



Monthly Summary Briefing

HL7 EHR Work Group (EHR-WG)



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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 and easy-to-use EHR-S FIM r3.0 in the Sparx Systems Enterprise Architect (EA) tool; where, VA issues with the r2.0 ballot are resolved.
 2. to produce a Meaningful Use profile for r2.0 and as-a-part-of r3.0.
- **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: <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](http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG), dated December-2013 is available at http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

EHR-S FIM Acronyms

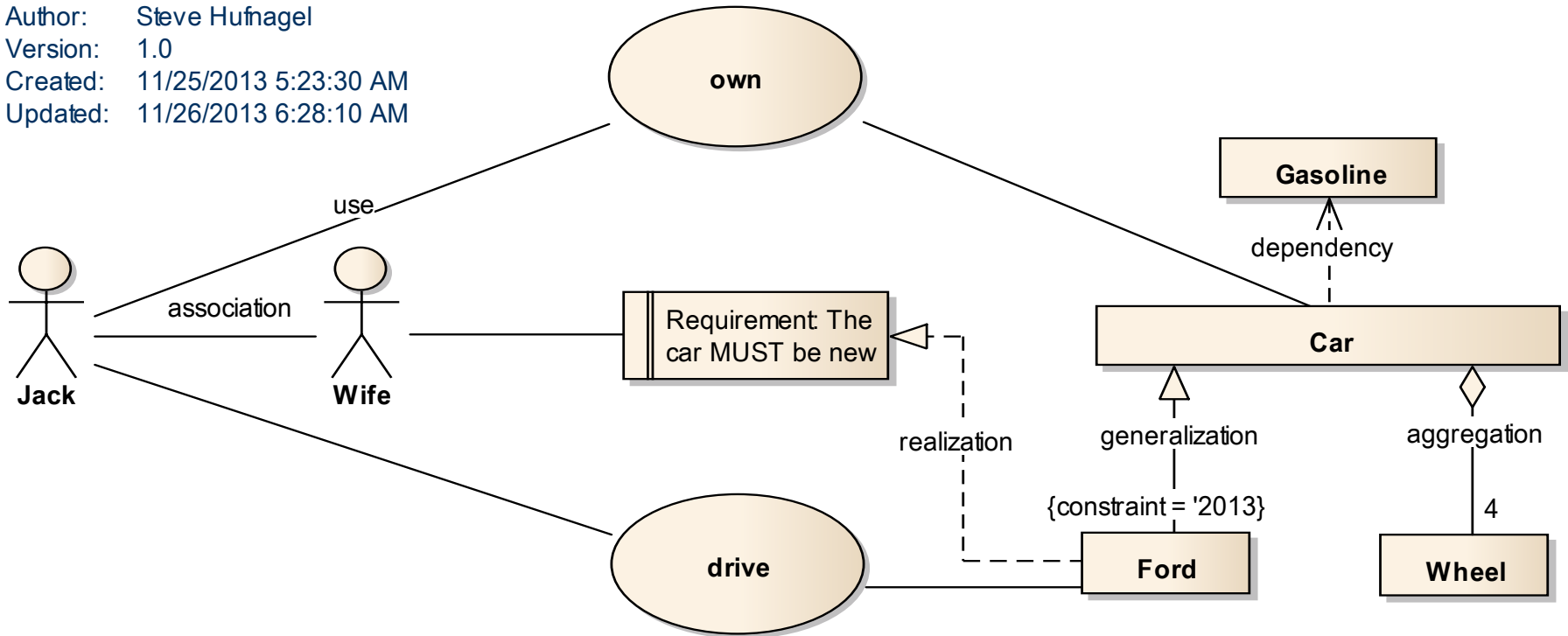
- **aka** also known as
- **CC** EHR-S FIM Conformance Criteria
- **CDA** **Clinical Document Architecture**
- **DD** Data Dictionary
- **CIM** Conceptual Information Model
- **CP** Care Provision
- **CPS** Care Provisioning Support
- **EA** Enterprise Architect
- **EHR-S** EHR System
- **EHR-S FIM** 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, intuitive and 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 FHIR (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

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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EHR-S RM

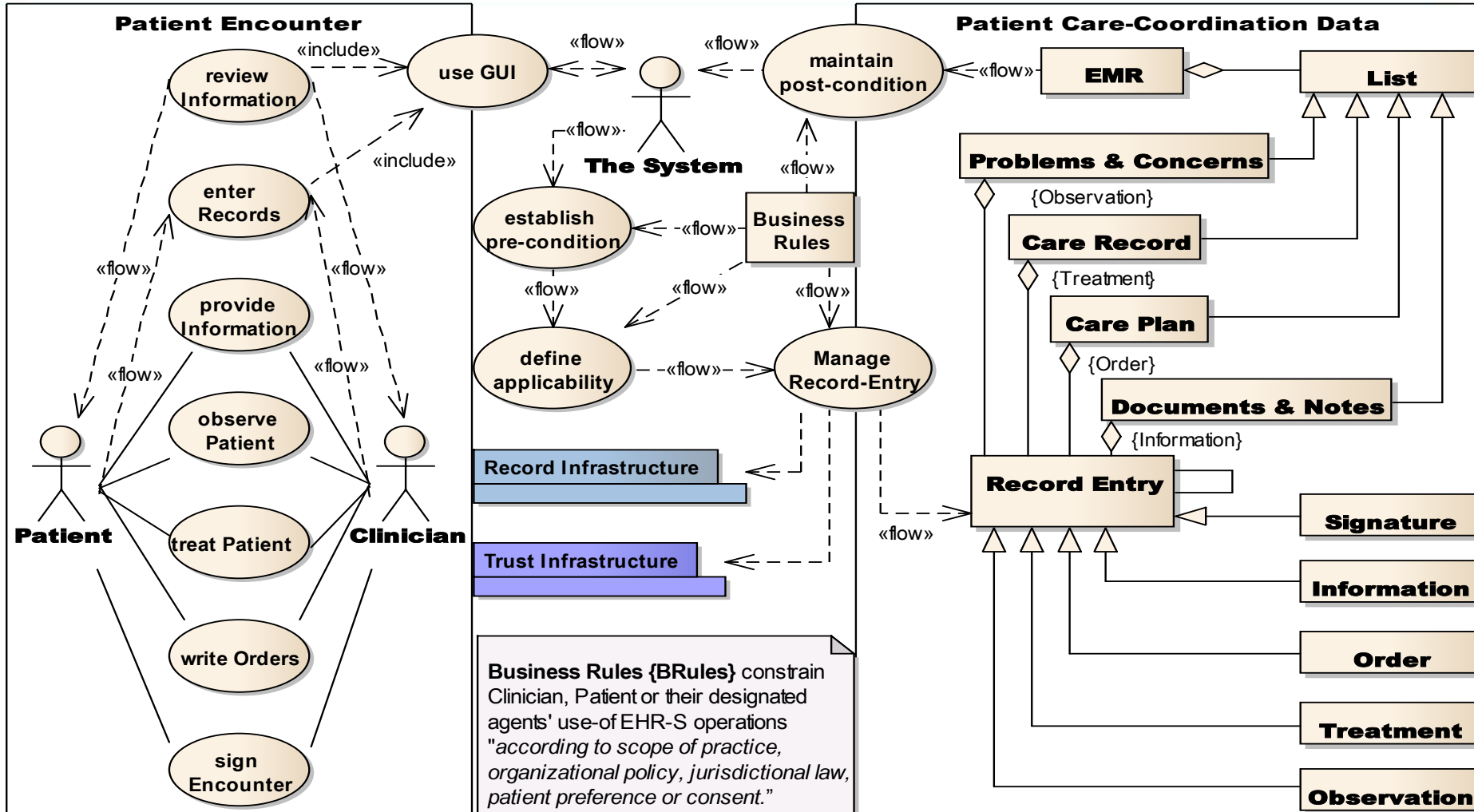
Concept-of-Operations (CONOPS)

Reference-Model (RM)

Humans-Actions

System-Actions

Conceptual-Information-Model



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

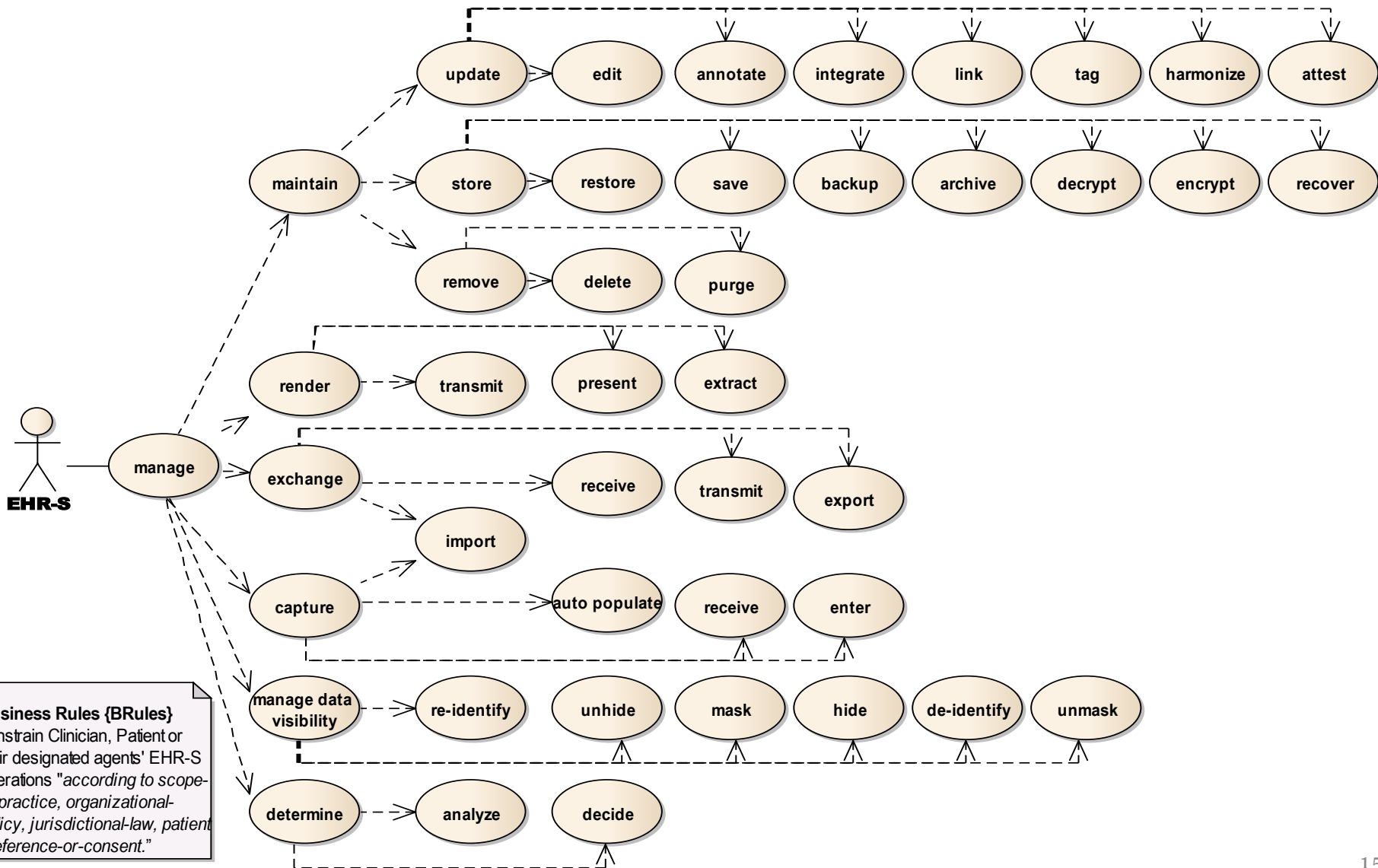
A Clinician and Patient and/or their designated Agents have Encounters; where, they *use an* EHR-S (EHR System) GUI (Graphical-User-Interface) to *manage* EMRs (Electronic Medical Records), in accordance with scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences; where,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



uc EHR-S Manager Anatomy (Verb Hierarchy)



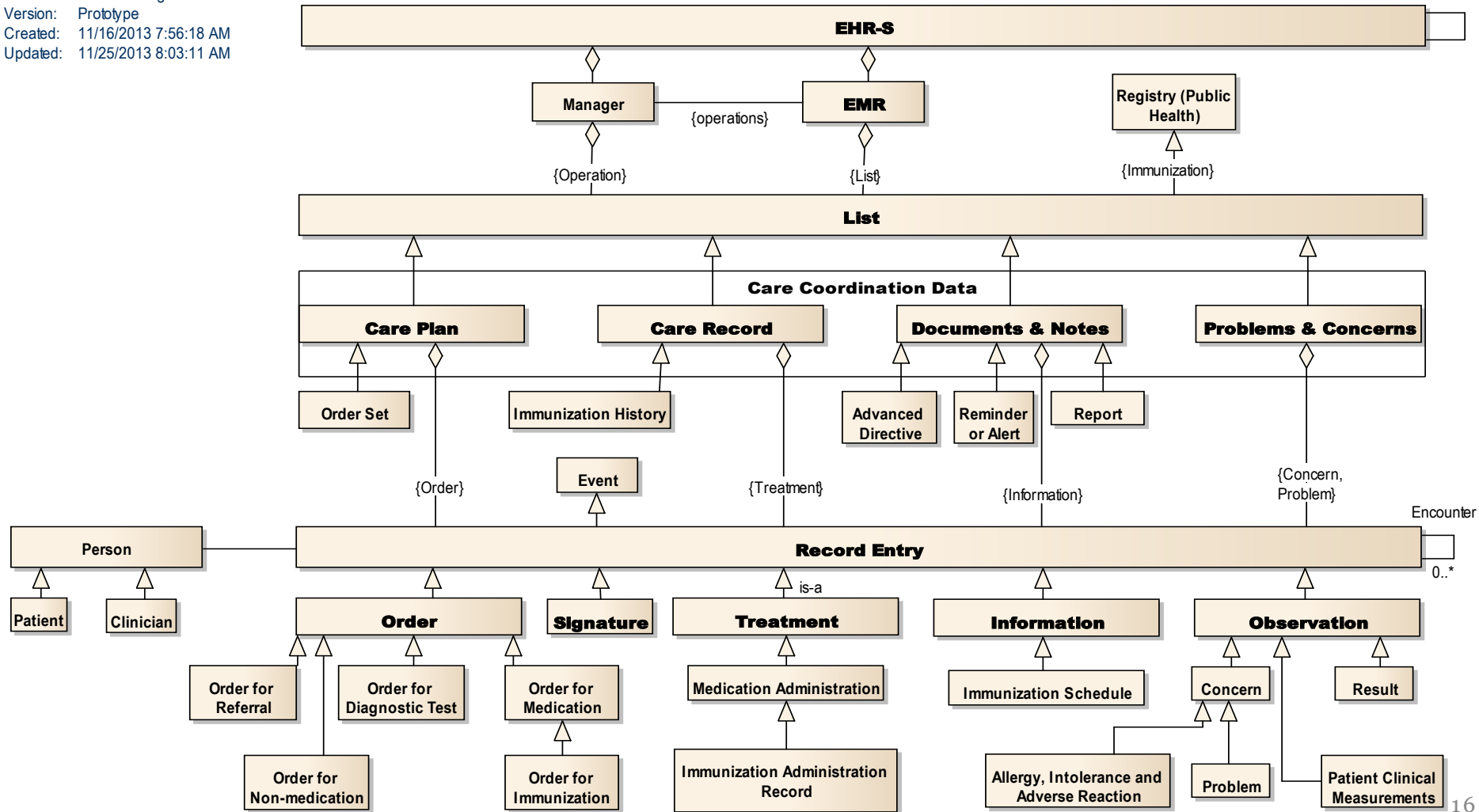
Business Rules (BRules)
 constrain Clinician, Patient or
 their designated agents' EHR-S
 operations "according to scope-
 of-practice, organizational-
 policy, jurisdictional-law, patient
 preference-or-consent."

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

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

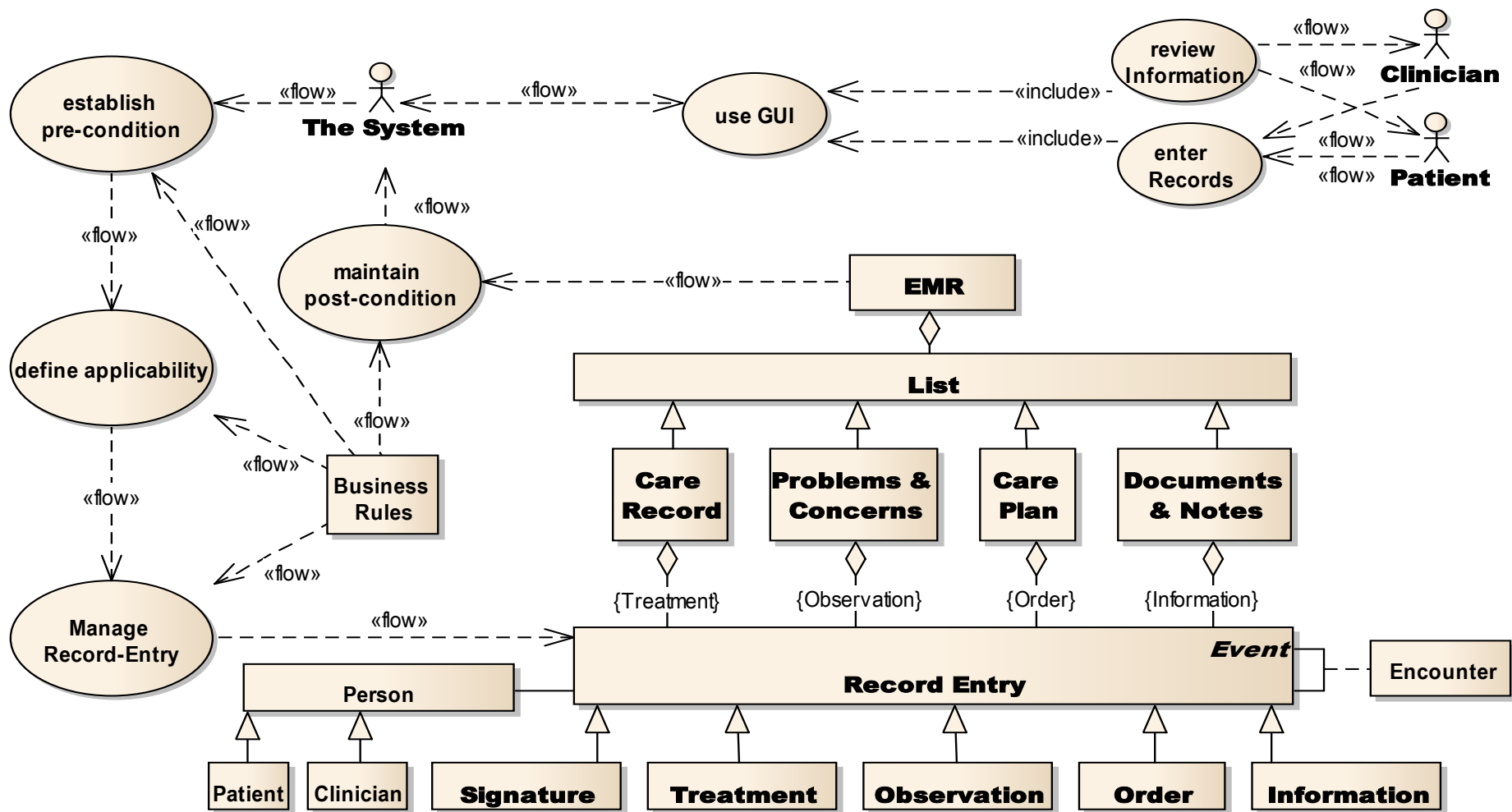
Name: EHR-S FIM Conceptual Information Model (4 Levels)
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/16/2013 7:56:18 AM
 Updated: 11/25/2013 8:03:11 AM

other EHR or related systems



System Reference Model

class R 3 EHR-S RM



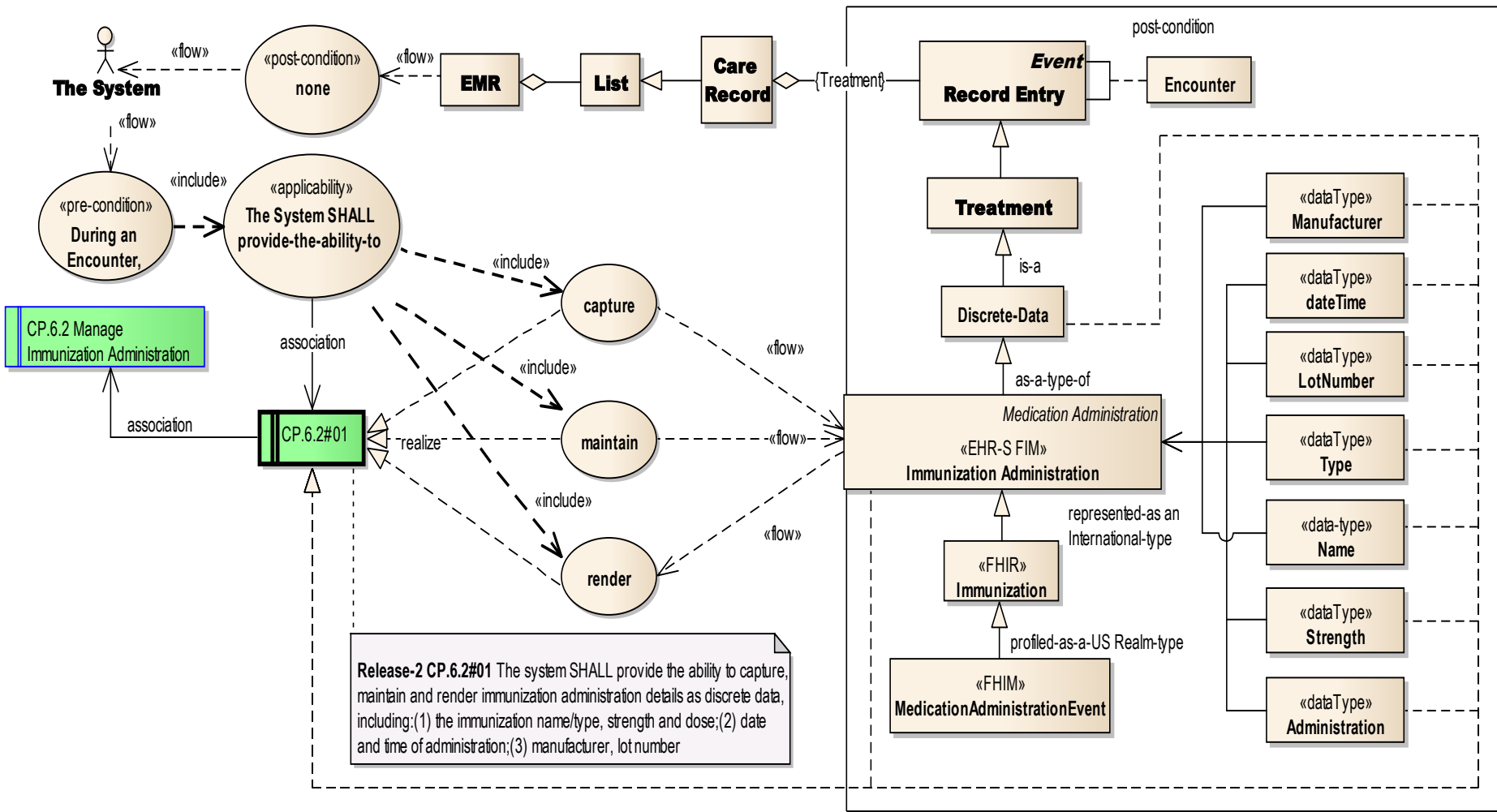
System Reference Model (RM)

- **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 3 EHR-S

CP.6.2#01 Immunization Management Model

class R3 EHR-S FIM CP.6.2#01



■ Release 3 EHR-S

CP.6.2#01 Immunization Management Scenario

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 Conclusion



EHR-or-PHR System-Functions are defined-by

1. Use-Cases of System-Actions, can be UML modelled; where, Use-Case/UML nouns-and-verbs define a lexicon-of

1. System-Action-types verb-hierarchy and
2. Record-Entry-types data-model; where,

2. Conformance-Criteria are System-Action Use-Case Scenario-threads; where, Scenario-Context is defined by

1. pre-condition triggers,
2. applicability of
 1. SHOULD/SHALL/MAY plus
 2. “provide-the-ability-to” or “directly”
3. post-condition Business-Rules are according-to scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences; where,

3. Information-Exchanges are defined-by Conformance-Criteria Scenarios mapped to

- 1. FHIR** (Fast Healthcare Interoperability Resource) representative of the International-Realm,
- 2. FHIM** (Federal Health Information Model) representative of US-Realm FHIR-profiles,
- 3. IHE** behavioral-protocols, refined by,
 1. local-workflow behavioral-protocols and associated
 2. Key Performance Parameters (KPPs); thereby,

4. Profiles are specified by sets-of System-Functions and their constrained context; where,

5. Interoperability-Specifications can then be generate from Profiles.

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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,”

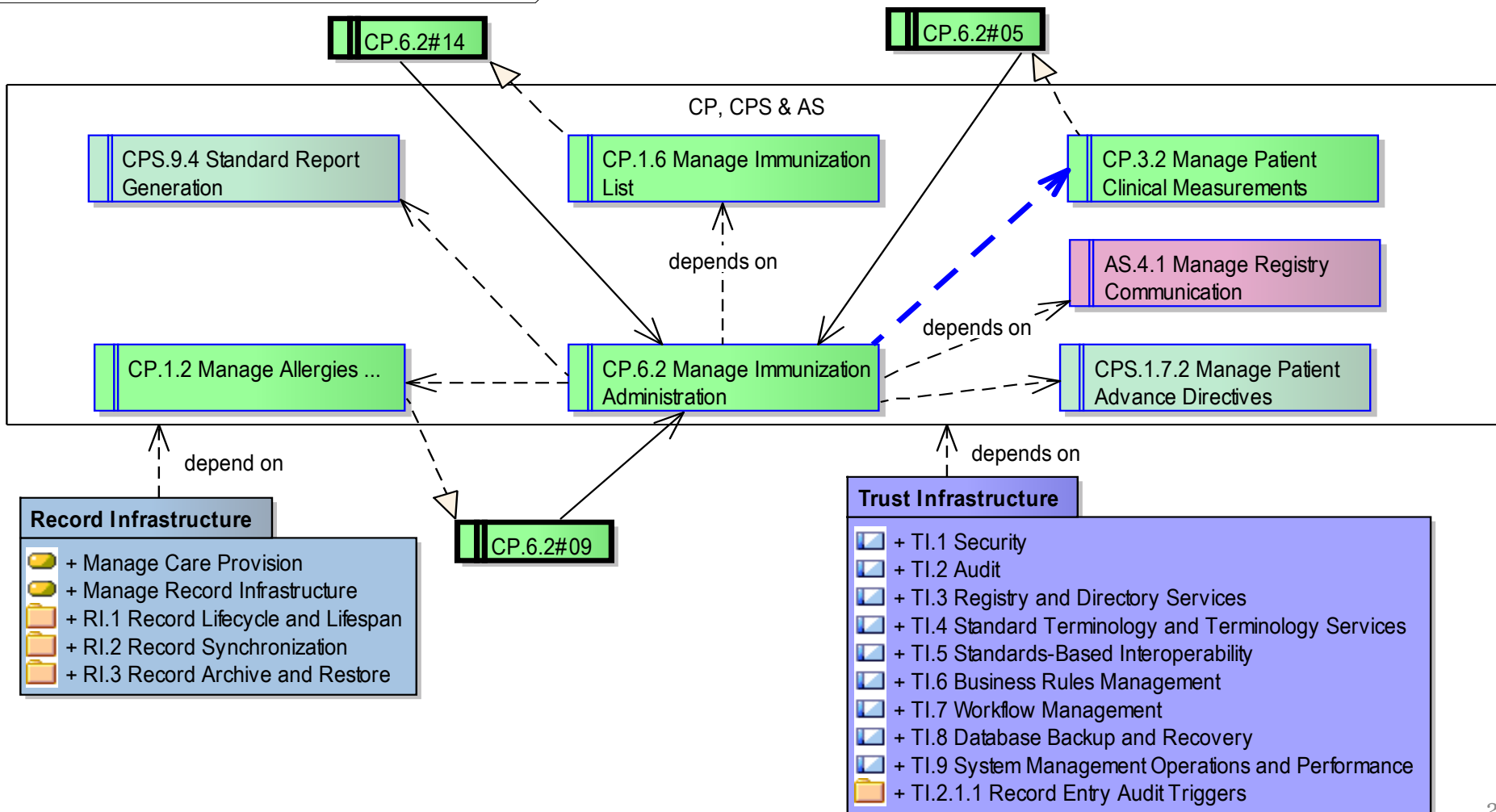
- **A Clinician uses the EHR-S, during an Encounter, to**
 - *review* EMR, Alerts-and-Notifications
 - *enter* Observations, Treatments, Orders and associated Documents and Notes
 - *sign* the Encounter
- **Immunization Management involves the following:**
 - **System-Actions:** *auto-populate, capture,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

Use-Case Dependencies

CP.6.2 Immunization Management



class CP.6.2 DEP Manage Immunization Administration

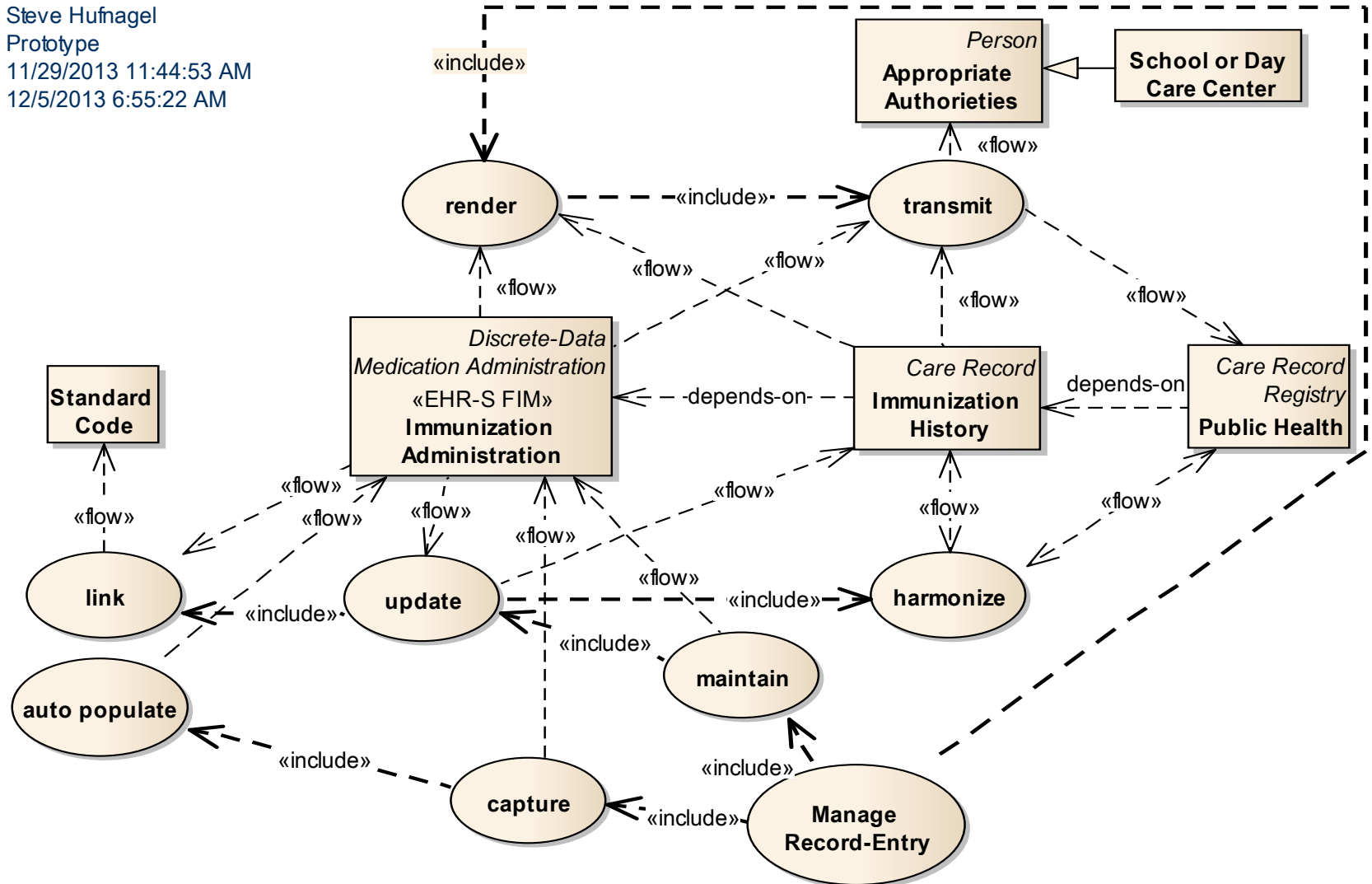


Resultant EHR-S FIM R3 CP.6.2 Use-Case Model



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

Name: EHR-S FM R3 CP.6.2 Refined System-Actions
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/29/2013 11:44:53 AM
 Updated: 12/5/2013 6:55:22 AM



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



The Release-3 EHR System Immunization-Management Function

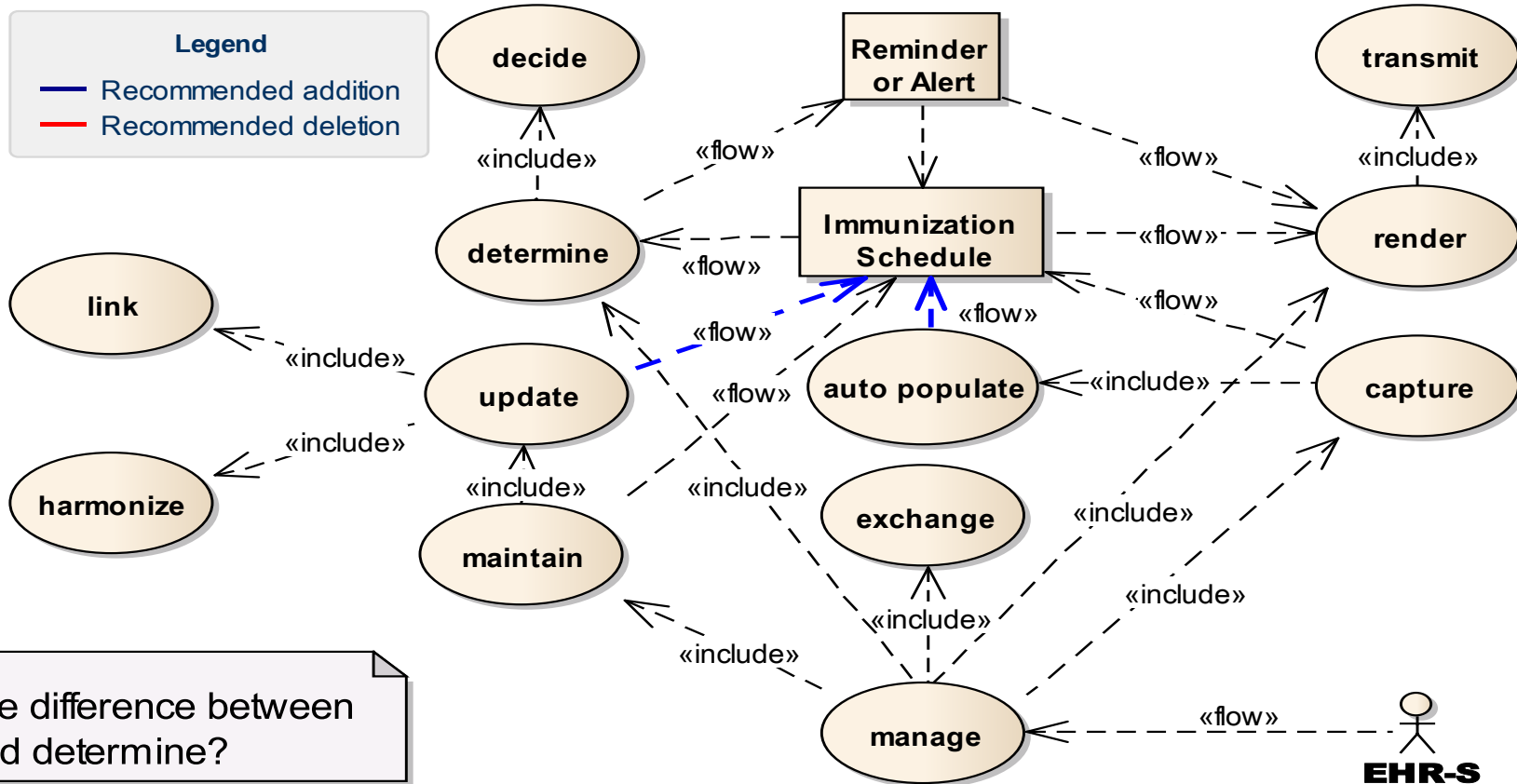
- *captures, auto-populates, links, renders, transmits, maintains* Immunization-Administration Record-Entries; where,
 - the *links* are with Standard-Codes
 - The *transmission* is to Population Health Registries
 - The *auto-population* is as a by-product of verification of Administering-Provider, 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.

EHR-S FIM R3 Immunization-Schedule System-Actions



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

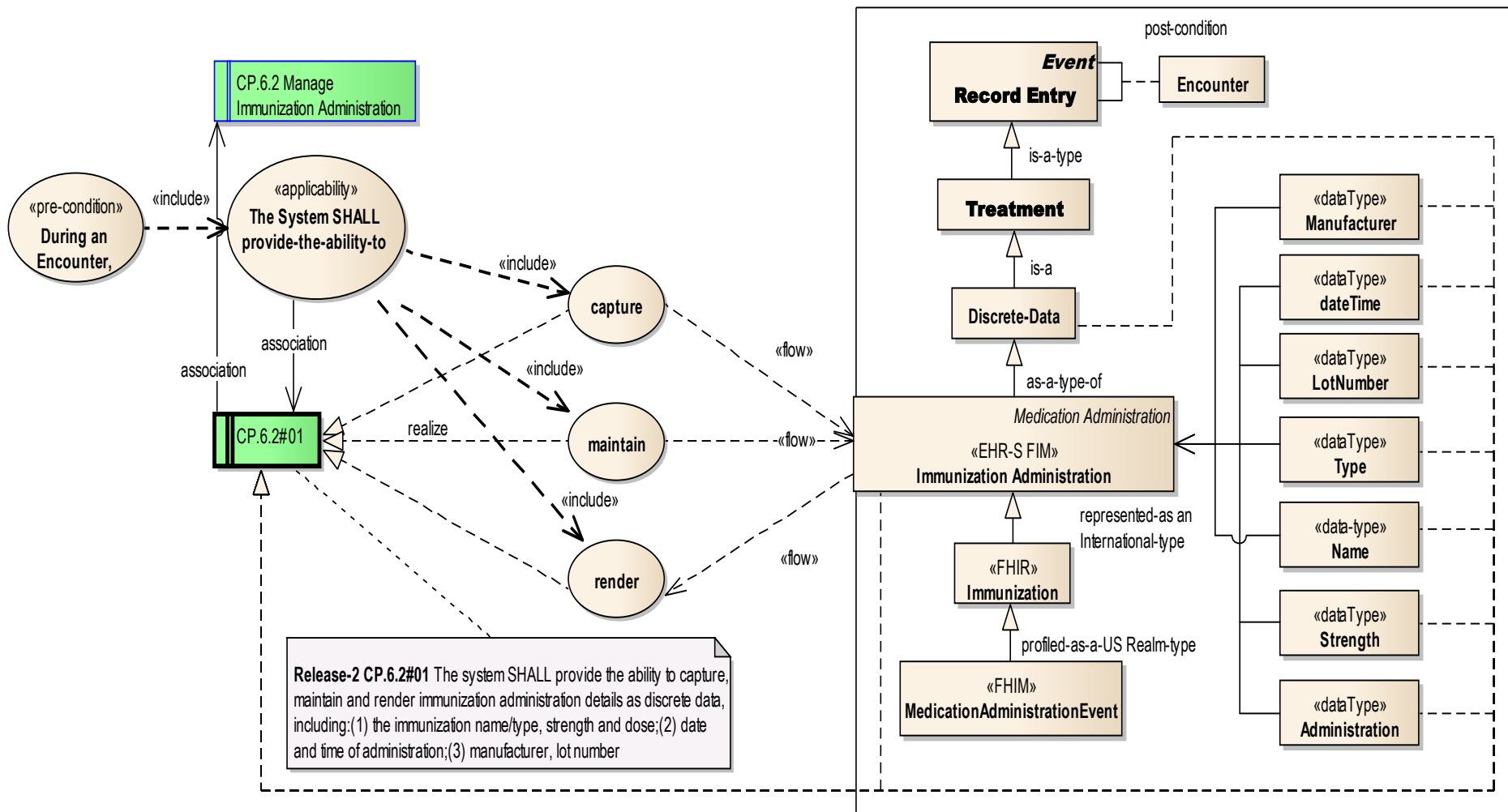


1. Is there one System-Wide Reference-Immunization-Schedule *linked-to* each Patient or does each Patient have an *auto-populated and then updated* Immunization-Schedule *harmonized-with* a reference Immunization-Schedule or don't we care?
2. Can the reference or individual Patient Immunization-Schedule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

Release EHR-S CC Model

CP.6.2#01 Immunization Management

class R 3 EHR-S FIM CP.6.2#01



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

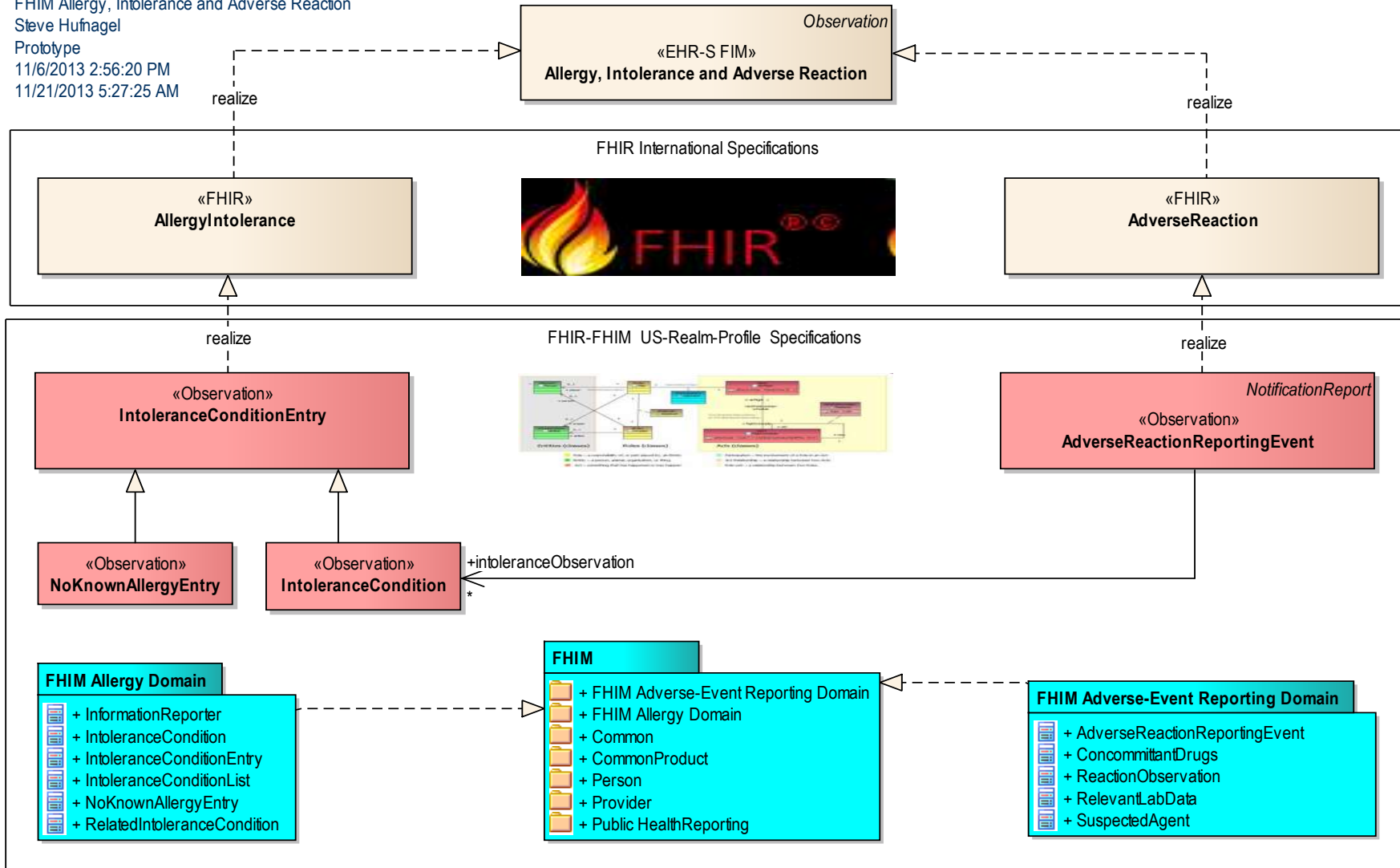
- **R2: CP.6.2#23** The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration.
- **R3: CP.6.2#23** At the time of immunization administration, the system SHOULD provide-the-ability-to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

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



class FHIM Allergy, Intolerance and Adverse Reaction

Name: FHIM Allergy, Intolerance and Adverse Reaction
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/6/2013 2:56:20 PM
 Updated: 11/21/2013 5:27:25 AM

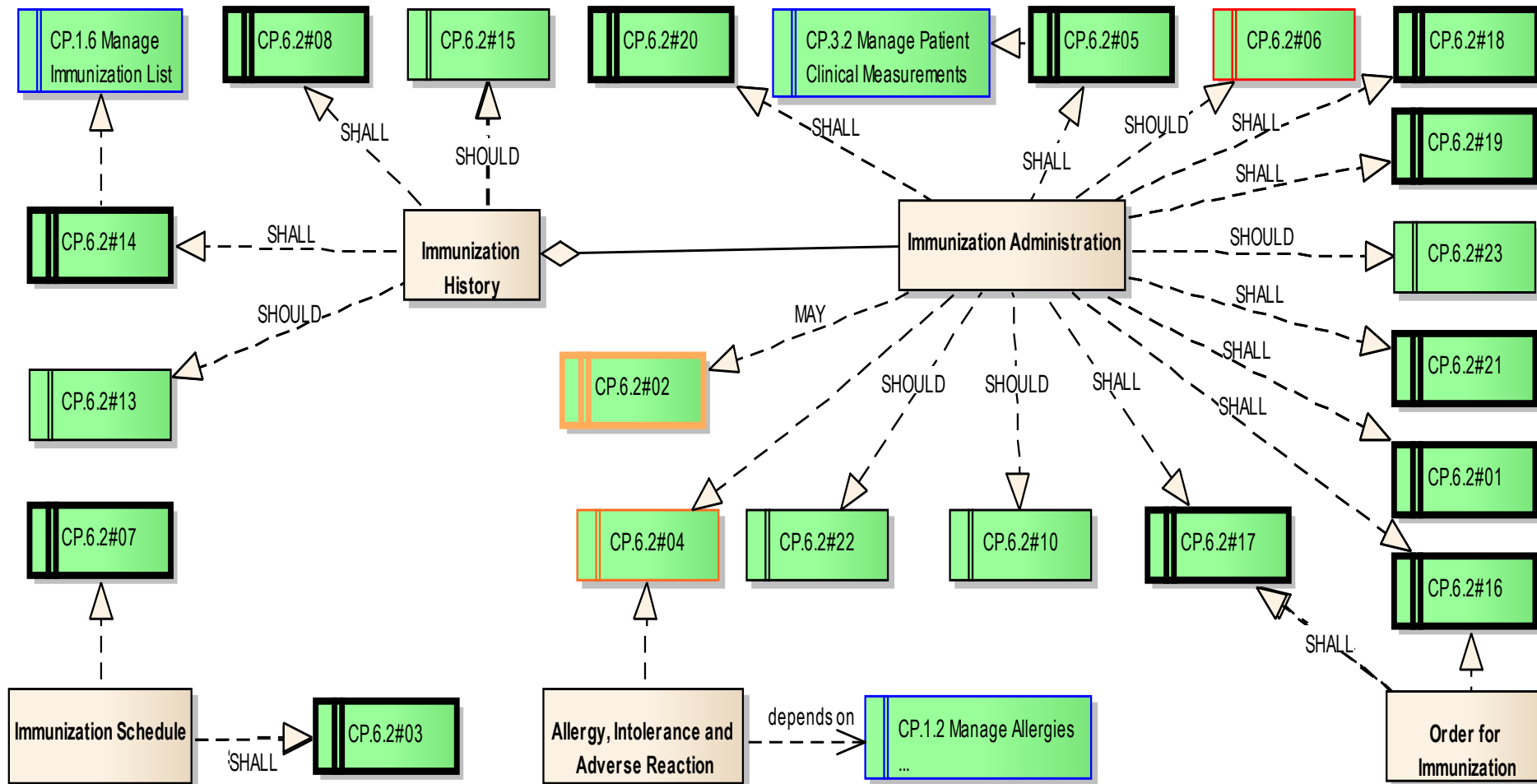


EHR-S-FIM



Conceptual Traceability Model CP.6.2 Immunization Management

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

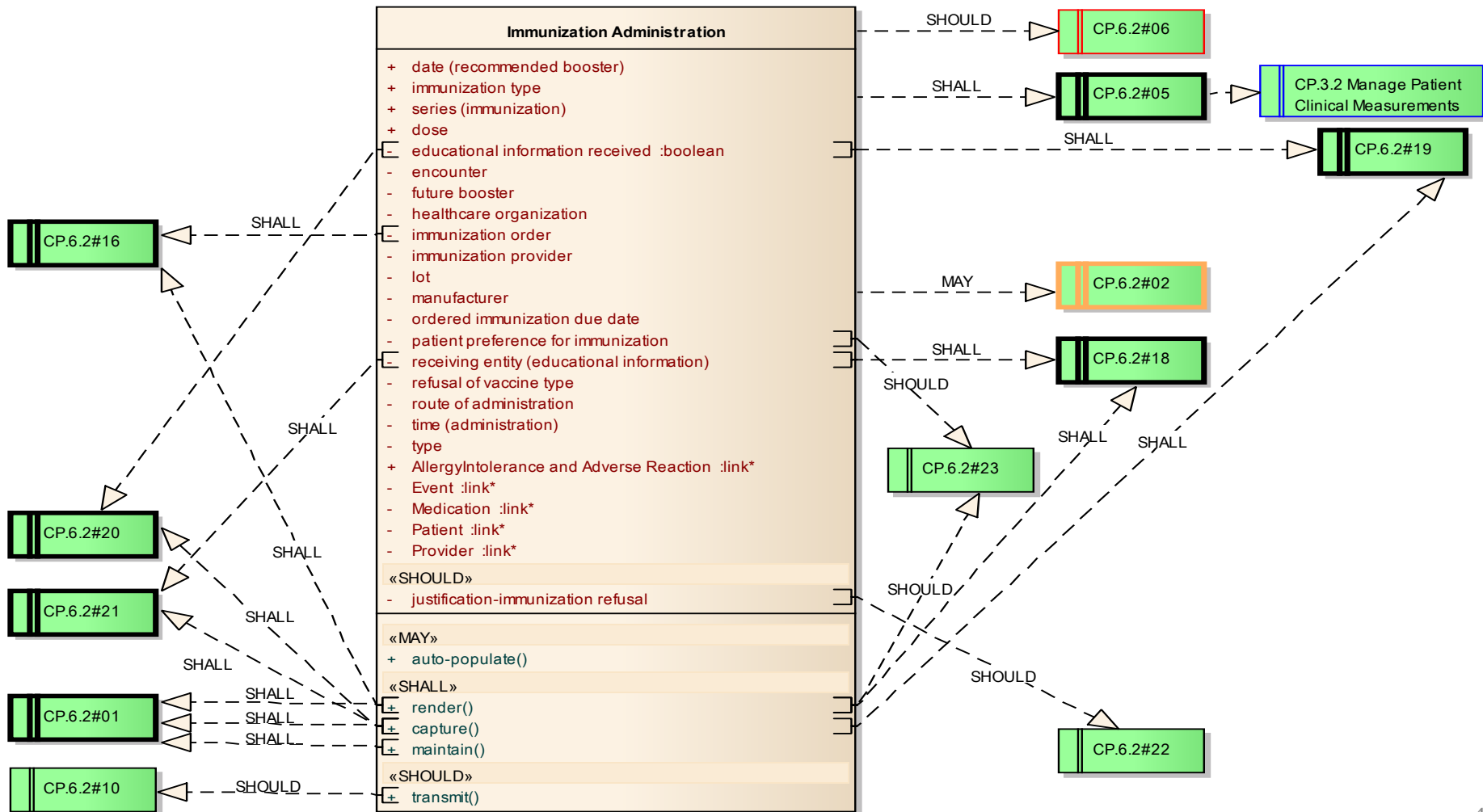


EHR-S FIM



Logical Traceability-Model CP.6.2 Immunization Management

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

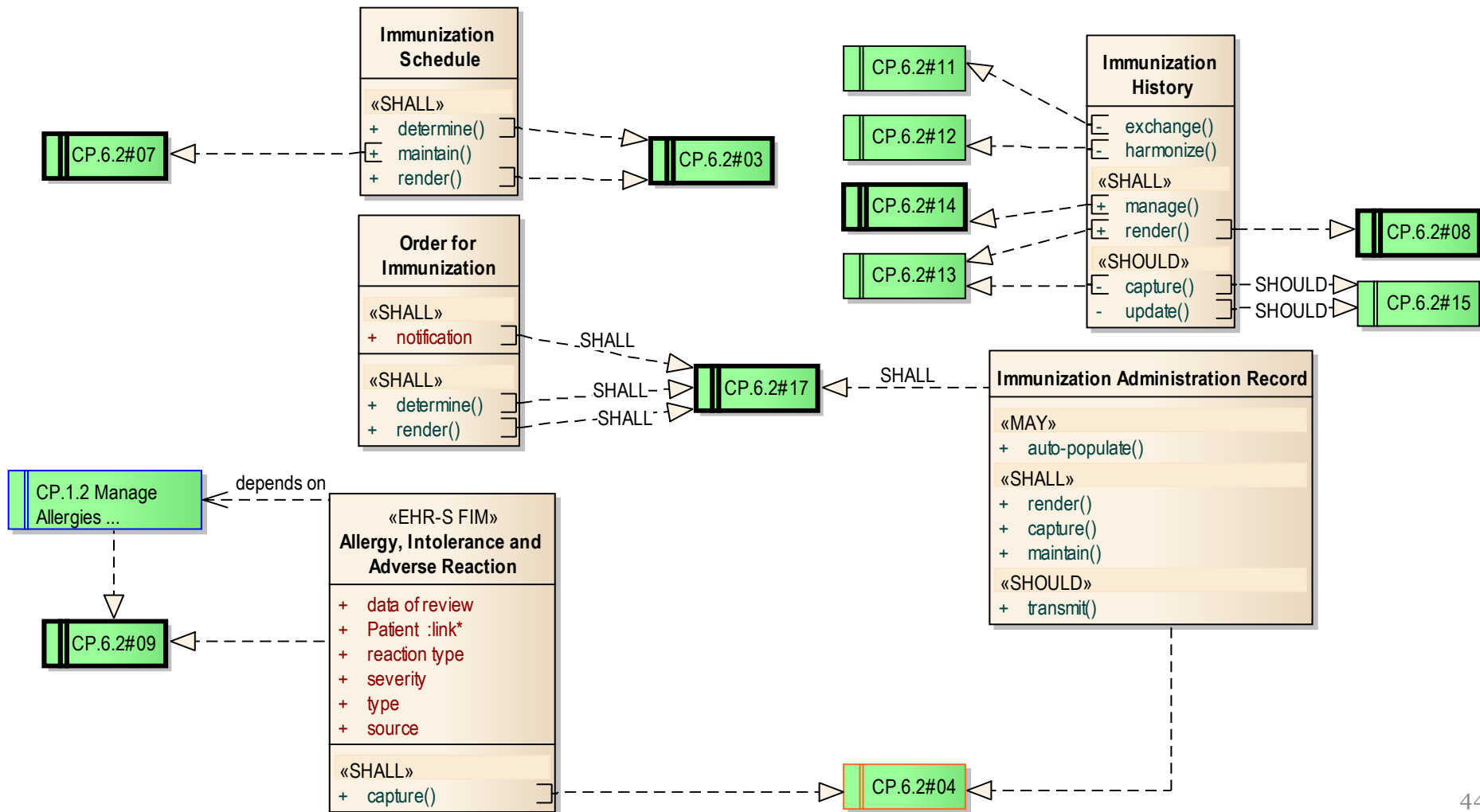


EHR-S FIM

Logical Traceability-Model CP.6.2 Immunization Management



class EHR-S FIM CP.6.2 Immunization Management (Logical Model-2)



■ 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*

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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

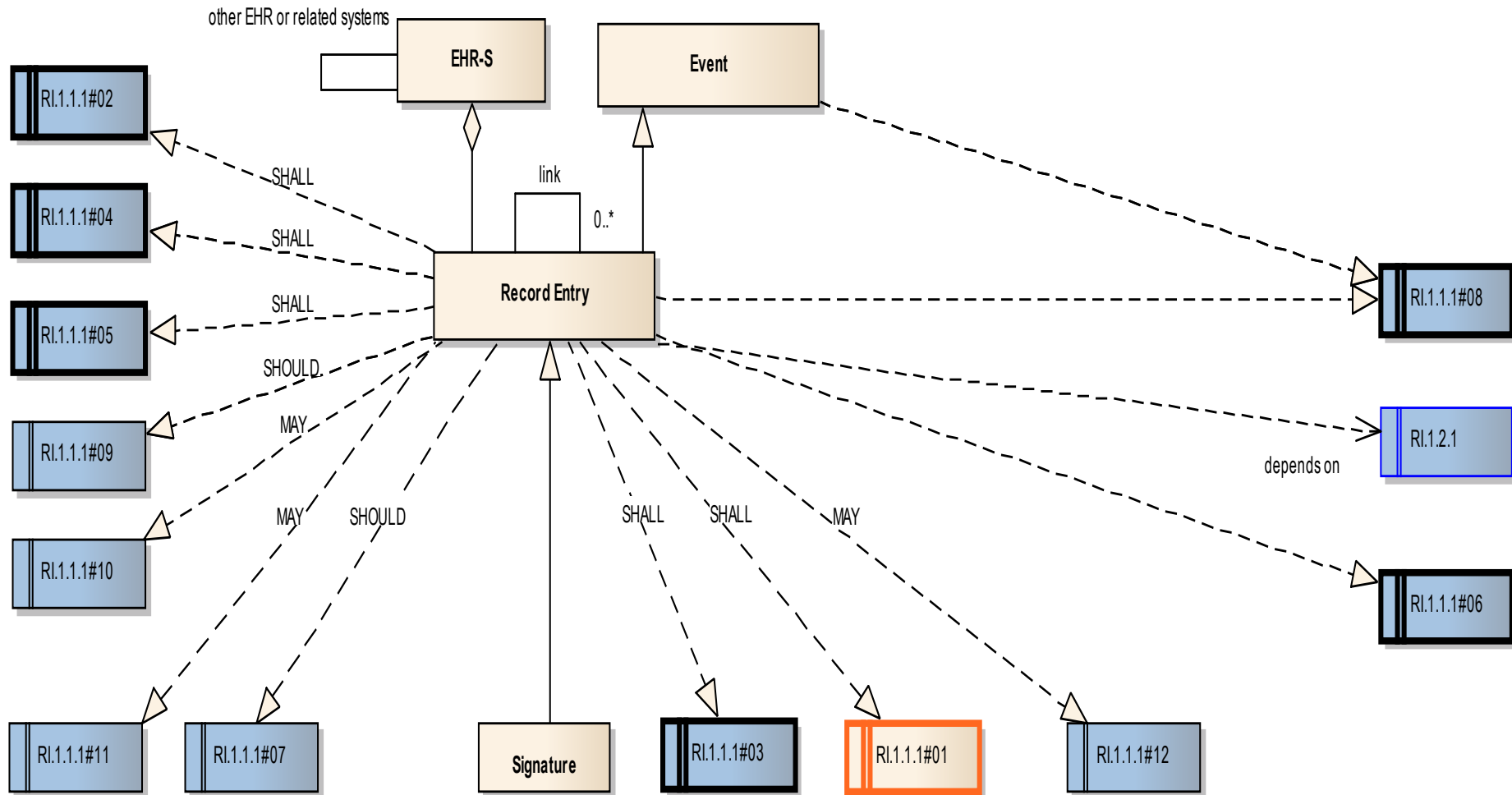
EHR-S FIM



Conceptual Information Model (CIM)

RI.1.1.1 Originate and Retain Record Entry

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



EHR-S FIM Traceability View

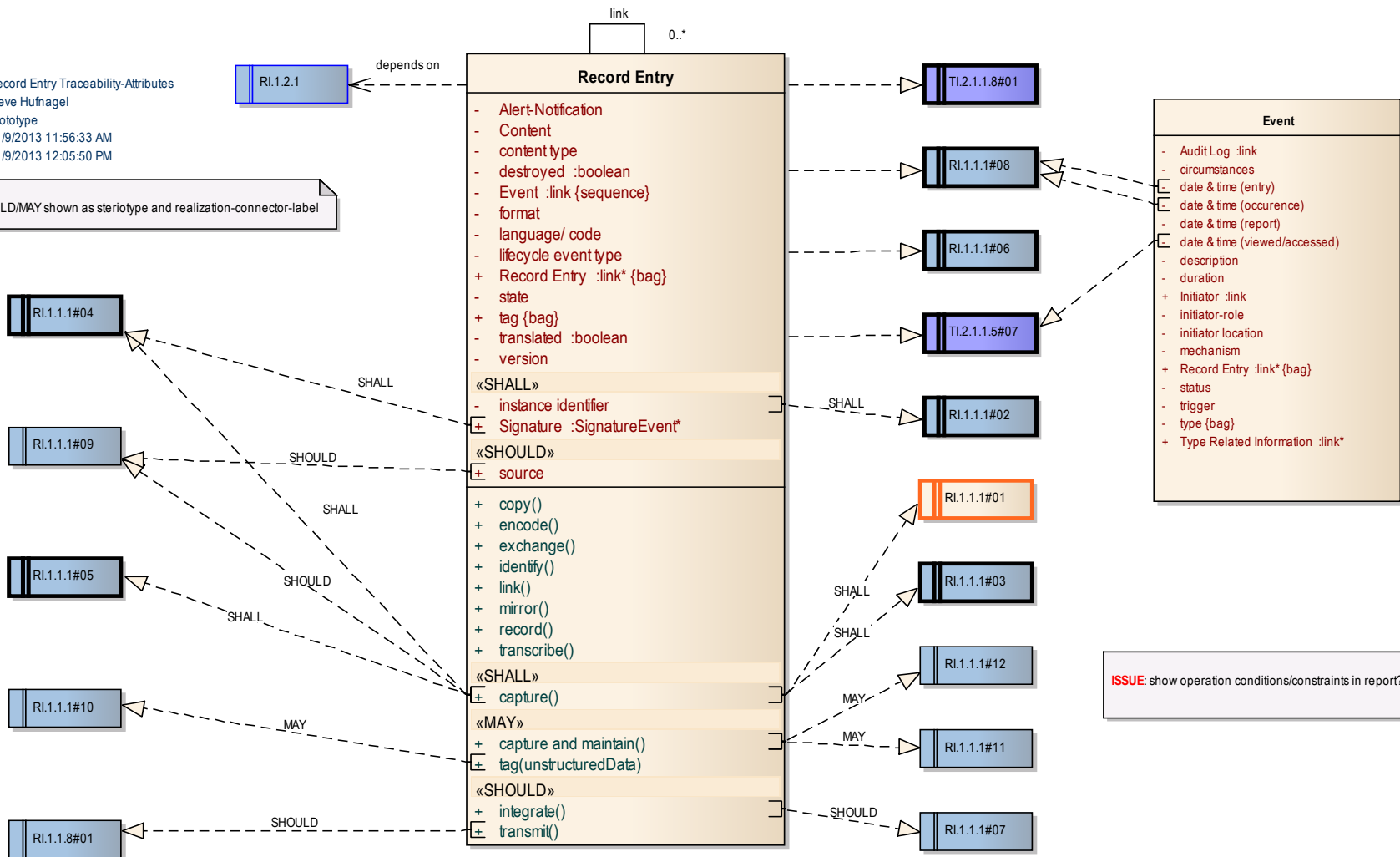
RI.1.1.1 Originate-and-Retain Record Entry



Record Entry Traceability-Attributes

Name: Record Entry Traceability-Attributes
 Author: Steve Hufnagel
 Version: prototype
 Created: 11/9/2013 11:56:33 AM
 Updated: 11/9/2013 12:05:50 PM

SHALL/SHOULD/MAY shown as steriotype and realization-connector-label



ISSUE: show operation conditions/constraints in report?

Conformance Criteria (CC)

RI.1.1.1 Originate-and-Retain Record-Entry

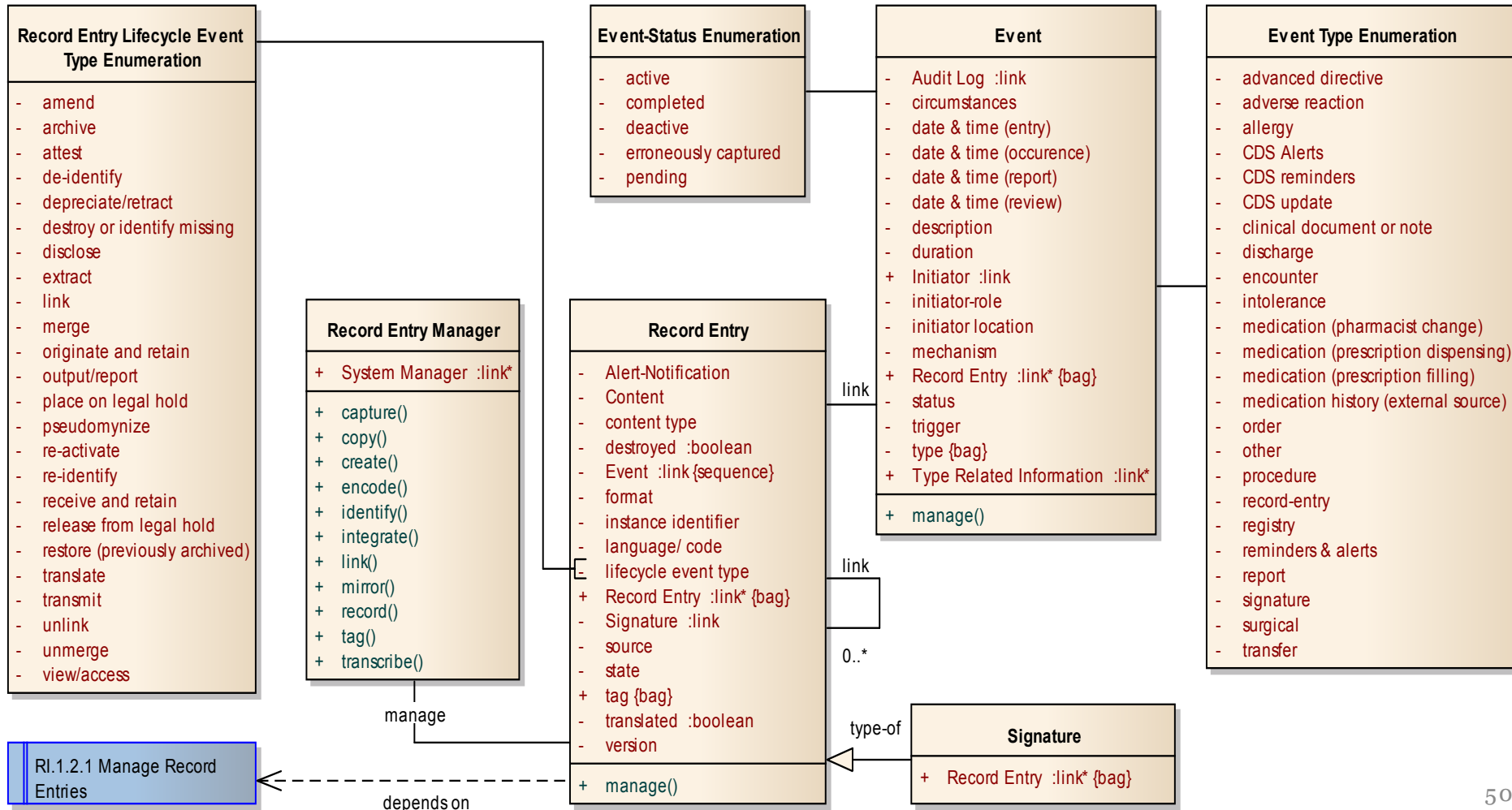
1. RI.1.1.1#01 The system **SHALL** provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
2. RI.1.1.1#02 The system **SHALL** capture a unique instance identifier for each Record Entry.
3. RI.1.1.1#03 The system **SHALL** conform to function 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 CDAR2 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)



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.

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

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

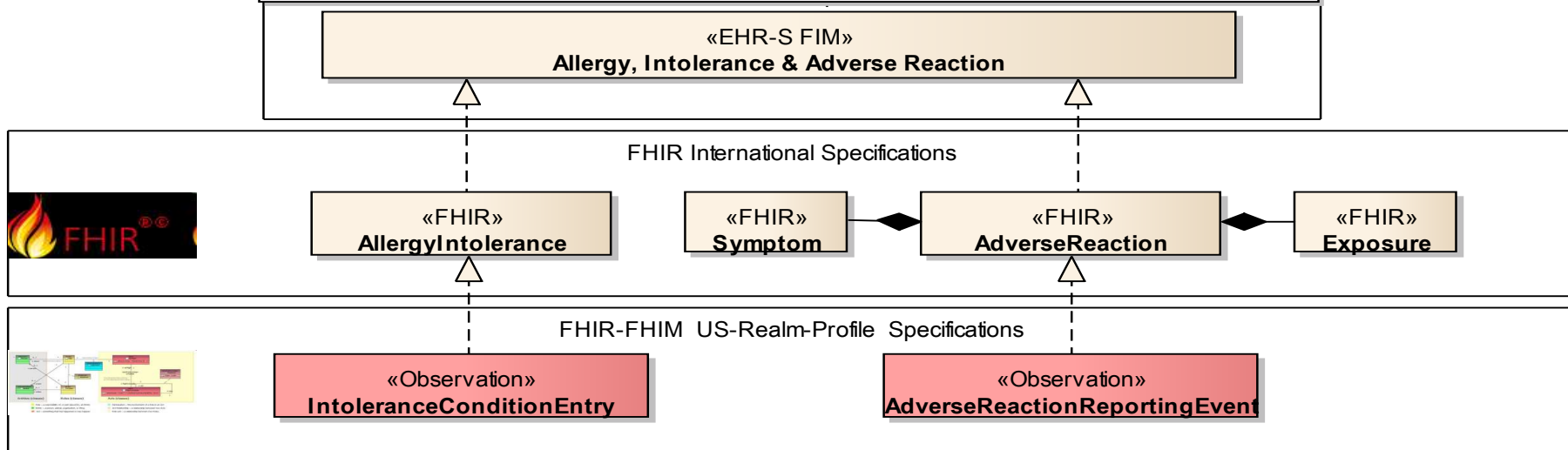
ISSUE: Should we map at Data Module Level or Conformance Criteria level? [Gary]

- The EHR-S FIM release-3 objective is for an analyst-or-architect to use the EA-tool to
1. Create a use case from a prescribed lexicon of Entities, Events, Modifiers and Actions; where,
 2. the lexicon is mapped to applicable EHR System Functions; where,
 3. 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



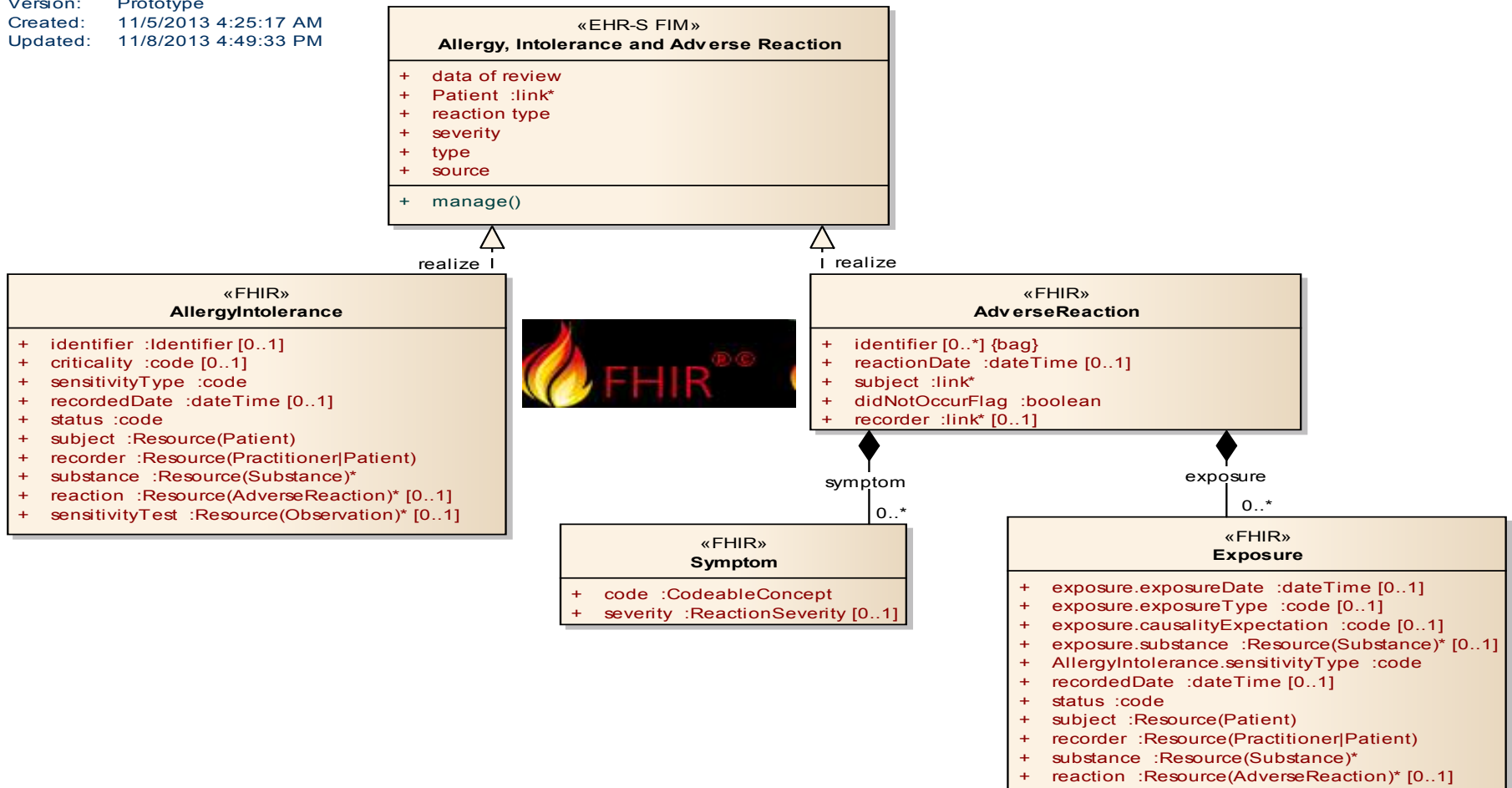
Prototype

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
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/5/2013 4:25:17 AM
 Updated: 11/8/2013 4:49:33 PM



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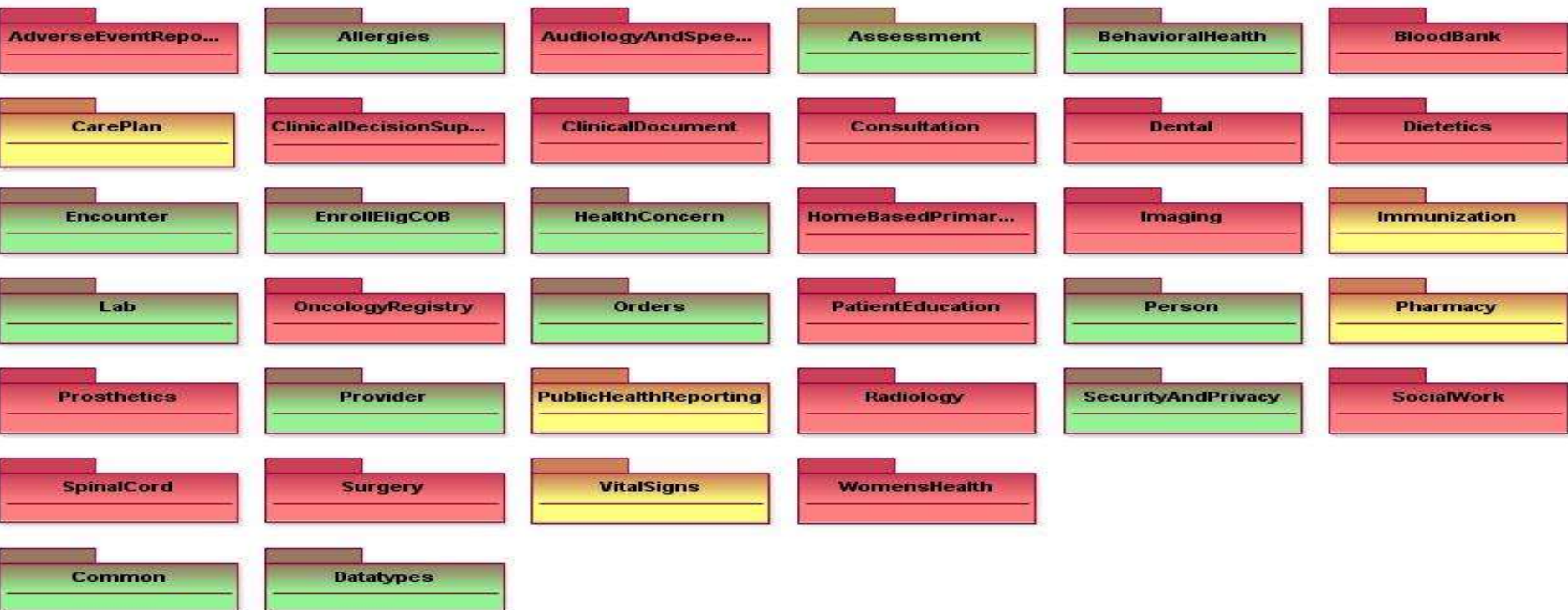
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http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

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



http://www.fhims.org/content/420A62FD03B6_root.html

FHA Federal Health Information Model (FHIM)



FHIM modeling complete

FHIM modeling in progress

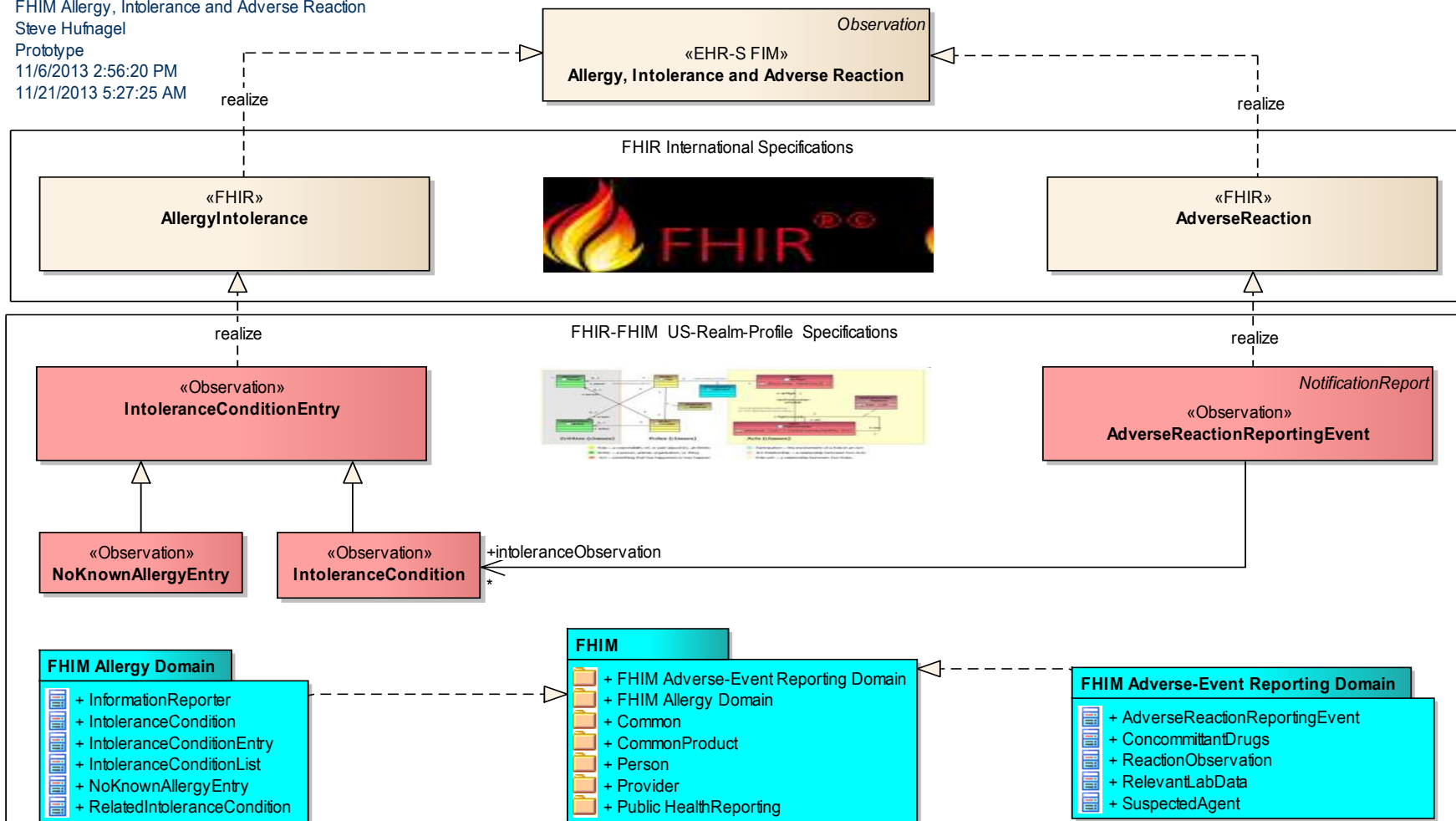
Unchanged from the VHIM

Color Key

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

class FHIM Allergy, Intolerance and Adverse Reaction

Name: FHIM Allergy, Intolerance and Adverse Reaction
 Author: Steve Hufnagel
 Version: Prototype
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 Updated: 11/21/2013 5:27:25 AM

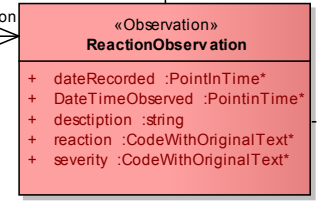
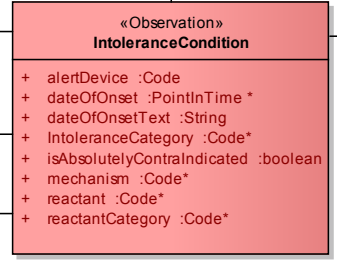
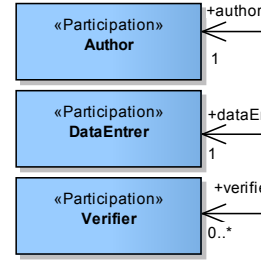
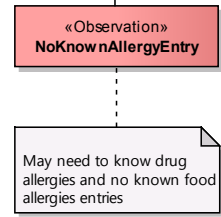
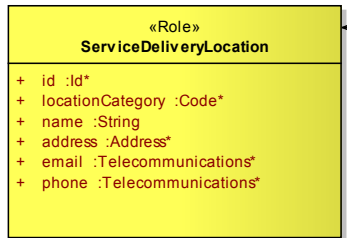
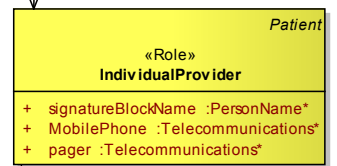
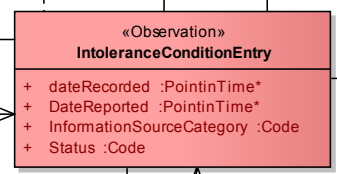
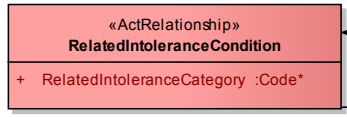
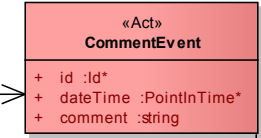
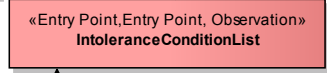
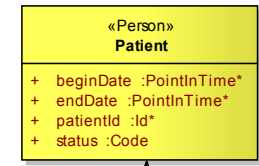
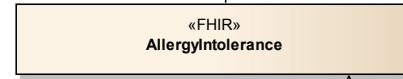
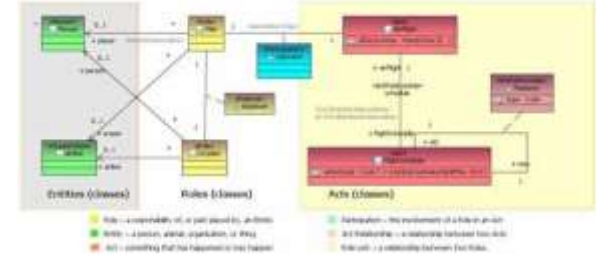
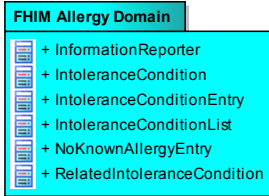
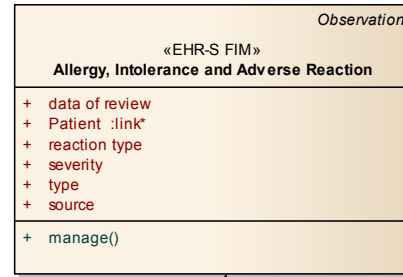


Prototype

FHIM-Detailed Allergy & Intolerance Specification

class FHIM Allergies Domain

Name: FHIM Allergies Domain
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/6/2013 4:40:24 AM
 Updated: 11/8/2013 4:50:55 PM



Note that participation classes are used when we need date/time or comments, otherwise, we point directly to Individual Provider. This why there are "authors" from Comment Event, etc., but Intolerance Condition uses the Author Participation.

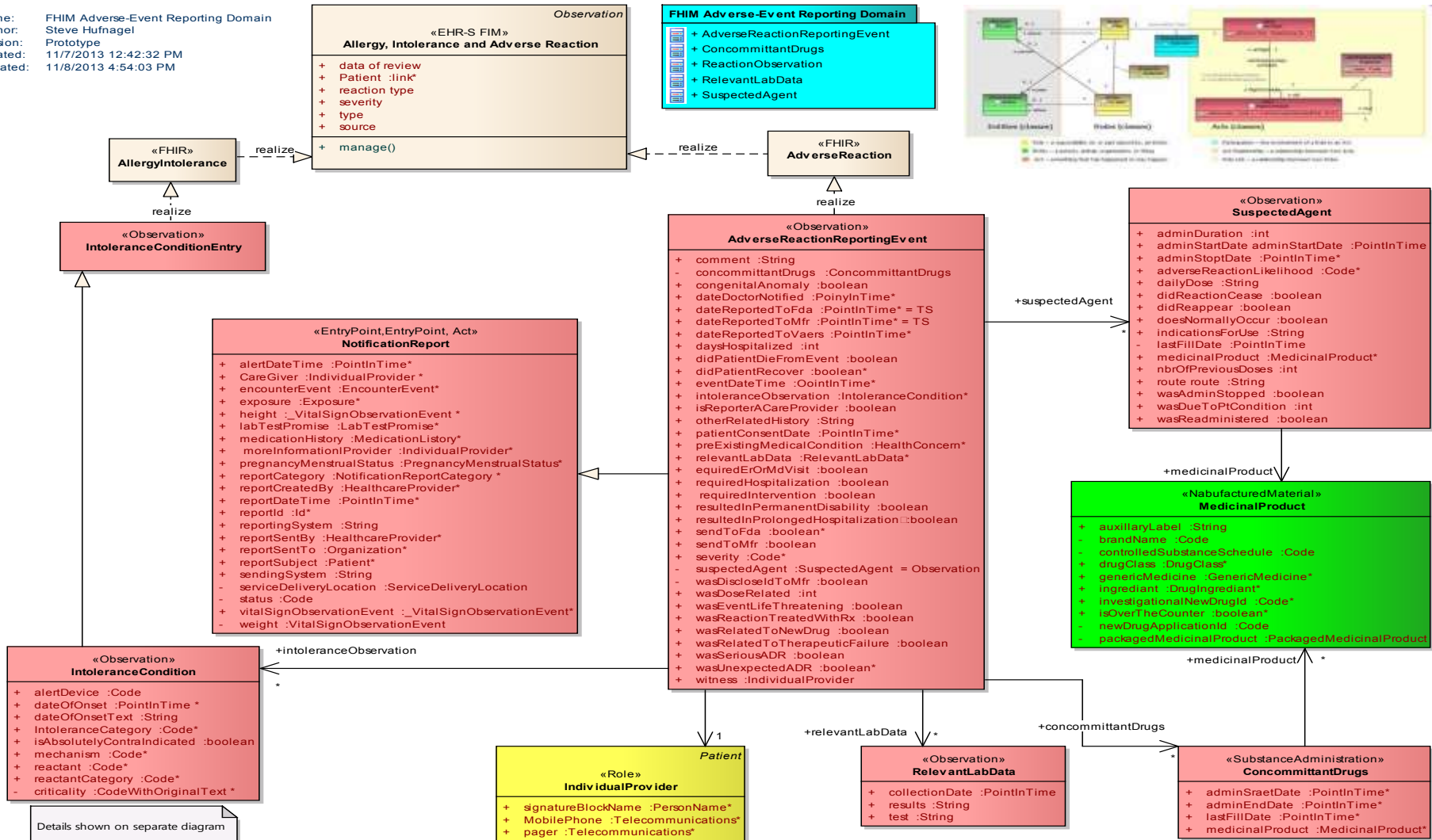
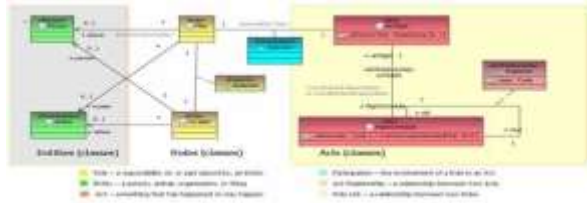
Prototype FHIM Detailed Adverse-Reaction Specification

class FHIM Adverse-Event Reporting Domain

Name: FHIM Adverse-Event Reporting Domain
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/7/2013 12:42:32 PM
 Updated: 11/8/2013 4:54:03 PM

FHIM Adverse-Event Reporting Domain

- + AdverseReactionReportingEvent
- + ConcomittantDrugs
- + ReactionObservation
- + RelevantLabData
- + SuspectedAgent



Details shown on separate diagram

■ 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 International Data-Specifications (“The 80% set”)
 - FHIM can define the US-FHA FHIR-Profile
 - 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