Contents







Winter 2021-22 Newsletter



Welcome from Program Director, Dr. Carla M. Davis

The Texas Children's Hospital Food Allergy Program has a mission to serve children with food allergies and their families. We provide personalized, high-quality patient care, increased access to cutting-edge research, innovative treatment advances, and quality patient support groups. Although the coronavirus pandemic hindered us from seeing you, our food allergy families, and supporters this year, our mission continued through telemedicine visits for patients, our annual Food Allergy Symposium, and the start of new research studies! We even developed new collaborations to care for allergic children with food insecurity, and are developing treatment for shrimp allergy.

The ability to diagnose and treat food allergic children has expanded in 2021 through the establishment of a new Food Allergy Diagnosis and Treatment Suite at the West Campus Hospital and the Main Campus Hospital and FDA approval of oral immunotherapy through the Food Manufacturing Center for development of treatment to tree nut allergies! This will enable all children to be seen in a timely manner to either treat tree nut allergy or clarify the foods causing their food allergic disease. Stay tuned for the opening of tree nut treatment trials in 2022!

We are thankful for all the patients we serve in our clinics, the children and families who engage in research in our program, our Food Allergy Family Network leaders, and everyone who supports us or attends our events! We are an amazing community! The TCH Food Allergy Program is excited about next year and looks forward to seeing everyone in person soon!

Thank you for your support!

To make a donation to the Food Allergy Program, contact: Priscilla L. Mondragón 832-824-2060 or <u>plluna@texaschildrens.org</u>



Food Allergy Program at Texas Children's Hospital* 8th Annual

Food Allergy Symposium

In 2021, the TCH Food Allergy Program Team again held a wonderful virtual food allergy symposium! Although the hybrid program had to pivot to a virtual one due to the pesky Delta variant of coronavirus, we were still able to reach over 100 food allergy families and physicians on 3 continents! We had attendees from Canada, Brazil, and Saudi Arabia!

The program opened with a welcome from Dr. Shannon Allen, Beaumont ISD Superintendent, followed by an overview of the recent research advances. The other sessions were extremely well received, and special appreciation goes to our own Dr. Sara Anvari, who spoke about COVID vaccines and allergies, Dr. Aikaterini Anagnostou who spoke about the new developments in food immunotherapy, and Melissa Hearrell, MSN, APRN, who spoke about oral food challenges. Ms. Amber Banken, Mental/Behavioral Health Specialist from Region 5, gave families grounding techniques for anxiety responses, and expert dietitians Ms. Jillian Davis, RD, and Emily Samuels, RD gave nutritional food allergy tips and tricks.

We are grateful for the session led by Food Allergy Family Network leader Mrs. Jennifer Mijangos and Food Allergy Family Network stories by the Tran, Oldham, and Mijangos families. Ms. Indrani Maitra, a high school Teen Advisory Board member, spoke about her Allergy-Friendly Choices program with the Houston Food Bank and West Houston Assistance Ministries, helping to match allergyfriendly donated food to the food allergy families who most need these safe specialty products.

As always, special appreciation goes to Ms. Christina Cowperthwait for her fantastic organization and Ms. Theresa Aldape for her consistent work with the TCH Food Allergy Family Network (FAFN), which keeps our families engaged and supported! We are grateful for Ms. Daisy Tran, who moderated and leads the TCH Food Allergy Program Teen Advisory Board.

Congratulations to the Food Allergy Program Team for another spectacular event!

The link to the symposium recording is here.

8th Annual Food Allergy Program Symposium Recap

> By Carla M. Davis, MD



Dr. Shannon Allen Beaumont ISD Superintendent



Indrani Maitra Teen Advisory Board Member



Amber Banken, MS, LPC Mental/Behavioral Health Specialist



Jillian Davis, RD & Emily Samuels, RD Page 2 | Winter 2020

Food Oral Immunotherapy (OIT) Program Update

by Carla M. Davis, MD



Growing up on peanut OIT!





We thank all our patients who participated in this study!

The TCH Food Allergy Program published a landmark trial* which showed peanut oral immunotherapy (OIT) can result in tolerance of large doses of peanut, but even after 3 years of treatment, does not provide a cure. Patients need to continue the treatment regularly. Importantly, the study found that a key marker for the ability to tolerate peanut during treatment is a blood marker called peanut IgG4.



This important finding has given other investigators more insight into the underlying immune causes of the effect of peanut OIT.

The landmark trial above was featured nationally by the Medscape website, the leading online global destination for physicians and healthcare professionals worldwide, offering the latest medical news and expert perspectives!

Medscape Allergy & Immunology

Peanut Desensitization Plummets 1 Month After Avoiding Exposure

Nancy A. Melville January 03, 2022

The findings "underscore the fact that the desensitization achieved with peanut oral immunotherapy is a transient immune state," report the authors of the study, published in December in *The Journal of Allergy and Clinical Immunology: In Practice.*



Therefore, "adherence to dosing [in peanut immunotherapy] is very important, and clinicians should expect a decline in tolerance with lapse in dosing," first author Carla M. Davis, MD, director of the Texas Children's Hospital Food Allergy Program at Baylor College of Medicine, in Houston, Texas, told *Medscape Medical News.*

Dr Carla Davis

If you are interested in participating in peanut OIT, please contact our allergy clinic on 832-822-3354 and ask for nurse Valerie Nichols.

*See publications page (Davis et al. 2021)

The TCH Food Allergy Program is grateful to the Scurlock Foundation for supporting this landmark study.



The year 2021 has been challenging for all of us, with Covid-19 continuing to affect our daily lives. We are grateful to the scientists who helped roll out the vaccination program, allowing us to achieve some level of protection and normality.

I am very proud of all our peanut oral immunotherapy participants for continuing their treatment. Twenty more children successfully reached their top maintenance dose in 2021 and we have had more families signing up for our POIT program this year.

Our Food Immunotherapy Program has grown so much, since it launched in January 2018, with over 100 families participating to date and we are excited to continue serving our community and improving the quality of life of children with food allergies. The FDA-approved drug Palforzia has also recently become available at Texas Children's with the first patient enrolled in 2021!

We continue to work towards launching our Tree Nut Oral Immunotherapy trial with funding applications in the works. We are also planning to look into milk and egg desensitization programs. All our families will receive an email once the above programs are up and running.

I am looking forward to a very busy and productive 2022 and wish everyone a wonderful year in good health!

If you are interested in participating in peanut OIT, please contact our allergy clinic on 832-822-3354 and ask for nurse Valerie Nichols.





Food Oral Immunotherapy (OIT) Program Update

by Aikaterini Anagnostou, MD, PhD

COVID-19 Vaccine Allergy Clinic

The Texas Children's Hospital COVID Vaccine Allergy Clinic was established in January 2021 to help support the evaluation of patients with a history of an allergic reaction to the COVID19 Vaccine or a history of PEG or polysorbate allergy. Dr. Sara Anvari is the Medical Director of this Clinic.

Immediate allergic reactions have been reported after receipt of COVID19 vaccines, including the mRNA vaccines (Pfizer, Moderna) and adenoviral vaccines (J&J), at similar rates of 2.5-4.7 cases per million doses administered. In a recent <u>cohort study</u> of patients <u>with a known history of allergy</u>, 1% had mild allergic symptoms and 0.7% had anaphylactic reactions after receiving the first or second dose of Pfizer-BioNTech COVID19 vaccine. Although the vaccine is not contraindicated in allergic patients and allergic reactions are rare, patients with a known history of allergy are more likely than those without history of allergy to have such reactions. Allergic reactions are usually caused by inactive ingredients or "<u>excipients</u>" such as polyethylene glycol (PEG) or polysorbate 80, which are contained in many vaccines, drugs, and cosmetic products.

Since its inception in Jan 2021, **The TCH COVID Vaccine Allergy Clinic has evaluated over 100 patients all of which who have successfully received their COVID vaccine.** This evaluation is based on the patient's clinical history, skin testing to polyethylene glycol 3350 (PEG 3350) and/or polysorbate 80. An oral challenge, known to be the gold standard for diagnosing drug allergies, would be performed using PEG 3350 (i.e. Miralax) in order to rule out a PEG allergy. Following a successful oral PEG challenge, patients were scheduled to receive their COVID vaccine the same day and observed 30-60 min following vaccination.

In addition to her COVID Vaccine Allergy Clinic, Dr. Anvari has also been actively collaborating with national COVID Vaccine Allergy Centers in Boston (MGH/Harvard) and Nashville (Vanderbilt) publishing work related to COVID vaccine allergic reactions and PEG allergies. 1, 2 Her work includes a publication in the New England Journal of Medicine, the leading journal in medicine, demonstrating that a delayed large local reaction (aka COVID arm) from the mRNA COVID vaccine was not a contraindication to receiving the 2nd vaccine dose. Additionally, she has also recently published data showing the safety of the mRNA COVID vaccine in patients with a prior history of PEG-asparaginase hypersensitivity.

Furthermore, Dr. Anvari has also provided guidance to providers at the TCH Vaccine Clinics to help facilitate their decision on whether or not a patient should receive the COVID vaccine. And, Dr. Anvari has been actively serving as a COVID vaccine expert on the COVID Vaccine Mandate Review Group for the United States Olympic and Paralympic Committee (USOPC).





Dr. Sara Anvari getting the COVID-19 vaccine

Food Allergy Family Network (FAFN) 2021 Update by Theresa Aldape, LMSW

The Food Alleray Family Network (FAFN) welcomed in 2022 with the dedication to continue providing education, and support to enhance the quality of life for children, adolescents and young adults with food allergies. They are proactive and contact organizations, event organizers, private business owners, elected officials and school personnel to bring awareness to food allergies and how they affect the lives of children, adolescents and families with food allergies. The leaders live in Houston and the surrounding areas and are a pivotal part of the success of the Texas Children's Hospital Food Allergy Program.

Throughout the year, the FAFN leaders provided over 150 different interactions known as contacts to individuals in their community. Every contact represents time spent providing food allergy awareness and supportive care services to community members via social media, phone calls, electronic mail,



Mr. Joe Penland handing a donation check to Dr. Carla Davis, Program Director of the Food Allergy Program at Texas Children's Hospital. Also pictured from left to right: Kaysie Davenport, Theresa Aldape and Frank Stowell.

The Penland Foundation has been instrumental in the community outreach arm of the Texas Children's Hospital Food Allergy Program. We are thankful for their support!

and via small groups taking into effect social distancing and other protective preventive measures. FAFN leaders are trained Texas Children's Hospital Volunteers and received updated information on the various treatment modalities, current research studies and upcoming studies for children, adolescents and young adults with food allergy at Texas Children's Hospital – Baylor College of Medicine. They are available to provide support to families regardless of the clinic or hospital where their child receives medical care.

- In May, Dr. Davis and Theresa Aldape, LMSW had a conference call with the FAFN leaders. Dr. Davis provided an update on the COVID-19 pandemic and vaccine updates at Texas Children's Hospital.
- Dr. Davis shared the results of the Food Allergy Oral and Patch Immunotherapy Studies at Texas Children's Hospital and the current state of treatment in food allergy.
- She discussed the open food allergy studies enrolling at Texas Children's Hospital Baylor College of Medicine and also gave an update on upcoming studies for 2021-2022. (See pages 12-14)



Food Allergy Family Network (FAFN) 2021 Update by Theresa Aldape, LMSW

Theresa Aldape, LMSW provided an update on the scheduled activities. The day at the Astros Game did not come to fruition due to the increasing numbers of COVID 19 cases in Houston, Harris County. However, we look forward to the Astros 2022 Season to hopefully be able to host a Food Allergy Friendly Day once again at Minute Maid Park.

Symposium 2021 Update: Our FAFN leader, Jennifer Mijangos, and teen advisory board member, Indrani Maitra were guest speakers of the 8th Annual Food Allergy Symposium on September 25, 2021. Last year, we had plans to travel to Beaumont, Texas to have a hybrid conference via ZOOM but, we had to cancel the meeting and have a virtual conference due to COVID-19 and the Delta Variant in our community. In spite of the change, our FAFN leaders were prepared for the virtual conference and shared their story and information about their outreach work and services delivery efforts in the community. Indrani worked with the Houston Food Bank to have allergy friendly food available for families in need of special items for their diet and well-being. She has expanded her program to other large metropolitan cities and provided an abundance of knowledge, first hand experiences and outreach throughout the United States.

Our leadership at Texas Children's Hospital, the Patient and Family Engagement Section at Texas Children's Hospital and the entire Food Allergy Staff at Texas Children's Hospital are so proud of all our FAFN leaders for the time they devote to helping families living food allergies in Houston and the surrounding areas.

The Patient and Family **Engagement Section at Texas** Children's Hospital has a monthly newsletter and feature the various support and educational groups at our hospital. The Food Allergy Program and the Food Allergy Family Network supportive services was the focus of the Texas Children's Hospital Newsletter in January 2022. Several of our families involved in FAFN wrote and send us pictures to describe their family's experience living with food allergies. (See pages 8-9)

The leaders are Texas Children's Hospital volunteers and are available to answer questions you may have about living with food allergies. They live in Houston and the surrounding areas and can provide peer support and share their experiences living with food allergies.

Food Allergy Family Network Leaders				
Name	E-mail	Houston Area	Phone Number	
Jennifer Mijangos	jenmijangos@att.net	East	(281) 793-8637	
Mike Oldham	oldham@reynoldsfrizzell.com	Central	(713) 485-7207	
Oliver Oldham	junior leader	Central		
Melanie Ringold	melanie.ringold@invesco.com	Central	(713) 214-5770	
Rahma Sarwar	rahma.sarwar@gmail.com	South Central	(832) 570-1035	
Thuy Tran	thuyatlaw@yahoo.com	West	(281) 772-9575	
Danielle Williams	daniwill78@hotmail.com	Central/North	(202) 213-9896	
Andrea Chaves Blackman	andreafchaves@hotmail.com	South	(832) 980-8029	
David Greenberg	davidavital24@gmail.com	South	(773) 450-2292	
Jyotsna Kottoor	Jyots76@gmail.com	South	(312) 731 3846	
Sherril Mackie	Shaydon903@hotmail.com	Central	(346) 316-9668	
Tammy Luster	<u>tammy_prukop@yahoo.com</u>	Southwest	(713) 254-7040	
Sachin Menon	Sachin_menon@hotmail.com	West	(281) 687-5350	
Texas Children's FAFN Support Staff				
Theresa Aldape, LMSW	tmaldape@texaschildrens.org	FAFN Liaison	(832) 824-1385	
Daisy Tran Vita, RN	dxtran1@texaschildrens.org	Lead Research Coordinator	(832) 824-3398	

Living with Food Allergies By Embracing Our Early Struggles and Helping Others Along A Similar Path

by The Oldham Family



The Oldham Family: Mike, Kristi, Oliver and Kenan



Our journey with Texas Children's began after our son Oliver, now 15, had his first food alleraic reaction in 2006 at another child's 1st birthday party. We had so many questions, and so many intense insecurities. Food alleraies were on the rise at that time, but we could find very few resources in Houston, or in Texas, to turn to. Right around that same time, Texas Children's fully embraced its mission to research the causes for food alleraies. develop desensitization methods, and work toward ways to eliminate food allergies. We are so grateful that Texas Children's leaped into the void! The TCH Food Allergy program continues to grow rapidly, and their inventive and passionate research in partnership with other institutions throughout the world is showing incredible strides.

But when we first learned that our son has lifethreatening food allergies, all we really wanted to know was how to get through a normal day without putting Oliver in harm's way, and without making him feel left out.

We had so many questions. What products are safe? What restaurants can we go to? Why does EVERY PRODUCT say it "might contain peanuts or tree nuts," regardless of their actual ingredients? How do we talk with friends or family members, who are not familiar with food allergies and may be skeptical about the severity, without upsetting or alienating them?

We quickly learned that we are not alone. Food allergies are prevalent these days, and so are caring families who remember their early fears and struggles and want to make the road a little easier for others. That is why we are so excited for the Food Allergy Family Network. It is a growing support network for families living with food allergies. You don't have to be a TCH patient, or even a local resident. It is just a way to share information, and for us all to support each other. I love it, and I am so grateful to TCH for creating and maintaining the FAFN for everyone's benefit.

Our Food Allergy Story By Thuy Tran

Our family began our food allergy journey 18 years ago, when our son Austin had his first allergic reaction to a bottle of infant formula at 3 months old. Luckily dad Sang, who also happens to be a Texas Children's Hospital pharmacist, was home when this happened and knew exactly what to do. When Austin was later tested, we discovered that he had multiple food allergies to milk protein, peanuts, tree nuts, and wheat. Our daughter Autumn was born less than two years later and she had even more food allergies than her big brother, one of which stood out among the rest: Autumn was allergic to beef!

Navigating life as parents of children with life threatening food allergies has been a challenge – from our early fears of how our kids would stay safe when food was brought into their classrooms, to episodes of food allergy bullying, to exploring



The Tran Family Sang, Thuy, Austin, & Autumn



colleges that would accommodate food allergies. Life as a food allergy family has presented us with many hurdles.

But our children's food allergies have also been an absolute blessing. When Austin & Autumn were first diagnosed, we were fortunate enough to receive support and reassurance from veteran food allergy families who understood the difficulties we were facing. We knew we were not alone. Having food allergies taught Austin & Autumn how to advocate for their safety from a young age. Most importantly, our family developed a level of empathy for others that we might not have otherwise known.

All of these blessings would not be possible were it not for our children's food allergy diagnosis. And while we've been fortunate enough to see Austin & Autumn's list of allergies get shorter over the years (we're down to just peanuts, milk protein, & a few tree nuts between the 2 of them!), our support of the food allergy community and the work done by TCH's Food Allergy Program continues to grow exponentially.

The Mijangos Food Allergy Story by Jennifer Mijangos

My daughter, Talía developed some terrible stomach pain and extreme nausea when she was in fourth grade. She missed a lot of school, and lost a lot of weight. Texas Children's did a lot of tests, and found that allergies were at the root of it - she was severely allergic to peanut. As soon as we got everything peanut-contaminated out of the house, she felt much better, and over the next year put the weight back on.

I tend to be anxious, and now she was, too. My husband and I were really scared of putting her at risk, and it seemed like all we did all day was read and re-read food labels. It was a massive relief to me to meet up with other parents in support groups who totally got what we were experiencing without me having to articulate it well.

When Texas Children's started having Food Allergy Symposiums (or when we started going to them) my husband didn't even want to go. But he tells me that when he did go, he was glad he did - he is



Talía Mijangos



very encouraged that people are working so hard on this issue that is so dear to our hearts. In his words, he felt that he could go on, and I know that's how I feel as well. From how allergies work to how to participate in social situations to how to travel safely, we have benefitted greatly from being connected to the Food Allergy Family Network. We have received so much help from Texas Children's - patient listening, great guidance on our right to carry emergency medication, and the need to have a clear plan.

We've had some scary moments, especially when Talía had a stuffed pepperoni sandwich at school and discovered her allergy to lupin. Between a reaction that wouldn't quit and her anxiety, we spent five days in the hospital. Dealing with food allergy required understanding, and we were happy to get the recommendation to see Dr. Self, a psychologist who understood that we were dealing with real risk, but needed to get our anxiety under control. Her advice was very helpful, and didn't minimize the dangers we face.

Now Talía is 21, and has been without a major reaction for years. She carries her epinephrine everywhere and advocates for herself, but I don't believe she would say she is living a limited life, just a thoughtful one.



Teenager Dating & Allergies Content Calendar

Texas Children's Hospital Social Media Series on Food Allergy

This Social Media Series is graciously funded by the Dillon Family Fund. The Food Allergy Program and the Teen Advisory Board is working with Texas Children's Social Media Team to share eight topics in 2022 to help teens be empowered to advocate for themselves and their peers with food allergies.

The first topic is "Dating and Food Allergies" and has already been posted. Be on the lookout for more food allergy posts in the official Texas Children's social media.



Texas Children's Hospital Published by Natalia Rodas @ · 1h · ④

It can be a stressful time for parents when their teenagers start dating -- and especially for parents of teens with food allergies. The Food Allergy Research & Education Teen Advisory Group shares tips for dating with food allergies: http://ow.ly/9b2f50Hv1WN



Food Allergy **Studies**

Research Studies – Open to Enrollment

FARE patient reaistry

This is an online survey study sponsored by FARE, evaluating patients with food allergies



and their caregivers. The goal is to create a registry where patients can conveniently and privately share their food alleray experiences through a simple online survey, in order to help advance food allergy research. It provides a unique opportunity for families to contribute directly to aroundbreaking food allergy research and share their personal story with the food allergy community.

Study Sponsor: Food Allergy Research and Education (FARE) Eligibility: Male or female of all ages with food allergy What is requested: Online survey completion

Preventing Asthma in High Risk Kids (PARK)

National Institute of Allergy and Infectious Diseases

This is an interventional clinical trial sponsored by the National Institute of Alleray and Infectious Diseases (NIAID/NIH). The PARK study is a randomized, double-blind, placebo-controlled trial designed to test whether two-year treatment of preschool children aged 2-3 years of age at high risk for asthma with omalizumab (anti-IgE monoclonal antibody) will prevent the progression to childhood asthma. The primary outcome of this study will measure an active asthma diagnosis and asthma severity and the secondary outcomes will measure the number of positive new allergies by skin prick testing and the decrease in number of wheezing episodes as a result of this therapy. The study is actively recruiting children between 24-47 months of age with 2-4 episodes of wheezing in the past 12 months and have at least one biological parent or sibling with a history of asthma or allergies.

Study Sponsor: The National Institute of Allergy and Infectious Diseases (NIAID)

Eligibility: The child should be between 24-47 months of age with 2-4 episodes of wheezing in the past 12 months. At least one biological parent or sibling with history of asthma or allergy.

What is requested: Monthly injection of Omalizumab or placebo, nasal swabs, saliva, blood, skin testing, environmental samples, urine, and stool sample.

(SUNBEAM)



National Institute of Allergy and Infectious Diseases



If you are interested in participating in our research trials, please email foodallergynurse@texaschildrens.org or call 832-824-3398

Systems Biology of Early Atopy



This is a prospective cohort study in which pregnant women (at any stage of pregnancy), the offspring's biological father, and the offspring will be enrolled and the offspring will be observed from birth to age 3 years.

Study Sponsor: The National Institute of Allergy and Infectious Diseases (NIAID)

Eligibility: Pregnant women age 18 years or older planning to give birth at the Texas Children's Hospital Pavilion for Women who agree to enroll offspring into the study at birth.

What is requested: Clinical assessments will be conducted, questionnaire information collected, and biological and environmental samples collected on the mother, father, and child in the prenatal, perinatal, and postnatal periods of the child's life.



Open for Enrollment Research Studies (cont.)

Outcome Measures for Eosinophilic Gastrointestinal Disease across Ages (CEGIR OMEGA)





National Institute of Allergy and Infectious Diseases

This is a longitudinal observational study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID/NIH). The OMEGA study is focused on finding the best measures to define how well a person with eosinophilic disorder is doing. Patients with eosinophilic esophagitis (EoE) and eosinophilic colitis (EC) normally undergo endoscopy and/or colonoscopy in order to have tissue specimens collected and examined microscopically. The treatments for these conditions are based on how the tissue looks. This study will follow EoE and EC patients over the course of time to see if standard questionnaires can provide an idea of how well the patients is doing. The study is actively seeking patients at least 3 years or older diagnosed with eosinophilic esophagitis (EoE), eosinophilic gastritis (EG) or eosinophilic colitis (EC). The caregiver will complete the questionnaire. An optional part of this study is to provide a sample tissue from your standard of care endoscopy and a blood sample.

A Prospective, Multicenter Study to Compare and Validate Endoscopic, Histologic, Molecular and Patient-Reported Outcomes in Pediatric and Adult Patients with Eosinophilic Esophagitis (EoE), Gastritis (EG) and Colitis (EC) Study Sponsor: National Institute of Allergy and Infectious Diseases (NIAID) Eligibility: Male or female 3 years of age or greater diagnosed with EoE, EG or EC.

What is requested: Completion of questionnaires. Optional: a sample of tissue from your standard of care endoscopy and blood sample collection.

Dupilumab Eosinophilic Gastritis Study (CEGIR DEGAS)

A phase 2 randomized double-blind, placebo-controlled clinical trial to evaluate the efficacy of Dupilumab in subjects with eosinophilic gastritis

Study Sponsor: National Institute of Allergy and Infectious Diseases (NIAID)

Expected start date: July 2021

Target enrollment: 3 patients

Eligibility: Male or female age 12 years and up with active eosinophilic gastritis as demonstrated by biopsy with a peak gastric count of \geq 30 eos/hpf in at least 5 hpfs in the gastric antrum and/or body. History by patient report of moderate to severe EG symptoms (stomach pain, stomach cramping, nausea, bloating, burning feeling in the chest, starting to eat and feeling full too guickly, loss of appetite, vomiting, or diarrhea at least 2 days per week in the 2 weeks prior to screening.

What is requested: Treatment with a shot of Dupilumab or Placebo, electronic diary completion, tissue sample from endoscopy procedure, and blood sample collection.



For more information on EGID studies, please contact Amanda Vega by phone at 832-824-0939 or email axvega6@texaschildrens.org

Food Allergy **Studies**



National Institute of Allergy and Infectious Diseases

Page 13 | Winter 2021-22

Food Allergy **Studies**



The aim of this study is to evaluate efficacy and safety of ligelizumab (a biologic medication, given as an injection), to ensure protection against peanut-allergic reactions.

Upcoming Research Studies

A 52-week, multi-center, randomized,

double-blind, placebo-controlled study to assess the clinical efficacy and safety of ligelizumab (QCE031) in decreasing

the sensitivity to peanuts in patients with

peanut alleray.

Study Sponsor: Novartis Expected start date: March 2022 Target Enrollment: 10 Eligibility: Peanut allergic children 6-17 years What is requested: Visits approximately every 4 weeks for a total of 52 weeks of treatment.

Improving Racial/Ethnic and Socioeconomic Diversity in our **Food Allergy Program**



The purpose of the study is to evaluate a program that provides allergy safe, nutritious foods to food insecure children using a recently developed online marketplace that supports patient choice in combination with 1:1 nutrition counseling. Study Sponsor: Texas Children's Hospital and Food Equality Initiative Eligibility: Contact staff for eligibility What is requested: Questionnaires



If you are interested in participating in our research trials, please email foodalleravnurse@texaschildrens.org or call 832-824-3398







Grants Awarded in 2021

Principal Investigator	Sponsor	Project Title
CARLA DAVIS, MD	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)	YEAR 3: CONTROLLING AND PREVENTING ASTHMA PROGRESSION AND SEVERITY IN KIDS WITH OMALIZUMAB
	NATIONAL INSTITUTES OF HEALTH (NIH)	A PROSPECTIVE, MULTICENTER STUDY TO COMPARE AND VALIDATE ENDOSCOPIC, HISTOLOGIC MOLECULAR, AND PATIENT-REPORTED OUTCOMES IN PEDIATRIC AND ADULT PATIENTS WITH EOSINOPHILIC ESOPHAGITIS (EOE), GASTRITIS (EG) AND COLITIS (EC)
	NATIONAL INSTITUTES OF HEALTH (NIH)	NEW HORIZONS IN THE PREVENTION AND TREATMENT OF FOOD ALLERGY - SUNBEAM
	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)	YR1: 1R34AI157948-01: SAFETY AND TOLERABILITY OF SHRIMP ORAL IMMUNOTHERAPY IN SHRIMP ALLERGIC SUBJECTS
	REGENERON PHARMACEUTICALS, INC (US)	A PHASE 3, RANDOMIZED, 3-PART STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF DUPILUMAB IN ADULT AND ADOLESCENT PATIENTS WITH EOSINOPHILIC ESOPHAGITIS (EOE).
	PFIZER, INC (US)	BAYLOR COLLEGE OF MEDICINE INFLAMMATORY DERMATOLOGICAL DISEASES FELLOWSHIP PROPOSAL FOR GENETIC CAUSES OF ATOPIC DERMATITIS
	REGENERON PHARMACEUTICALS, INC (US)	R668-EE-1877: A RANDOMIZED, DOUBLE-BLIND, PLACEBO- CONTROLLED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF DUPILUMAB IN PEDIATRIC PATIENTS WITH ACTIVE EOSINOPHILIC ESOPHAGITIS
	REGENERON PHARMACEUTICALS, INC (US)	CEGIR (DEGAS): A RANDOMIZED, DOUBLE-BLIND, PLACEBO- CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFICACY OF DUPILUMAB (ANTI-IL4RA) IN SUBJECTS WITH EOSINOPHILIC GASTRITIS DUPILUMAB EOSINOPHILIC GASTRITIS STUDY
AIKATERINI ANAGNOSTOU, MD, PHD	AIMMUNE THERAPEUTICS, INC	REAL-WORLD AR101 MARKET-SUPPORTING EXPERIENCE STUDY IN PEANUT-ALLERGIC CHILDREN AGES 4 TO 17 YEARS (RAMSES) (ARC007)
	AIMMUNE THERAPEUTICS, INC	A MULTICENTER, OPEN-LABEL, LONG-TERM SAFETY STUDY OF AR101 CHARACTERIZED ORAL DESENSITIZATION IMMUNOTHERAPY IN SUBJECTS WHO PARTICIPATED IN A PRIOR AR101 STUDY (PROTOCOL ARC008)
	FOOD ALLERGY RESEARCH AND EDUCATION, INC. (FARE)	FARE CLINICAL NETWORK (FCN) PATIENT REGISTRY DIVERSITY GRANT
	AIMMUNE THERAPEUTICS, INC	REAL-WORLD AR101MARKET-SUPPORTING EXPERIENCE STUDY IN PEANUT-ALLERGIC CHILDREN, ACTIVE TREATMENT ARM OPEN&LABEL EXTENSION STUDY (RAMSES OLE) (ARC011)
SARA ANVARI, MD	NATIONAL INSTITUTES OF HEALTH (NIH)	YEAR 3: MICRONEEDLES FOR TREATMENT OF PEANUT ALLERGY
	dbv technologies s.a. (france)	EPITOPE STUDY - A DOUBLE-BLIND, PLACEBO-CONTROLLED, RANDOMIZED PHASE III TRIAL TO ASSESS THE SAFETY AND EFFICACY OF VIASKIN® PEANUT IN PEANUT-ALLERGIC YOUNG CHILDREN 1-3 YEARS OF AGE -
	DBV TECHNOLOGIES S.A. (FRANCE)	REALISE (REAL LIFE USE AND SAFETY OF EPITOPE)
	dbv technologies s.a. (france)	EPOPEX - EPITOPE OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM CLINICAL BENEFIT AND SAFETY OF DBV712 IN PEANUT-ALLERGIC CHILDREN

Food Allergy Research Updates

RTIUM

PONSORE

Nin. Nin. ALLERGY

I







Publications by the Food Allergy Program



Davis CM, Anagnostou A, Devaraj S, Vita DT, Rivera F, Pitts K, Hearrell M, Minard C, Guffey D, Gupta M, Watkin L, Orange JS, Anvari S. Maximum Dose Food Challenges Reveal Transient Sustained Unresponsiveness in Peanut Oral Immunotherapy (POIMD study). J Allergy Clin Immunol Pract. 2021 Dec 7:S2213-2198(21)01363-5. doi: 10.1016/j.jaip.2021.10.074. Epub ahead of print. PMID: 34890827.

Cianferoni A, Jensen E, **Davis CM**. The Role of the Environment in Eosinophilic Esophagitis. J Allergy Clin Immunol Pract. 2021 Sep;9(9):3268-3274. doi: 10.1016/j.jaip.2021.07.032. PMID: 34507708. **Davis CM**. Moving FORWARD Toward Racial Equity in Food Allergy. J Allergy Clin Immunol Pract. 2021 Jul;9(7):2874-2875. doi: 10.1016/j.jaip.2021.04.066. PMID: 34246438.

Davis CM, Sampson HA. A Historical Perspective on the Substantial Progress in Understanding Eosinophilic Gastrointestinal Disease. J Allergy Clin Immunol Pract. 2021 Sep;9(9):3288-3289. doi: 10.1016/j.jaip.2021.07.033. PMID: 34507709.

COREOS Collaborators:, Ma C, Schoepfer AM, Dellon ES, Bredenoord AJ, Chehade M, Collins MH, Feagan BG, Furuta GT, Gupta SK, Hirano I, Jairath V, Katzka DA, Pai RK, Rothenberg ME, Straumann A, Aceves SS, Alexander JA, Arva NC, Atkins D, Biedermann L, Blanchard C, Cianferoni A, Ciriza de Los Rios C, Clayton F, Davis CM, de Bortoli N, Dias JA, Falk GW, Genta RM, Ghaffari G, Gonsalves N, Greuter T, Hopp R, Hsu Blatman KS, Jensen ET, Johnston D, Kagalwalla AF, Larsson HM, Leung J, Louis H, Masterson JC, Menard-Katcher C, Menard-Katcher PA, Moawad FJ, Muir AB, Mukkada VA, Penagini R, Pesek RD, Peterson K, Putnam PE, Ravelli A, Savarino EV, Schlag C, Schreiner P, Simon D, Smyrk TC, Spergel JM, Taft TH, Terreehorst I, Vanuytsel T, Venter C, Vieira MC, Vieth M, Vlieg-Boerstra B, von Arnim U, Walker MM, Wechsler JB, Woodland P, Woosley JT, Yang GY, Zevit N, Safroneeva E. Development of a core outcome set for therapeutic studies in eosinophilic esophagitis (COREOS). J Allergy Clin Immunol. 2021 Jul 6:S0091-6749(21)01059-9. doi: 10.1016/j.jaci.2021.07.001. Epub ahead of print. PMID: 34242635; PMCID: PMC8733049.Chatchatee P, Nowak-Wegrzyn A, Lange L, Benjaponpitak S, Chong KW, Sangsupawanich P, van Ampting MTJ, Oude Nijhuis MM, Harthoorn LF, Langford JE, Knol J, Knipping K, Garssen J, Trendelenburg V, Pesek R, Davis CM, Muraro A, Erlewyn-Lajeunesse M, Fox AT, Michaelis LJ, Beyer K; PRESTO study team. Tolerance development in cow's milk-allergic infants receiving amino acid-based formula: A randomized controlled trial. J Allergy Clin Immunol. 2021 Jul 2:S0091-6749(21)01053-8. doi: 10.1016/j.jaci.2021.06.025. Epub ahead of print. PMID: 34224785.

Davis CM, Apter AJ, Casillas A, Foggs MB, Louisias M, Morris EC, Nanda A, Nelson MR, Ogbogu PU, Walker-McGill CL, Wang J, Perry TT. Health disparities in allergic and immunologic conditions in racial and ethnic underserved populations: A Work Group Report of the AAAAI Committee on the Underserved. J Allergy Clin Immunol. 2021 May;147(5):1579-1593. doi: 10.1016/j.jaci.2021.02.034. Epub 2021 Mar 10. PMID: 33713767.

Publications by the Food Allergy Program

Chin A, Balasubramanyam S, **Davis CM**. Very Elevated IgE, Atopy, and Severe Infection: A Genomics-Based Diagnostic Approach to a Spectrum of Diseases. Case Reports Immunol. 2021 Sep 24;2021:2767012. doi: 10.1155/2021/2767012. PMID: 34603803; PMCID: PMC8486527.

Joshi TP, **Anvari S, Gupta MR, Davis CM**, Hajjar J. Case Report: Dupilumab Successfully Controls Severe Eczema in a Child With Elevated IgE Levels and Recurrent Skin Infections. Front Pediatr. 2021 Sep 29;9:646997. doi: 10.3389/fped.2021.646997. PMID: 34660469; PMCID: PMC8511520.

Anagnostou A, Sharma V, Herbert L, Turner PJ. Fatal Food Anaphylaxis: Distinguishing Fact From Fiction. J Allergy Clin Immunol Pract. 2022 Jan;10(1):11-17. doi: 10.1016/j.jaip.2021.10.008. Epub 2021 Oct 15. PMID: 34656799.

Anagnostou A. Addressing Common Misconceptions in Food Allergy: A Review. Children (Basel). 2021 Jun 11;8(6):497. doi: 10.3390/children8060497. PMID: 34207962; PMCID: PMC8230601.

Brough HA, Gourgey R, Radulovic S, Caubet JC, Lack G, **Anagnostou A**. Latest Developments in the Management of Nut Allergies. Curr Treat Options Allergy. 2021 Jun 15:1-14. doi: 10.1007/s40521-021-00290-2. Epub ahead of print. PMID: 34150446; PMCID: PMC8203721.

Carter MC, Saini SS, **Davis CM**. Diversity, Disparities, and the Allergy Immunology Pipeline. J Allergy Clin Immunol Pract. 2022 Jan 6:S2213-2198(22)00001-0. doi: 10.1016/j.jaip.2021.12.029. Epub ahead of print. PMID: 34999273.

Díaz Vidal VC, Gillispie A, Aranda C, **Anvari S**. Successful Elosulfase Alfa Desensitization Protocol in a Patient With Morquio A Syndrome. Pediatrics. 2022 Feb 1;149(2):e2021052648. doi: 10.1542/peds.2021-052648. PMID: 35059725.

Pongracic JA, Gagnon R, Sussman G, Siri D, Oriel RC, Brown-Whitehorn T, Green TD, Campbell DE, **Anvari S**, Berger WE, Bird JA, Chan ES, Cheema A, Chinthrajah S, Chong H, Dowling PJ, Fineman SM, Fleischer DM, Gonzalez-Reyes E, Kim EH, Lanser BJ, MacGinnitie A, Mehta H, Petroni D, Rupp N, Schneider LC, Scurlock AM, Sher LD, Shreffler WG, Sindher SB, Stillerman A, Wood R, Yang WH, Bois T, Sampson HA, Bégin P. Safety of Epicutaneous Immunotherapy in Peanut-Allergic Children: REALISE Randomized Clinical Trial Results. J Allergy Clin Immunol Pract. 2021 Nov 27:S2213-2198(21)01295-2. doi: 10.1016/j.jaip.2021.11.017. Epub ahead of print. PMID: 34848381.

Anvari S, Watkin L, Rajapakshe K, Hassan O, Schuster K, Coarfa C, **Davis CM**. Memory and naïve gamma delta regulatory T-cell gene expression in the first 24-weeks of peanut oral immunotherapy. Clin Immunol. 2021 Sep;230:108820. doi: 10.1016/j.clim.2021.108820. Epub 2021 Aug 6. PMID: 34365017; PMCID: PMC8607808. Palmieri JM, Diaz VC, Falcetano GA, Jasper CE, Chinn IK, **Anvari S**. A novel case discussion of pediatric lipid transfer protein syndrome. J Allergy Clin Immunol Pract. 2021 Oct;9(10):3836-3837. doi: 10.1016/j.jaip.2021.06.034. Epub 2021 Jul 2. PMID: 34224926.

Taylor M, **Anvari S**, Palazzi D. Unconfirmed penicillin allergy labels in the paediatric outpatient setting: A call for research and quality improvement initiatives. J Paediatr Child Health. 2021 May;57(5):607-610. doi: 10.1111/jpc.15445. Epub 2021 Mar 16. PMID: 33724610.

Blumenthal KG, Freeman EE, Saff RR, Robinson LB, Wolfson AR, Foreman RK, Hashimoto D, Banerji A, Li L, **Anvari S**, Shenoy ES. Delayed Large Local Reactions to mRNA-1273 Vaccine against SARS-CoV-2. N Engl J Med. 2021 Apr 1;384(13):1273-1277. doi: 10.1056/NEJMc2102131. Epub 2021 Mar 3. PMID: 33657292; PMCID: PMC7944952.

Anvari S, Schuster K, Grimbergen A, **Davis CM**, Makedonas G. Attenuation of GARP expression on regulatory T cells by protein transport inhibitors. J Immunol Methods. 2021 May;492:112998. doi: 10.1016/j.jim.2021.112998. Epub 2021 Feb 15. PMID: 33600819.

Szafron V, **Anvari S**, Pickett G, Staggers KA, Minard CG, Rogers J, Washington A, **Davis CM**. Assessing health-related quality of life in children with food allergy and eosinophilic esophagitis. J Allergy Clin Immunol Pract. 2021 Jun;9(6):2520-2523.e2. doi: 10.1016/j.jaip.2021.01.042. Epub 2021 Feb 9. PMID: 33577947.

Phipatanakul W, Mauger DT, Guilbert TW, Bacharier LB, Durrani S, Jackson DJ, Martinez FD, Fitzpatrick AM, Cunningham A, Kunselman S, Wheatley LM, Bauer C, **Davis CM**, Geng B, Kloepfer KM, Lapin C, Liu AH, Pongracic JA, Teach SJ, Chmiel J, Gaffin JM, Greenhawt M, **Gupta MR**, Lai PS, Lemanske RF, Morgan WJ, Sheehan WJ, Stokes J, Thorne PS, Oettgen HC, Israel E; PARK Study Team. Preventing asthma in high risk kids (PARK) with omalizumab: Design, rationale, methods, lessons learned and adaptation. Contemp Clin Trials. 2021 Jan;100:106228. doi: 10.1016/j.cct.2020.106228. Epub 2020 Nov 24. PMID: 33242697; PMCID: PMC7887056.

Nguyen DI, Sindher SB, Chinthrajah RS, Nadeau K, **Davis CM**. Shrimp-allergic patients in a multi-food oral immunotherapy trial. Pediatr Allergy Immunol. 2022 Jan;33(1):e13679. doi: 10.1111/pai.13679. Epub 2021 Oct 28. PMID: 34655480.

Anagnostou A. Optimizing Patient Care in Egg Allergy Diagnosis and Treatment. J Asthma Allergy. 2021 Jun 8;14:621-628. doi: 10.2147/JAA.S283307. PMID: 34135601; PMCID: PMC8197590.

Anagnostou A. A Practical, Stepwise Approach to Peanut Oral Immunotherapy in Clinical Practice: Benefits and Risks. J Asthma Allergy. 2021 Mar 25;14:277-285. doi: 10.2147/JAA.S290915. PMID: 33790583; PMCID: PMC8006756.

Anagnostou A. Weighing the benefits and risks of oral immunotherapy in clinical practice. Allergy Asthma Proc. 2021 Mar 1;42(2):118-123. doi: 10.2500/aap.2021.42.200107. PMID: 33685555; PMCID: PMC8133009. Baldwin S, Werther R, Hargrove A, Anagnostou A, Mehr S. Food protein-induced enterocolitis syndrome to nuts: An increasing phenomenon. Ann Allergy Asthma Immunol. 2021 May;126(5):464-466. doi: 10.1016/j.anai.2021.02.008. Epub 2021 Feb 14. PMID: 33592285.

Anagnostou A. Food immunotherapy: Choosing wisely. Clin Exp Allergy. 2021 Jan;51(1):9-13. doi: 10.1111/cea.13742. Epub 2020 Oct 18. PMID: 32970897.

Publications by the Food Allergy Program

To make a donation to the Food Allergy Program, contact: Priscilla L. Mondragón 832-824-2060 or <u>plluna@texaschildrens.org</u>