FARE Diagnostic Challenge

Call for Applications:

FARE INNOVATION AWARD DIAGNOSTIC CHALLENGE

A global, multi-million-dollar competition designed to promote crucial innovation in food allergy diagnosis

GOAL: Develop and validate a safe, accurate, innovative and accessible diagnostic alternative to the oral food challenge (OFC)

Background

The most common and accurate method currently used to diagnose individuals with food allergy is the decades-old oral food challenge (OFC). When a patient reports an allergy to a specific food, OFC testing requires that the patient eat that food in gradually increasing amounts while under medical supervision. While generally safe, OFCs expose allergic patients to potentially serious food allergy reactions. Due to the risks involved, an OFC can also have a long-lasting impact on patient anxiety and mental health.

At present, OFC is the most reliable way to diagnose or rule out a true food allergy. As such, it is frequently used as a baseline and endpoint for immunotherapy, and is also used by regulatory agencies to evaluate the efficacy of new treatments. Because the OFC can be a time-consuming and stressful experience for patients, reliance on the OFC complicates care management, stifles innovation, and creates barriers to patient enrollment in clinical research, as there is currently no other widely accepted measure to assess a patient's sensitivity and reactivity prior to commencing therapy. Patients, caregivers, and innovators seek to measure clinically relevant food allergy using an advanced, simple-to-administer test that is validated and regulatory agency-accepted. Development of an reliable, easy-to-use alternative to the OFC will facilitate advances in food allergy diagnosis, management, treatment, and clinical research.

The overarching purpose of this global effort is to fill critical scientific and technical gaps needed to advance strong candidate food allergy biomarkers toward diagnostic use in clinical practice and as clinical endpoints in clinical research and regulatory decision-making.

FARE Innovation Award Diagnostic Challenge Overview

The FARE Innovation Award Diagnostic Challenge ('the Challenge') is a collaborative, multi-year, multi-million-dollar, staged competition designed to accelerate research and technological innovation in food allergy diagnostics to achieve the goal of a suitable OFC alternative. A series of incentive awards are available for teams to develop and validate innovative technologies that will lead to a simple point-of-care test to both diagnose food allergy and quantify treatment effect (i.e., suitable for use as a primary efficacy endpoint). We intend for this new gold standard to be more accessible and easier to administer than OFC to diagnose food allergy.

FARE Diagnostic Challenge

Challenge Stages

Exploration Stage: Closed
During this first stage, each team participating in the Challenge was offered an opportunity to prove their concept and potentially receive modest financial incentives. At the end of the Exploration Stage, a ***$1 million (USD) cash prize*** was awarded to the team that offered the best chance at advancing this diagnostic to approved clinical practice. The team awarded for its Exploration Stage proposal was a global, academic and industry collaboration led by Beckman Coulter Life Sciences for their next-generation basophil activation test (BAT). This stage is now closed.

Assessment Stage: Open
Investigators who enter during (or advance to) the Assessment Stage will have the opportunity to demonstrate the clinical utility and performance characteristics of their assay(s). At the end of this second stage, FARE will confer a ***$2 million (USD) cash prize*** to a group (or groups) whose assay or approach demonstrates strong potential utility for diagnosing food allergy and who offers a strong plan for clinical validation. Approaches, processes, equipment, reagents, assays, or other proposals that may be complimentary to those used in the collaboration led by Beckman Coulter Life Sciences may be submitted as well. Proposed work should aim to be completed in 18-24 months of award initiation.

Please note: Exploration Stage (i.e., Round 1) applicants are both eligible and encouraged to reapply during the Assessment Stage (Round 2), but are not required to utilize the same proposal or strategy as previously employed. Completely novel or different approaches with or without collaboration may be proposed.

Validation Stage: *Not yet started*
FARE will focus resources on the most promising assay to confirm and clinically validate assay characteristics, examining additional variables at expanded testing sites. This will involve coordination with potential industry partners on assay development and potential commercialization with the goal of making the assay readily available and recognized by regulators as a suitable diagnostic.

Commercialization Stage: *Not yet started*
Building on relationships formed during the Validation Stage, the goal of the Commercialization Stage is to firmly establish the industry partnerships needed to standardize, create, and distribute assay kits for broader clinical use.

Regulatory Pathway
Ultimately, the new assay will be proposed to regulatory agencies as an alternative to the OFC, following all guidance for *in vitro* diagnostic products. This process may include a series of meetings to obtain agency recommendations prior to submission. Additional supportive documentation for approval may be required.

The Challenge is open to all applicants, whether academic or industry-based. Consortia of multiple investigators across multiple institutions and organizations are also encouraged to apply to the Challenge as collaborative teams.

Each Challenge team participating in this competition is responsible for funding research and development costs, publications, and reproduction of results necessary to validate their tool. For budgetary questions, please contact innovation@foodallergy.org.

The FARE Innovation Award Diagnostic Challenge is made possible by its generous supporters, including the Naddisy Foundation, the Carter Family, Nestlé Health Science, the Trachte Family, the Hittman Family Foundation, Dr. Louise Matthews, and Thomas Flickinger, Wende Fox Lawson and Jim Lawson, Stacy and Ron Klein, and an anonymous donor.

FARE reserves the right to split the $2M incentive prize among two or more compelling proposals based on innovative approach, clinical readiness, and proposal quality. In the event of a prize split, the minimum sum awarded to any one group would be $500,000 (USD).

Definition of a Successful Diagnostic as an Alternative to the Oral Food Challenge

This tool will be a combination of biomarker-based test(s) coupled with decision algorithms based on robust clinical science, and will be used alongside available medical history. The tool should also be applicable in clinical research settings as part of food allergy therapy as well as regulatory decision-making. The ideal candidate diagnostic to provide an OFC alternative should meet all or most of the following attributes:

- Potential applicability for multiple allergens
- Stand-alone assay not requiring additional laboratory-based testing
- Ideally quick turn-around time
- Ease of execution; not technically demanding
- Not heavily dependent on sophisticated instrumentation
- High sensitivity, high specificity, and robust reproducibility (using same samples)
- Ease of interpretation of results
- Meaningful employment in conjunction with patient medical records and history to confirm diagnosis and enable longitudinal tracking
- Comparable utility to oral food challenge
- Enables determination of risk for severe allergic reactions

Some additional criteria will be considered:

- Prior clinical utilization at multiple clinical sites
- Supportive data
- Ease of adoption and repetition
- Does not require discovery phase to identity candidate biomarkers
- Near-term evaluation potential
- Potential to use existing clinical samples to confirm utility
- Comparative food challenge data available

Additionally, proposals employing approaches, processes, equipment, reagents, assays, or other methods and collateral that may complement the work that is being conducted within the collaboration led by Beckman Coulter Life Sciences to develop a next-generation basophil activation test (BAT) may be submitted as well and considered for award.

FARE Diagnostic Challenge

Additional Information

- Applicants shall be responsible for filing patent protection for each invention or discovery conceived, reduced to practice, or developed as a result of performance. FARE will not have any responsibility for the expenses associated with filing for or maintaining patent protection.
- In exchange for financial support, candidates agree to grant FARE a fully paid up, non-exclusive, perpetual, sublicensable research license to any invention made.
- FARE teams and expert reviewers will be the only individuals reviewing all plans in their entirety. All reviewers must sign a non-disclosure agreement prior to review activities and will recuse themselves from reviewing any proposal where there may be a conflict of interest.
- Specific funding milestones will be developed and provided to each finalist, with progress regularly monitored.
- Incentive prizes will fund direct costs and cap indirect costs at 10 percent.
- Any individual, organization, business, or institution is eligible to apply.
- Finalists may be requested to provide additional information after submissions are received..

Planned Timeline

June 2023 — Launch of Challenge Round 2, Request for Applications
July 31, 2023 — Deadline for Letters of Intent (LOIs)
August 2023 – Applicants notified of decision to proceed to Full Submission
October 31, 2023 – Deadline for Full Submission
December 2023 to **January** 2024 **–** Comprehensive Reviews of Full Submissions
February 2024 **–** Outreach to applicants for additional information as needed
March 2024 **–** Panel Consensus on Finalist(s)
April 2024 **–** Finalist(s) and all applicants notified of award decision
May 2024 **–** Announcement of Finalist(s) for Second Incentive Prize of $2 million (USD)

Additional Timeline Details

- **July 31**, 2023: Letters of Intent (LOIs) due by 11:59 p.m. ET, submitted via the FARE Grants Management Portal.
- **October 31**, 2023: Final Submissions due by 11:59 p.m. ET, submitted via the FARE Grants Management Portal.

Where to Apply

Applicants should submit their materials on the FARE Grants Management Portal. Please contact innovation@foodallergy.org for information on how to register on our Grants Management Portal.

Letter of Intent Requirements (Mandatory Step)

Interested applicants should submit, no later than July 31, 2023, a Letter of Intent discussing the following:

- Principles and science behind the biomarker-based diagnostic tool
- Access to an established bench-grade / research biomarker method or technology

- Tool's alignment with preferred diagnostic criteria as defined above
- Any access to biospecimens from patients with confirmed food allergy as well as from healthy individuals as negative controls
- Approach to clinical validation of the biomarker(s)
- Credentials and qualifications of the investigative team and infrastructure
- Identified lead investigator to serve as main point of contact
- Proposed budget and timeline

LOIs should be submitted on the FARE Grants Management Portal and are limited to 1,500 words, excluding references or proposed budget and timeline. Applicants are encouraged to provide only those references that are directly relevant to the assessment of the LOI. Please contact innovation@foodallergy.org for information on how to register on our Grants Management Portal.

Expected Full Submission

Applicants invited to the Full Submission stage should submit, no later than October 31, 2023, a full submission package with the following:

- Research and Business Plan: Maximum of 10 pages, not including Appendix.
  Must include a mechanistic description, product details if applicable, intellectual property (IP) status, and a plan for approval processes, market application, and commercialization.
  - Title and Team Members
  - Executive Summary: Project goal(s) and how these specifically address the Challenge
  - Scientific Plan and Supporting Evidence
    - Detailed description of proposed tool
    - Mechanistic detail and scientific rationale
    - Inclusion of supporting data
  - Market Viability and Path to Commercialization
    - Market / competitor analysis
    - Stakeholder analysis (e.g., health care providers (HCPs), patients, regulators, payors)
    - Reimbursement strategy / process / compensation
    - Partnerships needed / desired
    - IP status
  - Timeline, Key Milestones and Funding Plan
    - Development and approval / certification plan
    - Investment needed to reach specific, key milestones; estimated time required to reach each milestone
    - Risks and gating factors (e.g., patient recruitment, samples, quality control (QC))
    - Disclosure of any existing funding sources and staging
  - Appendix
    - Team biosketches
    - Current pending grants and investments
    - Institutional assurances
    - Facilities and equipment descriptions as appropriate for tool development and validation
    - References / citations