



Clinical Development Day 2025

Ages and Stages of Food Allergy: Diagnosis and Treatment Across the Lifespan

The Ronald Reagan Building and International Trade Center

Friday, October 31, 2025

FARE's Clinical Development Day is a focused, one-day conference convening approximately 100 leaders in food allergy research, clinical care, regulation, and therapeutic development. Participants include academic investigators, practicing clinicians, representatives from the FDA and NIAID, biopharmaceutical and allergen product developers, and members of the investment community. The objective of the meeting is to facilitate open, cross-sector dialogue aimed at identifying actionable strategies to address persistent unmet needs in food allergy.

This year's theme—"Ages and Stages of Food Allergy: Diagnosis and Treatment Across the Lifespan"—emphasizes the need to better understand and respond to the evolving nature of food allergy. Particular attention will be given to the heterogeneity of disease expression, including age-related changes in phenotype that affect diagnosis, clinical management, and therapeutic development. We will also discuss underrecognized forms of food allergy, such as Alpha Gal, FPIES, and EoE.

The agenda comprises six topic-focused sessions, each moderated by a conference Co-Chair. Sessions begin with a concise 10-minute didactics to frame the key issues, followed by an extended, moderated discussion. Panelists will represent a diversity of perspectives, but all attendees are encouraged to contribute actively. This highly interactive format is intended to foster substantive dialogue, break down traditional silos, and advance collaborative solutions that improve outcomes for individuals living with food allergies across the lifespan.

All sessions on October 31st take place in Pavilion or adjacent foyer.

8:00 AM – 8:45 AM (45 minutes)	Breakfast and Recap with Ben Zoldan	Pavilion
8:45 AM – 9:00 AM (15 minutes)	Networking	Pavilion Foyer
9:00 AM – 9:10 AM (10 minutes)	Welcome & Opening Remarks <ul style="list-style-type: none"> • Stephen Tilles, MD, FARE • Sarita Patil, MD, Harvard Medical School • Yamini Virkud, MD, MA, MPH, University of North Carolina at Chapel Hill 	Pavilion
9:10 AM – 10:00 AM (50 minutes)	Immune Diversity in Food Allergy: Age Matters, Innovation Depends on It <p>Description: The clinical heterogeneity of food allergy—shaped by immune diversity and age-related changes—poses significant challenges for diagnosis and management. These complexities complicate the selection of appropriate regulatory and clinical development strategies. This session will examine how immune variation and age influence food allergy expression, the resulting challenges for product innovators, and potential approaches to address these issues.</p> <p>Moderator: Sarita Patil, MD</p> <p>Part 1: How Immune Phenotypes Differ with Age (10 minutes) Wayne Shreffler, MD, PhD, Harvard Medical School</p> <p>Part 2: Disease Heterogeneity and Its Impact on Innovation (10 minutes) Hugh Sampson, MD, Icahn School of Medicine at Mount Sinai</p> <p>Panelists (30 minutes Q&A)</p> <ul style="list-style-type: none"> • Joan Dunlap, MD, Novartis • Nancy Goodman, JD, KIDS V CANCER 	Pavilion
10:00 AM – 10:40 AM (40 minutes)	Feeding the Machine: The Next Generation of Food Allergy Diagnostics <p>Description: Machine learning offers powerful tools for integrating complex datasets—ranging from omics and clinical data to environmental exposures—to better characterize immune responses and food allergy phenotypes. However, the path to accurate diagnosis is challenged by limited predictive value of current tests and challenges associated with test validation (e.g. disease heterogeneity, age-related phenotypic changes, etc.). This session will discuss both new diagnostics under development and how advanced data science can inform next-generation diagnostics, including what evidence is needed to overcome regulatory, scientific, and economic barriers to clinical adoption.</p> <p>Moderator: Yamini Virkud, MD, MA, MPH</p> <p>Didactic: Supinda Bunyavanich, MD, MPH, MPhil, Icahn School of Medicine at Mount Sinai</p> <p>Panelists (30 minutes Q&A)</p> <ul style="list-style-type: none"> • David Fleischer, MD, University of Colorado • Daniel Rotrosen, MD, Division of Allergy, Immunology, and Transplantation, National Institute of Allergy and Infectious Diseases, National Institutes of Health • Alexandra Santos, MD, PhD, MSc, King's College London • Eric Wambre, PhD, Icahn School of Medicine at Mount Sinai 	Pavilion

10:40 AM – 10:55 AM (15 minutes)	Break	Pavilion Foyer
10:55 AM – 11:45 AM (50 minutes)	<p>Underrecognized Food Allergies: Alpha-Gal, FPIES, EoE, and More</p> <p>Description: As the food allergy epidemic grows, a range of underdiagnosed, food-induced immunologic disorders—including alpha-gal syndrome, food protein-induced enterocolitis syndrome (FPIES), eosinophilic esophagitis (EoE), and others—are gaining increased attention. These conditions present with distinct clinical features, immunologic mechanisms, and diagnostic challenges that fall outside traditional IgE-mediated paradigms. This session will highlight the unique barriers facing each of these syndromes, including gaps in awareness, delayed diagnosis, limited treatment options, and evolving regulatory frameworks. Through expert discussion, we will explore strategies to advance research, improve patient outcomes, and better integrate these conditions into the broader food allergy agenda.</p> <p>Moderator: Sarita Patil, MD</p> <p>Didactic: Anna Nowak-Wegrzyn, MD, PhD, NYU Langone</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Sara Anvari, MD, MSc, Baylor College of Medicine • Scott Commins, MD, PhD, University of North Carolina at Chapel Hill • Patricia Fulkerson, MD, PhD, Allergy, Asthma and Airway Biology Branch, Division of Allergy, Immunology and Transplantation, National Institute of Allergy and Infectious Disease, National Institutes of Health • Jennifer Malony, MD, Regeneron • Victoria Martin, MD, MPH, Harvard Medical School • Anubha Tripathi, MD, U.S. Food and Drug Administration 	Pavilion
11:45 AM – 12:25 PM (40 minutes)	<p>Sourcing Allergen as a Barrier to Optimal Food Allergy Diagnosis and Treatment</p> <p>Description: Allergen characterization and standardization are foundational considerations in the development of food allergy diagnostics and therapies, yet sourcing and characterizing food allergens for clinical and research use remains challenging due to inherent source variability in protein content and component allergen potency. While pharmaceutical-grade, well-characterized allergens may be essential in certain therapeutic contexts, they may not be necessary—or practical—for all patients in real-world practice. This session will examine the scientific, regulatory, and logistical barriers to achieving allergen standardization, and explore how to prioritize standardization efforts where they matter most. By convening experts from research, industry, and regulatory sectors, the session will seek actionable strategies to support safe, scalable, and targeted use of food allergen materials.</p> <p>Moderator: Stephen Tilles, MD</p> <p>Didactic: Antonella Muraro, MD, PhD, Regional Referral Centre for Food Allergy Diagnosis and Treatment in the Padua General University Hospital</p> <p>Panelists:</p> <ul style="list-style-type: none"> • Shannon Brown, Hollister-Stier • Tibor Nemes, Stallergenes Greer • Hendrik Nolte, MD, PhD, ALK-Abelló • Ronald Rabin, MD, U.S. Food and Drug Administration 	Pavilion
12:25 PM – 1:25 PM	Lunch & Group Photo	Pavilion Foyer

(60 min)		
1:25 PM – 2:45 PM (70 minutes)	Immunotherapy, Biologics, and Beyond: Current Options and Future Directions in Food Allergy Treatment Descriptor: As therapeutic strategies for food allergy continue to evolve, a new generation of biologics, immunotherapies, and novel interventions is advancing through industry-sponsored development programs. This session will provide an overview of current and emerging treatments, with discussion of how these innovations may be applied across different age groups and clinical phenotypes. Panelists will explore how disease heterogeneity, patient-specific factors, and real-world implementation challenges shape the future of food allergy management, offering both near-term insights and long-term perspectives on the treatment landscape Moderator: Yamini Virkud, MD, MA, MPH Didactic: Edwin Kim, MD, MS, University of North Carolina at Chapel Hill Innovation Spotlights <ul style="list-style-type: none"> • Jessica Grossman, MD, IgGennix • Samir Patel, PhD, Moonlight Therapeutics • Sara Prickett, PhD, Aravax • Brian Wong, MD, PhD, RAPT Therapeutics 30-minute Q&A	Pavilion
2:45 PM – 3:00 PM (15 minutes)	PM Break	Pavilion Foyer
3:00 PM – 3:50 PM (50 minutes)	Right Patient, Right Treatment—Even When It's Hard: Ethics and Access in Food Allergy Management Descriptor: As therapeutic options for food allergy expand, so too do the ethical and practical challenges of ensuring equitable, patient-centered care. This session will explore the complex intersection of access, ethics, and individualization in food allergy management. Topics will include health disparities in diagnosis and treatment access; the paradox of coverage; and the influence of financial incentives, conflicts of interest, and practice logistics on shared decision-making. Panelists will examine the real-world barriers to adopting current treatments—including the cost of biologics like omalizumab, the resource demands of oral immunotherapy, and the lack of regulatory approval for SLIT and other emerging approaches—and consider how to navigate these issues while prioritizing the right treatment for the right patient, even when it's hard. Moderator: Stephen Tilles, MD Didactic: Pamela Guerrerio, MD, PhD Panelists: <ul style="list-style-type: none"> • Carla Davis, MD, Howard University • Andrea Pappalardo, MD, University of Illinois Chicago • Marcus Shaker, MD, Dartmouth • Richard Wasserman, MD, PhD, Allergy Partners 	Pavilion
3:50 PM – 4:00 PM (10 minutes)	Closing Remarks Stephen Tilles, MD	Pavilion