

Transcript Details

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The Design, Endpoints, & Real-World Implications of Food Allergy Trials

Announcer Introduction

Welcome to *Cracking the Code on Peanut Allergies* on ReachMD, brought to you through an independent educational grant from Aimmune Therapeutics. Here's your host, Dr. Matt Birnholz.

Host Narration

Coming to you from the ReachMD studios in Fort Washington, Pennsylvania, this is *Cracking the Code on Peanut Allergies*. I'm Dr. Matt Birnholz. On this episode, we caught up with Dr. Maria Pasioti, a pediatric allergist and academic researcher practicing in Athens, Greece, who shared key insights on the design, endpoints, and real-world implications of food allergy trials. Here's an overview of what she shared with us.

When looking at how food allergy trials are designed, Dr. Pasioti noted that most start with either an open or double-blinded oral food challenge to determine the minimum dose that causes symptoms. After that, an initial dose escalation is performed to set the highest tolerated dose. Then, in a procedure known as the build-up phase, the implicated food is administered daily with gradual dose increases in predefined periods; it's usually over the course of 1 to 2 weeks, but it can even be monthly. This build-up phase continues until a predefined maintenance dose is reached. And once that occurs, the maintenance dose is administered daily for a long period, which varies from months to years.

Dr. Pasioti also listed important factors to consider when designing a food allergy trial. These include the target population, the verification of allergy by a baseline oral food challenge, the initiating dose, the rate of dose escalation, the primary outcome, the duration of therapy before assessing the efficacy, and finally, the duration of therapy discontinuation before assessing sustained unresponsiveness.

On the subject of food allergy trial endpoints, Dr. Pasioti explained that initially, primary outcomes aimed to increase the tolerated amounts of the food to normal servings. But an outcome that can lower the risk of adverse reactions from accidental exposure has also been found to be adequate, especially for peanut and tree allergies.

One of those efficacy outcomes is "desensitization," which is defined as the ability to safely consume foods containing the allergen while on therapy. Some researchers also use the term "partial desensitization" to describe an increase in the patient's threshold and "complete desensitization" when the patient can safely consume a normal serving of the food—or even a predefined arbitrary amount of the food. Another common endpoint mentioned earlier is called "sustained unresponsiveness," which refers to the ability to safely consume a normal serving of food containing the allergen, despite a period of absence of exposure.

Going back to the idea of desensitization, Dr. Pasioti noted that this is usually tested in an exit oral food challenge, the results of which are described using the "lowest observed adverse effect level," which is the lowest dose that provokes an allergic reaction, and the dose prior to that reaction, which is defined as the "maximum tolerated dose."

However, while most trials report safety endpoints, each trial uses a different grading system, and few trials assess the quality of life, which brings us to Dr. Pasioti's last point of focus: the real-world implications of food allergy trials.

This subject was brought up, Dr. Pasioti admitted that there were several obstacles often encountered when clinicians try to translate the results of a trial into practice. Heterogeneity, for example, has hindered the development of validated shared protocols, and as a result, allergists wind up using individualized criteria for patients' selection, up-dosing schedules, and maintenance doses. Additionally, efficacy in real-life is usually assessed by reaching the maintenance dose, which varies greatly between individual patients. A third obstacle is

that efficacy assessments and adverse events' reporting vary between trials, which is why the results should be interpreted with caution. Considering these various obstacles, Dr. Pasioti recommended that clinicians keep in mind the factors that can influence the outcomes of these trials: factors such as age, severity of the allergy, the implicated food, the dosing schedule, and the product used for immunotherapy.

These were some of main the highlights of our conversation with Dr. Pasioti on the design, endpoints, and real-world implications of food allergy trials. To check out the full interview or to find other episodes in this series, visit ReachMD.com/Peanut-Allergies for ReachMD, I'm Dr. Matt Birnholz, and thanks for joining us!

Announcer Close

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