Monthly Summary Briefing

HL7 EHR Work Group (EHR-WG)

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to Edmond-Scientific VA support-contract
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December 03, 2013 **Frequently-Updated Working-Draft**

http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

EHR Work Group
Goal & Objectives

- **Electronic Health Record (EHR) Work Group's 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).

NOTE: EHR-S FIM is NOT intended to imply a specific implementation architecture-or-workflow!

EHR WG Logistics

Schedule: http://www.hl7.org/concalls/default.aspx
List Server: http://www.hl7.org/myhl7/managelistservs.cfm

Health Level Seven – Electronic Health Record Work Group
Weekly Teleconference Schedule
Revised: 20 November 2013

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

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

1. **Introduction, Executive-Summary, Plan-of-Actions & Milestones**
2. EHR-S Concept-of-Operations Reference Use-Case and Model
3. CP.6.2 Immunization-Management Deep-Dive
4. 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
7. Traceability

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

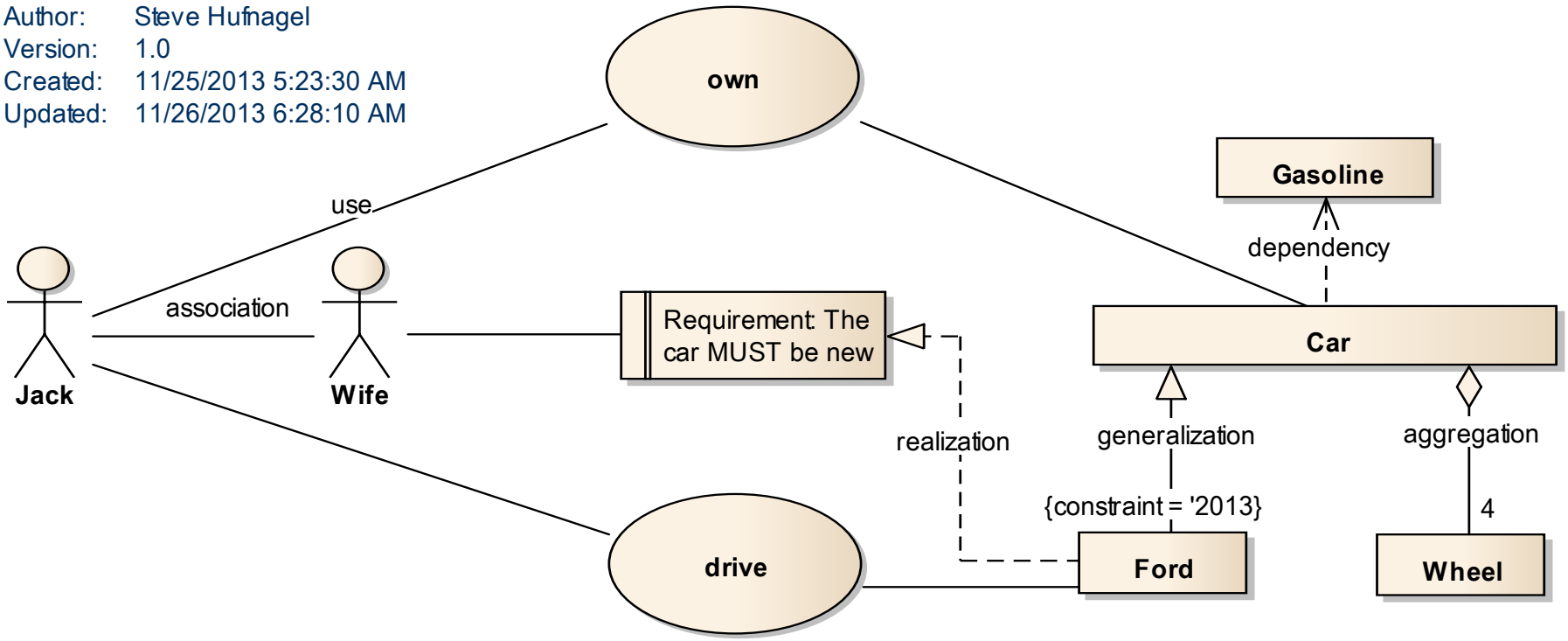
EHR-S FIM Acronyms

- **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 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

cmp Legend:Car

Name: Legend:Car
Author: Steve Hufnagel
Version: 1.0
Created: 11/25/2013 5:23:30 AM
Updated: 11/26/2013 6:28:10 AM



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)
  - US-Realm Interoperability-Specifications based-on FHA FHIM (Federal Health Information Model)
  - Behavioral Specifications can be included, based-on IHE or other Protocols.

NOTE: EHR-S FIM is NOT intended to imply a specific architecture or workflow!

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

October 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 hierarchical-lexicon of
     - nouns (Data-Entities) and noun qualifiers (Data-hierarchy or Sub-Types),
     - verbs (Actions) and verb qualifiers (Action-hierarchy or Sub-Types) with
     - conditions {Business Rules based on laws, policies, preferences}; where,
   - Conformance Criteria (CC) are scenario-threads 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."

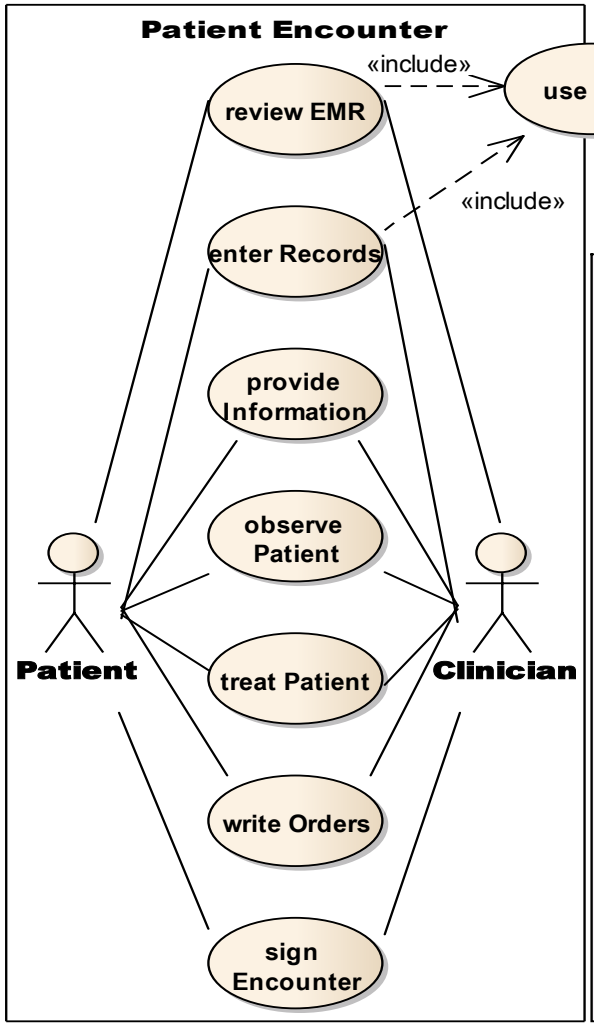
EHR-S RM Concept-of-Operations Reference Use-Case

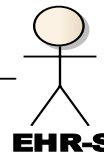
A Clinician and Patient and/or their designated Agents have Encounters; where, they *use an* EHR-S (EHR System) GUI (Graphical-User-Interface) to *manage* EMRs (Electronic Medical Records), in accordance with scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences; where,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

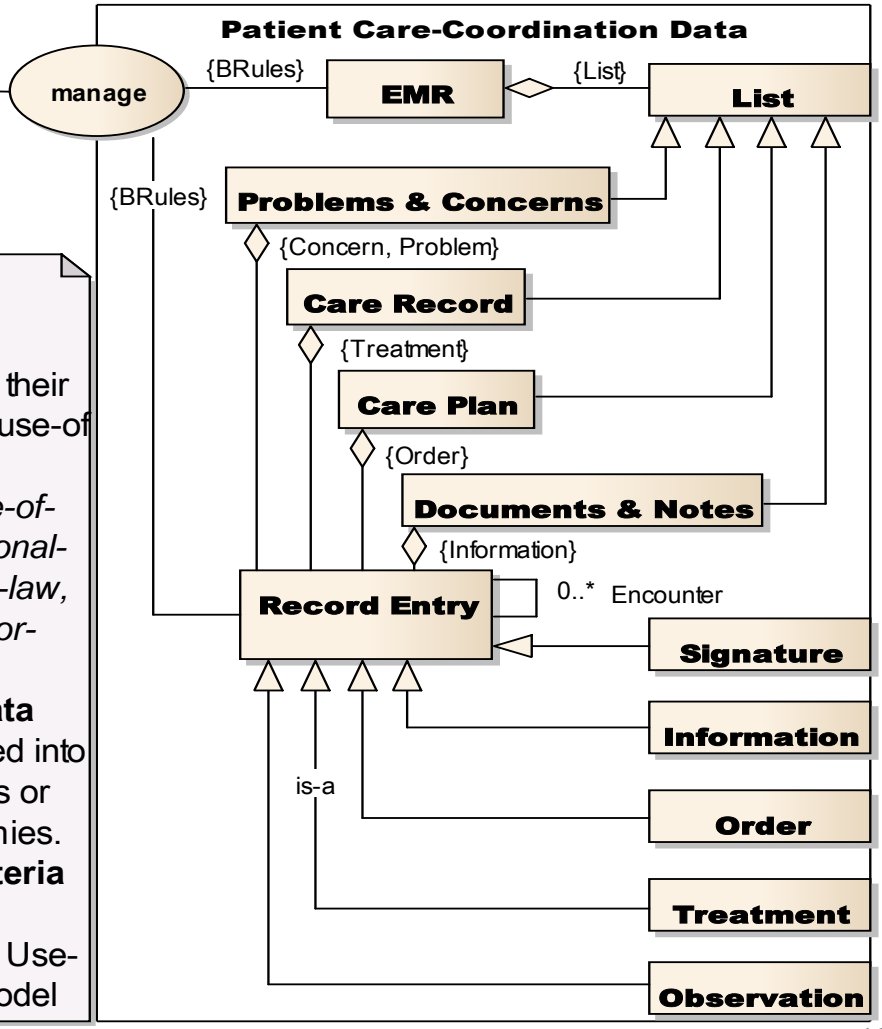
- *review* the Patient EMR (Electronic Medical Record) and associated Information
- *observe and treat the* Patient, *write Orders and document* the Encounter
- *provide* patient Information and educational-Information
- *enter* EMR Records and associated Information; where,
  - Record Entries are Orders, Treatments, Observations and associated Information
  - Lists are Care-Plans, Care-Records, Problems-and-Concerns, Documents & Notes
- *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**

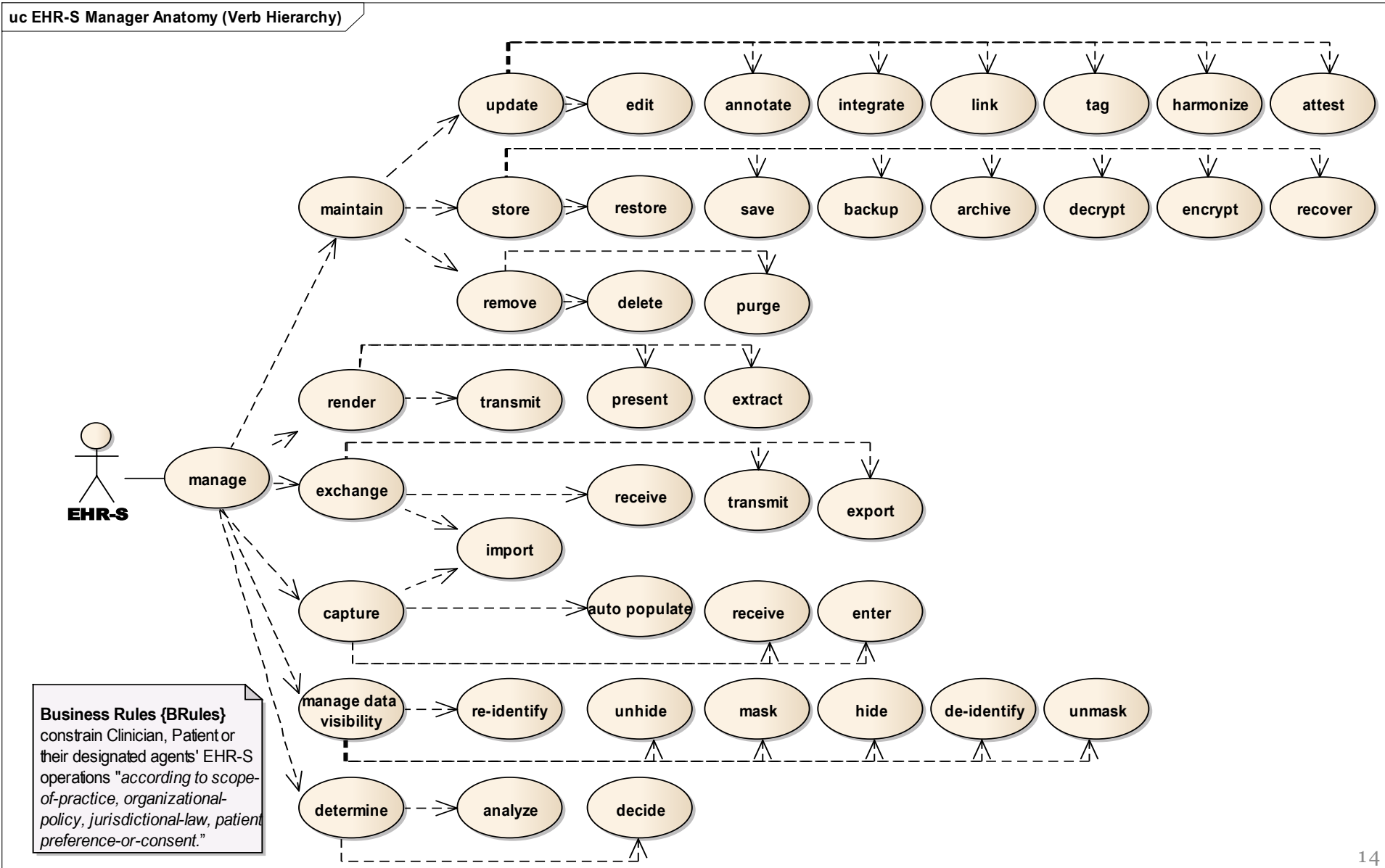






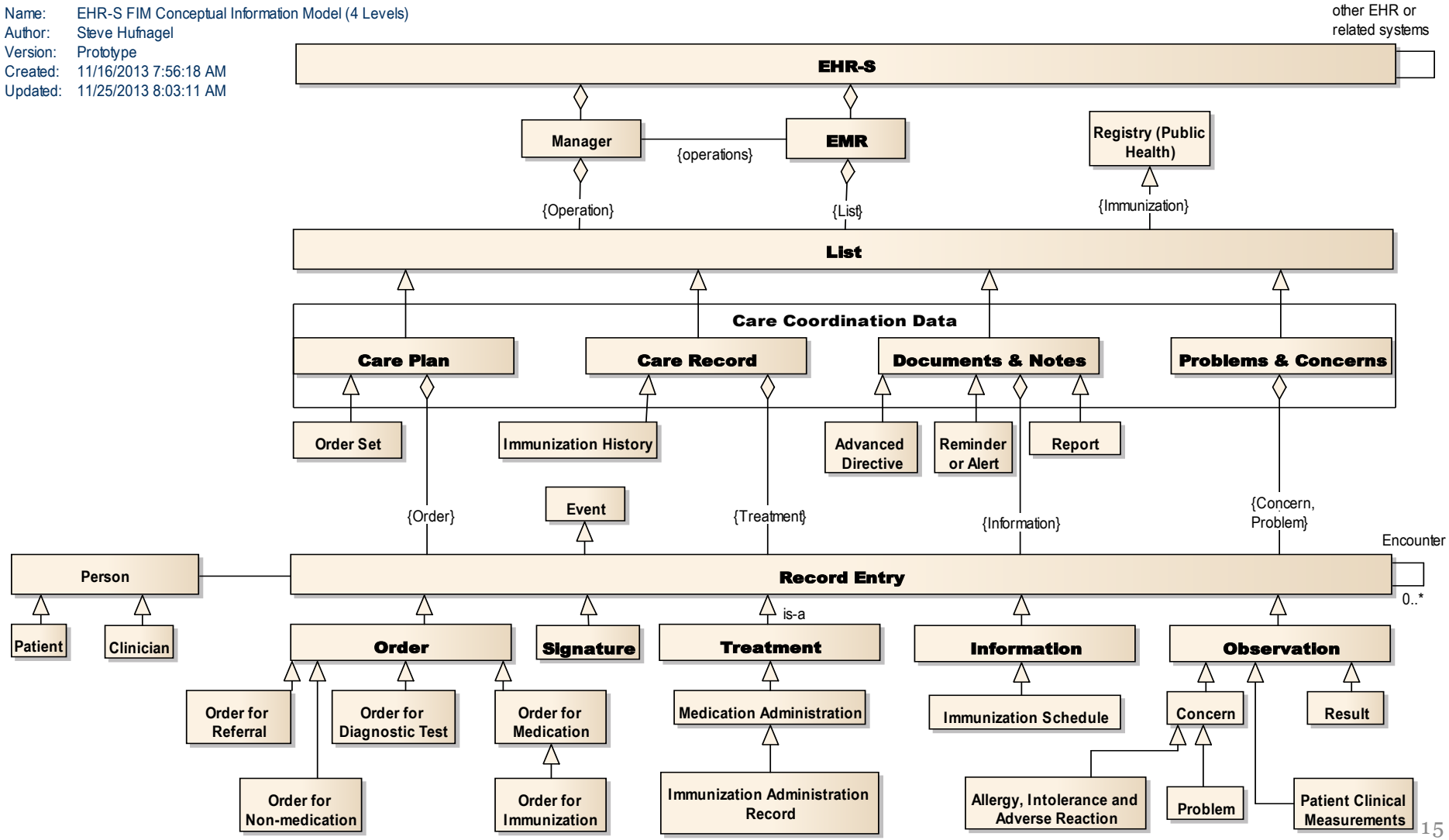
- **Business Rules {BRules}** constrain Clinician, Patient or their designated agents' use-of EHR-S operations "*according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.*"
- **Operation-and-Data Types** are organized into sub-type hierarchies or inheritance taxonomies.
- **Conformance Criteria (CCs)** are scenario threads through the Use-Case Reference Model

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

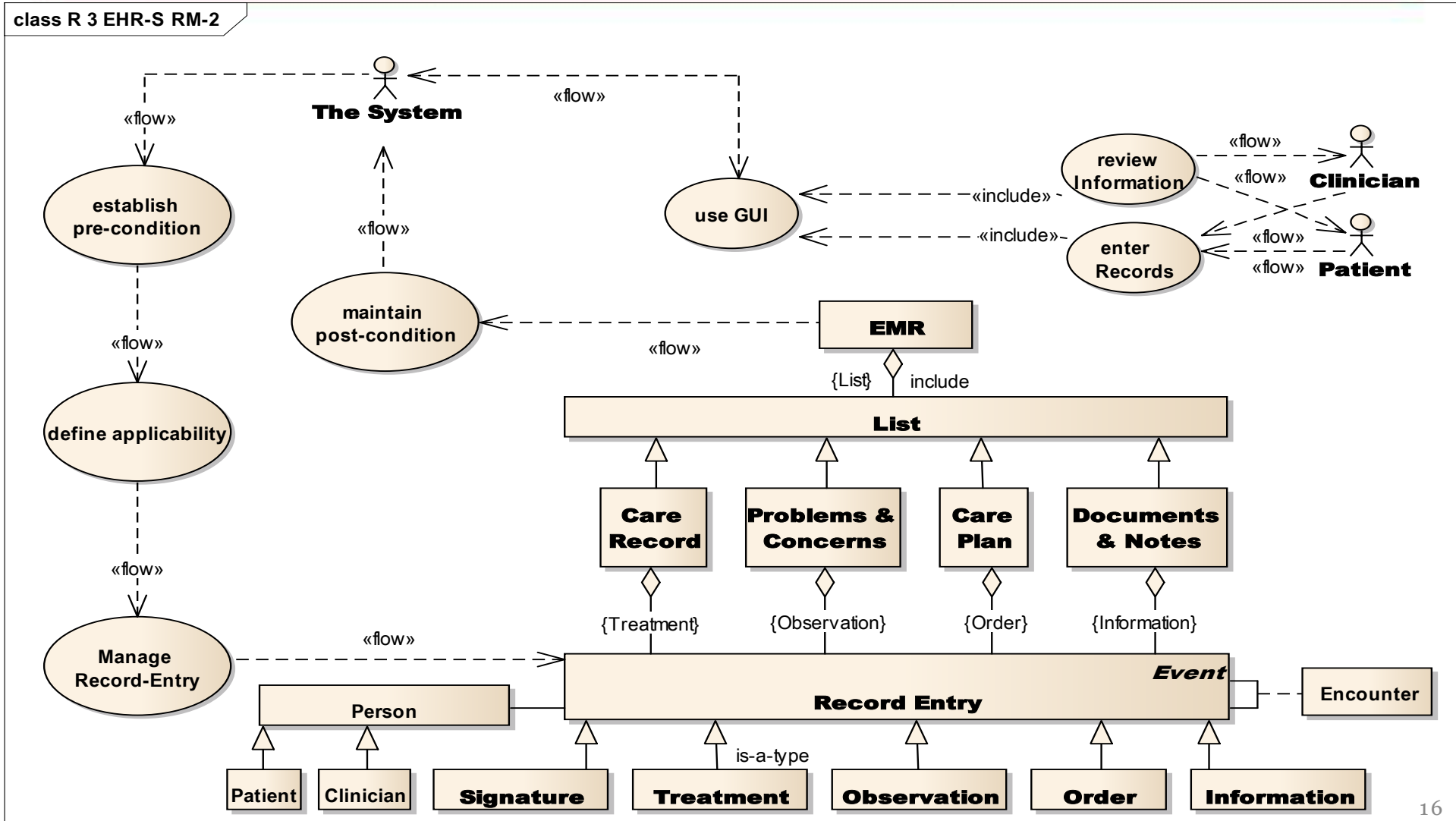


EHR-S RM Data Sub-Types aka Conceptual Information-Model

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



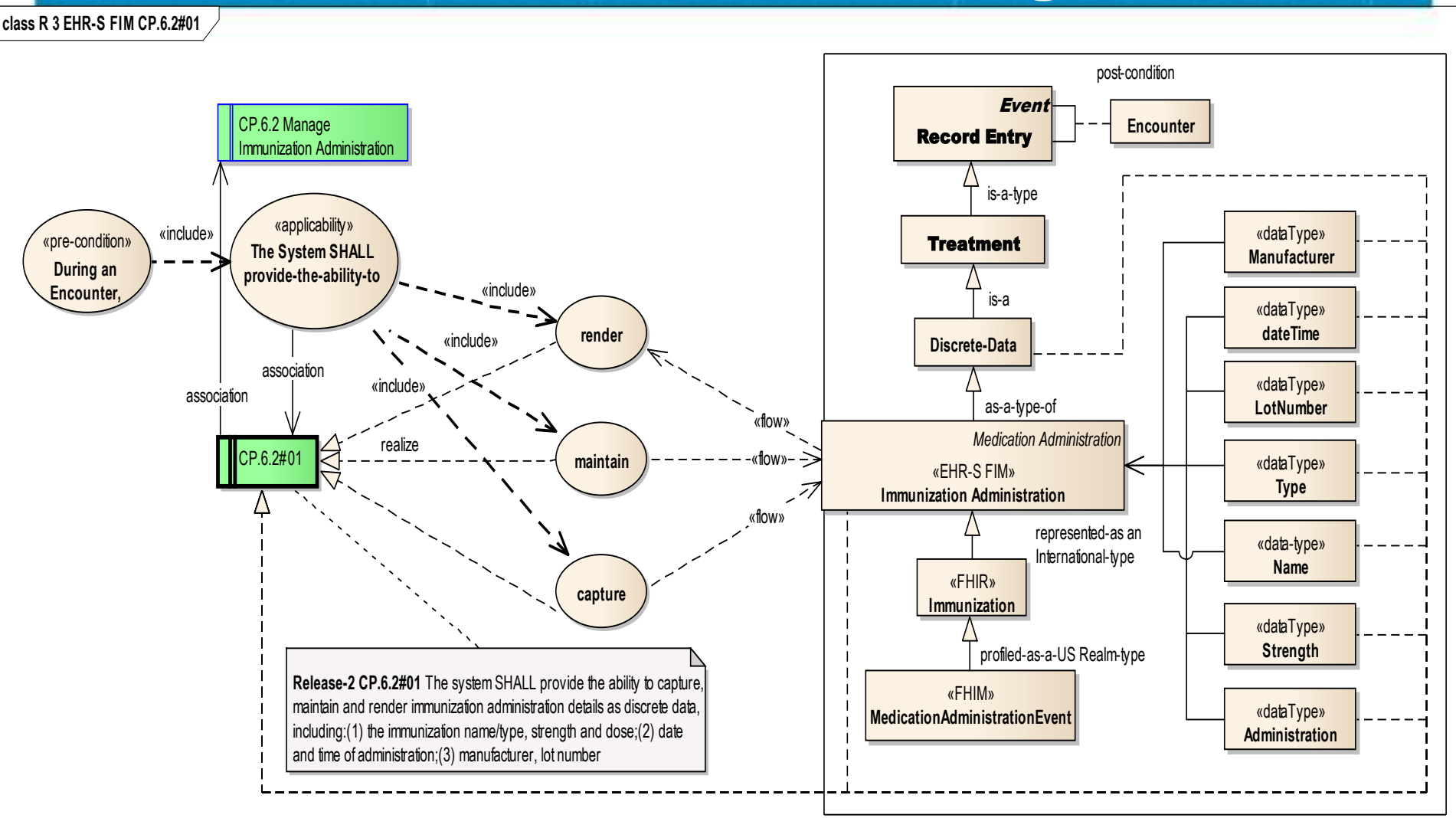
System Function (SF) Conformance Criteria RM



System Function (SF) Conformance Criteria RM

- **SF Invariant-condition** (context)
  - System Identifier (EHR or PHR)
  - System Function (SF) Identifier
  - Profile Identifier
- **SF CC Identifier** (Number)
- **SF CC Pre-condition** (trigger)
  - Pre-condition is a verb-clause.
  - After a Human-Action or System-Action; then,
- **SF CC Applicability**
  - The System SHALL, SHOULD or MAY
    - "provide-the-ability-to"
    - "directly"
- **SF CC System-Action Bindings**
  - Operation linked-to Data-Type; where, conditionally,
  - the *System-Actions depends-on* 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 CC Post-Condition** (expected-outcome)
  - Post-condition is a subordinate-clause.
  - "where, the System-Actions are …"
- **SF CC See Also**
  - Supporting or related SFs (e.g., Infrastructure)

Release EHR-S CC Model
CP.6.2#01 Immunization Management



Release 3 EHR-S CC Description
CP.6.2#01 Immunization Management

CP.6.2#01 During an Encounter, the system SHALL provide-the-ability-to *capture, maintain and render* Immunization Administration; where,

- Treatment Record-Entry details are as discrete-data, including
  - immunization name/type, strength and dose; date-and-time of administration;
  - manufacturer, lot number
- Immunization Administration can be realized-by FHIR; where,
  - Immunization-Administration is then associated with the following resources:
    - AdverseReaction and other Observations,
    - Patient , Practitioner, Organization, Location;
- Immunization-Administration can be realized-by FHIR-profiles based-on the US Realm FHIM Immunization and related Domains.

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 EHR-S RM (reference model) 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 Conceptual Information Model (CIM) and Conceptual Operations Model (COM) 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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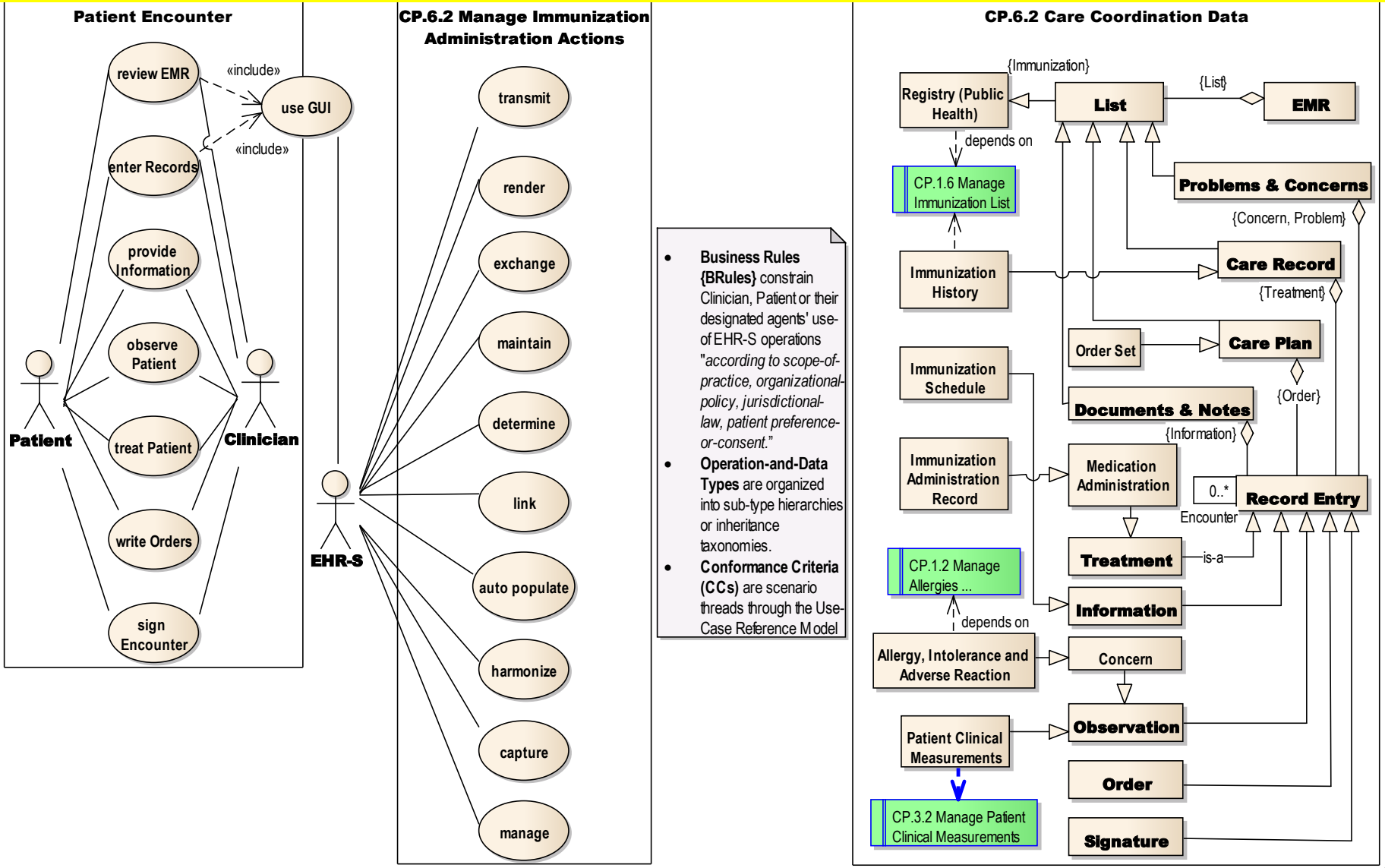
Initial EHR-S FM R2 CP.6.2
Reference Use-Case

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

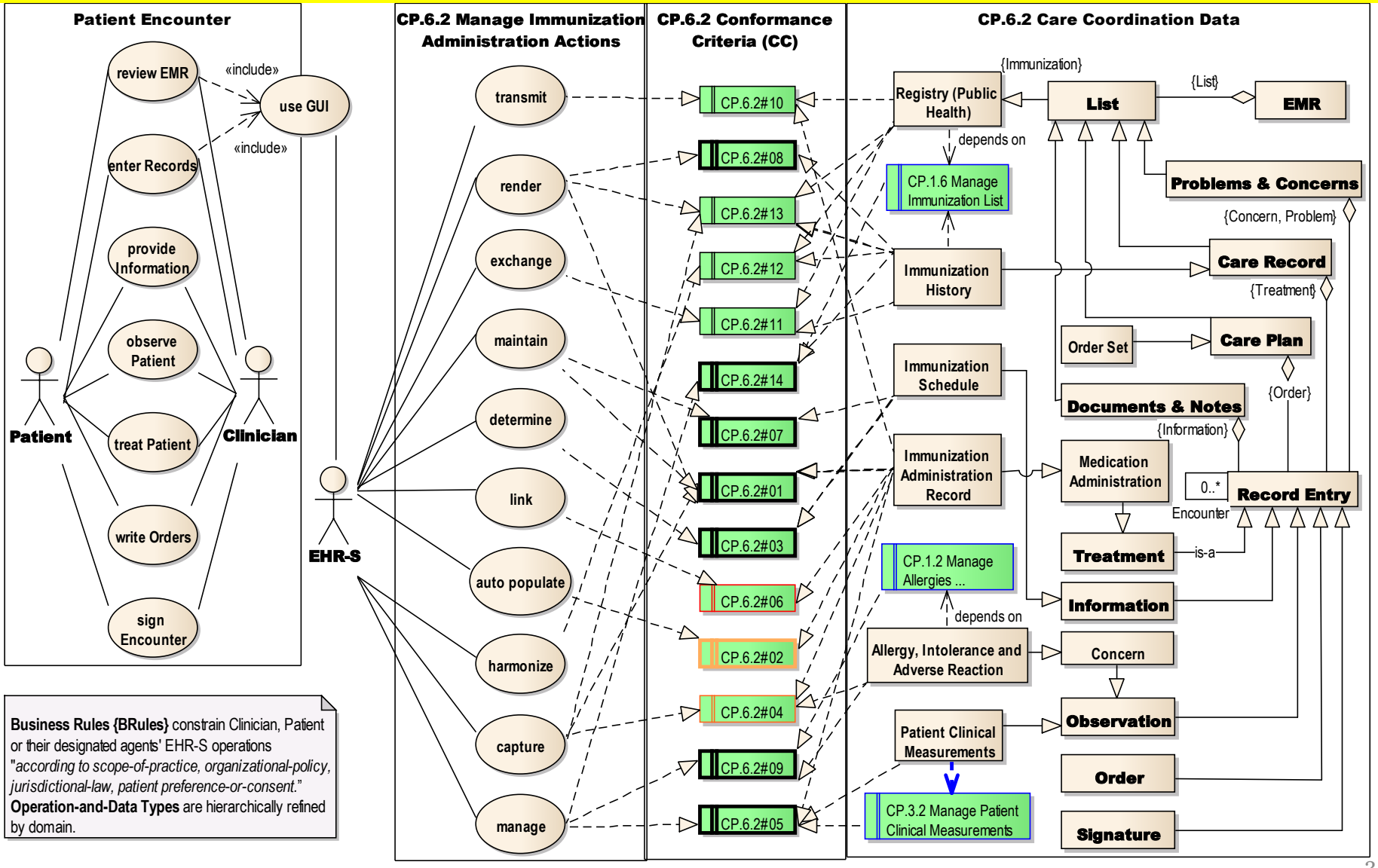
- **A Clinician *uses* the EHR-S, during an Encounter, to**
  - *review* EMR, Alerts-and-Notifications
  - *enter* Observations, Treatments, Orders and associated Documents and Notes
  - *sign* the Encounter
- **Immunization Management involves the following:**
  - **System-Actions:** *auto-populate, 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 | **System-Actions** | **Conceptual-Information Model**

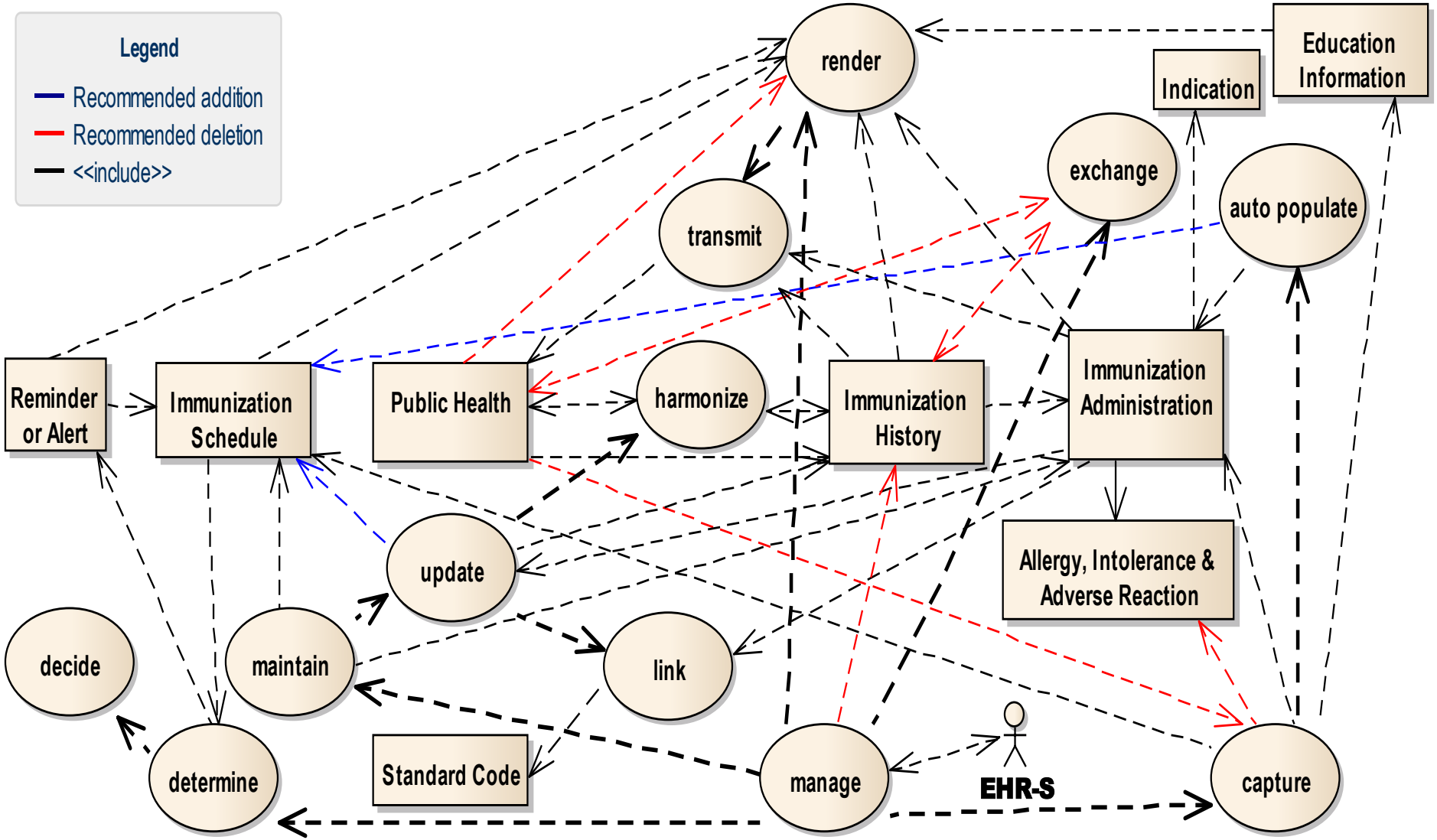


Initial EHR-S FM R2 CP.6.2 Conformance-Criteria

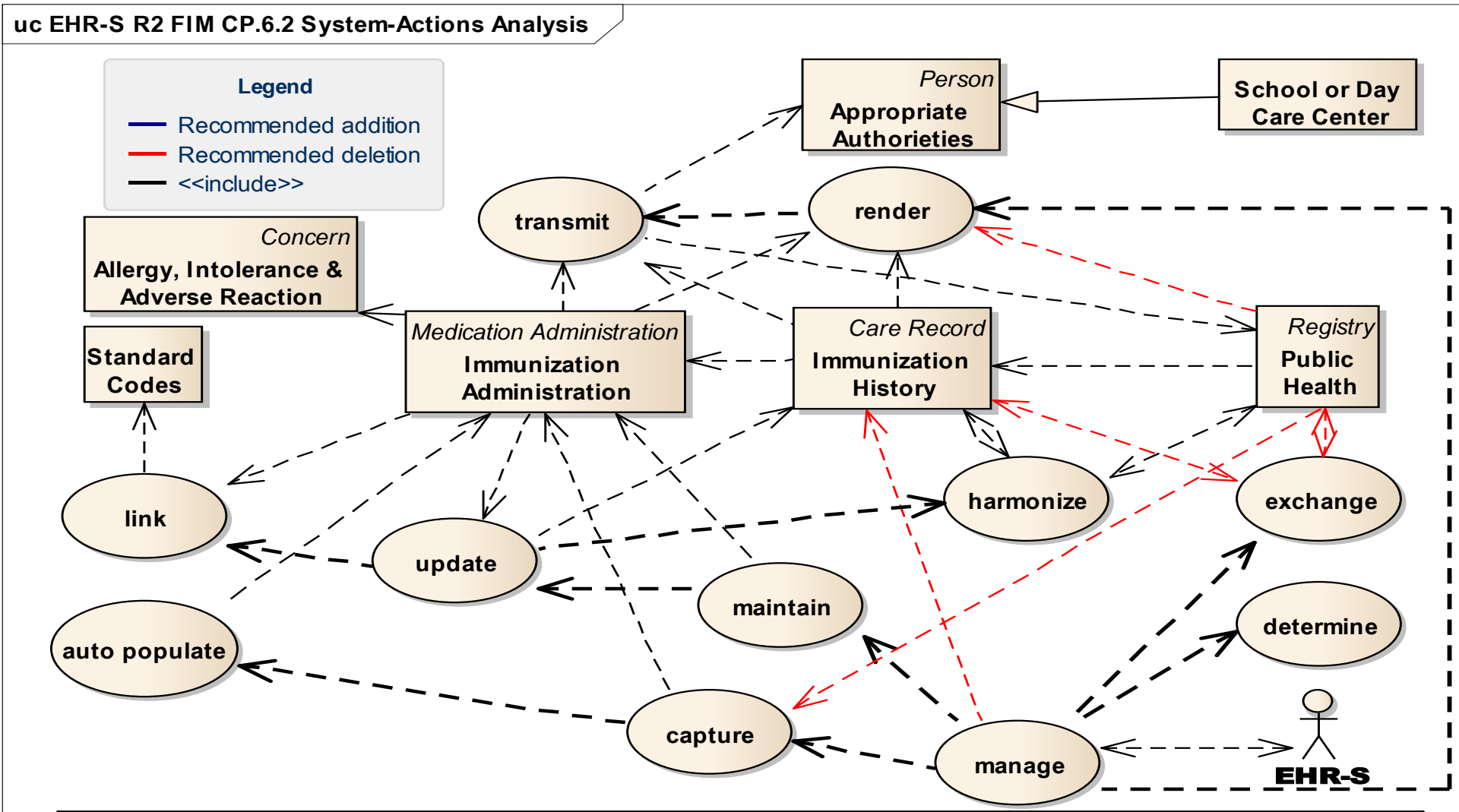


Initial EHR-S FM R2 CP.6.2
System-Actions based-on Release-2 CCs

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



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



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

The Release-3 EHR System Immunization-Management Function

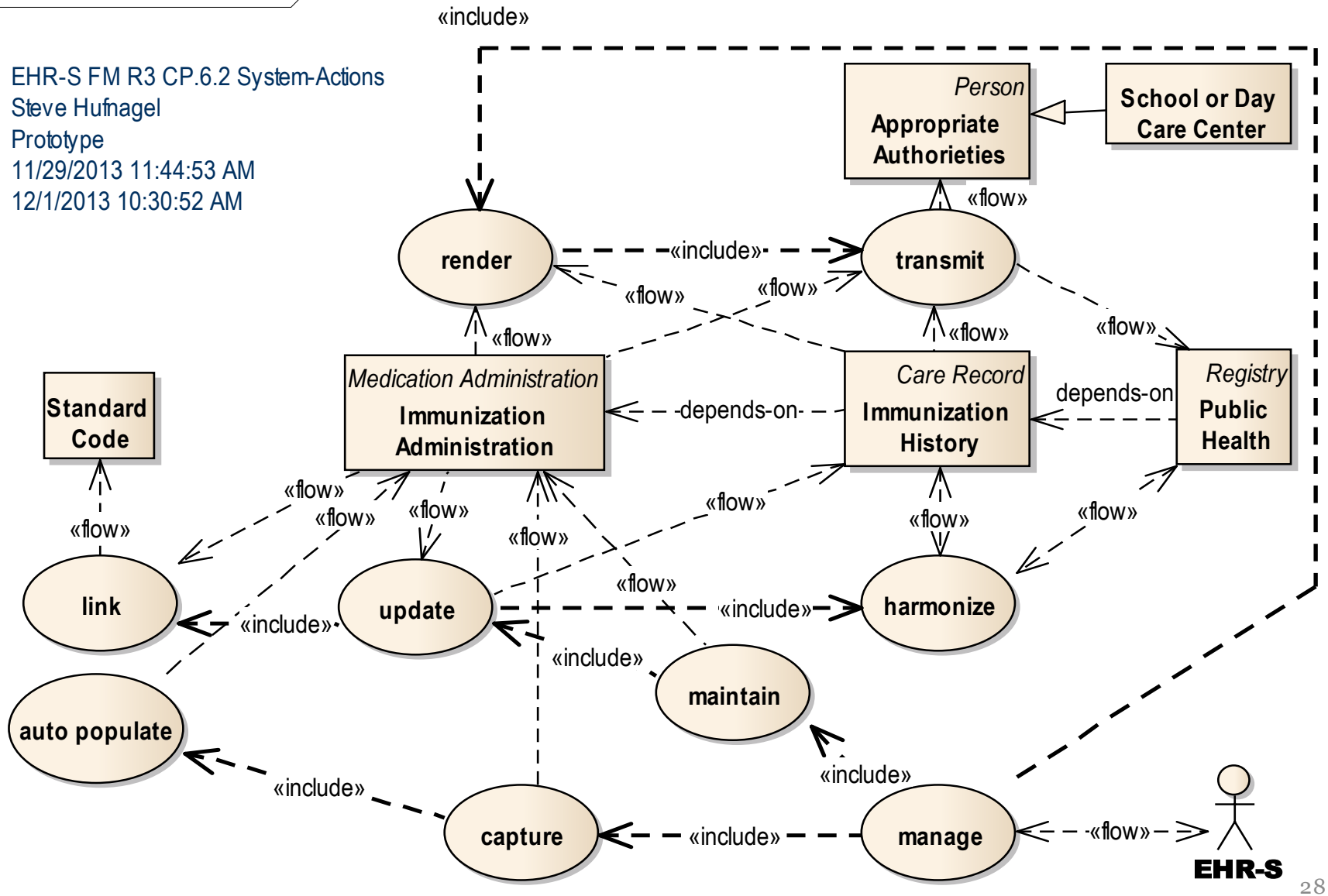
- *captures, auto-populates, links, renders, transmits, maintains* Immunization-Administration Record-Entries; where,
  - the *links* are with Standard-Codes
  - The *transmission* is to Population Health Registries
  - The *auto-population* is as a by-product of verification of Administering-Provider,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

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

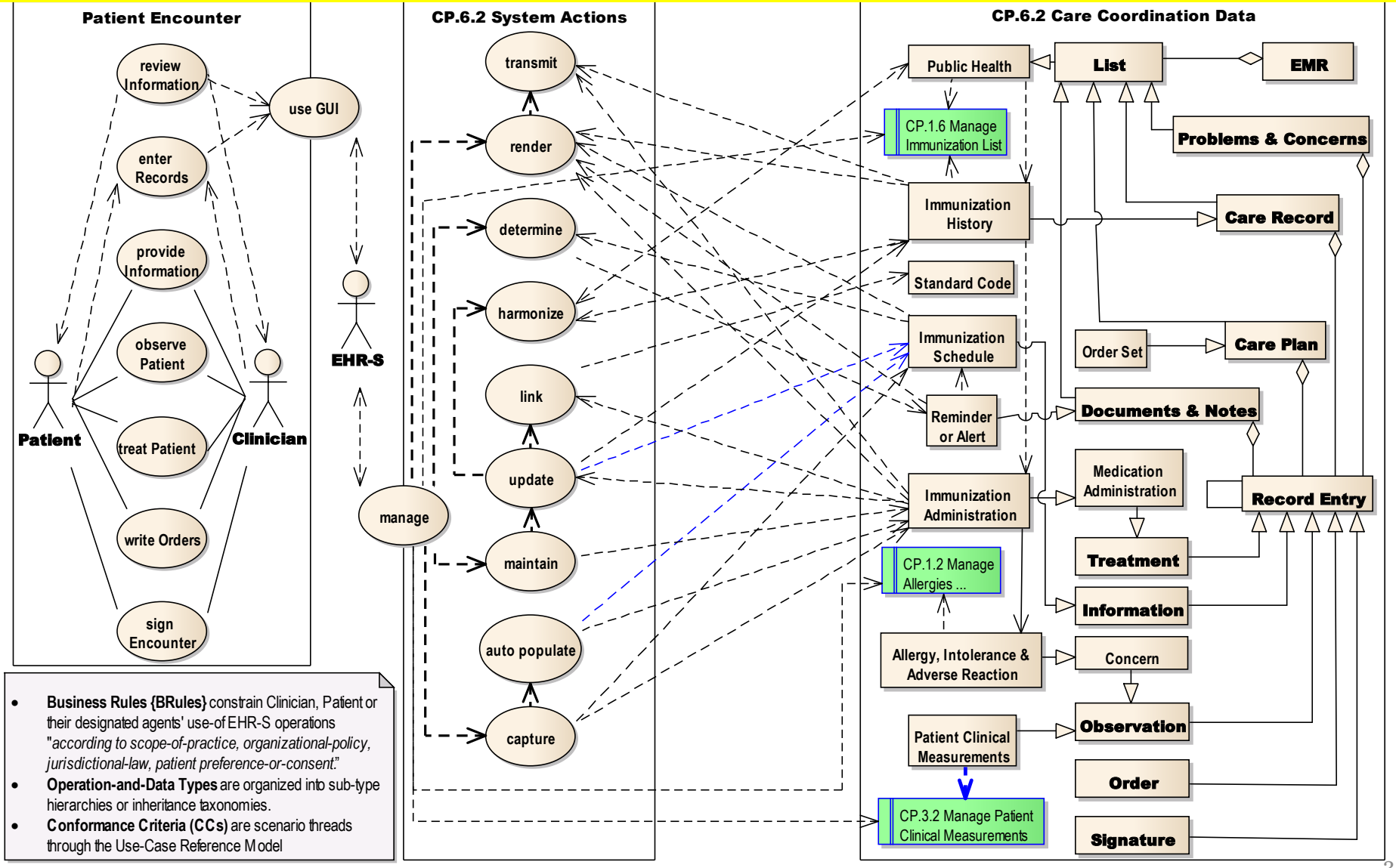
uc EHR-S FM R3 CP.6.2 System-Actions

Name: EHR-S FM R3 CP.6.2 System-Actions
Author: Steve Hufnagel
Version: Prototype
Created: 11/29/2013 11:44:53 AM
Updated: 12/1/2013 10:30:52 AM



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

Human-Actions | **System-Actions** | **CC Bindings** | **Conceptual-Information Model**



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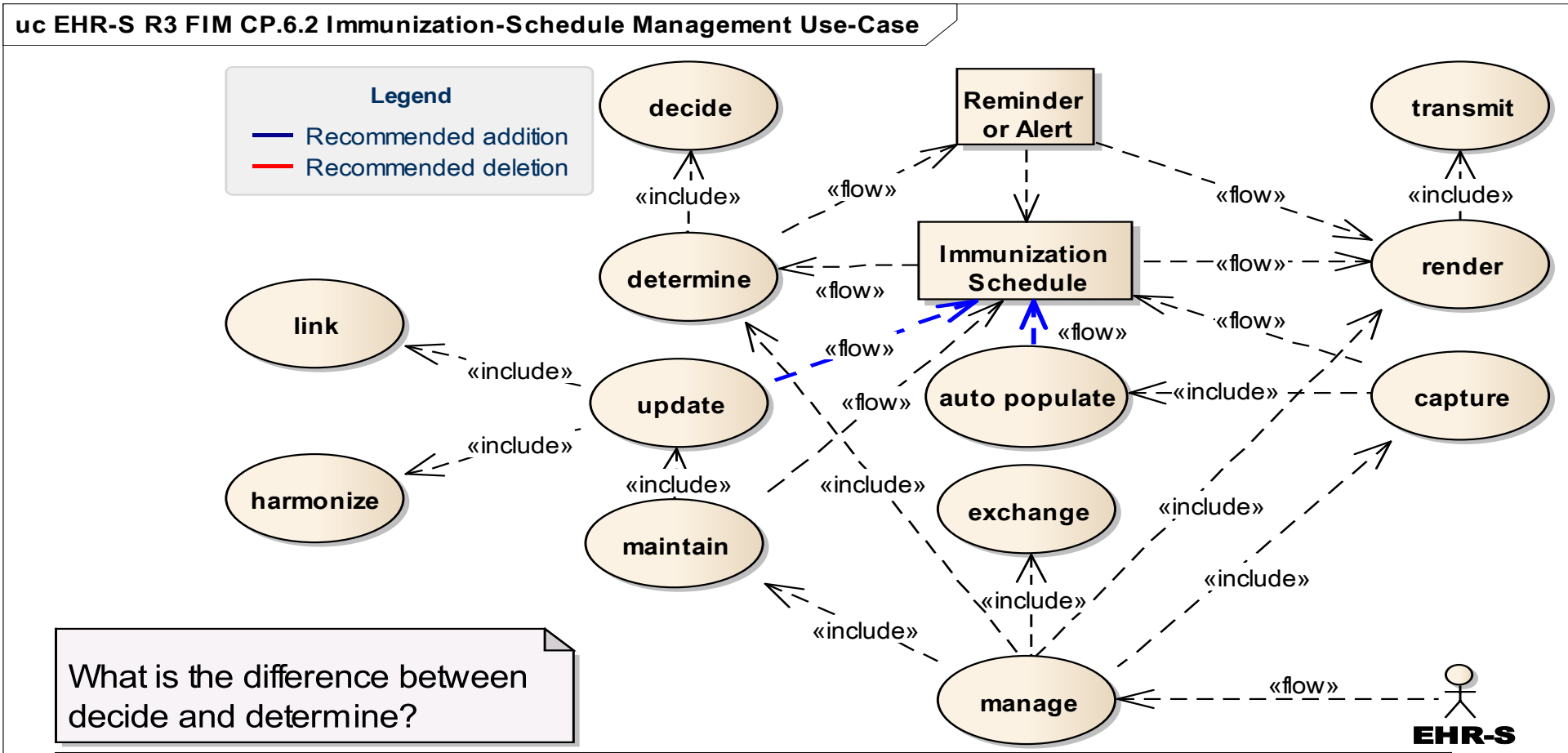
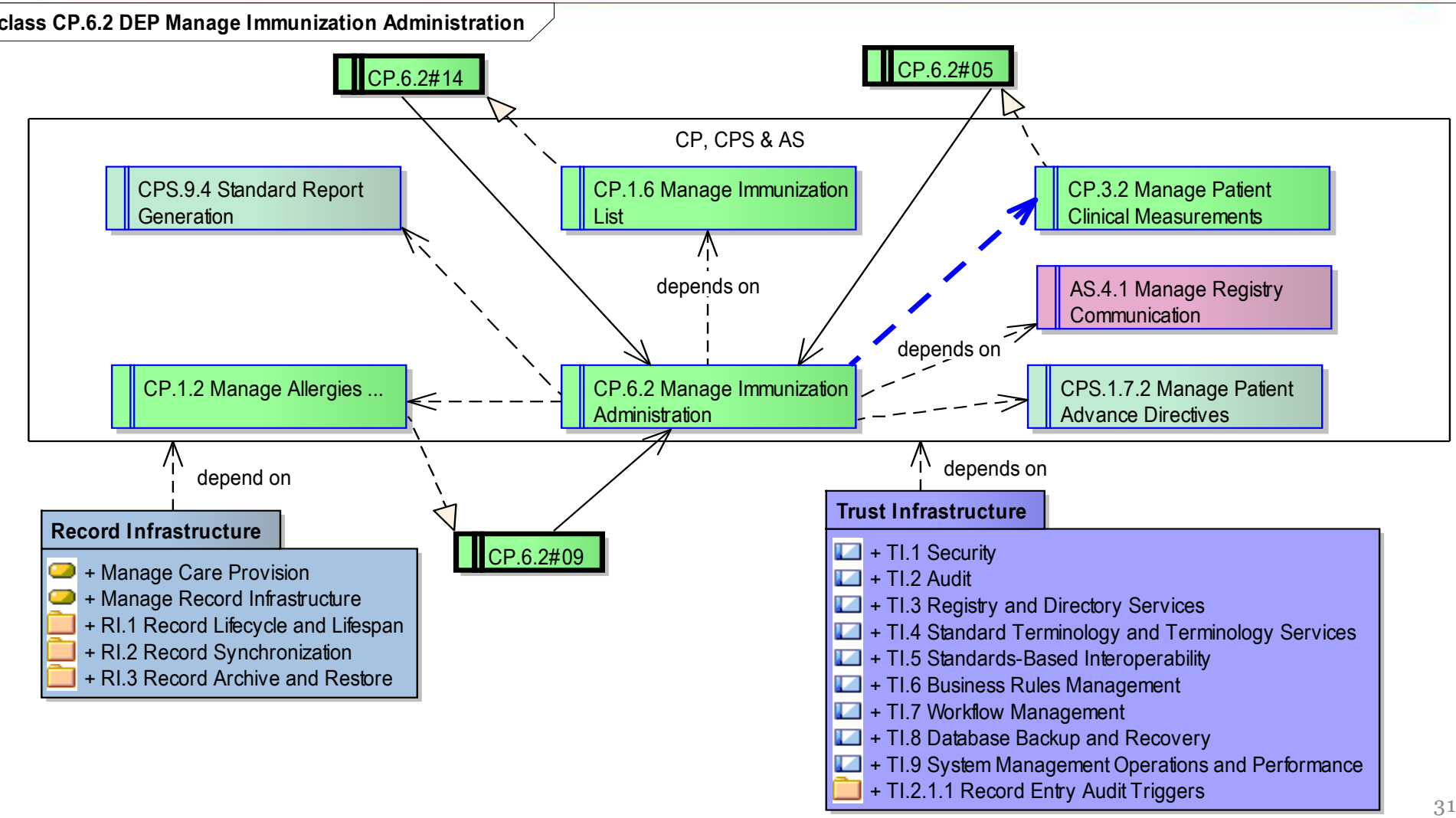
EHR-S FIM R3 Immunization-Schedule System-Actions



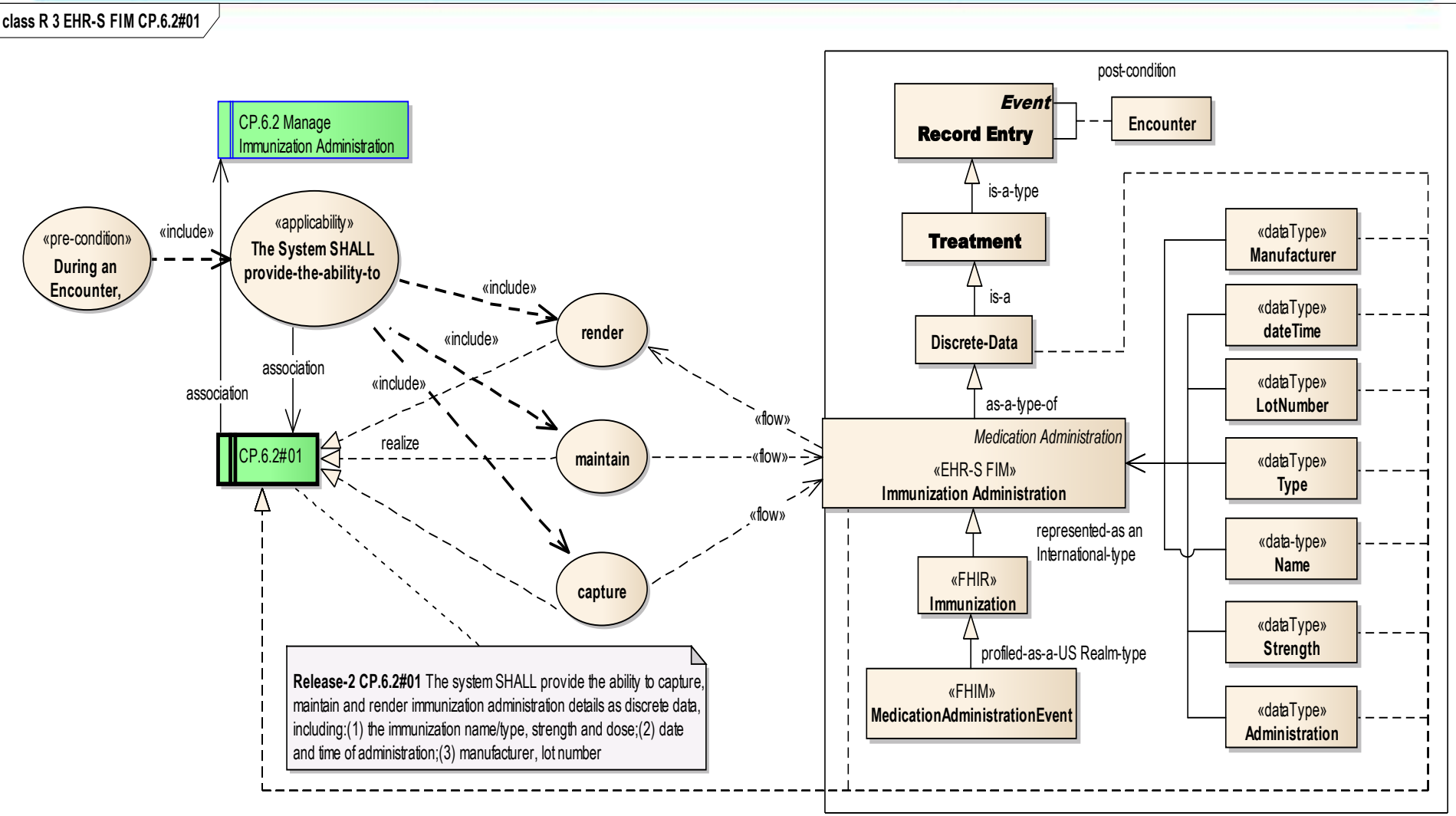
What is the difference between decide and determine?

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

Use-Case Dependencies
CP.6.2 Immunization Management



Release EHR-S CC Model
CP.6.2#01 Immunization Management



EHR-S-FM R2.0:2013 Conformance Criteria (CCs)

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-maintain-and-render an* Immunization-Administration;

- Treatment Record-Entry details are as discrete-data, including
  - immunization name/type, strength and dose; date-and-time of administration; manufacturer, lot number
- Immunization Administration can be realized-by FHIR; where,
  - Immunization-Administration is then associated with the following resources:
    - AdverseReaction and other Observations, Patient , Practitioner, Organization, Location;
- Immunization-Administration can be realized-by FHIR-profiles based-on the US Realm FHIM Immunization and related Domains.

EHR-S-FM R2.0:2013 Conformance Criteria (CCs)

CP.6.2 Immunization Management

***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 Immunization-Administration 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 Patient's Immunization-Schedule; where, the System-Actions are based on widely-accepted reference Immunization-Schedules.

EHR-S-FM R2.0:2013 Conformance Criteria (CCs)

CP.6.2 Immunization Management

***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 provide-the-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).

EHR-S-FM R2.0:2013 Conformance Criteria (CCs)

CP.6.2 Immunization Management

***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 Immunization-Administration, the system SHOULD provide-the-ability-to *link-to* Standard Codes; where, examples of Standard Codes 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 Immunization-Schedule.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

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 Patient's Immunization History; 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).

EHR-S-FM R2.0:2013 Conformance Criteria (CCs)

CP.6.2 Immunization Management

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* Immunization-Administration information; where, System-Actions are with Public-Health Immunization-Registries; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

exchange **Immunization History**

- **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 Public-Health Immunization-Registries; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

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 Public Health Immunization Registry; 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.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

manage Immunization-Administration 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 Immunization-Administration, the system SHOULD provide-the-ability-to *update* Immunization-Histories.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

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* Immunization-Administration Information, the system **SHALL** provide-the-ability-to *render* the Immunization Order; where, the Immunization Order 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.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

***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 Immunization-Administration Encounter, the system **SHALL** provide-the-ability-to *render* Patient Educational-Information; where, the System-Action is regarding the Immunization-Administration (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 Immunization-Administration, the system **SHALL** provide-the-ability-to *capture* an Indication; where, System-Actions are confirming-that Patient Educational Information (e.g., VIS) was provided.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

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 Immunization Administration, the system **SHALL** provide-the-ability-to *capture* Event Documentation; 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 Immunization-Administration Encounter and when Patient Education-Information is provided, the system **SHALL** provide-the-ability-to *capture* the Entity; where, the System-Actions identify the patient, representative or organization receiving the Patient Education-Information.

EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

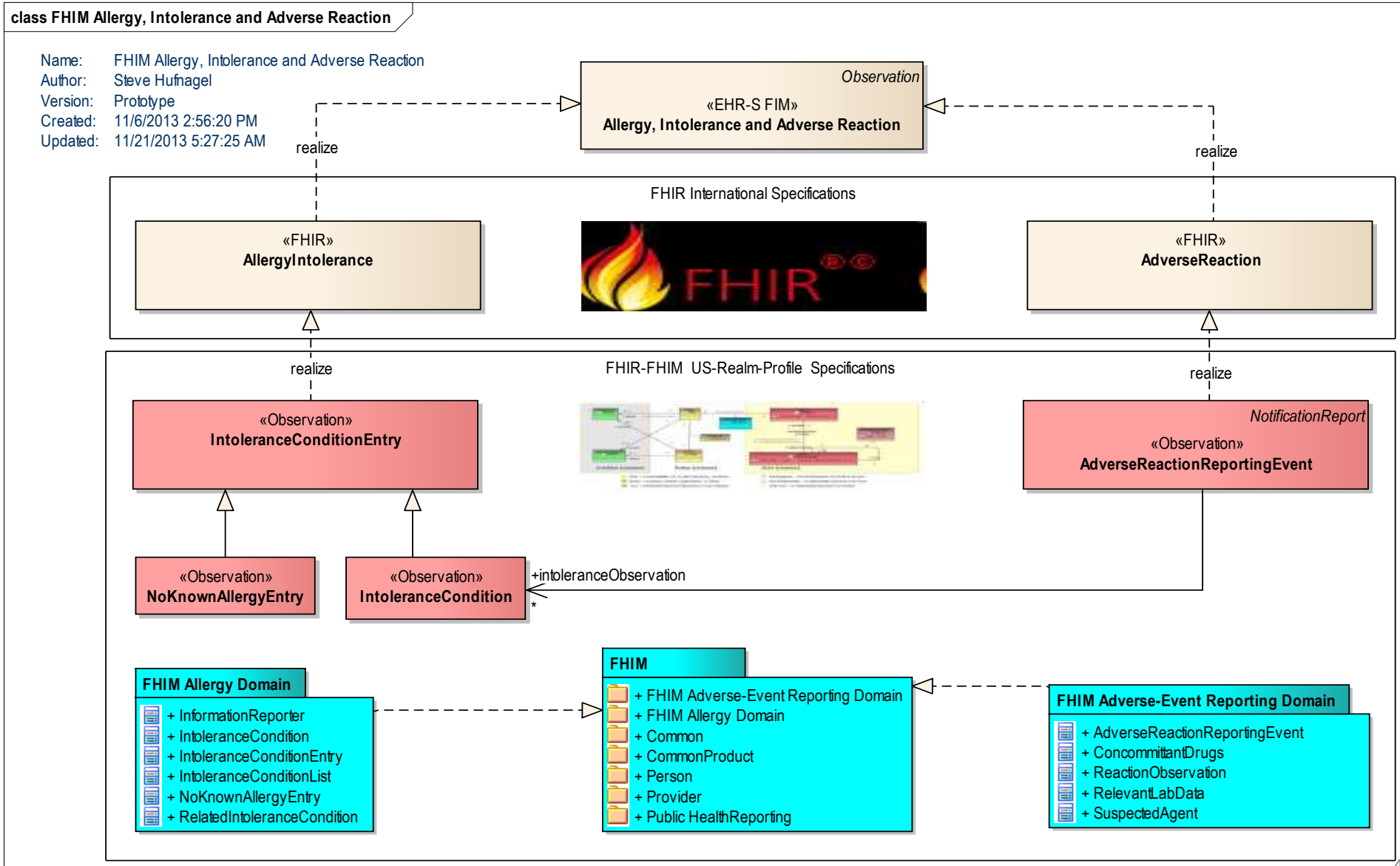
***capture and maintain* Justification**

- **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 Immunization-Administration is refused, the system SHOULD provide-the-ability-to *capture-and-maintain* Justification; where, System-Actions are to document the Justification as discrete-data-elements.

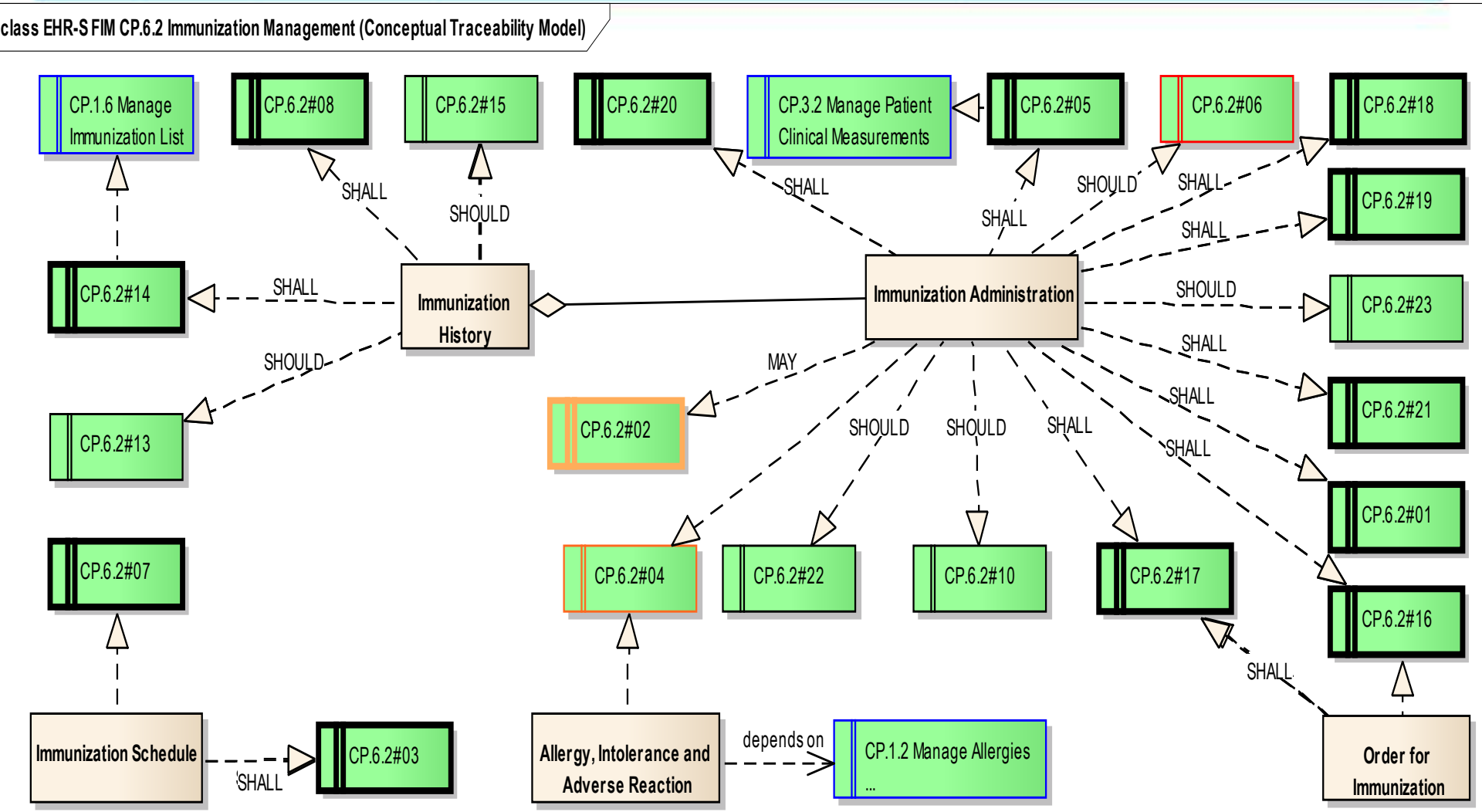
***capture* Patient's Preference**

- **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.

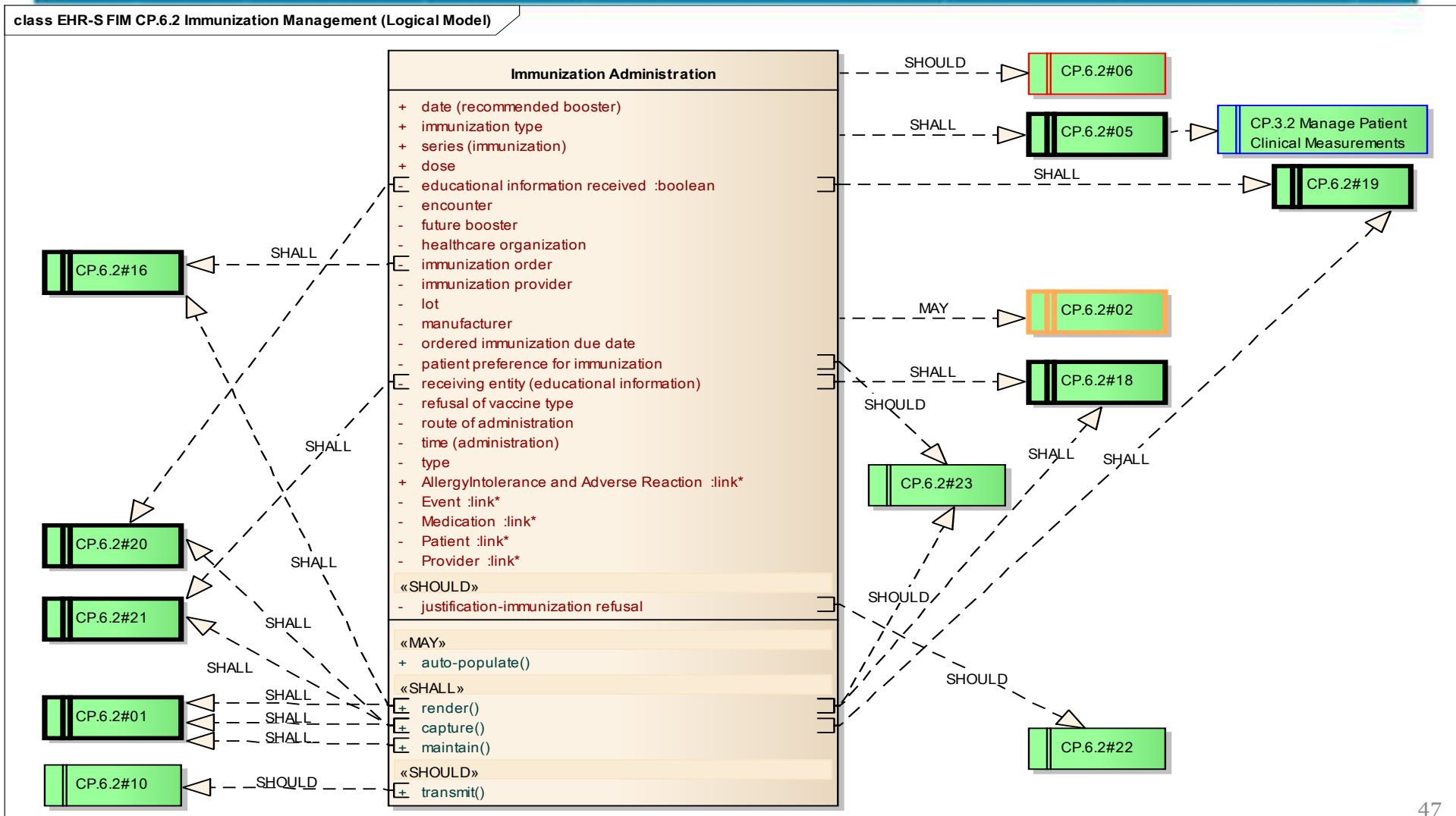
Example Linkage-to FHIR & FHIM for Allergy, Intolerance & Adverse-Reaction



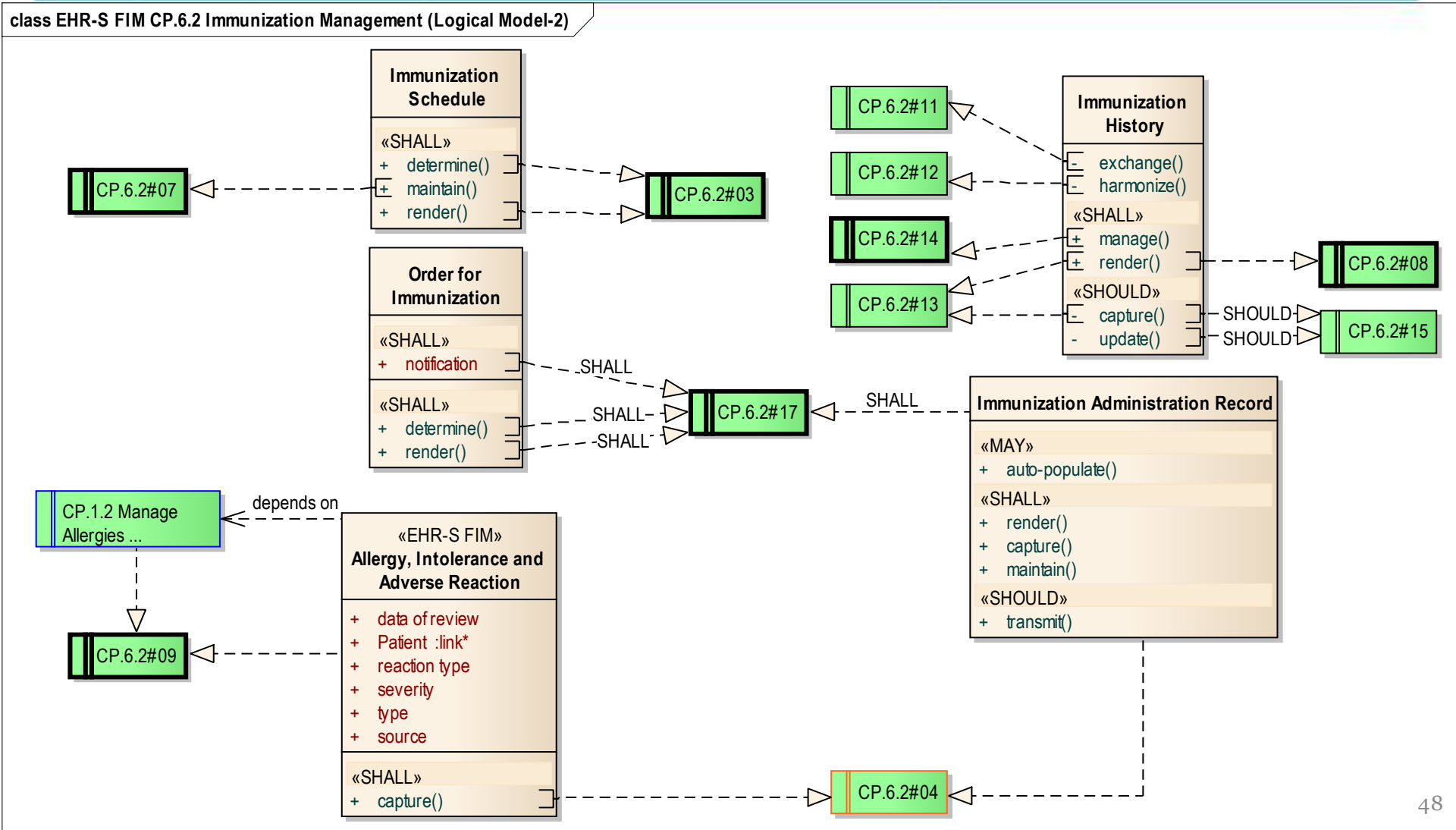
EHR-S-FIM
Conceptual Traceability Model
CP.6.2 Immunization Management



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

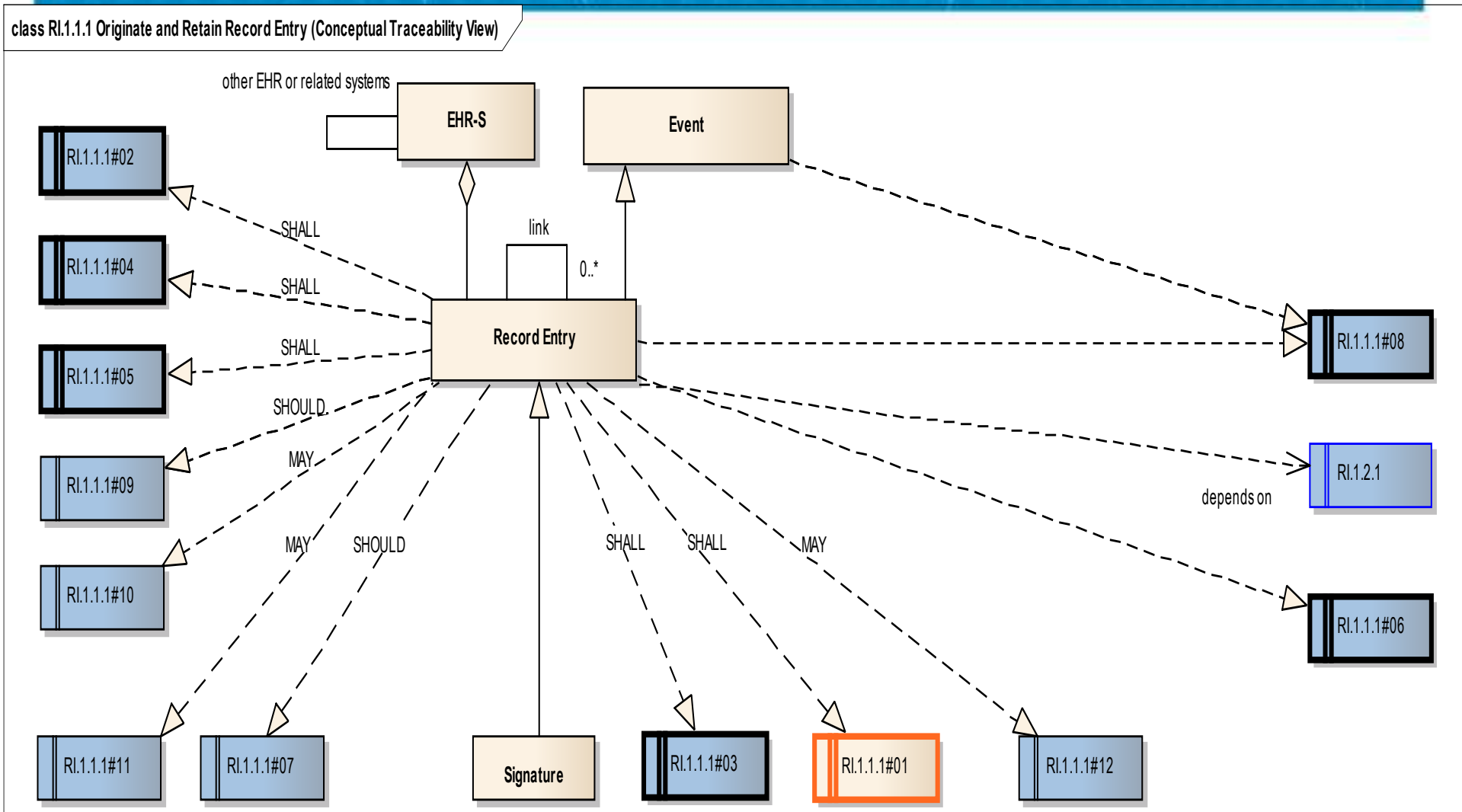
- Based on the Medication Management, Orders Management and Immunization Management functions, we see
  - A high-level EHR-S Information Model emerging as a set of
    - Patients, Providers, External Partners, Encounters, EMRs, Care Plans, Lists , Managers, Documents and Notes;
  - A high-level EHR-S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

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

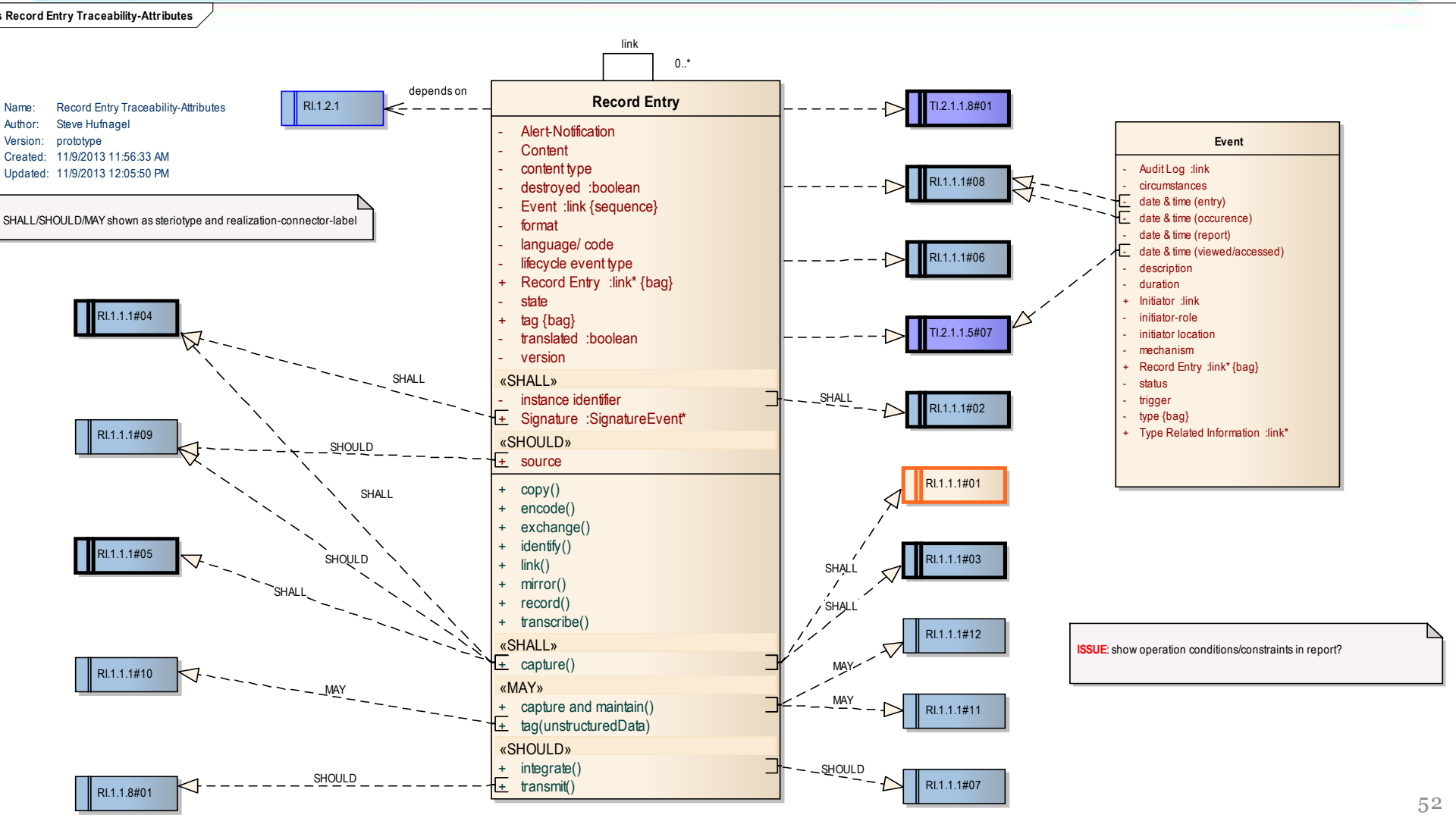
1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operations Reference Use-Case and Model
3. CP.6.2 Immunization-Management Deep-Dive
4. **RI.1.1.1 Originate-and-Retain Record-Entry Deep-Dive**
5. EHR-S FIM linked-to FHIR for Allergy, Intolerance and Adverse-Reaction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

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

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



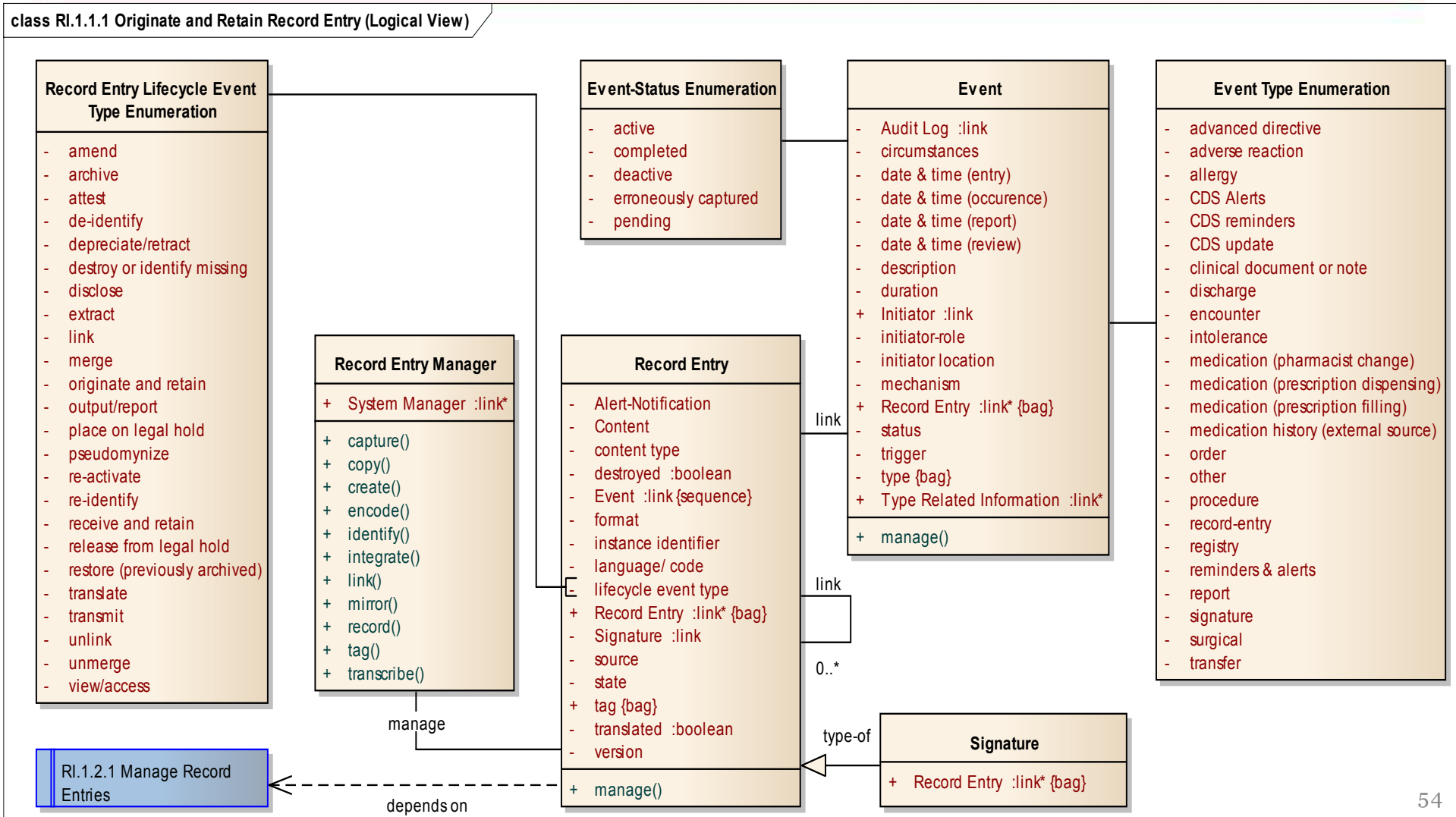
EHR-S FIM
Traceability View
RI.1.1.1 Originate-and-Retain Record Entry



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

1. RI.1.1.1#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 function TI.2.1.1.1 (Originate/Retain Record Entry Audit Trigger), including specified metadata.
4. 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.1.1.1#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



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

Resultant Description (Notional Scenario)

- The EHR-S Record-Entry 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 Record-Entries, Events, Record Entries and a Record Entry Manager
- which can *Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate*
  - structured-data or unstructured-data and link-to
  - associated Event-Metadata and Signature.