

Food Treatment Jeopardy

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Let's play to learn more about
Omalizumab, SLIT, and OIT!

START!



Disclosures:

Genentech APP Advisory Board Member, September 2023.

- Genentech manufactures and markets Omalizumab.

These two got me into the allergy field (and medicine in general)!



HOW IT STARTED.



HOW IT'S GOING.

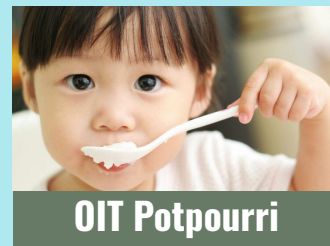


OMA

SLIT

OIT RX

OIT PO



100

100

100

100

200

200

200

200

300

300

300

300



OMA

SLIT

OIT RX

OIT PO



Omalizumab

100

200

300



OMA

SLIT

OIT RX

OIT PO



**Omalizumab
dosing for food
allergy is based
on THESE two
patient
parameters.**



Weight
10-150 kg¹

Table 1. Recommended Dosages for Xolair in the Treatment of IgE-Mediated Food Allergies

Body Weight (kg)	≥30 – 100 IU/mL	>100 – 200 IU/mL	>200 – 300 IU/mL	>300 – 400 IU/mL	>400 – 500 IU/mL	>500 IU/mL	>600 IU/mL
≥10-12 kg	75 mg	75 mg	75 mg	150 mg	150 mg	150 mg	See Table 2
>12-15 kg	75 mg	75 mg	75 mg	150 mg	150 mg	150 mg	See Table 2
>15-20 kg	75 mg	75 mg	150 mg	150 mg	225 mg	225 mg	225 mg
>20-25 kg	75 mg	150 mg	150 mg	225 mg	225 mg	300 mg	300 mg
>25-30 kg	75 mg	150 mg	150 mg	225 mg	300 mg	300 mg	See Table 2
>30-40 kg	75 mg	150 mg	225 mg	300 mg	450 mg	450 mg	450 mg
>40-50 kg	150 mg	300 mg	300 mg	450 mg	450 mg	600 mg	600 mg
>50-60 kg	150 mg	300 mg	300 mg	450 mg	600 mg	600 mg	See Table 2
>60-70 kg	150 mg	300 mg	450 mg	450 mg	600 mg	See Table 2	See Table 2
>70-80 kg	150 mg	300 mg	450 mg	600 mg	See Table 2	See Table 2	See Table 2
>80-90 kg	150 mg	300 mg	450 mg	600 mg	See Table 2	See Table 2	See Table 2
>90-125 kg	300 mg	450 mg	600 mg	See Table 2	See Table 2	See Table 2	See Table 2
>125-150 kg	300 mg	600 mg	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2

Spaces marked in ■ indicate insufficient data to recommend a dose.
Abbreviations: IgE, immunoglobulin E; IU/mL, international units per milliliter; kg, kilograms; mg, milligrams.
Xolair®. Prescribing information. Genentech, Inc.; 2024. Accessed February 26, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf

Minimum Age:
1 year¹

Table 2. Recommended Dosages for Xolair in the Treatment of IgE-Mediated Food Allergies

Body Weight (kg)	≥30 – 100 IU/mL	>100 – 200 IU/mL	>200 – 300 IU/mL	>300 – 400 IU/mL	>400 – 500 IU/mL	>500 IU/mL	>600 IU/mL	>700 IU/mL	>800 IU/mL	>900 IU/mL	>1000 IU/mL	>1100 IU/mL	>1200 IU/mL	>1300 IU/mL	>1400 IU/mL	>1500 IU/mL
≥10-12 kg	75 mg	75 mg	75 mg	150 mg	150 mg	150 mg	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1
>12-15 kg	75 mg	75 mg	75 mg	150 mg	150 mg	150 mg	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1
>15-20 kg	75 mg	75 mg	150 mg	150 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg	225 mg
>20-25 kg	75 mg	150 mg	150 mg	225 mg	225 mg	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg	300 mg
>25-30 kg	75 mg	150 mg	150 mg	225 mg	300 mg	300 mg	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2
>30-40 kg	75 mg	150 mg	225 mg	300 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg	450 mg
>40-50 kg	150 mg	300 mg	300 mg	450 mg	450 mg	600 mg	600 mg	600 mg	600 mg	600 mg	600 mg	600 mg	600 mg	600 mg	600 mg	600 mg
>50-60 kg	150 mg	300 mg	300 mg	450 mg	600 mg	600 mg	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2
>60-70 kg	150 mg	300 mg	450 mg	450 mg	600 mg	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2
>70-80 kg	150 mg	300 mg	450 mg	600 mg	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2	See Table 2
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Xolair®. Prescribing information. Genentech, Inc.; 2024. Accessed February 26, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf

Max Dose
600 mg
Q 2 wks¹

Total Serum
IgE
30 -
1,850
kU/L¹



OMA

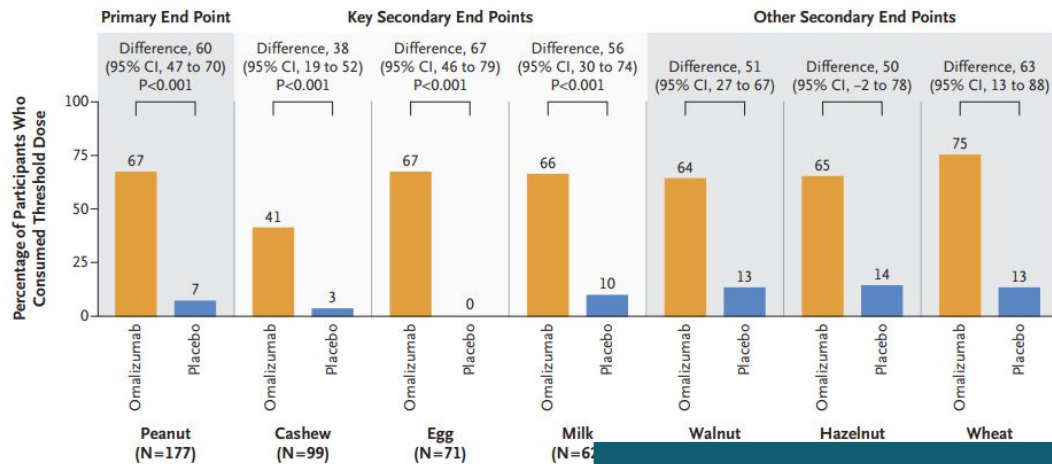
SLIT

OIT RX

OIT PO



Omalizumab is approved to reduce the risk of severe reactions to food and may allow patients to consume THESE products safely.



Between 41 and 75% of active OMA group could tolerate 1,000 mg of other allergen protein.²

Figure 1. Successful Consumption of Prespecified Threshold Dose at Week 2
 Shown are the percentages of participants in the two groups who consumed the prespecified threshold dose of allergen challenges at the end of the first stage of the trial; the challenges were conducted during the visits spanning up to a 4-week period. The prespecified threshold dose was at least 600 mg of peanut protein, 41 mg of cashew, egg, milk, walnut, hazelnut, and wheat protein, and 1000 mg. The 95% confidence interval was calculated using the standard two-sided test. P values for the primary and key secondary end points are shown.

67% of active OMA group could tolerate 600 mg of peanut protein.²

From 3 to 300 mg threshold: >99% risk reduction in reaction to CCed items.³

Percentage of eating occasions that would result in a predicted allergic reaction (risk for a peanut allergic individual)

	Snack chip mixes	Cookies	Doughnuts, snack cakes	Ice cream
Decrease in risk of reaction on consumption				
Peanut-allergic individual's threshold value (mg)	(%)	(%)	(%)	(%)
1	45.8	44.5	56.0	60.7
3	32.3	31.2	42.4	46.9
10	17.6	16.2	27.5	32.3
30	5.6	5.5	14.0	19.0
100	0.5	0.4	2.2	5.8
300	0.009	0.012	0.027	0.295
1000	NR	NR	NR	0.0040

NR: No reaction predicted.

Baumert et al. JACI 2018.



OMA

SLIT

OIT RX

OIT PO

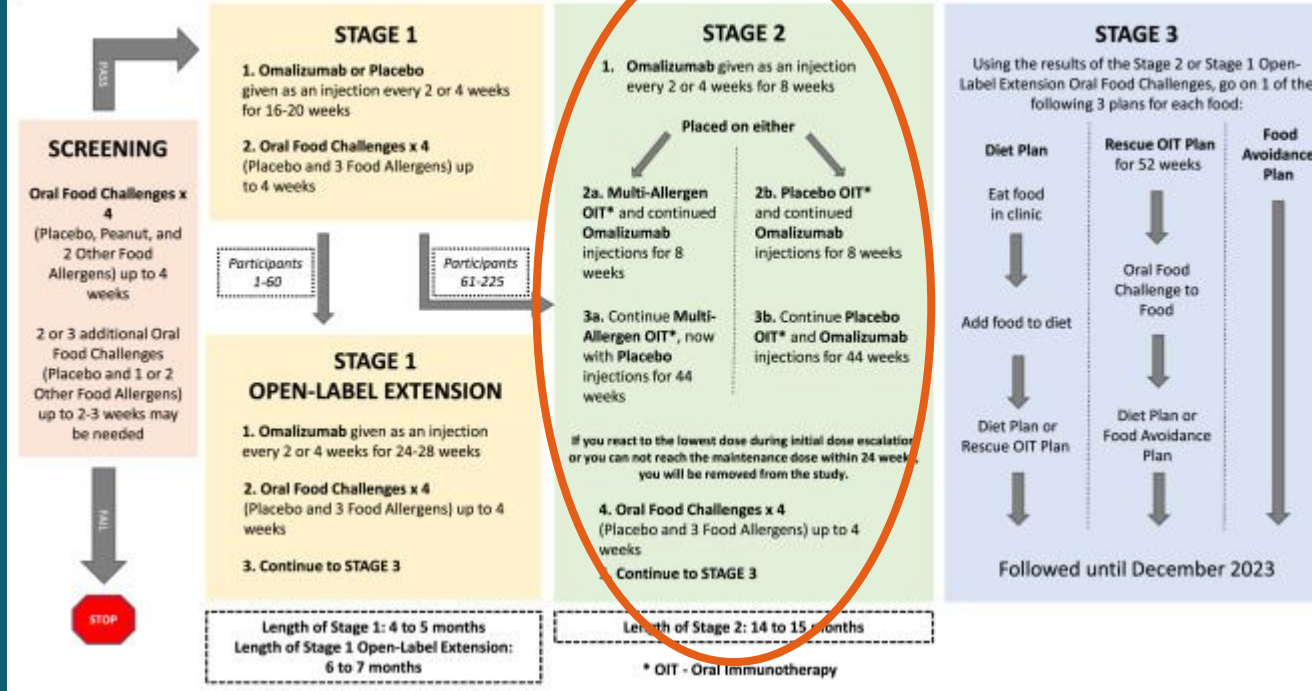


Omalizumab is currently being studied in conjunction with this food treatment modality.



Image Credit: <https://www.nih.gov/news-events/news-releases/clinical-trial-evaluate-experimental-treatment-people-allergic-multiple-foods>

OUTMATCH STUDY SUMMARY



OMA dosing Q 2-4 weeks, per dosing table.⁴

Max OIT dose of 1,000 mg protein x 3 foods.⁴

OFC cumulative dose 8,044 mg of protein of each food.⁴

Active OIT group progression:⁴

OMA or Placebo x 16-20 weeks followed by OFC (Stage 1)

Begin Stage 2: OMA x 8 weeks

Begin OIT with OMA x 8 more weeks

OIT without OMA x 44 weeks

Final OFC



OMA

SLIT

OIT RX

OIT PO



Food SLIT

100

200

300



OMA

SLIT

OIT RX

OIT PO



This adverse event is the most common symptom we see with food SLIT.

Image Credit: <https://www.aspireallergy.com/>





OMA

SLIT

OIT RX

OIT PO



~37%

of PN SLIT doses reported ORAL ITCH in a cohort of 12-40 year olds.⁵

- Fleischer et al. peanut SLIT (2013)
- Excluding oral itch, 95.2% of doses were symptom-free.⁵
- Only 1 epinephrine treated reaction in the cohort of 40 patients.⁵



~27%

of milk SLIT doses reported ORAL SYMPTOMS during the updose phase.⁶

- Keet et al. milk SLIT (2012)
- GI sxs = ~3% of doses, Skin sxs = ~2.2% of doses.⁶
- Upper respiratory sxs = 0.59%, Lower respiratory sxs = 0.45% of doses.⁶



3.6%

of PN SLIT doses reported ORAL ITCH in an open label study of 1-11 year olds.⁷

- Kim et al. peanut SLIT open label study (2023)
- No epinephrine use reported.⁷
- Skin sxs were the second most common at 0.14%.⁷



OMA

SLIT

OIT RX

OIT PO



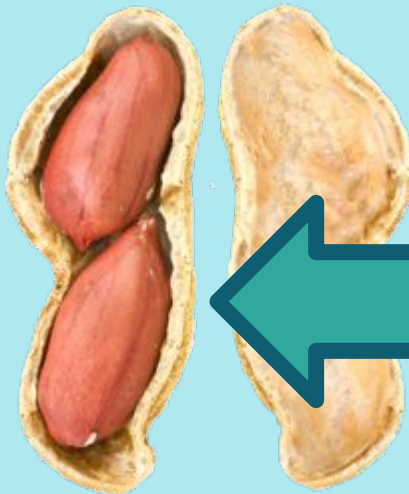
**Food SLIT doses
are very small
and comparable
to a dose we
would see on
THIS day of OIT
treatment.**

Image Credit: <https://stanmed.stanford.edu/i-can-eat-it/>

Aspire PN OIT Day One Doses

4	0.05mg/mL	
3	0.5mg/mL	
2	5mg/mL	
1	50mg/mL	

Dose #	Peanut Protein (mg)	Dilution - (mL)		
		#	Planned	Actual
1	0.025	4	0.5	
2	0.05	4	1	
3	0.1	3	0.2	
4	0.2	3	0.4	
5	0.4	3	0.8	
6	0.8	3	1.6	
7	1.5	2	0.3	
8	2	2	0.4	
9	2.5	2	0.5	
10	3	2	0.6	
11	4	2	0.8	
12	5	2	1	
13	6	2	1.2	



For perspective: A single peanut kernel weighs about 1 gram and contains 250-300 mg of protein.⁹

SLIT maintenance doses range from 1-7 mg of protein of the allergen per day, depending on the study/protocol.⁸



OMA

SLIT

OIT RX

OIT PO





OMA

SLIT

OIT RX

OIT PO



Caleb is a 6 year-old who has completed a year of maintenance for peanut SLIT. His serum IgE and skin prick wheals have declined nicely since beginning SLIT. The family would like to know if Caleb could tolerate candy that is cross contaminated with peanut. You schedule Caleb for THIS appointment to find out.



Ice Cream is the highest risk peanut cross contaminated snack food with a predicted reaction rate of ~0.3% upon eating occasion at a 300 mg tolerance threshold. CC risk for other allergens is not well-defined.³

HOW WELL DOES SLIT WORK?

In three randomized controlled peanut SLIT studies → **after 1 year** of SLIT, the median successfully consumed cumulative dose was **496 mg** of protein.⁸

In the same studies, after **2-3 years** in treatment, the the median successfully consumed cumulative dose rose to **996 mg**.⁸

In a peanut SLIT study of 1-11 year olds, **two-thirds of participants** could successfully consume **750 mg**.⁸

A MODIFIED OFC Protocol:

PEANUT

3mg	DOSE 1	0.02g
10mg	DOSE 2	0.04g
30mg	DOSE 3	0.12g
100mg	DOSE 4	0.40g
300mg	DOSE 5	1.2g
1000mg	DOSE 6	1.0g
4000mg	DOSE 7	16.0g



OMA

SLIT

OIT RX

OIT PO



OIT Reactions

100

200

300

Brooke is an 8 year-old in cashew OIT who has been experiencing intermittent nausea and vomiting between 3 and 23 hours after her daily OIT dose. You become concerned that Brooke has developed THIS condition.

Image Credit: <https://www.kidsstreeturgentcare.com/treating-nausea-and-stomach-aches-in-kids/>



OMA

SLIT

OIT RX

OIT PO





OMA

SLIT

OIT RX

OIT PO



~2.7%

Of patients in OIT trials were diagnosed with biopsy-proven EoE.¹⁰

- Biopsies are rarely performed because generally symptoms dissipate once OIT is stopped.¹¹

8-11%

Of patients in OIT may experience eosinophilic esophagitis-like OIT-related syndrome (ELORS).¹¹

- Symptoms of nausea and vomiting hours after dose.¹²
- Rise in serum peripheral eosinophils above baseline.¹²

50-75%

Of patients with ELORS symptoms are able to continue OIT.¹¹

- Down dose to a tolerated level and hold 4-12 wks.¹³
- Recheck peripheral Eos.¹³
- Slowly updose as tolerated.¹³



OMA

SLIT

OIT RX

OIT PO



Jackson is a 13 year-old with a severe oak pollen allergy who is also in OIT for cashew. Jackson is most likely to experience a significant reaction to his dose during this month.

Seasonal Peaks of OIT Adverse Events in Patients with Allergic Rhinitis

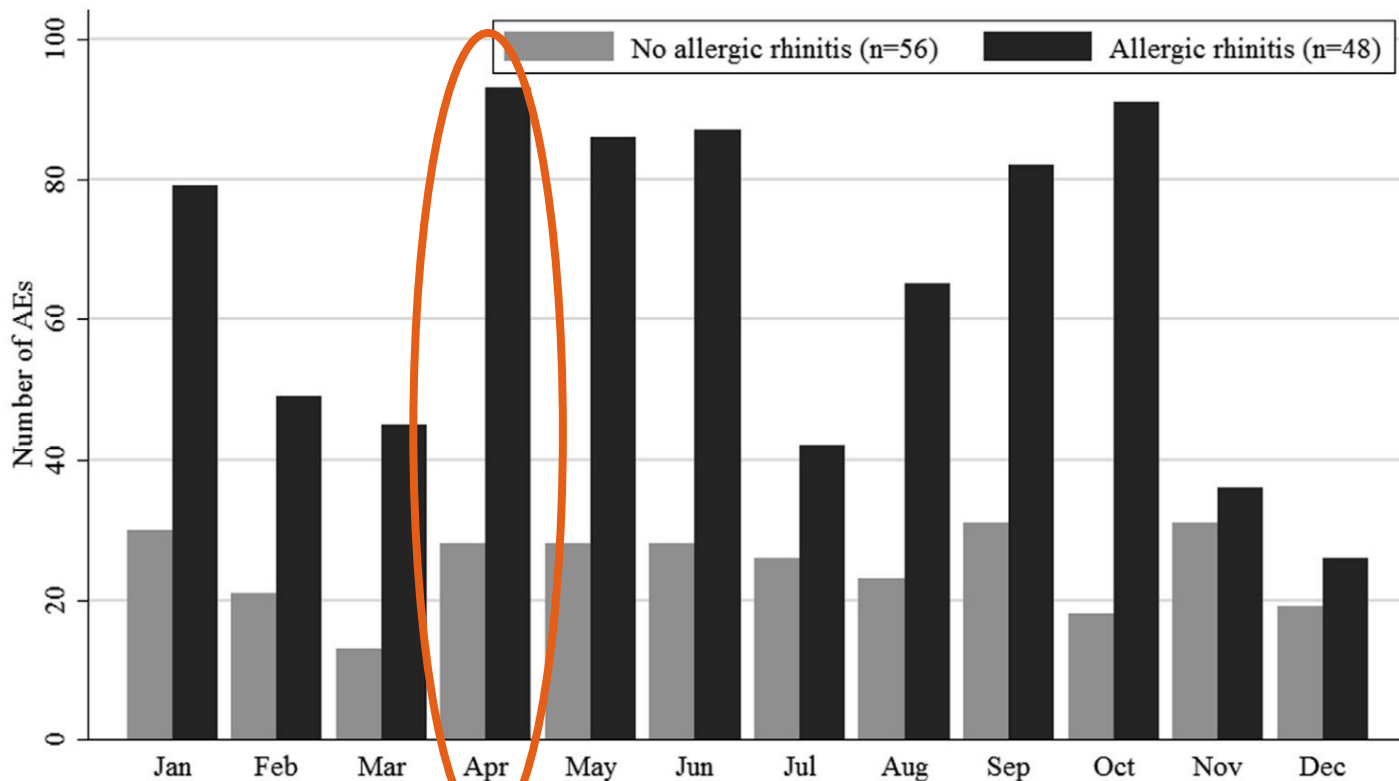


FIG 3. Distributions of AEs, by month and by AR status. $P < .001$.



OMA

SLIT

OIT RX

OIT PO



Ellie, a 14 year-old milk OIT patient, dosed at midnight because she had been out late that evening. She had cramps from her period earlier in the evening and took some acetaminophen around 10pm. You receive a message from her at 1am that she is having a reaction to her dose. These two co-factors may have played a role in her reaction.



OMA

SLIT

OIT RX

OIT PO



Triggers for IgE-Mediated Reactions¹³ and Prevention Strategies:

- **Menstruation** → consider down-dosing if pattern of reaction
- **Lack of sleep** → skip dose, no dosing after 9pm
- **Illness** → skip dose
- **Dental Procedures or cuts/sores in mouth** → skip dose
- **Uncontrolled asthma or allergic rhinitis** → medications/AIT
- **Exercise** → avoid 2 hours after dose
- **Heat (rise in body temperature)** → avoid 2 hours after dose
- **Missed Doses** → gradual build up back to current dose
- **Dosing on an empty stomach** → carbs before dosing
- **NSAIDs** → treat pain/fever with acetaminophen
- **Alcohol** → avoid consumption before or after doses



OMA

SLIT

OIT RX

OIT PO



OIT Potpourri

100

200

300

Mia is a 5 year-old OIT patient who skipped dosing yesterday due to illness. Mia is feeling better now, and mom contacts you to ask how to safely restart the dose. You tell mom that Mia should start back today at this fraction of a dose.



OMA

SLIT

OIT RX

OIT PO



**Guidelines for resuming OIT doses vary by practice and by patient.
At our practice we use the following guidelines with most patients:**



1 day missed

Resume at 1/2 dose

Full dose the following day



2-3 days missed

Resume at
1/4 dose

1/2 dose the
next day

3/4 dose the
following day

Full dose



OMA

4-7 days missed

Resume at
1/10 dose

1/4 dose

1/2 dose

3/4 dose

Full dose

SLIT

OIT RX

>7 days missed

In office
1/10 +
home 1/10

1/4 dose x
2-3 days

1/2 dose X
2-3 days

3/4 dose X
2-3 day

Full dose

OIT PO



Factors that can influence rate of dose resumption:

- Patients who have been in maintenance for years and/or who only dose a few days a week → can usually resume faster
- Patients who have a history of anaphylaxis to doses or ELORS → may need to resume more slowly

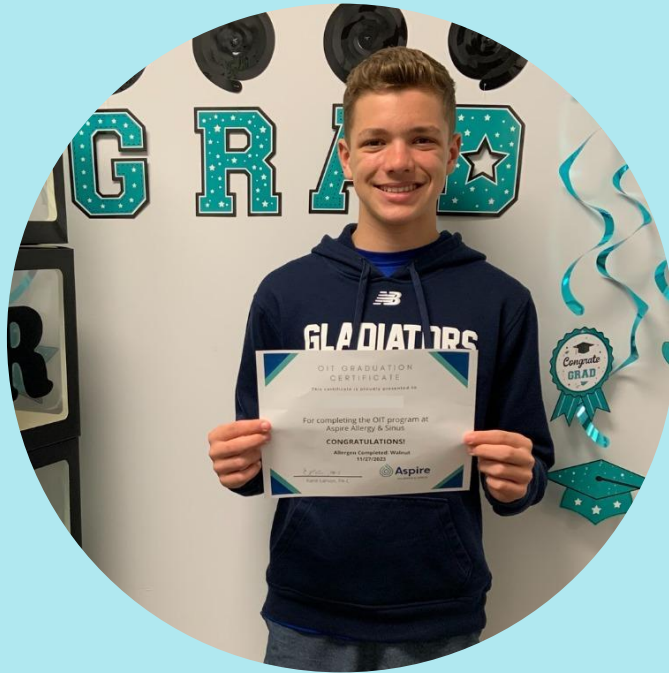


OMA

SLIT

OIT RX

OIT PO



Walker is a 14 year-old who completed walnut OIT two weeks ago. You schedule him for a food challenge to this nut, due its high cross reactivity with walnut.

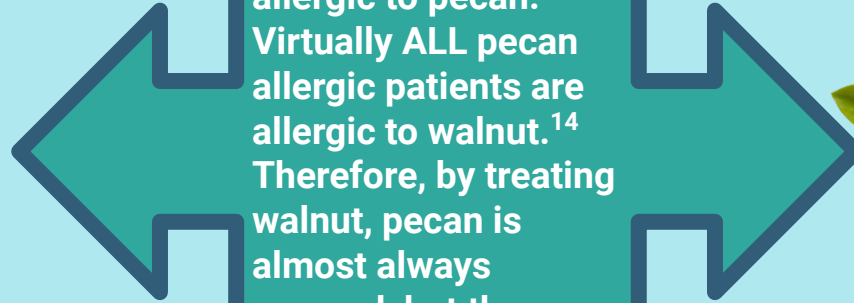


OMA

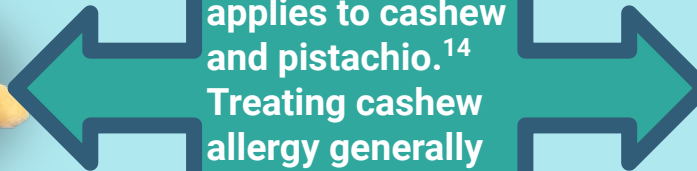
SLIT

OIT RX

OIT PO



Two-thirds of walnut allergic patients are allergic to pecan. Virtually ALL pecan allergic patients are allergic to walnut.¹⁴ Therefore, by treating walnut, pecan is almost always covered, but the reverse is not always true.¹⁵



The same data applies to cashew and pistachio.¹⁴ Treating cashew allergy generally covers pistachio.¹⁵



OMA

SLIT

OIT RX

OIT PO



Brendan is an 18 year-old male who completed egg OIT eight years ago. He is currently dosing 18 mL of liquid egg white three days a week. He is going to college next year, and mom would like to know if he can go even longer between doses. You consider scheduling Brendan for THIS specific type of food challenge a month from now.



OMA

SLIT

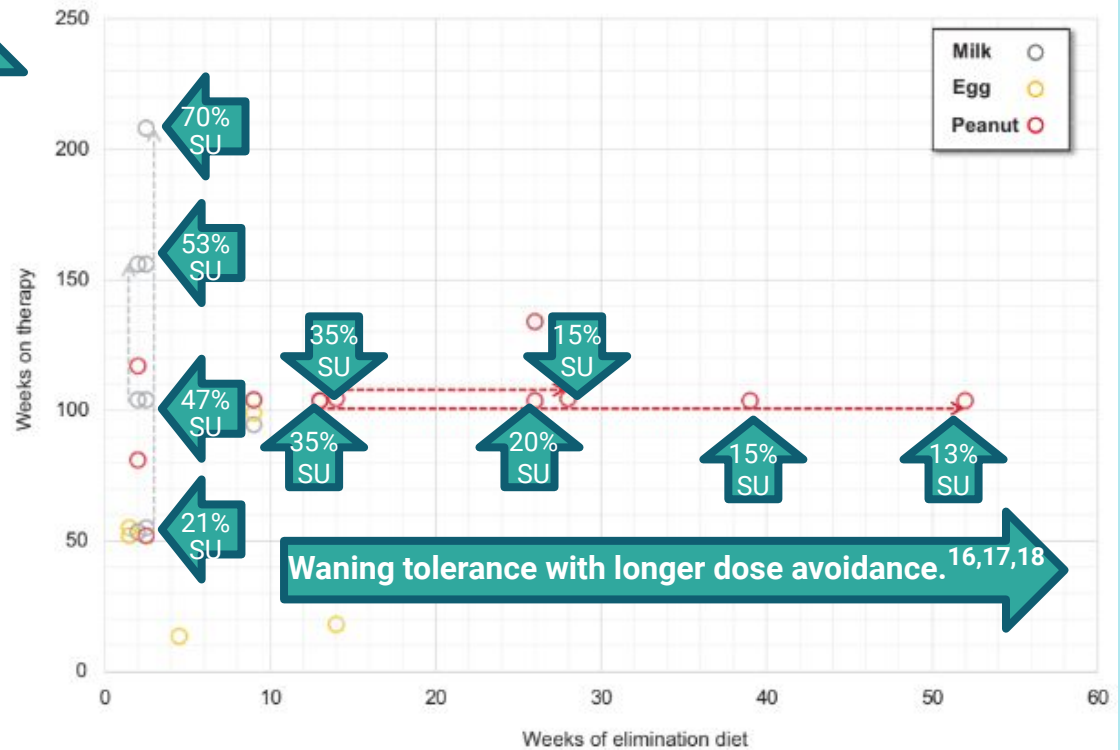
OIT RX

OIT PO



FIGURE 3 Sustained unresponsiveness key parameters of evaluation. There were five studies with exactly the same off therapy and treatment duration (2 and 52 weeks, respectively); for the graphical representation, these were slightly separated. Arrows link data from the same study where participants either were subjected to the same weeks on therapy or elimination diet with longer elimination diets or therapy periods, respectively. None of the hen's egg trials evaluated different periods in the same population. Longer period off therapy was only considered in peanut trials.

Increasing SU rates with longer therapy. 16,19



THANKS! QUESTIONS?

Reach out with any further questions:
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OMA

SLIT

OIT RX

OIT PO



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