



**FARE**  
Food Allergy Research & Education



# **FARE STRATEGIC PLAN**

UPDATED AUGUST 2020

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**Elevating the  
Patient Voice  
Through Research,  
Education and  
Advocacy**

# MESSAGE FROM THE CHAIR & CEO

Food allergies are at an inflection point. Each day, we learn of investors, researchers and innovators bringing new ideas in the consumer product goods, pharmaceutical, plant science, bioengineering and research industries to fruition. We are hopeful about the promise of a safer world but alarmed at the rise of the disease.

## Once considered rare, food allergies now impact an estimated 32 million Americans.

The number of children with food allergies – 5.6 million – has doubled in less than two decades, and the prevalence of peanut or tree nut allergies in children has tripled in only 10 years. Adult food allergies are also on the rise. Among the more than 26 million U.S. adults with food allergies, nearly half developed at least one food allergy in adulthood and more than one-quarter had no food allergies as children.

Approximately two children in every American classroom have a poorly understood disease that makes each encounter with food potentially dangerous – or even deadly. Insurance claims data confirm that medical procedures to treat anaphylaxis, a severe and potentially life-threatening reaction, resulting from food have climbed sharply in recent years, up 377 percent from 2007 to 2016. Each year, one million children and more than two million adults with food allergies receive emergency treatment for anaphylaxis.

To support this growing population, FARE is bringing out the voice of the patient and fully representing the community with a focus on diversity and inclusion in all that we do in education, research and advocacy. In June 2020, FARE released the Food Allergy Consumer Journey, a two-year, three-part study which details that nearly 85 million Americans rely on labeling of top nine food allergens to manage food allergies or intolerances, and supports the need for a more transparent, standardized and universal labeling structure.

Food allergies are an epidemic for which the cause is unknown and for which the only safeguard is avoidance. With the first peanut allergy treatment approved by the Food and Drug Administration (FDA) in January 2020, it is critical that we accelerate our investments to support and create scale for the science that will mitigate risk, identify innovations in prevention that can halt the rise of the disease, and ensure that knowledge derived from our investments is disseminated to medical and technically trained professionals working with patients.

FARE has committed to raising \$200 million and has already raised nearly half of this goal, which will go a long way toward reaching the critical mass of research and investment needed to create measurable, enduring impacts for food allergy patients and their families. We invite you to be part of this historic campaign to transform the quality of life for the one in 10 Americans with food allergies.

Best regards,  
Dave Bunning (Chair) and Lisa Gable (Chief Executive Officer)





**FARE is the largest private funder of food allergy research in the world** and a critical force within a comprehensive landscape of health and wellness partners.

## **Innovation & Transformation: Together, we will advance change around the world.**

FARE is the largest private funder of food allergy research in the world and a critical force within a comprehensive landscape of health and wellness partners.

FARE aims to partner with companies and researchers on an exciting journey of discovery. There is no limit to the potential to make discoveries together. Corporate partners' product and market capacity affects billions of lives, while FARE activates communities and harnesses an extensive network of researchers and collaborators.

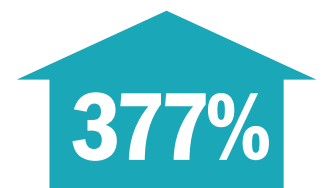
FARE is broadening our community impact with our educational programming and innovation collaboration globally. The integration of diverse and fun lifestyle content paired with engaging televisual experiences presented by leading content creators and influencers is expanding our audience by engaging the 85 million consumers impacted by food allergies or intolerances.



More than half of adults with food allergies have experienced a severe reaction.



More than 40 percent of children with food allergies have experienced a severe reaction.



Claim lines with diagnoses of anaphylactic food reactions increased 377 percent between 2007 and 2016.

# EMERGENCE OF PRIORITY INITIATIVES

FARE is transforming research, education, awareness, fundraising, advocacy and collaborations to amplify the patient voice to achieve five aims:

**1 ESTABLISHING** a baseline understanding of the disease to give us insights into how food allergies develop and to discover ways to prevent and cure them

**2 ELEVATING** the quality and accessibility of care by implementing guidelines and training

**3 EXPANDING** the number of therapies in food allergy by reducing barriers to drug development

**4 ACCELERATING** new innovations in treatment, diagnosis and patient care

**5 PREVENTING** the rise of food allergies through research



## A FIVE-YEAR CAMPAIGN TO RAISE \$200M FOR FOOD ALLERGIES

Tackling the food allergy epidemic demands game-changing advances in prevention, diagnosis and treatment, as well as outreach to all who are impacted. To achieve these key aims, FARE has launched a five-year transformative fundraising and awareness campaign to drive innovations in food allergy awareness, research, prevention and patient care. With new funding sources like the Department of Defense Authorization Bill, private funding ventures and new trial opportunities, there is great opportunity to surpass this goal.

As part of this campaign, Contains: Courage® highlights stories of patients' resilience in daily life to lead research and educate professionals and influencers protecting the food allergy community.

In addition, we are also broadening our conversations to engage the 85 million allergen-avoidant consumers by introducing the Living Teal™ channel. With many important events and occasions that bring people together being centered around food, it can be especially hard for those living with food allergies to feel included or connected. The Living Teal™ mission is to help our broad food allergy family navigate all of life's important moments, so everyone can live their best life. The Living Teal™ channel does this by integrating top-level talent with inspirational stories, educational resources, recipes, social media content, and experiences that bring the food allergy community together.

From a 2017 budget of more than \$100 for each American, **the National Institutes of Health (NIH) spent less than 20 cents on food allergy research.**



## STATE OF THE DISEASE

There is just one FDA-approved treatment for food allergy, and that treatment is limited to peanut allergy. Every day, food allergy patients have just one truly safe option, and that is to avoid their problem foods and carry epinephrine auto-injectors at all times should accidental exposure occur. A single mistake can be fatal. Coupled with the everyday burdens of fear, anxiety, vigilance and isolation are **\$25 billion in direct and indirect costs shouldered each year by families of children with food allergies.**

Important gaps in our understanding of food allergy contribute to the current, inadequate standards of care. We don't know what causes food allergy or why it has become more common, although new clues are emerging as more researchers join the field. In an era of sophisticated molecular medicine, advances in diagnostic testing for food allergies are lagging. None of the available tests can predict the severity of a patient's next food allergy reaction. The results of blood tests and skin prick tests are not always conclusive. The most accurate test – the oral food challenge – exacts a barbaric toll of stress and potential danger, especially for children who have been taught to always avoid a food but who are then required to eat that food to see if they react.

Recent research quantified the composition of the entire food allergy community, revealing that a disproportionate percentage of underserved black children are impacted by food allergies. There is a need to expand access and generate affordable solutions to better support underrepresented communities who face health disparities.

## SCALE IS REQUIRED

In addition, the progress made to date has not reached all of the families who could benefit from known advancements. While access to specialized food allergy care is improving, it remains limited, and some best practices have not been implemented effectively. For example, in 2015, the groundbreaking Learning Early About Peanut Allergy (LEAP) study showed that early introduction of peanut foods can dramatically reduce the risk of peanut allergy. Unfortunately, adoption of the 2017 federal guidelines based on that FARE-funded research has been uneven, particularly among pediatricians.

NIH spent less than 20 cents on food allergy research out of every \$100 in 2017 research expenditures, which though woefully insufficient, represented an increase in recent federal support. The initiatives identified in FARE’s plan have been strategically selected to engage and incentivize a coalition of partners – patient advocates; research foundations; clinical networks; government and non- governmental organizations; and consumer, healthcare and biopharma industries – to join us in committing resources to fight the food allergy epidemic.



## PREVENTING THE RISE OF THE DISEASE: THE START EATING EARLY DIET (SEED) INITIATIVE

Only 30% of U.S. pediatricians presently share early peanut introduction guidance with new parents, and nothing is being done to alter the rise in the other top nine food allergies. FARE has identified a unique opportunity to leverage new and existing collaborations to launch SEED, a comprehensive early introduction program. There are four connected but distinct aspects to our prevention strategy, model and approach.

**RESEARCH** In partnership with Dr. Ruchi Gupta and her team from Northwestern University Feinberg School of Medicine and Ann & Robert H. Lurie Children’s Hospital of Chicago, FARE will conduct a three-year randomized controlled trial (RCT) comparing early introduction of multiple highly allergenic foods versus standard of care in a large and diverse sample of infants.

**EDUCATION** FARE will leverage evidence-based and patient-centered insights to put into place education and support resources that make early food introduction feasible for all new parents. FARE will also develop professional education opportunities for pediatricians and registered dietitians to support patients and parents in the early introduction journey.

**AWARENESS** FARE will engage in comprehensive media and outreach efforts targeted to healthcare providers, particularly pediatricians, to emphasize integrating early introduction and food allergy prevention best practices into every infant well visit as standard care.

**ADVOCACY** FARE-established public-private partnerships will be guided by insights from our research and education efforts to push for the inclusion of multi-allergen early introduction in the 2025 U.S. Dietary Guidelines for Americans (DGA). Beyond the initial five years, long-term data collection and analysis will influence recommendations from the National Institute of Allergy and Infectious Diseases and the American Academy of Pediatrics.

# TRANSFORMING EDUCATION & AWARENESS

For more than two decades, FARE and its legacy organizations – Food Allergy Initiative and Food Allergy & Anaphylaxis Network – have worked to amplify the voices of patients with food allergies and to engage the broader community in promoting life, health and hope for all those managing food allergies.

FARE supports the strength of individuals with food allergies especially their ability to live safe, productive lives with the respect of others. Our Education and Advocacy efforts, combined with our new Living Teal initiative, position FARE to make a real difference in the lives of 85 million people including individuals with potentially life-threatening food allergies, individuals with food intolerances, and their families. FARE’s initiatives deliver stronger support than ever before to meet the needs of a diverse community.

FARE is also supporting the professionals that impact the lives of those living with food allergies through education and training to create food allergy standards and qualifications across the public health and medical communities.

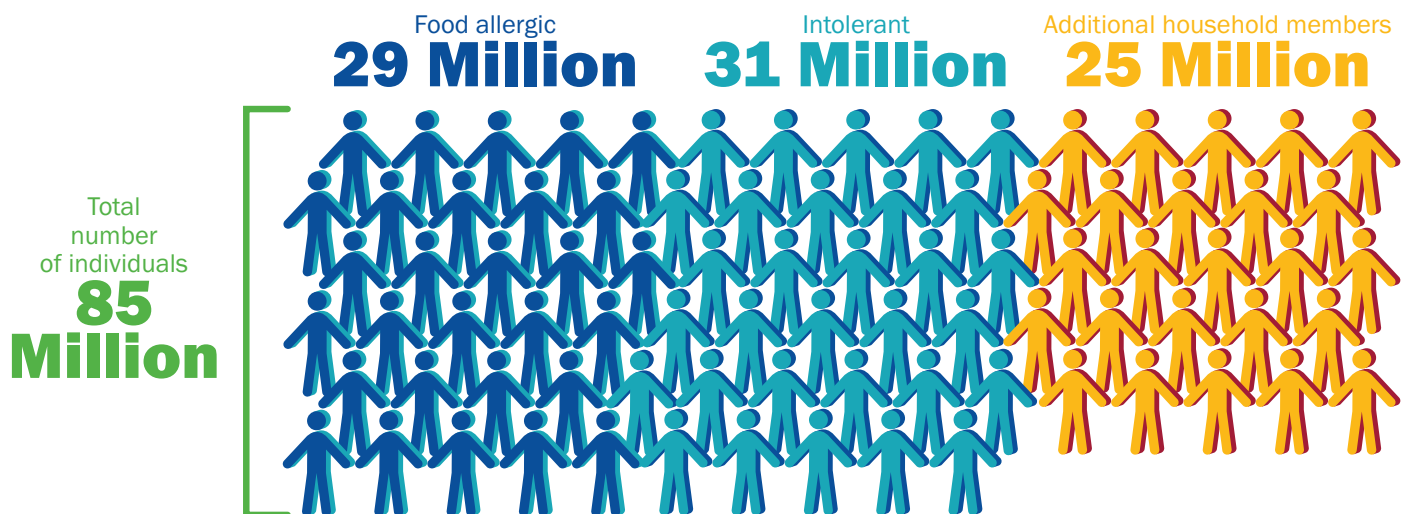


# PRIORITY INITIATIVES

- **Provide state-of-the-art, evidence-based education** to patients with food allergies and their families
- **Elevate the voice of the patient** with a dedication to diversity, equity, inclusion and access
- **Support professionals with up-to-date education and training in food allergy**, such as dietitians, allergists, school staff and food service personnel in a variety of settings
- **Inform new parents and physicians on the benefits of early introduction** and provide resources that make it feasible for all, like the BabysFirst.org microsite launched in 2020
- **Provide educational resources and opportunities** that support the K-12 and college/university settings to benefit students who live with food allergies and their families

## GOING BEYOND THE FOOD ALLERGIC

85M PEOPLE AVOID ONE OF THE TOP NINE ALLERGENS







## VOICE OF THE PATIENT: DIVERSITY AND INCLUSION

FARE has launched a set of initiatives dedicated to ensuring each and every individual's needs are met and that all members of the community have a seat at the table. We are committed to:

- **BUILDING TRUST ACROSS AND WITHIN ALL COMMUNITIES** to achieve a more accurate representation in FARE programs and research, ensuring inclusion of the entire food allergy community.
- **BETTER UNDERSTANDING THE NEEDS AND PREFERENCES** of the diverse patient community, including precautionary allergen labeling on the foods they buy for their families.
- **TAILORING FARE'S PATIENT-CENTERED RESEARCH ACTIVITIES** to uncover therapies, diagnostics and treatments that are more accessible and affordable for under-resourced communities.
- **LEADING AND COLLABORATING** on advocacy efforts to improve access and achieve affordable solutions to food allergy diagnosis and treatment for underrepresented communities.
- **CREATING LEADERSHIP PATHS** for Black business leaders, researchers and advocates in the food allergy patient and public health communities.

# ACHIEVING LEGISLATIVE & REGULATORY IMPACT THROUGH ADVOCACY

FARE has achieved many great successes in advocacy over the years, passing more than 100 pieces of legislation across the country with the help of dedicated advocates who established comprehensive food allergy guidelines in schools, allowed public entities to stock non-designated epinephrine auto-injectors, improved food allergy training in restaurants, and much more. In 2020, FARE actively advocated in support of legislation, the FASTER Act, H.R. 2117, S. 3451, introduced in both houses of Congress to make sesame the ninth labeled allergen and increase government spending on food allergy research.

As we look to the future and the challenges facing families with food allergies, we must ensure that the new and innovative treatments being developed today to desensitize and eventually cure food allergies are approved by the FDA and must improve access and achieve affordable solutions for underrepresented communities.

Over the next five years, FARE is expanding its advocacy capacity and capabilities with a multi-million dollar investment that will allow deeper engagement on the issues most important to our community and will elevate the organization's expertise and skills to better traverse the challenging terrain ahead. We will strengthen our relationships with federal agencies to affect action in Washington, D.C., for the food allergy community.

In utilizing best-in-class technology to grow our community of engaged advocates, we are bringing personal stories to the decision makers who can help make much-needed progress toward all of our policy goals. We will continue to influence the environment by utilizing the media and partnering with other organizations who share our goal of increasing awareness and education around food allergies, and establishing legislation and regulations that address the needs of the community.

## PRIORITY INITIATIVES

- **Secure enactment of the FASTER Act** (HR 2117 and S.3451)
- **Seek and secure \$200 million** in annual federal funding for food allergy research
- **Reduce regulatory barriers** to development of food allergy therapies, particularly enabling more treatment options for the full and diverse population of food allergy patients
- **Improve coverage and reimbursement of food allergy treatment**, which will spur new entrants into the market and encourage more allergists to enter the field
- **Ensure the voice of the patient is heard across key federal agencies** including National Institute of Allergy and Infectious Diseases (NIAID), U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), U.S. Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC)
- **Consideration of the underserved patient perspective** and implications for access to healthcare and candidate drugs based on affordability and ease of adoption



# TRANSFORMING RESEARCH & INNOVATION

FARE initiatives span education, awareness, advocacy and collaborations to amplify the patient voice, but our primary focus is developing advanced treatments and clinical options for our community. We are establishing foundational research platforms that enable clinicians and scientists to collaborate and access critical food allergy-related data to advance research, and we are accelerating new innovations through clinical trials, fundamental scientific studies and translational research initiatives to achieve four key strategic implementation goals:

- 1** **ACHIEVING** long-term desensitization to multiple allergens
- 2** **DEVELOPING** preventative therapies
- 3** **ASSESSING** and monitoring disease activity
- 4** **UNDERSTANDING** disease biology


## FARE'S COMMITMENT TO RESEARCH AND ADVOCACY HAS HELPED SPUR



**1,200%**  
increase in clinical trials  
for new therapies



**400%**  
increase in the number  
of patients enrolled in  
clinical trials



**\$100 Million**  
FARE investment in food  
allergy research



# ELEVATING QUALITY OF ACCESSIBILITY AND CARE FARE CLINICAL NETWORK

The FARE Clinical Network is a nationwide coalition of top food allergy research and clinical care centers coordinated and led by FARE. Since its launch in 2015, the FARE Clinical Network has advanced patient care and treatment while improving the quality of life for 32 million people impacted by food allergies. In addition to offering exceptional patient care across the country, food allergy centers in the Network are translating their research into best-practice recommendations that can be widely communicated and adopted to impact the care received by an even broader population of food allergy patients.

Recognizing critical needs within the food allergy community and unprecedented opportunities for advances in research, the FARE Clinical Network was expanded in 2020 to encompass 48 institutions located in 22 states and the District of Columbia, with additional sites anticipated in the future. The FARE Clinical Network now includes three types of Centers of Distinction, which draw on the individual strengths of each participating institution while ensuring that top-quality care is available in more communities:



## **DISCOVERY CENTERS OF DISTINCTION:**

World-class research network leading novel, consortia-based investigations



## **CLINICAL RESEARCH CENTERS OF DISTINCTION:**

Premiere clinical study network for conducting food allergy trials



## **CLINICAL CARE CENTERS OF DISTINCTION:**

Exceptional providers that deliver the best standard of care



# 48

Centers of Distinction in 22 states and Washington, D.C.



# 20,000

Oral food challenges given to patients



# 100,000

Food allergy patients seen at Centers of Distinction

# FARE DATA COMMONS



To expand the tools available to food allergy researchers, including those in the FARE Clinical Network, FARE is collaborating with the Center for Food Allergy and Asthma Research (CFAAR) at Northwestern University to develop the FARE Data Commons. This centralized patient data platform will enable medical entities around the globe to share and access privacy-protected data through a single point of contact, facilitating new collaborations to drive research forward, and ultimately leading to faster discoveries for food allergy patients.

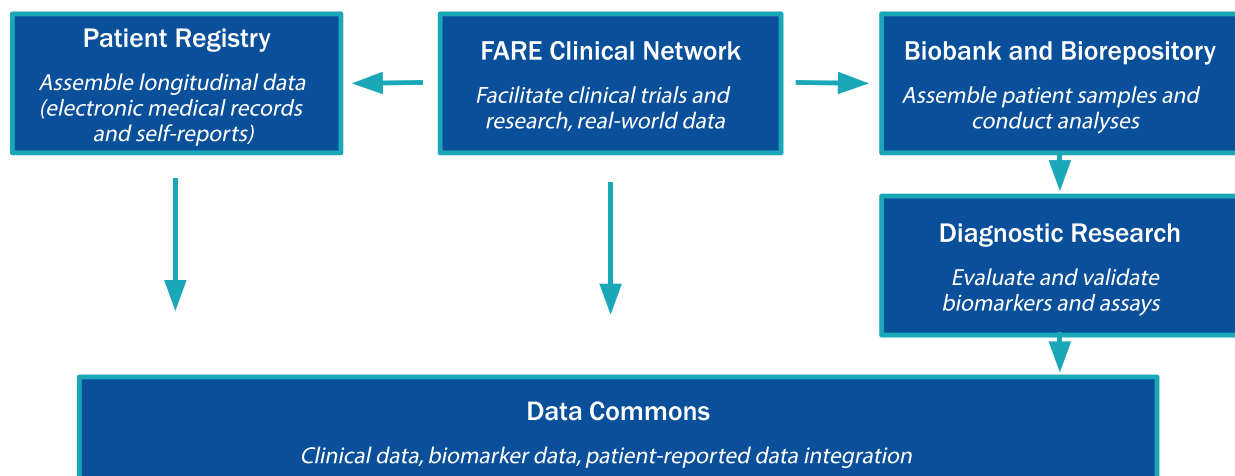
In addition to the FARE Clinical Network, the platform will also incorporate electronic data from the FARE Patient Registry, FARE Biobank and Biomarker Discovery Center, and other partnered sources of clinical research, clinical care and patient data.

FARE is working with the FARE Clinical Network and local organizations to broaden the demographics represented in the Patient Registry, with a focus on diverse and underserved populations. This will enable the information patients and caregivers provide to be more reflective of the diverse food allergy community.

## FARE DATA COMMONS KEY SOURCES

- **FARE Patient Registry** – A secure database through which food-allergic patients and their caregivers share health information with the research community. Enrolling 11,000+ participants since its 2017 launch, it is the largest registry capturing food allergy disease patterns of U.S. children and adults. FARE is working to expand the size and demographic breadth of the FARE Patient Registry to reflect the diverse food allergy community.
- **FARE Biobank and Biomarker Discovery Center** - A biorepository providing de-identified biological samples linked to de-identified electronic medical records data.
- **Data Coordinating Center** – An information hub enabling the collation and cross-referencing of data and that is responsible for coordinating the procedures and logistics of multi-center clinical trials within the FARE Clinical Network.

The following chart illustrates the flow of information and data within FARE's foundational research platforms.





# ACHIEVING LONG-TERM DESENSITIZATION TO MULTIPLE ALLERGENS

Recent years have seen the development and testing of therapies to treat single-food allergies including a peanut-based oral immunotherapy that is the first food allergy treatment to receive approval from the FDA. There are a number of therapies based on single food allergens currently at varying stages of drug development, but such products cannot address the full burden of disease for the estimated 14 million Americans who have allergies to more than one food.

## COMBINE TRIAL

FARE and Dr. Kari Nadeau's team at the Stanford University Sean N. Parker Center for Allergy and Asthma are embarking on the COMBINE Trial, a state-of-the-art, multi-allergen clinical study. This breakthrough two-phase multi-allergen trial uses two biologics in concert, with the goal of long-term desensitization of patients to food allergens. The COMBINE Trial is poised to take the next leap in oral immunotherapy (OIT) and bring multi-allergen solutions to all food allergy families.

- **A trial** of 110 patients with multiple food allergies, ages 6 to 25 years
- **Three cohorts** will allow the comparison of unique biologics and OIT treatment regimens

FARE's unique resources include the **world's largest registry of food allergy patients.**





# DEVELOPING PREVENTATIVE THERAPIES

## Start Eating Early Diet (SEED): A Groundbreaking Multi-Allergen Clinical Study

SEED is built on a groundbreaking multi-allergen clinical study that can change the trajectory of the food allergy crisis by further validating the benefits of early allergen introduction to reduce the risk of developing potentially life-threatening allergies and then scaling our findings globally. FARE is partnering with pediatricians from Northwestern University Feinberg School of Medicine and Ann & Robert H. Lurie Children’s Hospital of Chicago to conduct a comprehensive clinical study in multi-allergen early introduction that will be informed by patient insights.

This research is complemented by coordinated education, awareness-building and advocacy activities that seek to increase the practice of early introduction of foods. To ensure SEED’s success, FARE is leveraging new and existing collaborations with its medical advisors, the FARE Clinical Network, sister organizations, professional societies, federal and state legislators, and our dedicated philanthropic community.

## SEED STUDY

- **Qualitative and quantitative findings** on early allergenic food introduction and current infant feeding practices among U.S. families will help shape the trial design to maximize compliance and improve the effectiveness of ongoing educational and awareness-building activities on early introduction and prevention.
- **Beginning in 2021, FARE and Northwestern University** will conduct a randomized controlled trial (RCT) comparing early introduction of multiple potentially allergenic foods versus standard of care in a large and diverse sample of infants





# ASSESSING AND MONITORING DISEASE ACTIVITY

FARE’s goal of assessing and monitoring food allergy activity focuses on two crucial areas of research: (1) identifying and validating food allergy biomarkers and (2) replacing the oral food challenge.

Food allergy, a complex disease involving multiple systems, requires much more research to fully understand the root causes. Such research will accelerate innovation in food allergy treatment, whether through prevention to block disease onset, interception to arrest disease development, or a cure to eliminate food allergy completely and restore health.

## BIOMARKER RESEARCH INITIATIVE

**FARE’s Biomarker Research Grants Program** is focused on identifying and validating novel food allergy biomarkers that will impact and boost many aspects of food allergy research, from prediction to disease monitoring, the development of possible therapies, and beyond.





# ASSESSING AND MONITORING DISEASE ACTIVITY

## FAITH CHALLENGE (Food Allergy Identifier, Testing Humanely):

The currently accepted best practice for determining if someone is allergic to a food is to have them ingest it until they have an allergic reaction, which can be severe and require life-saving medication. The oral food challenge, as this practice is known, is a massive barrier to care, a significant hindrance to the acceleration of drug research and an archaic practice that needs to be eliminated.

FARE is launching the FAITH Challenge - a three-pronged, multi-million-dollar competition to replace the oral food challenge (OFC) and create a new gold standard for diagnosing food allergy and assessing tolerated food allergen thresholds, eliminating one of the biggest barriers to care. The FAITH Challenge will attract the best minds to develop and employ innovative technologies that will lead to a simple diagnostic test for food allergy.

## FAITH CHALLENGE

- **A \$1 million prize** will be awarded to the team or teams that offer the best chance at advancing this diagnostic to the end point.
- **FARE** will confer a \$2 million award on a group whose assay demonstrates strong potential utility for diagnosing food allergy and a strong plan for clinical validation.
- **FARE** has created a multi-faceted awareness campaign and will broadcast this opportunity globally to reach groups inside and outside the U.S. that are working on candidate diagnostics.





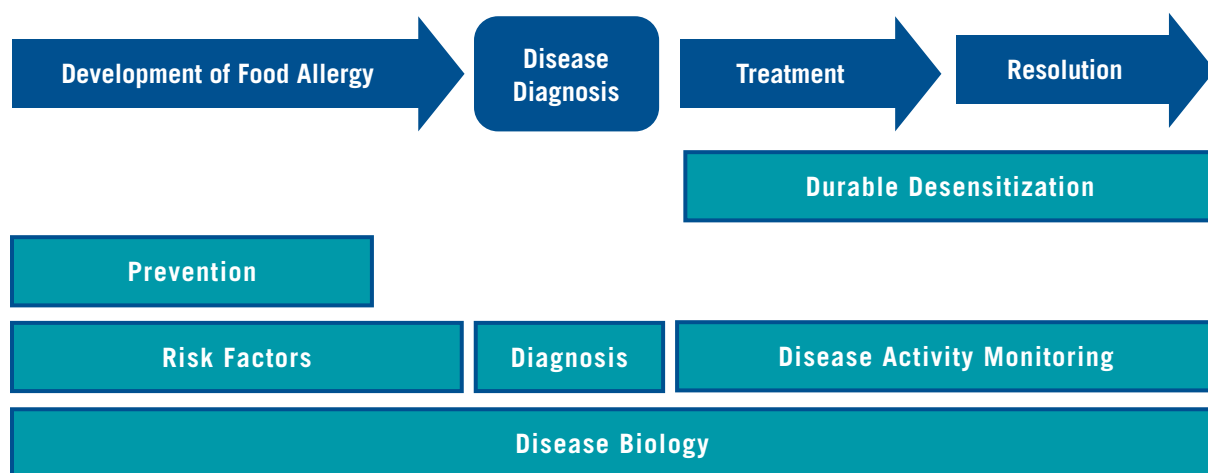
# UNDERSTANDING DISEASE BIOLOGY

Researchers have long believed the major driver behind food allergy is a dysregulated immune system that overreacts to particular stimuli – in this instance, food proteins – triggering allergic reaction. Despite decades of investigations based on this premise, food allergy remains poorly understood. New directions and innovative approaches are vital to achieve needed advances in diagnosis and treatment.

## NEUROIMMUNE SCIENTIFIC STUDY

**FARE** is partnering with the Broad Institute of MIT and Harvard on an unprecedented, comprehensive research program that will focus on the role of the nervous system in food allergy. By gaining a better understanding of the biology of brain-gut interactions in food allergy, we will uncover new pathways and targets, thereby expanding opportunities for future drug discovery efforts that culminate in the development of novel treatments for food allergy.

## FARE RESEARCH GOALS TAKE HOLISTIC APPROACH





# JOIN US

Growing recognition of the food allergy epidemic and advances in biomedical research have brought us to an inflection point, a time with great potential for change. The strategic investments proposed in this plan will lay the groundwork for breakthroughs in food allergy research, education, advocacy and awareness. Every dollar raised will bring us closer to improving the quality of life and the health of individuals with food allergies and providing them hope through the promise of new treatments.



**FARE**

Food Allergy Research & Education

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