



HL7 EHR Work Group (EHR-WG)

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### EHR Work Group Goal & Objectives

- <u>Electronic Health Record (EHR) Work Group's</u> goal is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability.
  - Functional and Information Requirements for Electronic Health Records (EHR) and systems (EHRS),
  - Functional and Information Requirements for Personal Health Records (PHR) and systems (PHRS),
- EHR Interoperability WG's objectives are
  - 1. to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 in the Sparx Systems Enterprise Architect (EA) tool; where, it addresses the issues identified by the VA negative r2.0 ballot.
  - 2. to produce a Meaningful Use profile for r2.0.
- Resource Management Evidentiary Support (RM-ES) project's objective is to provide expertise on records management, compliance, and data/record integrity and governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.
- EHR Usability WG's objective is developing a usability profile for the EHR-S FM
- PHR-S WG's objective is to maintain a Patient Healthcare System Functional Model (PHR-S FM).

### **EHR WG Logistics**



Schedule: <a href="http://www.hl7.org/concalls/default.aspx">http://www.hl7.org/concalls/default.aspx</a>

List Server: <a href="http://www.hl7.org/myhl7/managelistservs.cfm">http://www.hl7.org/myhl7/managelistservs.cfm</a>

Health Level Seven - Electronic Health Record Work Group

Weekly Teleconference Schedule

Revised: 20 November 2013

| Day  | Time<br>US ET | Activity                                   | Lead(s)                        | Dial-In                             | Screen<br>Sharing | List Server<br>(for agendas,<br>announcements) |  |
|------|---------------|--------------------------------------------|--------------------------------|-------------------------------------|-------------------|------------------------------------------------|--|
| Mon  | 1200          | Records Management/<br>Evidentiary Support | Warner, Gelzer                 | 1-877-668-4493<br>Code 927 002 088# | <u>Link</u>       | EHR Legal                                      |  |
| Tues | 1300          | EHRS FM Release 3<br>Planning              | Hufnagel,<br>Dickinson         | 1-770-657-9270,<br>Passcode 510269# | <u>Link</u>       | EHR Interop                                    |  |
|      | 1400          | Meaningful Use Functional Profile          | Datta, Dickinson               | 1-770-657-9270,<br>Passcode 510269# | <u>Link</u>       | EHR Interop                                    |  |
|      | 1500          | FULL EHR WG                                | Co-Chairs                      | 1-770-657-9270,<br>Passcode 510269# | <u>Link</u>       | EHR WG                                         |  |
| Wed  | 1200          | Personal Health Record WG                  | Ritter, Dickinson,<br>Doo      | 1-770-657-9270,<br>Passcode 510269# | ТВА               | EHR PHR                                        |  |
|      | 1300          | EHR System Usability WG                    | Mon, Ritter, Rocca,<br>Gartner | 1-770-657-9270,<br>Passcode 510269# | <u>Link</u>       | EHR Usability                                  |  |
| Thur | Open          | Open                                       |                                |                                     |                   |                                                |  |
| Fri  | 0930          | EHR WG Co-Chairs                           | Co-Chairs                      | 1-770-657-9270,<br>Passcode 510269# | ТВА               | N/A                                            |  |

### **Contents** FY2014Q1-Prototype Report EHR-S FIM Release-3:2016 Preparation

- Introduction, Executive-Summary, Plan-of-Actions & Milestones
- EHR-S Concept-of-Operations Reference Use-Case and Model
- CP.6.2 Immunization-Management Deep-Dive
- RI.1.1.1 Originate-and-Retain Record-Entry Deep-Dive
- 5. EHR-S FIM linked-to FHIR for Allergy, Intolerance and Adverse-Reaction
- 6. EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
- Traceability

The complete-and-current HL7 <u>EHR-System Function-and-Information Model Release-3</u> Development-Summary Presentation, dated December-2013 is available at http://wiki.hl7.org/index.php?title=EHR\_Interoperability\_WG

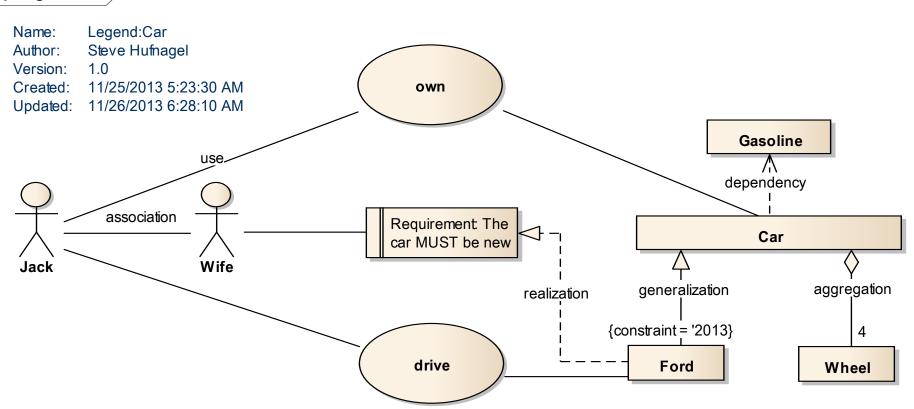
## **EHR-S FIM Acronyms**

| • | aka     | also known as                                  |  |  |  |  |
|---|---------|------------------------------------------------|--|--|--|--|
| • | CC      | EHR-S FIM Conformance Criteria                 |  |  |  |  |
| • | CDA     | Clinical Document Architecture                 |  |  |  |  |
| • | DD      | Data Dictionary                                |  |  |  |  |
| • | CIM     | Conceptual Information Model                   |  |  |  |  |
| • | CP      | Care Provision                                 |  |  |  |  |
| • | CPS     | Care Provisioning Support                      |  |  |  |  |
| • | EA      | Enterprise Architect                           |  |  |  |  |
| • | EHR-S   | EHR System                                     |  |  |  |  |
| • | EHR-S F | EHR-S FIM EHR-S Function and Information Model |  |  |  |  |
| • | FHA     | US Federal Health Architecture                 |  |  |  |  |
| • | FHIM    | US Federal Health Information Model            |  |  |  |  |
| • | FHIR    | Fast Healthcare Interoperability Resources     |  |  |  |  |
| • | FIM     | EHR-S Function and Information Model           |  |  |  |  |
| • | FIM(MU) | EHR-S FIM Meaningful Use profile               |  |  |  |  |
| • | FM      | Function Model                                 |  |  |  |  |
| • | FY      | Fiscal Year                                    |  |  |  |  |
| • | IHE     | Integrating the Healthcare Enterprise          |  |  |  |  |
| • | IM      | Information Model                              |  |  |  |  |
| • | MDHT    | Model Driven Health Tools                      |  |  |  |  |
| • | MU      | US Meaningful Use objectives-and-criteria      |  |  |  |  |
| • | ONC     | US Office of the National-Coordinator          |  |  |  |  |
| • | OHT     | Open Health Tools                              |  |  |  |  |
| • | POA&M   | Plan of Actions and Milestones                 |  |  |  |  |
| • | R 2/3   | Release 2 or 3                                 |  |  |  |  |
| • | RI      | Resource Infrastructure                        |  |  |  |  |
| • | RIM     | HL7 Reference Information Model                |  |  |  |  |
| • | S&I     | ONC Standards & Interoperability Framework     |  |  |  |  |
| • | WBS     | Work Breakdown Structure                       |  |  |  |  |
| • | WG      | Work Group                                     |  |  |  |  |

## **Legend UML Notation**







**USE CASE**: "Jack owns a car." "Jack drives a '2013 Ford Car."

**RELATIONSHIPS:** The Car has 4 wheels and depends-on gasoline.

**REQUIREMENT**: The car MUST be new.

The '2013 Ford Car is a realization of Jack's wife's requirement for Jack to drive a new car.

### Executive Summary EHR-S FIM r3:2016 Preparation

This executive-summary specifically addresses potential work-group impacts and/or trends, which are important for VA, IPO and DOD awareness.

### **EHR System Function-and-Information Model (EHR-S FIM)**

- Structured, based-on a fully-specified Reference Model (RM) for
  - Clear, complete, concise, correct, consistent and intuitive ease-of-use;
  - Sparx Enterprise Architect (EA) UML-model tool-based; where, release 3 (r3)
    - manages user-activities, system-functions. business-rules, interoperable-data separately; and,
    - Consistent-global r3 Conformance Criteria (CCs) replace ad-hoc-local r2 CCs
    - r3 Infrastructure-section contains previously-separate r2 Record-and-Trust Infrastructure-sections

### • EA Tool-generated Interoperability-Specifications based-on Use-Cases

- Use-Cases come-from HITSP & S&I Framework Use-Case Simplification work linked-to
- Requirements, which come-from EHR-S r2.0 Functions' and their restructured CCs linked-to
- International Interoperability-Specifications based-on HL7 FHIR (Fast Healthcare Interoperability Resources)
- <u>US-Realm Interoperability-Specifications</u> based-on FHAFHIM (Federal Health Information Model)
- Behavioral Specifications can be included, based-on IHE or other Protocols.

# Executive Summary Conclusions and Recommendations EHR-S FIM r3:2016 Preparation



- 1. EHR-S FIM vision is to become the "Easy Button" for EHR Interoperability Specifications
  - a. Easily-customizable to user-specific profiles.
  - b. Including a US-Realm Meaningful Use (MU) & FHIM profile
  - c. EHR-S FIM r3:2016 within Sparx EA represents a powerful HL7 product; where,
    - i. EA integrates FHIR, FHIM and S&I Framework's Use-Case Simplification, and
    - ii. The EA tool-based EHR-S FIM is consistently governed and configuration-managed
    - iii. The EA tool can generate both a navigable-web-site and printable-report
    - iv. user-specific profiles (e.g., WG project DAMs, DIMs, DCMs).can be supported.
- 2. EHR-S FIM Release-3 needs the same IP license as FHIR to foster user engagement
- 3. HL7.org/EHRSFIM web-site should be setup-and-managed by the EHR Interoperability WG
  - a. Supporting peer review, trial-use and stakeholder-contribution during Release-3 development.
- 4. EHR-S FIM development, tooling and balloting resources = (estimated) 6-FTE Man-years
  - a. 4 development FTEs + 1 Tooling FTE + 1 Balloting FTE
  - b. A marketing campaign is needed to justify EHR-S FIM r3:2016 resources

### Plan-of-Actions and Milestones FY2014Q1 POA&M



EHR-S FIM Release-3:2016 Preparation

| Oc                                                      | tober 2013 (Identify processes, tools and issues/risks)                    | Completed   |  |  |  |
|---------------------------------------------------------|----------------------------------------------------------------------------|-------------|--|--|--|
| •                                                       | Prototype CP.6.2 Immunization Management                                   | 22-Oct-13   |  |  |  |
| •                                                       | Prototype RI.1.1.1 Originate-and-Retain Record-Entry                       | 29-Oct-13   |  |  |  |
| November 2013 (Prototype complete process-and-products) |                                                                            |             |  |  |  |
| •                                                       | Prototype FHIR integration (Allergies, Intolerance & Adverse Reaction)     | 5-Nov-13    |  |  |  |
| •                                                       | Prototype FHIM integration (Allergies, Intolerance & Adverse Reaction)     | 8-Nov-13    |  |  |  |
| •                                                       | Define & Prototype EHR-S Reference Use-Case, Model and Approach            | 30-Nov-13   |  |  |  |
| •                                                       | Prototype Report generation of Immunization Interoperability-Specification | in-progress |  |  |  |
| December 2013 (Develop production WBS and POA&M)        |                                                                            |             |  |  |  |
| •                                                       | Harmonize with ISO/EN 13940 Continuity-of-Care System-of-Concepts          | pending     |  |  |  |
| •                                                       | Harmonize with Electronic Health Record Communication (ISO/EN 13606)       | pending     |  |  |  |
| •                                                       | Prototype EHR-S FIM Ballot Production process-and-products for prototype   | pending     |  |  |  |
| •                                                       | Create Release 3 Work-Break-Down Structure (WBS) & POA&M                   |             |  |  |  |
| January 2014 – 2016 (Approve & Execute Plan)            |                                                                            |             |  |  |  |

Jan 2013: Present Prototype, WBS & POA&M at HL7 WG meeting; then, execute POA&M.

- Establish public website to get broad peer-review
- Setup EA tool with finalized Release 2, after ISO ballot reconciliation

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## Reference Model (RM) Definition EHR-S FIM Release-3:2016 Preparation



The EHR-S reference model (RM) framework [based-on OASIS RM definition]

### 1. Structures significant-relationships among EHR-S entities

- defined-by EHR-S Action-and-Information Conceptual-Models; where,
- EHR-S RM is based-on a functional-use-case constrained <u>hierarchical-lexicon</u> of
  - <u>nouns</u> (Data-Entities) and <u>noun qualifiers</u> (Data-hierarchy or Sub-Types),
  - verbs (Actions) and verb qualifiers (Action-hierarchy or Sub-Types ) with
  - <u>conditions</u> {Business Rules based on laws, policies, preferences}; where,
- Conformance Criteria (CC) are <u>scenario-threads</u> through the reference use-case & model.

### 2. Defines Conformance-Criteria syntax-and-semantics; where,

- Functions and their profiles constrain the Verb sub-types, Noun sub-types and Conditions
- Functions can-be linked-to Information Exchanges (IEs),
- IEs can-be linked-to implementation standards-technologies-paradigms-and-patterns.
- According to the Organization for the Advancement of Structured Information Standards (OASIS) a reference model is "an abstract framework for understanding significant relationships among the entities of some environment, and for the development of consistent standards or specifications supporting that environment. A reference model is based on a small number of unifying concepts and may be used as a basis for education and explaining standards to a non-specialist. A reference model is not directly tied to any standards, technologies or other concrete implementation details, but it does seek to provide a common semantics that can be used unambiguously across and between different implementations."

# EHR-S RM Concept-of-Operations Reference Use-Case



A <u>Clinician</u> and <u>Patient</u> and/or their designated <u>Agents</u> have <u>Encounters</u>; where, they <u>use an EHR-S</u> (EHR System) <u>GUI</u> (Graphical-User-Interface) to <u>manage EMRs</u> (Electronic Medical Records), in accordance with scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences; where, they can

- review the Patient EMR (Electronic Medical Record) and associated Information
- observe and treat the Patient, write Orders and document the Encounter
- provide patient Information and educational-Information
- enter EMR Records and associated Information; where,
  - Record Entries are Orders, Treatments, Observations and associated Information
  - <u>Lists</u> are <u>Care-Plans</u>, <u>Care-Records</u>, <u>Problems-and-Concerns</u>, <u>Documents & Notes</u>
- sign Encounter by the Clinician(s) and possibly by the Patient

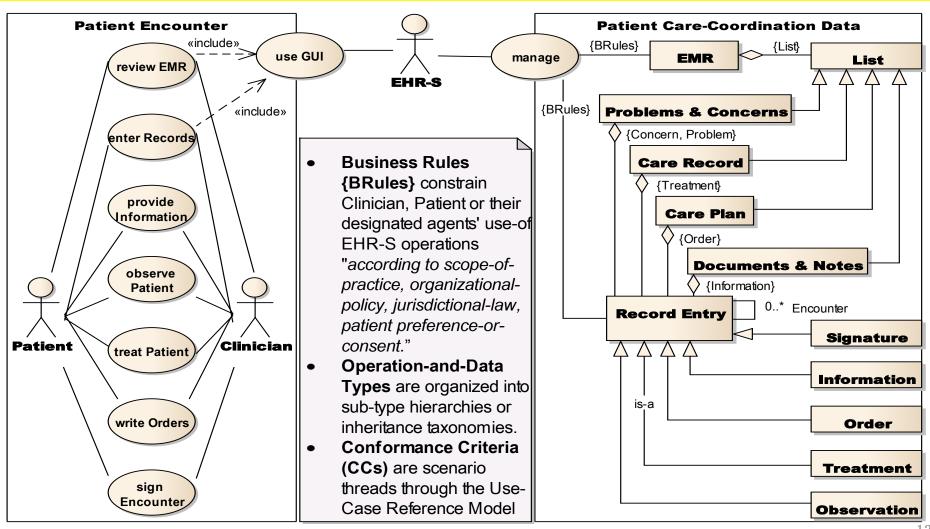
## EHR-S RM Concept-of-Operations Reference-Model (RM)



**Humans-Actions** 

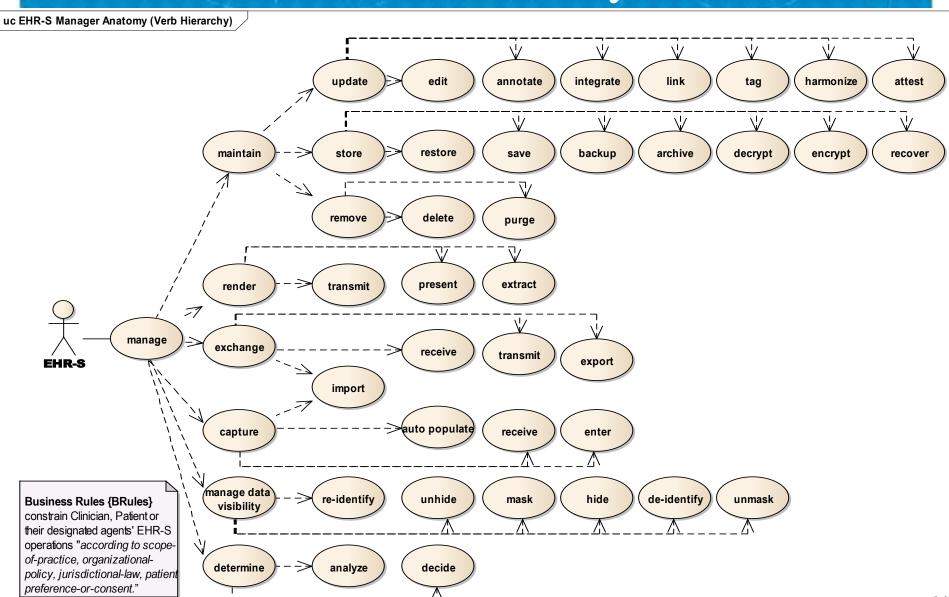
**System-Actions** 

**Conceptual-Information-Model** 



# EHR-S RM System-Actions Sub-Types aka Verb-Hierarchy

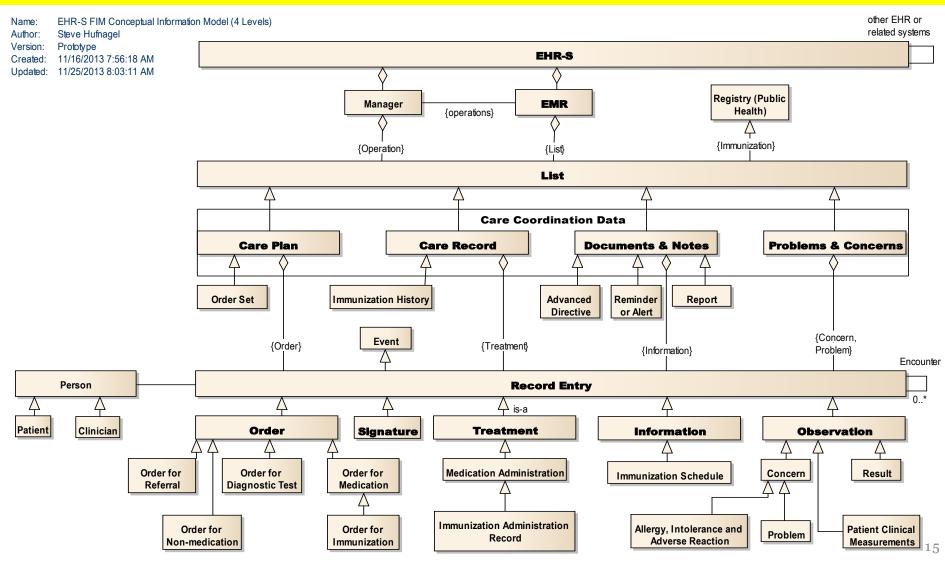




# **EHR-S RM Data-Entities Sub-Types** aka Conceptual Information-Model



**ISSUE**: Gora suggests only using aggregation to make the diagram more intuitive



## ■ EHR-S System Function (SF) Conformance-Criteria (CC) Syntax



- System
  - EHR or PHR
- **SF Invariant-condition** (context)
  - System Function (SF)
  - Profile
- **SF CC Identification** (Number)
- SF CC Pre-condition (trigger)
  - Pre-condition is a subordinate clause.
  - After a Human-Action or System-Action; then,
- SF CC Applicability
  - The System SHALL, SHOULD or MAY
- SF CC Type
  - "provide-the-ability-to"
  - "directly"

### SF CC Bindings

- Operation linked-to Data-Type; where, conditionally,
- SF the System-Actions conforms-to other-SF
- Data-Type are associated-with other Data-Types
- Information Exchange(s) are *linked-to* 
  - International Interoperability-Standards (e.g., FHIR)
  - Realm Interoperability-Specifications (e.g., FHIM)
  - Implementation Guides (e.g., Consolidated CDA)
  - Behavioral Interoperability-Specifications (e.g., IHE)
  - Service Level Agreement (e.g., local workflow)
- **SF Post-Condition** (expected-outcome)
  - Post-condition is a subordinate clause.
  - "where, the System-Actions are …"

#### See Also

Supporting or related SFs (e.g., Infrastructure)



## EHR-S Conformance Criteria Example CP.6.2 Immunization Management

CP.6.2#01 During an <u>Encounter</u>, the EHR system SHALL provide the ability to capture <u>Immunization Administration</u> details as discrete data-requirements, realized-by <u>FHIR</u> (Fast Healthcare Interoperability Resource) data-specifications; where, the <u>Immunization-Administration</u> <u>Record-Entry</u> is associated with the following resources:

- AdverseReaction and other Observations,
- Patient , Practitioner, Organization, Location;

In the US Realm, <u>Immunization-Administration</u> and associated resources are realized-by FHIR-profiles based-on FHIM (Federal Health Information Model) Domains of:

- Immunization, Adverse Reaction, Allergy and Intolerance, Care-Plan,
- Encounter, Health Concern, Person, Provider, Public Health Reporting, Patient Education, Vital Signs.



# EHR-S RM Interim Conclusions EHR-S FIM r3.0:2016 Preparation

- We have looked at Medication-and-Immunization Management, Orders-and-Results Management and Record Entry Management; where,
  - The <u>EHR-S RM (reference model)</u> was used to structure EHR-S functions-and-data; where, the function's conformance-criteria lexicon defines the grammar of nouns (entities), qualifiers (data-types), verbs (operations), qualifiers (verb-types) and constraints (conditions/business rules).
- The EHR-S <u>Conceptual Information Model (CIM)</u> and <u>Conceptual Operations Model (COM)</u> for CP.6.2 Immunization Management should generally-be-applicable for all of the Care Provisioning (CP) section of the EHR-S FM; where,
  - minor CIM modifications will likely occur as we analyze the rest of the CP & CPS sections
  - major COM components still must be substantially developed based-on the rest of the CP and CPS sections.



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The complete-and-current <u>HL7 EHR-System Function-and-Information Model Release-3</u> Development-Summary Presentation, dated December-2013 is available at http://wiki.hl7.org/index.php?title=EHR\_Interoperability\_WG 19



## Initial EHR-S FM R2 CP.6.2 Reference Use-Case

"According to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent,"

- A Clinician uses the EHR-S, during an Encounter, to
  - review EMR, Alerts-and-Notifications
  - enter Observations, Treatments, Orders and associated Documents and Notes
  - sign the Encounter
- Immunization Management involves the following:
  - **System-Actions:** auto-populate, capture, determine, exchange, harmonize, link, maintain, manage, render, transmit, update
  - Data: Immunization-Administration, Immunization-History, Public-Health Registry
  - Associated Data: Alerts-and-Notification, Allergy-Intolerance-or-Adverse-Event, Patient-Clinical-Measurement, Patient-Directive, Immunization-Schedule, Patient-Educational-Information, Signature.

### Initial EHR-S FM R2 CP.6.2 **Reference Model**



#### **Human-Actions** Patient Encounter CP.6.2 Manage Immunization Administration Actions «include» review EMR transmit use GUI «include» enter Records render provide exchange Information maintain observe Patient determine Clinician **Patient** treat Patient link write Orders EHR-S auto populate sign Encounter harmonize capture

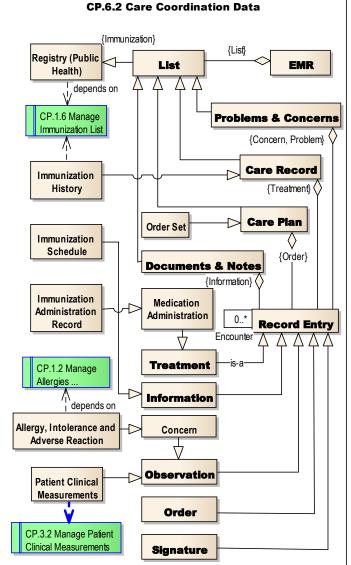
#### **System-Actions**

manage

#### **Business Rules** {BRules} constrain Clinician, Patient or their designated agents' useof EHR-S operations "according to scope-ofpractice, organizationalpolicy, jurisdictionallaw, patient preferenceor-consent."

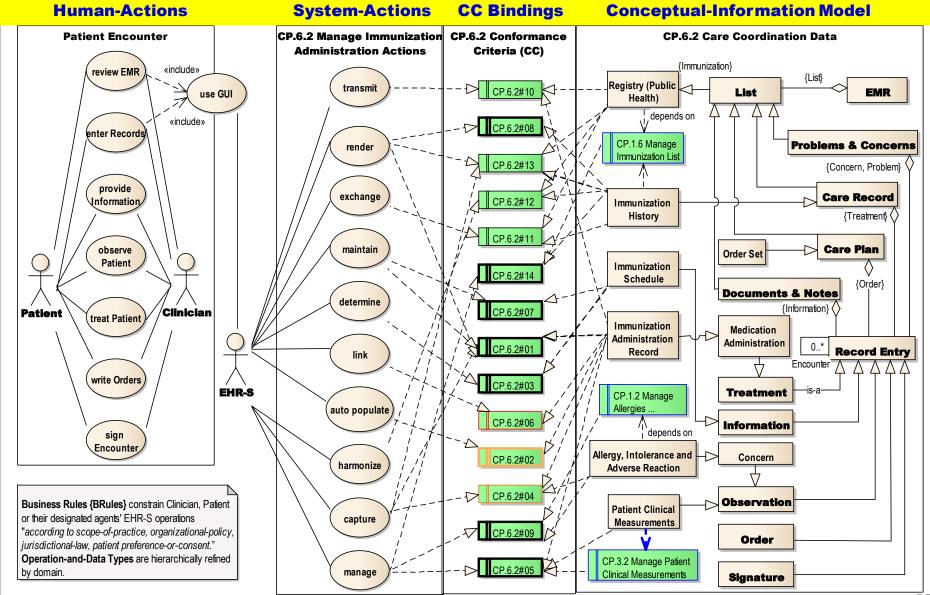
- Operation-and-Data Types are organized into sub-type hierarchies or inheritance taxonomies.
- Conformance Criteria (CCs) are scenario threads through the Use-Case Reference Model

#### **Conceptual-Information Model**



## Initial EHR-S FM R2 CP.6.2 Conformance-Criteria

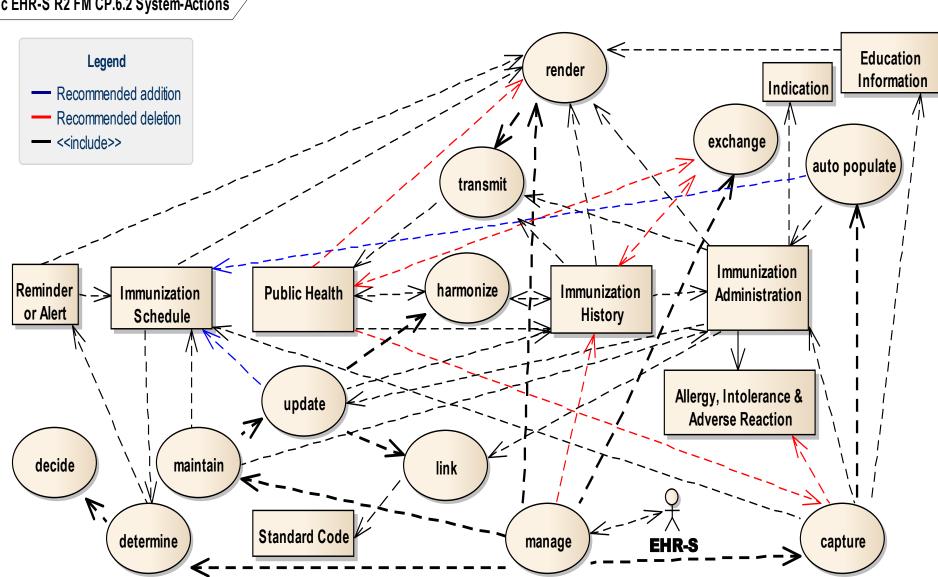




## Initial EHR-S FM R2 CP.6.2 System-Actions based-on Release-2 CCs



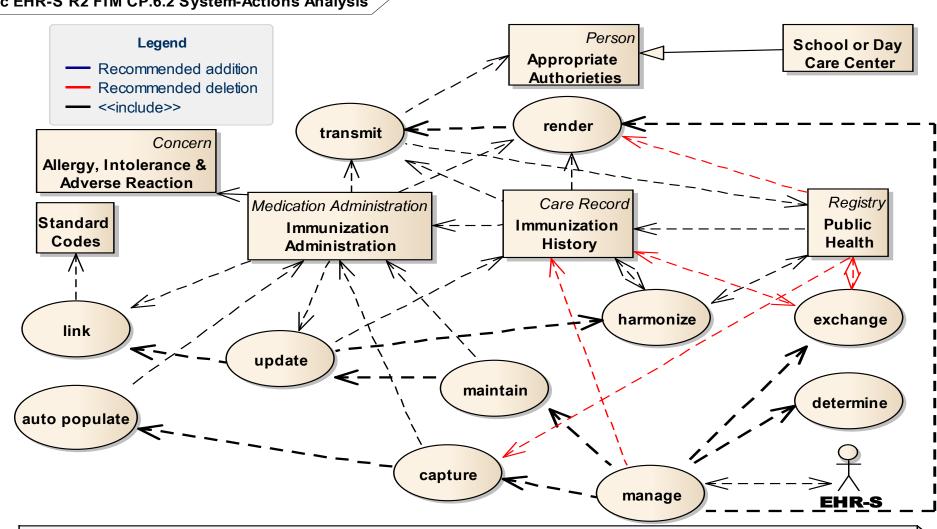
uc EHR-S R2 FM CP.6.2 System-Actions



### EHR-S FM R3 CP.6.2 System-Actions after Separated-Functions



uc EHR-S R2 FIM CP.6.2 System-Actions Analysis



Where, Allergies, Intolerance and Adverse-Reaction, Immunization-Schedule, Alerts and Notifications, Education-Information are treated separately.

## Resultant EHR-S FIM R3 CP.6.2 Concept-of-Operation Use-Case



25

The Release-3 EHR System Immunization-Management Function

- captures, auto-populates, links, renders, transmits, maintains Immunization-Administration Record-Entries; where,
  - the links are with <u>Standard-Codes</u>
  - The transmission is to Population Health Registries
  - The *auto-population* is as a by-product of verification of <u>Administering-Provider</u>, <u>Patient</u>, <u>Medication</u>, <u>Dose</u>, <u>Route</u> and <u>Time</u>.
- updates <u>Immunization-Histories</u> from the <u>Immunization-Administration Record-Entries</u>
- harmonizes Immunization-Histories with Public-Health Registries
- renders and transmits <u>Immunization-Histories</u>
- Where the *transmissions* are to <u>Appropriate Authorities</u> (e.g., <u>Schools and Day Care Centers</u>); and where, System-Actions are according-to scope-of-practice, organizational-policy and/or

jurisdictional-law.

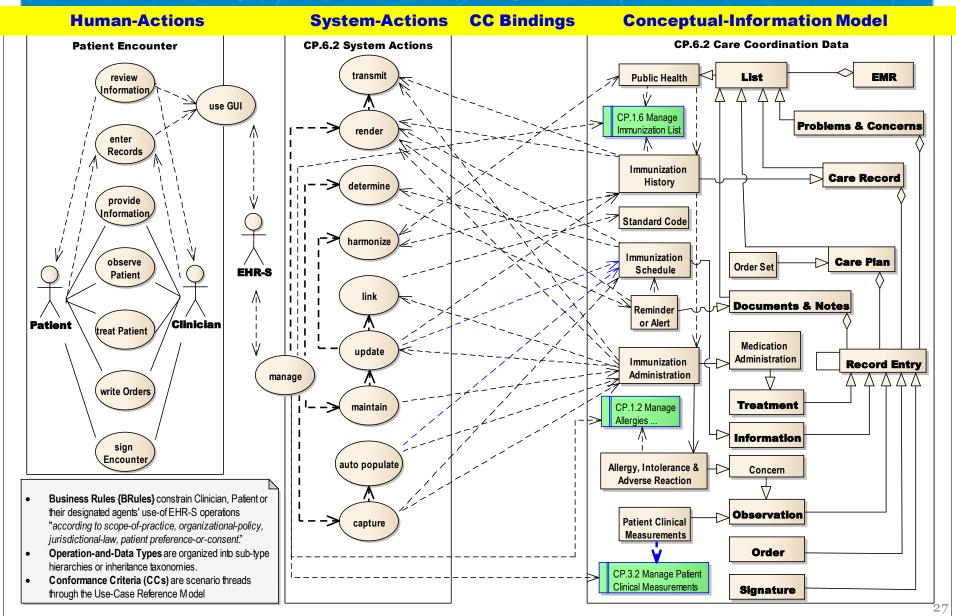
# Resultant EHR-S FIM R3 CP.6.2 Concept-of-Operations Model



uc EHR-S FM R3 CP.6.2 System-Actions «include» Name: EHR-S FM R3 CP.6.2 System-Actions Person School or Day Author: Steve Hufnagel **Appropriate Care Center** Version: Prototype **Authorieties** 11/29/2013 11:44:53 AM Created: «flow» 12/1/2013 10:30:52 AM Updated: -«include»render transmit «flow» «flow» «flow» ( /\\«flow» «flow» Registry Care Record Medication Administration depends-on Standard **Public** -depends-on- -**Immunization Immunization** Code Health History Administration «flow» «flow» «flow» «flow» «flow» «flow» «flow» «flow» link harmonize update «include»— «include» «include» maintain auto populate «include» «include» \_ -«flow» - =capture «include» manage **EHR-S** 

## Resultant EHR-S FIM R3 CP.6.2 Conformance-Criteria

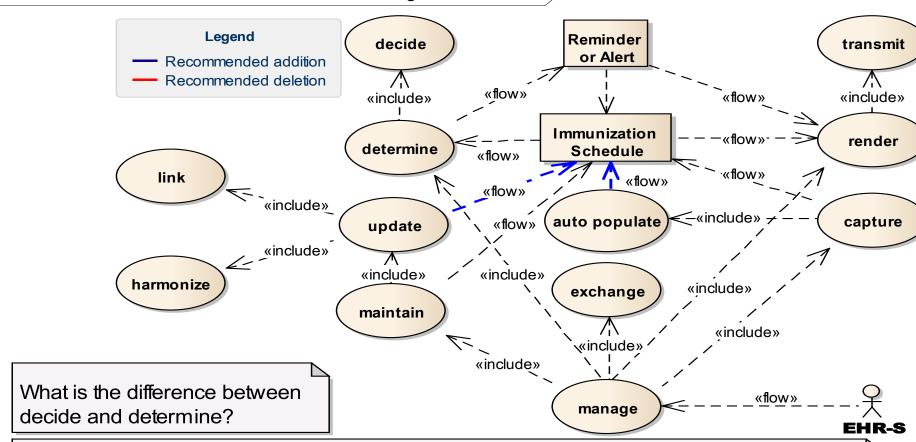




# **EHR-S FIM R3** Immunization-Schedule System-Actions



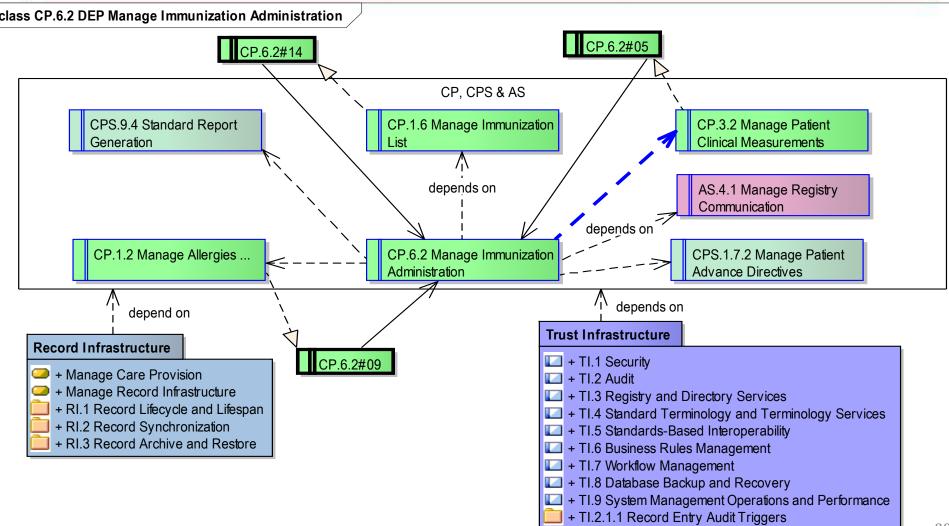
uc EHR-S R3 FIM CP.6.2 Immunization-Schedule Management Use-Case



- 1. Is there one System-Wide Reference-<u>Immunization-Schedule</u> *linked-to* each <u>Patient</u> or does each <u>Patient</u> have an *auto-populated and then updated* <u>Immunization-Schedule</u> *harmonized*-with a reference <u>Immunization-Schedule</u> or don't we care?
- 2. Can the reference or individual <u>Patient Immunization-Schedule</u> be *updated*?
- 3. Should their be a Manage Immunization-Schedule sub-function?

# Use-Case Dependencies CP.6.2 Immunization Management







### capture, maintain and render Immunization-Administration Record-Entry

- R2: CP.6.2#01 The system SHALL provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot number, expiration date,(4) route and site of administration;(5) administering provider;(6) observations, reactions and complications;(7) reason immunization not given and/or immunization related activity not performed; according-to scope-of-practice, organizational-policy and/or jurisdictional-law."
- R3: CP.6.2#01 During an Encounter, the EHR system SHALL provide-the-ability-to capture-maintainand-render an Immunization-Administration;
  - where, the System-Actions are documented in discrete <u>Record Entries</u> fields; and
  - where, data-requirements may-be realized-by FHIR (Fast Healthcare Interoperability Resource) data-specifications;
  - where, the Immunization-Administration is associated with AdverseReaction and other-Observations, Patient,
     Practitioner, Organization and Location resources;
  - where in the US-Realm, Immunization-Administration and associated data can be realized-by FHIR-profiles
     based-on FHIM (Federal Health Information Model) Domains of Immunization, Adverse Reaction, Allergy and Intolerance,
     Care-Plan, Encounter, Health Concern, Person, Provider, Public Health Reporting, Patient Education, Vital Signs<sub>30</sub>



### auto-populate Immunization-Administration Record

- R2: CP.6.2#02 The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope-of-practice, organizational-policy and/or jurisdictional-law.
- R3: CP.6.2#02 After verification-of Administering-Provider, Patient, Medication, Dose, Route and Time, the System MAY directly *auto-populate* the <a href="mailto:lmmunization-Administration">lmmunization-Administration</a> Record-Entry; where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

#### determine and render Immunization-Schedule

- **R2: CP.6.2#03** The system **SHALL** provide the ability to *determine and render required immunizations*, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.
- R3: CP.6.2#01 The System SHALL provide-the-ability-to *capture-determine-and-render* the <u>Patient</u>'s <u>Immunization-Schedule</u>; where, the System-Actions are based on widely-accepted reference <u>Immunization-Schedules</u>.



### capture Allergy, Intolerance and Adverse Event

- **R2: CP.6.2#04** The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific immunization.
- R3: CP.6.2#04 Associated-with a Patient Immunization-Administration, the system SHOULD providethe-ability-to *capture an* Allergy, Intolerance and Adverse Event; where, System-Actions are documented as discrete-data-elements.

#### capture Clinical-Data

- R2: CP.6.2#05 The system SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs).
- R3: CP.6.2#05 The system SHALL provide-the-ability-to *capture* Observations; where, they are pertinent to the immunization administration (e.g., vital signs); and where, the System-Actions are conformant-to function CP.3.2 (Manage Patient Clinical Measurements).



#### link Standard-Codes

- **R2: CP.6.2#06** The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization.
- R3: CP.6.2#06 For discrete-data-elements associated-with an <a href="Immunization-Administration">Immunization-Administration</a>, the system SHOULD provide-the-ability-to <a href="Iink-to">Iink-to</a> Standard Codes; where, examples of <a href="Standard Codes">Standard Codes</a> are NDC, LOINC, SNOMED or CPT.

#### maintain Immunization-Schedule

- R2: CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule.
- R3: CP.6.2#07 The system SHALL provide-the-ability-to maintain the <u>Immunization-Schedule</u>.



### render Immunization-History

- R2: CP.6.2#08 The system SHALL provide the ability to render a patient's immunization history upon
  request for appropriate authorities such as schools or day-care centers.
- R3: CP.6.2#08 Upon request from appropriate authorities, such as schools or day-care centers, the system SHALL provide-the-ability-to *render* a <u>Patient</u>'s <u>Immunization History</u>; where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

### manage Allergy, Intolerance and Adverse Reaction List

- R2: CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
- R3: CP.6.2#09 As appropriate, The system SHALL manage Allergy, Intolerance and Adverse Reaction Lists; where, System-Actions are conformant-to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).



### transmit Immunization-Administration Record-Entry

- R2: CP.6.2#10 The system SHOULD transmit required immunization administration information to a public health immunization registry according-to scope-of-practice, organizational-policy and/or jurisdictional-law.
- R3: CP.6.2#10 As appropriate, the System SHOULD directly *transmit* <u>Immunization-Administration</u> information; where, System-Actions are with <u>Public-Health Immunization-Registries</u>; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

### exchange <u>Immunization History</u>

- **R2: CP.6.2#11** The system SHOULD exchange immunization histories with public health immunization registries according to scope-of-practice, organizational-policy and/or jurisdictional-law.
- R3: CP.6.2#11 When Immunization History is *updated*, the System SHOULD directly *exchange* Immunization-Histories; where, the System-Actions are with <u>Public-Health Immunization-Registries</u>; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.



#### harmonize Immunization Histories

- **R2: CP.6.2#12** The system SHOULD harmonize Immunization histories with a public health immunization registry according-to scope-of-practice, organizational-policy and/or jurisdictional-law.
- R3: CP.6.2#12 When Immunization History is *updated*, the System SHOULD directly *harmonize* Immunization-Histories; where, System-Actions are with a <u>Public Health Immunization Registry</u>; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

### capture and render Immunization History from a Public-Health Registry

- R2: CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry.
- R3: CP.6.2#13 As appropriate, the system SHOULD harmonize *capture and render* Immunization

  Histories; where, System-Actions are with a Public Health Immunization Registry; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.



### manage <u>Immunization-Administration</u> List (History)

- R2: CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List).
- R3: CP.6.2#14 The system SHALL directly *manage* Immunization Lists; where, the System-Actions are conformant-to function CP.1.6 (Manage Immunization List).

### update Immunization History

- R2: CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.
- R3: CP.6.2#15 At the time of *capturing* an <u>Immunization-Administration</u>, the system SHOULD provide-the-ability-to *update* <u>Immunization-Histories</u>.



### render Immunization Order

- R2: CP.6.2#16 The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information.
- R3: CP.6.2#16 When *rendering* <u>Immunization-Administration</u> Information, the system **SHALL** providethe-ability-to *render* the <u>Immunization Order</u>; where, the <u>Immunization Order</u> is the exact clinician order language.

### determine and render Notification

- **R2: CP.6.2#17** The system **SHALL** provide the ability to determine due and overdue ordered immunizations and render a notification.
- R3: CP.6.2#17 For due-and-overdue ordered-immunizations, the system SHALL provide-the-ability-to determine and render a Notification.



### render Patient Educational Information

- R2: CP.6.2#18 The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)).
- R3: CP.6.2#18 During an <u>Immunization-Administration</u> <u>Encounter</u>, the system **SHALL** provide-the-ability-to <u>render Patient Educational-Information</u>; where, the System-Action is regarding the <u>Immunization-Administration</u> (e.g., Vaccine Information Statement (VIS)).

### capture Patient Educational-Information Provided-Flag

- R2: CP.6.2#19 The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration.
- R3: CP.6.2#19 At the time of <u>Immunization-Administration</u>, the system **SHALL** provide-the-ability-to capture an <u>Indication</u>; where, System-Actions are confirming-that Patient Educational Information (e.g., VIS) was provided.



### capture Patient Educational-Information Provided-Documentation

- R2: CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration.
- R3: CP.6.2#20 At the time of <u>Immunization Administration</u>, the system **SHALL** provide-the-ability-to capture <u>Event Documentation</u>; where, the System-Actions document the who, what, when, where, how of the patient receiving educational information (e.g., VIS).

### capture Receiving Entity

- **R2: CP.6.2#21** The system **SHALL** provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration.
- R3: CP.6.2#21 During an <u>Immunization-Administration Encounter</u> and when <u>Patient Education-Information</u> is provided, the system **SHALL** provide-the-ability-to *capture* the <u>Entity</u>; where, the System-Actions identify the patient, representative or organization receiving the <u>Patient Education-Information</u>.



### capture and maintain Justification

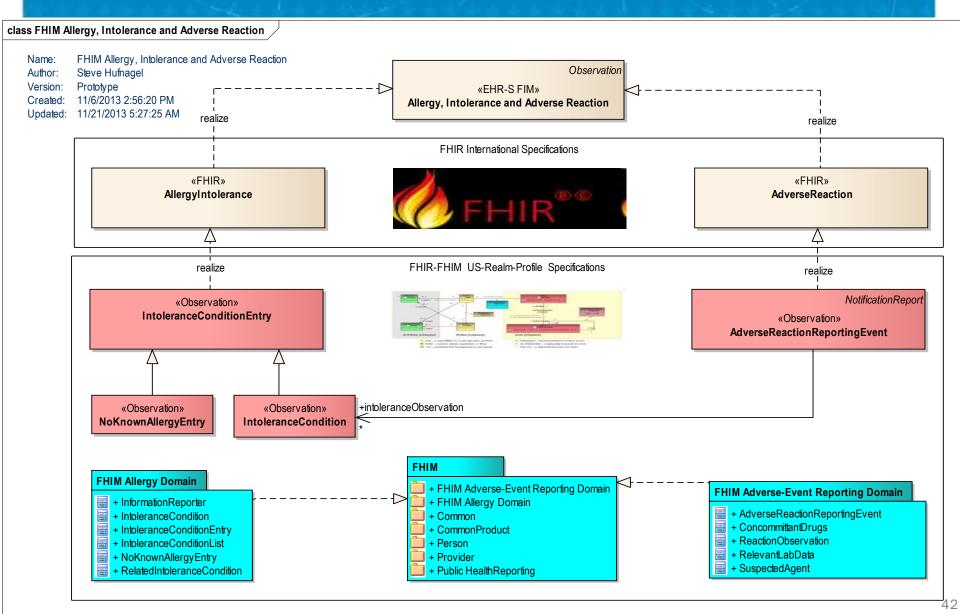
- R2: CP.6.2#22 The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.
- R3: CP.6.2#22 When <u>Immunization-Administration</u> is refused, the system SHOULD provide-the-ability-to *capture-and-maintain* <u>Justification</u>; where, System-Actions are to document the <u>Justification</u> as discrete-data-elements.

### capture Patient's Preference

- R2: CP.6.2#23 The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration.
- R3: CP.6.2#23 At the time of immunization administration, the system SHOULD provide-the-ability-to capture Patient-Preferences; where, the System-Actions are regarding refusal of certain vaccine types.

## Example Linkage-to FHIR & FHIM for Allergy, Intolerance & Adverse-Reaction

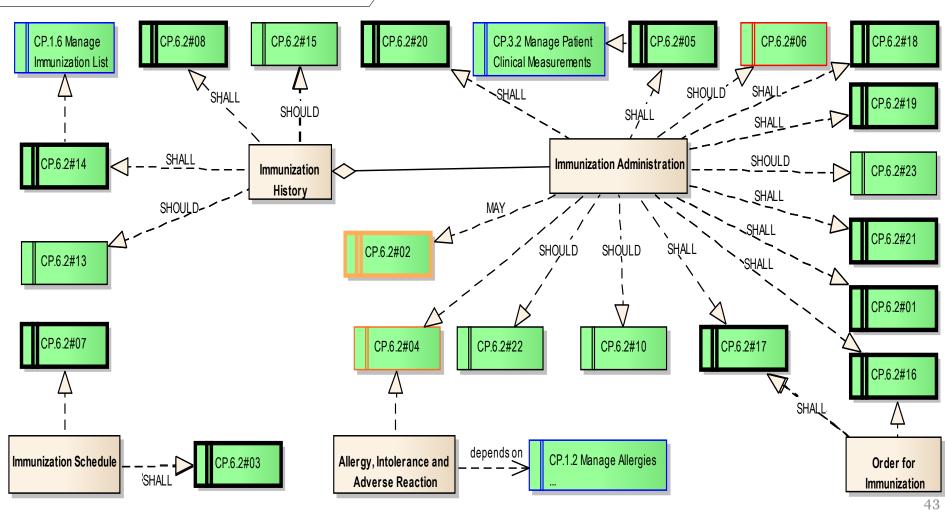






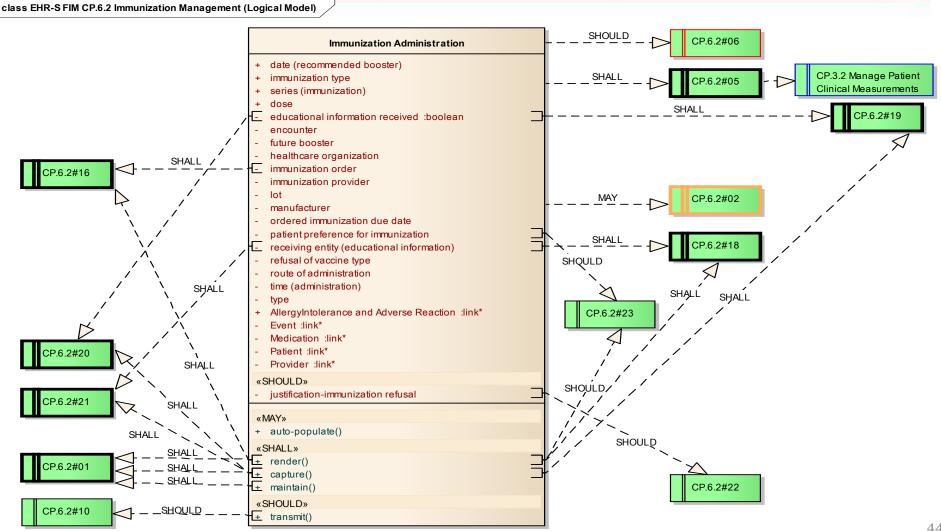
# EHR-S-FIM Conceptual Traceability Model CP.6.2 Immunization Management

class EHR-S FIM CP.6.2 Immunization Management (Conceptual Traceability Model)



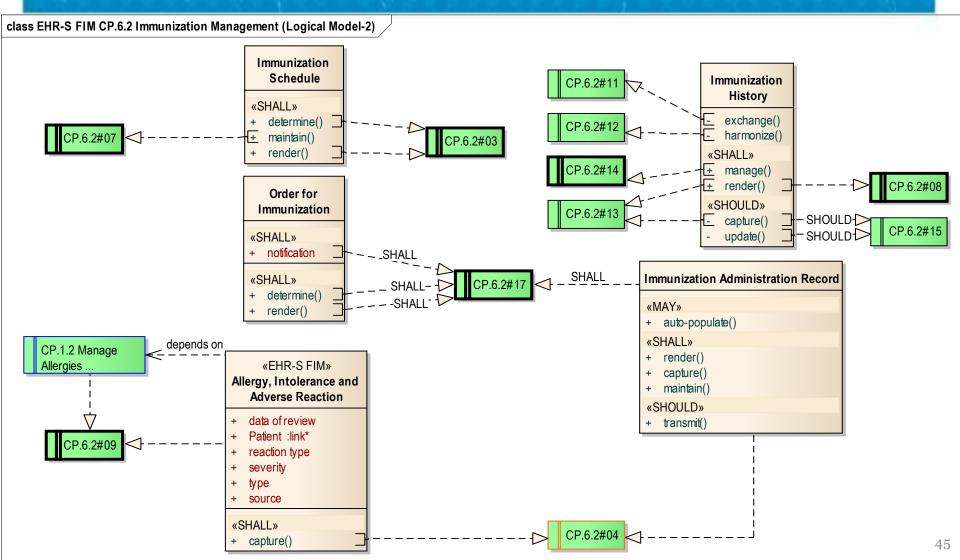


## **EHR-S FIM Logical Traceability-Model** CP.6.2 Immunization Management





# EHR-S FIM Logical Traceability-Model CP.6.2 Immunization Management



## Interim Conclusion EHR-S FIM CP.6.2 Immunization Management



- Based on the Medication Management, Orders Management and Immunization Management functions, we see
  - A high-level EHR-S Information Model emerging as a set of
    - Patients, Providers, External Partners, Encounters, EMRs, Care Plans, Lists, Managers, Documents and Notes;
  - A high-level EHR-S Manager Model is emerging to
    - Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine



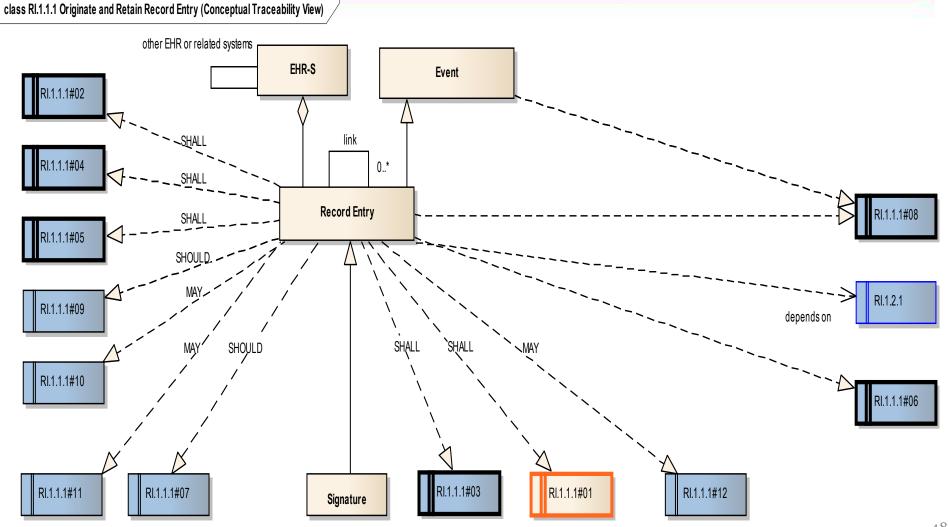


- Introduction, Executive-Summary, Plan-of-Actions & Milestones
- EHR-S Concept-of-Operations Reference Use-Case and Model
- CP.6.2 Immunization-Management Deep-Dive
- RI.1.1.1 Originate-and-Retain Record-Entry Deep-Dive
- 5. EHR-S FIM linked-to FHIR for Allergy, Intolerance and Adverse-Reaction
- EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
- Traceability

The complete-and-current HL7 <u>EHR-System Function-and-Information Model Release-3</u> Development-Summary Presentation, dated December-2013 is available at http://wiki.hl7.org/index.php?title=EHR\_Interoperability\_WG 47

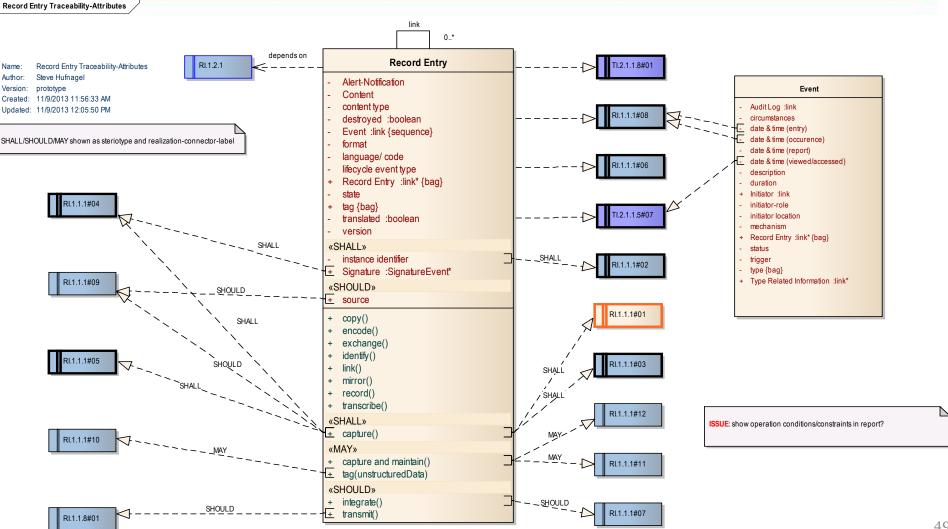
# EHR-S FIM Conceptual Information Model (CIM) RI.1.1.1 Originate and Retain Record Entry







## EHR-S FIM **Traceability View** RI.1.1.1 Originate-and-Retain Record Entry





### Conformance Criteria (CC) RI.1.1.1 Originate-and-Retain Record-Entry

- 1. RI.1.1.#01 The system **SHALL** provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
- 2. RI.1.1.1#02 The system **SHALL** capture a unique instance identifier for each Record Entry.
- 3. RI.1.1.1#03 The system **SHALL** conform to <u>function TI.2.1.1.1</u> (Originate/Retain Record Entry Audit Trigger), including specified metadata.
- RI.1.1.1#04 The system SHALL capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.
- 5. RI.1.1.1#05 The system **SHALL** provide the ability to capture both structured and unstructured content in Record Entries.
- 6. RI.1.1.1#06 The system **SHALL** provide the ability to capture Record Entries from information recorded during system downtime.
- 7. RI.1.1.1#07 The system SHOULD provide the ability to integrate Record Entries from Information recorded during system downtime.
- 8. RI.1.1.1#08 The system **SHALL** provide the ability to capture date/time an Action was taken or data was collected if different than date/time of the Record Entry.
- 9. RI.1.1.1#09 The system SHOULD capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).
- 10. RI.1.1.1#10 The system MAY provide the ability to tag unstructured Record Entry content to organize it according to need, for example, in a time-related fashion or by application-specific groups (such as photographs, handwritten notes, or auditory sounds)
- 11. RI.1.1.#11 The system MAY capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care or other HL7 CDA R2 Document).
- 12. RI.1.1.1#12 The system MAY capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.



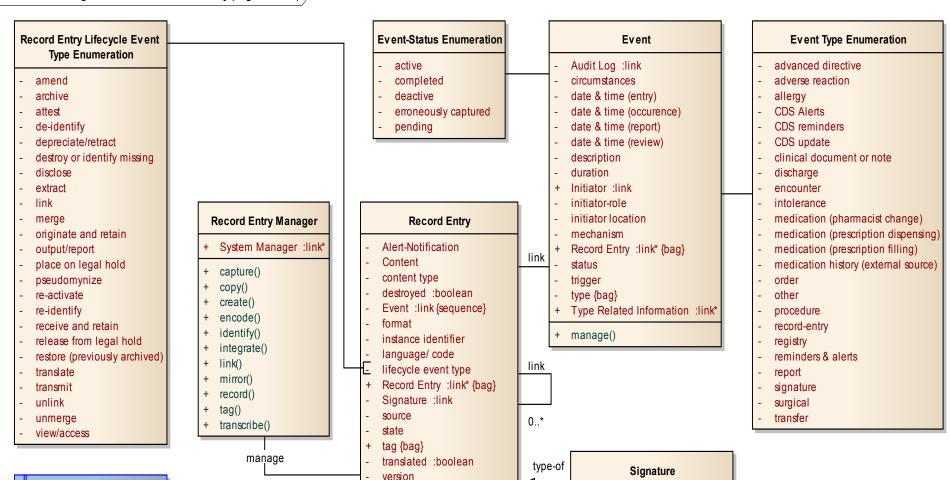
## EHR-S FIM Logical View

### RI.1.1.1 Originate-and-Retain Record Entry

class RI.1.1.1 Originate and Retain Record Entry (Logical View)

RI.1.2.1 Manage Record

Entries



+ manage()

depends on

+ Record Entry :link\* {bag}

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## EHR-S FIM RI.1.1.1 Originate and Retain Record Entry

### **Resultant Description (Notional Scenario)**

- The EHR-S <u>Record-Entry</u> manager can
  - Capture, Create, Copy, Record, Transcribe, Identify,
  - Link, Tag, Encode, Mirror, and Integrate
- Record-Entries as
  - structured or unstructured-data link-to associated
    - Event-Metadata and Signatures.

## Interim Conclusion EHR-S FIM



### **RI.1.1.1 Originate and Retain Record Entry**

we have only looked at the RI.1.1.1 function; yet,

- we see that the emergence of common <u>Record-Entries</u>, <u>Events</u>, <u>Record Entries</u> and a <u>Record Entry Manager</u>
- which can Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate
  - structured-data or unstructured-data and link-to
  - associated <u>Event-Metadata</u> and <u>Signature</u>.

## **Contents** FY2014Q1-Prototype Report EHR-S FIM Release-3:2016 Preparation

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### EHR-S FIM Using FHIR

**ISSUE**: EHR-S FM r2.0 Implied Information Model is Ad-Hoc; where, FHIR & FHIM Information Model & Data Dictionary are Configuration Managed.

### FHIR Administrative

- Attribution: Patient, RelatedPerson, Practitioner, Organization
- Resources: Device, Location, Substance, Group
- Workflow Management: Encounter, Alert, Supply, Order, OrderResponse
- Financial: Coverage

#### FHIR Clinical

- General: AdverseReaction, AllergyIntolerance, CarePlan, FamilyHistory, Condition, Procedure, Questionnaire
- Medications: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense,
   MedicationStatement, Immunization, ImmunizationProfile
- Diagnostic: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
- Device Interaction: DeviceCapabilities, DeviceLog, DeviceObservation

#### FHIR Infrastructure

- Support: List, Media, Other, DocumentReference, (Binary)
- Audit: Provenance, SecurityEvent
- Exchange: Document, Message, OperationOutcome, Query
- Conformance: Conformance, ValueSet, Profile

## ■ EHR-S FIM Prototype Allergy, Intolerance & Adverse-Reaction FIM-FHIR-FHIM Requirements-Specifications

ISSUE: Should we map at Data Module Level or Conformance Criteria level? [Gary]

FHIR-FHIM High-Level Specification for Allergy, Intolerance and Adverse Reaction Name: Author: Steve Hufnagel Version: Prototype The 2016 EHR-S FIM release-3 objective is for an analyst-or-architect to use the EA-tool to Created: 11/7/2013 4:26:03 AM Create a use case from a prescribed lexicon of Entities, Events, Modifiers and Actions; where, Updated: 11/18/2013 9:07:42 AM the lexicon is mapped to applicable EHR System Functions; where, the EA-tool can generate an Interoperability-Specification (IS) containing UML EHR-S-FIM/FHIR/FHIM profile, based-on the use-case including FHIR-XML (International) including FHIR-FHIM-XML (US Realm) with appropriate terminology value-set binding; Where, other realm models could be added to the EA-tool by interested stakeholders profiles can be further refined to support local needs. EHR-S-FIM is EHR System Function-and-Information model FHIR is Fast Healthcare Interoperability Resource **FHIM** is US Federal Health Information Model. **EHR-S FIM Requirements** «EHR-S FIM» Allergy, Intolerance and Adverse Reaction FHIR International Specifications «FHIR» «FHIR» «FHIR» «FHIR» AllergyIntolerance Symptom AdverseReaction FHIR-FHIM US-Realm-Profile Specifications «Observation» «Observation» IntoleranceConditionEntry AdverseReactionReportingEvent



# Prototype Allergy, Intolerance & Adverse-Reaction FHIR Design-Specification

class FHIR Specification for Allergy, Intolerance and Adverse Reaction

Name: FHIR Specification for Allergy, Intolerance and Adverse Reaction

realize

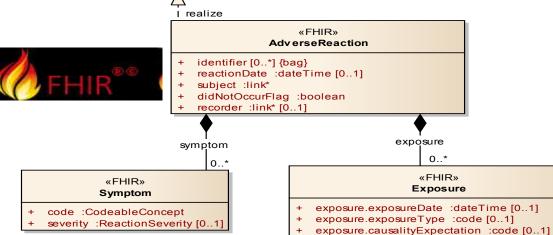
Author: Steve Hufnagel

Version: Prototype

Created: 11/5/2013 4:25:17 AM Updated: 11/8/2013 4:49:33 PM

# ### Allergy, Intolerance and Adverse Reaction ### data of review ### Patient :link\* ### reaction type ### severity ### type ### source #### manage()

# \*FHIR\* AllergyIntolerance + identifier :Identifier [0..1] + criticality :code [0..1] + sensitivityType :code + recordedDate :dateTime [0..1] + status :code + subject :Resource(Patient) + recorder :Resource(Practitioner|Patient) + substance :Resource(Substance)\* + reaction :Resource(AdverseReaction)\* [0..1] + sensitivityTest :Resource(Observation)\* [0..1]



exposure.substance :Resource(Substance)\* [0..1] AllergyIntolerance.sensitivityType :code

recordedDate :dateTime [0..1]

recorder :Resource(Practitioner|Patient) substance :Resource(Substance)\*

reaction :Resource(AdverseReaction)\* [0..1]

subject :Resource(Patient)

status :code



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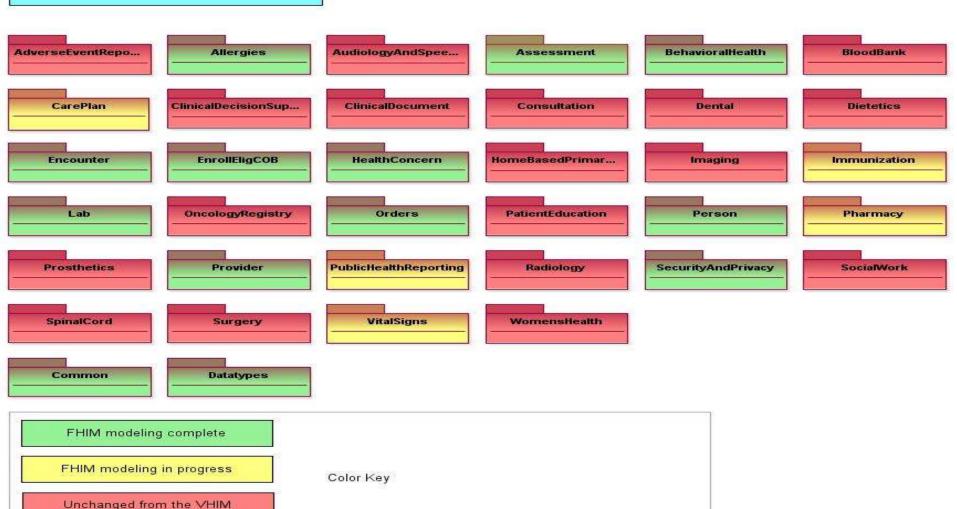
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## **EHR-S FIM Using Federal Health Information Model (FHIM)**



http://www.fhims.org/content/420A62FD03B6\_root.html

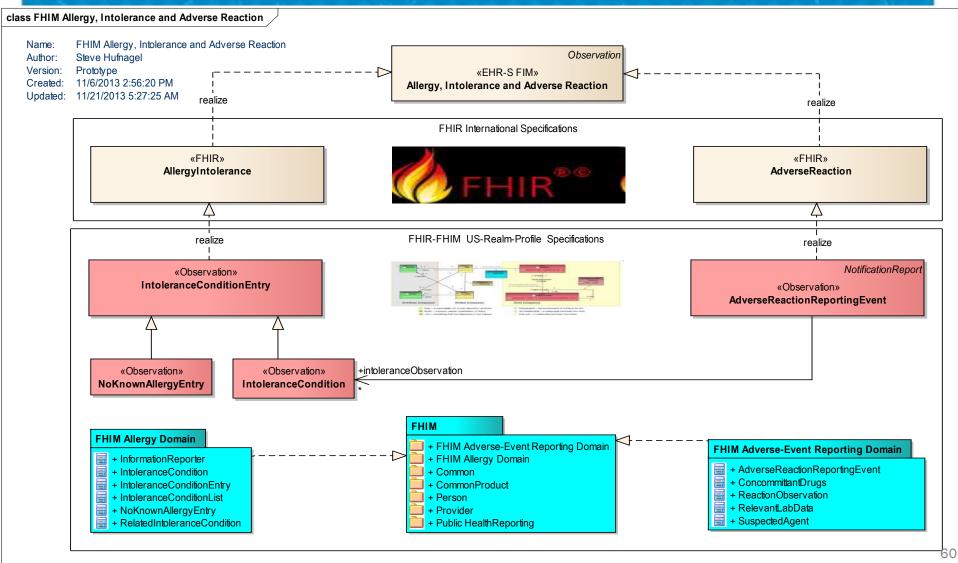
FHA Federal Health Information Model (FHIM)



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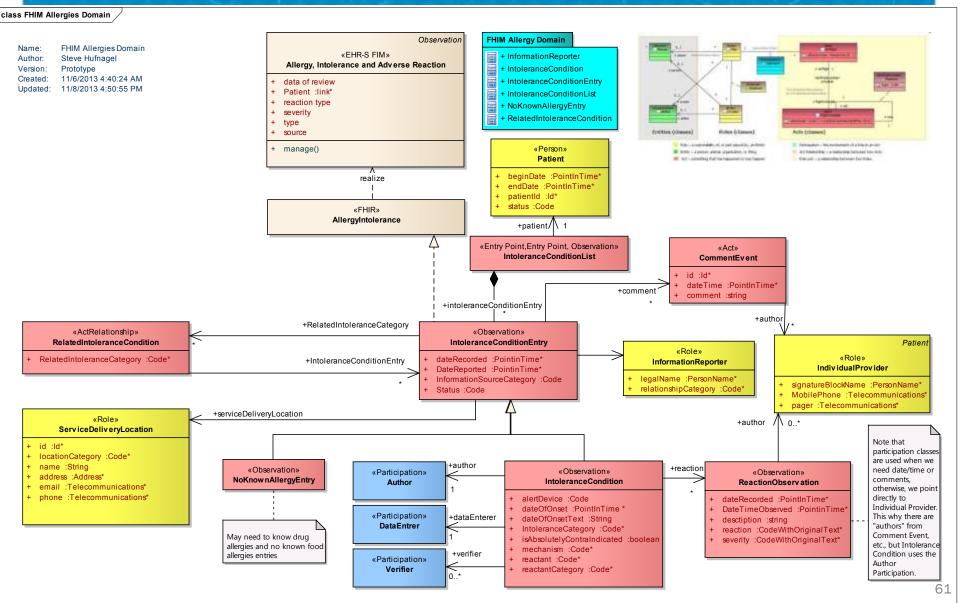


### Prototype Allergy, Intolerance & Adverse-Reaction FHIM High-Level US-Realm Specification



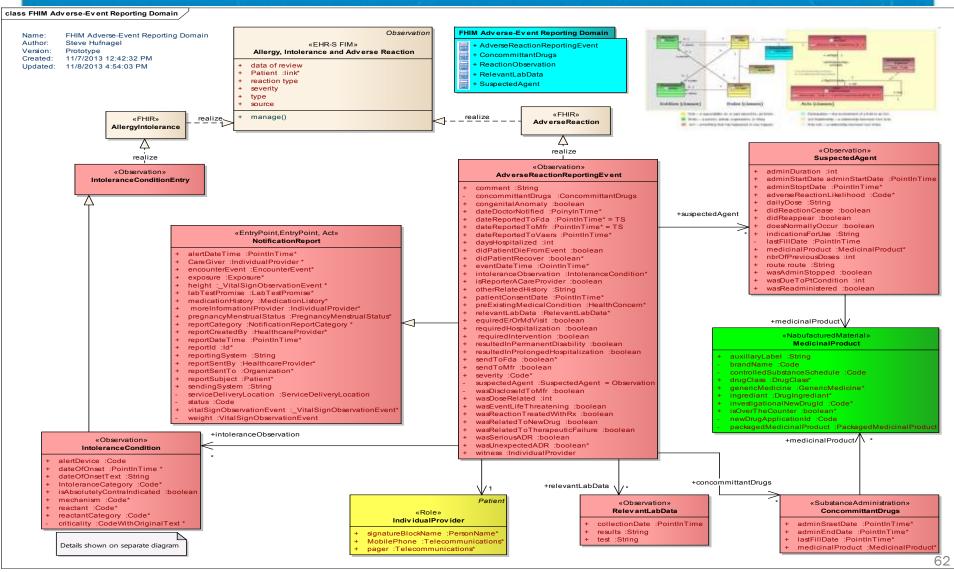
## Prototype FHIM-Detailed Allergy & Intolerance Specification







## Prototype FHIM Detailed Adverse-Reaction Specification





## Prototype Allergy, Intolerance & Adverse-Reaction FHIR & FHIM Design-Specifications

### INTERIM CONCLUSION

EHR-S FIM, FHIR and FHIM complement each other; where,

- EHR-S FIM defines Requirements; where,
  - EHR-S FIM needs data-specifications and Dictionary and
  - FHIR & FHIM provide data-specifications and Dictionary
- FHIR defines the <u>International Data-Specifications ("The 80% set")</u>
- FHIM can define the <u>US-FHA FHIR-Profile</u>
- Joint Configuration Management is essential for FIM/FHIR/FHIM consistent
   A FIM-FHIR-FHIM populated UML-Tool (e.g., EA or RSA) can manage
- Requirements from EHR-S FIM
- International Data-Specifications from FHIR
- US-Realm Data-Specifications-Profile from FHIM