



# EHR Work Group Summary Briefing

## HL7 EHR Work Group (EHR-WG)

by Stephen Hufnagel, Tiag subcontractor  
to Edmond-Scientific VA support-contract  
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**December 18, 2013 Complete-and-current working-drafts are at**  
[http://wiki.hl7.org/index.php?title=EHR\\_Interoperability\\_WG](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).

# Call for Participation

**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#	<a href="#">Link</a>	EHR Legal
Tues	1300	EHRS FM Release 3 Planning	Hufnagel, Dickinson	1-770-657-9270, Passcode 510269#	<a href="#">Link</a>	EHR Interop
	1400	Meaningful Use Functional Profile	Datta, Dickinson	1-770-657-9270, Passcode 510269#	<a href="#">Link</a>	EHR Interop
	1500	FULL EHR WG	Co-Chairs	1-770-657-9270, Passcode 510269#	<a href="#">Link</a>	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#	<a href="#">Link</a>	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 and PHR-S FIM Release-3 Preparation

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

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

The complete-and-current HL7 EHR-System Function-and-Information Model Release-3 Development-Summary Presentation, dated December-2013 is available at  
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# EHR-S FIM Acronyms

- **aka** also known as
- **CC** EHR-S FIM Conformance Criteria
- **CCB** Change Control Board
- **CDA** Clinical Document Architecture
- **CCDA** Consolidated Clinical Document Architecture
- **CIM** Conceptual Information Model
- **CM** Change Management
- **DD** Data Dictionary
- **CIM** Conceptual Information Model
- **CP** Care Provision
- **CPS** Care Provisioning Support
- **DFD** Data Flow Diagram
- **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** Function and Information Model
- **FIM (MU)** FIM Meaningful Use profile
- **FM** Function Model
- **FY** Fiscal Year
- **IHE** Integrating the Healthcare Enterprise
- **IM** Information Model
- **IV&V** Independent Verification and Validation
- **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
- **QA** Quality Assurance
- **R 2/3** Release 2 or 3
- **RI** Resource Infrastructure
- **RIM** (HL7) Reference Information Model
- **S&I** ONC Standards & Interoperability Framework
- **SDLC** Software Development Lifecycle
- **WBS** Work Breakdown Structure
- **WG** Work Group



# Executive Summary

## EHR-S and PHR-S FIM r3 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 Conformance Criteria (CCs)
    - One Infrastructure-section containing previously-separate 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
  - Information Exchanges and selectable implementation paradigms, such as
    - V2 & V3 messaging, CDA, SOARLUS Specifications
    - 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.

# ■ Executive Summary Conclusions and Recommendations EHR-S and PHR-S FIM r3 Preparation

1. **EHR-S FIM vision** is to become the "Easy Button" for *EHR Interoperability Specifications*
  - a. Easily-customizable to user-specific needs aka profiles.
  - b. Including a US-Realm Meaningful Use (MU) & FHIM profile
  - c. EHR-S and PHR-S FIM r3 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 Interoperability-Specification report
    - iv. user-specific profiles (e.g., WG project DAMs, DIMs, DCMs) can be supported.
2. **EHR-S & PHR-S FIM r3 needs the same IP license as FHIR to foster user engagement**
3. **HL7.org/EHR 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 and PHR-S FIM r3 resources

# ■ Plan-of-Actions and Milestones

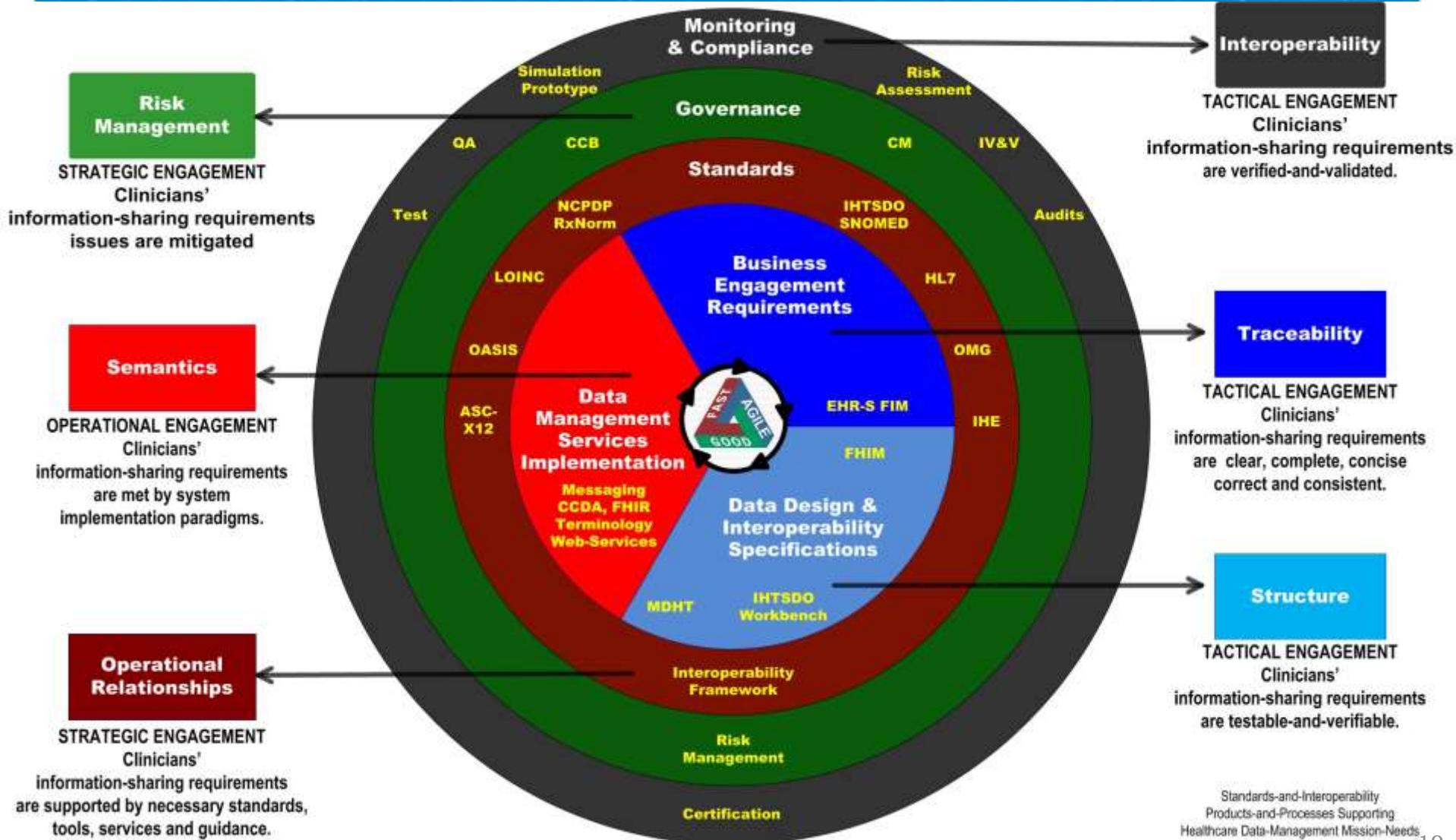
## FY2014Q1 POA&M

### EHR-S and PHR-S FIM Release-3 Preparation

	<b>Completed</b>
<b>October 2013 (Identify processes, tools and issues/risks)</b>	
• Prototype CP.6.2 Immunization Management	22-Oct-13
• Prototype RI.1.1.1 Originate-and-Retain Record-Entry	29-Oct-13
<b>November 2013 (Prototype complete process-and-products)</b>	
• 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
<b>December 2013 (Develop production WBS and POA&amp;M)</b>	
• Create Release 3 Work-Break-Down Structure (WBS) & POA&M	10-Dec-13
• Harmonize with Electronic Health Record Communication (ISO/EN 13606)	10-Dec-13
• Harmonize with ISO/EN 13940 Continuity-of-Care System-of-Concepts	pending
• Prototype EHR-S FIM Ballot Production process-and-products for prototype	pending
<b>January 2014 – 2016 (Approve &amp; Execute Plan)</b>	
• 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	

# EHR-and-PHR System Users-and-Values

## EHR-System Data-Management Mission-Needs Areas





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# Situation (1 of 4)

## ‘2016 EHR-S & PHR-S FIM Release-3

An EHR/PHR CONOPS is defined-and-refined into a System **Reference-Model** (RM); where,

- **System Functions** are defined-by **Use-Cases**; where,
  - **System-operations** are verbs refined into a “*manage* verb-hierarchy” aka operation-type model,
  - **System-entities** are subject-and-object nouns refined into a “Record-Entry data-model” aka data-type model
  - **Terminology value-sets** are bound-to “discrete-data-elements” within each Record-Entry.
- **Requirements** Conformance-Criteria are defined-by use-case scenarios; where,
- **Scenarios** define
  - **business-context** and
  - **subject-verb-object-terminology bindings**; where,



## Situation (2 of 4) ‘2016 EHR-S & PHR-S FIM Release-3

An EHR/PHR CONOPS was defined-and-refined into a System **Reference-Model** (RM); where,

- **Business-Context** is defines pre, post and invariant conditions; where,
  - **pre-condition** are triggers, followed by
  - **applicability**; where,
    - “The System SHOULD or SHALL or MAY”
    - “provide-the-ability-to-manage Record-Entries” or “directly-manage Record-Entries,” where,
      - a use-case constrained manage-hierarchy verbs apply and
      - a use-case constrained data-model nouns applies; where,
  - **post-condition** business-rules are “according-to scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences.”



## Situation (3 of 4) ‘2016 EHR-S & PHR-S FIM Release-3

An EHR/PHR CONOPS was defined-and-refined into a System **Reference-Model** (RM); where,

- **Information-Exchanges** are defined-by scenarios mapped to implementation-paradigms
  - **HL7 V2 and V3 message, RIM and CDA, SOA RLUS standards and related DAMS**
  - **FHIR** (Fast Healthcare Interoperability Resource) specifications, for the International-Realm,
  - **FHIM** (Federal Health Information Model) Specifications, for the US-Realm, bound to
  - **Terminology value-sets**,
  - **IHE information-exchange behavioral-protocols** refined by,
    - **SLA and DURSA** (Service-level-agreement *Data-Use-and-Reciprocal-Support-Agreement*) *and*
    - **KPPs** (Key Performance Parameters).
    - **Cost estimation factors**
- **EHR-S/PHR-S Profiles** are defined-by a set-of System-Function Use-Cases, with further constrained scenario' applicability, business-context and subject-verb-object-terminology bindings.



## Situation (4 of 4) ‘2016 EHR-S & PHR-S FIM Release-3

An EHR/PHR CONOPS was defined-and-refined into a System **Reference-Model** (RM); where,

- **Interoperability-Specifications** are generated with the FIM r3 reporting-tool.

The benefit of this formally-specified **Concept-of-Operation** (CONOPS) and **Reference Model** (RM) approach is

- a clear, complete, concise, correct and consistent
- EHR-S and PHR-S Function-and-Information Model (FIM), profiles and
- resultant Interoperability-Specifications (ISs);
- where, ISs include appropriate implementation-paradigm specifications
  - (V2 or V3 messaging, CDA, FHIR profiles, RLUS Data Services).

# ■ Reference Model (RM) Definition EHR-S and PHR-S FIM Release-3 Preparation



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

## 1. Structures significant-relationships among system entities

- defined-by system Action-and-Information Conceptual-Models; where,
- System RM is based-on a functional-use-case constrained hierarchical-lexicon of
  - nouns (Data-Entities) and noun qualifiers (Data-hierarchy or Sub-Types),
  - verbs (System-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 & PHR-S RM Reference Model (RM)



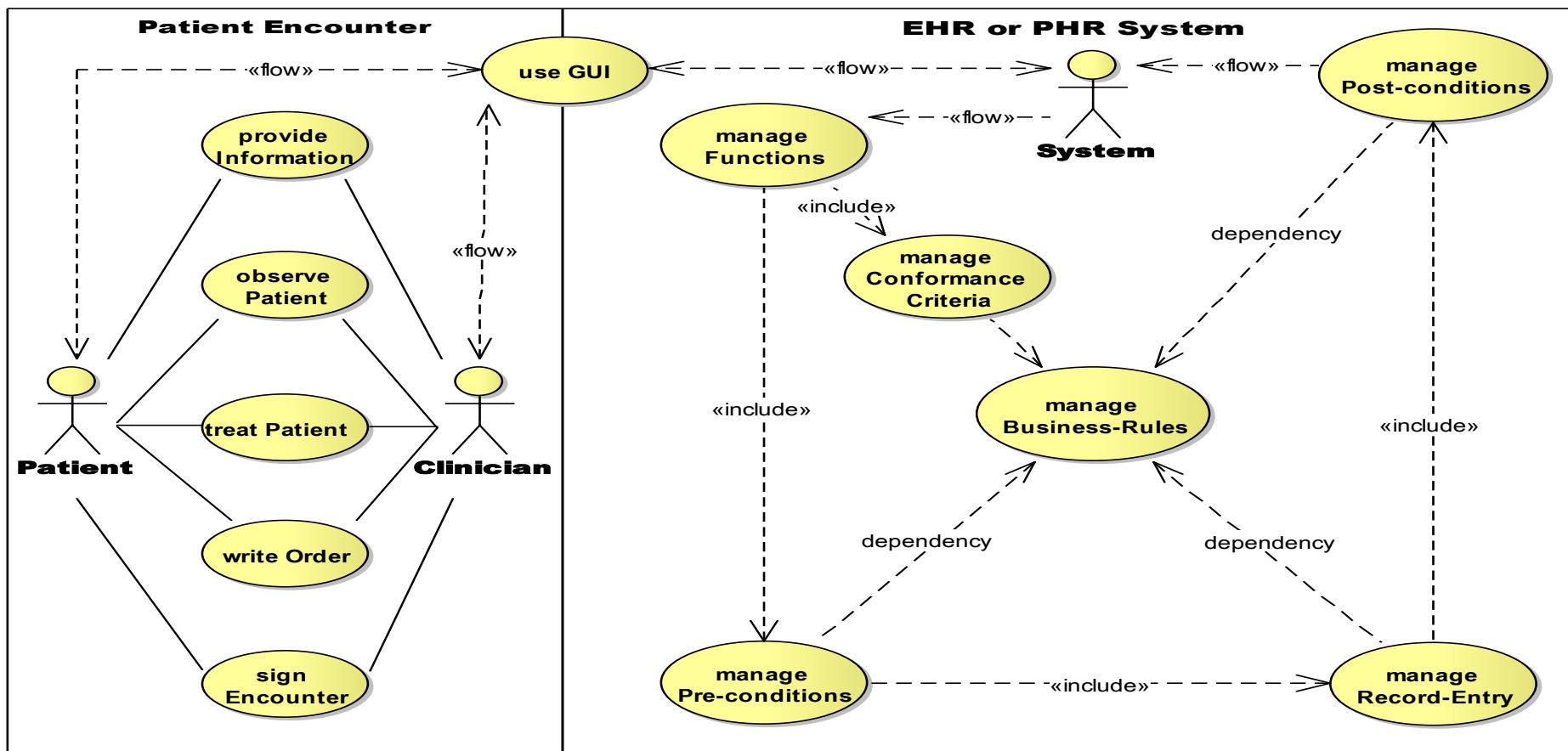
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 Version: EHR-S FIM (r3 2013 Prototype)  
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 Updated: 12/16/2013 5:33:52 AM

**Functions** are modeled-as "manage Record-Entry" sub-type **Use-Cases**.  
**Conformance Criteria** are modeled-as (subject, verb, object) **Scenarios**; where,  

- subjects-and-objects are Record-Entry sub-types
- verbs are *manage* sub-types

**Business Rules** are "according to scope of practice, organizational policy, jurisdictional law, patient preference or consent."



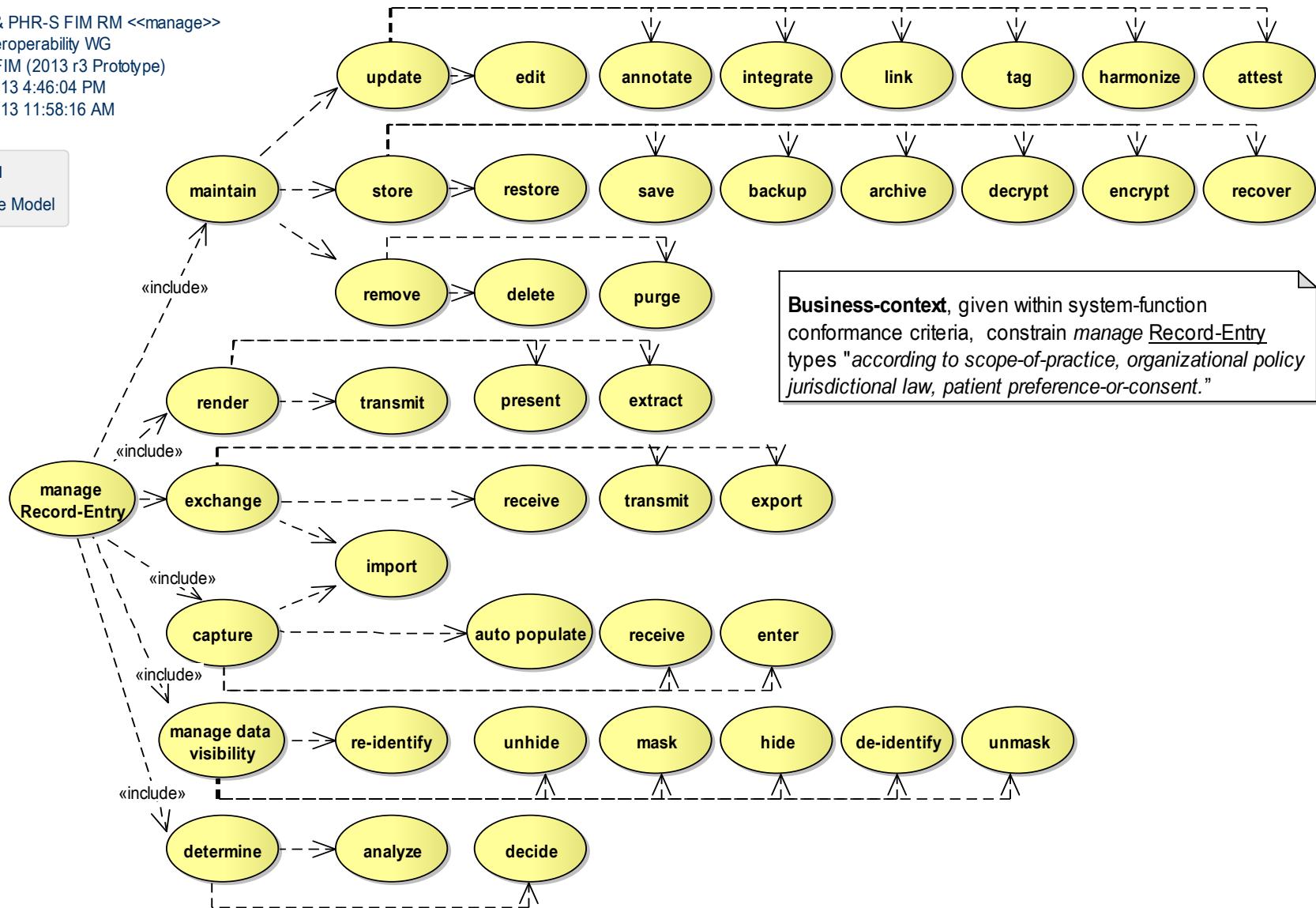
# EHR-S and PHR-S RM for <<manage>>

## System-Action Verb-Type Hierarchy



uc EHR-S & PHR-S FIM RM <<manage>>

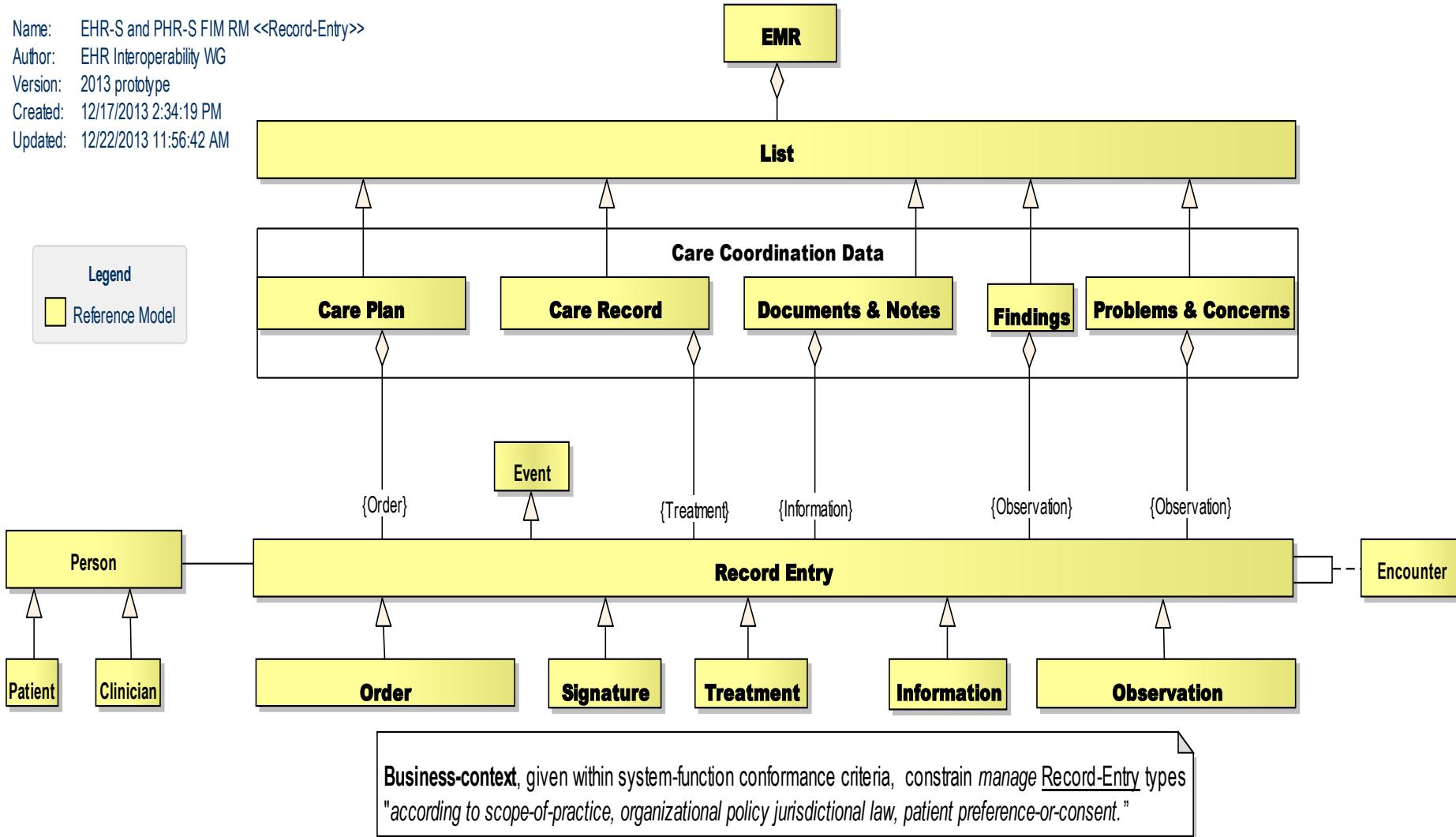
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# EHR-S and PHR-S RM for <<Record-Entry>> Data-Types

class EHR-S and PHR-S FIM RM <<Record-Entry>>

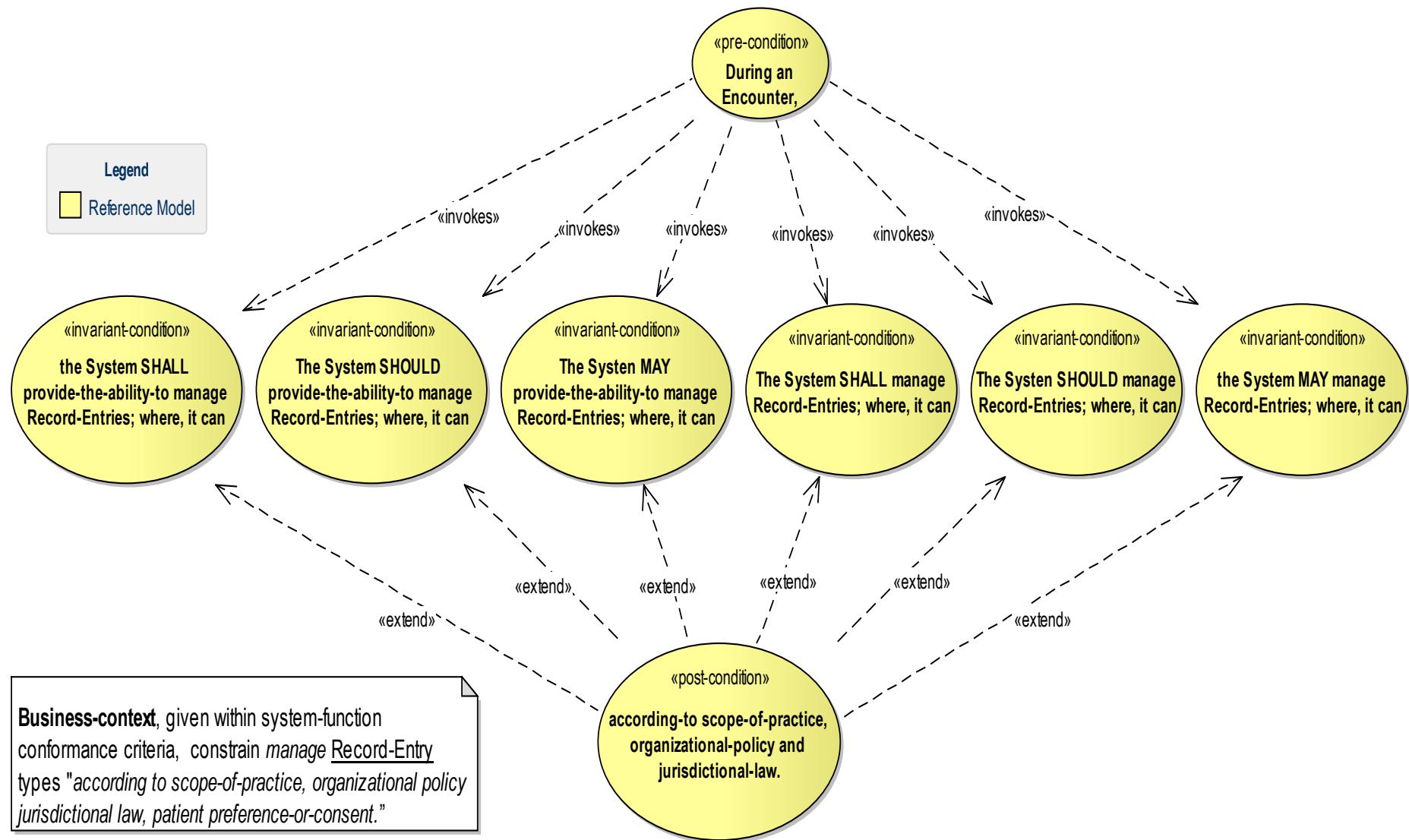
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# EHR-S and PHR-S RM for <<pre, invariant, post>> Condition-Types



class Release-3 EHR-S RM <<condition>>



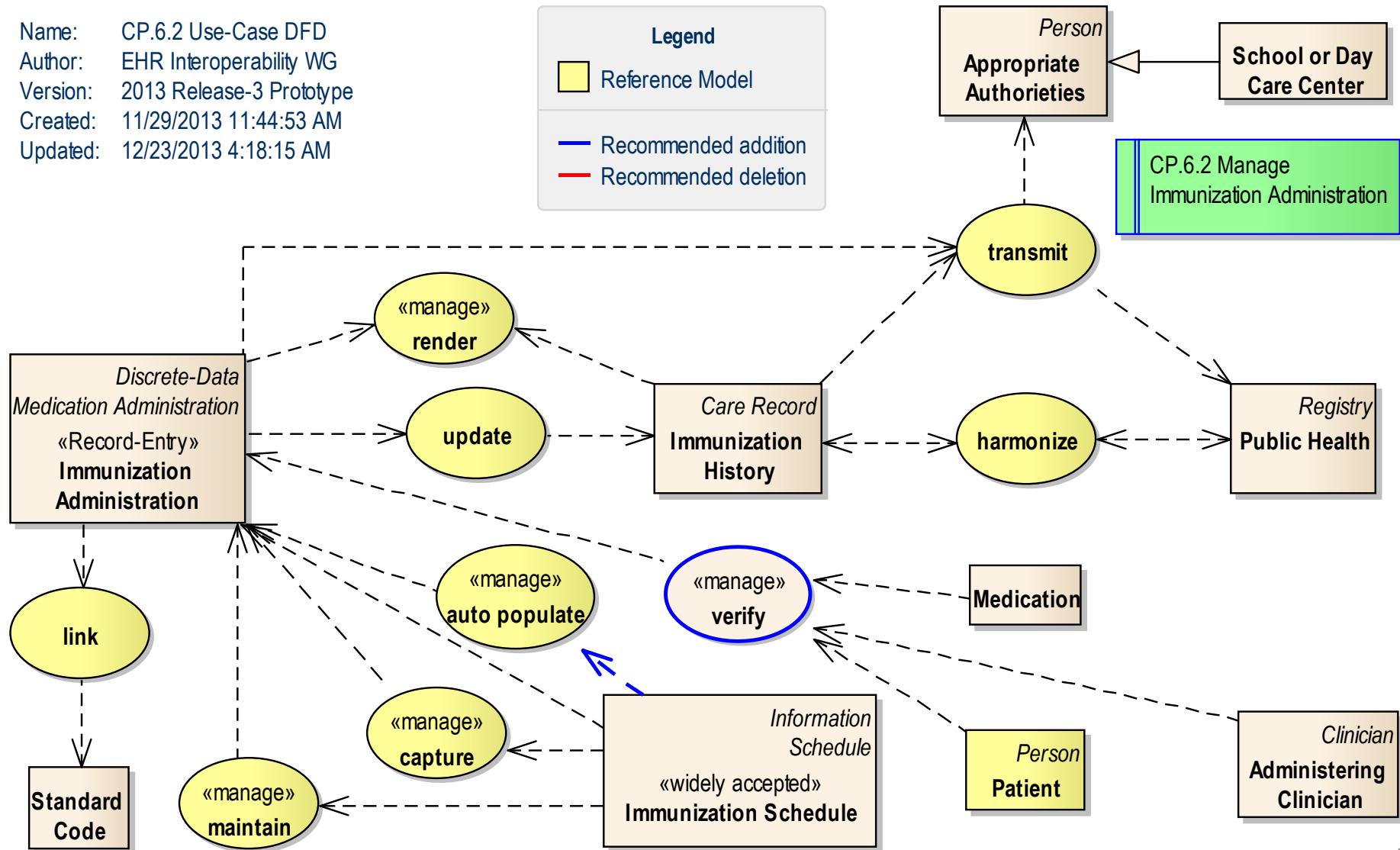
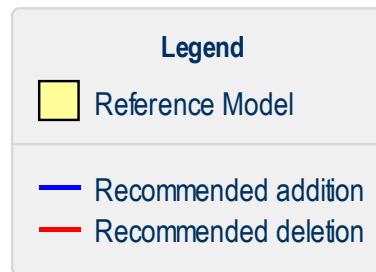
# Example RM-based Functional Use-Case DFD

## CP.6.2 Immunization Management



uc CP.6.2 Use-Case DFD

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 Version: 2013 Release-3 Prototype  
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 Updated: 12/23/2013 4:18:15 AM



## ■ Example RM-based Functional Use-Case CP.6.2 Immunization Management

“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.

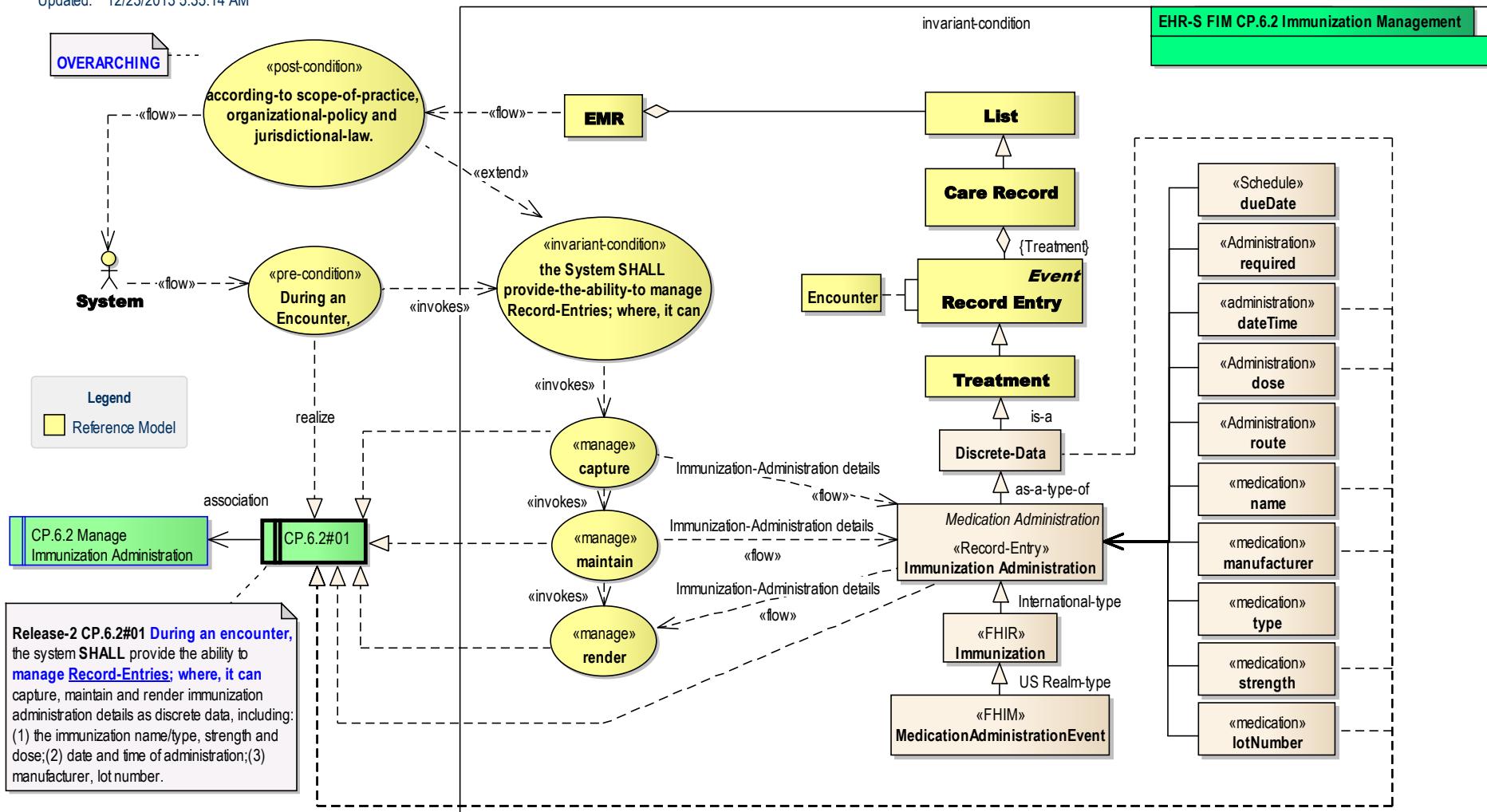
# Example RM Conformance Criteria Scenario

## CP.6.2 CC#01 Immunization Management



class EHR-S FIM CP.6.2 CC#01 Immunization Management Scenario

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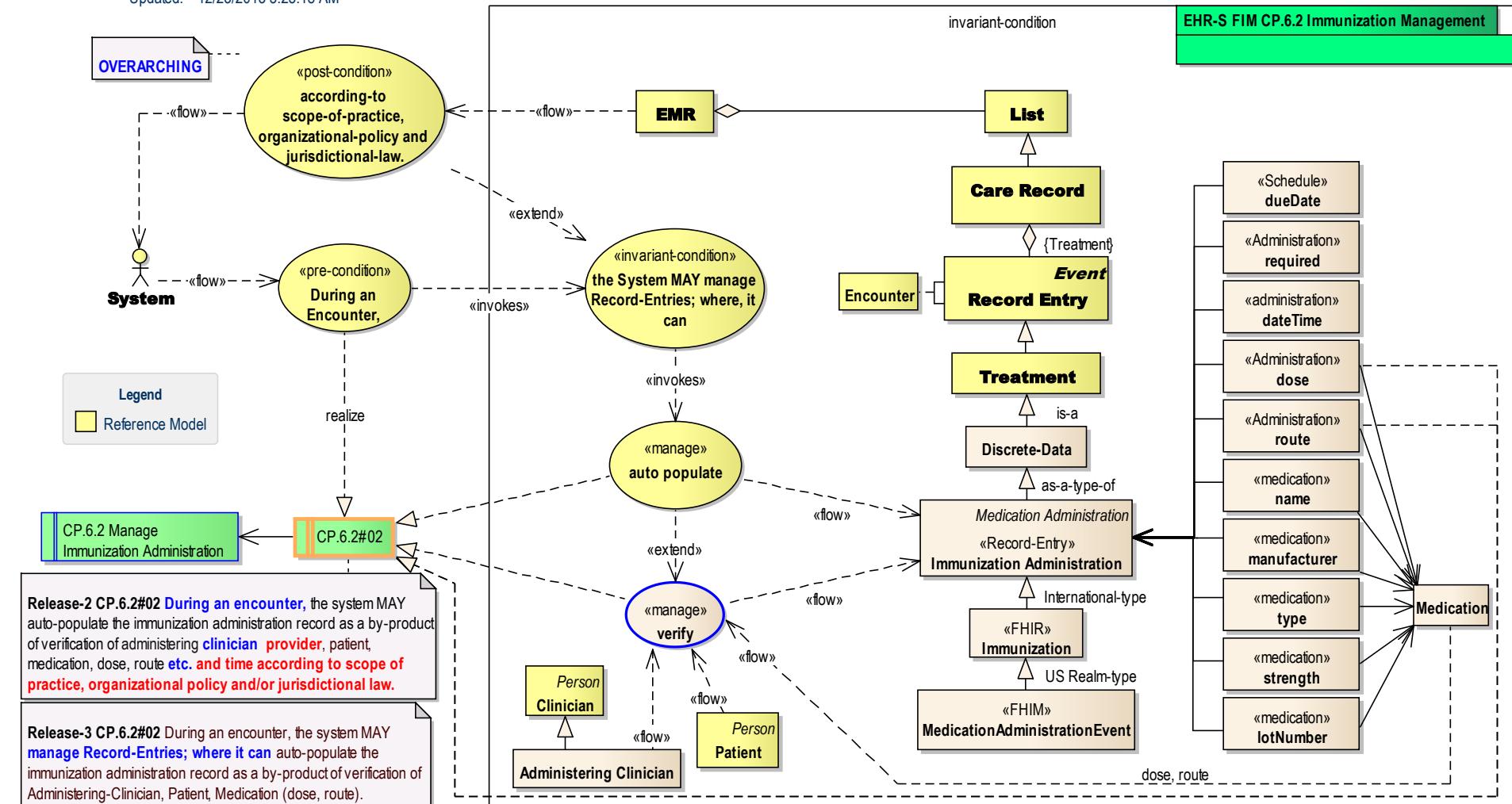
# Example RM Conformance Criteria Scenario

## CP.6.2 CC#02 Immunization Management



class EHR-S FIM CP.6.2 CC#02 Immunization Management Scenario

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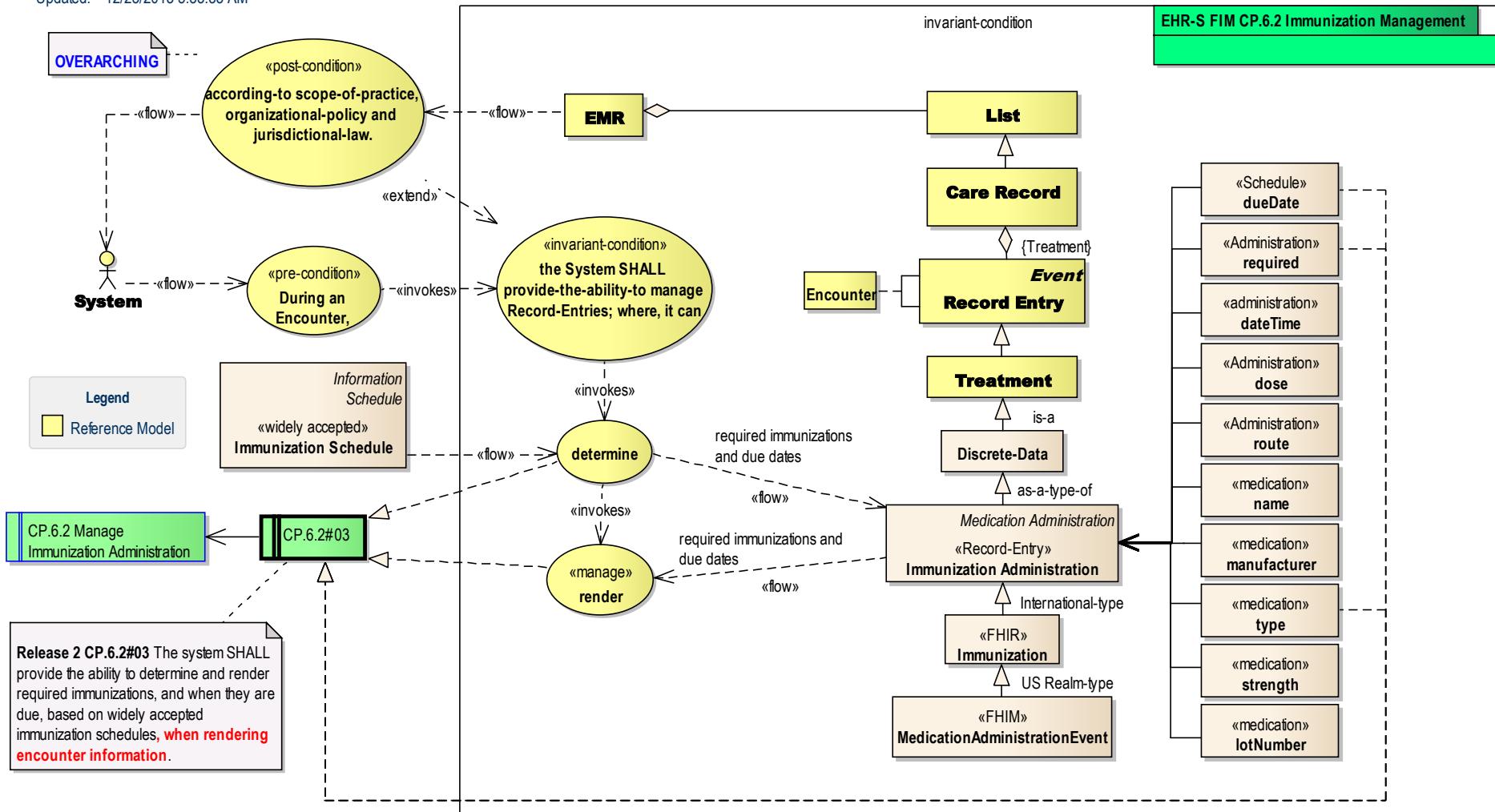
# Example RM Conformance Criteria Scenario

## CP.6.2 CC#03 Immunization Management



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 Version: 2013 Release-3 Prototype  
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 Updated: 12/23/2013 5:33:33 AM



# EHR-S & PHR-S FIM r3

## Interim Conclusion

EHR/PHR Concept-of-Operation is refined-into a **System Reference-Model** (RM); where,

1. **System Functions** are defined-by **Use-Cases** of UML-modelled **System-Actions** on **Record-Entries**; where, nouns-and-verbs define a lexicon-of
  - System-Action-type verb-hierarchy and
  - Record-Entry-type data-model
2. **Conformance-Criteria** are System-Action Use-Case Scenario-threads; where,  
Scenario-Context is defined by
  - pre-condition triggers, and the
  - applicability of
    - SHOULD/SHALL/MAY plus
    - “provide-the-ability-to” manage Record-Entries or “directly” manages Record-Entries
  - post-condition Business-Rules, which are “according-to scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences”
3. **Information-Exchanges** are defined-by Conformance-Criteria Scenarios mapped to
  - FHIR (Fast Healthcare Interoperability Resource) representative of the International-Realm,
  - FHIM (Federal Health Information Model) representative of US-Realm FHIR-profiles,
  - IHE information-exchange behavioral-protocols, refined by,
    - workflow behavioral-protocols and associated
    - Key Performance Parameters** (KPPs)
4. **Profiles** are specified by sets-of System-Functions and their constrained-context
5. **Interoperability-Specifications** can-be generated from Profiles.



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# EHR-S FIM Using FHIR

- **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

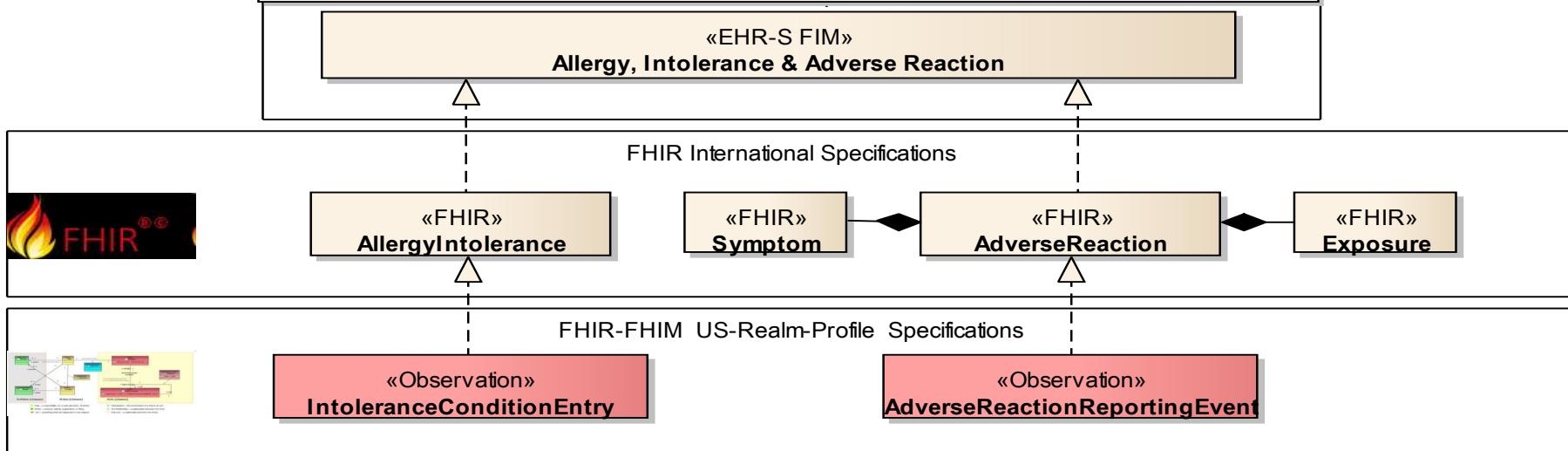
**CM ISSUE:** Should EHR-S FIM map at Data-Module or Data-Element Level?

- 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

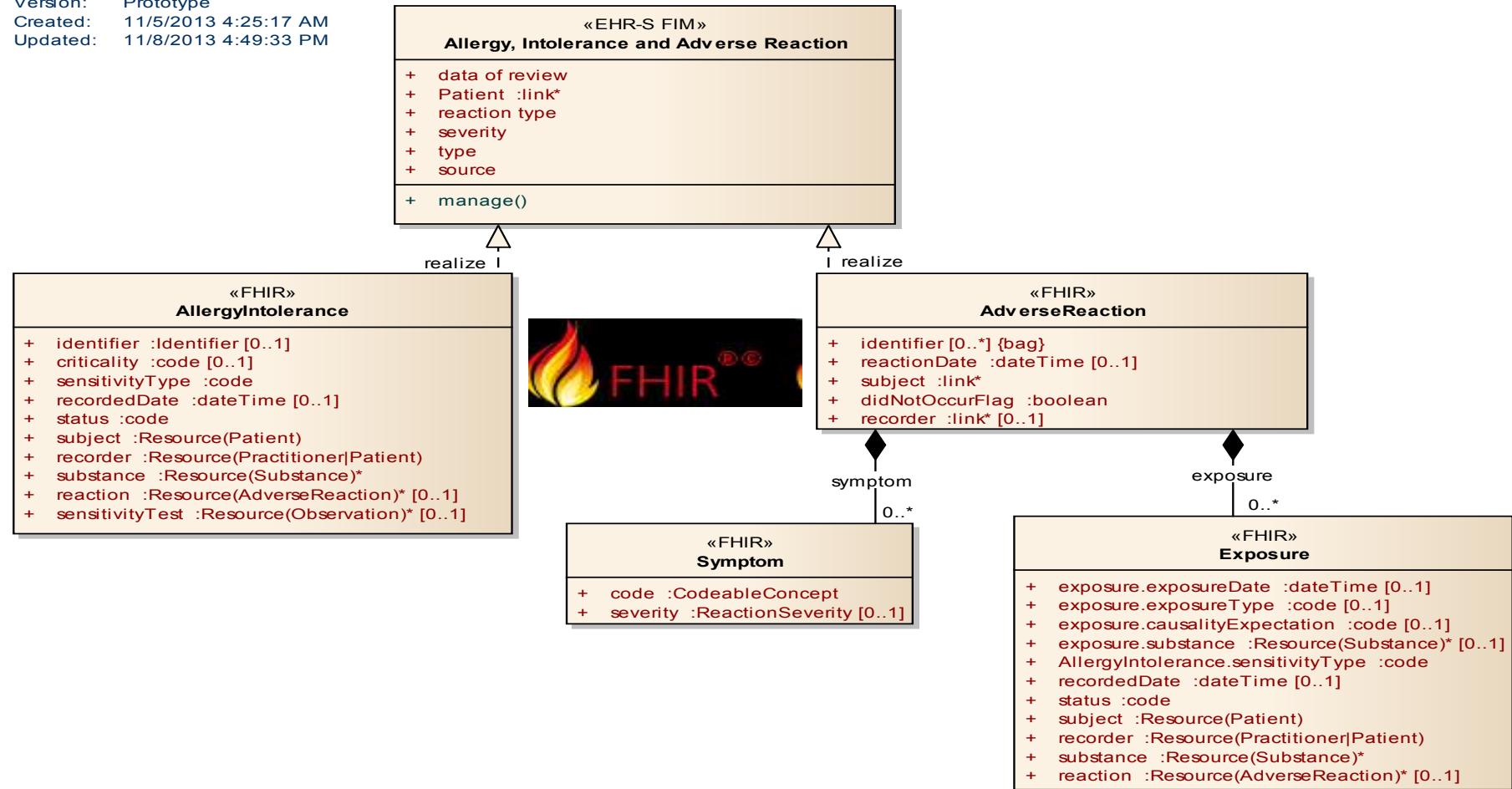
**FHIM** is US Federal Health Information Model



# ■ 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





# Contents

## FY2014Q1-Prototype Report EHR-S and PHR-S FIM Release-3 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

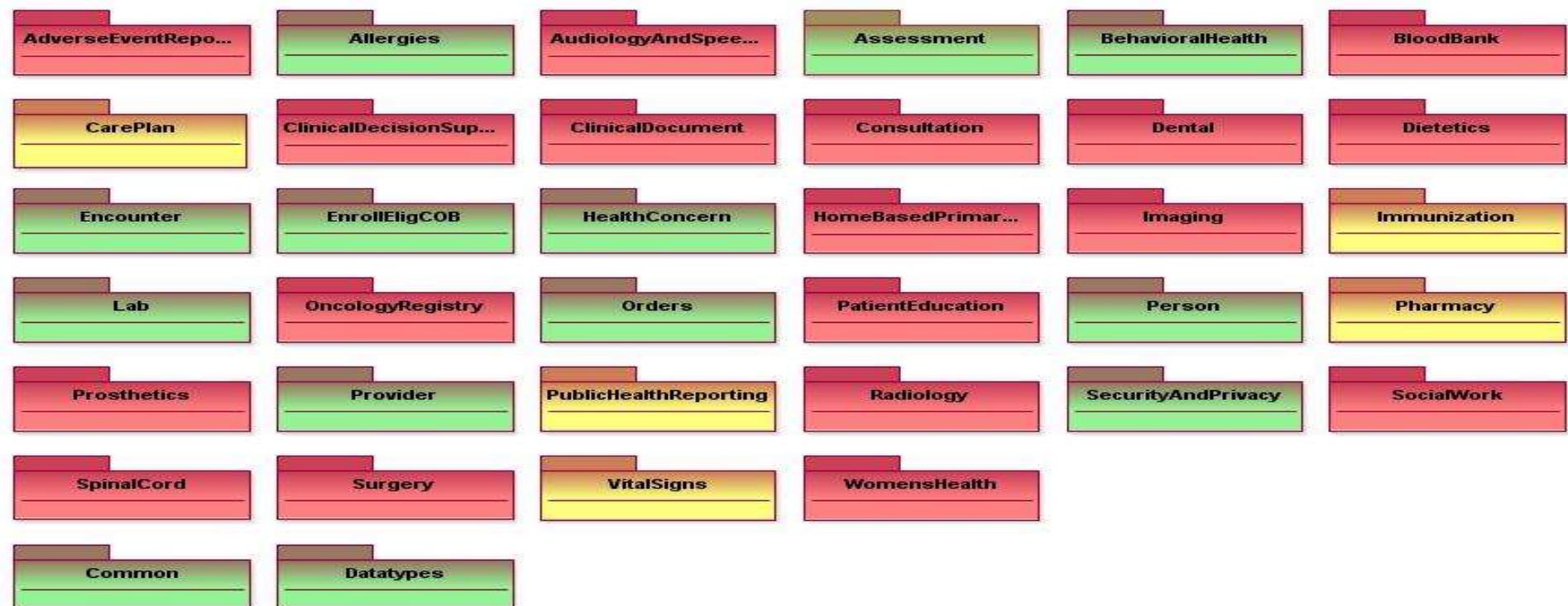
**NOTE:** EHR-S and PHR-S FIM is NOT intended to imply a specific architecture or workflow!

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](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](http://www.fhims.org/content/420A62FD03B6_root.html)

FHA Federal Health Information Model (FHIM)



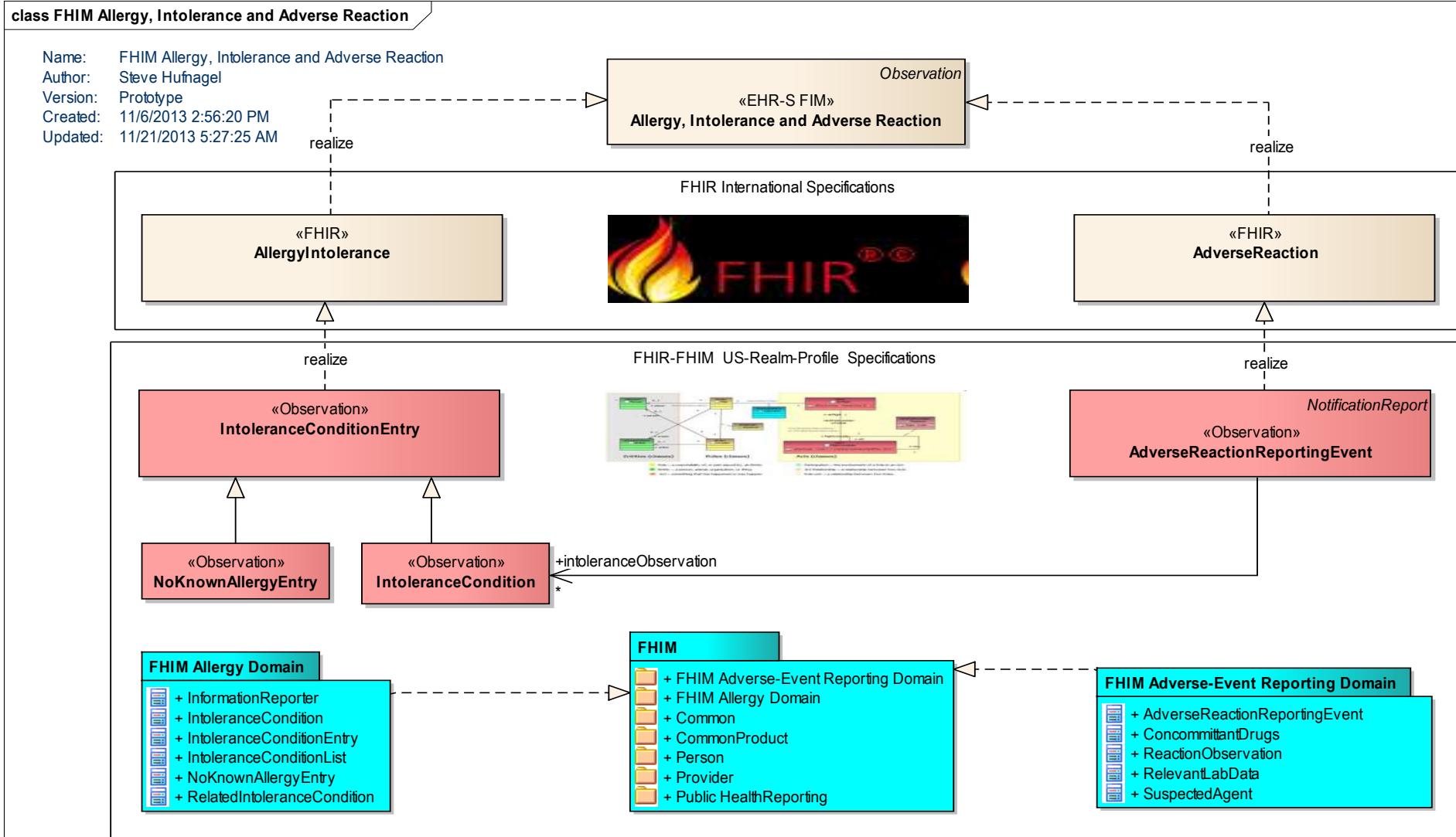
FHIM modeling complete

FHIM modeling in progress

Color Key

Unchanged from the VHIM

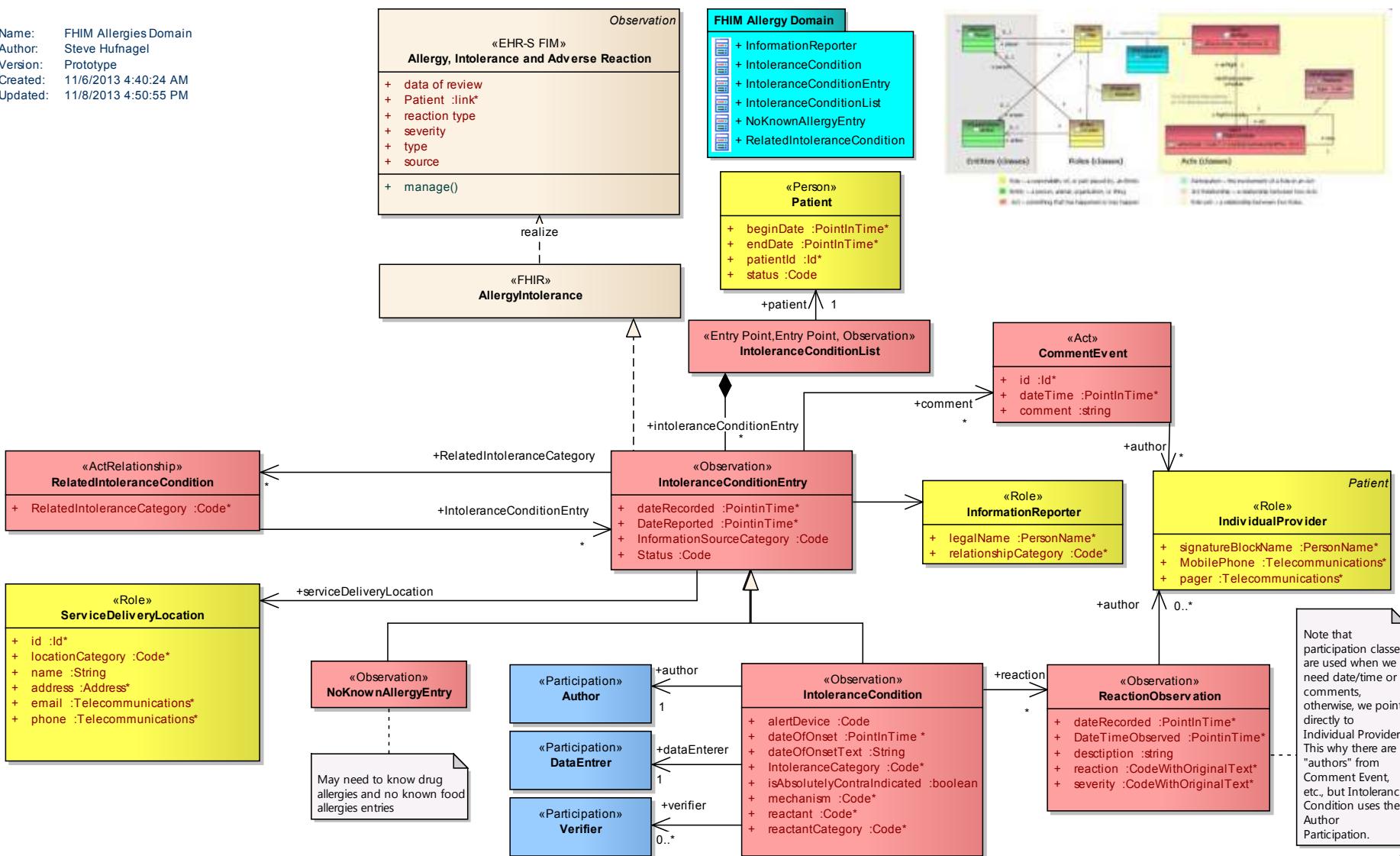
# ■ Prototype Allergy, Intolerance & Adverse-Reaction FHIM High-Level US-Realm Specification



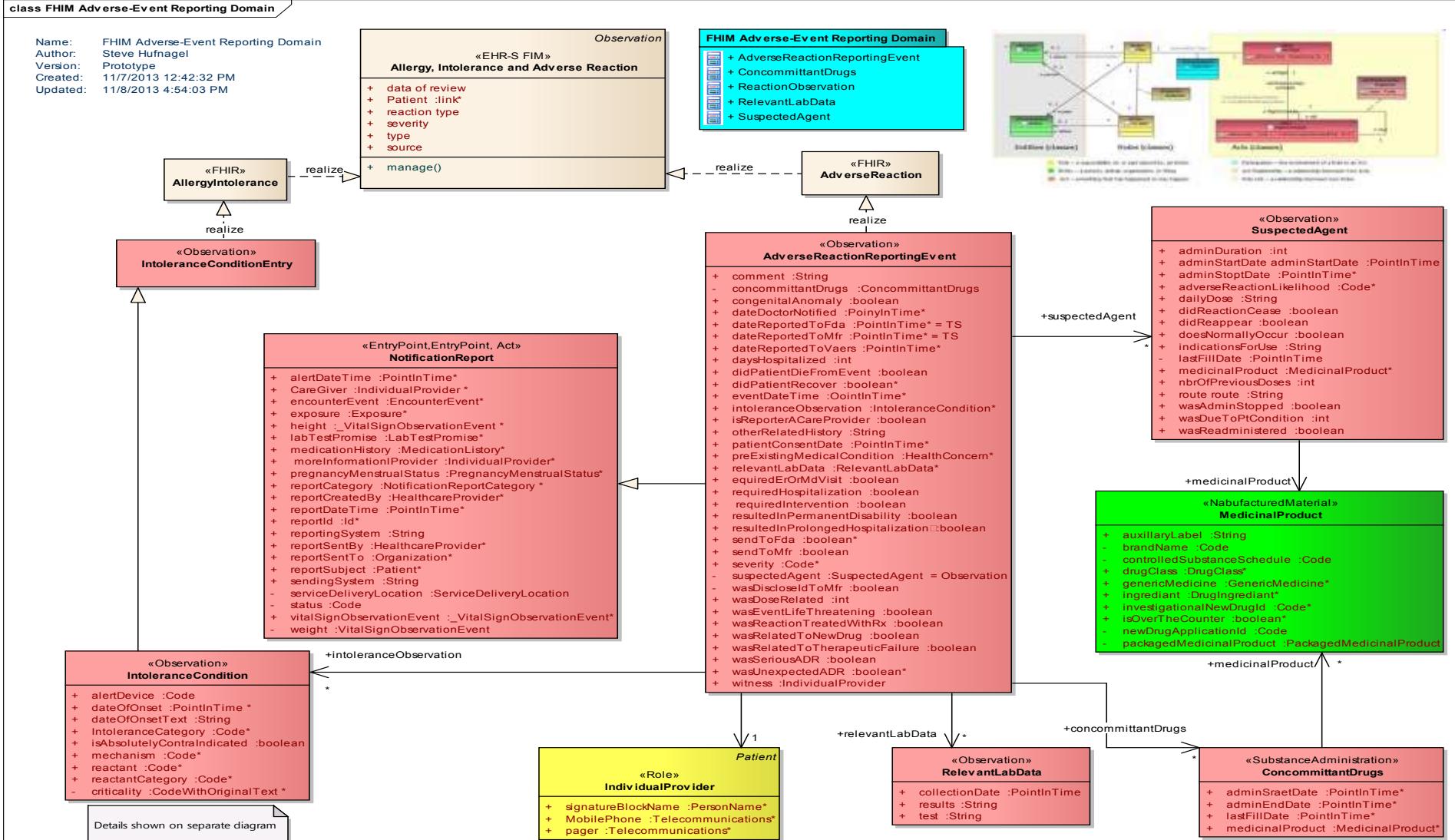
# Prototype FHIM-Detailed Allergy & Intolerance Specification

## 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 FHIR Detailed Adverse-Reaction Specification



Details shown on separate diagram



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

## Prototype Conclusions

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

- EHR-S FIM defines Requirements; including,
  - data context-applicability-and-use
- FHIR defines International Data-Specifications ("The 80% solution set")
- FHIM defines US-Realm FHIR-Profile, including terminology bindings
- MDHT defines Implementation Guides (e.g., CDA)
- Joint Configuration Mgmt. will help FIM/FHIR/FHIM consistency; ideally,
  - A single UML-Tool (e.g., EA or RSA) maintains FIM-FHIR-FHIM

**ISSUES:** FIM-FHIR-FHIM-MDHT consistency, tool usability, configuration mgmt, IP licensing.

**RECOMMENDATION:** [www.HL7.org/EHRSFIM](http://www.HL7.org/EHRSFIM) web site for browsing & feedback.