Biologics, Epicutaneous Immunotherapy (EPIT), and the Pipeline: Shifting the Food Allergy Paradigm

Food Allergy Support Team (FAST) OIT 9th Annual Meeting – Dallas, TX: June 12-13, 2026

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Conflict of Interest & Disclosures

Transparency Statement

Current Speaker: ARS Pharmaceuticals (Makers of **neffy®** [epinephrine nasal spray]) ARS Pharmaceuticals

Prior Speaker: Aimmune Therapeutics (Regarding **Palforzia®** [Peanut Allergen Powder-dnfp])

Unlabeled/Unapproved Uses: This presentation will discuss investigational pipelines, off-label biologic applications, and emerging therapies not yet fully approved by the FDA.

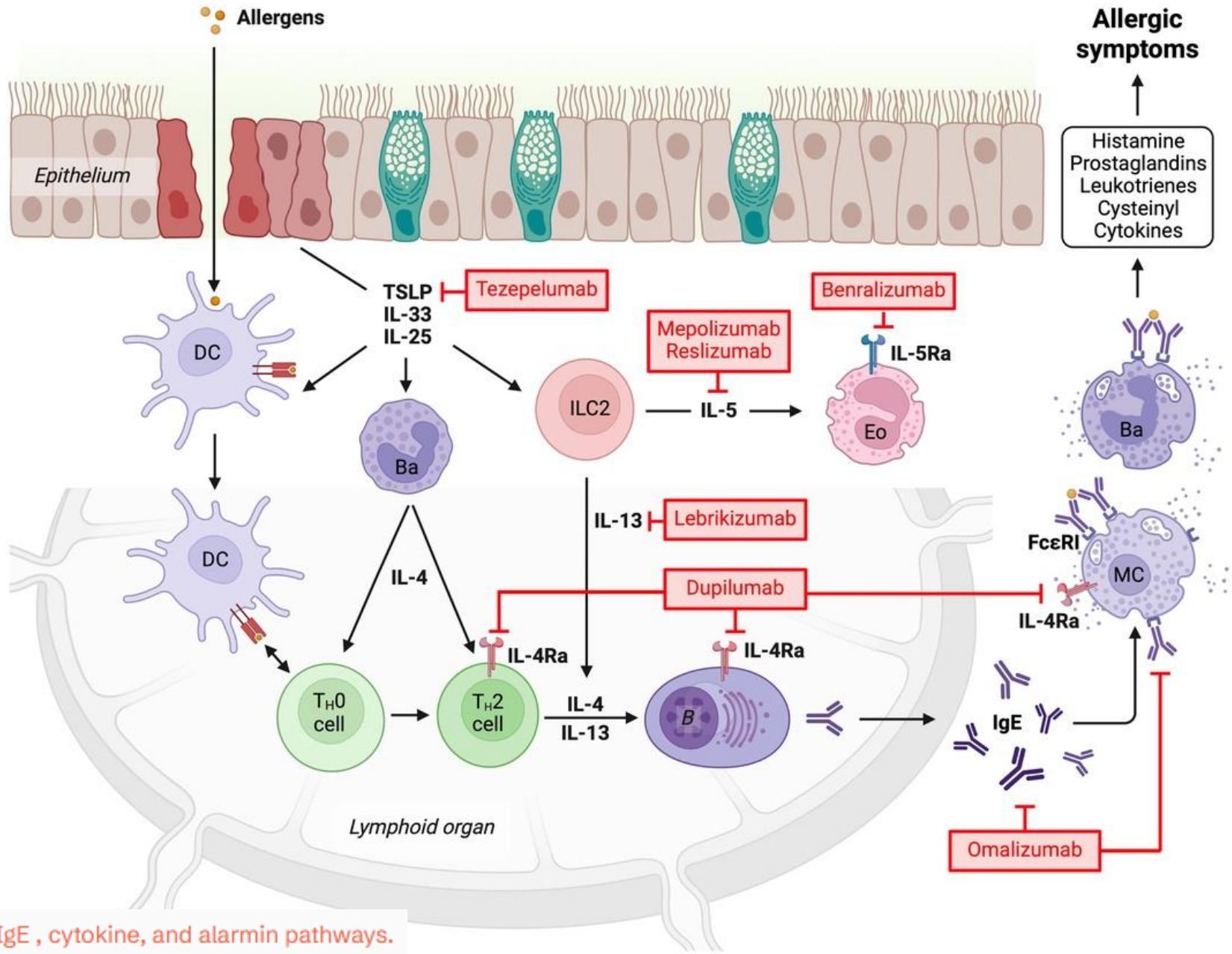
Yes, I'm giving the Biologics talk. Please don't throw tomatoes at me yet…

- Yes early introduction works
- Yes SLIT works
- Yes OIT works
- But it's still not for everyone in every season of their lives
- Anaphylaxis & attrition
- Anxiety & fear
- WE NEED OPTIONS FOR THAT GROUP OF PATIENTS WE ARE MISSING out on treating who NEVER WANT TO EVER PUT THEIR ALLERGEN FOOD IN THEIR MOUTH.

Core Objectives:

- Evaluate modern advanced therapeutics, comparative trial data, and actionable selection trees to safely advance beyond standard OIT monotherapy.

Key intervention points of approved monoclonal antibodies along the allergic cascade, providing context for the biologic targets discussed



Therapeutic monoclonal antibodies in allergy: Targeting IgE , cytokine, and alarmin pathways. Immunol Rev. October 31, 2024.

The Multi-Food Milestone: The OUtMATCH Trial Omalizumab

The NEW ENGLAND JOURNAL of MEDICINE

CURRENT ISSUE SPECIALTIES TOPICS

ORIGINAL ARTICLE

Omalizumab for the Treatment of Multiple Food Allergies

Authors: Robert A. Wood, M.D., Alkis Togias, M.D., Scott H. Sicherer, M.D., Wayne G. Shreffler, M.D., Ph.D., Edwin H. Kim, M.D., Stacie M. Jones, M.D., Donald Y.M. Leung, M.D., Ph.D., +31, and R. Sharon Chinthrajah, M.D. Author Info & Affiliations

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Omalizumab

- **Anti-IgE Monotherapy for Multi-Food Allergy**
- **Trial Name:** OUtMATCH Phase 3 (Published in NEJM Feb 2024)
- **Inclusion Criteria:**
  - Ages 1 to 55 years (mainly pediatric cohort).
  - Documented allergic reactions to peanut **AND** at least two other common foods.
  - Baseline eliciting dose (ED) $\leq$ 100 mg of food protein during double-blind, placebo-controlled food challenge (DBPCFC).
- **Primary Endpoint:** Proportion of pts tolerating a single dose $\geq$ 600 mg of peanut protein without dose-limiting symptoms at Week 16 to 28.
- **Secondary Endpoints:** Consumption of $\geq$ 1000 mg of peanut protein, and $\geq$ 600 mg of other target foods (milk, egg, wheat, cashew, hazelnut, walnut).
- **Multi-Food Endpoint:** Proportion tolerating $\geq$ 1044mg combined protein from 3 foods simultaneously

OUtMATCH Trial Design & Patient Population

Inclusion Criteria

- **Age:** 1 to 55 years old (177 children & adolescents 1-17yo)
- **Sensitivity:** Peanut allergy plus ≥ 2 other foods (milk, egg, wheat, cashew, hazelnut, walnut).
- **Lab Testing:** Skin prick test wheal ≥ 4 mm and food-specific IgE ≥ 6 kU_A/L.
- **Baseline Threshold:** Objective reaction to ≤100 mg peanut protein and ≤300 mg other food proteins.
- **Biologics:** Weight and total serum IgE must match the standard omalizumab dosing chart.

Exclusion Criteria

- **Asthma:** Severe or poorly controlled asthma or atopic dermatitis.
- **Past Reaction:** History of severe anaphylaxis causing neurological compromise or requiring intubation.
- **Recent Therapy:** Food immunotherapy or monoclonal antibodies within 6 months of screening.
- **Gastrointestinal:** Active or past diagnosis of Eosinophilic Gastrointestinal Disease (EGID).
- **Medication:** Systemic corticosteroid use lasting > 2 days within 30 days of screening.

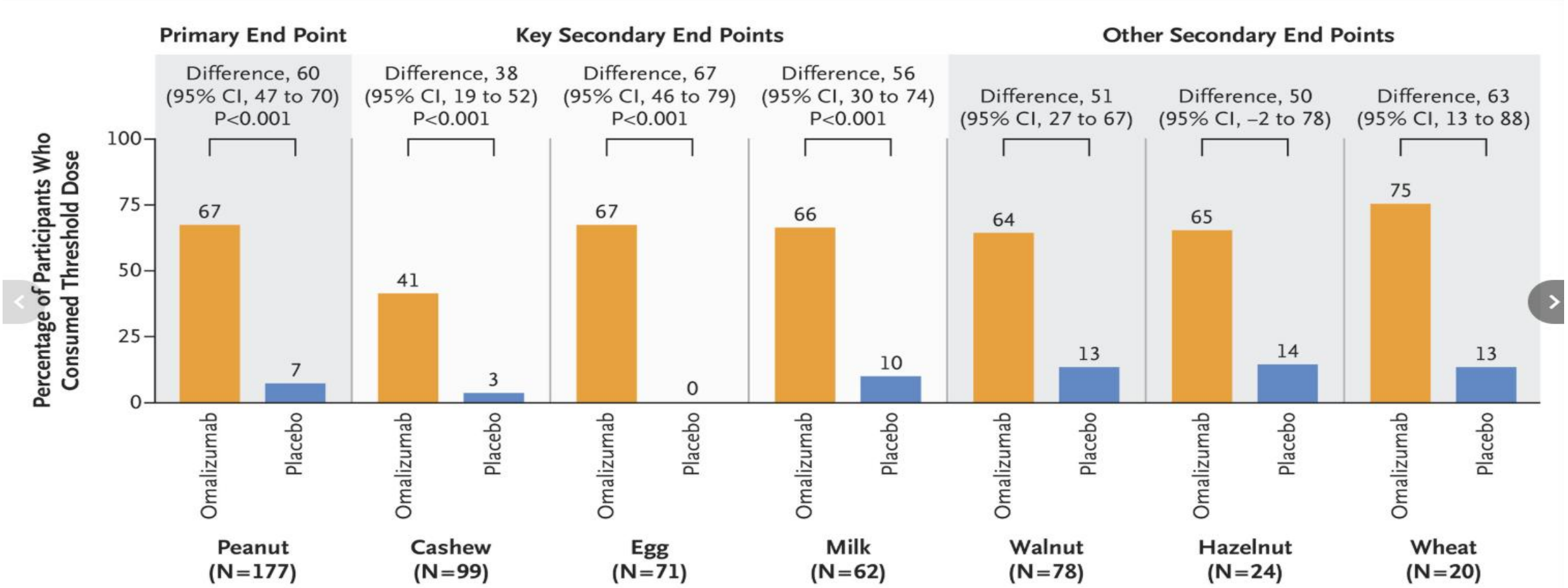
OUtMATCH Efficacy Data – Primary **Endpoint Outcome: MET WITH HIGH SIGNIFICANCE**

- **Peanut:**
  - **67%** (79/118) of omalizumab patients tolerated ≥600 mg of peanut (cumulative dose, 1044 mg, approx. 4 peanuts), and
  - **44%** tolerated cumul dose of 6044 mg (about 25 peanuts, the highest dose challenge in first stage of the trial).

  vs. **7%** (4/59) of placebo p <0.001).
- Results for the 2ndary endpoints were consistent (p<0.001 for all):
  - cashew, 41% vs. 3%
  - milk, 66% vs. 10%
  - egg, 67% vs. 0%.

Safety: Exceptionally clean; systemic injection site reactions were minimal, and no increased incidence of severe systemic adverse events occurred.

Successful Consumption of Prespecified Threshold Dose at Week 16



Wood et al, NEJM Feb 2024

DOSING: ADULT AND PEDIATRIC PATIENTS AGED ≥1 YEAR WITH IgE-MEDIATED FOOD ALLERGY[1]

Use the patient's pretreatment serum total IgE level (IU/mL) and body weight (kg) to determine the dose. Values falling outside the table range provide insufficient data for recommending a dose. For adult patients with IgE-mediated food allergy, allergic asthma, and chronic rhinosinusitis with nasal polyps, dosing determination should be based on the primary diagnosis for which XOLAIR is being prescribed.

Subcutaneous XOLAIR Dosing for Appropriate Adult and Pediatric IgE-Mediated Food Allergy Patients Aged ≥1 Year

Pretreatment Serum IgE (IU/mL)	Dosing Frequency	Body Weight (kg) ≥10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		Dose (mg)												
≥30-100	Every 4 weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100-200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200-300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300-400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400-500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500-600		150	150	225	300	300	450	600	600	375	450	450	600	
>600-700	Every 2 weeks	150	150	225	300	225	450	600	375	450	450	525		
>700-800		150	150	150	225	225	300	375	450	450	525	600		
>800-900		150	150	150	225	225	300	375	450	525	600			
>900-1000		150	150	225	225	300	375	450	525	600				
>1000-1100		150	150	225	225	300	375	450	600					
>1100-1200		150	150	225	300	300	450	525	600					
>1200-1300		150	225	225	300	375	450	525						
>1300-1500		150	225	300	300	375	525	600						
>1500-1850			225	300	375	450	600							

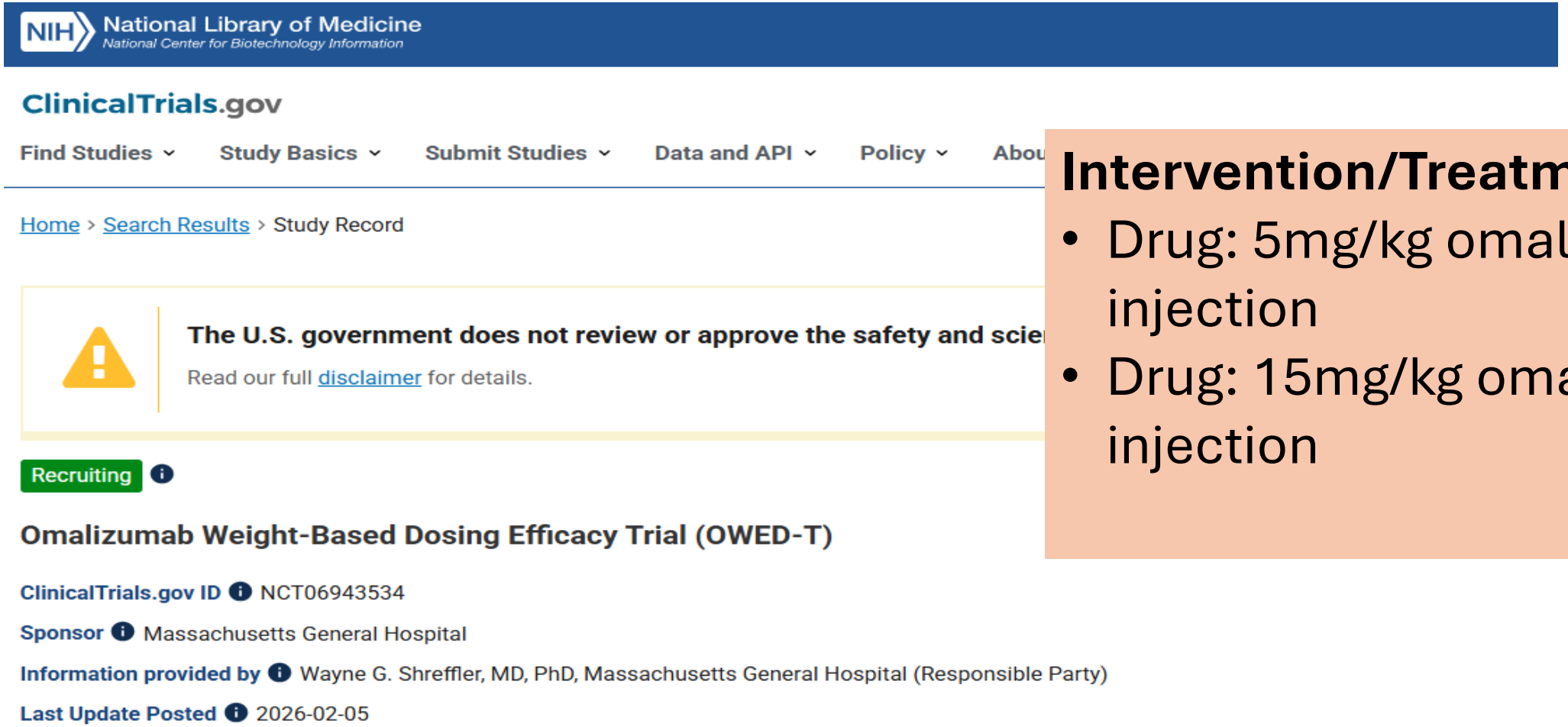
Insufficient data to recommend a dose

Dosing Frequency

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

FDA-approved dosing table for Xolair

What about the kid with sky-high IgE levels left out by current FDA approved Oma for FA dosing tables?



Intervention/Treatment

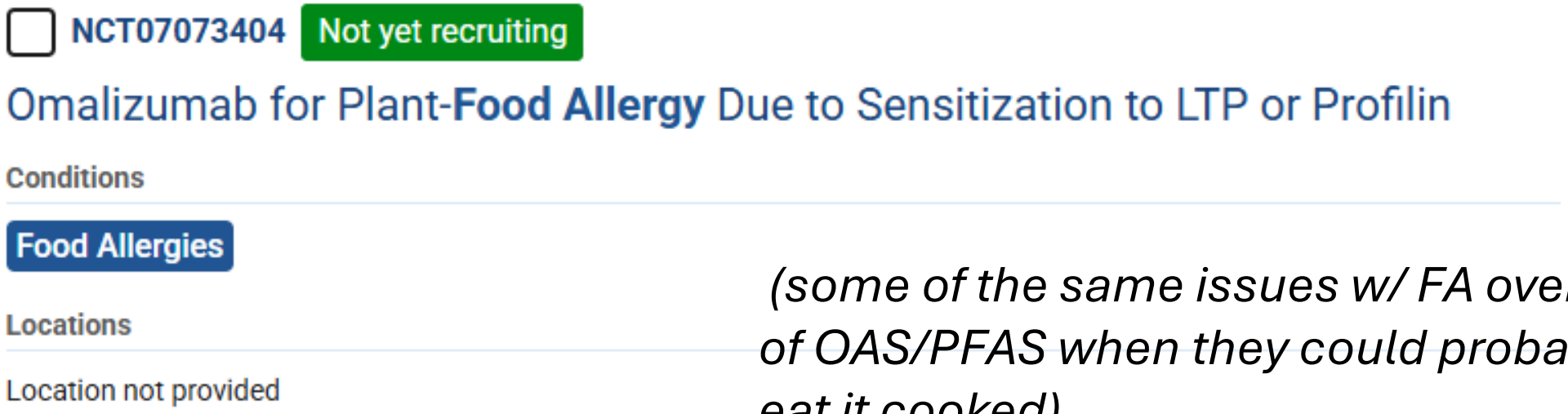
- Drug: 5mg/kg omalizumab injection
- Drug: 15mg/kg omalizumab injection

The Commercial Disruption: Omalizumab Biosimilars

- **Omlyclo® (omalizumab-igec):** Approved by the U.S. FDA as the **first interchangeable biosimilar** to Xolair®. Approved for IgE-mediated food allergy in adults and pediatric patients aged 12 months and older. Features an interchangeable designation, allowing pharmacy-level substitution depending on state laws.
- **Pipeline Competitors: ADL018** (Amneal) and other anti-IgE biosimilars are expanding portfolios.
- **Ligelizumab** – higher affinity for IgE than omalizumab, developed for CSU.
- **CX-10759 antibody** potently neutralizes soluble IgE similarly to omalizumab and can remove surface-bound IgE from FcεRI and FcεRII, potentially
- **UB-221** — a novel anti-IgE antibody with enhanced potency and a unique mechanism that both neutralizes free IgE and downregulates IgE production. Early results are promising for food allergy treatment.

But where does it end? Clinical Realities

The Clinical Catch ("The Xolair Trap"): This is an antigen-agnostic shield, **not a permanent cure**. If a patient discontinues omalizumab, their baseline sensitivity typically returns.



(some of the same issues w/ FA overdiagnosis of OAS/PFAS when they could probably just eat it cooked)

Omalizumab in Combination With OIT

- omalizumab-facilitated OIT = omalizumab as an OIT-adjunct, administered before OIT and discontinued after OIT initiation
- Reduce time to maintenance
- Administered 8 wks before and 8 weeks after initiation of multi-food OIT for a total of 16 wks.
- Not currently approved for OMA-facilitated OIT
  - Omalizumab is also being studied as an adjunct to multi-allergen OIT to improve safety during buildup, though it has not been shown to improve sustained unresponsiveness over OIT alone.

Need to know – omalizumab & biosimilars

- Get labs & SPT & OFC out of the way prior to starting OMA
- Stays in system for at least 6 months, & up to a year
- The AAAAI consensus guidance recommends waiting a minimum of 16–20 weeks before assessing response via oral food challenge.
- If using as adjunct on highly-reactive patients, consider discontinuation after reaching target OIT goal, but the *when to discontinue* is a matter of concern
- Phenotype of patient: eating anxiety/fear, multiple reactions, highly-sensitized, multiple foods, custody situations or multiple households, frequent travel, international trips *(¿como se dice cacahuete?)*

Non-IgE Targeting Therapeutic Strategies: Dupilumab

- IL-4/IL-13 – dupilumab
  - phase II trial in peanut-allergic children showed ~50% reductions in total and peanut-specific IgE, but only 8% met the primary endpoint of tolerating 444 mg peanut protein at 24 weeks.
  - Decreases sIgE labs but not SPT (at least not right away)
  - Not decreasing clinical reactivity (at least not right away)
  - Dupilumab is no longer being pursued as stand-alone therapy for food allergy but retains interest as a potential OIT adjunct.
  - Practical applications perhaps as an adjuvant to control comorbid AD & asthma, or potentially to “treat through” EOE

Antialarmins (upstream targets) – epithelial-derived cytokines “alarmins” that initiate Th2 cascade

- **Tezepelumab** – targets alarmin thymic stromal lymphopoietin (anti-TSLP) upstream of the IgE cascade, currently being investigated for EOE & has theoretical rationale for FA

- **Etokimab** (anti-IL-33) – single dose shoed efficacy in a small peanut allergy trial, with some patients tolerating peanut at a f/u challenge. Further work is needed.

Biologics That Stumbled or Failed

- **Lessons Learned from the Cutting Edge**
- **The Clinical Objective:** Not every mechanistically logical biologic has succeeded in food allergy clinical trials.
- **Ligelizumab (Next-Gen Anti-IgE):** Despite displaying significantly higher binding affinity for IgE compared to omalizumab, it failed to deliver a proportional jump in clinical efficacy for food desensitization. It was outpaced by simpler anti-IgE maintenance models.
- **Anti-IL-5 Agents (Mepolizumab / Reslizumab):** While highly effective at resolving tissue eosinophilia in Eosinophilic Esophagitis (EoE), these biologics failed to alter symptoms in EOE, & failed to alter IgE-mediated systemic thresholds during oral food challenges.
- **Takeaway:** Broad upstream axis blocking or absolute IgE sequestration outperforms down-stream effector cell modulation.

What if you hate shots?

- EPIT
- JAK inhibitors
- BTK inhibitors
- Metformin?!

Review > J Allergy Clin Immunol Pract. 2026 Apr;14(4):762-770. doi: 10.1016/j.jaip.2026.01.044.

Biologics and Novel Therapeutics in Food Allergy

Brent Anderson [1], Claire Pascal [1], M Gohazrua K Butler [1], Andrew R Chin [1], Andrew J Long [1], Sayantani B Sindher [1], Aikaterini Anagnostou [2], Stefania Arasi [3], Philippe Bégin [4], Christina E Ciaccio [5], Thomas Eiwegger [6], Alessandro Fiocchi [3], David M Fleischer [7], Maria Garcia-Llorett [8], Edwin H Kim [9], Stephanie Leonard [10], Zahida Rani Maskatia [11], Kirsten P Perrett [12], Wayne Shreffler [13], Julia Upton [14], R Sharon Chinthrajah [15]

Affiliations + expand

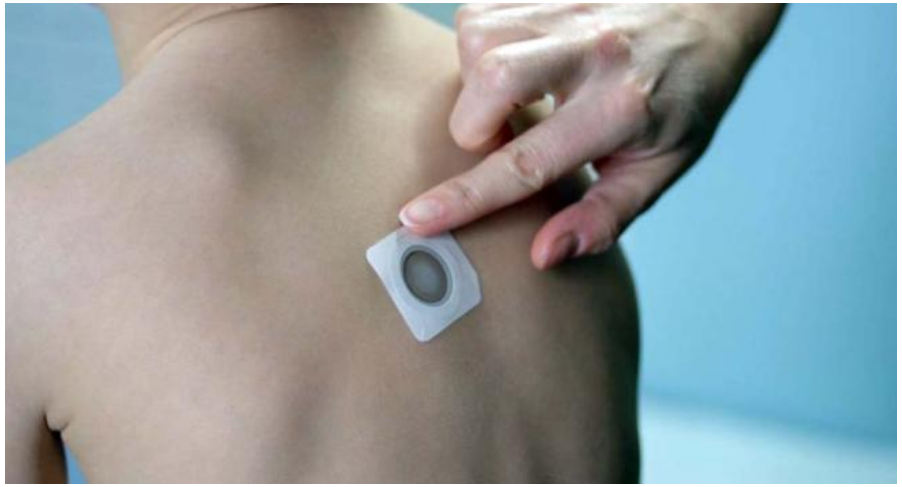
PMID: 41956612 DOI: 10.1016/j.jaip.2026.01.044

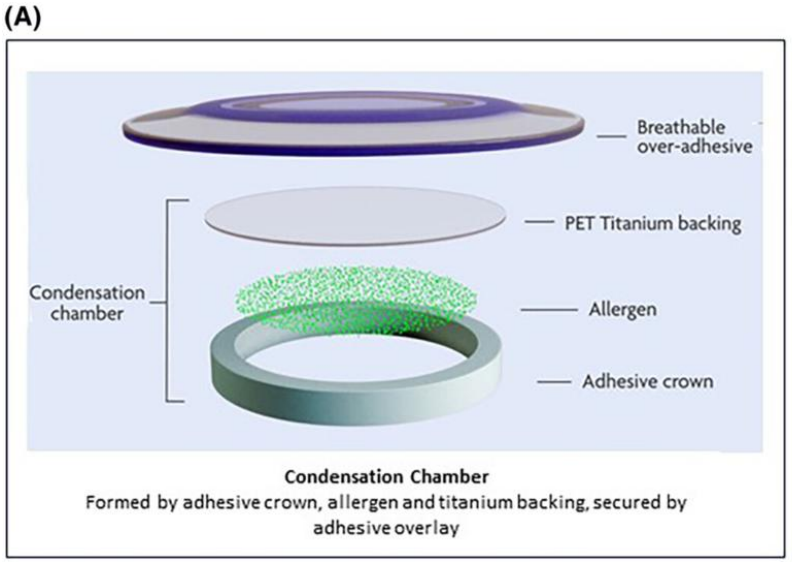
Abstract

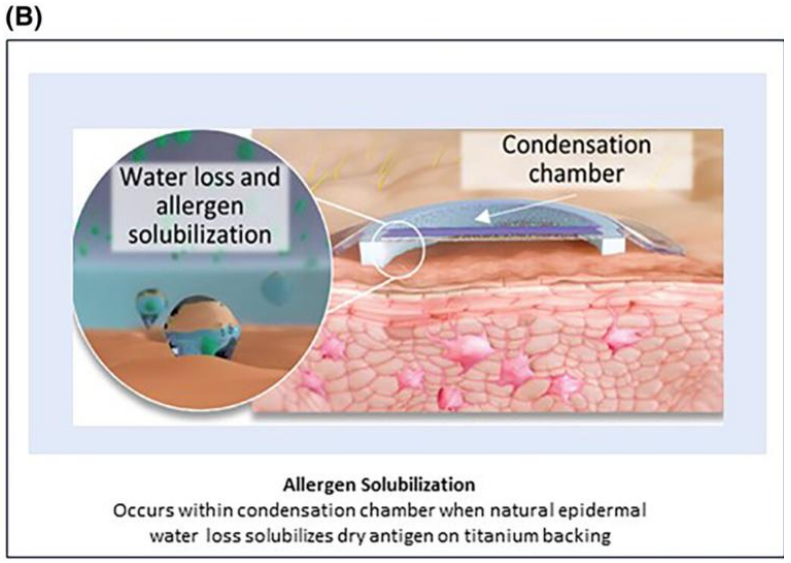
The US Food and Drug Administration approval of omalizumab for the treatment of food allergy has opened the door for therapeutics targeting the underlying mechanisms that drive food allergy. Here we discuss both approved and novel investigational therapeutic strategies targeting these allergic pathways for the treatment of food allergy.

Keywords: Biologics; Bruton's tyrosine kinase inhibitors; Food allergy; Janus tyrosine kinase inhibitors; Omalizumab; Vaccines.

Epicutaneous Immunotherapy (EPIT): Peanut Patches







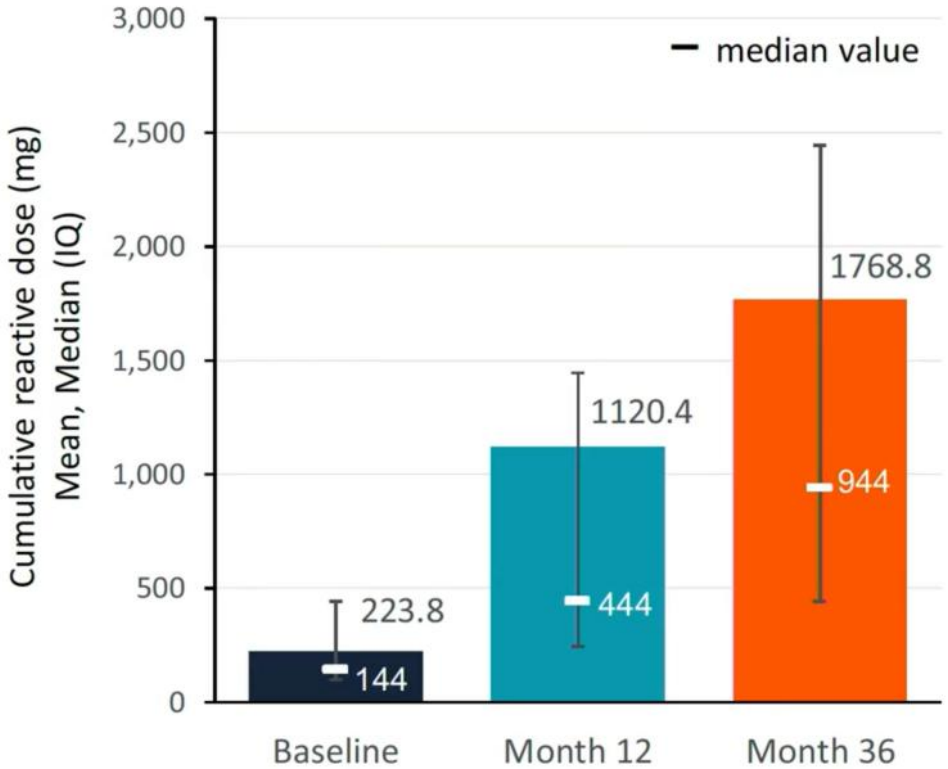
The Paradigm: Bypassing the gastrointestinal tract and deep vascular delivery by presenting microgram doses to the superficial epidermis on intact skin.

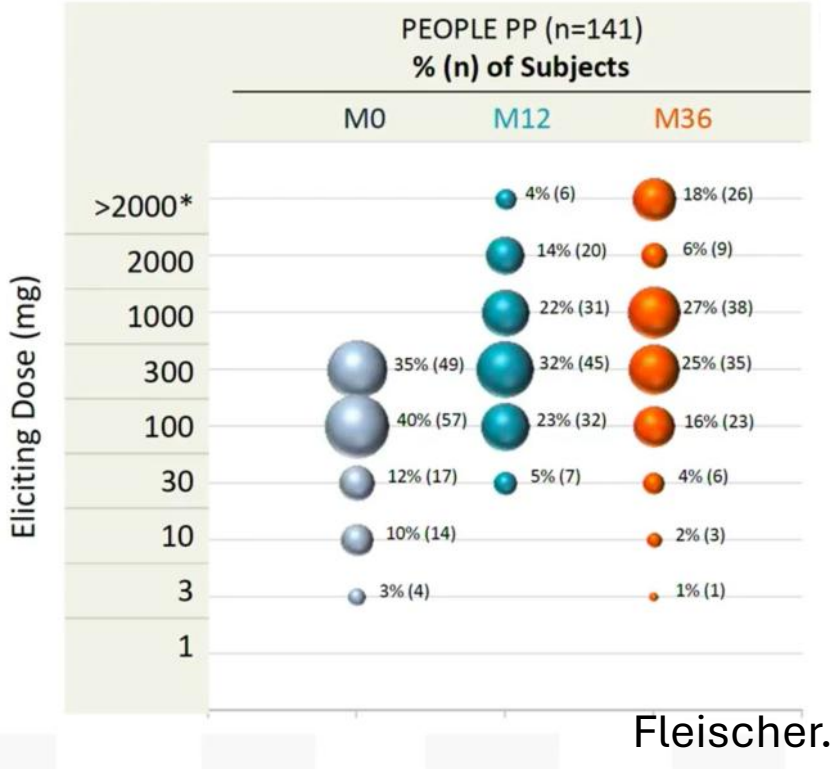
Viaskin® Peanut Patch: DBV Technologies' cutaneous patch applied daily to**250 mcg(1/1000 PN)** back.

Immunological Focus: Capturing allergen via epidermal Langerhans cells, which then migrate through the lymphatic system to mesenteric lymph nodes. This skews the immune profile toward Treg cells

Outcomes improve over time – longer time on peanut EPIT

- PEPITES (Peanut EPIT Efficacy & Safety) – phase 3 trial, 4-11yo
- While statistically significant, Did not meet primary endpoint
  - Baseline ED ≤10mg → responder if 1y ED ≥300mg
  - Baseline ED >10-300mg → responder if 1y ED ≥1000mg
- PEOPLE 3-year extension demonstrated further increased thresholds at 36 months





Fleischer. JACI 2020

EPITOPE trial – toddlers 1-3yo

The NEW ENGLAND JOURNAL of MEDICINE

CURRENT ISSUE SPECIALTIES TOPICS

ORIGINAL ARTICLE

Phase 3 Trial of Epicutaneous Immunotherapy in Toddlers with Peanut Allergy

Authors: Matthew Greenhawt, M.D., Sayantani B. Sindher, M.D., Julie Wang, M.D., Michael O'Sullivan, M.D., George du Toit, M.D., Edwin H. Kim, M.D., Deborah Albright, M.D., +58 , and A. Wesley Burks, M.D. Author Info & Affiliations

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- Kids 1-3yo with PN allergy confirmed by DBPCOFC
- ED $\leq$ 300mg PN protein
- Randomized 2:1 to EPIT or placebo for 1y
- 67% of treated kids met the primary responder endpoint vs 33.5% on placebo after 12 mos. ($p<0.001$)

Deep Dive: The VITESSE Phase 3 Trial

- **Inclusion Criteria:** kids 4-7yo with confirmed peanut allergy and a baseline eliciting dose ≤ 100mg peanut protein.
- **Primary Endpoint:** after 12 months, proportion of responders defined as achieving a post-treatment eliciting dose of
  - ≥ 300 mg (for those with baseline ≤ 10 mg) or
  - ≥ 1000 mg (for those with baseline > 10 mg).
- **Endpoint Status: SUCCESSFULLY MET**.
  - **46.6%** of treated children responded successfully vs **23.3%** for placebo group.
  - 83% using patch increased ED by at least one level during DBPC OFC.
  - 60% using patch increased ED by at least 2 levels (vs 23% in placebo group).
- **The "Placebo Drop" Nuance:** Notably, **24%** of children in the placebo group grew more sensitive to peanut over the 12-month period, with their ED decreasing compared to only **6%** on the active patch.

EPIT Safety and Imminent FDA Timelines

- **Minimal Anaphylaxis vs. Local Reactivity**
- **Systemic Safety Profile:** Outstandingly safe. Anaphylaxis rates related to the patch were exceptionally low at **1% to 2%**.
- **Adverse Events:** Localized patch-site reaction (erythema, pruritus) was nearly universal (>90%) but progressively waned after the initial weeks of therapy. Dropout rates due to safety were remarkably minimal.
- **Regulatory Milestones:**
  - **Ages 4-7 BLA Submission:** Expected in the "**first half of 2026**."
  - **Ages 1-3 Toddler Submission:** Awaiting final readouts from the **COMFORT Toddlers** supplemental safety trial to support a subsequent submission.
  - **Infant Expansion:** The **THRIVE Phase 2** study was initiated to screen infants aged 6 to 12 months. [DBV Technologies]

EPIT takeaways

- great for active kids who have oral aversions or anxious patients
- SAFETY is key advantage
- Need intact skin
- Good way to bridge to SLIT or even OIT
- Efficacy appears strongest in very young children (1–3 years), with benefit continuing to enhance with extended treatment up to 36 months.
- In older children (4–11 years), efficacy is more modest and appears better in the 4–7 age range.
- The Viaskin Peanut patch is in late-stage regulatory review, with additional studies ongoing in the 1–3 and 4–7 year age groups.

Advanced Pipelines: Upstream Blockers & Multi-Biologics

- **Dupilumab (Anti-IL-4Rα) in OIT:** Currently being investigated to see if blocking IL-4/IL-13 can prevent the production of allergen-specific IgE and speed up the safety of multi-allergen up-dosing.
- **The COMBINE Study:** (NCT03679676)
  - Evaluating the sequential or combined use of **Omalizumab + Dupilumab** alongside Multi-Allergen OIT (mOIT).
  - **Hypothesis:** Omalizumab provides an immediate safety shield, while Dupilumab remodels the Th2 axis to achieve true Sustained Unresponsiveness (SU) after treatment stops.
- **RPT904 (RAPT Therapeutics):** An oral, small-molecule CCR4 antagonist designed to selectively block Th2 cell migration into allergic tissues, entering Phase 2b monotherapy testing.

BTK inhibitors

- **Remibrutinib** — a next-generation, highly selective BTKi now FDA-approved for chronic spontaneous urticaria
- more favorable safety profile for chronic administration than the earlier-gen non-selective BTK inhibitors
- poised to become the first BTKi broadly used in the allergy space and may have future applications in food allergy.

BTK inhibitors

- **Acalabrutinib** - phase II open-label trial (n=10), just 4 doses of acalabrutinib (100 mg BID) increased the median tolerated peanut dose from 29 mg to **4,044 mg** (the maximum protocol amount), with 7 of 10 patients tolerating the full dose with no reaction.
- Remarkably, recent preclinical data show acalabrutinib can **abort ongoing anaphylaxis** in humanized mice when given within 2 minutes of allergen challenge, synergizing with epinephrine.

The concept of BTKis as **rapid-onset, on-demand rescue medications** for anaphylaxis (potentially complementing epinephrine) is a particularly exciting frontier.

JAK Inhibition in Food Allergy

- **Abrocitinib -** (JAK1 inhibitor, FDA-approved for atopic dermatitis)
- under investigation for IgE-mediated food allergy (NCT05069831).
- Preclinical work showed it suppressed effector T cell activation while preserving Treg function, decreased peanut-specific basophil activation, and suppressed peanut-induced cytokine release from PBMCs.
- The rationale is that JAK1 inhibition may improve the magnitude or durability of the treatment response when used as an adjunct to OIT.

Siglec-Targeting Agents

- **Lirentelimab (anti-Siglec-8)** — depletes eos and inhibits mast cell activation. failed to meet primary endpoints in phase II trials for CSU and atopic dermatitis, and the Siglec-8 program has been discontinued.
- **AK006 (anti-Siglec-6)** — a newer agonistic Ab, induces strong inhibitory signaling in mast cells and triggers mast cell reduction via ADCP. A phase I trial in healthy volunteers and CSU patients has been initiated (NCT06072157).
- **Siglec-2 (CD22) targeting** - can inhibit B cell receptor signaling and Ab production, potentially intervening in the sensitization phase of food allergy.

Unexpected/Repurposed Therapeutics

- **Metformin** - inhibits IgE- and aryl hydrocarbon receptor-mediated mast cell activation, suppressing degranulation, IL-13, TNF-α, and sphingosine-1-phosphate secretion.

- **Abatacept (CTLA4-Ig)** - modulates T cell co-stim by binding CD80/CD86. Currently being investigated as an adjuvant to peanut OIT (NCT04872218) with the goal of improving sustained unresponsiveness by promoting Treg responses.

Unexpected/Repurposed Therapeutics

- **Nanoparticle-based platforms** — Liver-targeting mRNA lipid nanoparticles (LNPs) deliver PN allergen epitopes to liver sinusoidal endothelial cells
  - Preclinical models inducedFoxP3+ Tregs and suppressed anaphylaxis.
  - These represent a fundamentally different approach — inducing true immune tolerance rather than desensitization.
- **DARPins (Designed Ankyrin Repeat Proteins)** — engineered protein scaffolds being evaluated as potential anti-IgE therapeutics with advantages in size, stability, and manufacturing over monoclonal antibodies.

The Next Paradigm: Vaccine Platforms

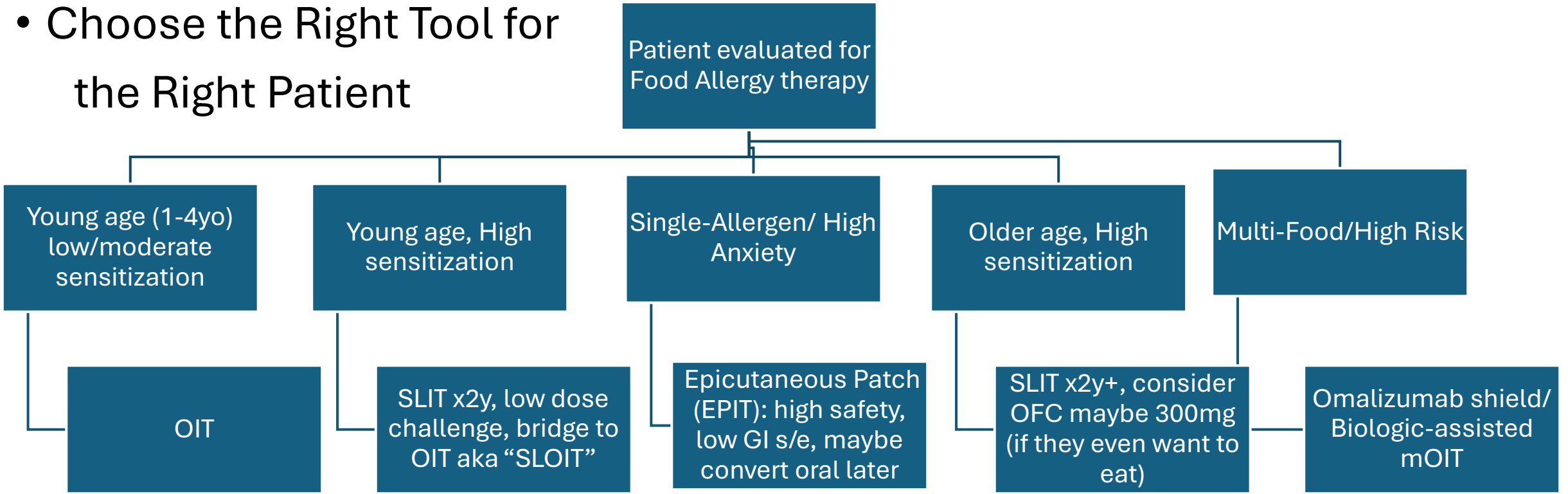
- **The Objective:** Desensitize the patient's immune system without ever exposing them to the intact, native allergens that cause anaphylaxis.
- **Peptide Immunotherapy (e.g., PVX108):**
  - Short, synthetic T-cell epitope sequences derived from Ara h2
  - **The Mechanism:** These fragments are physically too small to cross-link IgE on the surface of mast cells, entirely eliminating the risk of acute degranulation while still stimulating and tolerizing T-cells.
- **DNA & mRNA Vaccines:** Nucleic acid sequences packaged in lipid nanoparticles that instruct host cells to safely express modified, non-anaphylactic allergen fragments to drive a protective Th1/Treg immune response.

Other Pipeline Approaches

- **KIT inhibitors** — targeting wild-type KIT for mast cell suppression, already showing efficacy in mastocytosis and chronic urticaria, with potential extension to food allergy.
- **Cendakimab (anti-IL-13)** — in phase III for EoE (NCT04753697), targeting IL-13 binding to both receptor subtypes, potentially offering more inhibitory activity than dupilumab.
- **Allergen-specific vaccines** including LAMP DNA vaccines and modified protein approaches remain in early development.
- Modified allergens (boiled/baked, hypoallergenic proteins), nanoparticles (Cour, Selecta), & microbiome-driven therapies.

Phenotype-Driven Clinical Selection Tree

- Choose the Right Tool for the Right Patient



Future State: Transition to Vaccines/ Upstream Small Molecules for Tolerance

Summary: Core Takeaways for Practice

- **Biologics:** Anti-IgE monotherapy offers a powerful, antigen-agnostic safety shield, and the emergence of interchangeable biosimilars will soon resolve major insurance and cost barriers.
- **EPIT:** The Viaskin Peanut patch successfully met its Phase 3 VITESSE endpoints, providing an exceptionally safe option that is moving toward an FDA regulatory filing.
- **Pipeline:** Multi-biologic regimens (COMBINE) and peptide vaccines represent the next frontier, aiming to deliver long-term immune tolerance without the safety risks of native protein exposure.

In Conclusion: our job is to be the “**sherpa**”

- In a metaphorical or professional context, being a "sherpa" for another person means acting as a **trusted guide, protector, and mentor** through a challenging, complex, or high-stakes journey.

Core Sherpa responsibilities:

- **Bearing the Heavy Loads**
- **Mapping the Route**
- **Managing the Pace**
- **Remaining Invisible**

Conclusions

- Every patient defines their own summit. For one family, the summit is bite-proof protection against accidental exposure. For another, it is full dietary freedom.
- As we integrate these new biologics and procedures into our practices, let us promise to guide them safely & sustainably to ***their*** peak.

Clinical References & Key Literature

- **OUtMATCH Phase 3 Stage 1 (Omalizumab Monotherapy):**
  - Wood RA, Togias A, Sicherer SH, et al. Omalizumab for the Treatment of Multiple Food Allergies. *N Engl J Med*. 2024;390(11):989-999. doi:10.1056/NEJMoa2312382.
- **VITESSE Phase 3 Trial & Viaskin Clinical Development:**
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  - Greenhawt M, Sindher SB, Wang J, et al. Phase 3 Trial of Epicutaneous Immunotherapy in Peanut-Allergic Toddlers (EPITOPE). *N Engl J Med*. 2023;388(19):1755-1766. doi:10.1056/NEJMoa2212895.
- **Omalizumab Biosimilars & Regulatory Approvals:**
  - U.S. Food and Drug Administration. FDA Approves Omlyclo (omalizumab-igec) as the First Interchangeable Biosimilar to Xolair. FDA Regulatory Announcement; 2025.
- **COMBINE Multi-Biologic Trial Structure:**
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