CFAAR
Center for Food Allergy & Asthma Research

Northwestern University

NIH National Institute of Allergy and Infectious Diseases

Food Allergy Data Dictionary and CDEs

Shruti Sehgal, MD(Hom.), MS

Senior Research Data Analyst

Northwestern University

Washington, DC- March 7, 2024

Ann & Robert H. Lurie Children's Hospital of Chicago

Northwestern Medicine Feinberg School of Medicine

Disclosure

I have no conflicts of interest to disclose.

Acknowledgements

NIAID
- Dr. Alkis Togias
- Dr. Anupama Gururaj
- Dr. Dawei Lin

FADD core members
- Dr. Jonathan Spergel
- Dr. Melanie Makhija
- Dr. Christina Ciaccio
- Dr. Julie Wang

FACEP (Academia)
- Dr. Helen Brough
- Dr. Antonella Muraro
- Dr. Douglas P. Mack
- Dr. Nandinee Patel
- Dr. Stefania Arasi
- Dr. Alessandro Fiocchi
- Dr. Mimi Tang
- Dr. Graham Roberts
- Dr. Rachel Peters
- Dr. Jonathan M. Spergel
- Dr. Julie Wang
- Dr. Scott H Sicherer
- Dr. Anna Nowak-Wegrzyn
- Dr. Amy Scurlock
- Dr. Christina E. Ciaccio
- Dr. Edwin Kim

FACEP (Academia)
- Dr. Corinne Keet
- Dr. David Fleischer
- Dr. Katherine Anagnostou
- Dr. R. Sharon Chinthrajah
- Dr. Rima Rachid
- Dr. Wayne Shreffler
- Dr. Andrew Bird
- Dr. Jessica Stern
- Dr. Brian Vickery
- Dr. Idil Ezhutchachan
- Dr. Robert Wood
- Dr. Amal Assaad
- Dr. Hemant Sharma
- Dr. Mahboobeh Mahdavinia
- Dr. Sai Nimmagadda

FACEP (Industry)
- Dr. Sachin Gupta
- Dr. Todd Green
- Dr. Steve Tilles
- Jim Garner
- Ritu Shah
- Dr. Chris Harder
- Dr. Nayla Mumneh
- Dr. Ahmar Iqbal
- Meenal Lele

FACEP (Advocacy)
- Erin Martinez
- Anita Roach
- Byran LeRette
- Lynda Mitchell

Many thanks to the NIAID team, Food Allergy Data Dictionary (FADD), and Food Allergy CDE Expert Panel (FACEP) members!

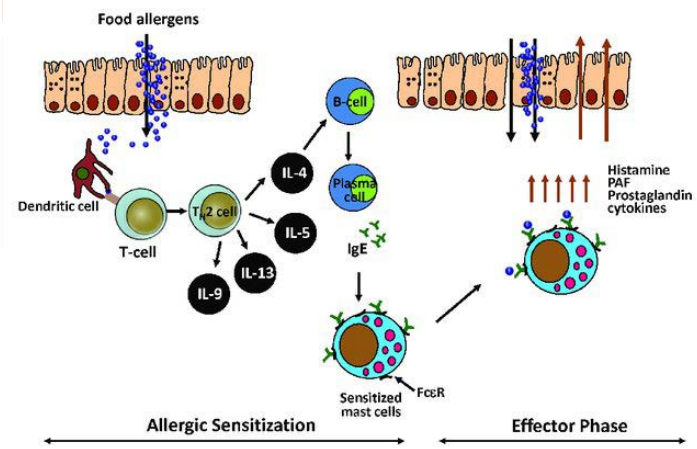
Agenda

- The Food Allergy Landscape
- Food Allergy Data Dictionary
- Food Allergy Clinical Note Templates
- Common Data Elements for Food Allergy
- Long Term Vision
- Meet our Team at Northwestern University

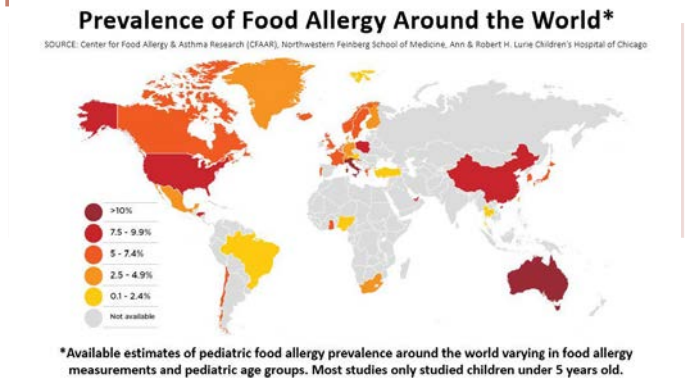
The Food Allergy (FA) Landscape

Overview

FAis an immune-mediated, chronic disorder

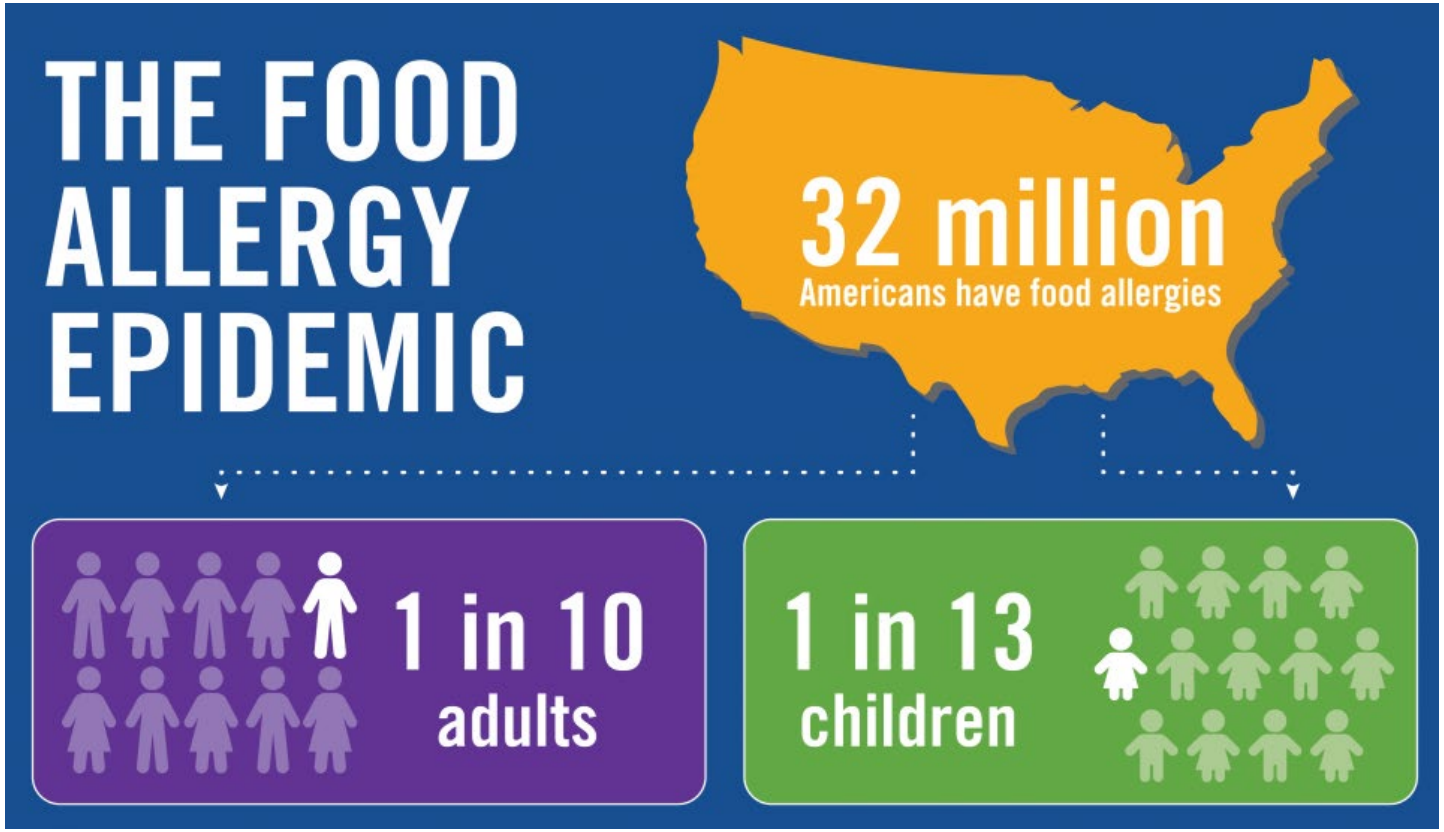


It is a public health issue of global importance

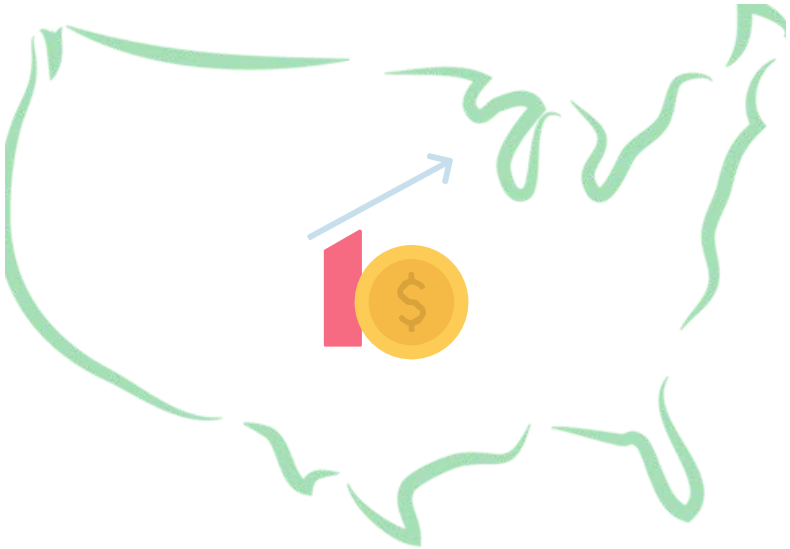


It has a massive clinical and economic impact

FA burden in the U.S.



Overall Economic Cost



$ 24.8 Billion

CFAAR Center for Food Allergy & Asthma Research

Gupta RS, Warren CM, Smith BM, Blumenstock JA, Jiang J, Davis MM, Nadeau KC. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. Pediatrics. 2018 Dec;142(6):e20181235. doi: 10.1542/peds.2018-1235. Epub 2018 Nov 19. Erratum in: Pediatrics. 2019 Mar;143(3): PMID: 30455345; PMCID: PMC6317772. Gupta R, Holdford D, Bilaver L, Dyer A, Holl JL, Meltzer D. The economic impact of childhood food allergy in the United States. JAMA Pediatr. 2013 Nov;167(11):1026-31. doi: 10.1001/jamapediatrics.2013.2376. Erratum in: JAMA Pediatr. 2013 Nov;167(11):1083. PMID: 24042236.

But we still don't really understand food allergy!

- Heterogeneous triggers, presentations, and prognoses
- Complex inheritance.
- Food Allergy has the hallmarks of a complex trait

The Challenge

- Sub-phenotyping (deep phenotyping, endophenotyping) requires **lots** of data from **lots** of patients
- Collecting lots of data together requires standardizing on common codes, forms, and structures
- Documentation is mostly free text or local coding schemes
- Manual chart extraction is not scalable
- Current coding systems capture food allergy data poorly

Food Allergy Data Dictionary

Food Allergy Data Dictionary: Need

- Food allergy domain lacks a common base of terminology and hinders data exchange among institutions.
- A requisite first step to enable multi-site data exchange is the creation of a Data Dictionary.
- Without this, there is no way to combine data from different sites or to compare across sites.

Sehgal S, Gupta RS, Wlodarski M, Bilaver LA, Wehbe FH, Spergel JM, Wang J, Ciaccio CE, Makhija M, Starren JB. Development of Food Allergy Data Dictionary: Toward a Food Allergy Data Commons. J Allergy Clin Immunol Pract. 2022 Jun;10(6):1614-1621.e1. doi: 10.1016/j.jaip.2022.02.024. Epub 2022 Mar 5. PMID: 35259539.

Food Allergy Data Dictionary (FADD)

Design criteria		
Build on current limited coding standards (Standards-based)	Encode CURRENT clinical practice (Community-based)	Usable by patients, clinicians, and researchers (Community-driven)

CFAAR
Center for Food Allergy & Asthma Research

Sehgal S, Gupta RS, Wlodarski M, Bilaver LA, Wehbe FH, Spergel JM, Wang J, Ciaccio CE, Makhija M, Starren JB. Development of Food Allergy Data Dictionary: Toward a Food Allergy Data Commons. J Allergy Clin Immunol Pract. 2022 Jun;10(6):1614-1621.e1. doi: 10.1016/j.jaip.2022.02.024. Epub 2022 Mar 5. PMID: 35259539.

Food Allergy Data Dictionary: Development

Ongoing efforts: FA clinical note templates + Common Data Elements development

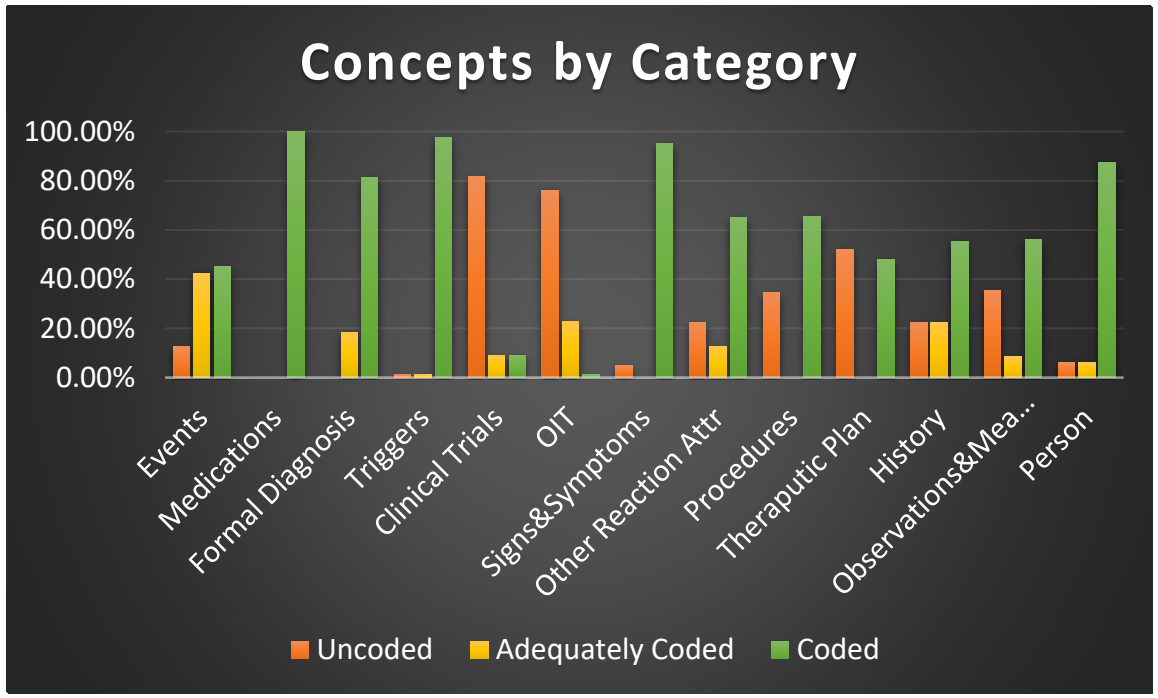
Sehgal S, Gupta RS, Wlodarski M, Bilaver LA, Wehbe FH, Spergel JM, Wang J, Ciaccio CE, Makhija M, Starren JB. Development of Food Allergy Data Dictionary: Toward a Food Allergy Data Commons. J Allergy Clin Immunol Pract. 2022 Jun;10(6):1614-1621.e1. doi: 10.1016/j.jaip.2022.02.024. Epub 2022 Mar 5. PMID: 35259539.

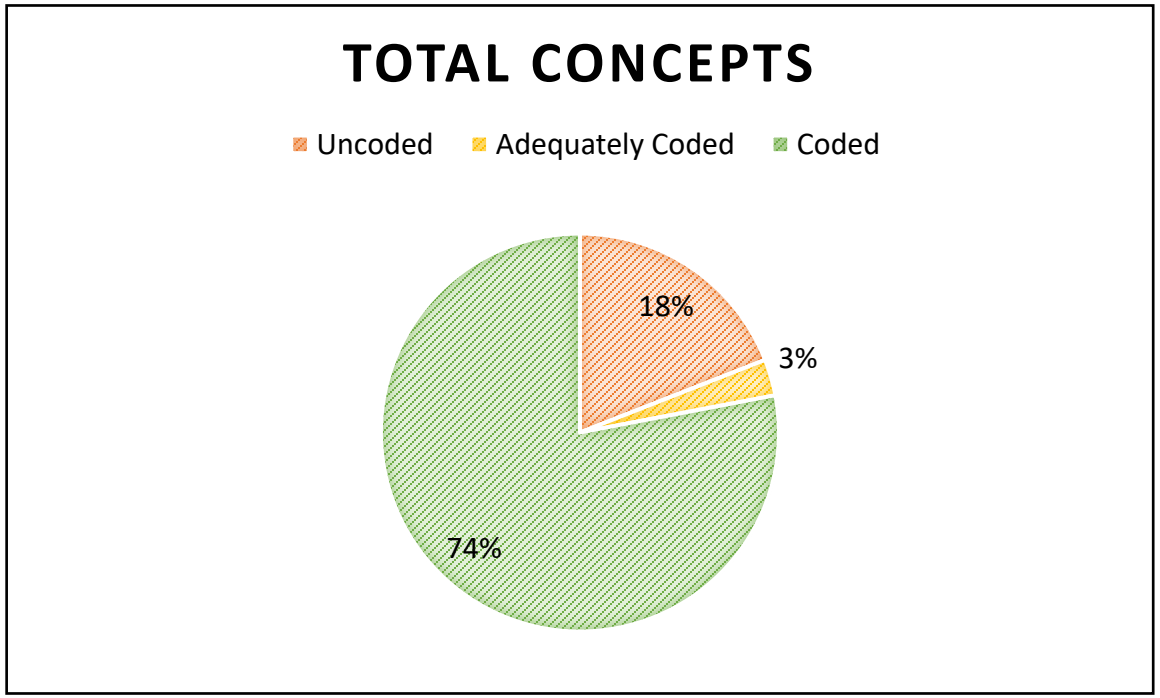
Mapping the FADD to OMOP

- Observational Medical Outcomes Partnership (OMOP)
- Mostly widely adopted model for sharing clinical data
- Ontologies including SNOMED, ICD10, RxNORM, LOINC, FoodOn, etc.

Sehgal S, Gupta RS, Wlodarski M, Bilaver LA, Wehbe FH, Spergel JM, Wang J, Ciaccio CE, Makhija M, Starren JB. Development of Food Allergy Data Dictionary: Toward a Food Allergy Data Commons. J Allergy Clin Immunol Pract. 2022 Jun;10(6):1614-1621.e1. doi: 10.1016/j.jaip.2022.02.024. Epub 2022 Mar 5. PMID: 35259539.

OMOP mapping results

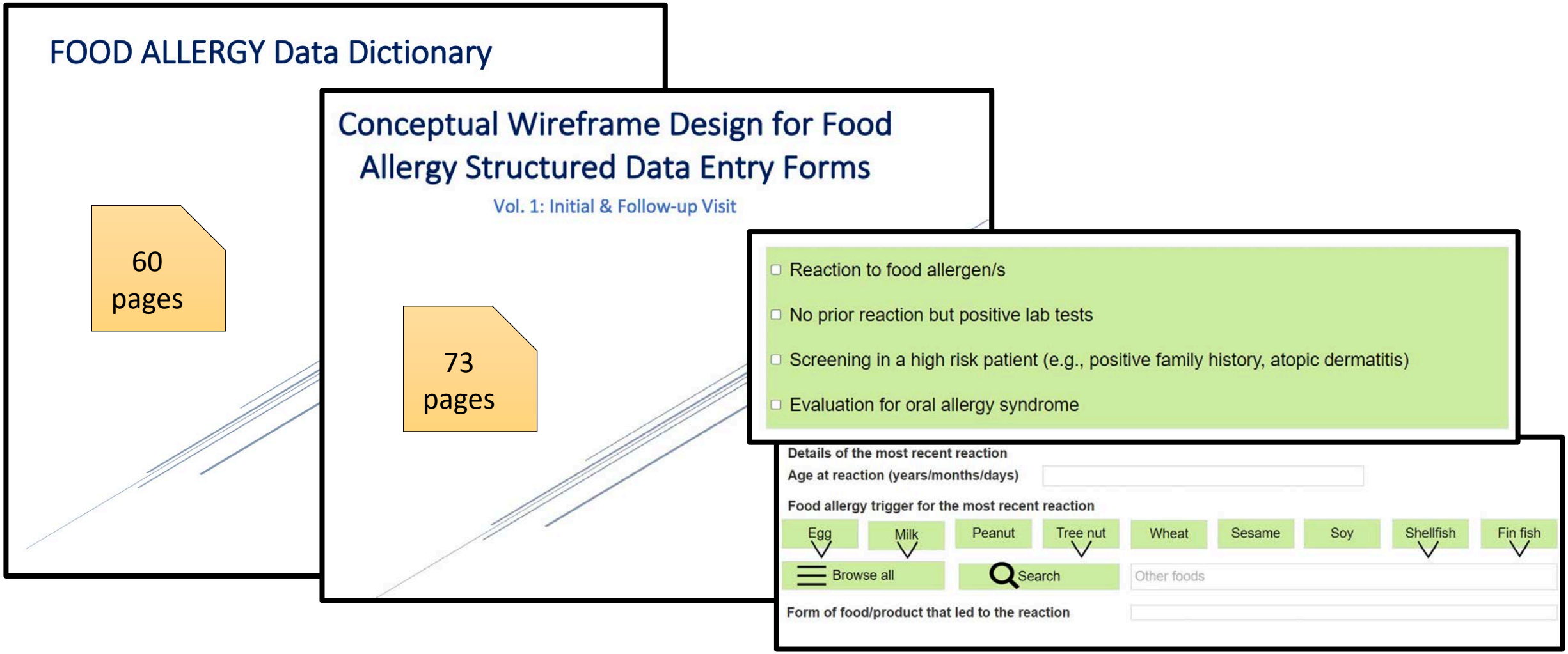




M. Wlodarski, S. Sehgal, F. Wehbe, L. Bilaver, J. Starren, R. Gupta. Improving the Coverage of Food Allergy in Clinical Terminologies. Poster presented at *American Medical Informatics Association (AMIA) Symposium; Washington, D.C., 2022 Nov 8.*

Food Allergy Clinical Note Templates

Concept to Implementation



Initial allergy note (SmartText)

Reason for Visit
{Reason For Visit:20223}

{Reaction to allergen(s) TEMPLATE:TXT,26279}
{No prior reaction but positive allergy testing TEMPLATE:TXT,26466}
{Screening in high-risk patient (e.g., atopic dermatitis, EoE, positive family history
{Evaluation of oral allergy syndrome TEMPLATE:TXT,26465}
Other reason for visit: ***

Epinephrine Review Se
Does the patient have ep

Review of Systems
General: {ROSGEN:76}
Nasal: {NASAL:79}
Throat: {THROAT:80}
Respiratory: {RESPRTRY:82}
Cardiovascular: {CV:83}
GI:{GI:84}
Skin:{SKIN:88}

All other systems reviewed and are negative

Physical Examination
@VITALS@
General: {PEGEN:280}
Head: {PHYSEX:89}
Ears: {EARSPE:303}
Eyes: {PEEYES:281}
Nose: {PENOSE:282}
Throat: {PETHRT:283}
Neck: {PENECK:284}
Chest/ungs: {PECHST:286}
Cardiovascular: {PECV:285}
Abdomen: {PEABD:288}
GU: {GU2:9390}
Extremities: {PEEXT:289}
Neuro: {PENEURO:290}
Skin: {PESKIN:291}

Initial Visit: Assessment Section
Definite/Confirmed food allergy to: {Allergen(s):20179}

Probable suspected food allergy to: {Allergen(s):20179}

Oral allergy syndrome to: {Oral Allergy Allergen list:20411}

Initial Visit: Plan Section
{SPT:20706}

Specific IgE ordered today for: {Allergen(s):20404}

Allergen component testing ordered today for:{Allergens:20332}

{Recommendations:20707}

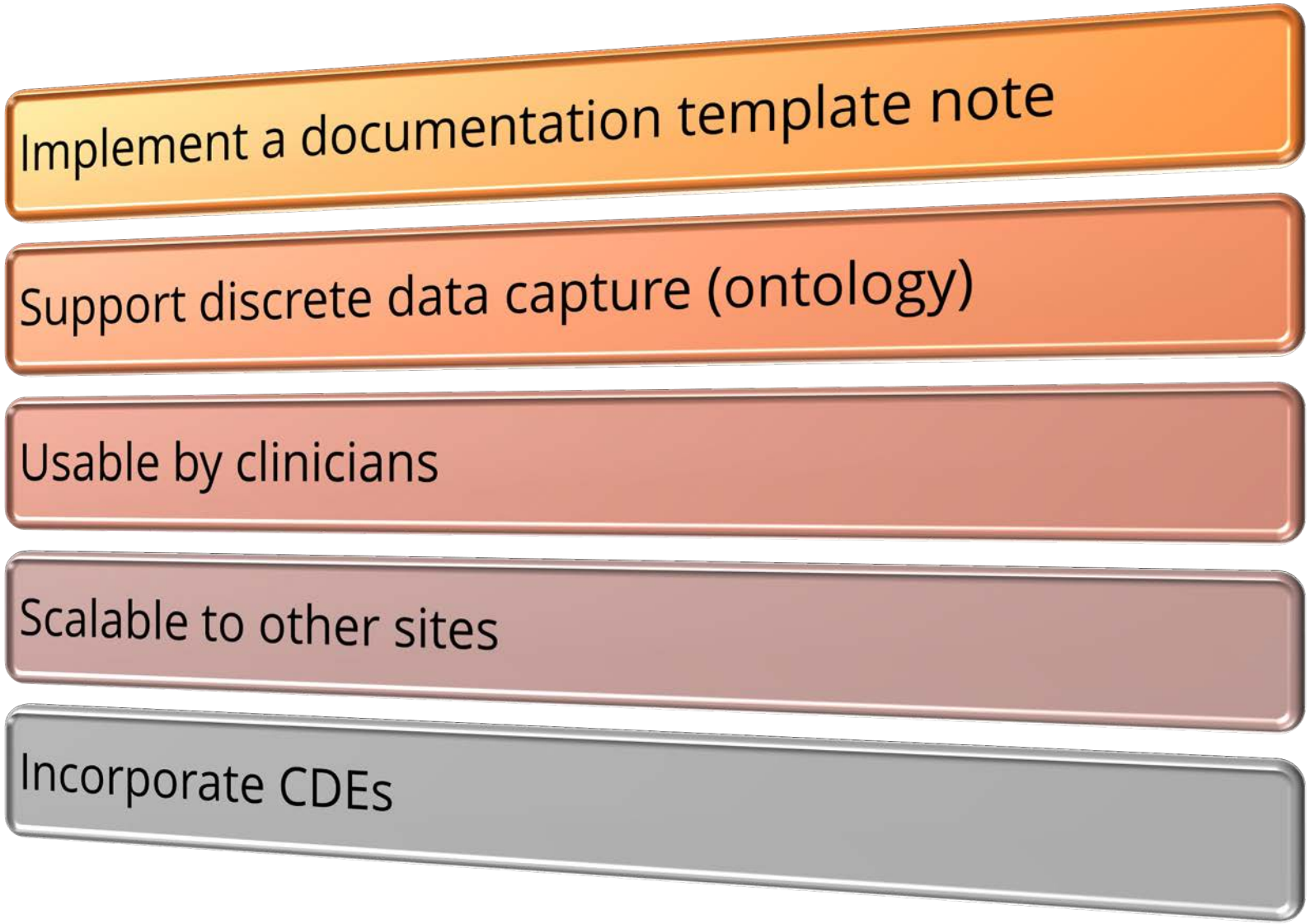
Additional instructions for home introduction:

Food allergy medications prescribed today:

Evaluation at Today's Visit

- ☐ Epinephrine status reviewed
- ☐ Natural history and FA prognosis reviewed with the patient/family/caregiver
- ☐ Allergen avoidance measures discussed with the patient/family/caregiver
- ☐ Written emergency health plan/Anaphylaxis management plan reviewed and given to thepatient/family/caregiver
- ☐ Food allergen education materials reviewed and given to the patient/family/caregiver

Goals of Lurie documentation project



Common Data Elements (CDEs) for Food Allergy

Why FA CDEs now?

- New therapies and increasing numbers of treatments being developed.
- Increased volume of clinical trials.
- Need to compare among trials
- Clinical trial data suffers from same lack of standardization as clinical data.

No NIH-endorsed CDEs address allergy

- Coverage of food allergy in the NIH's CDE repository is minimal.

- **Currently, there are over 23,000 CDEs from 18 NIH institutes and centers, of which 137 are NIH-endorsed.**

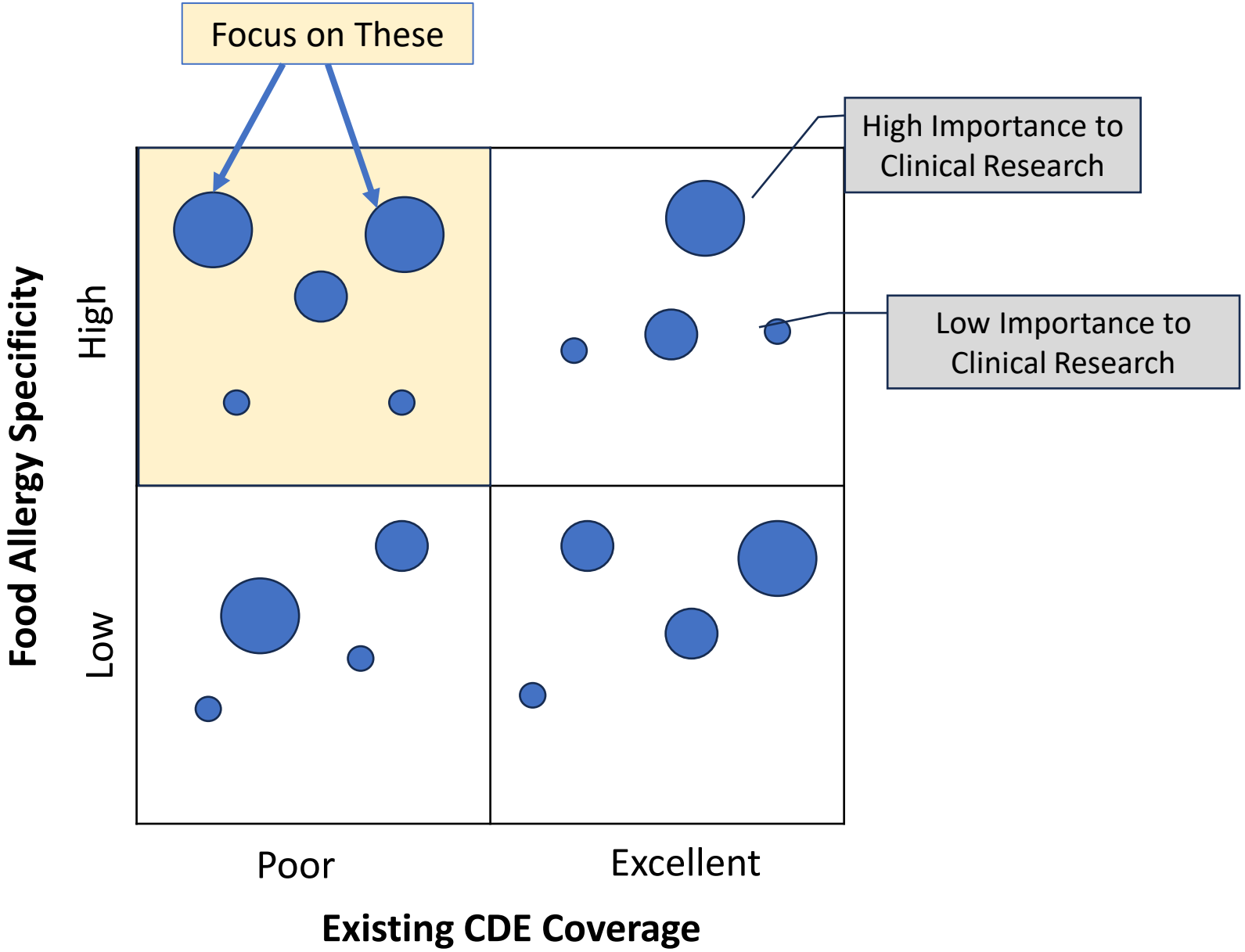
Learn more about CDEs at https://cde.nlm.nih.gov/home.

Project goals

- **Identify and develop a set of CDEs for FA** that can help provide consistency in the way FA clinical research data are collected.
- The limited project duration means that we **cannot define every possible FA-related CDE**
  - Focus on creating new FA-specific CDEs instead of recreating common CDEs.

CDEs for FA

Project Focus



The process

PHASE 1

FA CDE Expert Panel (FACEP) established

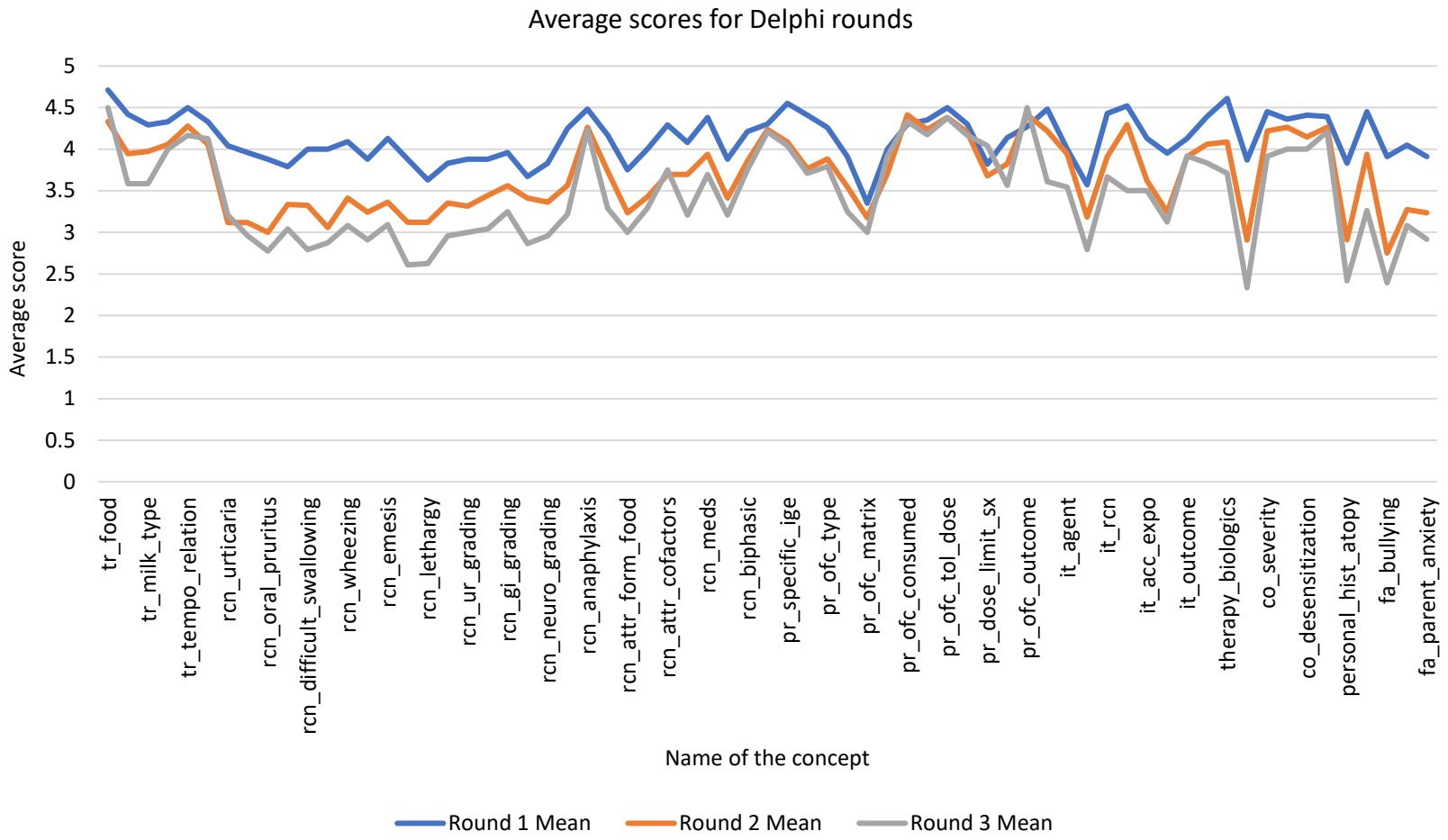
- Global collaboration: Five countries
  - Academia: 31
  - Industry: 11
  - Advocacy: 6

Reviewed the existing FA Data Dictionary to identify concepts (N=88).

- Additional candidate CDEs proposed by FACEP (N=121)

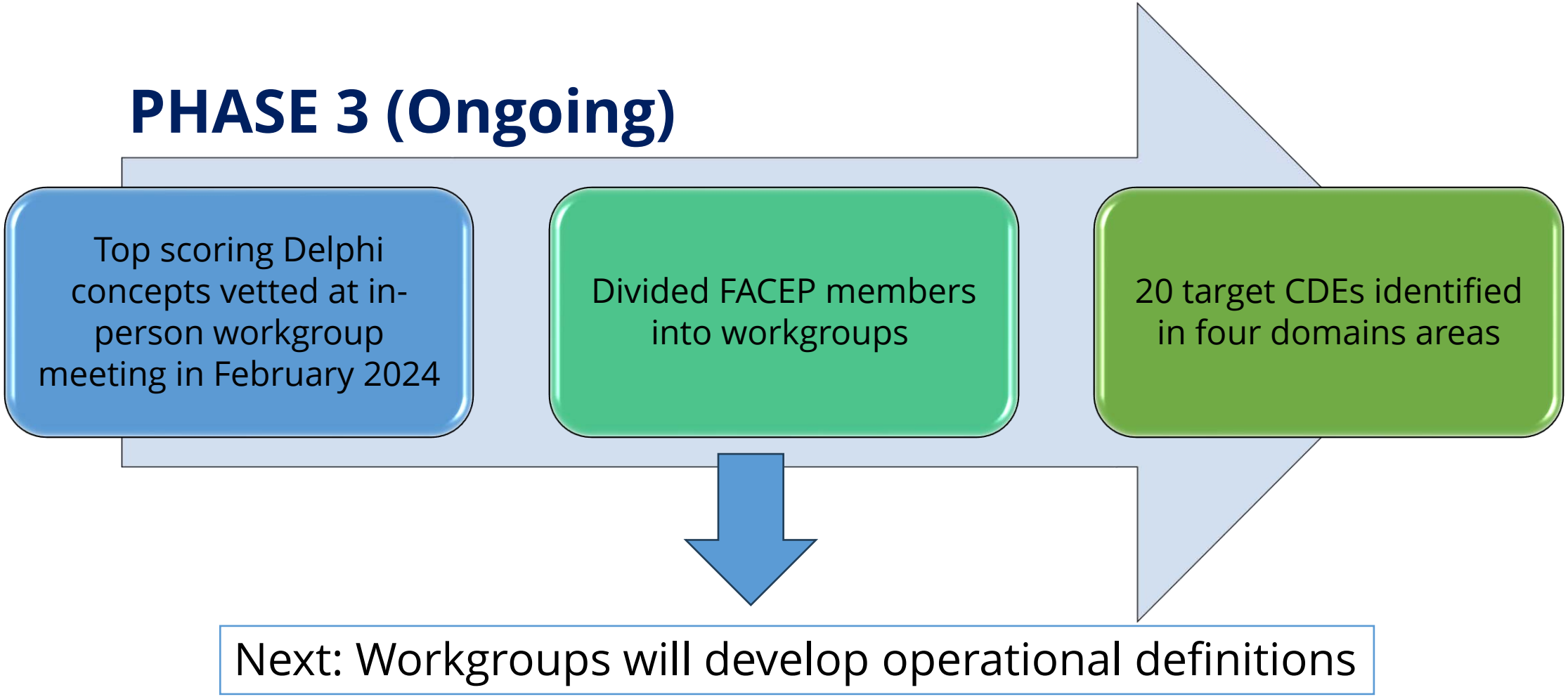
Phase 2: Summary of Delphi rounds 1-3

Executing Delphi rounds using REDCap (Three cycle Delphi)



Scored the concepts on a five-point Likert scale

The process

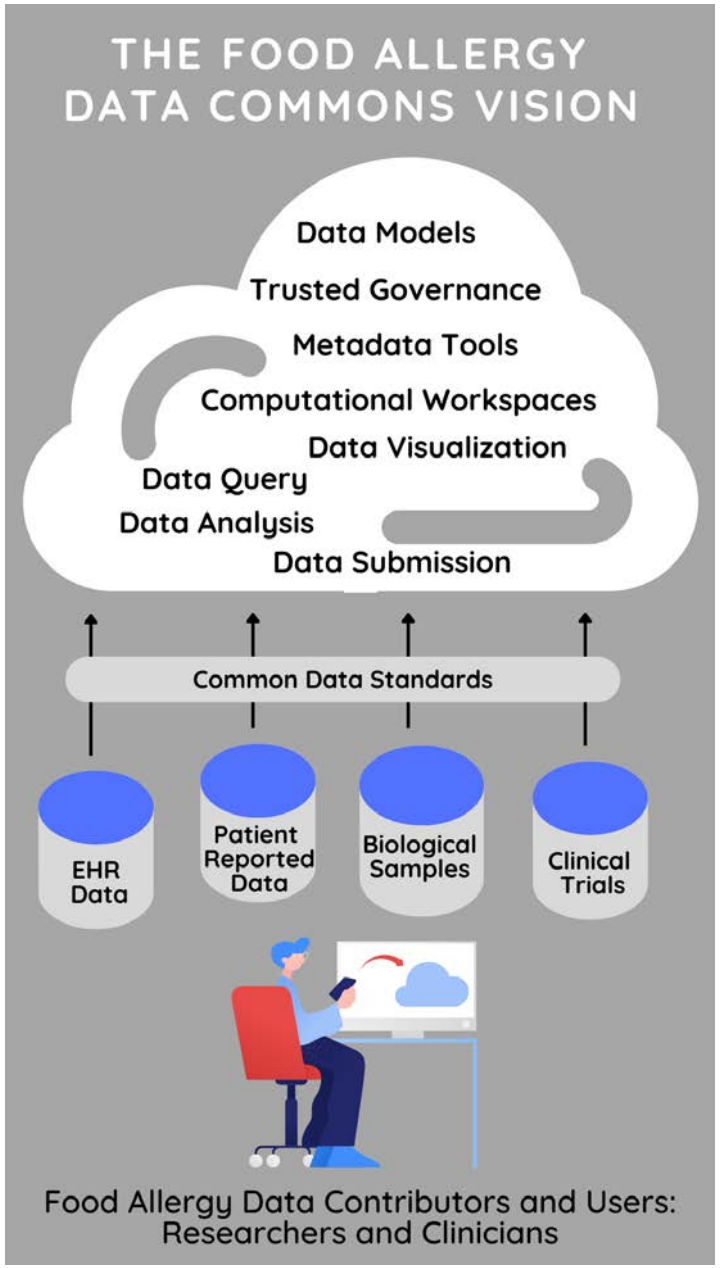

PHASE 3 (Ongoing)
Top scoring Delphi concepts vetted at in-person workgroup meeting in February 2024
Divided FACEP members into workgroups
20 target CDEs identified in four domains areas
Next: Workgroups will develop operational definitions

Long Term Vision

Towards a Food Allergy Data Commons

- Single, centralized resource that supports data aggregation, distribution, and analysis

- Scalable approach for addressing the data and analysis challenges of complex traits



CFAAR Center for Food Allergy & Asthma Research

Gupta RS, Sehgal S, Wlodarski M, Bilaver LA, Wehbe FH, Spergel JM, Wang J, Ciaccio CE, Nimmagadda SR, Assa'ad A, Mahdavinia M, Wasserman RL, Brown E, Sicherer SH, Bird JA, Roberts B, Sharma HP, Mendez K, Holding EG, Mitchell L, Corbett M, Makhija M, Starren JB. Accelerating Food Allergy Research: Need for a Data Commons. J Allergy Clin Immunol Pract. 2023 Apr;11(4):1063-1067. doi: 10.1016/j.jaip.2023.02.003. Epub 2023 Feb 14. PMID: 36796512.

Meet our Team at Northwestern University

Ruchi Gupta, MD, MPH

Founding Director, Center for Food Allergy and Asthma Research

Professor of Pediatrics & Medicine, Northwestern University

Clinical Attending, Ann & Robert H. Lurie Children's Hospital

Justin Starren, MD, PhD, FACMI

Chief, Division of Health and Biomedical Informatics

Deputy Director, Northwestern University Clinical and Translational Science Institute (NCATS)

Director, Center for Biomedical Informatics and Data Science (CBIDS)
Northwestern University

Lucy Bilaver, PhD

Associate Professor
Department of Pediatrics

Director, Health Sciences Integrated Program

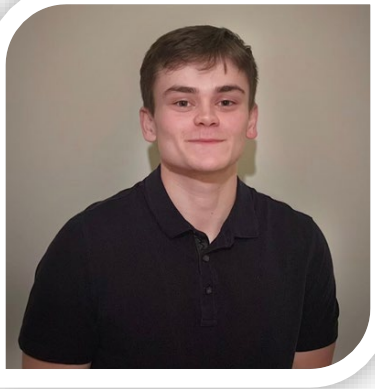
Director of Health Services and Informatics Research
Center for Food Allergy and Asthma Research,
Northwestern University

Shruti Sehgal, MD(Hom.), MS

Senior Research Data Analyst
Center for Food Allergy and Asthma Research,
Northwestern University

Mark Wlodarski, MS

Senior Data Analyst
Center for Food Allergy and Asthma Research,
Northwestern University



John Kosner

Research Coordinator
Center for Food Allergy and Asthma Research,
Northwestern University

CFAAR
Center for Food Allergy & Asthma Research

Northwestern Medicine®
Feinberg School of Medicine

Ann & Robert H. Lurie Children's Hospital of Chicago™

Thank you!

CFAAR Resources