CERSI
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Accelerating Product Development for Pediatric Systemic Lupus Erythematosus (SLE)

University of Maryland Center of Excellence in Regulatory Science and Innovation
Food and Drug Administration

Public In-Person/Virtual Workshop
July 30, 2026 | 9:00 AM – 4:40 PM Eastern Time
July 31, 2026 | 9:00 AM – 12:30 PM Eastern Time

Biographies

Tresa Ambooken, MD, MBA
Medical Officer
Division of Rheumatology and Transplant Medicine, FDA

Dr. Tresa Ambooken is a Medical Officer in the Division of Rheumatology and Transplant Medicine at the Food and Drug Administration (FDA), where she has been serving as a clinical reviewer since 2024. She attended St. George's University School of Medicine, where she obtained her MD and MBA degree. Following this, she completed Pediatric Residency Training at BronxCare Health System in Bronx, NY and then went on to complete Pediatric Rheumatology Fellowship at Hackensack University Medical Center, where research interests included autoinflammatory disease and development of novel biomarkers, juvenile dermatomyositis, as well as medical education.

Miah Andrade
Lupus Patient Representative and Advocate
Lupus and Allied Diseases Association (LADA)

Ms. Miah Andrade is a nationally recognized pediatric lupus advocate and ambassador for the lupus community. Diagnosed with lupus at age nine, Miah transformed her personal journey into a powerful platform for advocacy, awareness, and education. Through her work with LupusChat, the Lupus and Allied Diseases Association (LADA), and the Lupus Research Alliance (LRA), she has shared the patient perspective with researchers, healthcare professionals, policymakers, and fellow families affected by lupus. Through opportunities made possible by Lupus and Allied Diseases Association (LADA), Miah made history at the American College of Rheumatology (ACR) Convergence as the first pediatric patient presenter, where she served as a panelist for a session on cultural humility in pediatric rheumatology. Her groundbreaking participation was featured by *The Rheumatologist*, highlighting her efforts to improve healthcare equity and amplify the voices of young patients living with rheumatic diseases.

A passionate advocate for lupus awareness and research, Miah has spoken with legislators on Capitol Hill, participated in Patient-Focused Drug Development initiatives, helped promote Lupus Awareness Month proclamations in New York, New Jersey and her hometown of Kearny, and contributed to fundraising efforts supporting lupus research. Alongside her mother, Elizabeth SantaCruz, she has helped raise thousands of dollars through lupus walks and awareness campaigns while educating communities through school presentations, media interviews, and social media outreach. Recognized for her academic achievements, resilience, and commitment to service, Miah continues to inspire others by ensuring that the voices of children and young adults living with lupus are heard, respected, and included in shaping the future of lupus care and research.

Stacy Ardoin, MD, MSc
Professor, Chief of Division of Rheumatology
Nationwide Children's Hospital/Ohio State University

Dr. Stacy Ardoin is a pediatric and adult rheumatologist Professor and Division Chief of Pediatric Rheumatology at Nationwide Children's Hospital and Ohio State University.

She completed medical school and internal medicine and pediatrics residency at Ohio State University followed by a combined adult and pediatric rheumatology fellowship at Duke University.

Dr. Ardoin's clinical and scholarly work focuses on improving outcomes in systemic lupus erythematosus with particular with emphasis on real-world evidence, quality improvement, comparative effectiveness, and the development of consensus treatment plans through large collaborative networks. She has authored numerous peer-reviewed publications and has had leadership roles in several multicenter studies in pediatric rheumatology. She is the immediate Past President of the Childhood Arthritis and Rheumatology Research Alliance.

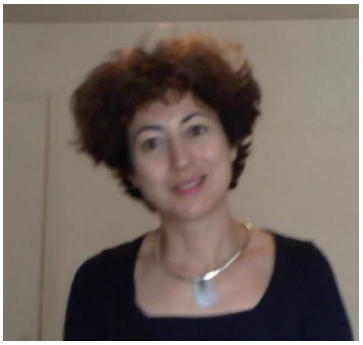
In addition to her research, Dr. Ardoin is deeply committed to mentorship and workforce development, actively training fellows and early-career investigators and contributing to national education initiatives through organizations such as the American College of Rheumatology.

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

Dr. Stephen Balevic is an Adult and Pediatric Rheumatologist at Duke University and Director of Pharmacometrics and Fit-for-Purpose Trials at the Duke Clinical Research Institute. He completed his PhD in Pharmaceutical Sciences from the UNC Eshelman School of Pharmacy. He maintains an active clinical practice, seeing both children and adults with SLE and other rheumatic diseases.

Dr. Balevic's research career focuses on conducting clinical trials and determining optimal medication dosing in children and other understudied populations. He has been active in several drug development programs and advancing regulatory science, including leading the first systematic comparison of the response to treatment between children and adults with SLE.

Caroline Benichou-Auriche, MD
Senior Clinical Expert
Icelandic Medicines Agency- Lyfjastofnun
EMA



Dr. Caroline Auriche is by training a Pharmacist and a Biologist, with a recent Master 2 in gene and cell therapy and immunotherapy.

Caroline has an over 30-year experience in clinical assessment of drugs in the French then the Icelandic Medicines Agency, and an over 16-year experience as member of the Scientific Advice Working Party at the European Medicines Agency (EMA), that delivers to Applicants regulatory scientific advice on schemes and details of their drugs development, with a focus on rare genetic diseases and autoimmune diseases. She is also assessing requests for Priority Medicines (PRIME) designation for acceleration of innovative medicines development and regulatory assessment at EMA.

She is since 2023 the Chairperson of the Immunology-Inflammatory Working Party in charge of the drafting of European clinical development Guidelines in the field at the EMA.

Mckenna M. Bowes, BS
Lupus Patient Representative and Advocate
Childhood Arthritis and Rheumatology Research Alliance (CARRA)

Medical Student
West Virginia University School of Medicine

Ms. Mckenna M. Bowes was diagnosed with systemic lupus erythematosus (SLE) in 2019 at age 16. Her experience as a pediatric patient sparked a passion for patient advocacy, research, and improving healthcare for individuals with autoimmune diseases. In 2021, she started at the University of Pittsburgh, where she began conducting research in Dr. Amr Sawalha's laboratory, studying the genetics, epigenetics, and molecular biology of autoimmune diseases, primarily lupus. Her experience as a student researcher further strengthened her interest in rheumatology and patient advocacy. Since 2022, she has also been actively involved with the Childhood Arthritis and Rheumatology Research Alliance (CARRA), contributing to workgroups, research initiatives, grant review, attending conferences, and engaging in patient-centered discussions with researchers, clinicians, and industry partners. Through these experiences, she has developed a strong commitment to advancing patient-centered care and amplifying patient voices, especially those of pediatric patients, in research.

Mckenna is currently a second-year medical student at the West Virginia University School of Medicine. She values the opportunity to integrate her perspectives as a patient, advocate, researcher, and future physician to help improve healthcare outcomes and patient experiences.

Hermine I. Brunner, MD, MSc, MBA
Professor, Pediatrics
Division Director, Rheumatology
Director, Cincinnati Children's Lupus Center
Cincinnati Children's Hospital Medical Center

Dr. Hermine I. Brunner is a pediatric rheumatologist whose career has been defined by advancing clinical trials and translational research in childhood-onset systemic lupus erythematosus (cSLE). As Professor of Pediatrics, Division Director of Rheumatology, and Director of the Cincinnati Children's Lupus Center, she has led or co-led numerous multicenter, international trials that transformed the evidence base for pediatric lupus therapy. Dr. Brunner has served as principal investigator or steering committee member for pivotal trials of biologic and targeted therapies in cSLE and lupus nephritis, including belimumab (IV and SC), anifrolumab, JAK inhibitors, and emerging cell-based approaches.

A central theme of her research is improving trial readiness through validated outcome measures and biomarkers. She is the developer and global validator of the Renal Activity Index for Lupus (RAIL) and has led NIH-funded programs establishing biomarker-driven endpoints and precision dosing strategies for lupus nephritis. Dr. Brunner has led or co-led international consensus criteria, remission definitions, and other initiatives to accelerate pediatric lupus drug development. With more than 400 peer-reviewed publications and sustained NIH funding, Dr. Brunner's work continues to work with academic and industry partners on clinical trial design, regulatory science, and patient-centered care for children and adolescents cSLE.

Jianmeng Chen, MD, PhD
Associate Director for Therapeutic Review
DIIP, OCP, OTS, CDER, FDA

Dr. Jianmeng Chen got her MD degree in Peking Union Medical College, and PhD degree in pharmacology in Johns Hopkins University, school of medicine. Following that, she did the postdoc training in the Division of clinical pharmacology in Johns Hopkins. She was board certified in clinical pharmacology in 2009. Jianmeng joined Office of Clinical Pharmacology (OCP) in 2012, and she is currently Associate Director for Therapeutic Review in Division of Inflammation and Immune Pharmacology (DIIP) in OCP.

Alvina Chu, MD
Head of Mid-stage Programs, Immunology Clinical Development
AbbVie

Dr. Alvina Chu is a practicing rheumatologist who leads clinical programs in mid-stage development at AbbVie. She holds a longstanding commitment to basic, translational, and clinical research in lupus and participates as an Executive Committee member in the Lupus Accelerating Breakthroughs Consortium (Lupus ABC) public-private partnership. At AbbVie, she continues to oversee the clinical development of investigational treatments for patients with lupus. Dr. Chu holds a Bachelor of Science degree from Stanford University and a Doctor of Medicine degree from the University at Buffalo School of Medicine. She completed an internal medicine residency at the University of Chicago Hospitals and a rheumatology fellowship at Stanford University Medical Center, where she holds a clinical adjunct faculty position for teaching and patient care.

Laurie Conklin, MD
Director, Child Health Innovation and Leadership Department
Johnson & Johnson Innovative Medicine

Dr. Laurie Conklin works within the Office of the Chief Medical Officer at Johnson & Johnson Innovative Medicine, where she is a leader in pediatric strategy. Previously, Dr. Conklin worked with ReveraGen BioPharma developing Agamree® for pediatric Duchenne muscular dystrophy. Dr. Conklin is a pediatric gastroenterologist and served as director of the IBD Program at Children's National Hospital, as well as a Medical Officer in Pediatrics/Maternal Health at the FDA. After completing a Pediatrics residency and Chief Residency at New York Presbyterian-Weill Cornell Medical Center, Dr. Conklin completed a fellowship at Johns Hopkins and earned a graduate certificate in Clinical/Translational Science at GWU.

Nia Cooper
Lupus Patient Representative and Advocate
Junior, Towson University

Ms. Nia Cooper is a rising junior at Towson University majoring in healthcare management and minoring in business administration. Her inspiration for choosing this career path came from her journey living with lupus since 2022. She is motivated to impact patient care and improve community health outcomes, especially children living with lupus, through optimizing healthcare efficiencies.

Nia traveled an all too familiar diagnostic journey of multiple doctor appointments without answers. She was living in immense pain which made things like walking, making a fist, climbing stairs, and dressing herself nearly impossible. With no definitive answer from traditional providers, her family lost trust in the traditional healthcare system and decided to go the holistic route. Unfortunately, her condition worsened which led to a hospital admission, a discovery of a pleural effusion, and finally a lupus diagnosis.

Today, Nia's lupus is well controlled with her medications. She is passionate about speaking on behalf of children with lupus to accelerate safe treatment options and increase transparency to foster trust for this great unmet need. Her ultimate goal is to use her own journey as a driver to make a change through increasing the treatment options that are available to children.

Martine Dehlinger-Kremer, PhD, MS
Senior Development Strategy Lead Pediatrics, Special Patient Populations
UCB Biosciences

Dr. Martine Dehlinger-Kremer brings over 30 years of experience in the research industry, with expertise in global regulatory affairs, medical affairs, maternal–fetal medicine, and pediatric drug development. In December 2025, Dr. Dehlinger-Kremer joined UCB Biosciences as Senior Development Strategy Lead Pediatrics within Special Patient Populations, where she focuses on advancing and optimizing global pediatric development strategies.

She has held numerous leadership and advisory roles, including serving as President of the European CRO Federation (EUCROF) until November 2025 and Chair of its Pediatric Working Group for more than 15 years. She has also contributed to the European Network for Pediatric Research at the European Medicines Agency (Enpr-EMA) as an observer member of the coordinating group.

Dr. Dehlinger-Kremer currently serves as a Board Member of the European Forum for Good Clinical Practice (EFGCP) and Co-Chair of its Children's Medicines Working Party. She is also an advisory board member of the International Children's Advisory Network (iCAN) and contributes to pediatric initiatives within EFPIA, PhRMA, TOPRA, and Enpr-EMA.

Her contributions have been recognized internationally, including being named among PharmaVOICE's 100 Most Inspiring People in Life Sciences, receiving the TOPRA Award for Regulatory Excellence, and being awarded honorary membership of EUCROF.

Roberto De Lisa, MD
Paediatric Medicines Office, Scientific Evidence Generation Department
European Medicines Agency (EMA)

Dr. Roberto De Lisa has a MD with specialty in Clinical Pharmacology and Neuroscience, joined the EMA in 2006. Since then, Dr. Roberto De Lisa has held various positions in Medical Information and Pharmacovigilance and then for more than 10 years in Paediatric Medicines Office of the EMA providing scientific and regulatory support to the Paediatric Committee. Dr. De Lisa expertise focuses on methodologies such as PK modelling and simulation, extrapolation, and in the development of products for the treatment of paediatric SLE. Prior to joining the EMA, Dr. De Lisa worked for the University Hospital San Giovanni di Dio in Cagliari, Italy, for five years, conducting clinical trials and participating in the activities of the local Ethic Committee and in the creation of the Pharmacovigilance Centre.

Richard Dimelow, PhD
Director, Clinical Pharmacology
GSK

Dr. Richard Dimelow is a Director of Clinical Pharmacology at GSK, working within the immunology therapeutic area. He has over 20 years of experience applying model-informed drug development approaches, supporting programs from preclinical translation through to Phase 3 registrational studies. Over the past decade, he has focused on autoimmune diseases, particularly SLE, serving as the clinical pharmacology lead for Benlysta. In this role, he successfully implemented extrapolation strategies to support expansion of the indication into pediatric populations.
Prior to joining GSK, Richard worked as a clinical pharmacometrician at Wright Dose, a consultancy firm, and held preclinical modelling roles at AstraZeneca and Cyprotex. He holds an MSci from the University of Cambridge and a PhD from the University of Manchester (UK).

Satyajit Ghosh, PhD
Mathematical Statistician
DPMM, OB, CDER, FDA

Dr. Satyajit Ghosh serves as a Mathematical Statistician (Statistical Reviewer) within the FDA's Office of Biostatistics, where he supports the Division of Pediatrics and Maternal Health. His work bridges regulatory review and methodology research, with a focus on Bayesian statistics, causal inference, and clinical trial design applied to endocrinology, diabetes, and pediatric drug development.

A graduate of the University of Florida with a PhD in Statistics, Dr. Ghosh also completed a two-year postdoctoral fellowship at Rutgers University. His active research centers on advancing Bayesian information borrowing and surrogate endpoint evaluation to optimize evidence generation and safely accelerate therapeutic development.

Amit Golding, MD, PhD
Lead Physician
DRTM, OII, OND, CDER, FDA

Dr. Amit Golding is currently a Lead Physician in the Division or Rheumatology and Transplant Medicine (DRTM) in FDA/CDER/OND/Office of Immunology and Inflammation. After completing clinical training in Internal Medicine (Johns Hopkins Bayview) and Rheumatology Fellowship (Johns Hopkins University SOM) and post-doctoral research in the laboratory of Dr. Ethan Shevach (NID/NIAID/LI/Cellular Immunology), Dr. Golding joined the University of Maryland School of Medicine Division of Rheumatology and Clinical Immunology as an Assistant Professor with a joint appointment at the Baltimore VA. Dr. Golding continues to actively participate in clinical care of adults with rheumatologic conditions, including SLE, at the Baltimore VA Arthritis Clinic.

Dr. Golding has been a full-time FDA employee since September 2019 and has presented on behalf of the FDA at the annual ACR Convergence meetings (2000, 2021, and 2022). As an FDA medical officer in DRTM, Dr. Golding has been involved in both primary and secondary review of multiple adult and pediatric SLE drug development programs. Dr. Golding has also been actively engaged with multiple external stakeholders, including patients, providers, academia and industry representatives, via the Lupus ABC Public Private Partnership (PPP).

Emily C. Gotschlich, MD
Clinical Reviewer
DRTM, OII, OND, CDER, FDA

Dr. Emily C. Gotschlich is a clinical reviewer in the Division of Rheumatology and Transplant Medicine (DRTM) in the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration (FDA). Dr. Gotschlich received her B.S. at Duke University and M.D. from New York University. She completed her pediatric residency at Mount Sinai School of Medicine in New York and went on to complete her fellowship in pediatric rheumatology at Children's National Hospital in D.C. and the National Institutes of Health (NIH) in Bethesda, MD. She joined the FDA in 2021 as a clinical reviewer and has been involved in the review of multiple rheumatology products, with a focus on pediatric drug development. She continues to see pediatric rheumatology patients in clinic every week at Children's National Hospital.

Mary T. Thanh Hai, MD
Director
OND, CDER, FDA

Dr. Mary Thanh Hai serves as the Director of the Office of New Drugs (OND) in the Center for Drug Evaluation and research. OND oversees the clinical and nonclinical investigations supporting drug development programs for prescription drugs and therapeutic biologics and non-prescription drugs.

Dr. Thanh Hai is an internist/endocrinologist with over 28 years of experience at the FDA in several leadership positions including Director of the Division of Metabolism and Endocrine Products (2006-2012), Deputy Office Director and Acting Office Director overseeing three review divisions regulating endocrine, pulmonary, allergy/immunology, pain, anesthesia, and addiction products (2012-2020), and Deputy Director in the Office of New Drugs (2020-2025). She has also served on several internal and external committees covering a wide range of issues, including serving as rapporteur for an ICH E19 expert work group to promote selective safety data collection in late-stage pre-market and post-marketing studies to increase efficiencies in trial conduct. She has been a member of the FDA PDUFA reauthorization negotiations team for PDUFA 6 and 7 and recently led the premarket subgroup for PDUFA 8 reauthorization.

Tao Liu, PhD
Clinical Pharmacology Team Leader
DIIP, OCP, CDER, FDA

Dr. Tao Liu is a Clinical Pharmacology Team Leader in the Division of Immune and Inflammation Pharmacology within the Office of Clinical Pharmacology at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. In this role, he leads and oversees clinical pharmacology reviews supporting regulatory decision-making for drug development programs in rheumatology and transplant medicine, working at the interface of clinical development strategy, quantitative evidence, and regulatory policy. Dr. Liu received formal training in pharmacometrics during his PhD studies at the University of Maryland, Baltimore. Since joining the U.S. Food and Drug Administration in 2017, he has served as a primary clinical pharmacology and pharmacometrics reviewer, applying an integrated, model-informed approach to support labeling and regulatory decision-making across multiple therapeutic areas, including rheumatologic and pulmonary diseases. His work frequently involves cross-functional engagement with clinical, statistical, and regulatory stakeholders to translate quantitative insights into actionable development and regulatory strategies for complex biologics and emerging immune-modulating therapies. He has made significant contributions to pediatric drug development, particularly in the application of efficacy extrapolation and quantitative frameworks to support dose selection, trial design, and regulatory decision-making in pediatric populations. Dr. Liu has authored numerous peer-reviewed publications and is actively engaged in advancing collaborative, science-driven approaches to efficient drug development.

Lily Mulugeta, PharmD
Acting Associate Director for Policy and Research
DPMM, ORPURM, CDER, FDA

Dr. Lily Mulugeta is the Associate Director for Policy and Research in the Division of Pediatrics and Maternal Health at the U.S. Food and Drug Administration (FDA). In this role, she leads scientific, regulatory, and research efforts related to pediatric drug development and represents the Division on the FDA Pediatric Review Committee (PeRC).

Before joining the Division of Pediatrics and Maternal Health in 2017, Dr. Mulugeta served as the Scientific Lead for Pediatrics in the Division of Pharmacometrics and as a pediatric clinical pharmacologist in the Office of Clinical Pharmacology at the FDA. Prior to joining the FDA, she practiced as a Critical Care Clinical Specialist at Children's National Medical Center in Washington, DC. She also held faculty appointments in the Department of Pediatrics at the George Washington University School of Medicine and Health Sciences and the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy.

Dr. Mulugeta earned her Doctor of Pharmacy degree from the University of Kentucky College of Pharmacy and completed a pediatric pharmacy residency at Inova Fairfax Hospital in Falls Church, Virginia.

Raj Nair, MD
Division Director
DRTM, OND, CDER, FDA

Dr. Raj Nair is the Division Director of the Division of Rheumatology and Transplant Medicine (DRTM) within the Office of New Drugs at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. A board-certified rheumatologist, Dr. Nair earned his medical degree from the University of South Alabama School of Medicine and completed his internal medicine residency at St. Joseph's Hospital before undertaking a rheumatology fellowship at the University of North Carolina Hospitals, where he was also recognized as a Clinical Research Scholar. Prior to joining the FDA as a Medical Officer in 2013, he served as an Assistant Professor of Medicine in the Division of Rheumatology at Washington Hospital Center, where he developed advanced expertise in musculoskeletal ultrasound. He assumed his current role as Division Director in November 2024.

Dr. Nair has played a central role in advancing regulatory science across rheumatologic and immunologic conditions, serving as signatory on landmark approvals including a new drug approval for lupus nephritis, the first-ever approval for IgG4-related disease, and approvals for psoriatic arthritis treatments. His commitment to pediatric development is reflected in his work on regulatory pathways for axial spondyloarthritis in children. He has contributed to the Lupus ABC Public Private Partnership, including its Research Committee, and has engaged in biomarker development initiatives for osteoarthritis and kidney transplant through FDA's DDT program. A moderator at the American College of Rheumatology Convergence and a speaker on model-informed drug development, Dr. Nair brings both scientific depth and a strong commitment to public-private collaboration to his work in service of patients with rheumatic disease.

Ekemini Ogbu, MD, MSc
Associate Professor of Pediatrics
Cincinnati Children's Hospital Medical Center

Dr. Ekemini Ogbu is a pediatric rheumatologist and physician-scientist. She is an Associate Professor of Pediatrics at Cincinnati Children's Hospital Medical Center (CCHMC) and University of Cincinnati, Ohio. She is the Director of Neuroinflammatory Disease Services in Rheumatology and Co-Director of the CCHMC Lupus Center. Dr Ogbu received her medical degree from the University of Ibadan, Nigeria. She completed her residency in pediatrics at Morehouse School of Medicine/Children's Healthcare of Atlanta, Georgia. She completed her fellowship in pediatric rheumatology with a Master of Science in Clinical Research at Emory University School of Medicine, Georgia. Dr. Ogbu's clinical and translational research program is focused on neuroinflammation, and hematologic abnormalities in childhood-onset systemic lupus. This includes her ongoing work in cerebrovascular disease and cognitive dysfunction supported by the Lupus Research Alliance and the Centers for Disease Control.

Dr. Ogbu is the Chair of the American College of Rheumatology (ACR) Committee on Pediatric Rheumatology. She co-leads the Neuropsychiatric Lupus Workgroup of the Childhood Arthritis and Rheumatology Research Alliance (CARRA). She serves on the Advisory Council of the Pediatric Rheumatology Collaborative Study Group (PRCSG). She serves on the Board of the Rheumatology Research Foundation and the Autoimmune Encephalitis Alliance.

Reshma Patel, MD
Pediatric Rheumatologist, Global Associate Medical Director, Lupus
Biogen

Dr. Reshma Patel is a Global Associate Medical Director in Immunology at Biogen, where she supports the lupus portfolio and works on scientific strategy, evidence generation, and stakeholder engagement across systemic and cutaneous lupus erythematosus. Prior to joining Biogen, Dr. Patel practiced pediatric rheumatology for more than a decade, caring for children and adolescents with autoimmune and inflammatory diseases, including childhood-onset systemic lupus erythematosus in Central California, where access to specialized care and treatment options often remained significant challenges. She also served as Clinical Assistant Professor affiliated with Stanford University School of Medicine.

Drawing on experience in both clinical practice and industry, Dr. Patel is committed to advancing the understanding and management of lupus through research, medical education, and scientific exchange. As a pediatric rheumatologist, she witnessed firsthand the substantial disease burden and limited treatment options faced by many children and adolescents living with lupus. She remains passionate about supporting efforts to improve outcomes for young people affected by the disease.

CAPT Suzette Peng, MD
Acting Team Leader
DRTM, OII, OND, CDER, FDA

CAPT Suzette Peng is a board certified internist and rheumatologist. She joined the FDA in 2012 and is currently an acting team leader in the Division of Rheumatology and Transplant Medicine in the Center of Drug Evaluation and Research. She received her BA from the University of Pennsylvania and MD from USF Morsani College of Medicine. She completed an internal medicine residency and rheumatology fellowship at Walter Reed Army Medical Center. She continues to see patients in the rheumatology clinic at AT Augusta Military Medical Center. She was an officer in the US Army and is now a Captain in the US Public Health Service with whom she has served in multiple national and global responses, including the Ebola crisis in 2014, Hurricane Maria in 2017, and the COVID-19 public health emergency in 2020.

Chloe Raymond
Lupus Patient Representative and Advocate

Ms. Chloe Raymond lives with Lupus. She struggled deeply with her diagnosis, finding it difficult to adapt to her new normal. She found it difficult to adapt to her new normal of juggling many medications, being able to keep up with kids her age, keeping up with numerous doctor's appointments with new specialists all while trying to manage her full time job. She often felt isolated because she didn't know anyone else living with childhood lupus who could relate to what she was going through.

Today, nearly three years later, her perspective has changed significantly and she found her voice to strongly advocate on behalf of children living with lupus. At her local institution, Chloe works with many rheumatologists and clinical research assistants to voice her opinions on Lupus related projects such as the GOLOW steroid project. Chloe strongly supports patient centered research where patients and care partners collaborate with researchers throughout the life cycle of research. To end that, Chloe serves as a member of the Implementation Partners Advisory Committee (IPAC) for the about time project which looks to implement proven heart health strategies for children with lupus. As an IPAC member, Chloe works with researchers, clinicians, patients, care partners, health policy professionals, and advocacy organization staff to advise on project progress and address challenges with project execution. In addition to collaborating in research, Chloe has also enrolled herself in research donating biosamples to learn the biological structure of childhood lupus which will hopefully lead to new treatment targets and ultimately new treatments.

Chloe feels fortunate to have access to effective medications; however, she knows many struggle to find something that works for them. She looks forward to working together to accelerate, as quickly as possible, new treatments that are safe and effective for children with lupus.

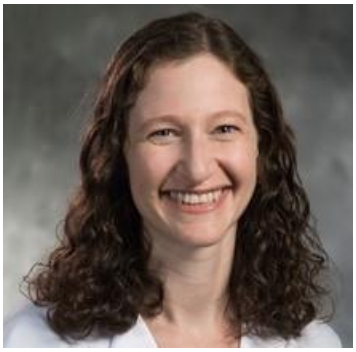
Sarah Ringold, PhD
Pediatric Rheumatologist, Pediatric Development Team
Johnson & Johnson Innovative Medicine

Dr. Sarah Ringold is a pediatric rheumatologist and currently serves is a member of the Pediatric Development Team at Johnson & Johnson Innovative Medicine, where she leads clinical development activities across pediatric rheumatology programs. Prior to joining Johnson & Johnson in 2021, Dr. Ringold was an Associate Professor in the Department of Pediatrics at the University of Washington. Her research focused on clinical outcomes in pediatric rheumatic diseases and the comparative effectiveness of medications for juvenile idiopathic arthritis, with a focus on observational study designs.

Jordon Roberts, MD, MPH
Global Development Associate Medical Director
AstraZeneca

Dr. Jordan Roberts is a Global Development Associate Medical Director at AstraZeneca in immunology clinical development where she works on pediatric lupus drug studies. She earned her undergraduate degree in Government from Harvard College and her MD from Weill Cornell Medical College, followed by pediatrics residency at the Boston Combined Program in Pediatrics at Boston Children's Hospital and Boston Medical Center, and fellowship in pediatric rheumatology at Boston Children's Hospital. Dr. Roberts also completed the Harvard-Wide Pediatric Health Services Research Fellowship and holds an MPH in Clinical Effectiveness from the Harvard School of Public Health. Previously, Dr. Roberts was an attending pediatric rheumatologist and clinical researcher at Seattle Children's Hospital and Research Institute where her academic work focused on outcomes of immunomodulatory therapies in children with lupus.

Rebecca Sadun, MD, PhD
Associate Professor of Medicine and Pediatrics
Duke University School of Medicine



Dr. Rebecca Sadun earned her MD/PhD from the Keck School of Medicine at the University of Southern California and then completed her Medicine/Pediatrics Residency and Combined Adult/Pediatric Rheumatology Fellowship at Duke University, where she is now an Associate Professor of Medicine and Pediatrics, caring for rheumatology patients of all ages. Her clinical expertise lies in the care of patients with systemic lupus erythematosus (SLE). She provides care to adult lupus patients in the Duke Lupus Clinic, co-directs the Duke Pediatric Lupus Nephritis Clinic, and created a multidisciplinary Rheumatology Young Adult Clinic that addresses the complex needs of young adults with childhood-onset rheumatic diseases, especially SLE, as they transition to adult care. Dr. Sadun serves as the Vice-Chair of the SLE Committee in the Childhood Arthritis and Rheumatology Research Alliance (CARRA) and is engaged in research that pertains to medication adherence, vaccine immunogenicity, patient reported outcomes, and predicting clinical outcomes for patients with SLE across the lifespan.

Elizabeth SantaCruz, BS
Lupus Advocate
Lupus and Allied Diseases Association (LADA)

Elizabeth SantaCruz, BS in Accounting, Director of Outreach & Communications for LupusChat, Member of the Lupus ABC (Lupus Accelerating Breakthroughs Consortium) Lupus Voices Council, Lupus Advocate, Caregiver/ Care Partner Voice Leader, and Community Advocate for the Lupus and Allied Diseases Association (LADA) and Lupus Research Alliance (LRA), is a dedicated advocate who has spent years elevating the voices of individuals and families affected by lupus. Inspired by her daughter Miah's pediatric lupus diagnosis after a prolonged journey to obtain answers, Elizabeth transformed her family's experience into a mission of advocacy, education, and awareness. She has represented the lupus community in Patient-Focused Drug Development (PFDD) efforts, collaborated with national advocacy organizations, participated in congressional advocacy meetings, and worked to advance lupus awareness at the local, state, and national levels. Through LupusChat, Elizabeth has helped amplify patient and caregiver voices while fostering education, support, and engagement across the lupus community

She has spoken at educational and scientific meetings, including programs supported by Lupus and Allied Diseases Association (LADA) and the American College of Rheumatology (ACR), helping to highlight pediatric lupus, cultural humility in healthcare, and the importance of incorporating patient and caregiver experiences into research and clinical care. She actively supports fundraising and awareness initiatives, including New York, New Jersey lupus walks and community outreach events, while promoting research participation, health equity, and social media engagement to expand awareness of lupus. Elizabeth remains committed to improving the lives of those impacted by lupus by strengthening the partnership between patients, caregivers, researchers, healthcare professionals, and policymakers. She lives in Kearny, New Jersey, with her husband and two children, where she continues her work to build a more informed, compassionate, and supportive future for the lupus community.

Laura Schanberg, MD
Professor of Pediatrics
Duke Clinical Research Institute, Duke University School of Medicine

Dr. Laura Schanberg is a lifelong Duke Blue Devil, having grown up in Durham, completed all her medical training at Duke and being on the Duke faculty for over 35 years. She is a clinical researcher and founding member of CARRA and the CARRA Registry, having served in multiple leadership positions including President during incorporation as a 501C3 and PI for the CARRA Registry. She also was co PI of the first CARRA trial, the NIH- funded Atherosclerosis Prevention in Pediatric Lupus Erythematosus (APPLE) study, the largest randomized controlled trial completed in pediatric SLE. Dr. Schanberg is currently PI of two PCORI-funded multisite comparative effectiveness trials including LIMIT-JIA and SMART-JIA. SMART JIA is CARRA's first international trial working collaboratively with the European Pediatric Rheumatology Society (PReS) and its research arm, PReSTaR. Dr. Schanberg also studies the use of patient reported outcomes (PROs) and the role of disease symptoms, especially pain, in the experience of children with rheumatic disease. She was the PI for PARTNERS (Patients, Advocates and Rheumatology Teams Network for Research and Service Consortium), a PCORnet patient powered research network and continues to advocate for engaging patient PIs in the design and conduct of clinical trials.

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

Dr. Vikram Sinha is a biopharmaceutical research and development executive-scientist with more than 25 years of experience leading translational medicine, clinical pharmacology, pharmacometrics, and quantitative sciences across the drug development continuum. He is currently a Senior Vice President, Translational and Quantitative Medicine at Flagship Pioneering where he is responsible for translational medicine, clinical pharmacology and application of predictive models for clinical development at Pioneering Medicine. In this role, he provides strategic oversight across a diverse portfolio of therapeutics, guiding decisions from target validation and candidate selection through proof-of-concept and regulatory submissions.

Dr. Sinha has held scientific and executive leadership roles in both large pharmaceutical companies including Novartis, Merck and Lilly and as a Division Director at CDER/USFDA where he established and scaled capabilities in clinical pharmacology, translational science, and quantitative drug development. He has led global teams supporting numerous development programs across immunology, inflammation, nephrology, metabolic disorders, rare diseases, oncology, and specialty medicines. His work has contributed to multiple regulatory submissions and approvals worldwide.

Dr. Sinha is widely recognized as a thought leader in model-informed drug development and quantitative systems pharmacology. He has advanced innovative translational approaches to deepen understanding of disease biology, optimize dose selection, predict clinical outcomes, and strengthen portfolio decisions. His leadership has helped organizations improve development efficiency, reduce risk, and increase the probability of technical and regulatory success. An accomplished people leader and strategic advisor, he is known for building collaborative, data-driven cultures, mentoring scientific leaders, and leading high-performing global organizations that enable clinical development and accelerate delivery of innovative therapies to patients.

Dr. Sinha holds a PhD in Pharmaceutical Sciences from the University of Arizona and has authored numerous scientific publications, research patents, presentations, advisory panels and contributions in the fields including regulatory guidance and academic consortia. He is an active advocate for advancing innovative approaches that bridge science and medicine to improve patient outcomes.

Mary Beth Son, MD
Associate Professor, Pediatrics
Harvard Medical School

Dr. Mary Beth Son attended the University of Massachusetts Medical School and completed internship, residency and chief residency in Pediatrics at Boston Children's Hospital (BCH), followed by fellowship in Pediatric Rheumatology at BCH. She is an Associate Professor of Pediatrics at Harvard Medical School and holds the Fred S. Rosen Chair in Pediatrics. Dr. Son is the Section Chief of Pediatric Rheumatology and Clinical Chief of the Division of Immunology. She pursues clinical research and has received funding from the Centers for Disease Control and Prevention, the NIH, and the American Heart Association to support her research interests, including outcomes in Kawasaki disease, Multisystem Inflammatory Syndrome in Children and childhood-onset systemic lupus erythematosus.

James Travis, PhD
Master Mathematical Statistician
DB II, OB, OTS, CDER, FDA

Dr. James Travis is a master mathematical statistician in the Division of Biometrics II in the US FDA Center for Drug Evaluation and Research. He is the technical lead for the pediatric and maternal health statistical scientists and has been supporting pediatric drug development since joining the Pediatric Review Committee in 2017. He has worked extensively on applications in the complex and innovative trial design program and led the development of the FDA draft guidance "Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products".

Flora Musuamba Tshinanu, PhD
Professor, Clinical Pharmacology and Pharmacotherapy
University of Namur and University of Lubum

Pharmacometrics Expert
Belgian Federal Agency for Medicines and Health Products (FAMHP)

Dr. Flora Musuamba is a Pharmacist by background and holds a PhD in Pharmacy and Biomedical Sciences from Université Catholique de Louvain, in Belgium. She is a Pharmacometrics expert at the Belgian Federal Medicines Agency (FAMHP). Flora Musuamba is the Chair a member of the Network Data Steering Group (NDSG), the methodology (MWP) and scientific advice working parties (SAWP) at the European Medicines Agency (EMA). She is also Professor of Clinical Pharmacology and Pharmacotherapy at University of Namur. Flora is currenty coordinating the Horizon-Europe project ERAMET.

Kalyanee Viraswami-Appanna, PhD
VP and Global Head, Biostatistics
EMD Serono, Inc.

Dr. Kalyanee Viraswami-Appanna is Vice-President and Global Head of Biostatistics in Clinical Measurement Sciences at EMD Serono, Inc., a business of Merck KGaA, Darmstadt, Germany. In this role, she provides functional leadership and expertise in applying rigorous statistical science across all stages of drug development. As a member of the CMS Leadership Team, she plays a vital role in shaping the overall CMS strategy and contributes to critical R&D initiatives, drives integrated evidence planning and champions quantitative decision-making. She leads a team of biostatisticians who leverage therapeutic area expertise, innovative statistical methods, and cross-industry, regulatory, and academic partnerships to generate fit-for-purpose evidence — ultimately bringing the right medicines to the right patients faster.

She holds a PhD in Statistics from the University of Toronto and completed a postdoctoral fellowship at the University of Oxford. She began her career in academia at the University of Waterloo before transitioning to the pharmaceutical industry, where she has held positions of increasing responsibility at Johnson & Johnson, Bristol Myers Squibb, Novartis, and EMD Serono, Inc. Over a career spanning more than 25 years, Kalyanee has provided strategic statistical leadership across a broad range of therapeutic areas, with a strong record of global regulatory submissions and approvals.

Lynne Yao, MD
Director
DPMH, OND, CDER, FDA

Dr. Lynne Yao is the Director, Division of Pediatric and Maternal Health (DPMH) in the Office of New Drugs, Center for Drug Evaluation and Research. Dr. Yao received a BS degree in Biology from Yale University, and an MD degree from the George Washington University School of Medicine. She is board certified in both Pediatrics and Pediatric Nephrology. Prior to joining FDA, Dr. Yao was the Director of Dialysis and Associate Pediatric Residency Program Director at the Inova Fairfax Hospital for Children in Fairfax, VA. She has been with the FDA since 2008 and has been DPMH Director since 2012. As DPMH Director, Dr. Yao oversees quality initiatives which promote and necessitate the study of drug and biological products in the pediatric population; and improve collection of data to support the safe use of drugs and biological products in pregnant and lactating individuals. She collaborates with numerous stakeholders both inside and outside of FDA to advance development of safe and effective therapies for children, and pregnant and lactating women.

Sule Yavuz, MD
Global Clinical Program Lead, Immunology
AstraZeneca

Dr. Sule Yavuz is a rheumatologist whose work has spanned clinical practice, translational research, and global drug development in autoimmune diseases, with a particular focus on systemic lupus erythematosus (SLE) and systemic sclerosis (SSc).

Her research has centered on B-cell biology and the type I interferon pathway, while her pharmaceutical career has encompassed leadership of early- and late-stage clinical development programs for innovative therapeutic modalities across SLE, SSc, and immune thrombocytopenia (ITP). She currently serves as Global Clinical Program Lead in Immunology at AstraZeneca, leading late-stage clinical development programs and overseeing pediatric development across SLE and LCM indications.

Prior to joining the pharmaceutical industry, Dr. Yavuz was an academic rheumatologist at University of Uppsala where her research focused on shared genetic risk factors across autoimmune rheumatic diseases and participated in multicenter clinical studies. She has over 160 peer-reviewed publications and has mentored postdoctoral fellows and junior faculty across multiple academic institutions.