	Yodit Belew, MD (Division of Antiviral Products, FDA)
	Molecular Targets – Oncology	Greg Reaman, MD (Office of Oncology Products, FDA)
	Enrolling Pediatric Patients in Adult Trials	Tara Altepeter, MD (Division of Gastroenterology and Inborn Error Products, FDA)
9:40 – 9:55	BREAK	
9:55– 12:05	THE BASICS (New Investigators)	
	Opening an IND (10min)	Michael Cohen-Wolkowiez, MD (Pediatric Trials Network)
	FDA Perspective of Study Design and Plan, Dose selection (20min)	John Alexander, MD (Division of Pediatric and Maternal Health, FDA)
	Ethical Considerations (10 min)	Melanie Bhatnagar, MD (FDA)
	Pediatric Formulations (15 min)	Julia Pinto, PhD (FDA)

	Non-clinical Data Requirements (15min)	Karen Davis-Bruno, PhD (FDA)
	Good Clinical Practice and Understanding the Regulations (15min)	Susan Leibenhaut, MD (FDA)
	Safety Considerations: Regulatory Definitions and Practical Considerations (15min) Discussion/Case Presentation (30 min)	Ramy Abdelrahman, MD (FDA) Michael Cohen, MD (Pediatric Trials Network) Jonathan Davis, MD (Tufts Medical Center)
12:05 – 1:00	LUNCH	
1:00- 2:00	Pediatric Trial Funding and Engagement Panel Discussion: Rohan Hazra, MD (NIH/NICHD) Jonathan Davis, MD, (Clinical and Translational Science Awards) Michael Cohen-Wolkowiez, MD (Duke University) Ed Connor, MD (Institute for Advance Clinical Trials for Children) Bridgette Jones, MD (AAP) Steven Hirschfeld, MD., Ph.D (NIH/NIDCD)	
2:00 – 3:30	Practical Applications with Case Studies (in person)	Lynne Yao, MD (Moderator) Table moderators: Susan McCune, MD Lily Mulugeta, PharmD Kevin Krudys, PhD Shirley Seo, PhD Yodit Belew, PhD Tara Altepeter, MD
3:30 – 3:45	BREAK	
3:45 – 4:30	General Questions and Answers	Full Panel with Lynne Yao (Moderator)