



Monthly Summary Briefing

HL7 EHR Work Group (EHR-WG)



by Stephen Hufnagel, Tiag subcontractor
to Edmund-Scientific VA support-contract
Shufnagel@tiag.net, 703-575-7912

November 24, 2013

Frequently-Updated Working-Draft

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





■ Contents

FY2014Q1-Prototype Report

EHR-S FIM Release-3:2016 Preparation

- 1. Introduction, Executive-Summary, Plan-of-Actions & Milestones**
2. EHR-S Concept-of-Operation and Reference-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 November-2013 is available at 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).

EHR WG



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

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

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 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. **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 FY14- Alpha & FY15-Beta development.
3. **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
- Prototype RI.1.1.1 Originate-and-Retain Record-Entry

22-Oct-13

29-Oct-13

November 2013 (Prototype complete process-and-products)

- Prototype FHIR integration (Allergies, Intolerance & Adverse Reaction)
- Prototype FHIM integration (Allergies, Intolerance & Adverse Reaction)
- Define EHR-S Reference-Model and Conceptual-Architecture
- Prototype Use-Case generation of Immunization Interoperability-Specification
- Harmonize with ISO/EN 13940 Continuity-of-Care System-of-Concepts
- Harmonize with Electronic Health Record Communication (ISO/EN 13606)
- Prototype EHR-S FIM Ballot Production process-and-products for prototype

5-Nov-13

8-Nov-13

15-Nov-13

in-progress

pending

December 2013 (Develop production WBS and POA&M)

- Create Release 3 Work-Break-Down Structure (WBS) & POA&M
- Setup EA tool with finalized Release 2, after ISO ballot reconciliation

January 2014 – 2016 (Approve & Execute Plan)

- Jan 2013: Present Prototype, WBS & POA&M at HL7 WG meeting; then, execute POA&M.
- Establish public www.EHR-S-FIM.org website to get broad peer-review



■ Contents

FY2014Q1-Prototype Report

EHR-S FIM Release-3:2016 Preparation

1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
- 2. EHR-S Concept-of-Operation and Reference-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), November-2013 is available at http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

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 operational-and-information conceptual-models; where,
- EHR-S RM conformance criteria contain a constrained-lexicon
 - of nouns (Data-Entities) and qualifiers (Data-Types), bound-to
 - verbs (Operations/Tasks) with constraints {Business Rules},
 - which may be used-as requirements-specifications.

2. Provides a common syntax-and-semantics for the EHR-S and PHR-S models

- Where, verbs (Operations), nouns (Data Types), constraints are refined within functions.
- Where, these models are
 - Linked-to implementation standards-technologies-paradigms-or-patterns.
 - Consistent-and-unambiguous across implementations, tests and certifications.

- 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."

■ Concept-of-Operations Reference Scenario EHR-S FIM Release-3:2016 Preparation

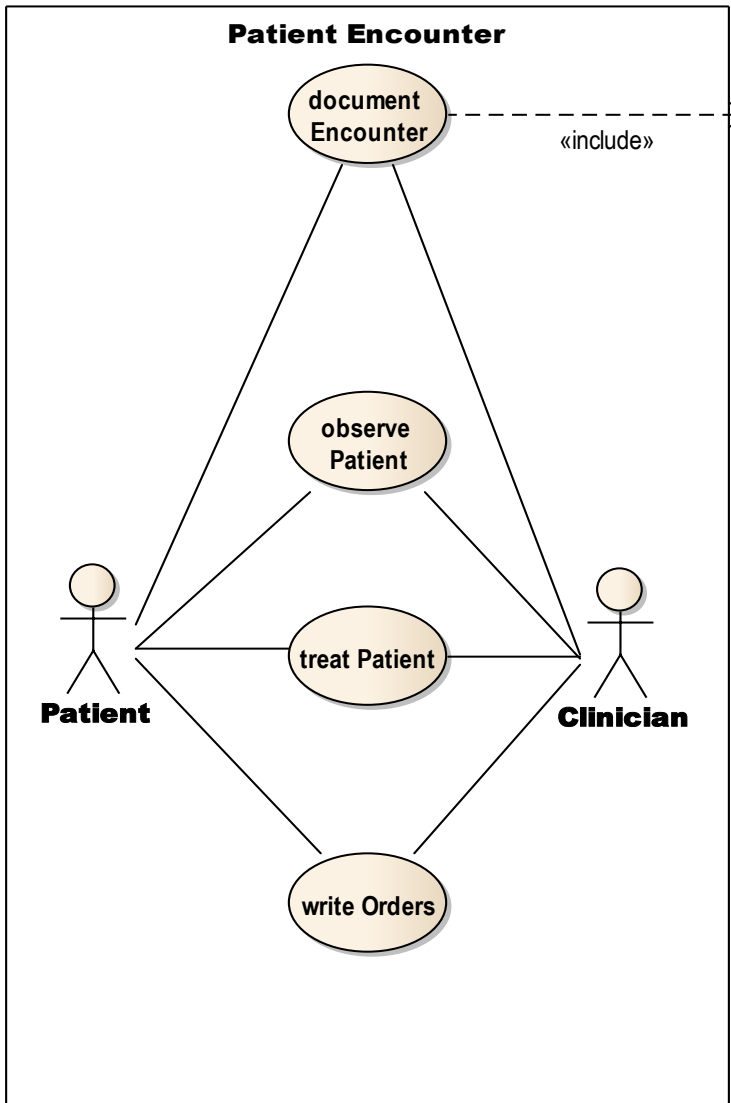
A Clinician and Patient and/or their designated Agents have Encounters; where, they may use EHR-S (EHR System) GUI (Graphical-User-Interface) to *manage* EMRs (Electronic Medical Records), in accordance with scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences:

- The Clinician *reviews* the Patient EMR (Electronic Medical Record) and associated Information
- The Clinician *observes and treats the* Patient, *writes-orders and documents* the Encounter
- The Patient *provides* requested-Information and is *provided* educational-Information
- The EHR-S *manages*
- Encounters are signed by the Clinician(s) and possibly by the Patient; where, they contain
 - Record Entries for Orders, Treatments, Observations and associated Information
 - Record-Entries organized into lists of EMR Care-Plans, Care-Records, Problems-and-Concerns, Documents & Notes

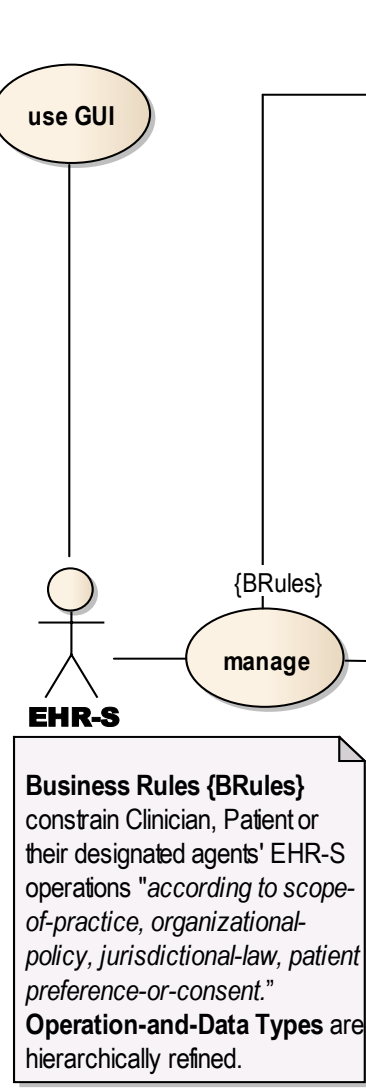
EHR-S Reference Model (RM)

EHR-S FIM Release-3:2016 Preparation

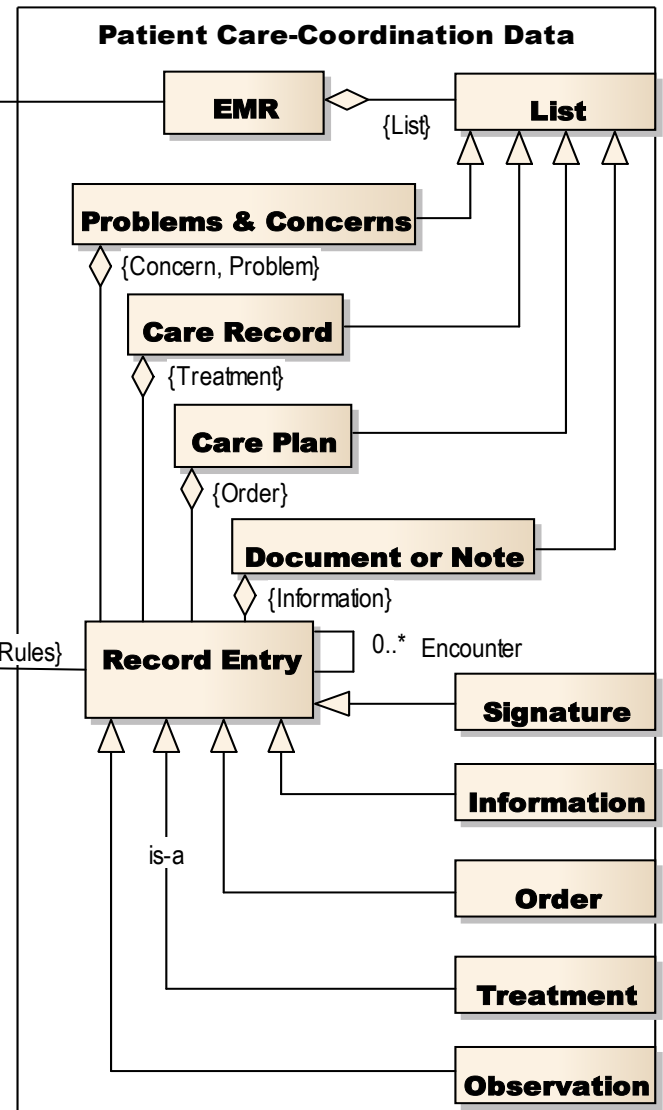
Human Entities and Actions



EHR-S Operations



EHR-S Data-Entities & Data-Types

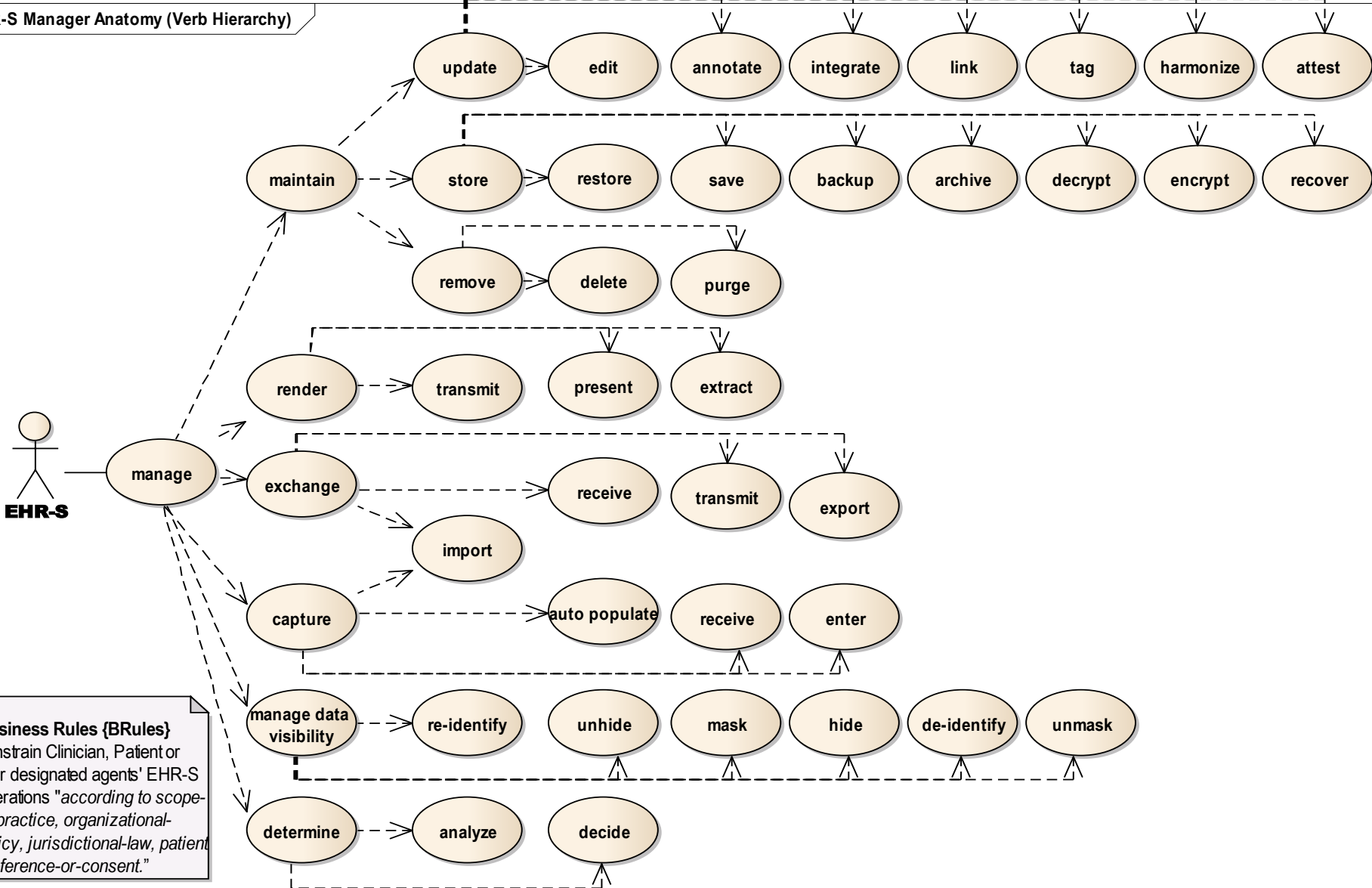


Operation Sub-Types aka Verb Hierarchy

EHR-S FIM Release-3:2016 Preparation



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



Conformance-Criteria RM EHR-S FIM Release-3:2016 Preparation

- **Human**
 - Clinician, Patient, Designated Agent
- **Human Action**
 - Linked-to Use-Case Actions
 - CLINICIAN: Observe, Treat, Write-Orders
 - such as Immunization Administration
- **System**
 - EHR or PHR
- **Applicability (SHALL, SHOULD or MAY)**
 - according to
 - Scope of practice,
 - Organizational policy,
 - Jurisdictional law,
 - Patient preference or consent.”
- **System Function Constraints**
 - Invariant-conditions (e.g., context)
 - Pre-conditions (e.g., triggers)
 - Post- conditions (e.g., goal, outcomes)
- **System Function Type**
 - System provides the ability (for a human) to
 - Or the system directly does
- **System Function EHR-S operations linked-to**
 - EHR-S Data-Type(s) (Immunization, Vital Sign, lab order)
 - Information Exchange(s) linked-to
 - International Interoperability-Standards (e.g., FHIR, W3C)
 - <Realm Interoperability-Specifications (e.g., FHIM, HITSP)>
 - <Implementation Guides (e.g., CDC Iz., CCDA)>
 - <Behavioral Interoperability-Specifications (e.g., IHE)>
 - <Service Level Agreement (e.g., local workflow)>
- **Associations & Dependencies**
 - Supporting components and functions
- **See Also**
 - Functions with significant common CCs

NOTE: < ... > means optional

■ EHR-S RM

Example Conformance-Criteria

EHR-S FIM Release-3:2016 Preparation

CP.6.2#01 During an Encounter, the EHR system SHALL provide the ability to *capture* Immunization Administration details as discrete data, linked-to Immunization FHIR (Fast Healthcare Interoperability Resource); where, the Immunization data is associated with the following resources:

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

And within the US Realm, the Immunization and associated resources are linked-to 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.

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 (record-entry actions) and constraints (conditions).
- 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 section; but,
 - major COM components still must be substantially developed based-on the Record-Infrastructure and Trust-Infrastructure sections.

■ Contents

FY2014Q1-Prototype Report

EHR-S FIM Release-3:2016 Preparation

1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operation and Reference-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 November-2013 is available at
http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

■ Use-Case Description

CP.6.2 Immunization Management EHR-S FIM Release-3:2016 Preparation

“According to scope-of-practice, organizational-policy,
Jurisdictional-law, patient preference-or-consent,”

- A Clinician uses the EHR-S to
 - document the encounter information.
 - *review* the patient’s EMR for Allergies and Intolerances, Immunization-Schedule, and Patient Directives
 - Document Patient Immunization Administration and Adverse-Reaction observation.
- The EHR-S manager can
 - *Capture, Auto-populate, Maintain, Render, Transmit, Exchange,*
 - *Harmonize, Update, or Determine*
- The following data-types:
 - Immunization-Administrations, Allergies, Intolerances, Adverse-Events
 - Events, Schedules, Plans and Educational Materials

Use-Case Conceptual-Model

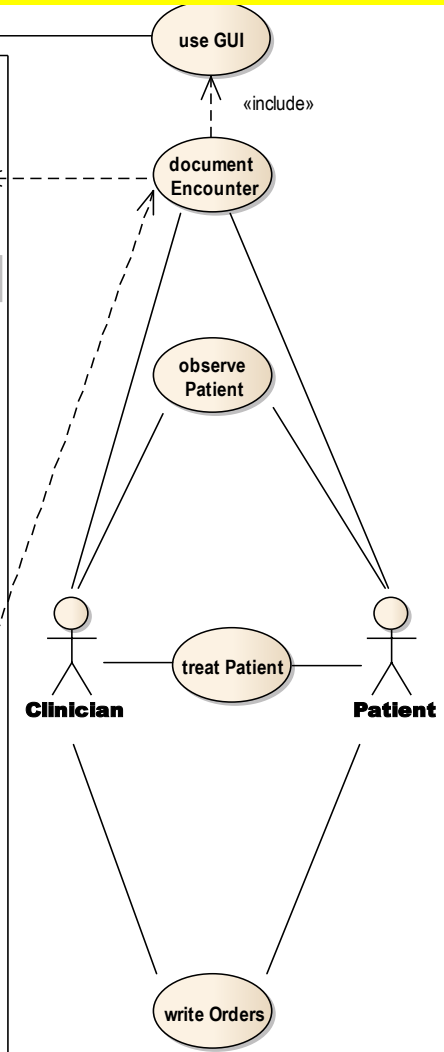
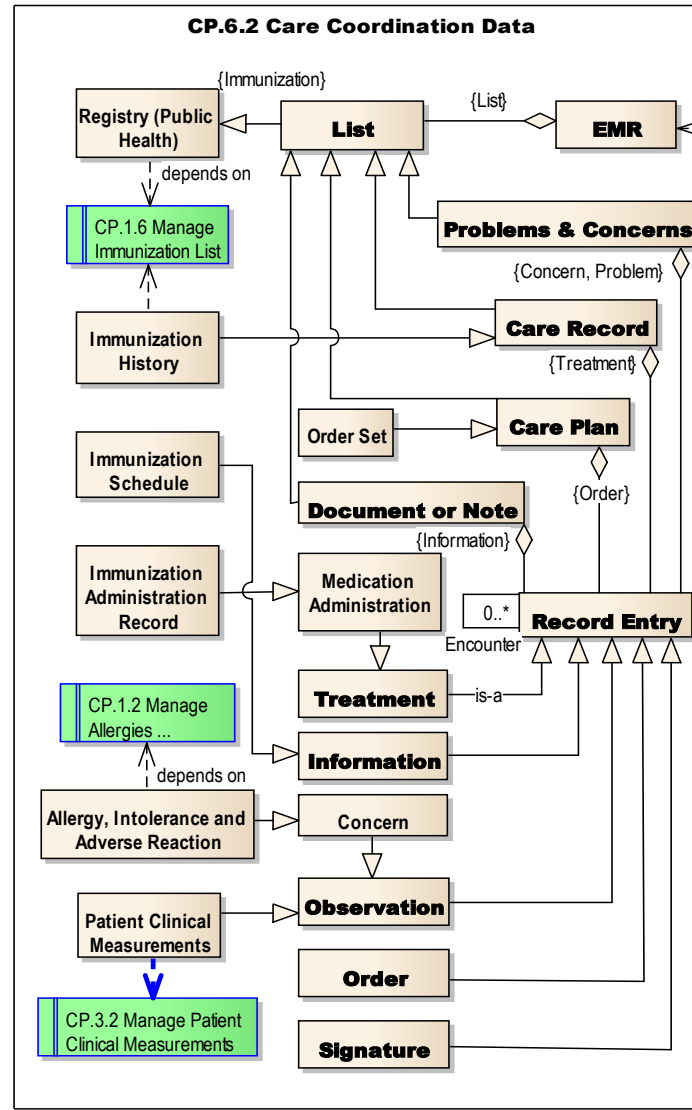
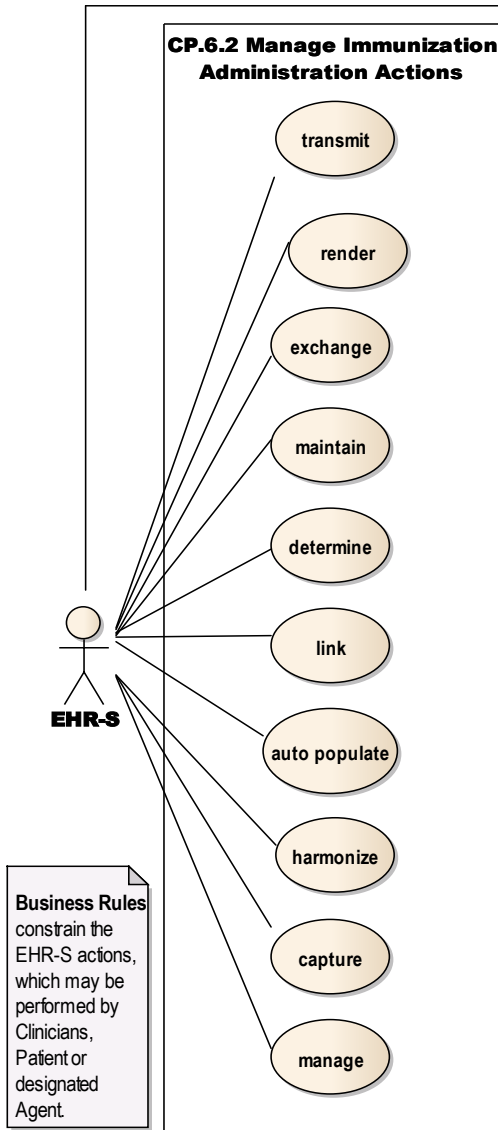
CP.6.2 Immunization Management Conformance Criteria



EHR-S Operations

EHR-S Data-Types & Data-Entities

Human Entities and Actions

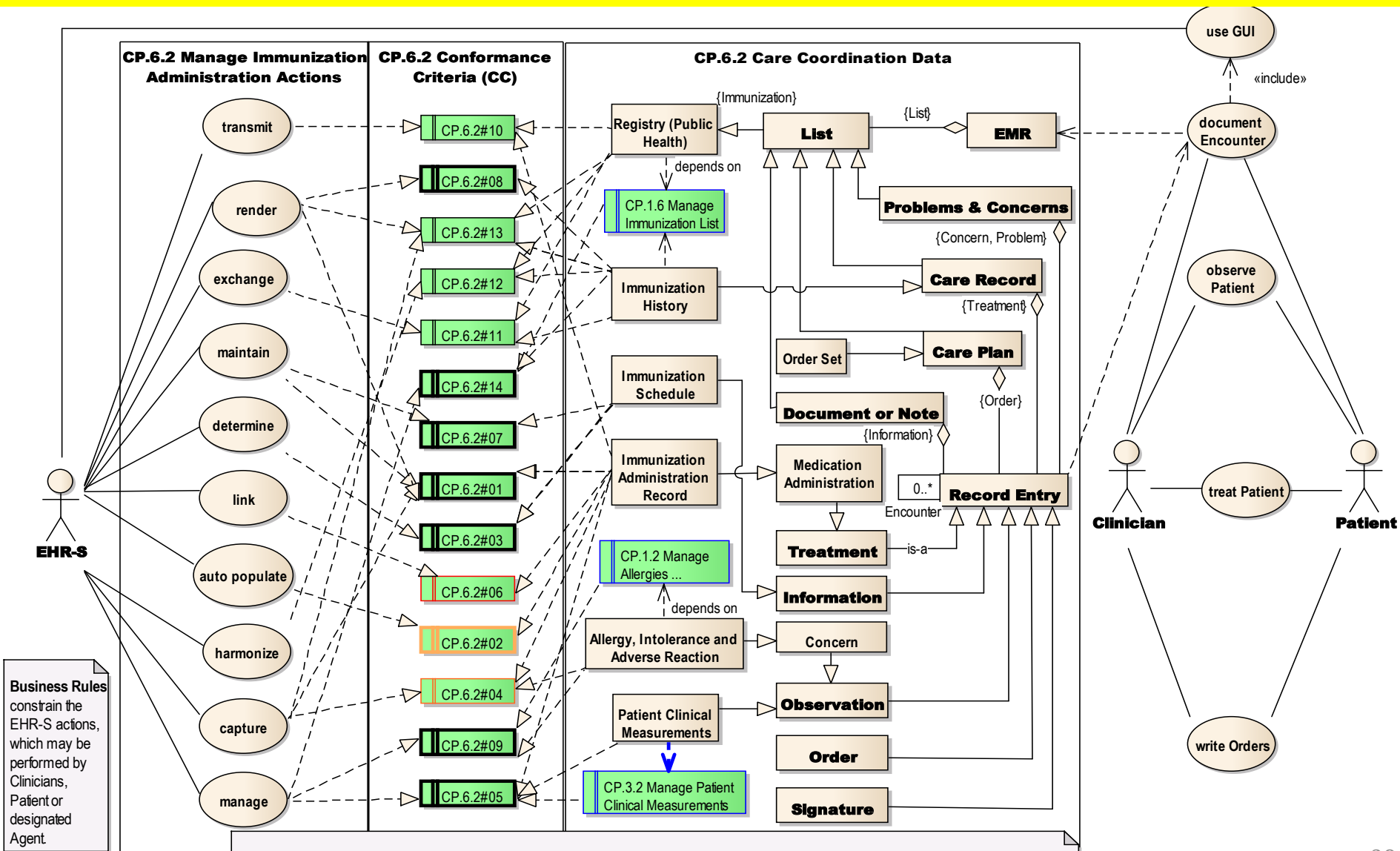


Example Use-Case Traceability-Analysis

CP.6.2 Immunization Management Conformance Criteria



EHR-S Operations CC Bindings EHR-S Data-Types & Data-Entities Human Entities and Actions

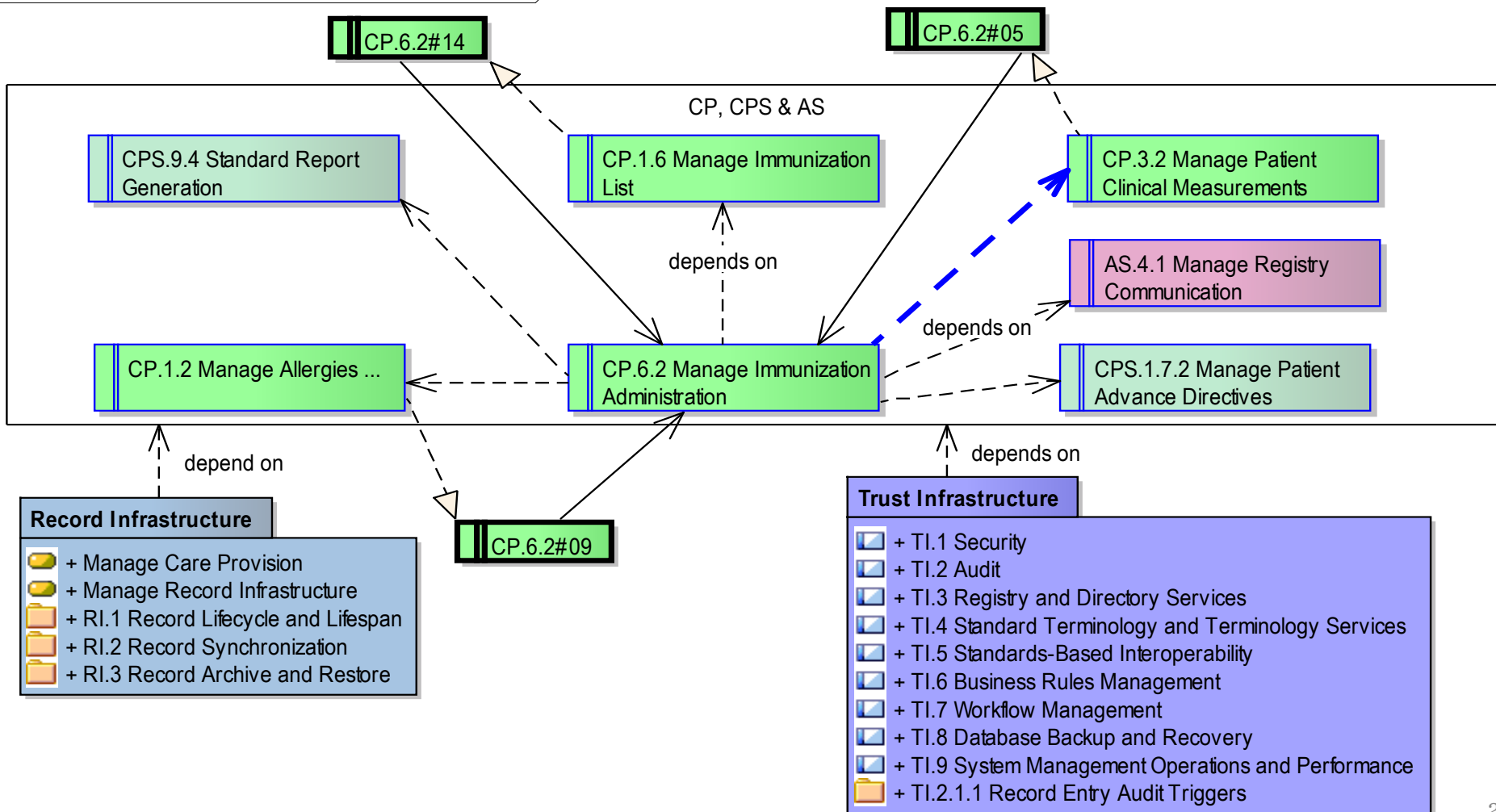


EHR-S-FIM

Dependencies

CP.6.2 Immunization Management

class CP.6.2 DEP Manage Immunization Administration

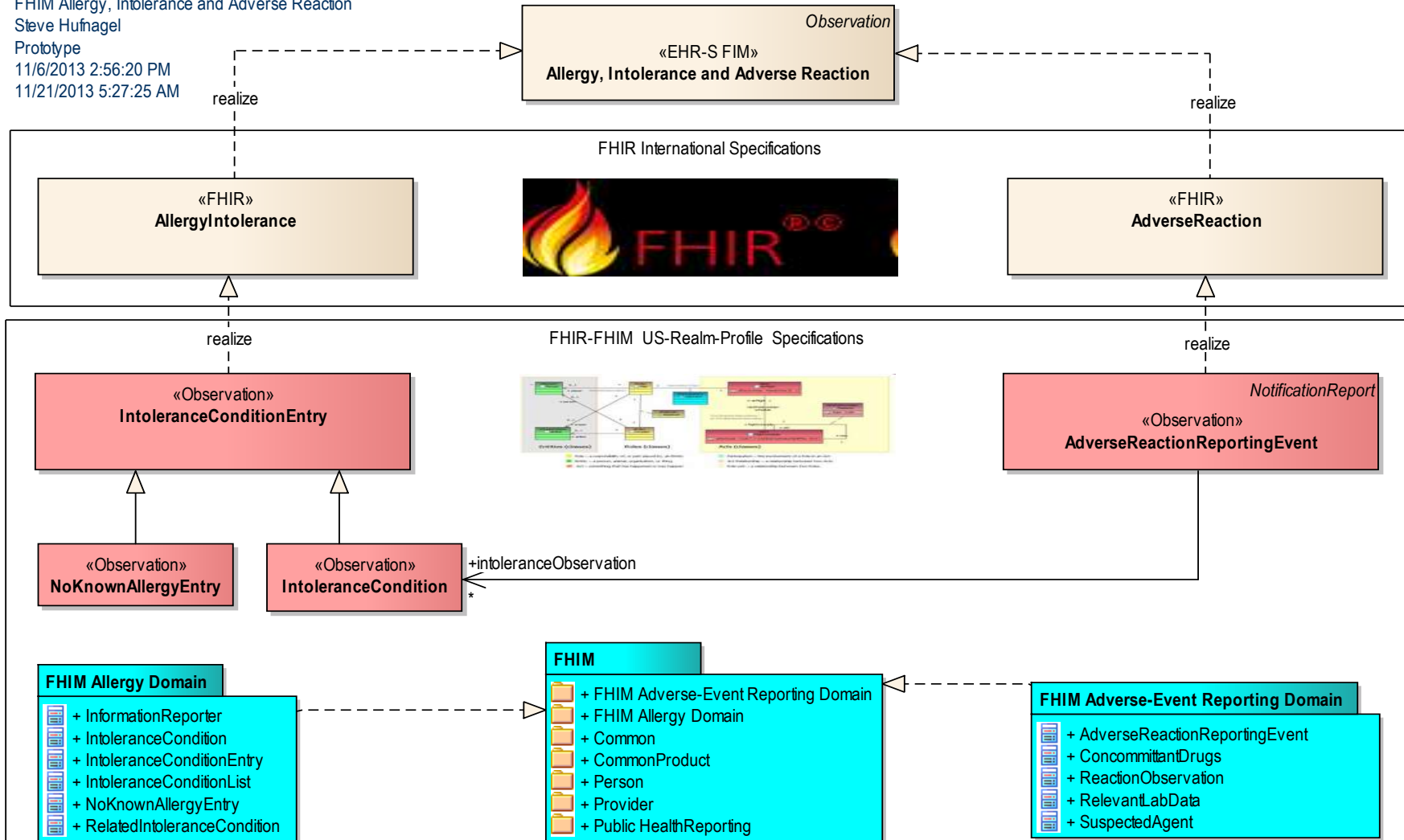


Example Linkage-to FHIR & FHIM for Allergy, Intolerance & Adverse-Reaction



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

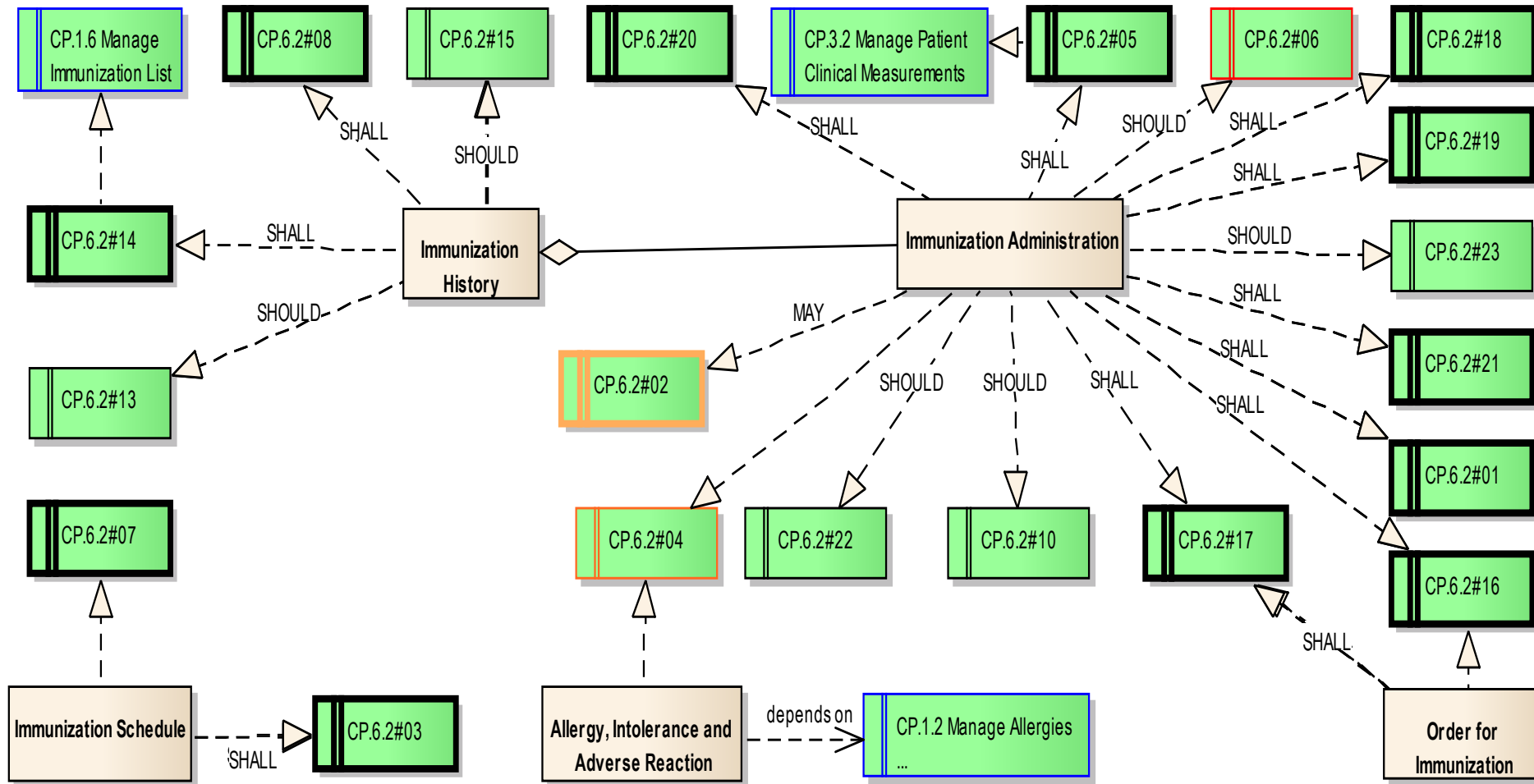


EHR-S-FIM



Conceptual Traceability Model CP.6.2 Immunization Management

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

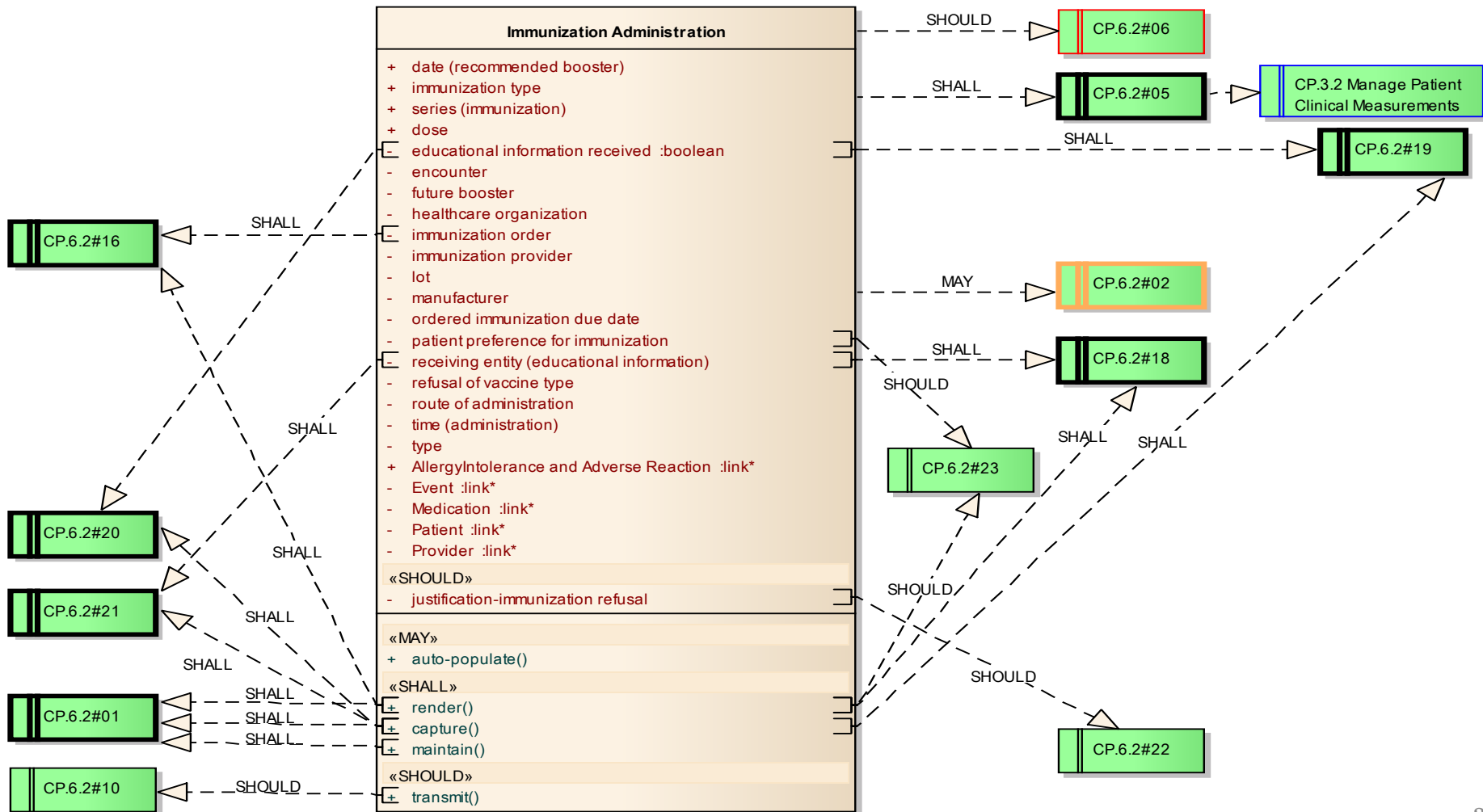


EHR-S FIM

Logical Traceability-Model CP.6.2 Immunization Management



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

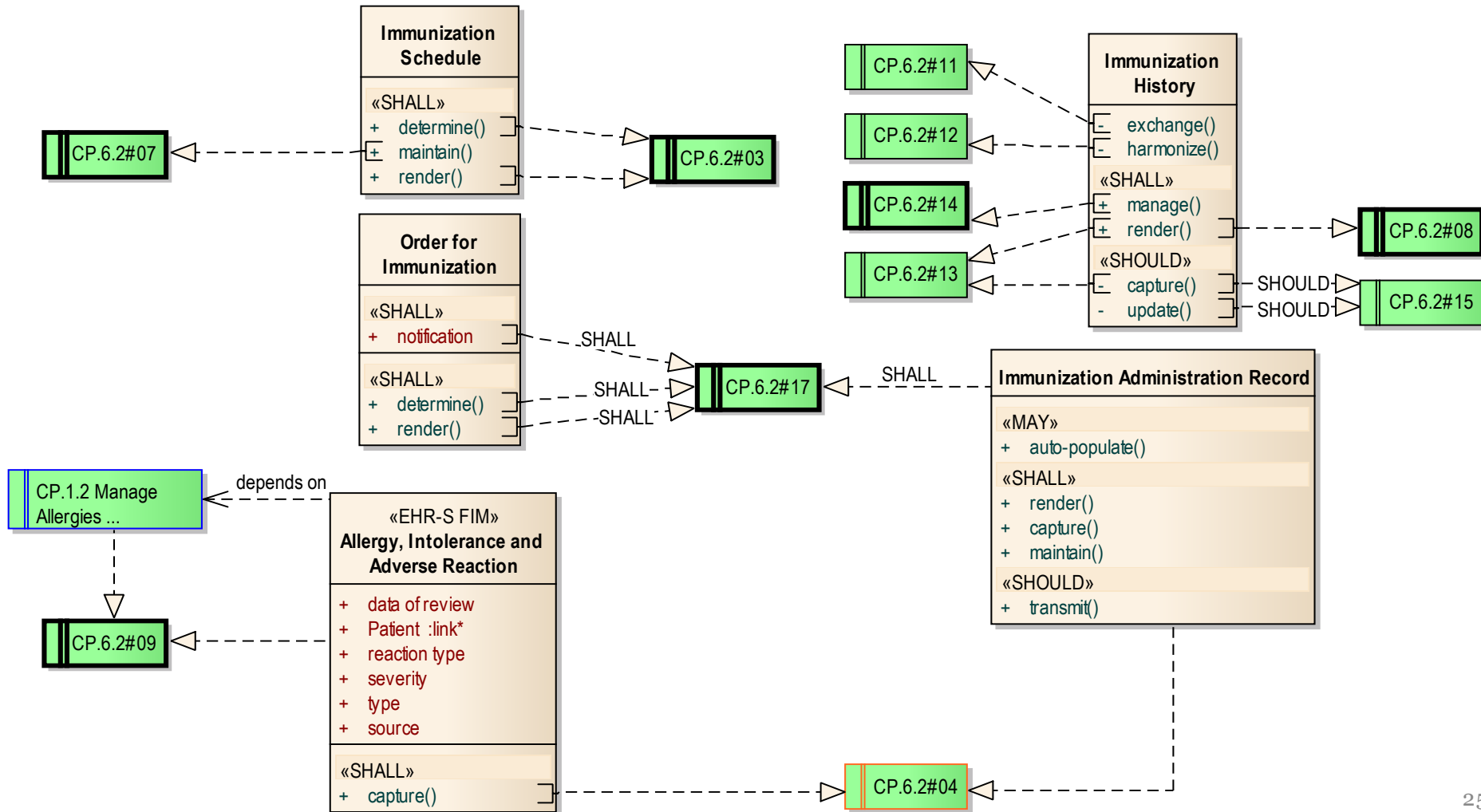


EHR-S FIM

Logical Traceability-Model CP.6.2 Immunization Management



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



EHR-S-FIM

Conformance Criteria (CCs)

CP.6.2 Immunization Management

1. 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."
2. 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.
3. 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.
4. The system **SHOULD** provide the ability to *capture, in a discrete field, an allergy/adverse reaction to a specific immunization*.
5. 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).
6. 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.
7. The system **SHALL** provide the ability to *maintain the immunization schedule*.
8. 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.
9. The system **SHALL** conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
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.
11. The system **SHOULD** exchange immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.

Conformance Criteria (CCs)

CP.6.2 Immunization Management

ISSUE: Consistency of Conformance Criteria (CC) across related functions, such as Medication-and-Immunization and Orders-and-Results Management.

12. The system **SHOULD** harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
13. The system **SHOULD** capture and render immunization histories from a public health immunization registry.
14. The system **SHALL** conform to function CP.1.6 (Manage Immunization List).
15. The system **SHOULD** provide the ability to update immunization histories at the time of capturing an immunization administration.
16. The system **SHALL** provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information.
17. "The system **SHALL** provide the ability to determine due and overdue ordered immunizations and render a notification. "
18. The system **SHALL** provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (**VIS**)).
19. The system **SHALL** provide the ability to capture that patient educational information (e.g., **VIS**) was provided at the time of immunization administration.
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.
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.
22. The system **SHOULD** provide the ability to capture and maintain immunization refusal reasons as discrete data.
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.

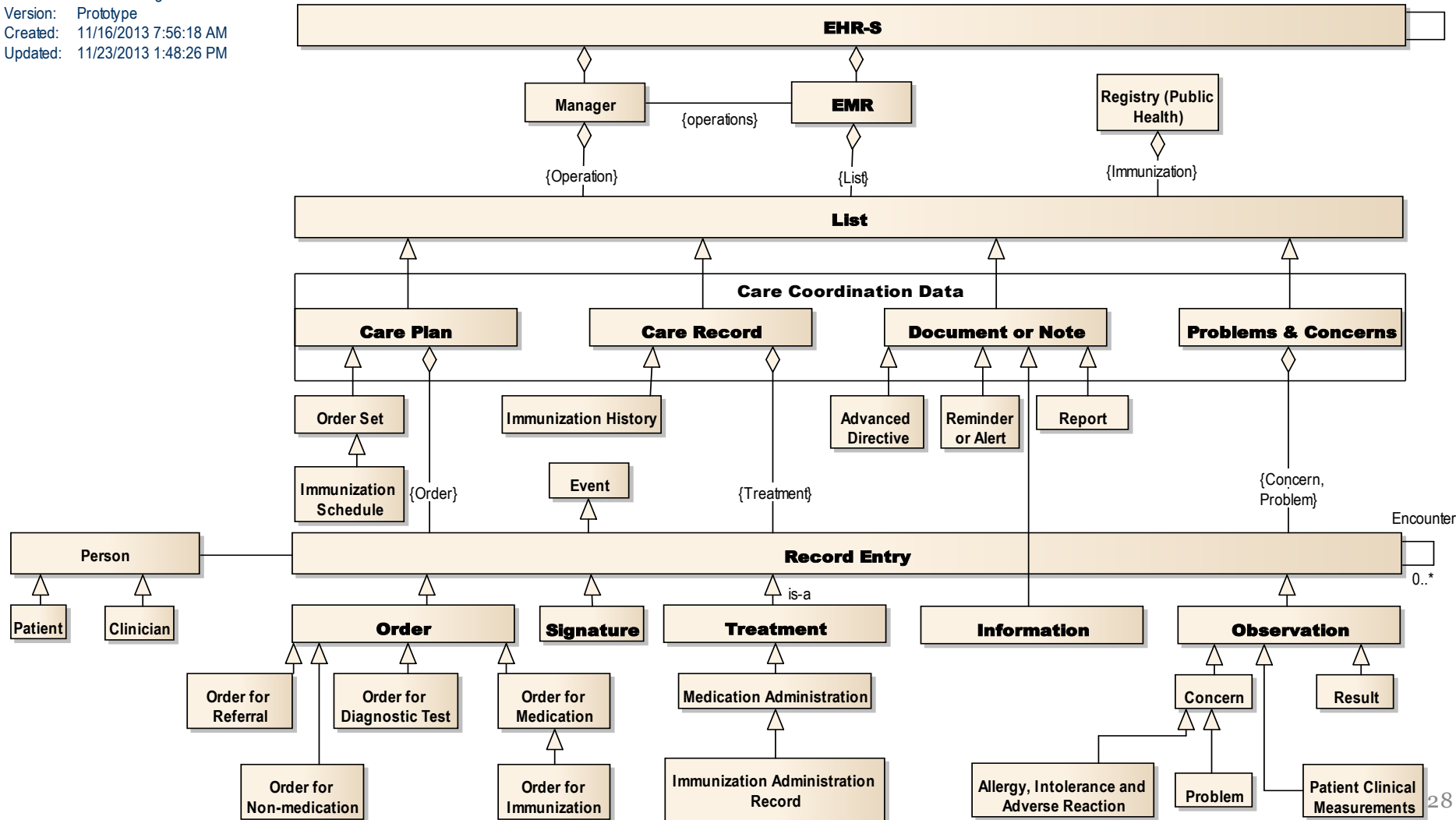
EHR-S FIM Anatomy (Structure) Conceptual Information-Model (Level 4)



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: 11/23/2013 1:48:26 PM

other EHR or related systems



■ 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-Operation and Reference-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 November-2013 is available at
http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

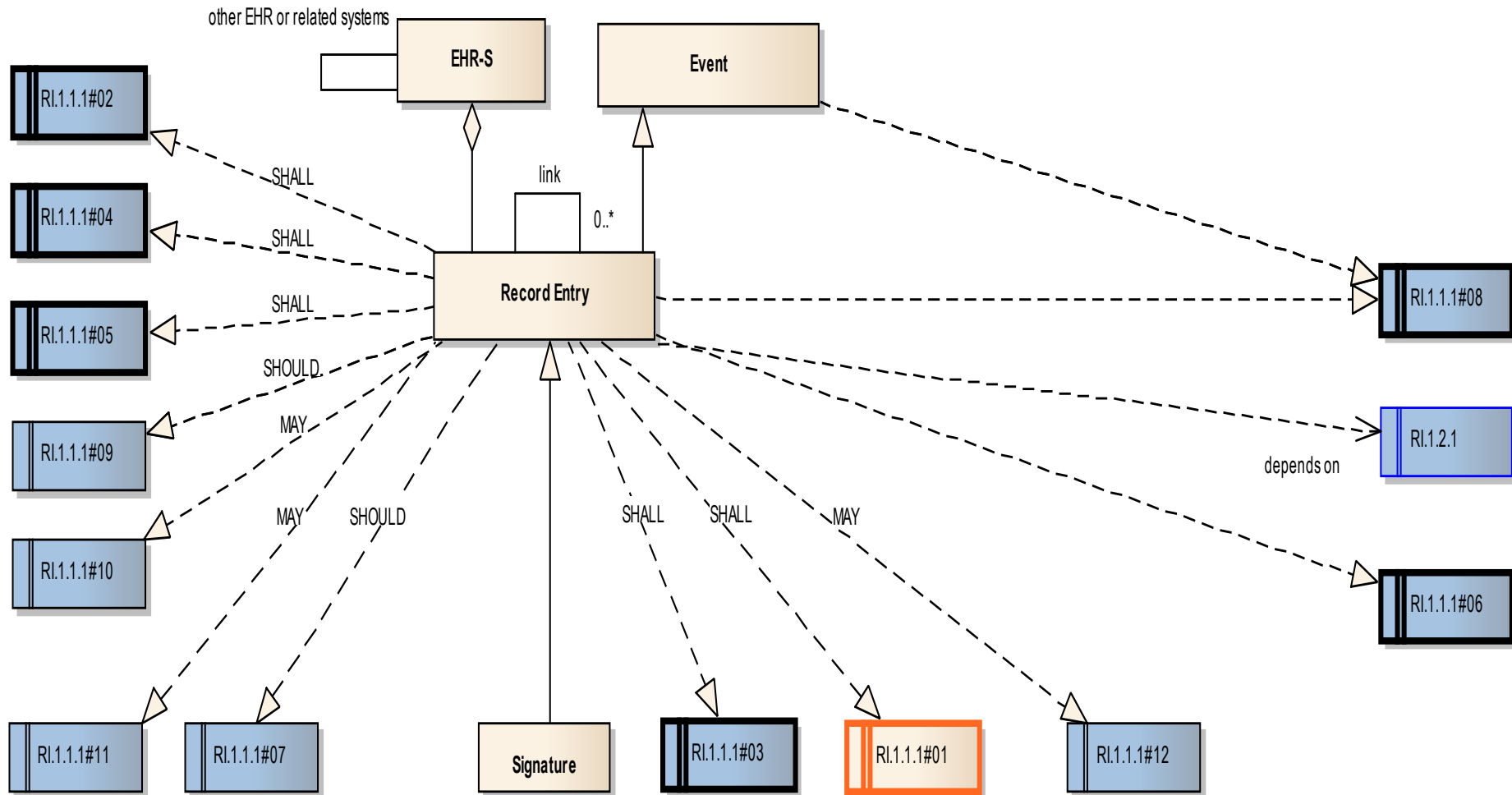
EHR-S FIM



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

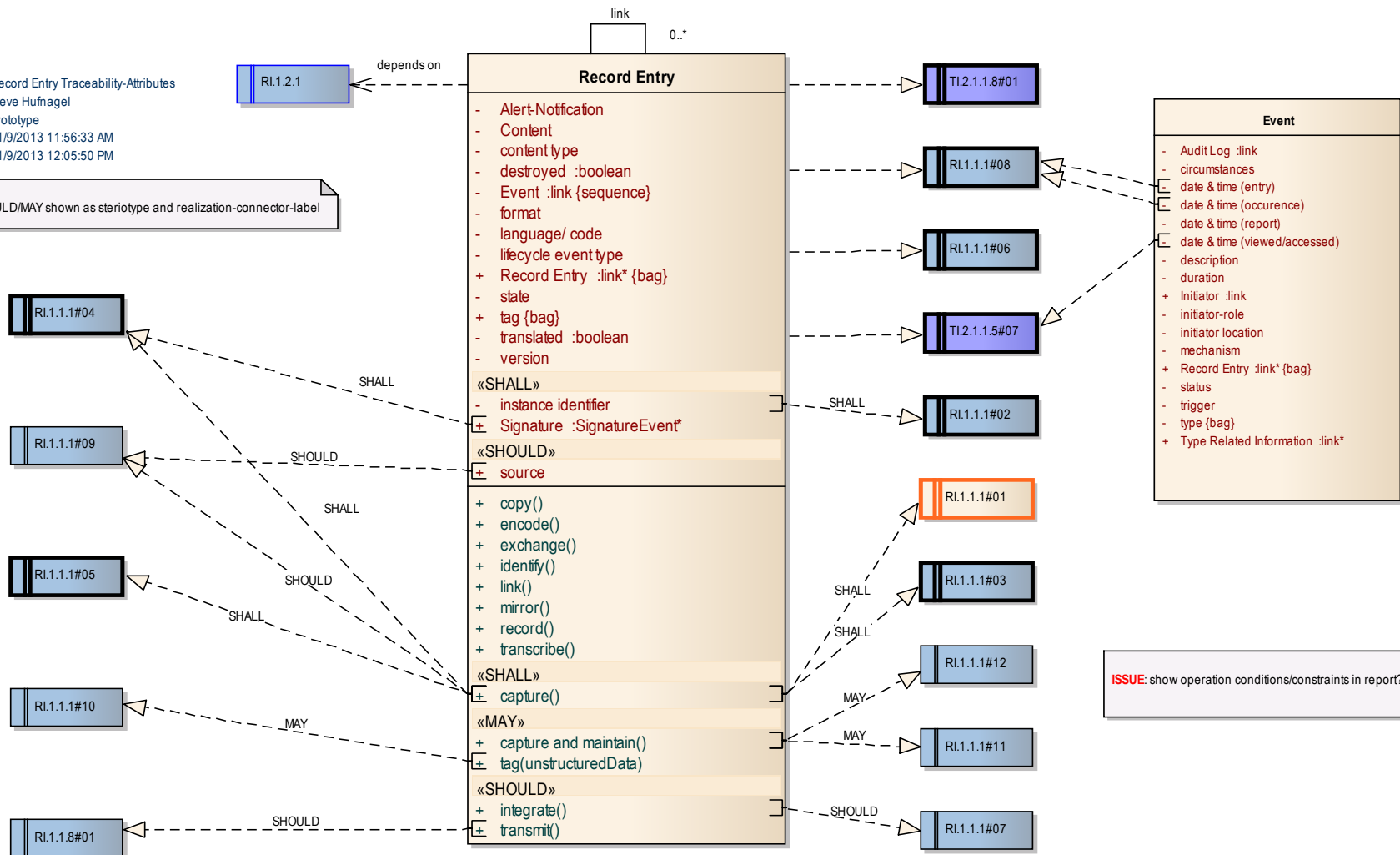
RI.1.1.1 Originate-and-Retain Record Entry



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

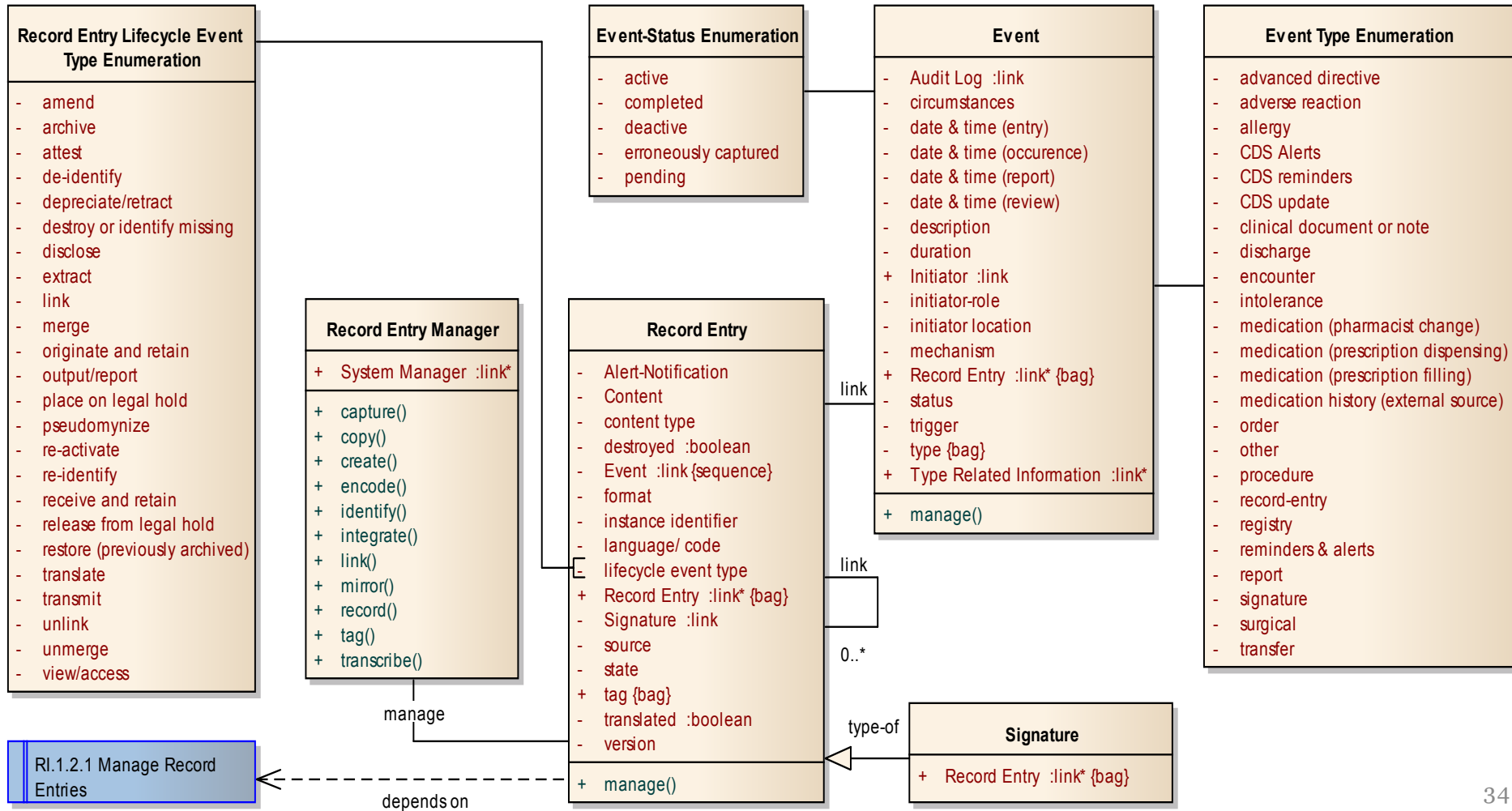
1. RI.1.1.1#01 The system **SHALL** provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
2. RI.1.1.1#02 The system **SHALL** capture a unique instance identifier for each Record Entry.
3. RI.1.1.1#03 The system **SHALL** conform to function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

■ Contents

FY2014Q1-Prototype Report

EHR-S FIM Release-3:2016 Preparation

1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operation and Reference-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 November-2013 is available at
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

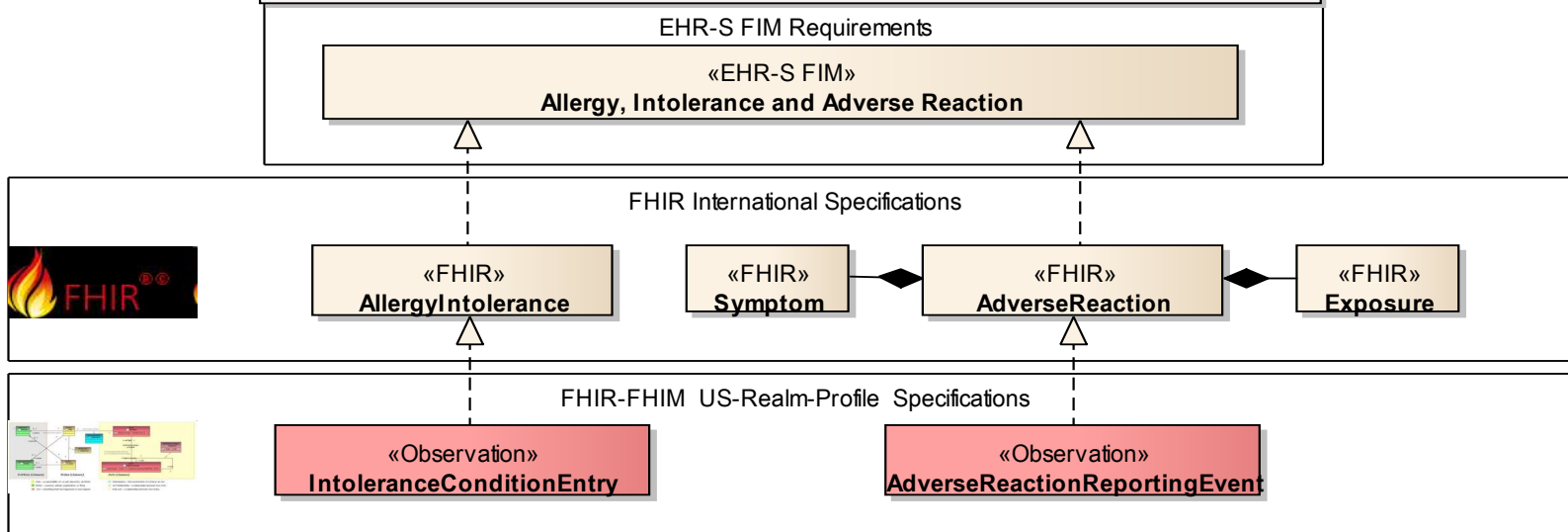
FIM-FHIR-FHIM Requirements-Specifications

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

Name: FHIR-FHIM High-Level Specification for Allergy, Intolerance and Adverse Reaction
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/7/2013 4:26:03 AM
 Updated: 11/18/2013 9:07:42 AM

- The 2016 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



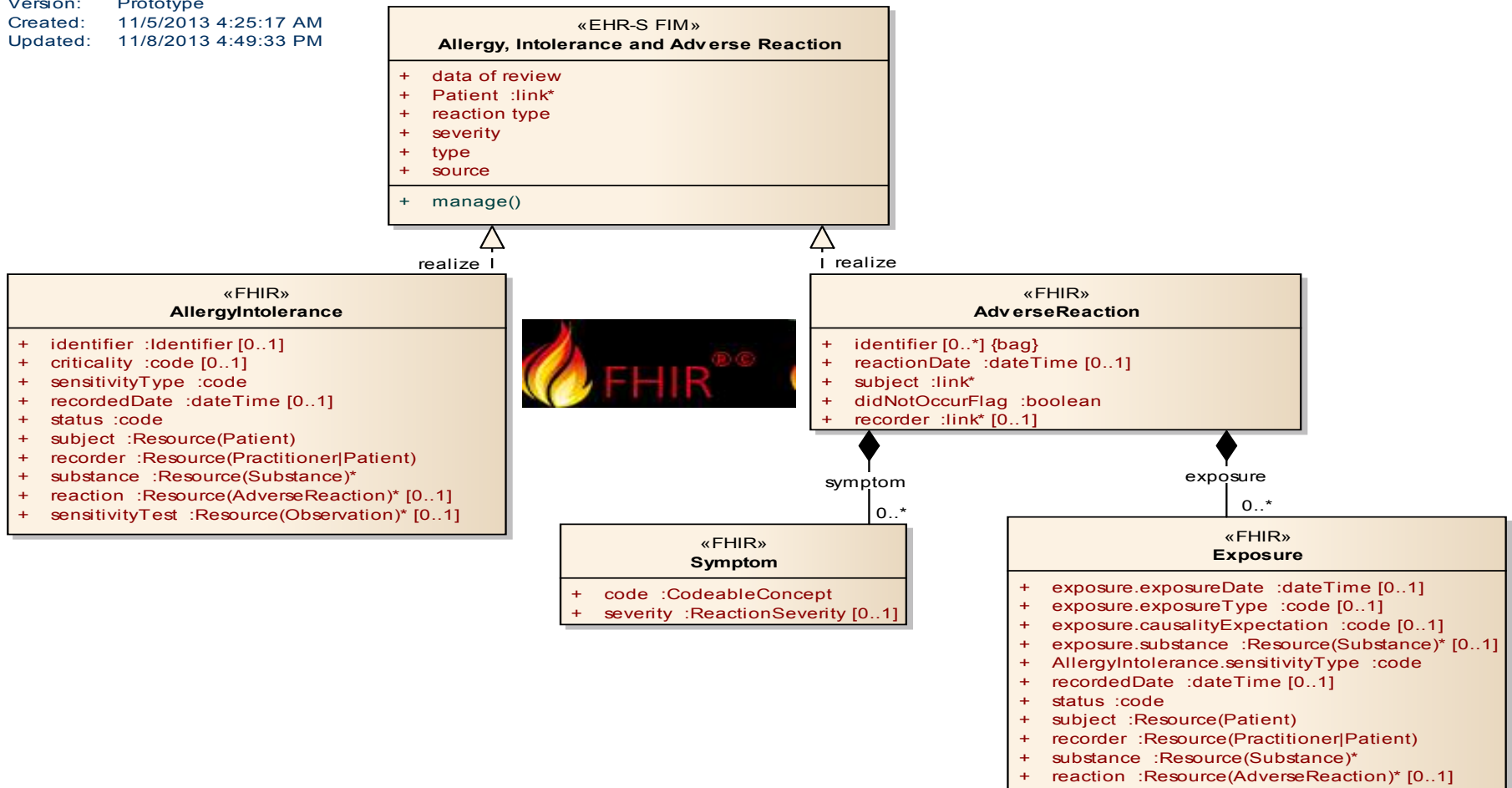
Prototype

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



Contents

FY2014Q1-Prototype Report

EHR-S FIM Release-3:2016 Preparation

1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operation and Reference-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

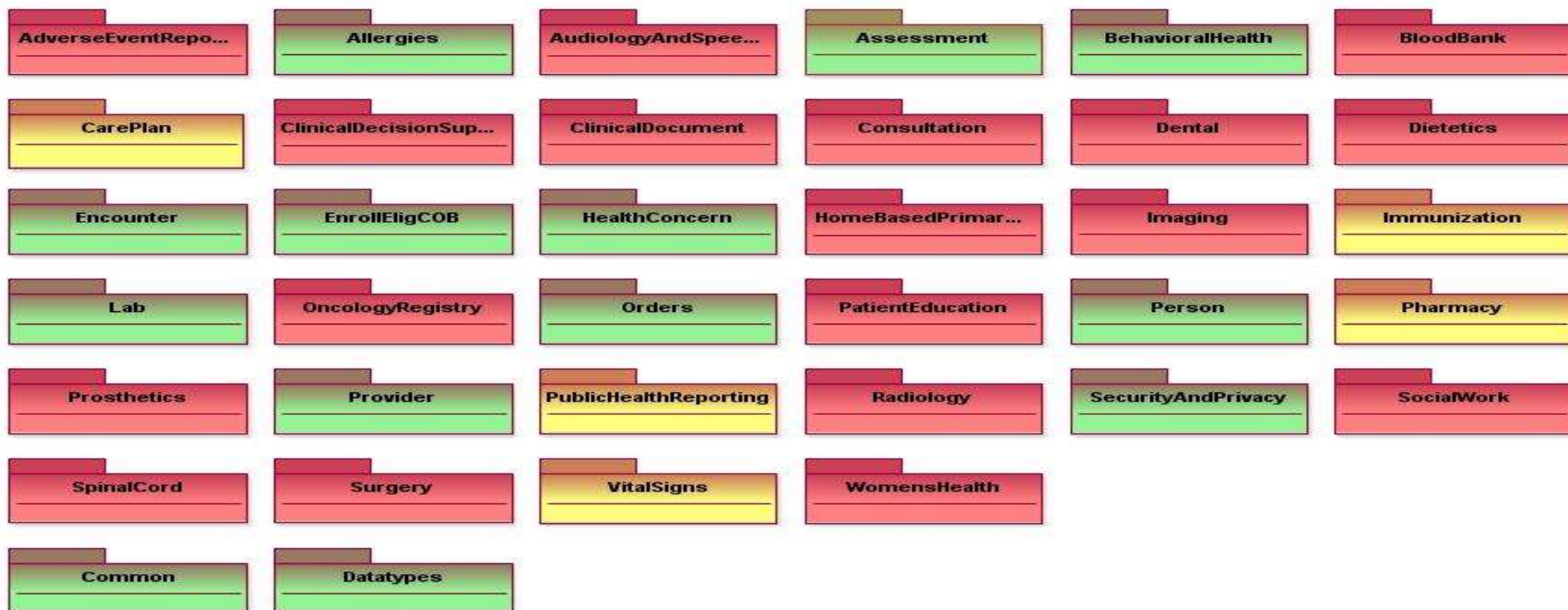
The complete-and-current HL7 EHR-System Function-and-Information Model Release-3 Development-Summary Presentation, dated November-2013 is available at http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

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

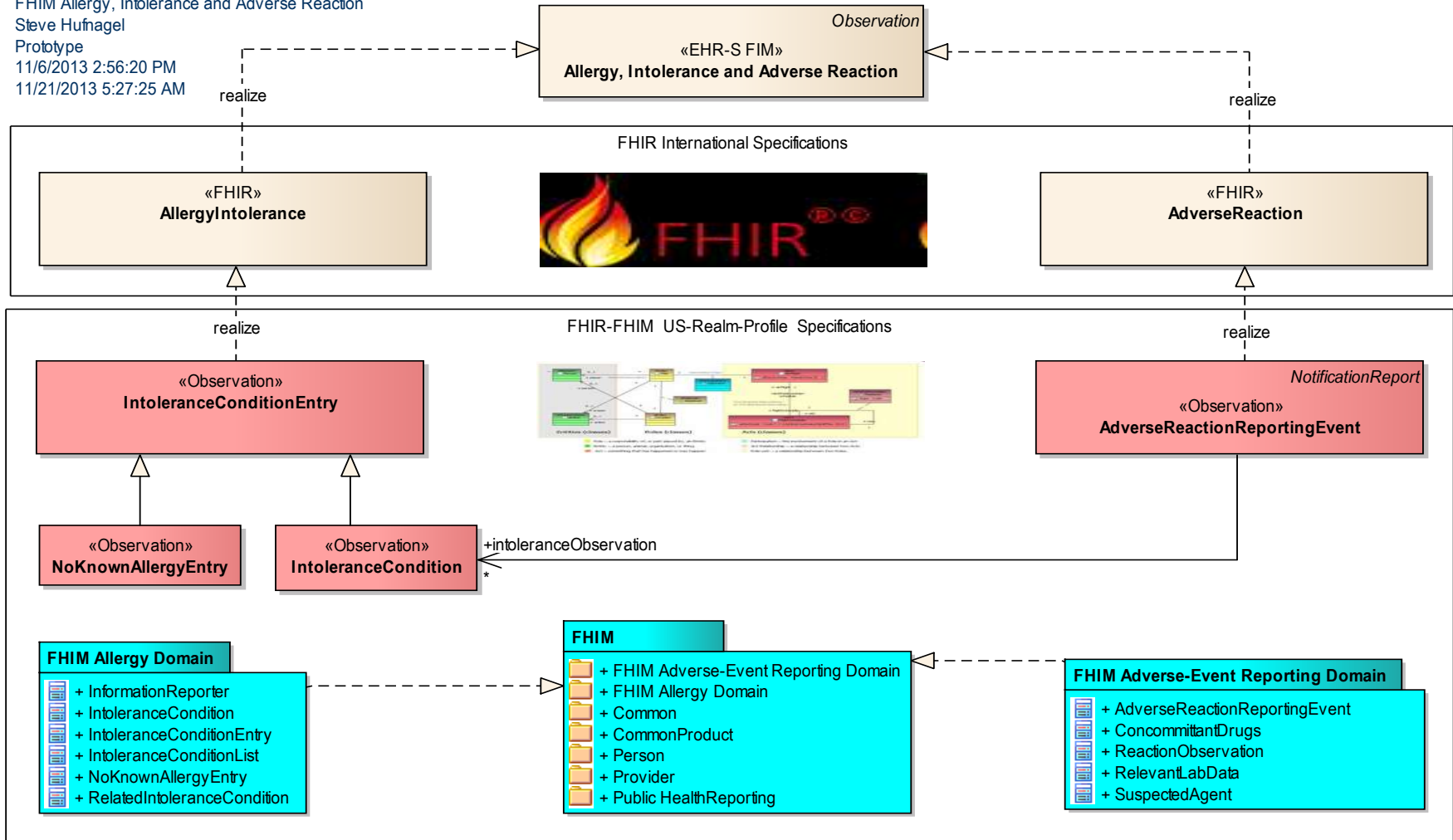
Unchanged from the VHIM

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
 Created: 11/6/2013 2:56:20 PM
 Updated: 11/21/2013 5:27:25 AM

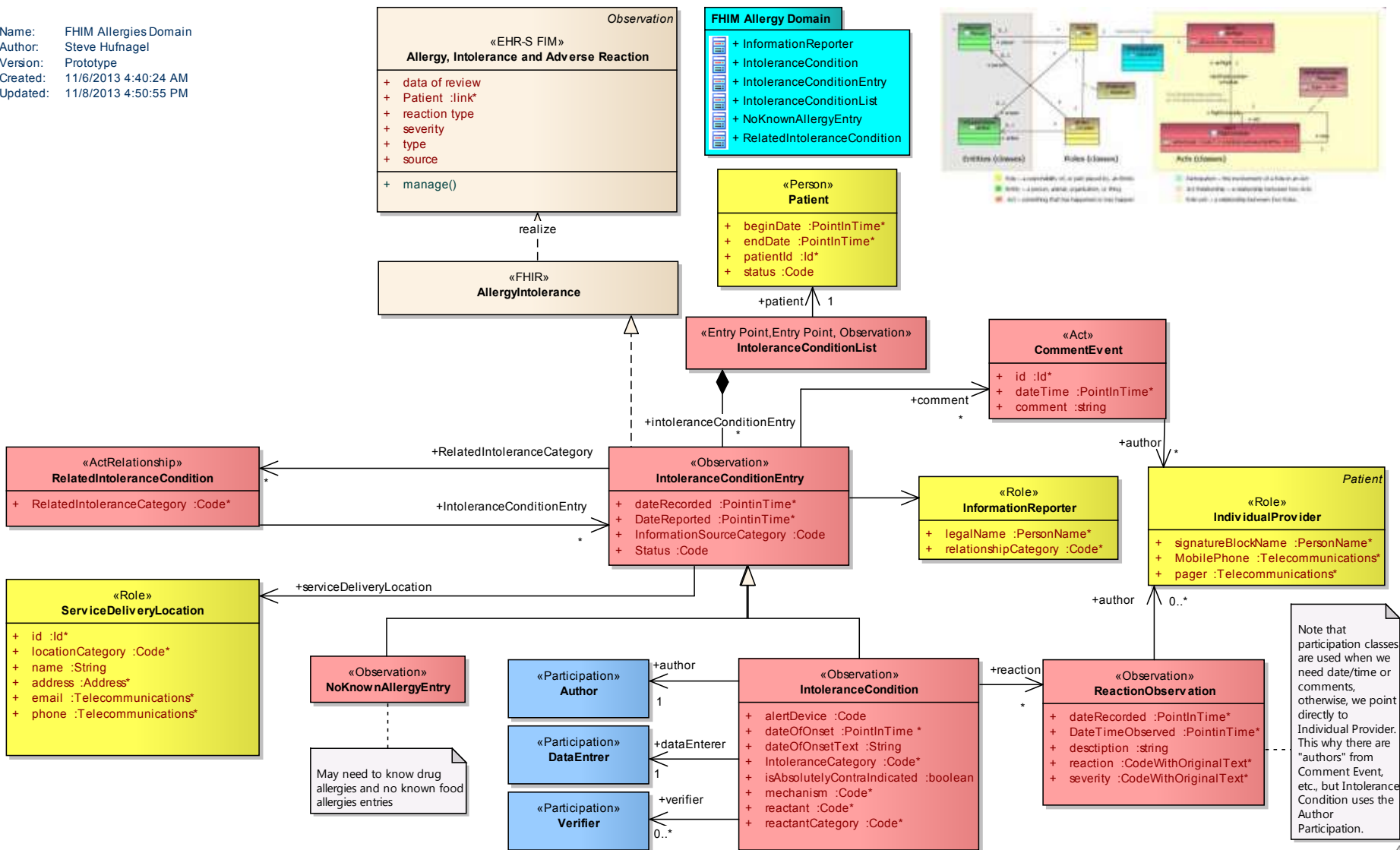


Prototype

FHIM-Detailed Allergy & Intolerance Specification

class FHIM Allergies Domain

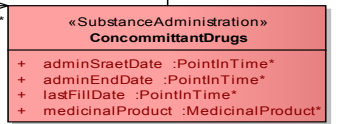
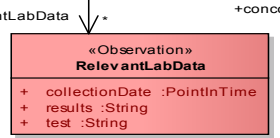
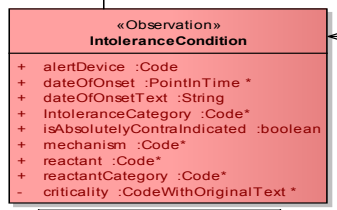
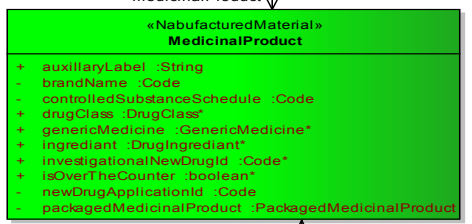
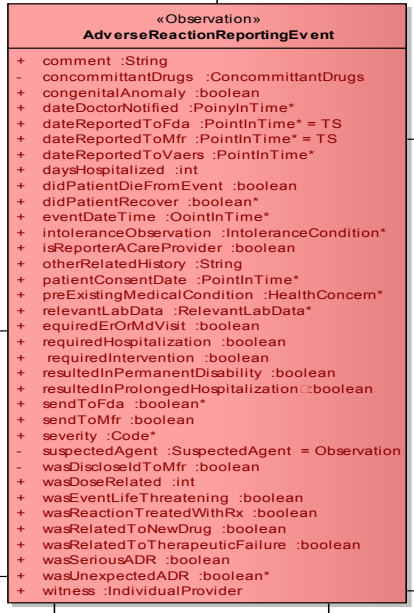
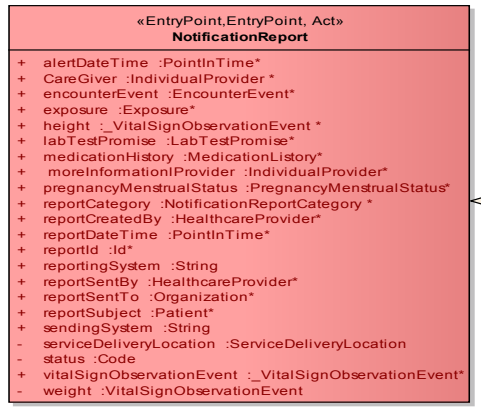
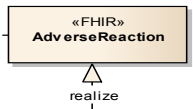
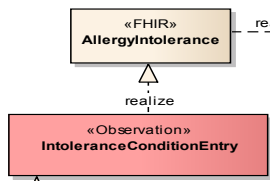
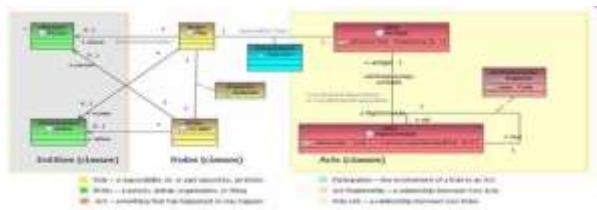
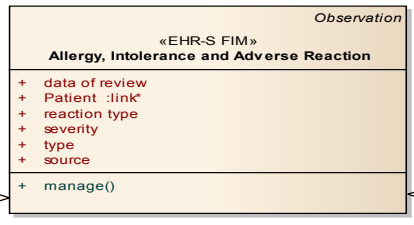
Name: FHIM Allergies Domain
 Author: Steve Hufnagel
 Version: Prototype
 Created: 11/6/2013 4:40:24 AM
 Updated: 11/8/2013 4:50:55 PM



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



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

Contents

FY2014Q1-Prototype Report

EHR-S FIM Release-3:2016 Preparation

1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operation and Reference-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 November-2013 is available at http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

EHR-S FIM Issue Traceability

ISSUE: EHR-S FM r2.0 traceability to UML Model Elements to EHR-S FIM r3.0, FHIR & FHIM

- **Workbook 1:** Class attributes & operations mapped-to EHR-S FM r2.0 Functions and LOCAL CCs
- **Workbook 2** Class attributes & operations mapped to EHR-S FIM r3.0 Functions and GLOBAL CCs
- **Workbook 3** EHR-S FM r2.0 Functions and CCs mapped-to EHR-S FIM r3.0 Functions and CCs
- **Workbook 4** EHR-S FM r2.0 Functions and LOCAL Conformance Criteria (**CC**) listed out for linking
- **Workbook 5** EHR-S FIM R3.0 Functions and UNIVERSAL CC listed out for linking
- **Workbook 6** EHR-S FIM UML-Model mapped-to FHIR
- **Workbook 7** EHR-S FIM UML-Model mapped-to FHIM (Federal Health Information Model)
- **Workbook 8** FHIR mapped-to FHIM (Federal Health Information Model)
- **Workbook 9** Master Data Dictionary (DD) (If we use FHIR or FHIM , they already have a DD)
- **ACTION:** Use Sparx EA to implement t raceability.

■ EHR-S FM Action-Verb Hierarchy Vs. EHR-S FIM Manager-Operations VS. Record Lifecycle Events

ISSUE: traceability of CC Verb-Hierarchy vs. Record Lifecycle Events.

Manage (Data)

Capture	Maintain			Render			Exchange	Determine		Manage-Data-Visibility
Auto-Populate Enter Import Receive	Store	Update	Remove	Extract	Present	Transmit	Export Import Receive Transmit	Analyze	Decide	De-Identify Hide Mask Re-Identify Unhide Unmask
	Archive Backup Decrypt Encrypt Recover Restore Save	Annotate Attest Edit Harmonize Integrate Link Tag	Delete Purge	<div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">Record Entry Lifecycle Event Type Enumeration</p> <ul style="list-style-type: none"> - originate and retain - amend - translate - attest - view/access - output/report - disclose - transmit - receive and retain - de-identify - pseudonymize - re-identify - extract - archive - restore (previously archived) - destroy or identify missing - depreciate/retract - re-activate - merge - unmerge - link - unlink - place on legal hold - release from legal hold </div>						

← Record-Entry Lifecycle Events are located here for convenience; but, how do they correspond to Verbs in the verbs hierarchy?.