

>> Glossary

<< Glossary





The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer](https://clinicaltrials.gov/about-site/disclaimer) (<https://clinicaltrials.gov/about-site/disclaimer>) for details.

ClinicalTrials.gov is a website and online database of clinical research studies and information about their results. The National Library of Medicine (NLM) maintains the website. **The study sponsor or investigator submits information** about their study to ClinicalTrials.gov and **is responsible for the safety, science, and accuracy** of any study they list.

Before joining a study, talk to your health care professional about possible risks and benefits. To learn more about taking part in studies, read [Learn About Studies](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Completed ⓘ

Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Participants (OUTMATCH)

ClinicalTrials.gov ID ⓘ NCT03881696

Sponsor

Inform

Last Update Posted ⓘ 2025-09-10

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
- To view one version of the study record, click the submitted date.
- To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.
 - Data that is changed in the study record is color coded:
 - Deletions from the study record are shown crossed out in **red highlights**.
 - Additions to the study record are shown in **green highlights**.

☐	1	2019-03-18	<ul style="list-style-type: none">• None (earliest version on record)
☐	2	2019-03-25	<ul style="list-style-type: none">• Study Status• Arms and Interventions

☐	3	2019-05-06	<ul style="list-style-type: none">• Study Status
☐	4	2019-06-11	<ul style="list-style-type: none">• Study Status
☐	5	2019-07-11	<ul style="list-style-type: none">• Study Status
☐	6	2019-07-23	<ul style="list-style-type: none">• Recruitment Status• Study Identification• Study Status• Contacts/Locations
☐	7	2019-08-20	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	8	2019-09-30	<ul style="list-style-type: none">• Study Status• Contacts/Locations
Version		Date submitted (YYYY-MM-DD)	Changes
			<ul style="list-style-type: none">• Contacts/Locations
☐	10	2019-11-07	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	11	2019-11-26	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	12	2019-12-20	<ul style="list-style-type: none">• Study Status• Contacts/Locations
Version		Date submitted (YYYY-MM-DD)	Changes
☐	14	2020-07-10	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	16	2020-11-24	<ul style="list-style-type: none">• Study Status• Conditions• Arms and Interventions• Eligibility• References
☐	17	2020-11-25	<ul style="list-style-type: none">• Study Status• Study Description• Eligibility• Contacts/Locations
☐	18	2021-03-03	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	19	2021-04-06	<ul style="list-style-type: none">• Study Status• Sponsor/Collaborators• Contacts/Locations
☐	20	2021-06-10	<ul style="list-style-type: none">• Study Status
☐	21	2021-06-16	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	22	2021-07-22	<ul style="list-style-type: none">• Study Status• Contacts/Locations
☐	23	2021-08-20	<ul style="list-style-type: none">• Study Status• Outcome Measures

☐	24	2021-09-14	<ul style="list-style-type: none">Study StatusContacts/Locations
☐	25	2022-03-22	<ul style="list-style-type: none">Study StatusOutcome Measures
☐	26	2022-05-02	<ul style="list-style-type: none">Study StatusContacts/Locations
☐	27	2022-09-07	<ul style="list-style-type: none">Study StatusArms and InterventionsContacts/Locations
☐	28	2022-11-21	<ul style="list-style-type: none">Study StatusContacts/Locations
☐	29	2023-02-24	<ul style="list-style-type: none">Study StatusContacts/Locations
☐	30	2023-03-21	<ul style="list-style-type: none">Study StatusContacts/Locations
☐	31	2023-04-21	<ul style="list-style-type: none">Recruitment StatusStudy StatusStudy DesignContacts/Locations
☐	32	2023-12-07	<ul style="list-style-type: none">Study Status
	Version	Date submitted (YYYY-MM-DD)	Changes
			<ul style="list-style-type: none">Outcome MeasuresDocument SectionParticipant FlowBaseline CharacteristicsOutcome Measures (Results)Adverse EventsMore Information <div> Quality Control Review Has Not Concluded Returned: 2024-04-09</div>
☐	34	2024-05-08	<ul style="list-style-type: none">Study StatusParticipant FlowAdverse Events
☐	35	2024-10-18	<ul style="list-style-type: none">Study StatusReferencesDocument Section
☐	36	2025-01-08	<ul style="list-style-type: none">Study StatusOutcome MeasuresOutcome Measures (Results)
☐	37	2025-05-20	<ul style="list-style-type: none">Study StatusDocument Section
☐	38	2025-09-08	<ul style="list-style-type: none">Recruitment StatusStudy StatusDocument SectionMore Information



Viewing V26 (2022-05-02)

Study Details

Study Identification

Unique Protocol ID	DAIT CoFAR-11
Brief Title	Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen OIT in Food Allergic Participants
Official Title	Omalizumab as Monotherapy and as Adjunct Therapy to Multi-Allergen Oral Immunotherapy (OIT) in Food Allergic Children and Adults (CoFAR-11)
Secondary IDs	CoFAR-11, NIAID CRMS ID#: 38625

Study Status

Record Verification	2022-05
Overall Status	Recruiting
Study Start	2019-07-22 [Actual]
Primary Completion	2022-10 [Estimated]
Study Completion	2023-12 [Estimated]
First Submitted	2019-03-15
First Submitted that Met QC Criteria	2019-03-18
First Posted	2019-03-19 [Actual]
Last Update Submitted that Met QC Criteria	2022-05-02
Last Update Posted	2022-05-04 [Actual]

Sponsor/Collaborators

Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Responsible Party	Sponsor
Collaborators	Genentech, Inc. Novartis Pharmaceuticals Rho Federal Systems Division, Inc.

Oversight

U.S. FDA-regulated Drug	Yes
U.S. FDA-regulated Device	No
Data Monitoring	Yes

Study Description

Brief Summary	<p>This study is a multi-center, randomized, double-blind, placebo-controlled study in participants 1 to less than 56 years of age who are allergic to peanut and at least two other foods (including milk, egg, wheat, cashew, hazelnut, or walnut). While each participant may be allergic to more than two other foods, the primary endpoint/outcome in this study will only be assessed in peanut and two other foods for each participant. The primary objective of the study is to compare the ability to consume foods without dose-limiting symptoms during a double-blind placebo-controlled food challenge (DBPCFC), after treatment with either omalizumab or placebo for omalizumab.</p>
Detailed Description	<p>Food allergy affects about 15 million people in the United States. This includes 6 million children. The current treatment for food allergy is to avoid eating the foods that may cause an allergic reaction and have medications such as epinephrine (adrenaline) in case of a reaction. However, accidental exposures can be extremely difficult to avoid, particularly if you are allergic to multiple foods. The risks of accidental exposures and life-threatening reactions can place a large burden on patients and their families.</p> <p>Investigators in this study would like to learn if omalizumab injections alone or in combination with multi-allergen oral immunotherapy (OIT) will help people with multiple food allergies eat foods to which they are allergic. Oral means that you will take the food allergen (peanut and 2 other foods to which you are allergic) by mouth. If you are allergic to more than 3 foods, this study will only provide OIT for peanut and 2 other foods.</p> <p>There are 3 stages to the study:</p> <p>In Stage 1, investigators would like to learn:</p> <ul style="list-style-type: none">• If omalizumab stops or decreases allergic reactions to peanut and other common food allergens after taking it for a length of time. <p>Stage 1 will also have an extra part so that 60 participants will receive omalizumab and everyone (the investigators conducting the research and study participants) will know it. This is why it is called the open label extension. This part of the study will assist investigators in learning if receiving omalizumab for a longer time may work better at decreasing allergic reactions.</p> <p>In Stage 2, investigators would like to learn:</p> <ul style="list-style-type: none">• How a short course of omalizumab combined with Multi-allergen OIT compares with a longer course of omalizumab in decreasing allergic reactions. <p>In Stage 3, investigators would like to learn:</p> <ul style="list-style-type: none">• If, after participants stop both treatments, will they be able to eat the peanut and the 2 other foods in the form that is normally eaten. <p>In all stages, investigators would like to learn:</p> <ul style="list-style-type: none">• How safe and effective the treatments are and• How the OIT affects the immune system.

Participation will last up to 56 months (4 years and 8 months).

Conditions

Condition	Peanut Allergy Multi-food Allergy
Keywords	peanut allergic multi-food allergic omalizumab placebo multi-allergen oral immunotherapy (OIT) double-blind placebo-controlled food challenge (DBPCFC) oral food challenge (OFC)

Study Design

Study Type	Interventional
Primary Purpose	Treatment
Study Phase	Phase 3
Interventional Study Model	Sequential Assignment
Number of Arms	7
Masking	Triple (Participant, Care Provider, Investigator)
Allocation	Randomized
Enrollment	225 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
<p>Experimental: Stage 1:Omalizumab as Monotherapy</p> <p>Eligible participants are randomized to receive omalizumab by subcutaneous injection either every 2 weeks or every 4 weeks for 16 to 20 weeks. The dose administered and the dosing interval are determined by serum total IgE level and body weight (measured before the start of treatment) per the study drug dosing table.</p> <p>After 16 weeks of treatment, each participant will complete double-blind placebo-controlled food challenge (DBPCFCs) to each of their three specific foods to a cumulative dose of 6044 mg protein of each food.</p> <p>Throughout Stage 1, each participant will be instructed to strictly avoid all foods to which they are allergic.</p> <p>The first 60 participants who complete all four DBPCFCs at the end of Stage 1 will participate in the Stage 1 Open Label Extension (OLE).All other participants who complete all four DBPCFCs will move Stage 2 of the study.</p>	<p>Drug: Omalizumab</p> <ul style="list-style-type: none">• Omalizumab will be supplied in pre-filled syringes (PFS). PFS of omalizumab will be provided to the clinical research units as 75 mg and 150 mg dosage forms.• Other Names:<ul style="list-style-type: none">◦ Xolair®

Experimental: Stage 1: Omalizumab OLE

OLE: Open Label Extension, Long-Term Treatment with Omalizumab. Participants will receive 24 weeks of open label omalizumab in accordance with the omalizumab dosing table defined in the study protocol. Omalizumab is administered by subcutaneous injection either every 2 weeks or every 4 weeks for 24 weeks. The dose administered and the dosing interval are determined by serum total IgE level and body weight (measured before the start of treatment) per the study drug dosing table.

After 24 weeks of treatment, each participant will complete DBPCFCs to each of their three specific foods to a cumulative dose of 8044 mg protein of each food. Each participant who completes all four DBPCFCs at the end of the Stage 1 OLE will move on to Stage 3 of the study.

Throughout Stage 1 OLE, each participant will be instructed to strictly avoid all foods to which they are allergic.

Drug: Omalizumab

- Omalizumab will be supplied in pre-filled syringes (PFS). PFS of omalizumab will be provided to the clinical research units as 75 mg and 150 mg dosage forms.
- Other Names:
 - Xolair®

Placebo Comparator: Stage 1: Placebo for Omalizumab as Monotherapy

Eligible participants are randomized to receive placebo for omalizumab by subcutaneous injection either every 2 weeks or every 4 weeks for 16 to 20 weeks. The dose administered and the dosing interval are determined by serum total IgE level and body weight (measured before the start of treatment) per the study drug dosing table.

After 16 weeks of treatment, each participant will complete DBPCFCs to each of their three specific foods to a cumulative dose of 6044 mg protein of each food.

Throughout Stage 1, each participant will be instructed to strictly avoid all foods to which they are allergic.

The first 60 participants who complete all four DBPCFCs at the end of Stage 1 will participate in the Stage 1 OLE. All other participants who complete all four DBPCFCs will move Stage 2 of the study.

Drug: Placebo for Omalizumab

- Placebo contains the same ingredients as the omalizumab formulation, excluding omalizumab. Placebo will be supplied in pre-filled syringes (PFS). PFS of placebo will be provided to the clinical research units as 75 mg and 150 mg dosage forms.
- Other Names:
 - Placebo

Experimental: Stage 2: Omalizumab

Participants will receive eight weeks of treatment with open label omalizumab in accordance with the omalizumab dosing table specified in the study protocol, administered by subcutaneous injection. The dose administered and the dosing interval are determined by serum total IgE level and body weight (measured before the start of treatment) per the study drug dosing table.

After completion of eight weeks of open label omalizumab, participants will be randomized 1:1 to either:

- Omalizumab-facilitated oral immunotherapy (OIT): Open label omalizumab + Multi-allergen OIT for eight weeks, followed by placebo for

Drug: Omalizumab

- Omalizumab will be supplied in pre-filled syringes (PFS). PFS of omalizumab will be provided to the clinical research units as 75 mg and 150 mg dosage forms.
- Other Names:
 - Xolair®

<p>omalizumab + Multi-allergen OIT for 44 weeks OR</p> <ul style="list-style-type: none"> • Omalizumab + placebo OIT: Open label omalizumab + placebo for Multi-allergen OIT for eight weeks, followed by omalizumab + placebo for Multi-allergen OIT for 44 weeks. <p>Throughout Stage 2, each participant will be instructed to strictly avoid all foods to which they are allergic.</p>	
<p>Experimental: Stage 2: Omalizumab-Facilitated OIT</p> <p>OIT: oral immunotherapy-Omalizumab as Adjunct Therapy to Multi-Allergen Oral Immunotherapy</p> <p>Participants randomized to open label omalizumab + Multi-allergen OIT for eight weeks, followed by placebo for omalizumab + Multi-allergen OIT for 44 weeks.</p> <p>Throughout Stage 2, each participant will be instructed to strictly avoid all foods to which they are allergic.</p>	<p>Drug: Omalizumab</p> <ul style="list-style-type: none"> • Omalizumab will be supplied in pre-filled syringes (PFS). PFS of omalizumab will be provided to the clinical research units as 75 mg and 150 mg dosage forms. • Other Names: <ul style="list-style-type: none"> ◦ Xolair® <p>Drug: Multi-Allergen Oral Immunotherapy</p> <ul style="list-style-type: none"> • Multi-allergen OIT will be any of the following drug products: peanut, milk, egg, wheat, cashew, hazelnut, and walnut (all food protein flours). <p>A prescription for each participant for the appropriate dose of each of the allergens will be prepared. The pharmacist will compound the appropriate allergens and dispense the Multi-allergen OIT dose in a blinded (masked) fashion. The Clinical Research Unit (CRU) staff will administer food flour to the participant orally in an age-appropriate food vehicle (e.g., applesauce, pudding, etc.). Dosage will be administered according to the study protocol.</p> <ul style="list-style-type: none"> • Other Names: <ul style="list-style-type: none"> ◦ Multi-Allergen OIT
<p>Experimental: Stage 2: Omalizumab + Placebo OIT</p> <p>OIT: oral immunotherapy Participants randomized to open label omalizumab + placebo for Multi-allergen OIT for eight weeks, followed by omalizumab + placebo for Multi-allergen OIT for 44 weeks.</p> <p>Throughout Stage 2, each participant will be instructed to strictly avoid all foods to which they are allergic.</p>	<p>Drug: Omalizumab</p> <ul style="list-style-type: none"> • Omalizumab will be supplied in pre-filled syringes (PFS). PFS of omalizumab will be provided to the clinical research units as 75 mg and 150 mg dosage forms. • Other Names: <ul style="list-style-type: none"> ◦ Xolair® <p>Drug: Placebo for Multi-Allergen Oral Immunotherapy</p> <ul style="list-style-type: none"> • Oat flour will be used for placebo for Multi-allergen OIT. Route: by mouth/oral. Dosage will be administered according to the study protocol. • Other Names: <ul style="list-style-type: none"> ◦ Placebo for Multi-Allergen OIT
<p>Other: Stage 3: DBPCFC Based Treatment</p> <p>DBPCFC Based Treatment-Long-term Follow-up Treatment Plan for Peanut and Each of the Two Other Participant-Specific Foods.</p> <p>Upon completion of the DBPCFCs at the end of Stage 1 OLE or Stage 2, each participant will receive a separate treatment plan for peanut and each of the two other participant-specific foods based on the</p>	<p>Other: Double-Blind Placebo-Controlled Food Challenge Based Treatment</p> <ul style="list-style-type: none"> • Each participant will receive a separate treatment plan for peanut and each of the two other participant-specific foods. A treatment plan will include instructions for one of the following: <ul style="list-style-type: none"> ◦ Long-term follow-up with dietary consumption of a food; or

results of the DBPCFCs. A treatment plan will include instructions for one of the following:

- Long-term follow-up with dietary consumption of a food;
- Long-term follow-up with avoidance of a food; or
- Rescue OIT for a food.

The treatment plan for each food may change throughout Stage 3 depending on a participant's response to treatment. Once a participant enters Stage 3, the participant will remain in Stage 3 until December 2023.

Note: Participants will be instructed to strictly avoid a food if they receive rescue OIT for the food during Stage 3.

- Long-term follow-up with avoidance of a food; or
- Rescue OIT for a food. The treatment plan for each food may change depending on a participant's response to prescribed treatment over time.

- Other Names:
 - DBPCFC Based Treatment

Outcome Measures

Primary Outcome Measures

1. Number of Participants by Stage 1 Treatment Assignment, Omalizumab versus Placebo, Who Successfully Consume a Single Dose of ≥ 600 mg of Peanut Protein Without Dose-Limiting Symptoms During the DBPCFC Conducted at the End of Treatment Stage 1
Number of participants who successfully consume a single dose of ≥ 600 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

Secondary Outcome Measures

1. Number of Participants by Stage 1 Treatment Assignment, Omalizumab versus Placebo, who successfully consume a single dose of ≥ 1000 mg of cashew protein without dose-limiting symptoms during the DBPCFC conducted at the end of Stage 1
Number of participants who successfully consume a single dose of ≥ 1000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
2. Number of Participants by Stage 1 Treatment Assignment, Omalizumab versus Placebo, who successfully consume a single dose of ≥ 1000 mg of milk protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1
Number of participants who successfully consume a single dose of ≥ 1000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment

with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

3. Number of Participants by Stage 1 Treatment Assignment, Omalizumab versus Placebo, who successfully consume a single dose of ≥ 1000 mg of egg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1
Number of participants who successfully consume a single dose of ≥ 1000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
4. Number of participants who successfully consume a single dose of ≥ 600 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
5. Number of participants who successfully consume a single dose of ≥ 600 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
6. Number of participants who successfully consume a single dose of ≥ 600 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting

symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

7. Number of participants who successfully consume a single dose of ≥ 600 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
8. Number of participants who successfully consume a single dose of ≥ 600 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
9. Number of participants who successfully consume a single dose of ≥ 600 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
10. Number of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC), at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab.

Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

11. Number of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for at least three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC), at the end of Stage 1
Proportion of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
12. Number of participants who successfully consume a single dose of ≥ 1000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1.
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
13. Number of participants who successfully consume a single dose of ≥ 1000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1.
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
14. Number of participants who successfully consume a single dose of ≥ 1000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1.
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting

symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

15. Number of participants who successfully consume a single dose of ≥ 1000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1.

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

16. Number of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

17. Number of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

18. Number of participants who successfully consume ≥ 1 dose of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting

symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

19. Number of participants who successfully consume ≥ 1 dose of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

20. Number of participants who successfully consume ≥ 1 dose of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

21. Number of participants who successfully consume ≥ 1 dose of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

22. Number of participants who successfully consume ≥ 1 dose of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting

symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

23. Number of participants who successfully consume ≥ 1 dose of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
24. Number of participants who successfully consume ≥ 1 dose of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
25. Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
26. Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC), at the end of Stage 1
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab.

Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

27. Proportion of participants who successfully consume 2 doses of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume 2 doses of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]]

28. Proportion of participants who successfully consume 2 doses of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume 2 doses of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

29. Number of participants who successfully consume 2 doses of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume 2 doses of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

30. Number of participants who successfully consume 2 doses of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume 2 doses of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting

symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

31. Number of participants who successfully consume 2 doses of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
- Proportion of participants who successfully consume 2 doses of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
- [Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
32. Number of participants who successfully consume 2 doses of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
- Proportion of participants who successfully consume 2 doses of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
- [Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
33. Number of participants who successfully consume 2 doses of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
- Proportion of participants who successfully consume 2 doses of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
- [Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]
34. Number of participants who successfully consume 2 doses of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1
- Proportion of participants who successfully consume 2 doses of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab.

Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

35. Number of participants who successfully consume 2 doses of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 1

Proportion of participants who successfully consume 2 doses of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 1 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab or placebo for omalizumab. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

36. 33. Number of foods consumed at a single dose of ≥ 600 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

37. Number of foods consumed at a single dose of ≥ 1000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

38. Number of foods consumed at ≥ 1 dose of 2000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

39. Number of foods consumed at 2 doses of 2000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 1.

[Time Frame: During the DBPCFC at the end of Stage 1: 16 to 20 weeks after Stage 1 treatment initiation]

40. Number of participants who successfully consume a single dose of ≥ 600 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 600 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

41. Number of participants who successfully consume a single dose of ≥ 600 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 600 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2

treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

42. Number of participants who successfully consume a single dose of ≥ 600 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 600 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

43. Number of participants who successfully consume a single dose of ≥ 600 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 600 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

44. Number of participants who successfully consume a single dose of ≥ 600 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 600 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

45. Number of participants who successfully consume a single dose of ≥ 600 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 600 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods

without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

46. Number of participants who successfully consume a single dose of ≥ 600 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 600 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
47. Number of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
48. Number of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 600 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
49. Number of participants who successfully consume a single dose of ≥ 1000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2

treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

50. Number of participants who successfully consume a single dose of ≥ 1000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage treatment initiation]

51. Number of participants who successfully consume a single dose of ≥ 1000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

52. Number of participants who successfully consume a single dose of ≥ 1000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

53. Number of participants who successfully consume a single dose of ≥ 1000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2

Proportion of participants who successfully consume a single dose of ≥ 1000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods

without dose-limiting symptoms during a DBPCFC after treatment either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

54. Number of participants who successfully consume a single dose of ≥ 1000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
55. Number of participants who successfully consume a single dose of ≥ 1000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
56. Number of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
57. Number of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume a single dose of ≥ 1000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to

consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

58. Number of participants who successfully consume ≥ 1 dose of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
- Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
- [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
59. Number of participants who successfully consume ≥ 1 dose of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage
- Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
- [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
60. Number of participants who successfully consume ≥ 1 dose of 2000mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
- Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
- [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
61. Number of participants who successfully consume ≥ 1 dose of 2000mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
- Proportion of participants who successfully consume ≥ 1 dose of 2000mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods

without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

62. Number of participants who successfully consume ≥ 1 dose of 2000mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 1 dose of 2000mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
63. Number of participants who successfully consume ≥ 1 dose of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
64. Number of participants who successfully consume ≥ 1 dose of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
65. Number of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC

after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.

[Time Frame: Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

66. Number of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 1 dose of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
67. Number of participants who successfully consume ≥ 2 doses of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
68. Number of participants who successfully consume ≥ 2 doses of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
69. Number of participants who successfully consume ≥ 2 doses of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods

without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

70. Number of participants who successfully consume ≥ 2 doses of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
71. Number of participants who successfully consume ≥ 2 doses of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
72. Number of participants who successfully consume ≥ 2 doses of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
73. Number of participants who successfully consume ≥ 2 doses of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment

with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

74. Number of participants who successfully consume ≥ 2 doses of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
75. Number of participants who successfully consume ≥ 2 doses of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume ≥ 2 doses of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
76. Number of participants who successfully consume 3 doses of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of peanut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
77. Number of participants who successfully consume 3 doses of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of milk protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods

without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

78. Number of participants who successfully consume 3 doses of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of egg protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
79. Proportion of participants who successfully consume 3 doses of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of wheat protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
80. Number of participants who successfully consume 3 doses of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of cashew protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
81. Number of participants who successfully consume 3 doses of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of hazelnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment

with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]

82. Number of participants who successfully consume 3 doses of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of walnut protein without dose-limiting symptoms during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
83. Number of participants who successfully consume 3 doses of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of food protein without dose-limiting symptoms for at least two treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
84. Number of participants who successfully consume 3 doses of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) at the end of Stage 2
Proportion of participants who successfully consume 3 doses of 2000 mg of food protein without dose-limiting symptoms for all three treated food allergens during the double-blind placebo-controlled oral food challenge (DBPCFC) conducted in a controlled clinic setting, at the end of Stage 2 treatment, to compare the ability of participants to consume foods without dose-limiting symptoms during a DBPCFC after treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT. Dose-limiting symptoms are those that in the view of the principal investigator indicate a true allergic reaction. [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
85. Number of foods consumed at a single dose of ≥ 600 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 2.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
86. Number of foods consumed at a single dose of ≥ 1000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 2.

- [Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
87. Number of foods consumed at ≥ 1 dose of 2000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 2.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
 88. Number of foods consumed at ≥ 2 doses of 2000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 2.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
 89. Number of foods consumed at 3 doses of 2000 mg protein without dose-limiting symptoms during the DBPCFC at the end of Stage 2.
[Time Frame: During the DBPCFC at the end of Stage 2: 60 to 64 Weeks after Stage 2 treatment initiation]
 90. During Stage 1: Occurrence of Adverse Event(s) Related to Study Therapy Regimen, Omalizumab versus Placebo
To evaluate safety during treatment with either omalizumab or placebo for omalizumab during Stage 1 masked (blinded) treatment.
[Time Frame: Up to 20 Weeks after initiating Stage 1 randomized treatment initiation]
 91. During Stage 1 OLE : Occurrence of Adverse Event(s) Related Study to Therapy Regimen, Open Label Extension (OLE)
To evaluate safety during this open label omalizumab study therapy regimen during Stage 1.
[Time Frame: Up to 28 Weeks after initiating Stage 1 Open Label omalizumab study therapy regimen]
 92. During Stage 2: Occurrence of Adverse Event(s) Related to Study Therapy Regimen
To evaluate safety during treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT during Stage 2.
[Time Frame: Up to 64 Weeks after initiating Stage 2 study therapy regimen]
 93. During Stage 3: Occurrence of Adverse Event(s) Related to Oral Food Intake
To evaluate safety after the conclusion of treatment with either omalizumab-facilitated oral immunotherapy (OIT) or omalizumab + placebo OIT during a follow-up period in which participants either received guided dietary instructions and/or rescue OIT for up to three foods (Stage 3).
[Time Frame: Up to 2 years after initiating Stage 3 Oral Food Intake regimen]
 94. Number of weeks in each eight-week period during Stage 3 where ≥ 300 mg protein of each food is consumed at least twice per week
To compare dietary consumption of foods after the conclusion of treatment with either omalizumab facilitated OIT or omalizumab + placebo OIT during a follow-up period in which participants either received guided dietary instructions and/or rescue oral immunotherapy (OIT) for up to three foods (Stage 3).
[Time Frame: From initial 8-week period during Stage 3 up to the last possible 8-week period during Stage 3 (i.e., Up to N=13 possible 8-week intervals during a 2-year period of time in Stage 3)]
 95. Number of weeks in each eight-week period during Stage 3 where each food is not consumed
To compare dietary consumption of foods after the conclusion of treatment with either omalizumab facilitated OIT or omalizumab + placebo OIT during a follow-up period in which participants either received guided dietary instructions and/or rescue oral immunotherapy (OIT) for up to three foods (Stage 3).

[Time Frame: From initial 8-week period during Stage 3 up to the last possible 8-week period during Stage 3 (i.e., Up to N=13 possible 8-week intervals during a 2-year period of time in Stage 3)]

Eligibility

Minimum Age	1 Year
Maximum Age	55 Years
Sex	All
Gender-based Eligibility	
Gender Eligibility Description	
Accepts Healthy Volunteers	No
Criteria	<p>Inclusion Criteria:</p> <p>Individuals who meet all of the following criteria are eligible for enrollment as study participants:</p> <ol style="list-style-type: none">Participant and/or parent/legal guardian must be able to understand and provide informed consent and/or assent, as applicable;Peanut allergic: participant must meet all of the following criteria to minimize the chance that the participant will develop natural tolerance to peanut over the course of the study:<ol style="list-style-type: none">Positive skin prick test (SPT) defined as ≥ 4 mm wheal greater than saline control) to peanut,Positive peanut immunoglobulin E (IgE), ≥ 6 kUA/L, at Screening or within three months of Screening, determined by ImmunoCap, andPositive double-blind placebo-controlled food challenge (DBPCFC), defined as experiencing dose-limiting symptoms at a single dose of ≤ 100 mg of peanut protein.Allergic to at least two of the six other foods (milk, egg, wheat, cashew, hazelnut, walnut): each participant must meet all of the following criteria for at least two of the six other foods to minimize the chance that the participant will develop natural tolerance to at least two of the six other foods over the course of the study:<ol style="list-style-type: none">Positive SPT (≥ 4 mm wheal) to food,Positive food specific IgE (≥ 6 kUA/L) at Screening or within three months of Screening, determined by ImmunoCap, andPositive DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤ 300 mg of food protein.With body weight (as measured at Screening) and total serum IgE level (as measured within three months of Screening) suitable for omalizumab dosing;If female of child-bearing potential, must have a negative urine or serum pregnancy test;For women of childbearing potential, must agree to,during the treatment period and for 60 days after the last dose of study drug:<ul style="list-style-type: none">remain abstinent (refrain from heterosexual intercourse), oruse acceptable contraceptive methods (barrier methods, ororal, injected, or implanted hormonal methods of contraception, orother forms of hormonal contraception that have comparable efficacy).Plan to remain in the study area of an OUTMATCH clinical research unit (CRU) during the trial; andBe willing to be trained on the proper use of an epinephrine autoinjector for the duration of the study.

Exclusion Criteria:

Individuals who meet any of the following criteria are not eligible for enrollment as study participants:

1. Inability or unwillingness of a participant and/or parent/legal guardian to give written informed consent and/or assent or comply with the study protocol;
2. Clinically significant laboratory abnormalities at Screening;
3. Dose-limiting symptoms to the placebo portion of the Screening DBPCFC;
4. Sensitivity or suspected/known allergy to any ingredients (including excipients) of the
 - active or placebo oral food challenge (OFC) material,
 - multi-allergen oral immunotherapy (OIT), or
 - drugs related to omalizumab (e.g., monoclonal antibodies, polyclonal gamma globulin).
 - Note: Guidance for determination of sensitivity to excipients will be detailed in the study's Manual of Procedures (MOP).
5. Poorly controlled atopic dermatitis (AD) at Screening, per the Principal Investigator's PI's discretion;
6. Poorly controlled or severe asthma/wheezing at Screening, defined by at least one of the following criteria:
 1. Global Initiative for Asthma (GINA) criteria regarding asthma control latest guidelines,
 2. History of two or more systemic corticosteroid courses within six months of Screening or one course of systemic corticosteroids within three months of Screening to treat asthma/wheezing,
 3. Prior intubation/mechanical ventilation for asthma/wheezing,
 4. One hospitalization or Emergency Department (ED) visit for asthma/wheezing within six months of Screening,
 5. Forced expiratory volume in one second (FEV1) <80 percent of predicted or FEV1/forced vital capacity (FVC) <75 percent, with or without controller medications (only for participants who are aged seven years or older and are able to perform spirometry), or
 6. Inhaled corticosteroid (ICS) dosing of >500 mcg daily fluticasone (or equivalent ICS based on the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI) dosing chart).
7. History of severe anaphylaxis to participant-specific foods that will be used in this study, defined as neurological compromise or requiring intubation;
8. Treatment with a burst of oral, intramuscular (IM), or intravenous (IV) steroids of more than two days for an indication other than asthma/wheezing within 30 days of Screening;
9. Currently receiving oral, intramuscular, or intravenous corticosteroids, tricyclic antidepressants, or beta-blockers (oral or topical);
10. Past or current history of eosinophilic gastrointestinal (GI) disease within three years of Screening;
11. Past or current history of cancer, or currently being investigated for possible cancer;
12. Previous adverse reaction to omalizumab;
13. Past or current history of any immunotherapy to any of the foods being treated in this study (e.g., OIT, sublingual immunotherapy [SLIT], EPIT) within 6 months of Screening;
14. Treatment with monoclonal antibody therapy, such as omalizumab (Xolair®), dupilumab (Dupixent®), benralizumab (Fasenra™), mepolizumab (Nucala®), reslizumab (Cinqair®), or other immunomodulatory therapy within six months of Screening;
15. Currently on "build-up phase" of inhalant allergen immunotherapy (i.e., has not reached maintenance dosing). Note: Individuals tolerating

- maintenance allergen immunotherapy can be enrolled;
- 16. Inability to discontinue antihistamines for the minimum wash-out periods required for SPTs, or OFCs;
 - 17. Current participation in another therapeutic or interventional clinical trial or participation within 90 days of Screening;
 - 18. Use of investigational drugs within 24 weeks of Screening;
 - 19. Pregnant or breastfeeding, or intending to become pregnant during the study or within 60 days after the last dose of omalizumab or placebo for omalizumab;
 - 20. Has a first-degree relative already enrolled in the study; or
 - 21. Past or current medical problems (e.g., severe latex allergy), history of other chronic diseases (other than asthma/wheezing, AD, or rhinitis) requiring therapy (e.g., heart disease, diabetes), findings from physical assessment, or abnormalities in clinical laboratory testing that are not listed above, which, in the opinion of the PI, may:
 - pose additional risks from participation in the study,
 - may interfere with the participant's ability to comply with study requirements, or
 - may impact the quality or interpretation of the data obtained from the study.

Contacts/Locations

Central Contact Person	
Study Officials	<div><div><div>Name</div><div>Robert A. Wood, MD</div></div><div><div>Role</div><div>Study Chair</div></div><div><div>Affiliation</div><div>Department of Pediatrics at the Johns Hopkins University School of Medicine</div></div></div> <div><div><div>Name</div><div>Sharon Chinthrajah, MD</div></div><div><div>Role</div><div>Study Chair</div></div><div><div>Affiliation</div><div>Department of Medicine, Stanford University School of Medicine</div></div></div>
Location	<div><div><div><div>Little Rock, Arkansas, United States, 72202</div><div>Status: Recruiting</div></div><div><div>Facility:</div><div>Arkansas Children's Hospital Research Institute: Department of Pediatrics, Allergy & Immunology</div></div><div><div>Contact:</div><div><div><div>Contact</div><div><div>Aprile Wicker</div><div>501-364-1998</div><div>wickeraj@archildrens.org</div></div></div><div><div>Principal Investigator</div><div>Stacie M. Jones, MD</div></div></div></div></div><div><div><div><div>Stanford, California, United States, 94305</div><div>Status: Recruiting</div></div><div><div>Facility:</div><div>Stanford School of Medicine: Sean N. Parker Center for Allergy & Asthma Research</div></div><div><div>Contact:</div><div><div><div>Contact</div><div><div>Frida Caledron</div><div>650-521-7237</div><div>snpallergy@stanford.edu</div></div></div><div><div>Principal Investigator</div><div>Rebecca S. Chinthrajah, MD</div></div></div></div></div><div><div><div>Denver, Colorado, United States, 80206</div></div></div></div></div>

Status: **Recruiting**

Facility: National Jewish Health: Division of Pediatric Allergy and Clinical Immunology

Contact:

- Contact
 - Caroline Bronchick
 - 303-270-2207
 - bronchickc@njhealth.org
- Contact
 - Susan Leung
 - 303-398-1549
 - leungs@NJHealth.org
- Principal Investigator
 - Donald YM Leung, MD, PhD

• **Atlanta, Georgia, United States, 30307**

Status: **Recruiting**

Facility: Emory University School of Medicine: Children's Healthcare of Atlanta Pediatrics

Contact:

- Contact
 - Mary Vess
 - 404-785-4476
 - mary.vess@choa.org
- Contact
 - Ashley Dulson
 - 404-785-5437
 - ashley.dulson@choa.org
- Principal Investigator
 - Brian P. Vickery, MD

• **Baltimore, Maryland, United States, 21287**

Status: **Recruiting**

Facility: Johns Hopkins Children's Center: Department of Allergy & Immunology

Contact:

- Contact
 - Maureen Jones
 - 410-502-1711
 - mjone241@JHMI.edu
- Principal Investigator
 - Robert A. Wood, MD

• **Boston, Massachusetts, United States, 02114**

Status: **Recruiting**

Facility: Massachusetts General Hospital, Department of Medicine: Allergy & Clinical Immunology Unit

Contact:

- Contact
 - Michael Marget
 - 617-643-5833
 - MMarget@mgh.harvard.edu
- Principal Investigator
 - Wayne G. Shreffler, MD, PhD

• **New York, New York, United States, 10029**

Status: **Recruiting**

Facility: Icahn School of Medicine at Mount Sinai: Department of Pediatrics Allergy & Immunology

Contact:

- Contact
 - Jaime Ross, RN, MSN
 - 212-241-6577
 - jaime.ross@mssm.edu
- Principal Investigator
 - Scott H. Sicherer, MD

- **Chapel Hill, North Carolina, United States, 27599-7000**
Status: **Recruiting**
Facility: North Carolina Children's Hospital: Department of Pediatrics, Division of Allergy, Immunology and Rheumatology
Contact:
 - Contact
 - Sarah Bennick, MSN,APRN,CPNP
 - 919-962-4409
 - sbennick@email.unc.edu
 - Contact
 - Lauren Herlihy, RN,MSN,CPNP
 - 919-962-4406
 - lekoch@email.unc.edu
 - Principal Investigator
 - Edwin H. Kim, MD
 - **Philadelphia, Pennsylvania, United States, 19104**
Status: **Recruiting**
Facility: Children's Hospital of Philadelphia: Division of Allergy and Immunology
Contact:
 - Contact
 - Noreen Dugan
 - 267-425-0010
 - dugann@chop.edu
 - Principal Investigator
 - Jonathan M. Spergel, MD
 - **Dallas, Texas, United States, 75390**
Status: **Recruiting**
Facility: University of Texas Southwestern Medical Center: Division of Allergy and Immunology
Contact:
 - Contact
 - Amy Arneson
 - 214-456-1438
 - amy.arneson@childrens.com
 - Contact
 - Kaylee Lirely
 - 214-456-3971
 - kaylee.lirely@childrens.com
 - Principal Investigator
 - Andrew Bird, MD

IPD Sharing

IPD information

References

Citations

- [\[General\] Sampson HA, Berin MC, Plaut M, Sicherer SH, Jones S, Burks AW, Lindblad R, Leung DYM, Wood RA. The Consortium for Food Allergy Research \(CoFAR\): The first generation. J Allergy Clin Immunol. 2019 Feb;143\(2\):486-493. doi: 10.1016/j.jaci.2018.12.989. Epub 2018 Dec 23. \(https://pubmed.ncbi.nlm.nih.gov/30586557\).](#)

Links	Division of Allergy, Immunology, and Transplantation (http://www.niaid.nih.gov/about/dait). National Institute of Allergy and Infectious Diseases (http://www.niaid.nih.gov/)
Available IPD/Information	

Document Section