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ORIGINAL ARTICLE

Biological Therapies in IgE-Mediated Food Allergy: Narrative review

Marcelina Rybińska[1], Hanna Rzepka[2], Paweł Stępowski[3], Mateusz Tajster[4]

[1,2,3,4]Military Clinical Hospital and Polyclinic IPHC Weigla 5, 53-114 Wrocław

Corresponding author: Marcelina Rybińska
e-mai: marcelina.rybinska@gmail.com

ABSTRAKT

IgE-mediated food allergy is a chronic immune-mediated condition of growing global concern, carrying the risk of severe and potentially fatal allergic reactions. For decades, clinical management rested entirely on allergen avoidance and emergency epinephrine, with no approved disease-modifying therapy available. The recent regulatory approval of omalizumab, a monoclonal anti-IgE antibody, as the first biologic licensed specifically for the reduction of multi-food allergic reactions marks a paradigm shift in this field. This literature review examines the immunological rationale for biologic intervention in IgE-mediated food allergy, synthesises the pivotal evidence from the OUtMATCH clinical trial programme, and surveys the emerging pipeline of agents currently under investigation including dupilumab and anti-alarmin therapies. The comparative evidence between biologics and oral immunotherapy is appraised, and the most pressing evidence gaps and future research priorities are identified.
The aim of the work: This work aims to review the current evidence on biological therapies for IgE-mediated food allergy, examine the key immunological mechanisms that underpin their therapeutic rationale, and identify the most significant gaps that future research should address.**Methods and materials:** A narrative review methodology was employed to evaluate the scientific literature concerning the use of biological agents in the treatment of IgE-mediated food allergy. Relevant literature was identified through systematic searches of electronic databases including PubMed, Google Scholar, and Scopus. Eligible sources comprised peer-reviewed original research articles, systematic reviews, meta-analyses, and narrative reviews available in English and published between 2003 and 2025. Inclusion decisions were guided by the relevance of each source to biologic treatment outcomes, the pathophysiology of IgE-mediated hypersensitivity, or clinical and epidemiological data relating to food allergy burden and management. Literature search and selection were conducted during February 2026.

KEYWORDS

food allergy, IgE, omalizumab, biologics, oral immunotherapy, anaphylaxis, mast cell, Th2

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Introduction

IgE-mediated food allergy is an increasingly recognised public health concern. Population-based survey data from the United States indicate that convincing IgE-mediated food allergy likely affects approximately one in ten adults and one in twelve children, though self-reported rates are substantially higher, reflecting widespread diagnostic uncertainty and the difficulty of distinguishing true IgE-mediated allergy from intolerance and oral allergy syndrome (Warren et al., 2020). The gap between perceived and confirmed food allergy is itself clinically meaningful, as it contributes to unnecessary dietary restriction and reduced quality of life among those who may not have true IgE-mediated disease. Among those with confirmed allergy, concurrent sensitisation to multiple foods is far more common than widely appreciated, and available population-based data indicate that multi-food allergy imposes a substantially higher psychosocial and healthcare burden than single-food allergy, with affected individuals reporting significantly greater rates of anaphylaxis, emergency department visits, and quality-of-life impairment (Warren et al., 2023).

The clinical and psychosocial consequences of living with food allergy extend well beyond the acute allergic reaction. Food-allergic individuals and their caregivers describe a pervasive state of vigilance shaped by the awareness that accidental exposure can occur despite careful avoidance for example in social settings, through cross-contamination, or through mislabelled products. This burden compounds considerably in those with multiple food allergies, who must navigate a far more restricted dietary landscape. The economic costs are also substantial, encompassing direct medical consultations, emergency department visits, epinephrine prescriptions, and significant indirect costs from dietary adaptation and productivity loss (Warren et al., 2020). Beyond the economic dimension, population-level data consistently document impairments in health-related quality of life, anxiety, social participation, and educational and occupational functioning among food-allergic individuals and their families (Warren et al., 2021). The psychosocial burden is particularly pronounced in children, where food allergy-related school absences, social restriction, and caregiver anxiety compound the direct clinical risks (Anagnostou, 2024).

Anaphylaxis is the most severe and potentially fatal manifestation of IgE-mediated food allergy, it represents the defining clinical risk that shapes management decisions at every level. It is a rapidly progressing, multisystem hypersensitivity reaction for which intramuscular epinephrine is the established first-line treatment (Whyte et al., 2022). Despite this, epinephrine remains substantially underused in both community and healthcare settings, and the management of anaphylaxis continues to evolve in response to growing evidence about diagnostic criteria, severity stratification, and the appropriate role of emergency services (Shaker, 2024). The standard care for food allergy which is strict allergen avoidance combined with self-injectable epinephrine, remains the cornerstone of current management but is inherently limited. Avoidance depends on reliable allergen labelling, consistent patient education, and vigilance across all eating contexts, none of which can be guaranteed in everyday life. Allergen-specific oral immunotherapy (OIT) emerged as the first approach capable of raising the threshold at which reactions are triggered, yet it remains allergen-specific by design, requires separate protocols for each sensitised food, and carries a meaningful burden of adverse reactions during dose escalation (Sindher et al., 2023). For patients allergic to multiple foods simultaneously, the practical and logistical challenges of OIT are particularly significant.

It is against this backdrop that the approval of omalizumab by the US Food and Drug Administration on 16 February 2024 for the reduction of allergic reactions to one or more foods in patients aged one year and older represents a genuinely transformative development (Wood et al., 2024). For the first time, a single biologic agent has been shown to raise the allergic reaction threshold across multiple foods simultaneously, offering an allergen-agnostic approach that does not require food-specific protocols (Anagnostou, 2024).

Pathophysiology of IgE-Mediated Food Allergy

The immune mechanisms underpinning IgE-mediated food allergy involve two sequential events: an initial sensitisation phase, in which the immune system mounts an inappropriate IgE response against a dietary antigen, and an effector phase, in which subsequent exposure triggers a rapid and potentially severe allergic reaction (Shreffler, 2020). Understanding both phases is essential for appreciating the rationale for biologic intervention.

Sensitisation begins at epithelial barrier sites, primarily the gastrointestinal tract and the skin where structural or functional compromise allows dietary antigens to penetrate into the submucosal immune environment. Epithelial cells respond by releasing alarmins, primarily TSLP, IL-33, and IL-25, which act on local dendritic cells and promote a phenotypic shift that biases subsequent T cell differentiation toward a Th2 profile (Ramsey & Berin, 2021). This alarmin-conditioned environment further reinforces Th2 polarisation while suppressing the generation of regulatory T cells

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that would otherwise promote oral tolerance. Type 2 innate lymphoid cells (ILC2s), which respond to the same alarmin signals, serve as an additional amplifying source of IL-4, IL-5, and IL-13 during the sensitisation phase, reinforcing IgE production and the recruitment of effector cell populations in the mucosa (Ramsey & Berin, 2021).

Once a Th2-skewed response is established, the resulting cytokine environment which is dominated by IL-4 and IL-13, drives B cell class-switch recombination toward IgE production. There is a growing understanding that IL-13 in particular plays a key role in inducing high-affinity IgE, and that continual T cell help is required for the maintenance of long-lived IgE, an insight with direct implications for therapies targeting the IL-4/IL-13 axis (Ramsey & Berin, 2021). Allergen-specific IgE antibodies bind with high affinity to the FcεRI receptor on the surface of mast cells and basophils, effectively loading these effector cells and priming them for rapid activation upon subsequent allergen encounter (Shreffler, 2020).

The effector phase is triggered when a sensitised individual ingests the offending allergen. Crosslinking of adjacent IgE molecules on mast cell surfaces initiates degranulation, with release of preformed mediators (including histamine, tryptase, and prostaglandins) driving the multi-organ manifestations of the allergic reaction (Shreffler, 2020). An important further insight is that mast cells are not merely passive effectors but active participants in shaping the broader immunological environment through their subsequent cytokine production, creating a self-reinforcing cycle that contributes to chronicity (Shreffler, 2020). This layered immunological architecture, involving redundant cytokine pathways, both innate and adaptive immune compartments, and amplifying feedback loops, explains why approaches targeting a single downstream effector have historically struggled to achieve durable disease modification, and forms the mechanistic basis for the biologic approaches examined in this review.

Omalizumab in IgE-Mediated Food Allergy

Omalizumab is a recombinant humanised IgG1 monoclonal antibody that selectively targets the Fc portion of free circulating IgE, the same domain through which IgE would otherwise bind to its high-affinity receptor, FcεRI, on the surface of mast cells, basophils, and dendritic cells (MacGlashan et al., 2007). By occupying this binding site, omalizumab prevents newly produced IgE molecules from attaching to effector cells, thereby interrupting the IgE-mediated allergic cascade at its proximal step. Importantly, omalizumab cannot dislodge IgE that is already surface-bound, it acts exclusively on free, circulating IgE which is why its clinical effects develop progressively rather than immediately (Sindher et al., 2024).

The downstream consequences of sustained free IgE depletion extend well beyond simple sequestration. As circulating free IgE falls, the density of FcεRI receptors on the surface of basophils, mast cells, and dendritic cells gradually declines through a receptor downregulation process driven by reduced receptor occupancy (Eckman et al., 2010). The kinetics of this downregulation differ between cell types: basophil FcεRI expression falls rapidly within days of initiating treatment, while reductions in skin mast cell receptor density occur over a longer timescale of weeks to months (Beck et al., 2004). This secondary receptor-level effect is now considered a critical component of omalizumab's therapeutic mechanism, as it substantially reduces the responsiveness of effector cells to any allergen they encounter regardless of which food it derives from (MacGlashan et al., 2007). This allergen-agnostic desensitisation of effector cells forms the immunological basis for omalizumab's ability to simultaneously raise the reaction threshold across multiple unrelated food allergens, a property that distinguishes it fundamentally from allergen-specific OIT. Omalizumab also reduces FcεRI expression on circulating dendritic cells, which may carry additional immunomodulatory implications by limiting allergen presentation to Th2 cells and thereby attenuating the adaptive immune signals that sustain IgE production over time (Prussin et al., 2003). Whether this effect translates into durable immunological modification as opposed to reversible threshold elevation dependent on continuous treatment, remains one of the central open questions in the field.

The pivotal clinical evidence supporting omalizumab's use in food allergy was generated by the OUtMATCH trial which was a multi-stage, double-blind, randomised, placebo-controlled phase III study sponsored by the National Institute of Allergy and Infectious Diseases and conducted across ten clinical sites in the United States (Wood et al., 2024). The study enrolled individuals aged one to fifty-five years with confirmed allergy to peanut and at least two additional foods from a pre-specified list including cashew, milk, egg, walnut, wheat, and hazelnut. Eligibility required documented reactivity to small quantities of each allergen during standardised oral food challenge, ensuring that enrolled participants had clinically meaningful and objectively confirmed multi-food allergy rather than sensitisation alone. Participants were randomly assigned in a two-to-one ratio to receive subcutaneous omalizumab or placebo, with dosing determined by body weight and baseline serum IgE level. The primary

endpoint was the ability to consume a single dose of at least 600 mg of peanut protein without dose-limiting allergic symptoms during a supervised oral food challenge at the end of the treatment period a threshold that none of the participants had been able to reach at baseline. Results demonstrated that a substantially greater proportion of omalizumab-treated participants met this primary endpoint compared with the placebo group, and secondary endpoints for cashew, milk, and egg showed similarly meaningful differences between the arms (Wood et al., 2024). These findings established that a single biologic agent, administered for a relatively brief period, could simultaneously raise the allergic reaction threshold across multiple structurally unrelated food allergens, a clinically unprecedented result that formed the basis for regulatory approval.

Based on these data, the FDA approved omalizumab on 16 February 2024 as the first biologic licensed specifically to reduce allergic reactions, including anaphylaxis, in adults and children aged one year and older with one or more IgE-mediated food allergies (Wood et al., 2024). It is important to emphasise, however, that the approval targets the reduction of accidental exposure reactions rather than the induction of tolerance. Patients are still required to maintain allergen avoidance alongside treatment, and omalizumab is not indicated for the emergency treatment of acute anaphylaxis once a reaction has begun. Several important limitations temper these conclusions. The OUtMATCH population consisted predominantly of children and adolescents, meaning that the generalisability of findings to adults remains to be fully established. The trial's primary endpoint was defined at a single oral food challenge time point and does not directly reflect real-world protection during uncontrolled exposures. The durability of the effect beyond the active treatment period also remains uncertain. The mechanism of action, dependent on sustained free IgE suppression, strongly suggests that protection would diminish following treatment discontinuation, implying the likely need for indefinite ongoing dosing to maintain clinical benefit. Cost, access, and the practicalities of regular subcutaneous injections are additional considerations that will shape real-world uptake (Wood et al., 2024).

Emerging Biological Therapies

While omalizumab currently stands as the only biologic with regulatory approval specifically for IgE-mediated food allergy, several other targeted agents are under active investigation, each approaching the allergic immune response from a different mechanistic angle. The rationale for exploring these alternatives is compelling: omalizumab raises the reaction threshold without inducing immunological tolerance, requires indefinite treatment to maintain its effect, and may not achieve sufficient IgE suppression in all patients, particularly those with very high baseline IgE levels. Agents capable of targeting the allergic cascade at an earlier, more proximal level offer the theoretical prospect of more durable or even curative outcomes.

Dupilumab, a monoclonal antibody targeting the shared IL-4Rα subunit and thereby blocking both IL-4 and IL-13 signalling, has attracted considerable interest as a potential food allergy therapy given its established efficacy across multiple atopic conditions and its mechanistic rationale for reducing IgE production at source. Because IL-4 is the principal cytokine driving B cell class-switch recombination toward IgE, and IL-13 sustains the Th2 environment that supports ongoing IgE synthesis, dupilumab's dual blockade was hypothesised to progressively reduce food-specific IgE levels and potentially raise the threshold for allergic reactions over time (Ramsey & Berin, 2021). Real-world and retrospective data have provided some support for this hypothesis: studies in paediatric patients with atopic dermatitis receiving dupilumab for their skin disease have documented meaningful and progressive reductions in food-specific IgE levels across multiple allergens during treatment (Spekhorst et al., 2024). However, the critical question of whether these biomarker changes translate into clinically meaningful protection against food-induced reactions has not been convincingly answered. A phase II study evaluating dupilumab monotherapy in children and adolescents with peanut allergy found that only a small minority of treated participants were able to pass a double-blind, placebo-controlled food challenge at 24 weeks, leading investigators to conclude that dupilumab monotherapy is unlikely to achieve desensitisation as a standalone treatment (Sindher et al., 2025). The more promising hypothesis currently under investigation is whether dupilumab might serve as a valuable adjunct to allergen-specific OIT by reducing the immunological reactivity of the patient during the up-dosing phase, potentially improving both the safety and the efficacy of OIT in those who have previously been unable to tolerate it (Chinthrajah et al., 2025).

Targeting the upstream alarmins such as TSLP, IL-33, and IL-25 represents a mechanistically distinct and theoretically attractive approach, as these epithelial cytokines sit at the very top of the allergic cascade and are responsible for initiating the Th2 polarisation that ultimately drives IgE production and effector cell priming. By intervening at this proximal level, anti-alarmin therapies might simultaneously suppress multiple downstream allergic pathways rather than targeting any single cytokine or effector. Tezepelumab, an

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approved anti-TSLP antibody with established efficacy in severe asthma, has been explored in combination with allergen immunotherapy for allergic rhinitis, with data suggesting that TSLP blockade can augment the immunological changes induced by subcutaneous immunotherapy and may promote more durable tolerance after treatment completion (Corren et al., 2023). Whether these findings translate meaningfully to the food allergy context remains an open and actively investigated question, though the mechanistic rationale is well grounded in the shared alarmin-driven pathophysiology of atopic diseases (Berin, 2023).

A further emerging avenue involves the combination of biologics with OIT rather than their use as standalone agents. The theoretical basis is straightforward: biologics that reduce effector cell sensitivity whether through IgE suppression or upstream Th2 attenuation, could in principle make OIT safer and more tolerable, enabling patients who have previously failed OIT due to adverse reactions to complete the build-up phase successfully. Early-stage clinical evidence supports the feasibility of this approach, with studies suggesting that omalizumab-facilitated multi-food OIT can enable simultaneous desensitisation to several allergens in patients who could not tolerate OIT alone (Sindher et al., 2024). The COMBINE trial which is one of the first studies to explore the simultaneous use of omalizumab and dupilumab alongside multi-food OIT, represents a further step toward understanding whether targeting allergic pathways from multiple angles simultaneously might yield synergistic benefits (Sindher et al., 2023).

Biologics vs. Oral Immunotherapy

Oral immunotherapy and biologic therapy represent two fundamentally different approaches to managing IgE-mediated food allergy, and understanding their distinct mechanisms, limitations, and potential complementarity is essential for informed clinical decision-making. OIT works by gradually exposing the immune system to increasing quantities of the offending allergen under controlled conditions, with the aim of raising the reaction threshold through a process of desensitisation. Clinical trials have demonstrated efficacy across several foods including peanut, milk, egg, and tree nuts, and long-term safety data from pooled analyses of multiple peanut OIT trials support its tolerability profile when supervised appropriately (Nilsson et al., 2023). However, OIT carries important limitations that substantially affect its real-world applicability. Adverse reactions during the dose-escalation phase are common, and some patients experience reactions severe enough to necessitate discontinuation of the protocol. The treatment is inherently allergen-specific, meaning that patients with multiple concurrent food allergies would in principle require separate protocols for each food, imposing a significant time commitment and cumulative adverse event burden on patients and families (Sindher et al., 2023). Furthermore, the long-term durability of the desensitisation achieved through OIT is not guaranteed: a proportion of patients lose their protection after discontinuing daily maintenance dosing, raising questions about whether OIT induces true immunological tolerance or a more transient state of clinical unresponsiveness (Bégin et al., 2023).

Biologic therapy operates through an entirely different logic. Rather than retraining the immune system through allergen exposure, it reduces the functional capacity of effector cells to mount a severe reaction regardless of which allergen is encountered. This allergen-agnostic mechanism means that a single agent can simultaneously raise the reaction threshold for multiple foods, without requiring any exposure to the allergens themselves during the treatment period (Sindher et al., 2024). This property is particularly relevant for multi-food allergic patients, where the OIT burden is highest and the therapeutic need is most acute. The trade-off, however, is that omalizumab as monotherapy does not appear to reprogram the underlying allergic immune response, it provides protection only for as long as it is continued, and available evidence suggests that this protection diminishes following treatment discontinuation, meaning that ongoing therapy would likely be required indefinitely to maintain clinical benefit (Sindher et al., 2023).

These complementary profiles have generated considerable interest in the possibility of combining biologics with OIT. By suppressing effector cell reactivity during the dose-escalation phase of OIT, biologics could make the protocol safer and more tolerable, enabling patients who have previously failed OIT due to adverse reactions to complete the build-up phase successfully. At the same time, the immunological reprogramming achieved through sustained allergen exposure during OIT might reduce the need for ongoing biologic therapy, creating a treatment strategy where the biologic serves as a temporary facilitator rather than a permanent requirement. Early-stage clinical evidence supports the feasibility of this approach, with studies suggesting that omalizumab-facilitated multi-food OIT can enable simultaneous desensitisation to several allergens in patients who could not tolerate OIT alone (Sindher et al., 2024). The COMBINE trial, exploring the simultaneous use of both omalizumab and dupilumab alongside multi-food OIT, represents a further step toward understanding whether targeting

allergic pathways from multiple angles simultaneously might yield synergistic benefits (Sindher et al., 2023).

From a practical standpoint, the choice between biologics alone, OIT alone, or a combined approach will need to be individualised according to patient profile. Patients with a single well-characterised food allergy, motivated to pursue potential long-term tolerance, and without contraindications to OIT may be well suited for allergen-specific immunotherapy. Those with multiple concurrent food allergies, a history of severe reactions that makes OIT uposing unsafe, or who cannot commit to the intensive follow-up schedule required by OIT protocols may be better candidates for biologic monotherapy (Sindher et al., 2024). The combined approach may emerge as the optimal strategy for a broader population, though this will depend on the results of ongoing large randomised trials, the development of clearer treatment protocols, and improvements in cost and access that currently limit the real-world availability of both OIT programmes and biologic therapies for food allergy.

Evidence Gaps and Future Directions

Despite the genuine progress represented by omalizumab's approval, the evidence base for biologic therapy in IgE-mediated food allergy remains in its early stages, and several critical questions will need to be answered before this field matures into a fully evidence-guided clinical discipline. The most fundamental unresolved issue is the question of durability. Available data strongly suggest that the threshold-raising effect of omalizumab is contingent on continuous treatment, and that protection diminishes when therapy is discontinued yet no adequately powered, long-term study has formally characterised the rate and clinical significance of this decline, or identified predictors of which patients might retain some residual benefit after stopping (Nurmatov et al., 2025). This gap has direct implications for treatment planning, patient counselling, and the cost-effectiveness assessments that will shape payer decisions and access policies in the years ahead.

A closely related gap concerns the absence of validated biomarkers capable of predicting treatment response, guiding dosing decisions, or identifying patients most likely to benefit from biologic therapy versus OIT or a combined approach. Current clinical practice relies on serum total IgE levels to determine omalizumab dosing, but total IgE is a poor surrogate for the complexity of the underlying allergic immune state. Emerging biomarker tools including basophil activation tests, allergen-specific IgE component profiling, and T cell immunotyping hold considerable promise as more nuanced predictors of both reactivity threshold and therapeutic response, but none have been prospectively validated for this purpose in the context of biologic therapy (Fitzhugh, 2025). The FDA hosted a dedicated workshop specifically to address the regulatory pathway for biomarker validation in food allergy drug development, underscoring the institutional recognition of this gap (Rabin et al., 2025). Progress in this area would be transformative, enabling genuinely personalised treatment selection rather than the largely empirical approach that currently prevails.

The question of whether any currently available or emerging biologic can induce true immunological tolerance, a durable state of allergen unresponsiveness that persists after treatment discontinuation, remains one of the most important and as yet unanswered questions in the field. The distinction between desensitisation, which requires ongoing treatment to maintain, and sustained unresponsiveness or tolerance, which does not, is clinically critical (Dolence et al., 2022). OIT has shown the capacity to induce sustained unresponsiveness in a proportion of patients, particularly when started early in life, but the rates are inconsistent and the predictors poorly understood. Whether biologics can improve the rates of sustained unresponsiveness by reducing immunological reactivity during allergen exposure and allowing more effective immune reprogramming is an active area of investigation. The results of ongoing combination trials, including the COMBINE study, are among the most eagerly awaited data in the field (Sindher et al., 2023).

Representation of adult patients in the current evidence base is another significant limitation. The OUtMATCH trial enrolled primarily children and adolescents, and the majority of OIT studies have similarly focused on paediatric populations. Adults with established, long-standing food allergy may have distinct immunological profiles and different risk-benefit calculations compared with children, and it cannot be assumed that paediatric trial findings translate directly (Nurmatov et al., 2025). Dedicated trials in adult populations are an important research priority. Similarly, the evidence base for patients with very high baseline serum IgE in whom omalizumab dosing reaches its ceiling and efficacy may be attenuated is limited, and alternative strategies for this subgroup require investigation.

Looking ahead, the therapeutic landscape of IgE-mediated food allergy is likely to become considerably more complex and more capable over the next decade. The emerging data on anti-alarmin agents suggest that targeting the upstream drivers of the allergic cascade may yield more durable effects than downstream IgE blockade alone, particularly when combined with allergen-specific immunotherapy (Dolence et al., 2022).

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Novel approaches including ligelizumab, a next-generation high-affinity anti-IgE antibody with greater potency than omalizumab, are entering clinical evaluation for food allergy indications. The ultimate ambition of the field which is to develop a safe, broadly applicable, and durable treatment that can induce lasting tolerance across multiple food allergens simultaneously, remains aspirational, but the convergence of improved mechanistic understanding, expanding biologic pipelines, and increasingly sophisticated combination strategies suggests that this goal is more realistically within reach than at any previous point in the history of food allergy therapeutics (Dreskin et al., 2025).

Conclusion

Biological therapy has entered the management of IgE-mediated food allergy as a clinically validated and regulatory-approved treatment option for the first time, with omalizumab representing a meaningful and practical advance for patients with multi-food allergy. The evidence base, while promising, remains limited by short follow-up periods, predominantly paediatric trial populations, the absence of validated biomarkers, and the unresolved question of durable tolerance induction. As the pipeline of emerging agents expands and combination strategies with OIT are refined, the field is positioned for continued and rapid progress. Clinicians, researchers, and policymakers will need to work in close collaboration to ensure that this progress translates into equitable, evidence-guided, and patient-centred care across the full spectrum of those affected by food allergy.

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Author's Contribution:
Conceptualization: MR, HRZ, PS, MT
Methodology: MR, HRZ, PS, MT
Formal analysis: MR, HRZ, PS, MT
Investigation: MR, HRZ, PS, MT
Supervision: MR, HRZ, PS, MT
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At all stages, AI functioned strictly as an auxiliary tool under continuous human oversight. The interpretation of results, the identification and classification of reasoning errors, and the formulation of conclusions were carried out exclusively by specialists in clinical medicine and formal logic. The use of AI was limited to supporting tasks such as data preparation, pattern recognition, and language editing, and it did not replace human judgment at any point in the study.