

Treatment of food allergy: Question 1

Regarding food challenge studies to assess effectiveness of immunotherapy in allergic individuals, please discuss:

- objective criteria for determining the eliciting dose (ED), particularly in children <5 years of age;
- clinically meaningful parameters, including amplitude of response and duration of time off therapy, that could be used to demonstrate the effectiveness of immunotherapy for:
 - “desensitization”
 - “sustained unresponsiveness” (i.e., maintenance of desensitization off therapy)
- safety considerations for the food challenge

Treatment of food allergy: Question 2

Please discuss approaches other than food challenge studies to demonstrate the effectiveness of immunotherapy products intended for use in food allergic individuals.

Treatment of food allergy: Question 3

Taking into account the route of administration of immunotherapy in food allergic subjects, and the age of study subjects, please discuss specific safety monitoring for signs and symptoms of allergic reactions.

Prevention of development of asthma: Question 1

Studies to demonstrate effectiveness of allergy immunotherapy to prevent the development of asthma will likely enroll a population at increased risk for the development of asthma, including children 6 months of age and older. Please discuss:

- factors to consider in the identification of subjects at increased risk of developing asthma;
- the diagnosis of asthma in infants and young children;
- factors to consider regarding the timing of the assessment of asthma endpoints (e.g. age, time on therapy, time off therapy, others)

Prevention of development of asthma: Question 2

Please discuss the assessment of safety in infants and young children receiving aeroallergen immunotherapy to prevent the development of asthma.