FDA-University of Maryland CERSI Public Workshop:
Accelerating Product Development for Pediatric Systemic Lupus Erythematosus (SLE)

July 30 & 31, 2026

Great Room, FDA White Oak Campus

Silver Spring, MD

Background:

Systemic lupus erythematosus (SLE) is a chronic, multisystem autoimmune disease characterized by inflammation, autoantibody production, and alternating periods of disease flares and remission. Approximately 10–20% of cases have onset during childhood. Currently, only one biologic therapy is approved for pediatric SLE, leaving a substantial unmet need for additional safe and effective treatment options.

Conducting clinical trials in pediatric SLE presents several challenges, including a small patient population, limited specialized centers, and difficulties with recruitment and retention. In addition, there is a need to evaluate how existing data, often from adult SLE studies, may be appropriately extrapolated to pediatric populations to streamline drug development and reduce the burden of clinical research in pediatric patients with SLE to ensure timely availability of safe and effective therapies in this population.

Welcome & Introduction

9:00 AM – 9:05 AM	**Welcome and Overview Scope of Workshop**	
	Lily Mulugeta, PharmD	**Associate Director, DPMH, CDER, FDA**
9:05 AM – 9:15 AM	**Introductory Remarks**	
	Mary Tran Thanh Hai, MD	**Office Director, OND, CDER, FDA**
9:15 AM – 9:30 AM	**Keynote Talk**	
	Mckenna Bowes, BS	**Patient Perspective**
9:30 AM – 9:45 AM	**Regulatory Framework for Drug Development and Pediatric Extrapolation**	
	Lily Mulugeta, PharmD	**Associate Director, DPMH, CDER, FDA**
9:45 AM – 10:15 AM	**Landscape of Pediatric SLE Drug Development: Regulatory Perspective**	
	Emily C. Gotschlich, MD	**Clinical Reviewer, DRTM, CDER, FDA**
	Roberto De Lisa, MD, MSc	**Clinical Pharmacologist; Scientific Officer at European Medicines Agency (EMA)-Paediatric Medicines**

Session 1: Evaluation of Disease in Adult and Pediatric SLE

10:15 AM – 10:45 AM	**Pediatric SLE Presentation and Relationship to Adult SLE: Clinical and Pathophysiological Considerations**	
	Stephen Balevic, MD, PhD, MHS	**Associate Professor, Departments of Medicine and Pediatrics, Duke University**
	Rebecca Sadun, MD, PhD	**Associate Professor, Departments of Medicine and Pediatrics, Duke University**
	Stacy Ardoin, MD	**Professor, Pediatric and Adult Rheumatology, Nationwide Children's Hospital, The Ohio State University College of Medicine**
10:45 AM – 11:00 AM	**BREAK**	
11:00 AM – 11:15 AM	**Treatment Paradigm, Landscape of Products Used, and Unmet Needs in Pediatric SLE**	
	Ekemini A. Ogbu MD, MSc	**Associate Professor of Pediatrics, University of Cincinnati, Director, Neuroinflammatory Disease Services in Rheumatology; Co-director, Cincinnati Children's Lupus Center; Cincinnati Children's Hospital Medical Center**
11:15 AM – 12:00 PM	**Panel Discussion**	
Moderator:	**Suzette Peng, MD**	**Medical Reviewer, DRTM, CDER, FDA**
Panelists:	**Tresa Ambooken, MD**	**Medical Officer (Clinical Reviewer), FDA**
	Rebecca Sadun, MD, PhD	**Associate Professor, Departments of Medicine and Pediatrics, Duke University**
	Stacy Ardoin, MD	**Professor, Pediatric and Adult Rheumatology, Nationwide Children's Hospital, The Ohio State University College of Medicine**
	Ekemini A. Ogbu MD, MSc	**Associate Professor of Pediatrics, University of Cincinnati, Director, Neuroinflammatory Disease Services in Rheumatology; Co-director, Cincinnati Children's Lupus Center; Cincinnati Children's Hospital Medical Center**

	Alvina Chu, MD	Head of Mid-Stage Programs; Immunology Clinical Development, AbbVie
	Reshma Patel, MD	Global Associate Medical Director, Lupus, Biogen
	Miah Andrade	Patient/Family Representative
	Elizabeth SantaCruz, BS	Patient/Family Representative

12:00 PM – 1:00 PM **LUNCH**

Session 2: Evaluation of Dose Selection and Response in Adult and Pediatric SLE

1:00 PM – 1:15 PM **Response Similarity Between Adult and Pediatric SLE: Lessons Learned from Belimumab**

Tao Liu, PhD	Team Leader, Division of Inflammation and Immune Pharmacology, Office of Clinical Pharmacology, FDA
Satyajit Ghosh, PhD	Mathematical Statistician, DB II, OB, CDER, FDA

1:15 PM – 1:30 PM **Similarities and Differences of Response and Exposure-Response**

Stephen Balevic, MD, PhD, MHS	Associate Professor, Departments of Medicine and Pediatrics, Duke University

1:30 PM – 1:45 PM **Role of MIDD to Accelerate Dose Selection and Optimization**

Vikram Sinha, PhD	Senior Vice President, Translational and Quantitative Medicine, Flagship Pioneering

1:45 PM – 2:30 PM **Panel Discussion**

Moderator:	Lily Mulugeta, PharmD	Associate Director, DPMH, CDER, FDA
Panelists:	Jianmeng Chen, MD, PhD	Associate Director, Division of Inflammation and Immune Pharmacology Clinical Pharmacology, Office of Clinical Pharmacology, FDA
	James Travis, PhD	Master Statistician, Office of Biostatistics, FDA
	Amit Golding, MD, PhD	Lead Physician, DRTM, CDER, FDA
	Flora Musuamba Tshinanu, PhD	Pharmacometrics and Pharmacovigilance Internal Expert, Belgian Federal Medicines Agency (FAMHP), European Medicines Agency (EMA)
	Stephen Balevic, MD, PhD, MHS	Associate Professor, Departments of Medicine and Pediatrics, Duke University
	Vikram Sinha, PhD	Senior Vice President, Translational and Quantitative Medicine, Flagship Pioneering
	Laura E. Schanberg, MD	Professor, Pediatrics, Duke Clinical Research Institute, Duke University School of Medicine
	Mckenna Bowes, BS	Patient Perspective

2:30 PM – 2:45 PM **BREAK**

Session 3: Extrapolation of Efficacy

2:45 PM – 3:15 PM **Lessons Learned from Conducting Clinical Trials in Pediatric SLE**

Hermine I. Brunner, MD, MSc, MBA	Professor of Pediatrics University of Cincinnati; Director, Division of Rheumatology at Cincinnati Children's Hospital
Sule Yavuz, MD	Global Clinical Program Lead, AstraZeneca

3:15 PM – 3:35 PM **Patient/Family Panel: Risk Tolerance and Enrollment in Clinical Trials**

Moderator:	Stacy Ardoin, MD	Professor, Pediatric and Adult Rheumatology, Nationwide Children's Hospital, The Ohio State University College of Medicine

	Panelists:	Mckenna Bowes, BS	Patient Representative
		Chloe Raymond	Patient Representative
		Nia Cooper	Patient Representative
		Miah Andrade	Patient/Family Representative
		Elizabeth SantaCruz BS	Patient/Family Representative
3:35 PM – 3:50 PM	**Extrapolation of Efficacy from Adults: Gaps in Knowledge and Remaining Uncertainties**		
		Rebecca Sadun, MD, PhD	Associate Professor, Departments of Medicine and Pediatrics, Duke University
3:50 PM – 4:30 PM	**Panel Discussion and Q/A**		
	Moderators:	Laura E. Schanberg, MD	Professor, Pediatrics, Duke Clinical Research Institute, Duke University School of Medicine
		Lily Mulugeta, PharmD	Associate Director, DPMH, CDER, FDA
	Panelists:	Raj Nair, MD	Division Director, DRTM, CDER, FDA
		Caroline Benichou-Auriche, MD	EMA-Senior Clinical Expert, Icelandic Medicines Agency-Lyfjastofnun
		Rebecca Sadun, MD, PhD	Associate Professor, Medicine, Pediatrics, Dept of Medicine, Duke University School of Medicine
		Hermine I. Brunner, MD, MSc, MBA	Professor of Pediatrics University of Cincinnati; Director, Division of Rheumatology at Cincinnati Children's Hospital
		Richard Dimelow, PhD	Director, Clinical Pharmacology at GSK, GlaxoSmithKline
		Jordan Roberts, MD, MPH	Global Development Medical Associate Director, AstraZeneca
		Sule Yavuz, MD	Global Clinical Program Lead, AstraZeneca
		Chloe Raymond	Patient Representative
4:30 PM – 4:40 PM	**Closing Remarks**		
		Suzette Peng, MD	Acting Clinical Team Leader, DRTM, CDER, FDA

Day 2 of Workshop

Session 4: Trial Design Considerations (Efficacy & Safety)

9:00 AM – 9:10 AM	**Opening Remarks**		
		Lily Mulugeta, PharmD	Associate Director, DPMH, CDER, FDA
9:10 AM – 9:25 AM	**Safety Assessment in Pediatric SLE—Challenges and Opportunities**		
		Mary Beth Son, MD	Associate Professor, Clinical Chief, Division of Immunology Section Chief, Rheumatology Program, Boston Children's Hospital, Harvard Medical School
9:25 AM – 9:40 AM	**Safety Assessment and Extrapolation in Pediatric SLE—Challenges and Opportunities**		
		Laurie Conklin, MD	Director, Child Health Innovation and Leadership Department, Johnson & Johnson
9:40 AM – 10:15 AM	**Alternative Approaches/Trial Design Considerations**		
		Hermine I. Brunner, MD, MSc, MBA	Professor of Pediatrics University of Cincinnati; Director, Division of Rheumatology at Cincinnati Children's Hospital
		Martine Dehlinger-Kremer, PhD, MS	Senior Development Strategy Lead Pediatrics, Special Patient Populations, UCB Biosciences
10:15 AM – 10:30 AM	**BREAK**		

10:30 AM—12:15 PM	**Panel Discussion and Q/A (Future direction)**		
Moderator:	**Raj Nair, MD**	**Division Director, DRTM, CDER, FDA**
Panelists:	**Lynne Yao, MD**	**Division Director, DPMH, CDER, FDA**
	Stacy Ardoin, MD	**Professor, Pediatric and Adult Rheumatology, Nationwide Children's Hospital, The Ohio State University College of Medicine**
	Hermine I. Brunner, MD, MSc, MBA	**Professor of Pediatrics University of Cincinnati; Director, Division of Rheumatology at Cincinnati Children's Hospital**
	Stephen Balevic, MD, PhD, MHS	**Associate Professor, Departments of Medicine and Pediatrics, Duke University**
	Sarah Ringold, MD, MS	**Medical Director, Pediatric Development Team, Immunology, Johnson & Johnson**
	Kalyanee Appanna, PhD	**Vice President, Global Head of Biostatistics, EMD Serono**
	Jordan Roberts, MD, MPH	**Global Development Medical Associate Director, AstraZeneca**
	Caroline Benichou-Auriche, MD	**EMA-Senior Clinical Expert, Icelandic Medicines Agency-Lyfjastofnun**
	Nia Cooper	**Patient Representative**
12:15 PM – 12:30 PM	**Closing Remarks**	
	Raj Nair, MD	**Division Director, DRTM, CDER, FDA**