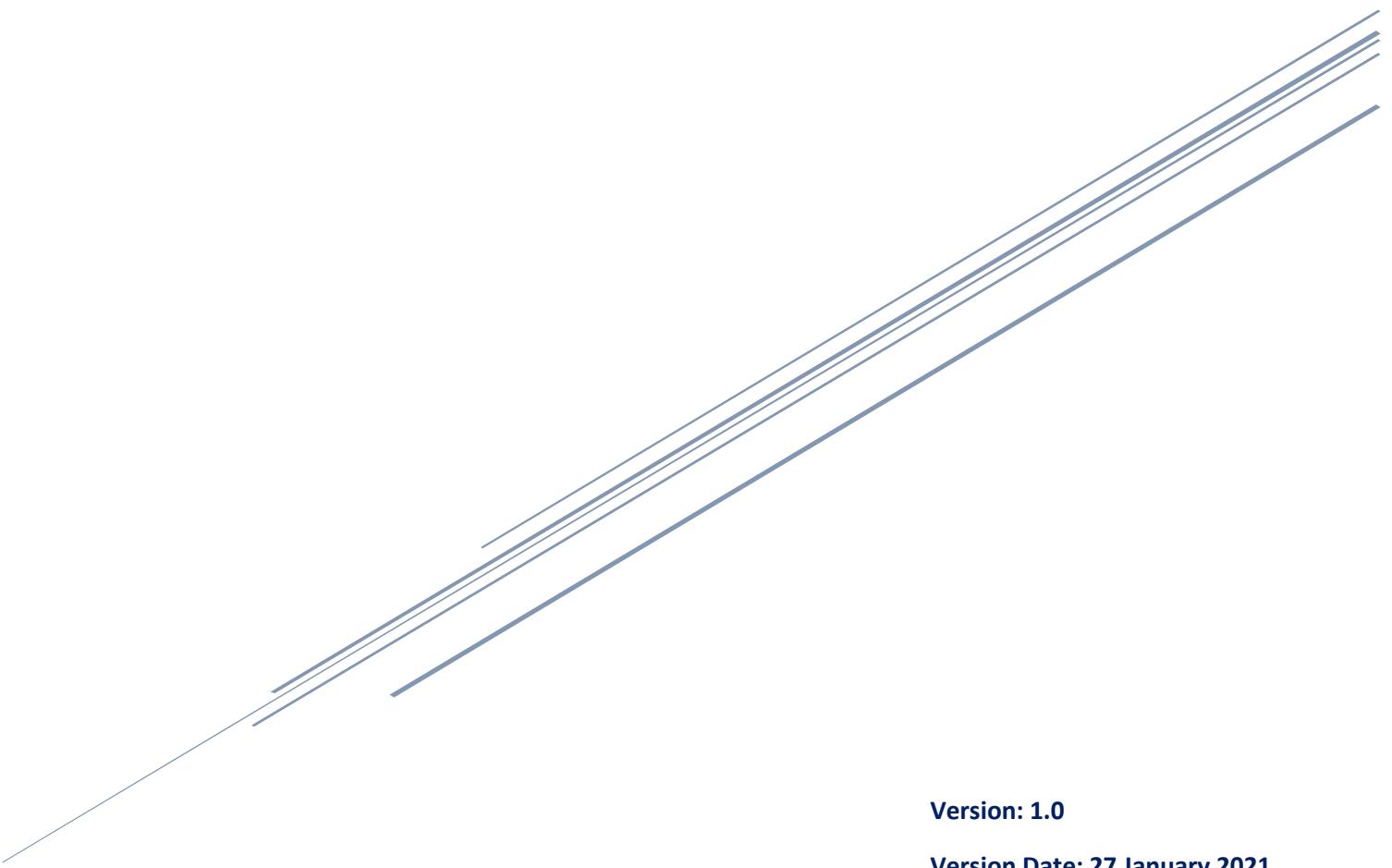


FOOD ALLERGY Data Dictionary



Version: 1.0

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Rationale and Project Goal

Food allergy (FA) research lacks a clear and widely adopted terminological base. Existing terminological systems only provide partial coverage and lack necessary detail. Therefore, there is a definite need to establish a core lexicon and ontology for food allergy concepts. We are aiming to develop a food allergy data dictionary that will support standardization across enterprises and allow for the sharing, evaluation, and aggregation of clinical data at local, national, and even international levels. We also aim to develop consensus on key EMR data elements pertinent to food allergy to be integrated in Electronic Health Record systems that will facilitate standardized documentation of food allergy clinical encounters.

The long-term goal is to build a comprehensive Food Allergy Data Commons. Center for Food Allergy and Asthma Research (CFAAR) at Northwestern University (NU) has partnered with FARE (Food Allergy Research and Education) to develop FARE data commons (FDC) that will host and facilitate understanding of the large, complex, multi-institutional data resources necessary to advance scientific discovery. This would allow food allergy stakeholders all over the globe to input and access data to answer critical questions around food allergy development, progression, severity and potential for natural tolerance. Additionally, determining outcomes of treatments, QOL, economics and more could be discovered.

Once fully developed this platform will provide an interactive system, making the data easier to use for the food allergy community.

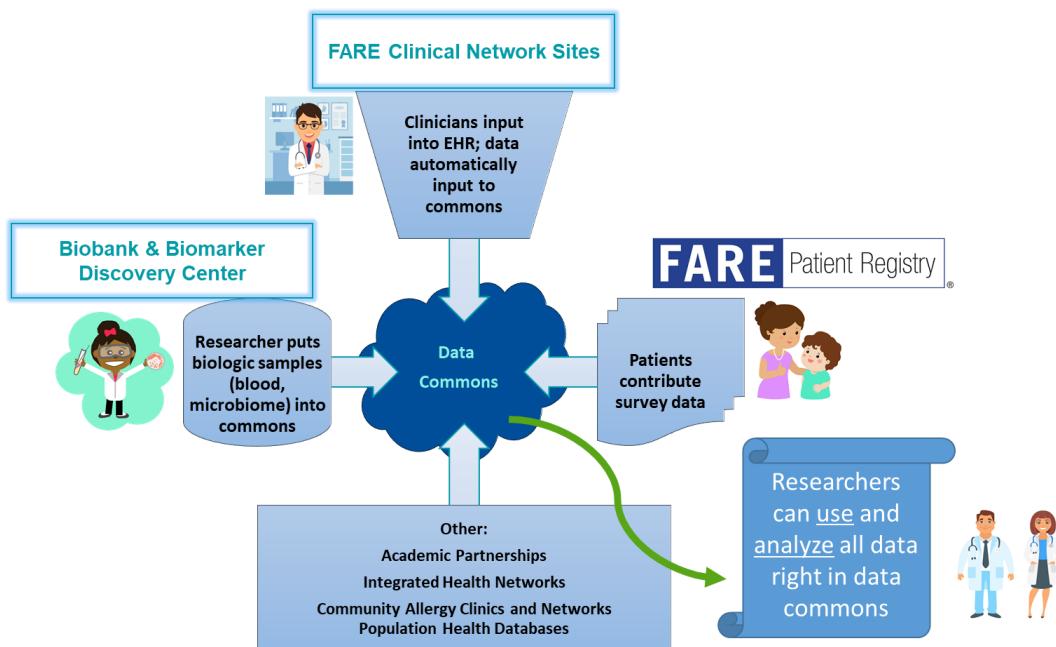


Figure I: FARE Data Commons Vision

Food Allergy Data Dictionary

During the first phase of building the FDC, subject matter experts from four FARE Clinical Network (FCN) sites (Lurie Children's Hospital, University of Chicago, Mount Sinai, Children's Hospital of Philadelphia) were assembled to work collaboratively with the data commons team at Northwestern University (NU).

Establishing a core lexicon and ontology for food allergy concepts was a multi-step process. The initial step involved identifying relevant clinical artifacts, such as patient intake forms, notes templates, clinical notes, and pre-compiled fill-in phrases used across multiple institutions. The concepts identified were collated. Second, clinical encounters were observed and documented. Finally, the dictionary validation was extended to 22 additional FCN sites and three corporations for feedback and review.

In order to maximize interoperability with other biomedical data sharing initiatives, the target structure for the data commons is Observational Medical Outcomes Partnership (OMOP) 5.3 (with plans to migrate to 6.0). The identified vocabulary concepts have been mapped to existing OMOP terminology to identify inconsistencies. We realize that not all concepts and relations listed in the dictionary are currently supported by OMOP and Automated Terminology Harmonization, Extraction and Normalization for Analytics (ATHENA). We will leverage the relationship table to add necessary relationships and are working with the Observational Health Data Sciences and Informatics (OHDSI) leadership to addressing missing codes.

How to use this document

Please use this section as a guide as you're looking through the data dictionary concept domains. Each concept domain discussed below has a description followed by a tabular representation of entity-attribute relation.

These relationships can be hierarchical (parent-child or "is-a") or non-hierarchical ("is-a component-of").

The first column in each table represents a unique ID# corresponding to the data element.

Note: This document presents the critical concepts to be included in the FDC. It is not intended to provide complete information necessary to create an FDC-compliant OMOP instance. A subsequent coding guide will provide information on the preferred OMOP codes to use for each concept, as well as allowed attribute types and values. A database schema document will provide mappings from concepts to OMOP tables, as well as information on constructing post-coordinated concepts. Some concept types do not current list default coding systems because not all required codes currently exist. We are working with the OMOP to correct these gaps. In addition, some data types may map codes from multiple source terminologies.

Data Dictionary Structure

Data Dictionary Top-level Concepts

The FA data dictionary comprises of 14 identified food allergy concepts detailed below (*Table I*). The concept tabulation is followed by the ER diagram (*Figure II*) that presents a high-level overview of the data dictionary concepts.

Table I: Food Allergy Data Dictionary Concepts

S.No.	CATEGORY	SHORT DESCRIPTION	DEFAULT CODING SYSTEM	EXAMPLES	WHERE USED
1.	Events	Things we want to know if they happened and when they happened.		Initial visits, follow-up visits, prior hospitalizations, ICU admission, ER/ED visit, food reaction, disease exacerbations, etc.	PMH, HPI, Patient reported
2.	Medications	FDA approved medications.	Rx Norm / NDC		Current medication list, past medication list, in-clinic medications, as for OFC reaction
3.	Formal Diagnoses	Formal diagnoses, as opposed to symptoms or unconfirmed reactions. Include food allergy and comorbid conditions.	ICD	Peanut Allergy, Asthma, Rhinoconjunctivitis, etc.	PMH, HPI, FH, Patient reported
4.	Triggers	Foods that triggered (or failed to trigger) an allergic reaction. Will code most common and use free-text for less common foods. It also includes triggers for non-food allergic conditions.		Food triggers- Egg, milk, shellfish, etc. Environmental triggers- Pollen, tree, weed, etc.	PMH, current dx., FH, events
5.	Clinical Trials	Is / was patient on a clinical trial.	CT.gov		
6.	OIT	Oral Immunotherapy. Special case of medication because of complex dosing/timing issues.	Rx Norm + custom codes	Initiation, OIT up-dosing phase, ongoing maintenance, OIT completion, including reason for discontinuation.	Current and past medication, in-office visit
7.	Reactions	Clinical manifestations of food allergy reactions that include signs and symptoms, and other reaction attributes.			
7.1	Signs and Symptoms	Objective, observable evidence indicating possible FA reaction, observed by an allergist and subjective complaints reported by the patient. It also includes physical exam findings.	SNOMED / LOINC	Sign- Rash, Erythema, etc. Symptom- Nausea, Oral Pruritis, etc.	PMH, current dx., FH, events,
7.2	Other Reaction Attributes	Other reaction characteristics as amount of food that triggered the reaction, temporal relation, type		Type of exposure- Accidental, intentional, etc.	PMH, current dx., events,

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		of exposure, exposure mode, and environmental location.		Environmental location- Ingestion, Contact, Inhalation. Location- Home, School, etc.	
8.	Procedures	Sub-divided into FA diagnostic procedures and other codable procedures performed on a patient.			
8.1	FA Diagnostic Procedures	Procedures specifically related to diagnosis of food allergy.	CPT/ LOINC	Skin Prick Test, Blood testing, Oral Food Challenge, Contact challenge, Inhalation challenge test.	HPI, PMH
8.2	Other Procedures	Any codable procedure performed on a patient.	CPT	e.g. Laboratory test, Endoscopy	PMH
9.	Therapeutic Plan	Clinical management plan for the patient.	Custom	FA recommendations, including dietary recommendations, Anaphylaxis management plan/ Emergency action plan, and Follow-up.	
10.	Family History	This concept includes record of health information about a person's close relatives, including parents, brothers and sisters.		Family history of food allergy	FH
11.	History	The history concept captures person's breastfeeding history and personal history.		Breastfeeding history, personal history of other diseases.	HPI, PMH
12.	Other Observations & Measurements	Financial, and psycho-social factors that may influence condition and treatment. Information gained from a procedure.		Other observations- Environmental factors, Economic determinants, Dietary preferences. Measurements- Vitals, test result values, as, IgE.	
13.	Person	The Person concept contains records that uniquely identify each patient in the source data.		Commons ID, Location, External identifiers, etc.	
14.	Provider	The provider table contains a list of uniquely identified healthcare providers, including physicians, nurses, behavioral therapists etc.		NPI, Speciality, Care site, etc.	

Entity Relationship (ER) Diagram

As indicated above, the ER diagram (*Figure II*) gives an overview of the identified concept categories present in the Data Dictionary. It illustrates the most pertinent relationships between these categories that have been modeled with arrows and a brief description has been added. Additionally, you can learn more about the OMOP tables that the category maps best to. This has been included under the section: "Role of OMOP Common Data Model (CDM)".

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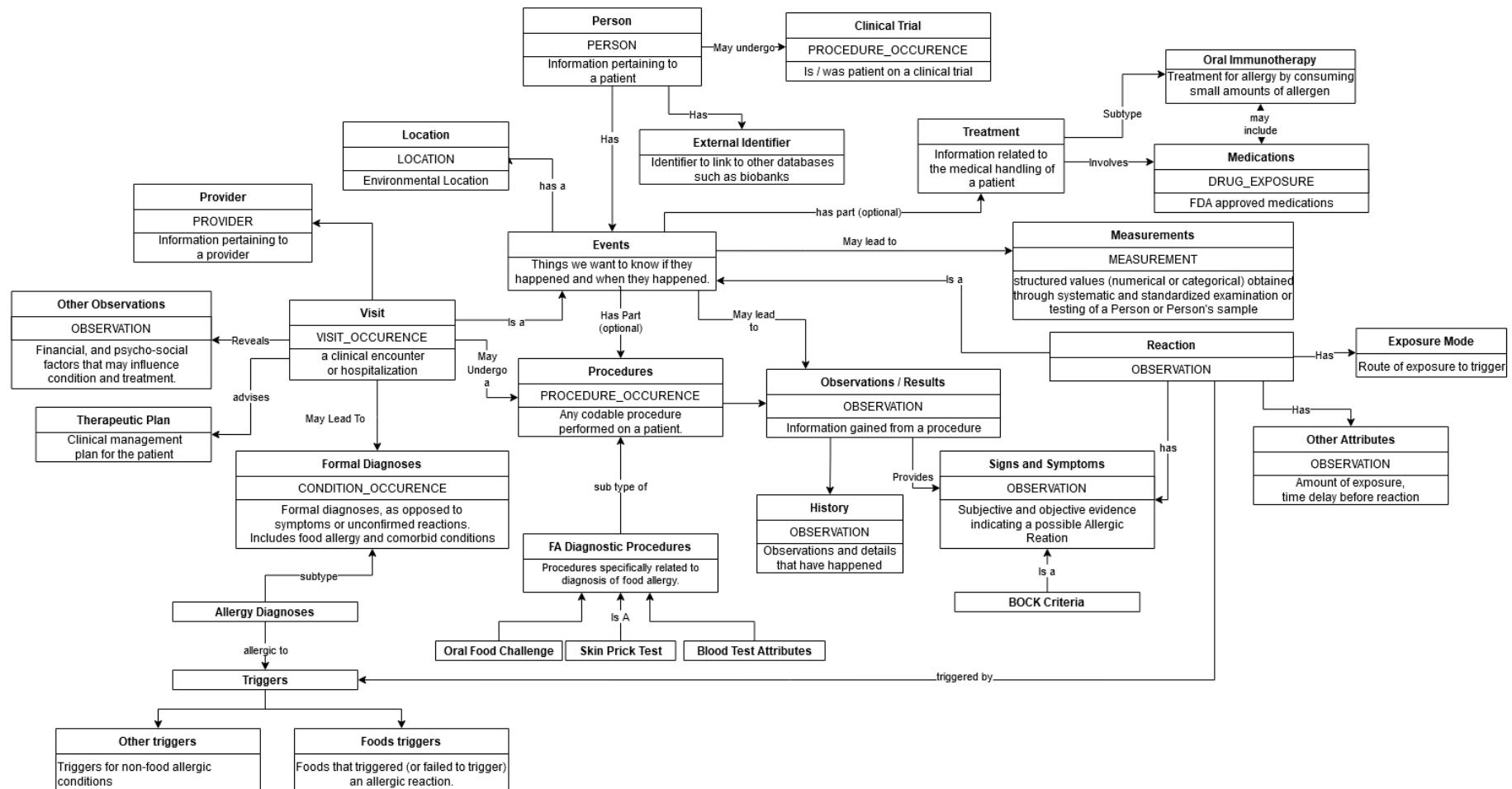


Figure II: High-level ER Diagram Representing Food Allergy Data Dictionary Concepts

Data Dictionary Concept Domains

We will now discuss each of these concept domains in detail.

1. EVENTS

Description: This concept encompasses occurrences/ incidences that we want to know if they happened and when they happened. This includes clinical encounters, food allergy reaction, atopic flares, and infectious events.

Clinical encounters typically are visit occurrences recorded for each engagement of a patient within the healthcare system. This includes standard visit concept of out-patient visits, hospitalization, ER/ED visit, and urgent care visit. Events have also been used to indicate “Atopic flares” that typically refer to disease episodes requiring an escalation of treatment or seeking additional medical advice. Infectious events represent most frequently encountered infections in relation to food allergy.

Table 1: Events Related to Food Allergy

1.1.	Clinical Encounters			
1.1.1.		Outpatient visit ¹		
1.1.1.1.			PCP visit	
1.1.1.1.1.				Family practitioner visit
1.1.1.1.2.				Pediatrician visit
1.1.1.1.3.				Internist visit
1.1.1.2.			Allergist visit	
1.1.1.2.1.				Allergist NP/PA visit
1.1.1.3.			Dermatologist visit	
1.1.1.4.			Nutritional visit	
1.1.1.4.1.				Nutritionist visit
1.1.1.4.2.				Dietician visit
1.1.1.5.			ENT visit	
1.1.1.6.			Pulmonologist visit	
1.1.1.7.			Gastroenterologist visit	
1.1.1.8.			Rheumatology Visit	
1.1.1.9.			Alternative therapy visit/ Complementary and integrative therapy visit	
1.1.1.10.			Behavioral therapy visit	
1.1.1.10.1.				Psychologist visit
1.1.1.10.2.				Psychiatrist visit
1.1.1.10.3.				Social worker visit
1.1.1.10.4.				Nurse behavioral therapist visit
1.1.2.	Hospitalization		Hospitalization with ICU	
1.1.2.1.				

¹ Out-patient visit attributes have been further categorized into 5 visit types (Table 1A).

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1.1.2.2.			Hospitalization with ICU and Intubation	
1.1.3.		ER/ED visit		
1.1.3.1.			ER/ ED visit with Observation Unit	
1.1.4.		Urgent care visit		
1.2.	Food Allergy Reactions²			
1.3.	Atopic Flares			
1.3.1.		Asthma		
1.3.2.		Atopic Dermatitis		
1.3.3.		Drug reaction		
1.3.4.		Rhinoconjunctivitis		
1.3.5.		Urticaria		
1.3.6.		Venom reaction		
1.4.	Infectious Events			
1.4.1.		Gastroenteritis		
1.4.2.		Otitis		
1.4.3.		Pneumonia		
1.4.4.		Sinusitis		

Table 1A: Attributes for an Out Patient Visit

1.1.1.	Outpatient visit attributes		
1.1.1.A		Visit Type	
1.1.1.A i			Initial Consult
1.1.1.A ii			Initial New Patient
1.1.1.A iii			Follow-up
1.1.1.A iv			Procedural Diagnostic
1.1.1.A v			Procedural Therapeutic

² Food allergy reactions have been described separately in the data dictionary (Table 7.1 & 7.2).

2. MEDICATIONS

Description: This concept includes, but may not be limited to, current and past medications prescribed by physicians, over-the-counter medicines, and drugs administered as part of in-office procedures, as for an Oral Food Challenge (OFC) reaction. Although, the list below encompasses most frequently prescribed medicines in relation to food allergy and co-existing diseases, other FDA approved medications can also be stored. OMOP can store any medication that has a Rx norm code irrespective of indication. The list that is presented below is to help prioritize data entry and does not limit what is/can be stored in the data commons.

Table 2: Common Medications for Treating Food-Allergic Reactions and Associated Comorbid Conditions

2.1. Inhalation Medications			
2.1.1.	Controllers		
2.1.1.1.		Beclomethasone (Qvar)	
2.1.1.2.		Budesonide (Pulmicort)	
2.1.1.3.		Ciclesonide (Alvesco)	
2.1.1.4.		Flunisolide (Aerospan)	
2.1.1.5.		Fluticasone (Flovent)	
2.1.1.6.		Mometasone (Asmanex)	
2.1.2.	Combination Medications (Controllers)		
2.1.2.1.		Budesonide / Formoterol (Symbicort)	
2.1.2.2.		Fluticasone / Salmeterol (Advair, AirDuo)	
2.1.2.3.		Fluticasone / Vilanterol (Breo)	
2.1.2.4.		Formoterol / Mometasone (Dulera)	
2.1.3.	Rescue Medications		
2.1.3.1.		Albuterol (Combivent, DuoNeb)	
2.1.3.2.		Ipratropium (Atrovent)	
2.1.3.3.		Levalbuterol	
2.1.3.4.		Tiotropium (Spiriva)	
2.2. Nasal Medications			
2.2.1.	Azelastine (Astelin)		
2.2.2.	Beclomethasone (Qnasl)		
2.2.3.	Budesonide (Rhinocort)		
2.2.4.	Fluticasone (Flonase)		

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2.2.5.		Mometasone (Nasonex)		
2.2.6.		Olopatadine (Patanase)		
2.2.7.		Triamcinolone (Nasacort AQ)		
2.3.	Oral Medications			
2.3.1.		Antihistamines		
2.3.1.1.			Cetirizine	
2.3.1.2.			Diphenhydramine	
2.3.1.3.			Fexofenadine	
2.3.1.4.			Hydroxyzine	
2.3.1.5.			Levocetirizine	
2.3.1.6.			Ioratadine	
2.3.1.7.			Desloratadine	
2.3.2.		Leukotriene Antagonists		
2.3.2.1.			Montelukast (Singulair)	
2.3.2.2.			Zileutin	
2.3.3.		GI Medications		
2.3.3.1.			Cyproheptadine	
2.3.3.2.			Iansoprazole	
2.3.3.3.			Omeprazole	
2.3.3.4.			Dexlansoprazole	
2.3.3.5.			Esomeprazole	
2.3.3.6.			Rabeprazole	
2.3.3.7.			Ranitidine	
2.3.3.8.			Cimetidine	
2.3.3.9.			Famotidine	
2.3.3.10.			Nizatidine	
2.3.4.		Antiemetics		
2.3.4.1.			Dimenhydrinate	
2.3.4.2.			Ondansetron	
2.3.5.		NSAIDs		

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2.3.5.1.		Aspirin	
2.3.5.2.		Diclofenac	
2.3.5.3.		Ibuprofen	
2.3.5.4.		Meloxicam	
2.3.5.5.		Naproxen	
2.3.5.6.		Oxaprozin	
2.3.5.7.		Piroxicam	
2.3.5.8.		Sulindac	
2.3.5.9.		Tolmetin	
2.3.6.	Cardiac Beta-Blockers		
2.3.6.1.		Acebutolol	
2.3.6.2.		Atenolol	
2.3.6.3.		Bisoprolol	
2.3.6.4.		Metoprolol	
2.3.6.5.		Nadolol	
2.3.6.6.		Nebivolol	
2.3.6.7.		Propranolol	
2.3.7.	Oral Immunotherapy		
2.3.7.1.		Palforzia	
2.3.8.	Others		
2.3.8.1.		Budesonide (Swallowed)	
2.3.8.2.		Fluticasone (Swallowed)	
2.3.8.3.		Methylprednisolone	
2.3.8.4.		Prednisolone	
2.3.8.5.		Prednisone	
2.3.8.6.		Dexamethasone	
2.4.	Injections		
2.4.1.	Glucagon		
2.4.2.	Epinephrine (EpiPen, Auvi-q, Adrenaclick)		
2.4.3.	Biologics		

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2.4.3.1.			Benralizumab (Fasenra)	
2.4.3.2.			Dupilumab (Dupixent)	
2.4.3.3.			Mepolizumab (Nucala)	
2.4.3.4.			Omalizumab (Xolair)	
2.4.3.5.			Reslizumab (Cinqueair)	
2.5.	Ayurvedic Medications			
2.6.	Herbal Medications			
2.7.	Supplements			
2.8.	Allergen Immunotherapy			
2.8.1.		Sublingual Immunotherapy		
2.8.1.1.			FDA approved medications	
2.8.1.1.1.			American house dust mite allergenic extract / European house dust mite allergenic extract (Odactra)	
2.8.1.1.2.			Kentucky bluegrass pollen extract / orchard grass pollen extract / perennial rye grass pollen extract / sweet vernal grass pollen extract / Timothy grass pollen extract (Oralair)	
2.8.1.1.3.			Short Ragweed pollen extract (Ragwitek)	
2.8.1.1.4.			Timothy grass pollen extract (Grastek)	
2.8.2.	Subcutaneous Immunotherapy			
2.8.2.1.			Grasses	
2.8.2.1.1.			Orchard	
2.8.2.1.2.			Timothy	
2.8.2.2.			Molds	
2.8.2.2.1.			Alternaria alternata	
2.8.2.2.2.			Aspergillus fumigatus	
2.8.2.2.3.			Cladosporium	
2.8.2.2.4.			Epicoccum nigrum	
2.8.2.2.5.			Fusarium	
2.8.2.2.6.			Penicillium chrysogenum or penicillium notatum	
2.8.2.3.			Trees	
2.8.2.3.1.			American Elm	

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2.8.2.3.2.			Birch
2.8.2.3.3.			Box Elder
2.8.2.3.4.			Maple
2.8.2.3.5.			White Ash
2.8.2.3.6.			White Oak
2.8.2.4.		Weeds	
2.8.2.4.1.			Giant Ragweed
2.8.2.4.2.			Mugwort
2.8.2.4.3.			Pigweed
2.8.2.4.4.			Russian Thistle
2.8.2.4.5.			Short Ragweed

3. FORMAL DIAGNOSES

Description: This concept includes standard medical conditions primarily responsible for the patient's need for treatment or investigation. These are formal diagnoses as opposed to signs and symptoms or ill-defined reactions. It can encompass conditions as "admitting diagnosis", "final diagnosis", or "preliminary diagnosis". These include, but are not limited to, adverse reaction to food, atopic conditions, and other diagnoses related to food allergy.

Table 3: Formal Diagnoses

3.1.	Adverse reaction to food			
3.1.1.		Immune mediated		
3.1.1.1.			Food Allergy	
3.1.1.1.1.				IgE mediated
3.1.1.1.1.1.				Classic Food Allergy
3.1.1.1.1.2.				Pollen-food allergy syndrome
3.1.1.1.1.3.				Food-induced exercise-induced anaphylaxis
3.1.1.1.1.4.				Alpha-gal allergy
3.1.1.1.2.				Non- IgE mediated
3.1.1.1.2.1.				Food protein-induced enterocolitis syndrome
3.1.1.1.2.2.				Eosinophilic Esophagitis
3.1.1.1.2.3.				Eosinophilic gastritis or gastroenteritis

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3.1.1.1.2.4.					Eosinophilic colitis
3.1.1.1.2.5.					Cow's milk protein intolerance/ Allergic proctocolitis
3.1.1.1.2.6.					Celiac disease
3.1.2.	Non-Immune mediated				
3.1.2.1.		Metabolic			
3.1.2.1.1.			Lactose Intolerance		
3.1.2.2.		Pharmacologic			
3.1.2.2.1.			Caffeine		
3.1.2.3.		Toxic			
3.1.2.3.1.			Scombrotoxin		
3.2.	Atopic conditions				
3.2.1.	Allergic rhinoconjunctivitis				
3.2.1.1.		Allergic rhinitis due to pollen			
3.2.1.2.		Other seasonal allergic rhinitis			
3.2.1.3.		Allergic rhinitis due to animal (cat) (dog) hair and dander			
3.2.1.4.		Other allergic rhinitis			
3.2.1.5.		Allergic conjunctivitis			
3.2.2.	Asthma				
3.2.2.1.		Allergic			
3.2.2.2.		Intermittent			
3.2.2.2.1.			With exacerbation		
3.2.2.3.		Persistent			
3.2.2.3.1.			Mild		
3.2.2.3.1.1.				With exacerbation	
3.2.2.3.2.			Moderate		
3.2.2.3.2.1.				With exacerbation	
3.2.2.3.3.			Severe		
3.2.2.3.3.1.				With exacerbation	
3.2.2.4.		With hospitalization			

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3.2.2.5.			Reactive airway disease		
3.2.3.		Atopic dermatitis			
3.2.3.1.			Mild		
3.2.3.2.			Moderate		
3.2.3.3.			Severe		
3.2.3.4.			Atopic dermatitis due to food		
3.2.4.		Drug Allergy			
3.2.5.		Venom reaction			
3.3.	Other Diagnoses with Importance to Food Allergy				
3.3.1.		Allergic contact dermatitis			
3.3.2.		Immunodeficiency			
3.3.3.		Dermatographia			
3.3.4.		Urticaria			
3.3.4.1.			Chronic Idiopathic		
3.3.4.2.			Cold induced		
3.3.4.3.			Physical		
3.3.4.4.			Viral induced		
3.3.4.5.			Cholinergic		
3.3.5.		Wheezing			
3.4.	Any other ICD diagnosis				
3.4.1.		Abnormal weight gain			
3.4.2.		Failure to thrive			
3.4.3.		Short stature			

4. TRIGGERS

Description: This concept comprises triggering factors for food allergic reactions as well as triggers for non-food allergic conditions including drug allergies. These can represent attributes of a diagnosis or a reaction, challenge food, or therapy food.

Table 4: Triggers for Food Allergic and Non-Food Allergic Reactions

4.1.	Food triggers			
4.1.1.	Milk (Mammalian)			
4.1.1.1.		Cow's milk		
4.1.1.2.		Baked milk/ Milk baked into a matrix		
4.1.1.3.		Goat milk		
4.1.1.4.		Sheep milk		
4.1.2.	Egg (Hen's)			
4.1.2.1.		Raw egg white/ Minimally cooked egg/ Incompletely cooked/ Regular/ Unbaked egg/ Regular egg		
4.1.2.2.		Baked egg/ Egg baked into a matrix		
4.1.3.	Fish			
4.1.3.1.		Fish mix		
4.1.3.2.		Finfish		
4.1.3.2.1.			Anchovy	
4.1.3.2.2.			Bass	
4.1.3.2.3.			Catfish	
4.1.3.2.4.			Cod	
4.1.3.2.5.			Eel	
4.1.3.2.6.			Flounder	
4.1.3.2.7.			Haddock	
4.1.3.2.8.			Hake	
4.1.3.2.9.			Halibut	
4.1.3.2.10.			Herring	
4.1.3.2.11.			Mackerel	
4.1.3.2.12.			Megrim	
4.1.3.2.13.			Perch	
4.1.3.2.14.			Plaice	
4.1.3.2.15.			Pollock	
4.1.3.2.16.			Salmon	

FOOD ALLERGY Data Dictionary

4.1.3.2.17.			Sardine	
4.1.3.2.18.			Snapper	
4.1.3.2.19.			Sole	
4.1.3.2.20.			Swordfish	
4.1.3.2.21.			Tilapia	
4.1.3.2.22.			Trout	
4.1.3.2.23.			Tuna	
4.1.3.2.24.			Whitefish (Inconnu)	
4.1.4.	Shellfish			
4.1.4.1.		Shellfish mix		
4.1.4.2.		Molluscs		
4.1.4.2.1.			Clam	
4.1.4.2.2.			Mussel	
4.1.4.2.3.			Octopus	
4.1.4.2.4.			Oyster	
4.1.4.2.5.			Scallop	
4.1.4.2.6.			Snail	
4.1.4.2.7.			Squid	
4.1.4.3.		Crustaceans		
4.1.4.3.1.			Crab	
4.1.4.3.2.			Crayfish	
4.1.4.3.3.			Lobster	
4.1.4.3.4.			Shrimp	
4.1.5.	Peanut			
4.1.6.	Tree Nuts			
4.1.6.1.		Almond		
4.1.6.2.		Brazil nut		
4.1.6.3.		Cashew		
4.1.6.4.		Chestnut		
4.1.6.5.		Coconut		
4.1.6.6.		Hazelnut		
4.1.6.7.		Macadamia		
4.1.6.8.		Pecan		

FOOD ALLERGY Data Dictionary

4.1.6.9.			Pinenut		
4.1.6.10.			Pistachio		
4.1.6.11.			Walnut		
4.1.7.	Seeds				
4.1.7.1.			Chia seed		
4.1.7.2.			Chocolate (Cacao)		
4.1.7.3.			Flaxseed		
4.1.7.4.			Mustard seed		
4.1.7.5.			Poppy seed		
4.1.7.6.			Pumpkin seed		
4.1.7.7.			Sesame seed		
4.1.7.8.			Sunflower seed		
4.1.8.	Meat				
4.1.8.1.			Beef		
4.1.8.2.			Chicken		
4.1.8.3.			Duck		
4.1.8.4.			Gelatin		
4.1.8.5.			Goat		
4.1.8.6.			Horse		
4.1.8.7.			Lamb		
4.1.8.8.			Pork		
4.1.8.9.			Turkey		
4.1.8.10.			Venison		
4.1.9.	Cereals, or Grains				
4.1.9.1.			Barley		
4.1.9.2.			Buckwheat		
4.1.9.3.			Millet		
4.1.9.4.			Oat		
4.1.9.5.			Quinoa		
4.1.9.6.			Rice		
4.1.9.7.			Rye		
4.1.9.8.			Spelt		
4.1.9.9.			Wheat		

FOOD ALLERGY Data Dictionary

4.1.10.		Beans, Legumes, or Pulses			
4.1.10.1.			Black Beans		
4.1.10.2.			Chick Pea		
4.1.10.3.			Green Beans/ String Beans		
4.1.10.4.			Green Peas		
4.1.10.5.			Yellow Peas		
4.1.10.6.			Lentils		
4.1.10.7.			Navy bean		
4.1.10.8.			Pinto bean		
4.1.10.9.			Red kidney beans		
4.1.10.10.			Soybean		
4.1.11.		Spices			
4.1.11.1.			Aniseed/ Anise		
4.1.11.2.			Basil		
4.1.11.3.			Bay leaf		
4.1.11.4.			Black pepper		
4.1.11.5.			Chamomile		
4.1.11.6.			Caraway		
4.1.11.7.			Cardamom		
4.1.11.8.			Cayenne		
4.1.11.9.			Cinnamon		
4.1.11.10.			Clove		
4.1.11.11.			Coriander		
4.1.11.12.			Cumin		
4.1.11.13.			Curry		
4.1.11.14.			Dandelion		
4.1.11.15.			Echinacea		
4.1.11.16.			Fennel		
4.1.11.17.			Fenugreek		
4.1.11.18.			Ginger		
4.1.11.19.			Hibiscus		
4.1.11.20.			Hops		
4.1.11.21.			Nutmeg		

FOOD ALLERGY Data Dictionary

4.1.11.22.			Oregano		
4.1.11.23.			Paprika		
4.1.11.24.			Parsley		
4.1.11.25.			Peppermint		
4.1.11.26.			Saffron		
4.1.11.27.			Sage		
4.1.11.28.			Spearmint		
4.1.11.29.			Turmeric		
4.1.11.30.			Vanilla		
4.1.12.	Fruits				
4.1.12.1.			Apple		
4.1.12.2.			Apricot		
4.1.12.3.			Avocado		
4.1.12.4.			Banana		
4.1.12.5.			Blackberry		
4.1.12.6.			Blueberry		
4.1.12.7.			Cherry		
4.1.12.8.			Grape		
4.1.12.9.			Grapefruit		
4.1.12.10.			Guava		
4.1.12.11.			Jackfruit		
4.1.12.12.			Kiwi		
4.1.12.13.			Mango		
4.1.12.14.			Melons		
4.1.12.14.1.				Cantaloupe	
4.1.12.14.2.				Honeydew	
4.1.12.14.3.				Watermelon	
4.1.12.15.			Orange		
4.1.12.16.			Peach		
4.1.12.17.			Pear		
4.1.12.18.			Pineapple		
4.1.12.19.			Plum		
4.1.12.20.			Raspberry		

FOOD ALLERGY Data Dictionary

4.1.12.21.			Strawberry		
4.1.12.22.			Tomato		
4.1.13.		Vegetables			
4.1.13.1.			Artichoke		
4.1.13.2.			Bell pepper		
4.1.13.3.			Broccoli		
4.1.13.4.			Cabbage		
4.1.13.5.			Carrot		
4.1.13.6.			Cauliflower		
4.1.13.7.			Celery		
4.1.13.8.			Chard		
4.1.13.9.			Corn		
4.1.13.10.			Cucumber		
4.1.13.11.			Eggplant/ Aubergine		
4.1.13.12.			Garlic		
4.1.13.13.			Onion		
4.1.13.14.			Parsley		
4.1.13.15.			Pumpkin		
4.1.13.16.			Spinach		
4.1.13.17.			Sweet potato		
4.1.13.18.			White potato		
4.1.13.19.			Zucchini		
4.2.	Environmental allergens				
4.2.1.		Animal Dander			
4.2.1.1.			Cat		
4.2.1.2.			Dog		
4.2.1.3.			Gerbil		
4.2.1.4.			Hamster		
4.2.1.5.			Horse		
4.2.1.6.			Mouse		
4.2.1.7.			Guinea pig		
4.2.1.8.			Rabbit		

FOOD ALLERGY Data Dictionary

4.2.1.9.		Rat		
4.2.2.	Feathers			
4.2.2.1.		Parakeet		
4.2.2.2.		Mixed		
4.2.3.	Insects			
4.2.3.1.		Cockroach		
4.2.3.2.		Dust mites		
4.2.3.2.1.			D. pteronyssinus	
4.2.3.2.2.			D. farinae	
4.2.4.	Mold			
4.2.4.1.		Alternaria alternata		
4.2.4.2.		Aspergillus fumigatus		
4.2.4.3.		Cladosporium herbarum		
4.2.4.4.		Epicoccum nigrum		
4.2.4.5.		Fusarium		
4.2.4.6.		P. notatum		
4.2.5.	Pollens			
4.2.5.1.		Grass		
4.2.5.1.1.			Bahia grass	
4.2.5.1.2.			Barley	
4.2.5.1.3.			Bermuda grass	
4.2.5.1.4.			Brome grass	
4.2.5.1.5.			Canary grass	
4.2.5.1.6.			Cocksfoot	
4.2.5.1.7.			Common reed	
4.2.5.1.8.			Cultivated oat	
4.2.5.1.9.			Cultivated rye	
4.2.5.1.10.			Cultivated wheat	
4.2.5.1.11.			False oat-grass	
4.2.5.1.12.			Johnson grass	
4.2.5.1.13.			Maize, Corn	
4.2.5.1.14.			Meadow fescue	
4.2.5.1.15.			Meadow foxtail	

FOOD ALLERGY Data Dictionary

4.2.5.1.16.				Meadow grass, Kentucky blue	
4.2.5.1.17.				Redtop, Bentgrass	
4.2.5.1.18.				Rye-grass	
4.2.5.1.19.				Salt grass	
4.2.5.1.20.				Sweet vernal grass	
4.2.5.1.21.				Timothy grass	
4.2.5.1.22.				Velvet grass	
4.2.5.1.23.				Wild rye grass	
4.2.5.1.24.				Grass Mix	
4.2.5.2.		Tree			
4.2.5.2.1.				Acacia	
4.2.5.2.2.				American beech	
4.2.5.2.3.				American elm	
4.2.5.2.4.				Australian pine	
4.2.5.2.5.				Bald cypress	
4.2.5.2.6.				Bayberry	
4.2.5.2.7.				Birch	
4.2.5.2.8.				Box-elder	
4.2.5.2.9.				Cedar	
4.2.5.2.10.				Cedar elm	
4.2.5.2.11.				Chestnut	
4.2.5.2.12.				Common silver birch	
4.2.5.2.13.				Cotton wood	
4.2.5.2.14.				Cypress	
4.2.5.2.15.				Date	
4.2.5.2.16.				Douglas fir	
4.2.5.2.17.				Elder	
4.2.5.2.18.				Elm	
4.2.5.2.19.				Eucalyptus, Gum-tree	
4.2.5.2.20.				European ash	
4.2.5.2.21.				Grey alder	
4.2.5.2.22.				Hackberry	
4.2.5.2.23.				Hazel	

FOOD ALLERGY Data Dictionary

4.2.5.2.24.			Horn beam	
4.2.5.2.25.			Horse chestnut	
4.2.5.2.26.			Italian/Mediterranean/Funeral cypress	
4.2.5.2.27.			Japanese cedar	
4.2.5.2.28.			Juniper	
4.2.5.2.29.			Linden	
4.2.5.2.30.			Maple leaf sycamore, London plane	
4.2.5.2.31.			Melaleuca, Cajeput-tree	
4.2.5.2.32.			Mesquite	
4.2.5.2.33.			Mountain Cedar	
4.2.5.2.34.			Mountain juniper	
4.2.5.2.35.			Mulberry	
4.2.5.2.36.			Oak	
4.2.5.2.37.			Oil Palm	
4.2.5.2.38.			Olive	
4.2.5.2.39.			Pecan, Hickory	
4.2.5.2.40.			Peppertree	
4.2.5.2.41.			Pine	
4.2.5.2.42.			Privet	
4.2.5.2.43.			Queen palm	
4.2.5.2.44.			Red cedar	
4.2.5.2.45.			Red mulberry	
4.2.5.2.46.			Russian olive	
4.2.5.2.47.			Scotch broom	
4.2.5.2.48.			Spruce	
4.2.5.2.49.			Sweet gum	
4.2.5.2.50.			Walnut	
4.2.5.2.51.			White ash	
4.2.5.2.52.			White hickory	
4.2.5.2.53.			White oak	
4.2.5.2.54.			White pine	
4.2.5.2.55.			Willow	

FOOD ALLERGY Data Dictionary

4.2.5.2.56.				Virginia live oak	
4.2.5.2.57.				Tree mix	
4.2.5.3.		Weed			
4.2.5.3.1.				Alfalfa	
4.2.5.3.2.				Cannabis	
4.2.5.3.3.				Camomile	
4.2.5.3.4.				Careless weed	
4.2.5.3.5.				Cocklebur	
4.2.5.3.6.				Common pigweed	
4.2.5.3.7.				Common ragweed	
4.2.5.3.8.				Dandelion	
4.2.5.3.9.				Dog fennel	
4.2.5.3.10.				False ragweed	
4.2.5.3.11.				Firebush (Kochia)	
4.2.5.3.12.				Giant ragweed	
4.2.5.3.13.				Goldenrod	
4.2.5.3.14.				Goosefoot, Lamb's quarters	
4.2.5.3.15.				Japanese Hop	
4.2.5.3.16.				Lupin	
4.2.5.3.17.				Marguerite, Ox-eye daisy	
4.2.5.3.18.				Mugwort	
4.2.5.3.19.				Nettle	
4.2.5.3.20.				Plantain (English), Ribwort	
4.2.5.3.21.				Rape	
4.2.5.3.22.				Rough marshelder	
4.2.5.3.23.				Saltwort (prickly), Russian thistle	
4.2.5.3.24.				Scale, Lenscale	
4.2.5.3.25.				Sheep sorrel	
4.2.5.3.26.				Sugar-beet	
4.2.5.3.27.				Sunflower	
4.2.5.3.28.				Wall pellitory	
4.2.5.3.29.				Wall pellitory	
4.2.5.3.30.				Western ragweed	

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4.2.5.3.31.				Wormwood	
4.2.5.3.32.				Yellow dock	
4.2.5.3.33.				Weed mix	
4.3.	Drug allergy triggers				
4.3.1.		Rx Norm			

5. CLINICAL TRIALS

Description: This concept identifies if a patient is or was enrolled in a food- allergy clinical trial registered with CT.gov, including therapeutic trials, diagnostic trials, combination trials.

Table 5: Food Allergy Clinical Trials

5.1.	Patient enrollment in a Food Allergy Clinical trial			
5.1.1.		Yes / No		
5.1.2.		CT.gov Number		
5.1.3.		Phase		
5.1.3.1.		Phase 1		
5.1.3.2.		Phase 2		
5.1.3.3.		Phase 3		
5.1.3.4.		Phase 4		
5.1.4.		Intervention type ³		
5.1.4.1.		Biologics		
5.1.4.2.		Epicutaneous		
5.1.4.3.		Oral immunotherapy		
5.1.4.4.		Sublingual immunotherapy		
5.1.4.5.		Vaccines		
5.1.4.6.		Probiotics		
5.1.4.7.		Adjuvants		
5.1.4.8.		Behavioral		

³ More than one intervention type may be selected.

6. OIT

Description: This concept consists of the following 4 phases of OIT- (1) An OIT initiation phase that includes in-office initial escalation day where the highest tolerated dose of allergen that can be safely consumed is determined, (2) an up-dosing visit or escalation phase of varying length when the allergen dose is gradually increased over time till a predetermined maintenance dose is reached, (3) a dose maintenance phase of variable length, and (4) OIT completion phase/ Stop OIT. The characteristics of each of these phases will be captured.

Table 6: Phases of Oral Immunotherapy

6.1.	OIT initiation phase				
6.1.1.	In-office initial escalation				
6.1.1.1.		Therapeutic agent			
6.1.1.1.1.			Treatment food (FDA approved {Rx Norm} or Home-based)		
6.1.1.1.2.			Delivery form (e.g., Apple sauce)		
6.1.1.2.		Considerations for OIT initial escalation			
6.1.1.2.1.			Full stomach		
6.1.1.3.		Escalation n			
6.1.1.3.1.			Dose		
6.1.1.3.2.			Time between doses		
6.1.1.3.3.			Reaction observed		
6.1.1.3.3.1.				Yes	
6.1.1.3.3.1.1.					Time since last dose
6.1.1.3.3.1.2.					Description (Point to reaction description) ⁴
6.1.1.3.3.2.				No	
6.1.1.4.		Assessment of initial escalation day			
6.1.1.4.1.			Tolerated initial escalation/ Reacted to initial escalation		
6.1.1.4.2.			Home dose		
6.1.1.5.		Plan			
6.1.1.5.1.			Directions for home administration		
6.1.1.5.2.			Stop OIT (Point to stop OIT event)		
6.2.	Up-dosing visit/ Escalation phase				
6.2.1.	Interval since last appointment				
6.2.2.	Interval history				
6.2.2.1.		Previous dose			

⁴ Reaction description includes signs and symptoms of reaction and other reaction attributes.

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6.2.2.2.		Frequency of home dosing/ Dose compliance			
6.2.2.2.1.			Number of missed doses		
6.2.2.3.		Date of last menstrual cycle			
6.2.2.4.		Restrictions followed at home			
6.2.2.4.1.			Hot shower/ hot bath		
6.2.2.4.2.			Alcohol		
6.2.2.4.3.			Doses around the same time everyday		
6.2.2.4.4.			NSAIDs avoidance		
6.2.2.4.5.			Exercise around time of dosing- before the dose, and 2 hours after the dose		
6.2.2.5.		Accidental exposures to treatment food outside of dosing			
6.2.2.5.1.			Reaction		
6.2.2.5.1.1.				Yes (Point to reaction description)	
6.2.2.5.1.2.				No	
6.2.2.6.		Reactions with home dosing			
6.2.2.6.1.			Yes		
6.2.2.6.1.1.				Time since last dose	
6.2.2.6.1.2.				Point to reaction description	
6.2.2.6.2.			No		
6.2.2.7.		Epinephrine autoinjector use (since last visit)			
6.2.2.7.1.			Yes		
6.2.2.7.2.			No		
6.2.2.8.		Carries autoinjector today			
6.2.2.8.1.			Yes		
6.2.2.8.2.			No		
6.2.2.9.		Antihistamine use with daily dosing/ pre-dosing			
6.2.2.9.1.			Yes (Name of antihistamine)		
6.2.2.9.2.			No		
6.2.2.10.		Probiotic use with daily dosing/ pre-dosing			
6.2.2.10.1.			Yes		
6.2.2.10.2.			No		
6.2.2.11.		Prebiotic use with daily dosing/ pre-dosing			
6.2.2.11.1.			Yes		
6.2.2.11.2.			No		

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6.2.3.	In-office escalation dose				
6.2.3.1.		Assessment of asthma status			
6.2.3.1.1.			Change in asthma status since last visit		
6.2.3.1.2.			Asthma exacerbation since last visit		
6.2.3.1.3.			Albuterol use since last visit		
6.2.3.2.		Any pre medications today			
6.2.3.2.1.			Yes		
6.2.3.2.2.			No		
6.2.3.3.		Considerations for OIT escalation			
6.2.3.3.1.			Full stomach		
6.2.3.3.2.			No running after dosing		
6.2.3.4.		Therapeutic agent			
6.2.3.4.1.			Treatment food (FDA approved {Rx Norm} or Home-based)		
6.2.3.4.2.			Dose at current visit		
6.2.3.4.3.			Delivery form (e.g., Apple sauce)		
6.2.3.5.		Reaction observed			
6.2.3.5.1.			Yes		
6.2.3.5.1.1.				Time since last dose	
6.2.3.5.1.2.				Point to reaction description	
6.2.3.5.2.			No		
6.2.3.6.		Assessment of escalation cycle			
6.2.3.6.1.			Tolerated up-dosing/ Reacted to up-dosing		
6.2.3.6.2.			Home dose		
6.2.3.7.		Plan			
6.2.3.7.1.			Directions for home administration		
6.2.3.7.2.			Stop OIT		
6.3.	Maintenance phase				
6.3.1.	Interval since last appointment				
6.3.2.	Interval history				
6.3.2.1.		Therapeutic agent			
6.3.2.1.1.			Treatment food (FDA approved {Rx Norm} or Home-based)		
6.3.2.1.2.			Delivery form (e.g., Whole wheat crackers)		
6.3.2.2.		Frequency of maintenance dose/ Dose compliance			
6.3.2.2.1.			Number of missed doses		
6.3.2.3.		Date of last menstrual cycle			

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6.3.2.4.		Restrictions followed at home			
6.3.2.4.1.			Hot shower/ hot bath		
6.3.2.4.2.			Alcohol		
6.3.2.4.3.			Doses around the same time everyday		
6.3.2.4.4.			NSAIDs avoidance		
6.3.2.4.5.			Exercise around time of dosing- before the dose, and 2 hours after the dose		
6.3.2.5.		Accidental exposures to treatment food outside of maintenance dose			
6.3.2.5.1.			Reaction		
6.3.2.5.1.1.				Yes (Point to reaction description)	
6.3.2.5.1.2.				No	
6.3.2.6.		Reactions with maintenance dose			
6.3.2.6.1.			Yes		
6.3.2.6.1.1.				Time since last dose	
6.3.2.6.1.2.				Point to reaction description	
6.3.2.6.2.			No		
6.3.2.7.		Epinephrine autoinjector use (since last visit)			
6.3.2.7.1.			Yes		
6.3.2.7.2.			No		
6.3.2.8.		Carries autoinjector today			
6.3.2.8.1.			Yes		
6.3.2.8.2.			No		
6.3.2.9.		Antihistamine use with daily dosing/ pre-dosing			
6.3.2.9.1.			Yes (Name of antihistamine)		
6.3.2.9.2.			No		
6.3.2.10.		Probiotic use with daily dosing/ pre-dosing			
6.3.2.10.1.			Yes		
6.3.2.10.2.			No		
6.3.2.11.		Prebiotic use with daily dosing/ pre-dosing			
6.3.2.11.1.			Yes		
6.3.2.11.2.			No		
6.3.3.	Assessment of maintenance phase				
6.3.3.1.		Tolerated maintenance dose/ Reacted to maintenance dose			

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6.3.3.2.		Home dose			
6.3.4.	Plan				
6.3.4.1.		Directions for home administration			
6.3.4.2.		Stop OIT			
6.4.	Stop OIT				
6.4.1.	Reason for stopping OIT				
6.4.1.1.		Physician recommendation			
6.4.1.1.1.			Dose not tolerated/ Reacted		
6.4.1.1.1.1.				Point to reaction description	
6.4.1.2.		Patient/ parent/ care-giver refusal			
6.4.1.2.1.			Too many reactions		
6.4.1.2.2.			Side effects		
6.4.1.2.3.			Inconvenient		
6.4.1.2.4.			Anxiety		

7. REACTIONS

Description: This concept includes clinical manifestations of a food-allergic reaction and other reaction attributes described below.

7.1 SIGNS AND SYMPTOMS

Description: This concept domain outlines objective and subjective clinical manifestations of food allergy. Signs and symptoms pertaining to the most commonly involved organ systems have been covered, including the skin, GI and respiratory tracts, and cardiovascular and neurologic system. Additionally, this concept will capture severity of reactions classified according to Bock's criteria.

Table 7.1: Signs & Symptoms of Food Allergic Reactions Including Reaction Severity Classified According to Bock's Criteria

7.1.1.	Skin			
7.1.1.1.		Pruritis		
7.1.1.1.1.			Present	
7.1.1.1.2.			Absent	
7.1.1.1.3.			Bock skin complaints scoring	
7.1.1.1.3.1.				0 = Absent
7.1.1.1.3.2.				1 = Mild, occasional scratching
7.1.1.1.3.3.				2 = Moderate -scratching continuously for > 2 minutes at a time

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7.1.1.1.3.4.				3 = Severe hard continuous scratching excoriations	
7.1.1.2.		Flushing			
7.1.1.2.1.			Present		
7.1.1.2.2.			Absent		
7.1.1.3.		Urticaria			
7.1.1.3.1.			Present		
7.1.1.3.1.1.				Less than 3	
7.1.1.3.1.2.				3-10	
7.1.1.3.1.3.				>10 or generalized involvement	
7.1.1.3.2.			Absent		
7.1.1.3.3.			Bock objective skin complaints scoring		
7.1.1.3.3.1.				0 = Absent	
7.1.1.3.3.2.				1 = Mild < 3 hives, or mild lip edema	
7.1.1.3.3.3.				2 = Moderate - < 10 hives but >3, or significant lip or face edema	
7.1.1.3.3.4.				3 = Severe generalized	
7.1.1.4.		Angioedema (Swelling)			
7.1.1.4.1.			Present		
7.1.1.4.1.1.				Location	
7.1.1.4.1.1.1.					Periocular
7.1.1.4.1.1.2.					Tongue
7.1.1.4.1.1.3.					Lip
7.1.1.4.1.1.4.					Face
7.1.1.4.1.1.5.					Throat
7.1.1.4.1.1.6.					Generalized

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7.1.1.4.1.2.				Severity	
7.1.1.4.2.		Absent			
7.1.1.4.3.		Bock objective skin complaints scoring			
7.1.1.4.3.1.			0 = Absent		
7.1.1.4.3.2.			1 = Mild < 3 hives, or mild lip edema		
7.1.1.4.3.3.			2 = Moderate - < 10 hives but >3, or significant lip or face edema		
7.1.1.4.3.4.			3 = Severe generalized involvement		
7.1.1.5.	Rash				
7.1.1.5.1.		Present			
7.1.1.5.2.		Absent			
7.1.1.5.3.		Bock objective skin complaints scoring			
7.1.1.5.3.1.			0 = Absent		
7.1.1.5.3.2.			1 = Mild few areas of faint erythema		
7.1.1.5.3.3.			2 = Moderate areas of erythema		
7.1.1.5.3.4.			3 = Severe generalized marked erythema (>50%)		
7.1.1.6.	Erythema				
7.1.1.6.1.		Present			
7.1.1.6.2.		Absent			
7.1.1.6.3.		Bock objective skin complaints scoring			
7.1.1.6.3.1.			% of body involved_____		
7.1.1.7.	Eczema flare				
7.1.1.7.1.		Present			
7.1.1.7.2.		Absent			
7.1.2.	Gastrointestinal				
7.1.2.1.	Subjective				

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7.1.2.1.1.			Oral pruritis		
7.1.2.1.1.1.				Present	
7.1.2.1.1.2.				Absent	
7.1.2.1.2.			Oral tingling		
7.1.2.1.2.1.				Present	
7.1.2.1.2.2.				Absent	
7.1.2.1.3.			Difficulty swallowing/ Choking		
7.1.2.1.3.1.				Present	
7.1.2.1.3.2.				Absent	
7.1.2.1.4.			Abdominal pain		
7.1.2.1.4.1.				Present	
7.1.2.1.4.1.1.					Mild
7.1.2.1.4.1.2.					Moderate
7.1.2.1.4.1.3.					Severe
7.1.2.1.4.2.				Absent	
7.1.2.1.5.			Nausea		
7.1.2.1.5.1.				Present	
7.1.2.1.5.2.				Absent	
7.1.2.1.6.			Bock subjective GI complaints scoring		
7.1.2.1.6.1.				0 = Absent	
7.1.2.1.6.2.				1 = Mild complaints of nausea or abdominal pain, itchy mouth/throat	
7.1.2.1.6.3.				2 = Moderate frequent c/o nausea or pain with normal activity	
7.1.2.1.6.4.				3 = Severe - notably distressed due to GI symptoms with decreased activity	
7.1.2.2.		Objective			

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7.1.2.2.1.			Emesis		
7.1.2.2.1.1.				Present	
7.1.2.2.1.1.1.					Count
7.1.2.2.1.2.				Absent	
7.1.2.2.2.			Diarrhea		
7.1.2.2.2.1.				Present	
7.1.2.2.2.1.1.					Count
7.1.2.2.2.2.				Absent	
7.1.2.2.3.			Bock objective GI complaints scoring		
7.1.2.2.3.1.				0 = Absent	
7.1.2.2.3.2.				1 = Mild 1 episode of emesis or diarrhea	
7.1.2.2.3.3.				2 = Moderate 2-3 episodes of emesis or diarrhea or 1 of each	
7.1.2.2.3.4.				3 = Severe >3 episodes of emesis or diarrhea or 2 of each	
7.1.3.	Respiratory				
7.1.3.1.		Upper airways			
7.1.3.1.1.			Nasal congestion		
7.1.3.1.1.1.				Present	
7.1.3.1.1.2.				Absent	
7.1.3.1.2.			Nasal pruritis		
7.1.3.1.2.1.				Present	
7.1.3.1.2.2.				Absent	
7.1.3.1.3.			Sneezing		
7.1.3.1.3.1.				Present	
7.1.3.1.3.2.				Absent	

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7.1.3.1.4.		Rhinorrhea		
7.1.3.1.4.1.			Present	
7.1.3.1.4.2.			Absent	
7.1.3.1.5.		Pain in throat		
7.1.3.1.5.1.			Present	
7.1.3.1.5.2.			Absent	
7.1.3.1.6.		Throat pruritis		
7.1.3.1.6.1.			Present	
7.1.3.1.6.2.			Absent	
7.1.3.1.7.		Throat tightness		
7.1.3.1.7.1.			Present	
7.1.3.1.7.2.			Absent	
7.1.3.1.8.		Throat clearing		
7.1.3.1.8.1.			Present	
7.1.3.1.8.2.			Absent	
7.1.3.1.9.		Hoarseness		
7.1.3.1.9.1.			Present	
7.1.3.1.9.2.			Absent	
7.1.3.1.10.		Bock upper respiratory scoring		
7.1.3.1.10.1.			Sneezing/Itching	
7.1.3.1.10.2.			0 = Absent	
7.1.3.1.10.3.			1 = Mild rare bursts, occasional sniffing	
7.1.3.1.10.4.			2 = Moderate bursts < 10, intermittent rubbing of nose, and/or eyes or frequent sniffing	
7.1.3.1.10.5.			3 = Severe continuous rubbing of nose and/or eyes, periocular swelling and/or long bursts of sneezing, persistent rhinorrhea	

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7.1.3.2.		Lower airways			
7.1.3.2.1.			Chest tightness		
7.1.3.2.1.1.				Present	
7.1.3.2.1.2.				Absent	
7.1.3.2.2.			Wheezing		
7.1.3.2.2.1.				Present	
7.1.3.2.2.2.				Absent	
7.1.3.2.2.3.				Bock lower respiratory scoring	
7.1.3.2.2.3.1.					0= Absent
7.1.3.2.2.3.2.					1 = Mild expiratory wheezing to auscultation
7.1.3.2.2.3.3.					2 = Moderate inspiratory and expiratory wheezing
7.1.3.2.2.3.4.					3 = Severe use of accessory muscles, audible wheezing
7.1.3.2.3.			Dyspnea		
7.1.3.2.3.1.				Present	
7.1.3.2.3.2.				Absent	
7.1.3.2.4.			Cough		
7.1.3.2.4.1.				Present (Frequency)	
7.1.3.2.4.1.1.					Intermittent
7.1.3.2.4.1.2.					Continuous
7.1.3.2.4.2.				Absent	
7.1.3.2.5.			Tachypnea		
7.1.3.2.5.1.				Present	
7.1.3.2.5.2.				Absent	
7.1.3.2.6.			Cyanosis		

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7.1.3.2.6.1.				Present	
7.1.3.2.6.2.				Absent	
7.1.3.2.7.			Respiratory arrest		
7.1.3.2.7.1.				Present	
7.1.3.2.7.2.				Absent	
7.1.3.2.8.			Respiratory retractions		
7.1.3.2.8.1.				Present	
7.1.3.2.8.2.				Absent	
7.1.3.2.9.			Bock lower respiratory scoring		
7.1.3.2.9.1.				Laryngeal	
7.1.3.2.9.1.1.					0= Absent
7.1.3.2.9.1.2.					1 = Mild >3 discrete episodes of throat clearing or cough, or persistent throat tightness/pain
7.1.3.2.9.1.3.					2 = Moderate hoarseness, frequent dry cough
7.1.3.2.9.1.4.					3 = Severe stridor
7.1.4.	Cardiovascular				
7.1.4.1.		Tachycardia			
7.1.4.1.1.			Present		
7.1.4.1.2.			Absent		
7.1.4.2.		Dysrhythmia			
7.1.4.2.1.			Present		
7.1.4.2.2.			Absent		
7.1.4.3.		Bradycardia			
7.1.4.3.1.			Present		
7.1.4.3.2.			Absent		

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7.1.4.4.		Hypotension			
7.1.4.4.1.			Present		
7.1.4.4.2.			Absent		
7.1.4.5.		Chest pain			
7.1.4.5.1.			Present		
7.1.4.5.2.			Absent		
7.1.4.6.		Palpitations			
7.1.4.6.1.			Present		
7.1.4.6.2.			Absent		
7.1.4.7.		Cardiac arrest			
7.1.4.7.1.			Present		
7.1.4.7.2.			Absent		
7.1.4.8.		Bock Cardiovascular/ Neurological scoring			
7.1.4.8.1.			0 = normal heart rate or BP for age/baseline		
7.1.4.8.2.			1 = mild-subjective response (weak, dizzy), or tachycardia		
7.1.4.8.3.			2 = moderate-drop in blood pressure and/or >20% from baseline, or significant change in mental status.		
7.1.4.8.4.			3 = severe-cardiovascular collapse, signs of impaired circulation (unconscious)		
7.1.5.	Neurological				
7.1.5.1.		Change in activity level			
7.1.5.1.1.			Present		
7.1.5.1.2.			Absent		
7.1.5.2.		Confusion			

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7.1.5.2.1.			Present		
7.1.5.2.2.			Absent		
7.1.5.3.		Anxiety			
7.1.5.3.1.			Present		
7.1.5.3.2.			Absent		
7.1.5.4.		Fussy and Irritable			
7.1.5.4.1.			Present		
7.1.5.4.2.			Absent		
7.1.5.5.		Weakness			
7.1.5.5.1.			Present		
7.1.5.5.2.			Absent		
7.1.5.6.		Feeling of "impending doom"			
7.1.5.6.1.			Present		
7.1.5.6.2.			Absent		
7.1.5.7.		Loss of consciousness			
7.1.5.7.1.			Present		
7.1.5.7.2.			Absent		
7.1.6. Other symptoms					
7.1.6.1.		Food refusal			
7.1.6.1.1.			Present		
7.1.6.1.2.			Absent		
7.1.6.2.		Genitourinary			
7.1.6.2.1.			Uterine cramps		
7.1.6.2.1.1.				Present	
7.1.6.2.1.2.				Absent	

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7.1.6.3.		Ocular			
7.1.6.3.1.			Itchy/ Rubbing of eyes		
7.1.6.3.1.1.				Present	
7.1.6.3.1.2.				Absent	
7.1.6.3.2.			Watery eyes		
7.1.6.3.2.1.				Present	
7.1.6.3.2.2.				Absent	
7.1.6.3.3.			Redness of eyes		
7.1.6.3.3.1.				Present	
7.1.6.3.3.2.				Absent	

7.2 OTHER REACTION ATTRIBUTES

Description: This consists of characteristics other than signs and symptoms and includes factors such as amount of food that triggered the reaction, temporal relation, treatment, and disposition. In addition, other significant attributes such as, type of exposure, exposure mode, and environmental location of reaction are covered under this concept domain.

Table 7.2: Reaction Attributes Other Than Signs & Symptoms

7.2.1.	Trigger for reaction			
7.2.1.1.		Food (Point to food trigger)		
7.2.1.1.1.			Quantity of food that triggered the reaction	
7.2.1.1.2.			Eliciting dose	
7.2.1.2.		Environmental (Point to environmental trigger)		
7.2.2.	Temporal relation (Time interval between food exposure and reaction onset)			
7.2.3.	Treatment			
7.2.3.1.		Epinephrine		
7.2.3.1.1.			Dose	
7.2.3.1.2.			Route	
7.2.3.1.3.			Response	
7.2.3.2.		Ondansetron		
7.2.3.2.1.			Dose	
7.2.3.2.2.			Route	

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7.2.3.2.3.			Response	
7.2.3.3.	IV fluids			
7.2.3.3.1.		Dose		
7.2.3.3.2.		Route		
7.2.3.3.3.		Response		
7.2.3.4.	Steroids			
7.2.3.4.1.		Dose		
7.2.3.4.2.		Route		
7.2.3.4.3.		Response		
7.2.3.5.	Albuterol			
7.2.3.5.1.		Dose		
7.2.3.5.2.		Route		
7.2.3.5.3.		Response		
7.2.3.6.	Antihistamines			
7.2.3.6.1.		Dose		
7.2.3.6.2.		Route		
7.2.3.6.3.		Response		
7.2.3.7.	Benadryl			
7.2.3.7.1.		Dose		
7.2.3.7.2.		Route		
7.2.3.7.3.		Response		
7.2.3.8.	Prednisolone			
7.2.3.8.1.		Dose		
7.2.3.8.2.		Route		
7.2.3.8.3.		Response		
7.2.4.	Disposition			
7.2.4.1.	Home			
7.2.4.2.	ED			
7.2.4.2.1.		Transportation		
7.2.4.2.1.1.			Ambulance	
7.2.4.2.1.2.			Car	
7.2.4.3.	Urgent care			
7.2.4.4.	Primary care			
7.2.4.5.	Hospitalization			
7.2.4.6.	ICU			
7.2.4.7.	Observation unit			
7.2.5.	Prior avoidance			
7.2.6.	Exposure			
7.2.6.1.	Accidental			
7.2.6.2.	Intentional/ Self challenge			
7.2.6.3.	Assault			
7.2.6.4.	OFC dose			
7.2.6.5.	Related to OIT dose			

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7.2.7.	Exposure mode			
7.2.7.1.		Ingestion		
7.2.7.2.		Contact		
7.2.7.3.		Inhalation		
7.2.8.	Cofactors			
7.2.8.1.		Viral illness/ Fever		
7.2.8.2.		Antibiotic use		
7.2.8.3.		Alcohol		
7.2.8.4.		Exercise		
7.2.8.5.		NSAIDs		
7.2.8.6.		Menstruation		
7.2.9.	Environmental location			
7.2.9.1.		Home		
7.2.9.2.		School		
7.2.9.3.		Restaurants		

8. PROCEDURES

Description: This concept encompasses processes ordered by a healthcare provider that typically have a diagnostic or therapeutic purpose.

8.1 FA DIAGNOSTIC PROCEDURES

Description: This concept domain includes physician orders/ medical procedures performed to diagnose food allergy, or to determine course of treatment and monitor the disease. It includes Skin testing, Blood testing, Challenge testing, and Endoscopy. The attributes for former three have been discussed below.

Table 8.1: Procedures for Food Allergy Diagnosis and Management

8.1.1.	Skin Testing		
8.1.1.1.		Skin Prick Test (SPT)	
8.1.2.	Blood Testing		
8.1.2.1.		Allergen specific IgE	
8.1.2.2.		Allergen specific IgG4	
8.1.2.3.		Allergy component testing	
8.1.2.4.		Total IgE	
8.1.3.	Challenge Testing		
8.1.3.1.		Oral Food Challenge (OFC)	
8.1.3.2.		Contact challenge	
8.1.3.3.		Proximity Challenge/ Inhalation Challenge	

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8.1.4.	Endoscopy		
8.1.4.1.		EREFs (Endoscopic reference score)	
8.1.4.2.		Eos/HPF	
8.1.4.3.		EoEHSS (Histology scoring system)	

8.1.1.1. SKIN PRICK TEST ATTRIBUTES

Description: SPT attributes have been broadly categorized into procedural and result observations. Procedural attributes include devices for skin prick test, extract used for testing (not limited to food extracts), and extract application site. While we strongly encourage practitioners to report outcomes of a SPT reaction by recording the size of the wheal and flare in standard units (mm), results reported by qualitative grading (1+/2+/3+/4+) without any indication of the size of the reaction will also be stored for legacy compatibility.

Table 8.1.1.1.: Attributes for Skin Prick Test

8.1.1.1.1.	Procedural attributes				
8.1.1.1.1.1.		Type of testing device used			
8.1.1.1.1.1.1.			Single allergen test		
8.1.1.1.1.1.1.1.				Single-headed devices	
8.1.1.1.1.1.1.1.1.					Greer Pick (Greer Labs)
8.1.1.1.1.1.1.1.2.					Quintip (HS ⁵)
8.1.1.1.1.1.1.1.3.					Needle
8.1.1.1.1.1.1.2.				Bifurcated needle	
8.1.1.1.1.1.1.2.1.					PMP ⁶
8.1.1.1.1.1.1.2.2.					Duotip Test II (ALK Labs)
8.1.1.1.1.1.1.2.3.					Duotip Test II (LD ⁷)
8.1.1.1.1.1.1.3.				Lancet (HS)	
8.1.1.1.1.1.2.			Multi-allergen test		
8.1.1.1.1.1.2.1.				Multiheaded devices	
8.1.1.1.1.1.2.1.1.					Multi-Test (LD)

⁵ HS- Hollister-Stier

⁶ PMP- Precision Medical Products

⁷ LD- Lincoln Diagnostics

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8.1.1.1.1.2.1.2.					Multi-Test II (ALK Labs)
8.1.1.1.1.2.1.3.					Multi-Test II (LD)
8.1.1.1.1.2.1.4.					Multi-Test PC (ALK Labs)
8.1.1.1.1.2.1.5.					Multi-Test PC (LD)
8.1.1.1.1.2.1.6.					OMNI (QTI Corporation)
8.1.1.1.1.2.1.7.					Quintest (HS)
8.1.1.1.1.2.	Location				
8.1.1.1.1.2.1.		Arm			
8.1.1.1.1.2.2.		Back			
8.1.1.1.1.3.	Prior antihistamine use				
8.1.1.1.1.4.	Control				
8.1.1.1.1.4.1.		Histamine			
8.1.1.1.1.4.2.		Saline			
8.1.1.1.1.5.	Extract				
8.1.1.1.1.5.1.		Food extract (Point to food & Text field)			
8.1.1.1.1.5.1.1.			Commercial/ Pharmacologic (Drug codes)		
8.1.1.1.1.5.1.2.			In-office compounding/ Fresh food		
8.1.1.1.1.5.2.		Environmental extracts			
8.1.1.1.1.5.3.		Latex (fresh)			

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8.1.2. BLOOD TESTS

Description: This concept includes laboratory procedures for diagnosing immune-mediated food-allergy, such as, Allergen specific IgE and Allergen specific IgG4, Allergy component testing, and Total IgE measure (Table 8.2). Allergen specific tests would encompass both food and environmental allergens. Test result attributes consist of name of the test, test value, range, unit of measurement, and point in time.

Table 8.1.2.: Test Result Attributes for Food-Allergy Diagnostic Blood Tests

8.1.2.1.	Test Attributes	
8.1.2.1.1.		Point to allergen {Food /Environmental (e.g., Birch & Ragweed)/ Component (e.g., Ara h-1)}

8.1.3.1. ORAL FOOD CHALLENGE ATTRIBUTES

Description: It comprises procedural attributes including special considerations for administering an OFC, challenge food, dose, and reaction observed. Result attributes deal with the interpretation of an OFC outcome. While we strongly encourage recording the challenge food dose in quantitative weight measures (mg or gm), serving size or dose administered in “pieces” during an OFC will also be stored for legacy compatibility.

Table 8.1.3.1.: Attributes for Oral Food Challenge

8.1.3.1.1.	Procedural attributes		
8.1.3.1.1.1.		Considerations	
8.1.3.1.1.1.1.		Recent use of antihistamines	
8.1.3.1.1.1.2.		Viral illness	
8.1.3.1.1.1.3.		Skin rash/ Change from baseline	
8.1.3.1.1.1.4.		Asthma flare	
8.1.3.1.1.1.5.		Antibiotic use	
8.1.3.1.1.2.		Challenge food	
8.1.3.1.1.2.1.		Delivery form	
8.1.3.1.1.3.		Dose	
8.1.3.1.1.3.1.		Total dose (Wt (mg or gm)/ Serving size/ Pieces)	
8.1.3.1.1.3.2.		Eliciting dose (Wt (mg or gm)/ Serving size/ Pieces)	
8.1.3.1.1.3.3.		Cumulative reactive dose (Wt (mg or gm)/ Serving size/ Pieces)	
8.1.3.1.1.4.		Reaction observed	
8.1.3.1.1.4.1.		Yes (Point to reaction description)	
8.1.3.1.1.4.2.		No	

8.1.3.2. CONTACT CHALLENGE ATTRIBUTES

Description: It comprises procedural attributes including special considerations for administering a contact challenge, challenge food, length of exposure, total dose, and reaction observed. Result attributes deal with the interpretation of a contact challenge outcome.

Table 8.1.3.2.: Attributes for Contact Challenge

8.1.3.2.1.	Procedural attributes		
8.1.3.2.1.1.		Considerations	
8.1.3.2.1.1.1.			Recent use of antihistamines
8.1.3.2.1.1.2.			Viral illness
8.1.3.2.1.1.3.			Skin rash/ Change from baseline
8.1.3.2.1.1.4.			Asthma flare
8.1.3.2.1.1.5.			Antibiotic use
8.1.3.2.1.2.	Challenge food		
8.1.3.2.1.3.	Length of exposure		
8.1.3.2.1.4.	Total dose		
8.1.3.2.1.5.	Reaction observed		
8.1.3.2.1.5.1.			Yes (Point to reaction description)
8.1.3.2.1.5.2.			No

8.1.3.3. PROXIMITY/ INHALATION CHALLENGE ATTRIBUTES

Description: It comprises procedural attributes including special considerations for administering a proximity/ inhalation challenge, challenge food, length of exposure, total dose, and reaction observed. Result attributes deal with the interpretation of an inhalation challenge outcome.

Table 8.1.3.3.: Attributes for Proximity/ Inhalation Challenge

8.1.3.3.1.	Procedural attributes		
8.1.3.3.1.1.		Considerations	
8.1.3.3.1.1.1.			Recent use of antihistamines
8.1.3.3.1.1.2.			Viral illness
8.1.3.3.1.1.3.			Skin rash/ Change from baseline
8.1.3.3.1.1.4.			Asthma flare
8.1.3.3.1.1.5.			Antibiotic use

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8.1.3.3.1.2.		Challenge food	
8.1.3.3.1.3.		Length of exposure	
8.1.3.3.1.4.		Total dose	
8.1.3.3.1.5.		Reaction observed	
8.1.3.3.1.5.1.			Yes (Point to reaction description)
8.1.3.3.1.5.2.			No

8.2. OTHER PROCEDURES

Description: This includes other relevant codable procedures ordered for a patient with food allergy or to assess any comorbid conditions.

Table 8.2: Other Relevant Procedures for a Food-Allergy Encounter

8.2.1.	Endoscopic biopsy	
8.2.2.	Spirometry	
8.2.3.	Blood Tests	
8.2.3.1.		Complete Blood Count
8.2.3.2.		Absolute Eosinophil Count
8.2.3.3.		Vit D
8.2.3.4.		Complete Metabolic Panel
8.2.3.5.		Ca

9. THERAPEUTIC PLAN

Description: This concept domain focuses on education for patient and family on allergen avoidance, dietary recommendations, anaphylaxis emergency action plan implementation, epinephrine self-administration training, and recommendations for follow-up, or referral to other specialists.

Table 9: Food Allergy Therapeutic Plan

9.1.	Food Allergy Recommendations				
9.1.1.		Dietary recommendations			
9.1.1.1.			Strict avoidance		
9.1.1.2.			Foods to be introduced at home		
9.1.2.		Emergency action plan/ Anaphylaxis management plan reviewed and given to family			
9.1.2.1.			Yes		
9.1.2.2.			No		

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9.1.3.		FA counselling given			
9.1.3.1.			Yes		
9.1.3.1.1.				Food avoidance	
9.1.3.1.2.				Epinephrine	
9.1.3.1.2.1.					Carry epinephrine autoinjector at all times
9.1.3.1.2.2.					Indications of use
9.1.3.1.2.3.					Correct administration technique
9.1.3.1.3.				Food Allergy Prognosis	
9.1.3.2.			No		
9.1.4.	Follow-up				
9.1.4.1.			OFC visit		
9.1.4.2.			OIT visit		
9.1.4.3.			Referrals		
9.1.4.3.1.				Dermatologist visit	
9.1.4.3.2.				Nutritional visit	
9.1.4.3.2.1.					Nutritionist visit
9.1.4.3.2.2.					Dietician visit
9.1.4.3.3.				ENT visit	
9.1.4.3.4.				Pulmonologist visit	
9.1.4.3.5.				Gastroenterologist visit	
9.1.4.3.6.				Behavioral therapy visit	
9.1.4.3.6.1.					Psychologist visit
9.1.4.3.6.2.					Psychiatrist visit
9.1.4.3.6.3.					Social worker visit
9.1.4.3.6.4.					Nurse behavioral therapist visit

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10. FAMILY HISTORY

Description: This concept includes record of health information about a person's close relatives, including parents, brothers and sisters.

Table 10: Family History

10.1.	Family history of food allergy			
10.1.1.		Yes		
10.1.2.		No		
10.2.	Family History Diagnoses⁸			
10.2.1.		Diagnosis Code		
10.2.2.		OMOP Relation Modifier		

11. HISTORY

Description: This history concept captures person's breastfeeding history and personal history.

Table 11: History

11.1.	Timing of allergenic food introduction			
11.2.	Breastfeeding history			
11.2.1.		Yes		
11.2.1.1.			Duration of breastfeeding	
11.2.1.2.			Exclusive or not	
11.2.1.2.1.				Yes
11.2.1.2.2.				No
11.2.1.2.3.				Duration
11.2.1.3.			Allergenic food consumed by mother during breastfeeding	
11.2.1.3.1.				Yes (Point to triggers table)
11.2.1.3.2.				No
11.2.2.		No		
11.3.	Personal history of other diseases			
11.3.1.		Point to formal diagnoses		

⁸ These will be stored using the OMOP family-history-of modifier. Stored as tuples.

12. OTHER OBSERVATIONS AND MEASUREMENTS

Description: Measurements include structured values of a standardized examination or testing performed on a person. Observations are outcomes that are routinely collected as part of clinical care but are not specifically tied to a reaction event. Other observations capture economic, environmental, and psycho-social determinants that influence diverse dimensions of food allergy including disease development, treatment, management and quality of life (QOL).

Table 12: Other Observations & Measurements

12.1.	Vitals			
12.1.1.		Pulse		
12.1.2.		Respiratory rate		
12.1.3.		Temp		
12.1.4.		Blood pressure		
12.2.	O₂ Saturation Levels			
12.3.	Anthropometric measures			
12.3.1.		Height		
12.3.2.		Weight		
12.4.	SPT result attributes			
12.4.1.		Size of result		
12.4.1.1.			Wheal & Flare	
12.4.1.1.1.				Unit- mm
12.4.1.1.2.				Gradation (1+/ 2+/ 3+/4+)
12.4.2.		Time placed/ time of application		
12.4.3.		Time read		
12.5.	Blood test result attributes			
12.5.1.		Test value		
12.5.2.		Range		
12.5.3.		Unit of measurement		
12.5.4.		Point in time		
12.6.	Spirometry values			
12.6.1.		FEV ₁		
12.6.2.		FEV ₁ / FVC		
12.6.3.		PEF		
12.7.	OFC result attributes			
12.7.1.		Assessment		
12.7.1.1.			Tolerated	
12.7.1.2.			Did not tolerate	
12.7.1.3.			Indeterminate	
12.7.1.4.			Did not complete	
12.8.	Contact challenge result attributes			
12.8.1.		Assessment		
12.8.1.1.			Reacted	

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12.8.1.2.			Did not react		
12.8.1.3.			Indeterminate		
12.8.1.4.			Did not complete		
12.9.	Proximity/ Inhalation challenge result attributes				
12.9.1.		Assessment			
12.9.1.1.			Reacted		
12.9.1.2.			Did not react		
12.9.1.3.			Indeterminate		
12.9.1.4.			Did not complete		
12.10.	Economic determinants				
12.10.1.		Food insecurity			
12.10.2.		Insurance status/ Health coverage			
12.10.2.1.			HMO		
12.10.2.2.			Medicaid		
12.10.2.3.			No Insurance		
12.10.2.4.			PPO		
12.10.2.5.			Private		
12.10.2.6.			Tricare		
12.11.	Dietary preferences				
12.11.1.		Individual			
12.11.1.1.			Gluten-free		
12.11.1.2.			Halal		
12.11.1.3.			Keto		
12.11.1.4.			Kosher		
12.11.1.5.			Vegan		
12.11.1.6.			Vegetarian		
12.11.2.		Household			
12.11.2.1.			Gluten-free		
12.11.2.2.			Halal		
12.11.2.3.			Keto		
12.11.2.4.			Kosher		
12.11.2.5.			Vegan		
12.11.2.6.			Vegetarian		
12.12.	Environmental factors				
12.12.1.		Density			
12.12.1.1.			Rural-Urban Communities Categorization		
12.12.1.1.1.				Rural	
12.12.1.1.2.				Suburban	
12.12.1.1.3.				Urban	
12.12.1.2.			RUCA (Rural Urban Commuting Area) Codes		

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12.12.2.	Pets			
12.12.2.1.		Bird		
12.12.2.2.		Cat		
12.12.2.3.		Dog		
12.12.2.4.		Gerbil		
12.12.2.5.		Guinea Pig		
12.12.2.6.		Hamster		
12.12.2.7.		Fish		
12.12.2.8.		Rabbit		
12.12.2.9.		Rat		
12.12.2.10.		Turtle		
12.12.3.	School issues	Policies		
12.12.3.1.			Cafeteria	
12.12.3.1.1.			Class room	
12.12.3.1.2.			Special events	
12.12.3.1.3.				In-class parties
12.12.3.1.3.1.				
12.12.3.1.3.2.				After-school events
12.12.3.1.3.3.				School clubs
12.12.3.1.4.			School bus	
12.12.3.2.		Missed school days over past 12 months due to food allergy (Count)		
12.12.3.2.1.			Food allergic reaction	
12.12.3.2.2.			Anxiety	
12.12.3.2.3.			Treatment visit	
12.12.3.2.3.1.				OIT
12.12.3.2.3.2.				Biologics
12.12.3.2.4.			Diagnostic visit	
12.12.3.3.		Emergency plan in school		
12.12.3.4.		504 Plan		
12.12.3.4.1.			Yes	
12.12.3.4.2.			No	
12.12.4.	Food allergy-related bullying			
12.12.5.	Psycho-social issues			
12.12.5.1.		Anxiety about living with food-allergy		
12.12.5.1.1.			Yes	
12.12.5.1.2.			No	

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12.12.5.2.			Anxiety about oral food challenges		
12.12.5.2.1.				Yes	
12.12.5.2.2.				No	
12.12.5.3.			Anxiety after an allergic reaction		
12.12.5.3.1.				Yes	
12.12.5.3.2.				No	
12.12.5.4.			Anxiety after administering epinephrine		
12.12.5.4.1.				Yes	
12.12.5.4.2.				No	
12.12.5.5.			Needle phobia or other medical procedure anxiety		
12.12.5.5.1.				Yes	
12.12.5.5.2.				No	
12.12.5.6.			Panic attacks		
12.12.5.6.1.				Yes	
12.12.5.6.2.				No	
12.12.5.7.			Activity restriction		
12.12.5.7.1.				Yes	
12.12.5.7.2.				No	
12.12.5.8.			Parents/ Caregivers Anxiety		
12.12.5.8.1.			Anxiety about child living with food-allergy		
12.12.5.8.1.1.					Yes
12.12.5.8.1.2.					No
12.12.5.8.2.			Anxiety about child's oral food challenges		
12.12.5.8.2.1.					Yes
12.12.5.8.2.2.					No
12.12.5.8.3.			Anxiety after an allergic reaction		
12.12.5.8.3.1.					Yes
12.12.5.8.3.2.					No
12.12.5.8.4.			Anxiety after administering epinephrine		
12.12.5.8.4.1.					Yes
12.12.5.8.4.2.					No
12.12.5.8.5.			Anxiety about child's medical procedure		
12.12.5.8.5.1.					Yes
12.12.5.8.5.2.					No

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12.12.5.8.6.				Anxiety about restricting the child's activity	
12.12.5.8.6.1.					Yes
12.12.5.8.6.2.					No
12.12.5.8.7.				Fear for the safety of their child	
12.12.5.8.7.1.					Yes
12.12.5.8.7.2.					No
12.12.5.8.8.				Fear of restricting the child's diet	
12.12.5.8.8.1.					Yes
12.12.5.8.8.2.					No
12.12.5.8.9.				Fear of trusting others with care of child	
12.12.5.8.9.1.					Yes
12.12.5.8.9.2.					No
12.12.5.8.10.				Stress of managing health of child	
12.12.5.8.10.1.					Yes
12.12.5.8.10.2.					No
12.12.6.	Epi related issues				
12.12.6.1.			Has epinephrine		
12.12.6.2.			Carries epinephrine injector		
12.12.6.3.			Used epinephrine since last visit		
12.12.6.4.			Epinephrine prescription up to date		

13. PERSON

Description: The Person concept contains records that uniquely identify each patient in the source data.

Table 13: Person Table

13.1.	Commons ID			
13.2.	Gender			
13.3.	Year of birth			
13.4.	Race			
13.4.1.		White		
13.4.2.		Black/African American		
13.4.3.		Asian		
13.4.4.		Native American/Alaskan Native		
13.4.5.		Pacific Islander		
13.4.6.		Mixed race		
13.5.	Ethnicity			

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13.5.1.		Hispanic or Latino		
13.5.2.		Not Hispanic or Latino		
13.6.	Location			
13.6.1.		City		
13.6.2.		ZIP		
13.6.3.		Country		
13.6.4.		Geocode		
13.7.	External identifiers ⁹			
13.7.1.		Provider		
13.7.1.1.			MRN ¹⁰	
13.7.2.		Biobank ID		
13.7.3.		Registry ID		

14. PROVIDER

Description: The provider table contains a list of uniquely identified healthcare providers, including physicians, nurses, behavioral therapists etc.

Table 14: Provider Table

14.1.	Provider ID			
14.2.	NPI			
14.3.	Specialty			
14.4.	Care site			
14.4.1.		ID		
14.4.2.		Place of service		
14.4.3.		Location		

⁹ These will not be stored in OMOP.

¹⁰ Stored as tuples.

Role of OMOP Common Data Model (CDM)

The data repository will use an OMOP data model. The OMOP CDM allows for the systematic analysis of disparate observational databases. The concept behind this approach is to transform data contained within those databases into a common format (data model) as well as a common representation (terminologies, vocabularies, coding schemes). Even though all codes are mapped to the Standardized Vocabularies, the model also stores the original source code to ensure no information is lost.

Over the past few years, the reliance on the OMOP CDM has increased for sharing and pooling of data from disparate data source to the point where it is fast becoming the de facto method for the storing of medical data. The CDM can accommodate both administrative claims and Electronic Medical Records (EMR) data, allowing users to generate evidence from a wide variety of sources. It would also support collaborative research across data sources both within and outside the United States, in addition to being manageable for data owners and useful for data users.

Although, the data commons will be designed to include any OMOP compliant information, the current data dictionary version typically represents a subset of OMOP vocabulary pertinent to FA that we strongly encourage sites to document and report. All other concepts or data elements not on the list can also be stored. Additionally, not all concepts in the data dictionary can be currently mapped to the corresponding OMOP vocabulary. Non-existing or un-mappable concepts, such as, Oral Immunotherapy (OIT) will be addressed subsequently as we work with the OHDSI leadership to address the missing codes.

While OMOP mappings are not within the scope of this document and are available on request, we have included OMOP tables (*Figure III*) that most closely align with the data dictionary concept category. OMOP tables store the core information about clinical events occurring during valid Observation Periods for each Person, as well as demographic information for the Person. Information obtained during a Visit_Occurrence is stored in the most appropriate table depending on the source and context of information.

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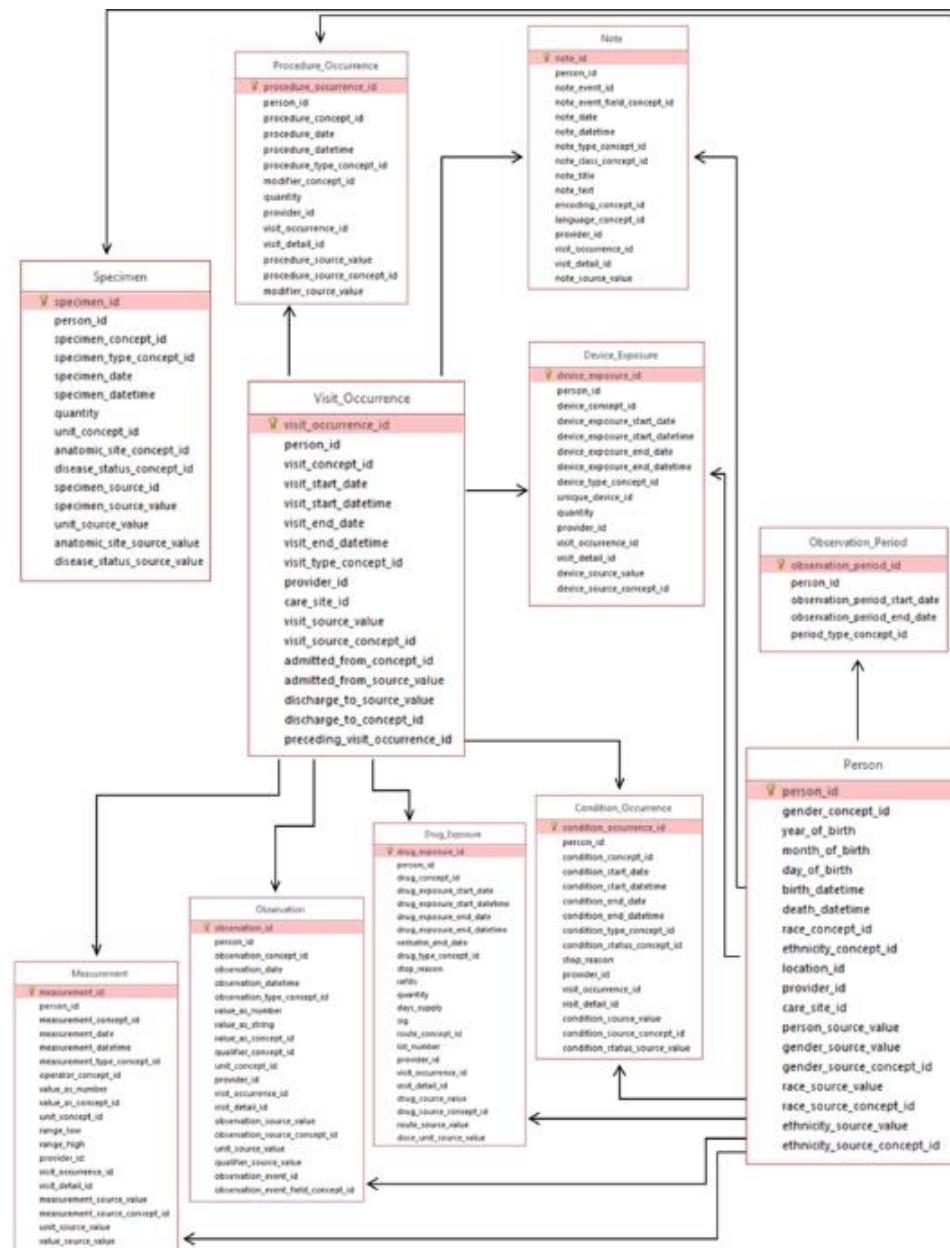


Figure III: OMOP Tables for Medical Data Storage