

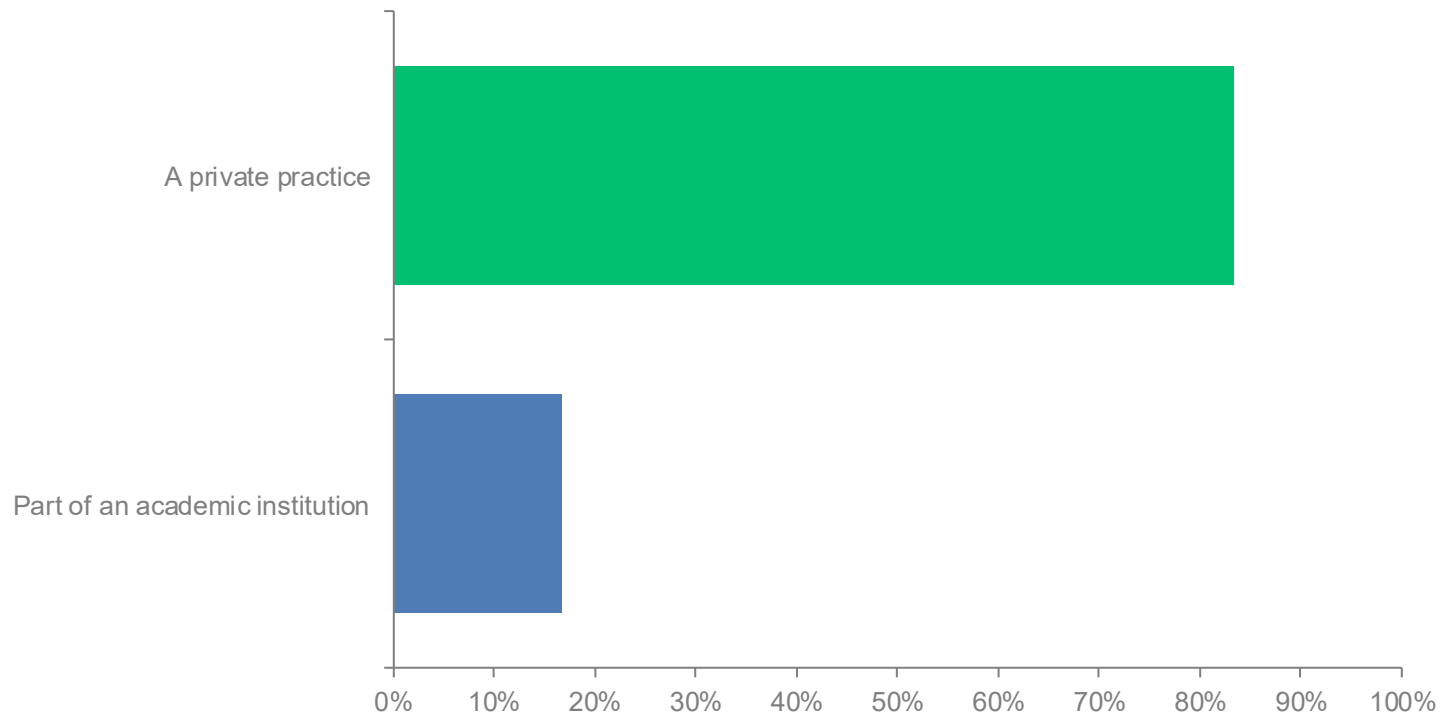
Data Collection

Richard L. Wasserman, MD, PhD

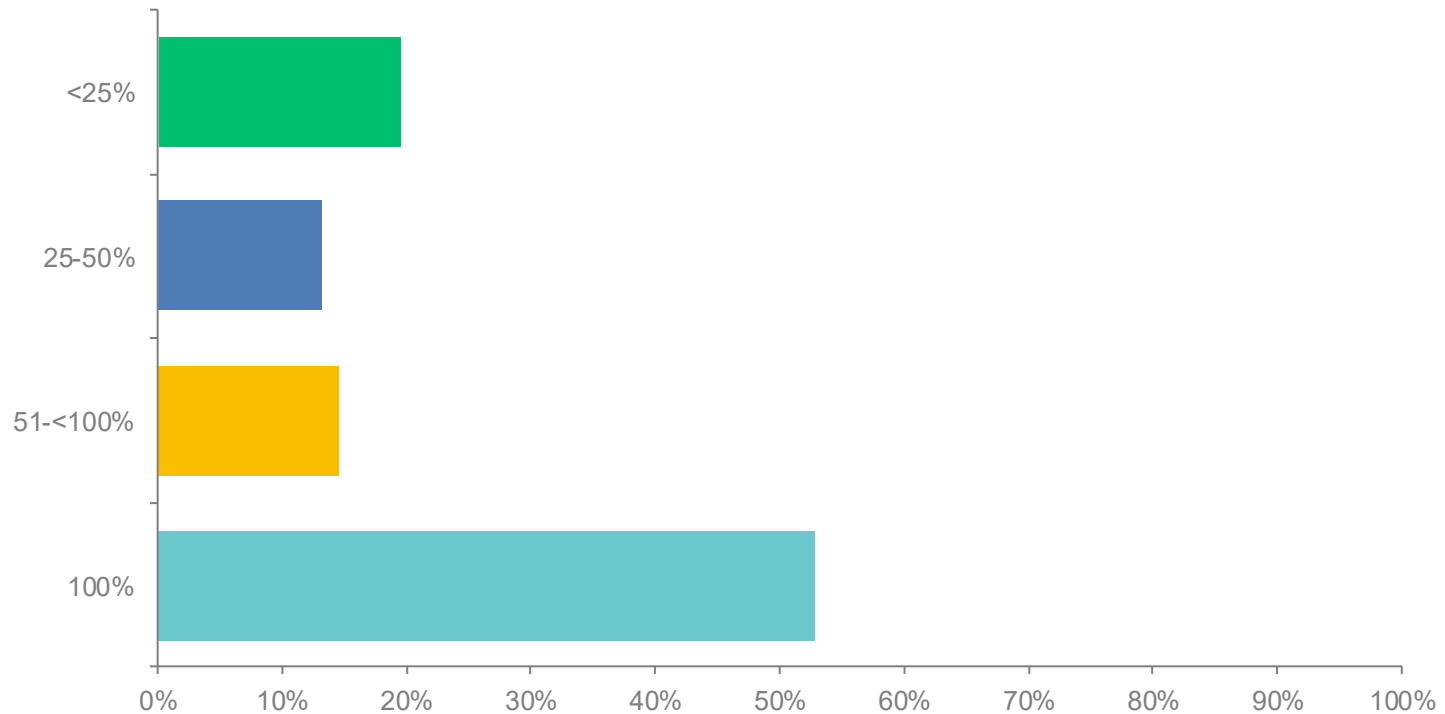
Director of Medical Affairs

CureNet Research, LLC

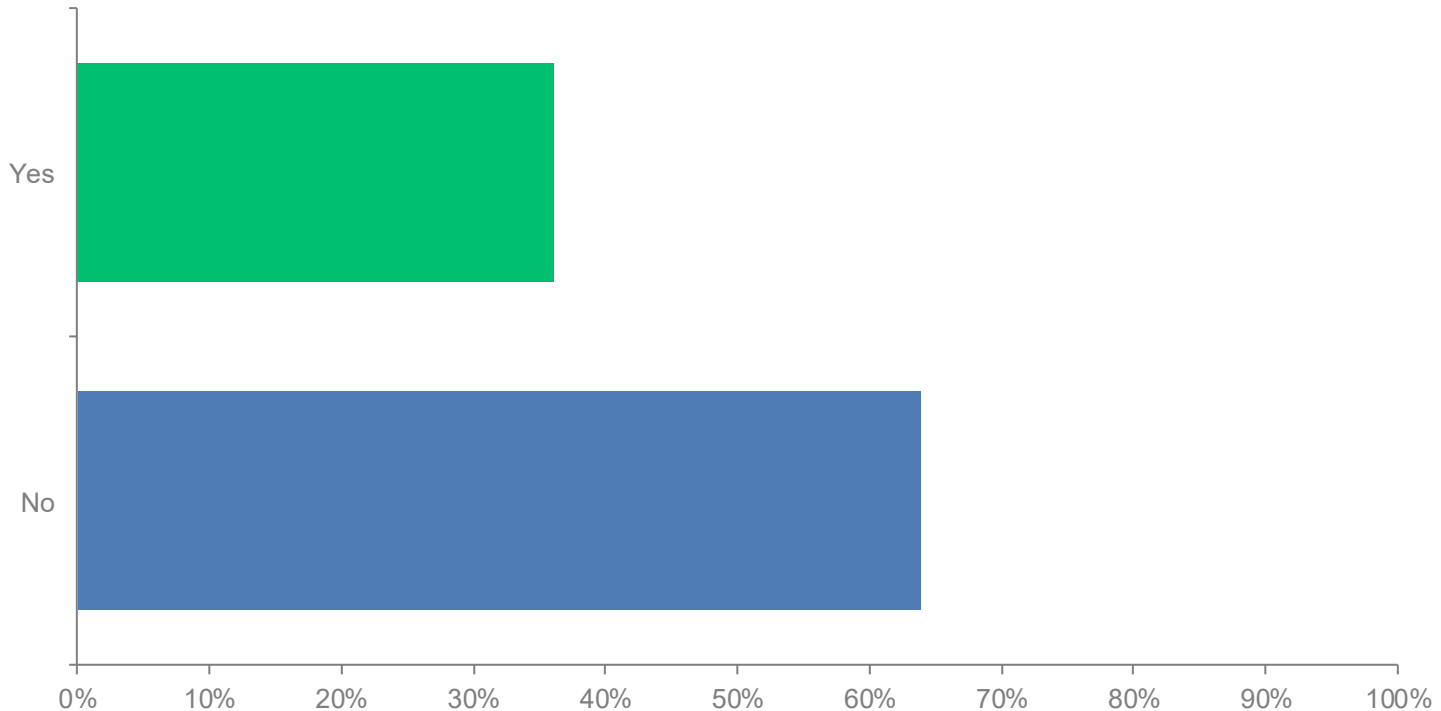
Private Practice vs Academic Practice



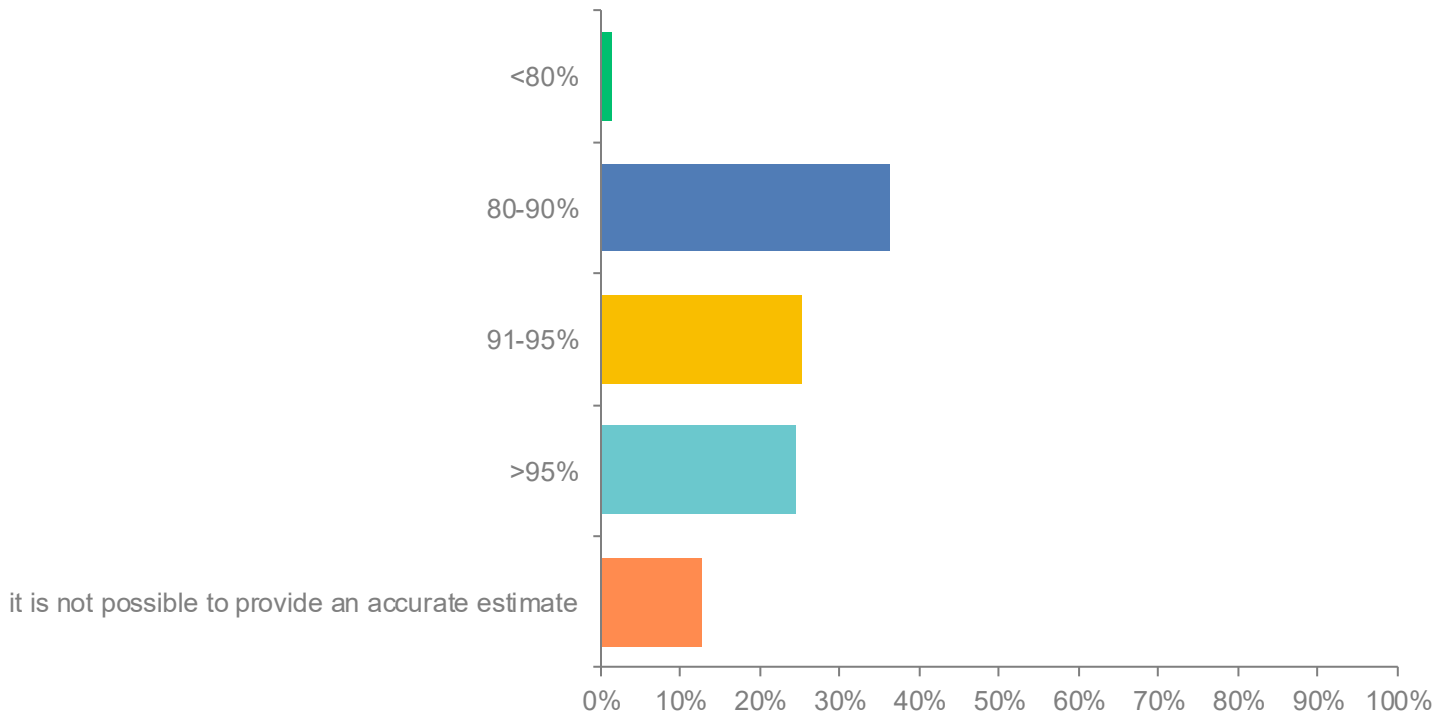
Percentage of the physician members of the practice participate in OIT or SLIT



Practices Actively Collecting Baseline, Adverse Event, or Outcome Data on AIT Patients



What percentage of your OIT starts reach their target dose; whatever their pre-determined target might be



Why Collect AIT Data in Your Practice?

- **Improve patient care**
 - Identify problems in your AIT procedures
 - Monitor outcomes and adverse events
- **Initial patient/family education**
 - How many patients treated
 - Percentage of patients reaching their target dose
 - Rate of epinephrine treated reactions
- **Marketing your practice**
- **Compare your patients' experience with other practices**
 - Improve outcomes
 - Improve efficiency
 - Reduce patient burden of care
- **Your experience will assist other AIT allergists**
- **Data is the only way to protect AIT practice from replacement by pharma**

Barriers to Collecting Data in an Allergy Practice

- **Obtaining Consent**

- Consent to collect patient data within a practice does not require a separate consent
- Data collection consent can be included in the general consent to treat or as a component of the consent to allergen immunotherapy
- Data be de-identified

- **Institutional Review Board approval is required**

- AIT data collection is part of the internal quality improvement activity
- IRB approval is not necessary for QA projects
- IRB approval is needed only for publication
- Retrospective record reviews (e.g., data collections) are typically “Exempt”

- **Data entry is laborious, time consuming, and costly**

- Data entry cost is directly related to the number of data elements collected
- Medical records design can facilitate data collection

What OIT/SLIT Data Should You Collect?

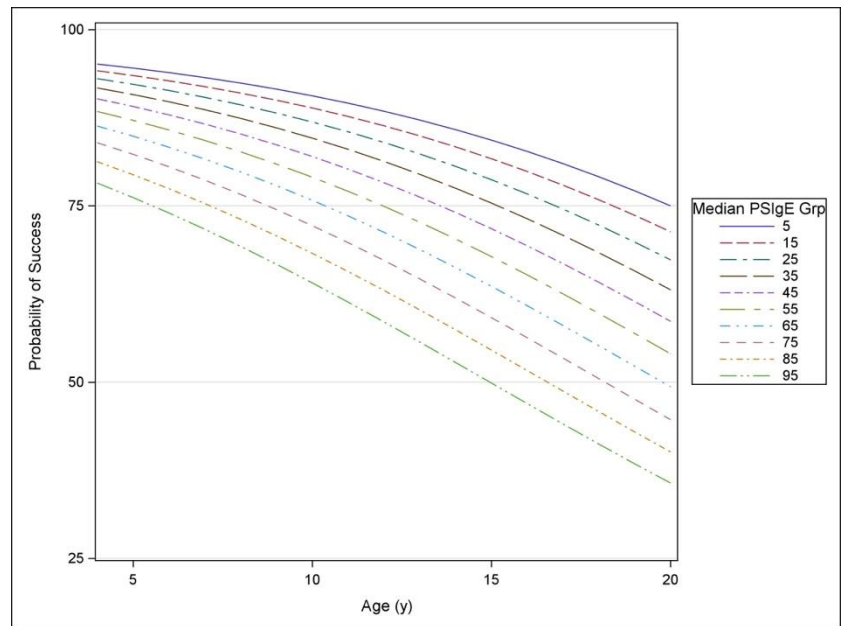
- **Minimal data set**
 - Name, medical record number, or unique identifier
 - Start date
 - Food(s) treated
 - Maintenance start date
- **Limited data set (add to minimal data collection)**
 - Major adverse events
 - Epinephrine use
 - ELORS (**E**osinophilic esophagitis-**L**ike **O**ral immunotherapy-**R**elated **S**ndrome)
 - Pre-treatment sIgE, AEC
 - Atopic co-morbidities – asthma, eczema

Extended Data Set

- **Additional Baseline laboratory testing**
 - CBC
 - Vitamin D
 - Total IgE
 - sIgE components
 - sIgG4
 - sIgG4 components
 - BAT
- **Additional Clinical Data**
 - PFTs, f/u lab, baseline OFC, f/u OFC, meds used during treatment
- **Enter all new food allergy diagnoses**
 - Collect SDM outcome: Avoidance, OIT, SLIT, OMA, OMA-facilitated OIT

Lessons Learned at Allergy Partners of North Texas

- Mild persistent asthma was under-recognized
- ELORS risk factors
 - High sIgE
 - Eczema
- Vitamin D insufficiency and deficiency is common among food allergy patients of South Asian descent
- Age is inversely correlated with achieving the target OIT dose
- Age and sIgE predict success



FAST Data-Collection Tools

- Available for download by September, 2026
- Modifiable Excel AIT data collection templates
- Sample text for IRB submissions

FAST Data Collection Mini-Grants

- \$2,500 grants in support of practice AIT data collection
- Two-page application
 - Practice information
 - Current status of AIT practice data collection
 - Plan for using the grant
- Potential Mini-Grant uses
 - Set up the AIT data collection process
 - Data entry
 - Data analysis

Rostrum

**Consensus report from the Food Allergy
Research & Education (FARE) 2019 Oral
Immunotherapy for Food Allergy Summit**



**Exploiting nut cross-reactivity to facilitate real-
world treatment of tree nut allergy - Annals**

Original Article

**Real-World Experience with Peanut Oral
Immunotherapy: Lessons Learned From 270
Patients**



Original Article

**Oral Immunotherapy for Peanut Allergy: Multipractice
Experience With Epinephrine-treated Reactions**
