



EHR Work Group Summary Briefing

HL7 EHR Work Group (EHR-WG)

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December 18, 2013 Complete-and-current working-drafts are 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 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/managelistsevs.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



■ Contents

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

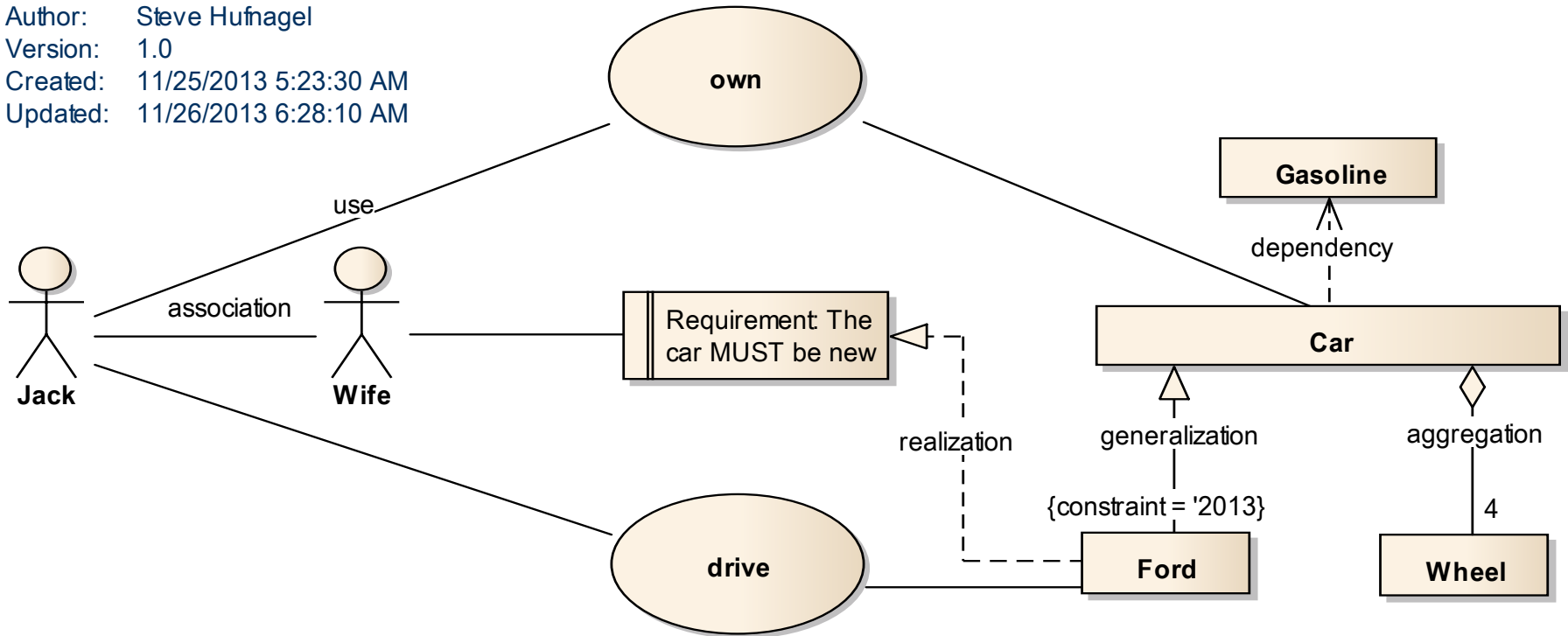
- **aka** also known as
- **CC** EHR-S FIM Conformance Criteria
- **CDA** **Clinical Document Architecture**
- **DD** Data Dictionary
- **CIM** Conceptual Information Model
- **CP** Care Provision
- **CPS** Care Provisioning Support
- **DFD** Data Flow Diagram
- **EA** Enterprise Architect
- **EHR-S** 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** 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 Tool
- **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)

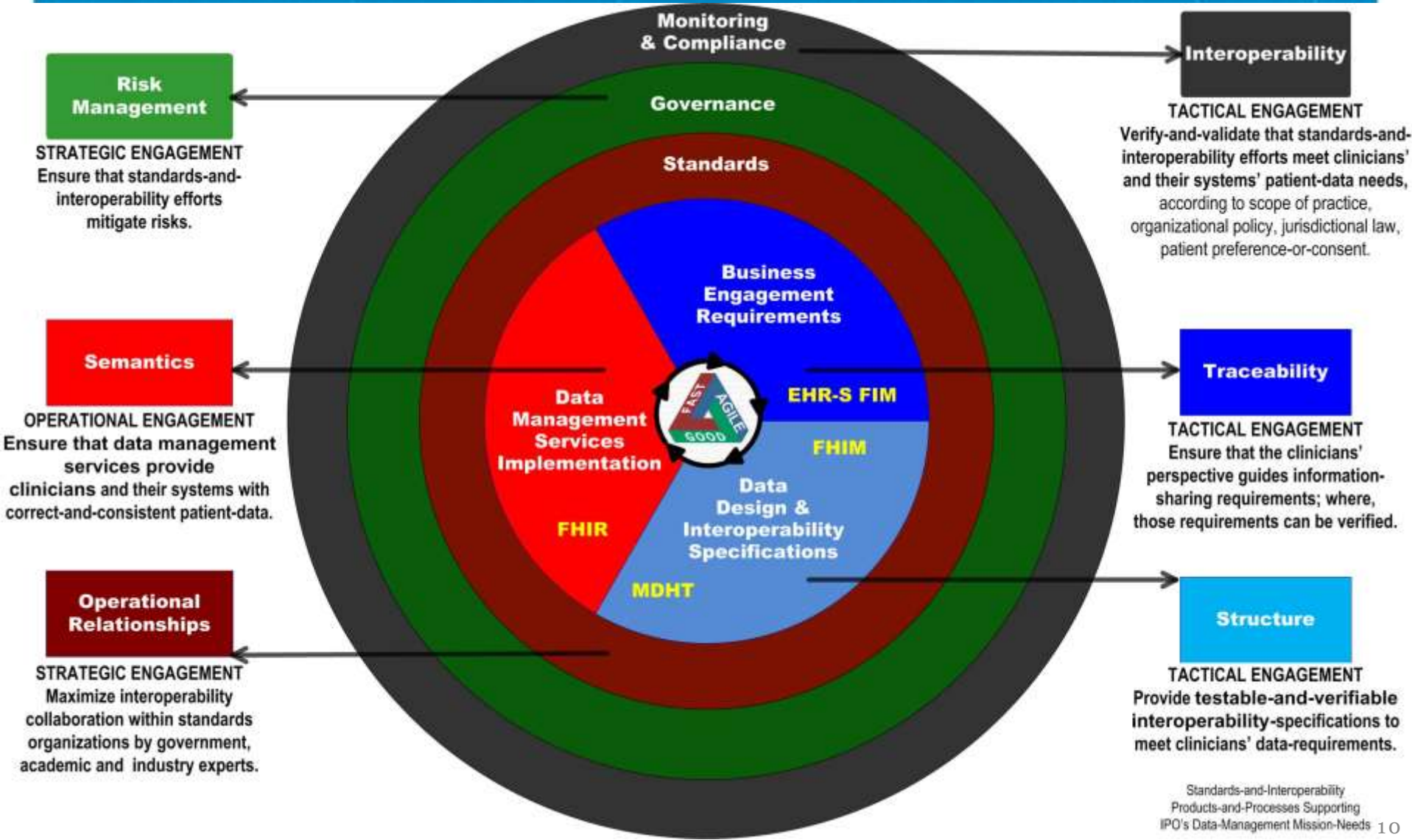
- Create Release 3 Work-Break-Down Structure (WBS) & POA&M 10-Dec-13
- Harmonize with ISO/EN 13940 Continuity-of-Care System-of-Concepts pending
- Harmonize with Electronic Health Record Communication (ISO/EN 13606) pending
- Prototype EHR-S FIM Ballot Production process-and-products for prototype pending

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

EHR-and-PHR System Users-and-Values

EHR-System Data-Management Mission-Needs Areas





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Reference Model (RM) Definition

EHR-S FIM Release-3:2016 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."

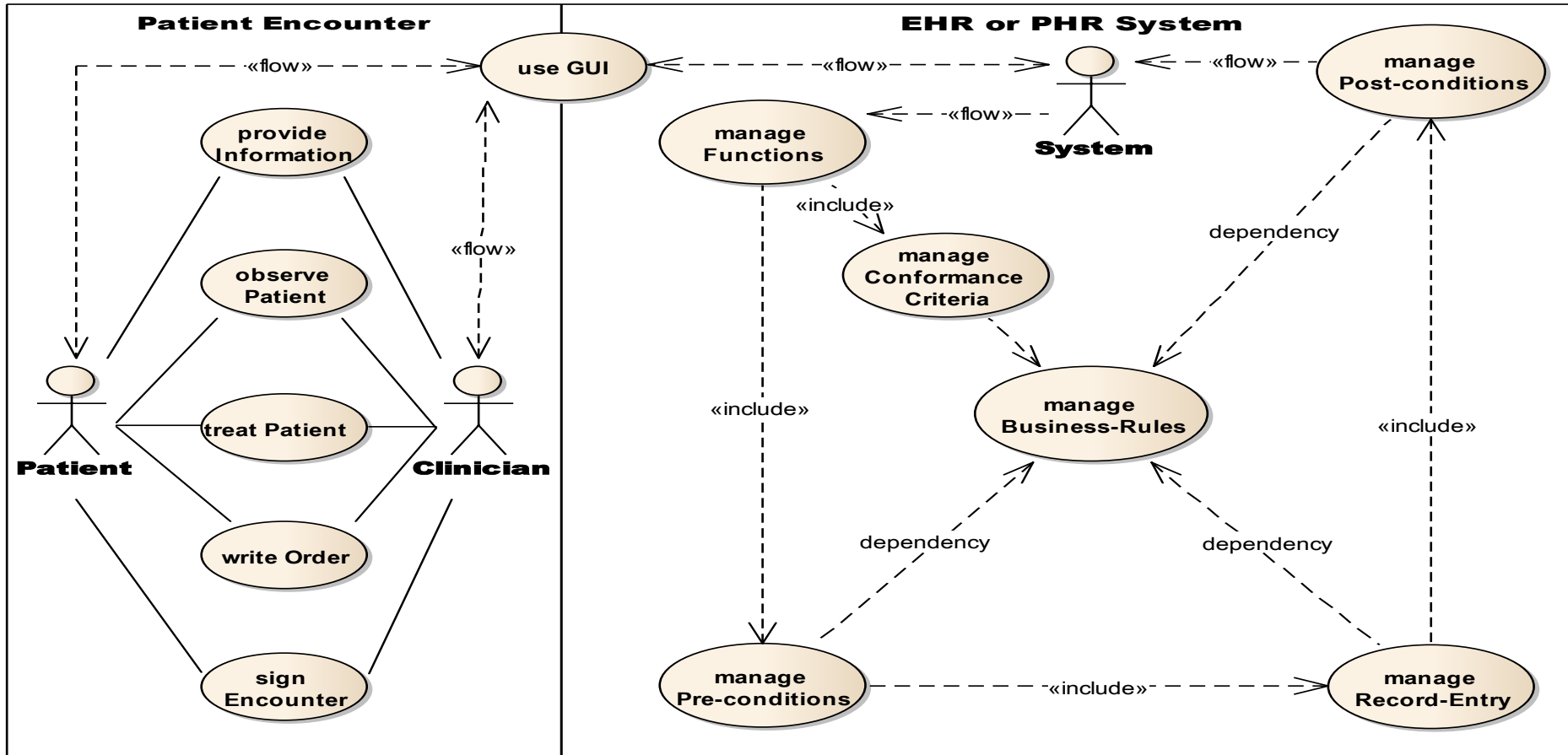
EHR-S & PHR-S RM Reference Model (RM)



uc EHR-S & PHR-S Reference-Model

Name: EHR-S & PHR-S Reference-Model
 Author: EHR Interoperability WG
 Version: EHR-S FIM (r3 2013 Prototype)
 Created: 12/14/2013 1:18:17 PM
 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 & PHR-S Reference Model (RM)



The **EHR-S and PHR-S Reference Model** includes Functions and their Conformance-Criteria (CC); where,

- Functions are modelled as “*manage Record-Entry*” **Use-Cases**; where, use-cases contain multiple CCs.
- Conformance-Criteria (CC) are modelled as individual “*manage Record-Entry*” **Scenarios**
- Clinicians and Patient have Encounters; where, they use System-GUIs (Graphical-User-Interface); such that,

The Clinicians, Patients or their designated agent may

review the Patient EMR (Electronic Medical Record) and other types of Information

Observe, treat, write Orders and document the Patient-Encounter

provide Patient-Information and Educational-Information

sign Encounters

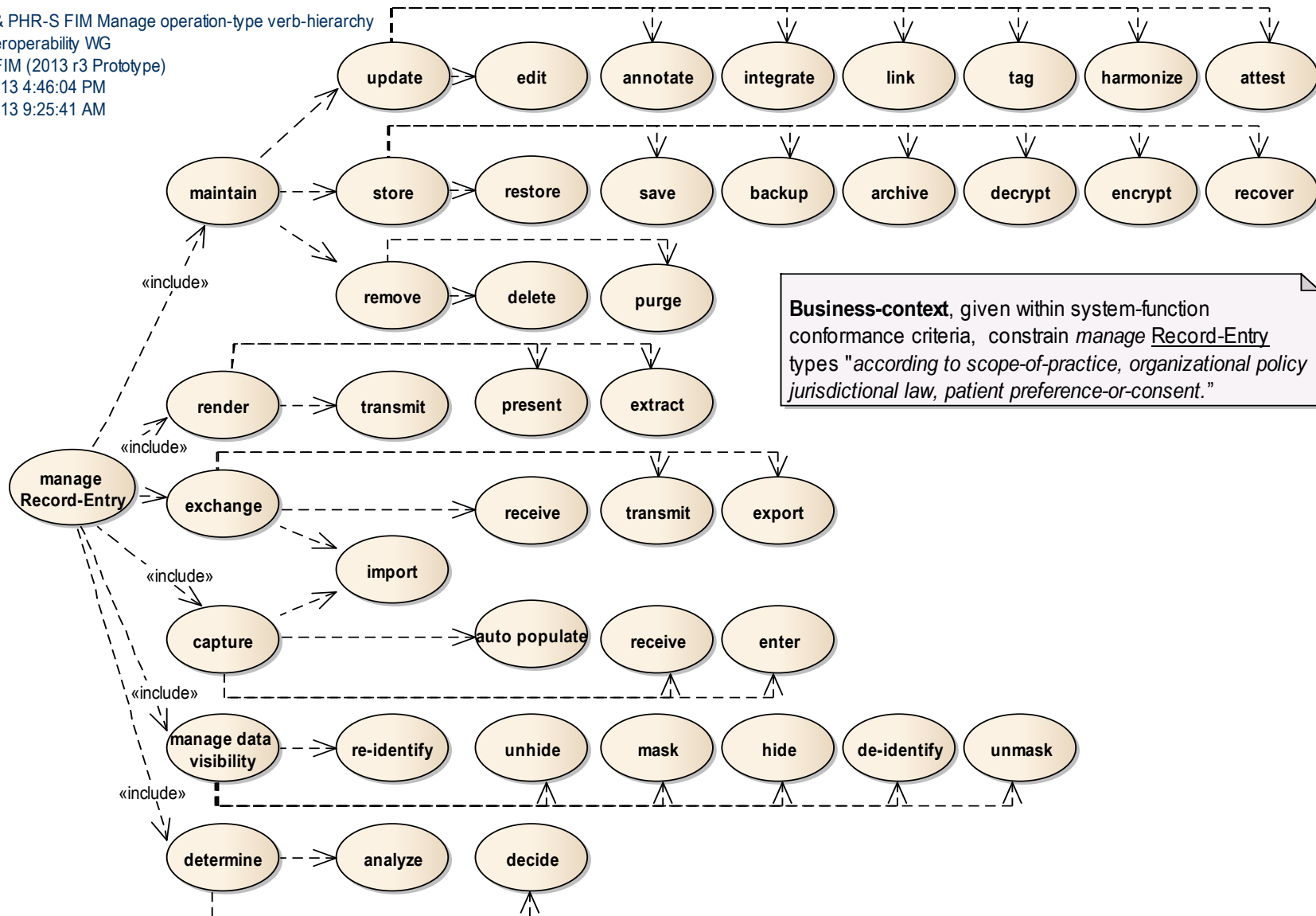
- Systems Functions include multiple *manage Record-Entry* Conformance Criteria (CC); where,
 - CC manage verb-sub-types and Record-Entry noun-sub-types are used
 - CC Pre-Condition Business-Rules manage entering-data-flows and data-context
 - CC Data-management Business-Rules manage applicability (SHALL/SHOULD/MAY)
 - CC Post-Condition Business-Rules manage exiting-data-flows and data-use
 - CC Business-Rules are in-accordance with
 - scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences.

EHR-S and PHR-S RM for “Manage” Verb-Type Hierarchy



uc EHR-S & PHR-S FIM Manage operation-type verb-hierarchy

Name: EHR-S & PHR-S FIM Manage operation-type verb-hierarchy
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 Version: EHR-S FIM (2013 r3 Prototype)
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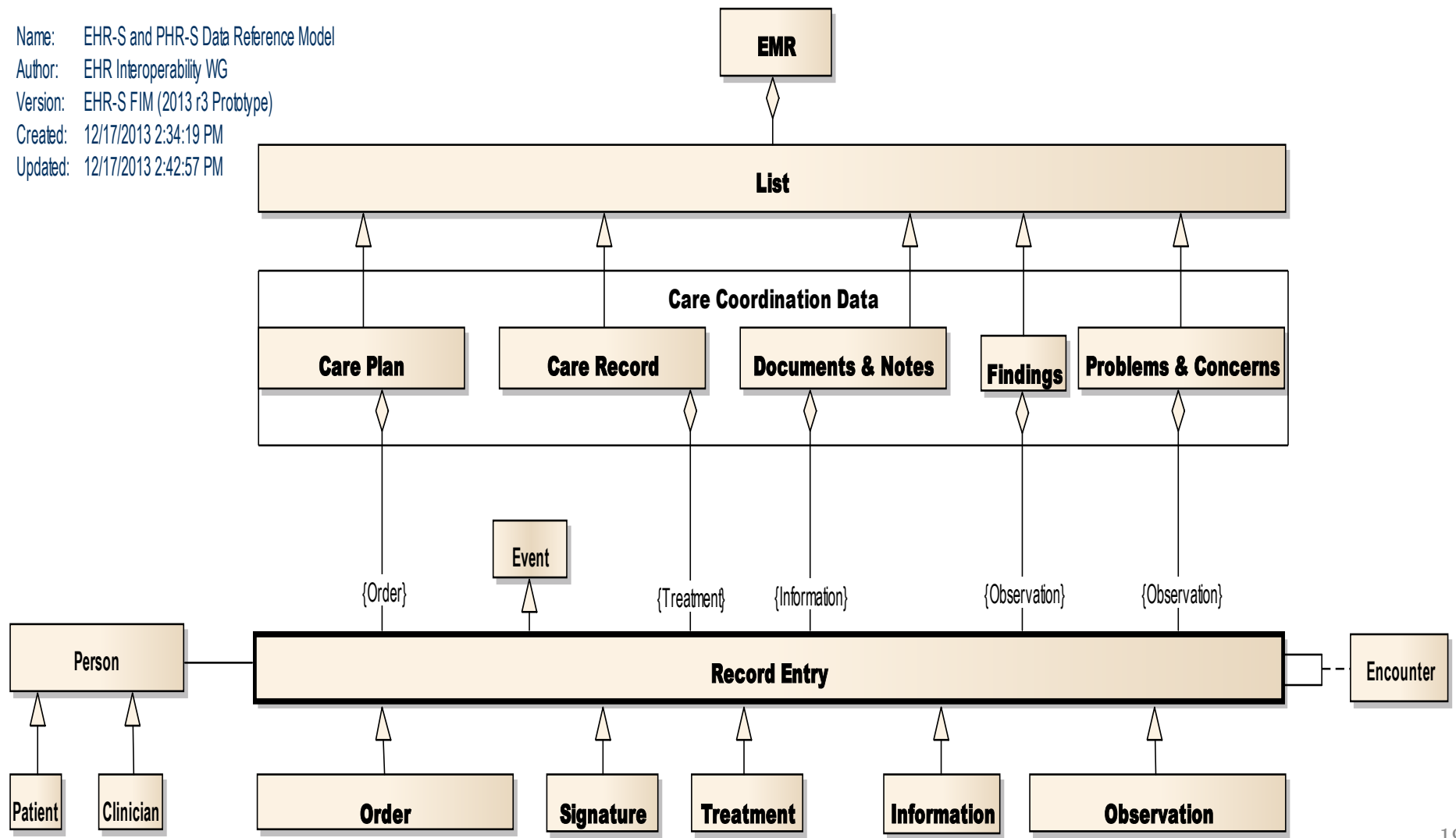


Business-context, given within system-function conformance criteria, constrain *manage Record-Entry* types "according to scope-of-practice, organizational policy jurisdictional law, patient preference-or-consent."

EHR-S and PHR-S RM for “Record-Entry” Data-Type Taxonomy

class EHR-S and PHR-S Data Reference Model

Name: EHR-S and PHR-S Data Reference Model
 Author: EHR Interoperability WG
 Version: EHR-S FIM (2013 r3 Prototype)
 Created: 12/17/2013 2:34:19 PM
 Updated: 12/17/2013 2:42:57 PM



EHR-S & PHR-S RM for Conformance Criteria

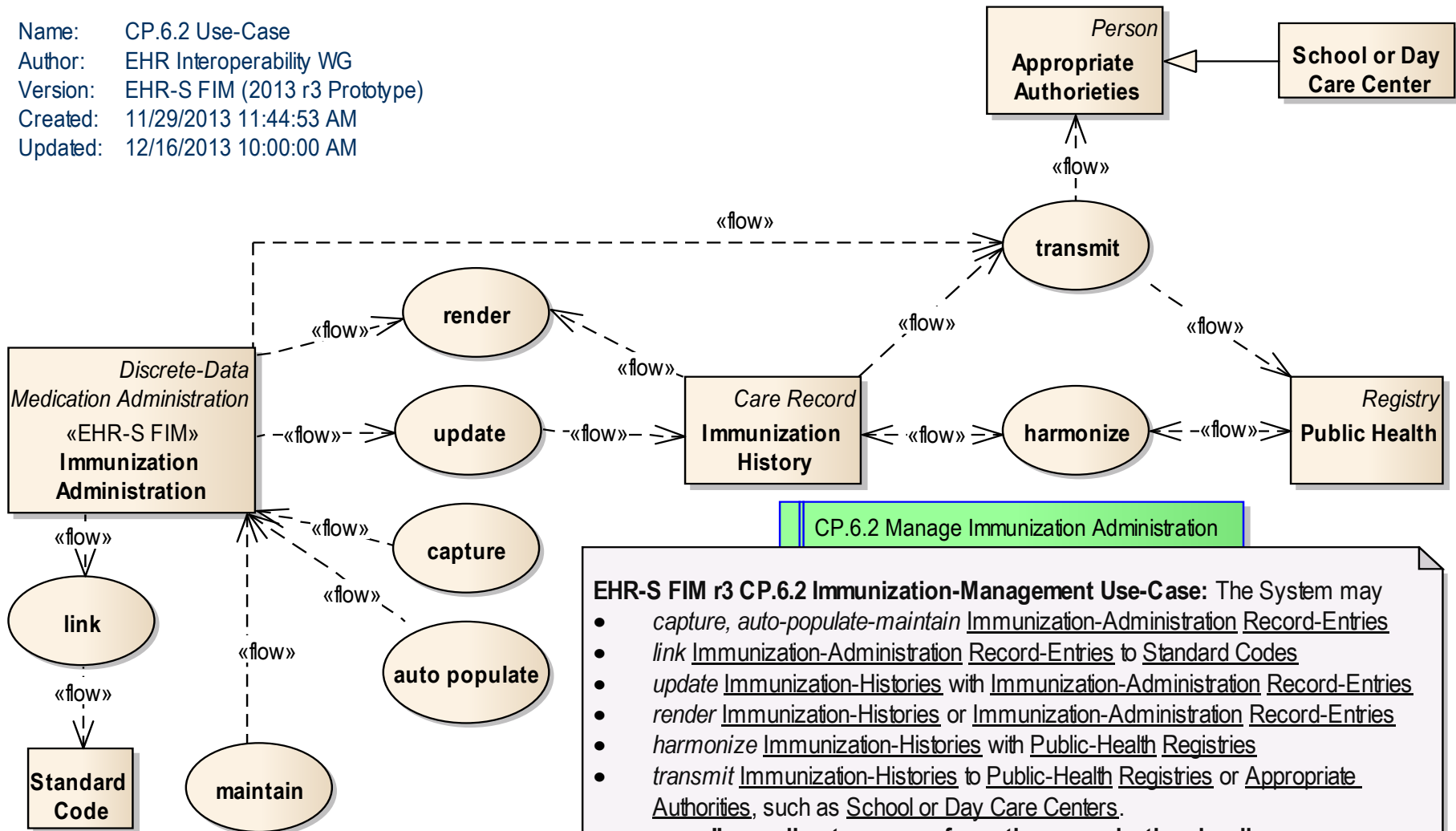
- **SF CC Invariant-condition** (context)
 - System Identifier (EHR or PHR)
 - System Function (SF) Identifier
 - Profile Identifier
- **SF CC Identifier** (number)
- **SF CC Pre-condition** (trigger)
 - Pre-condition is a verb-clause.
 - After a Human-Action or System-Action; then,
- **SF CC Applicability**
 - The System SHALL, SHOULD or MAY
 - “provide-the-ability-to” or
 - “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)

Example RM-based Functional Use-Case

CP.6.2 Immunization Management

uc CP.6.2 Use-Case

Name: CP.6.2 Use-Case
 Author: EHR Interoperability WG
 Version: EHR-S FIM (2013 r3 Prototype)
 Created: 11/29/2013 11:44:53 AM
 Updated: 12/16/2013 10:00:00 AM



CP.6.2 Manage Immunization Administration

EHR-S FIM r3 CP.6.2 Immunization-Management Use-Case: The System may

- capture, auto-populate-maintain Immunization-Administration Record-Entries
- link Immunization-Administration Record-Entries to Standard Codes
- update Immunization-Histories with Immunization-Administration Record-Entries
- render Immunization-Histories or Immunization-Administration Record-Entries
- harmonize Immunization-Histories with Public-Health Registries
- transmit Immunization-Histories to Public-Health Registries or Appropriate Authorities, such as School or Day Care Centers.

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

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

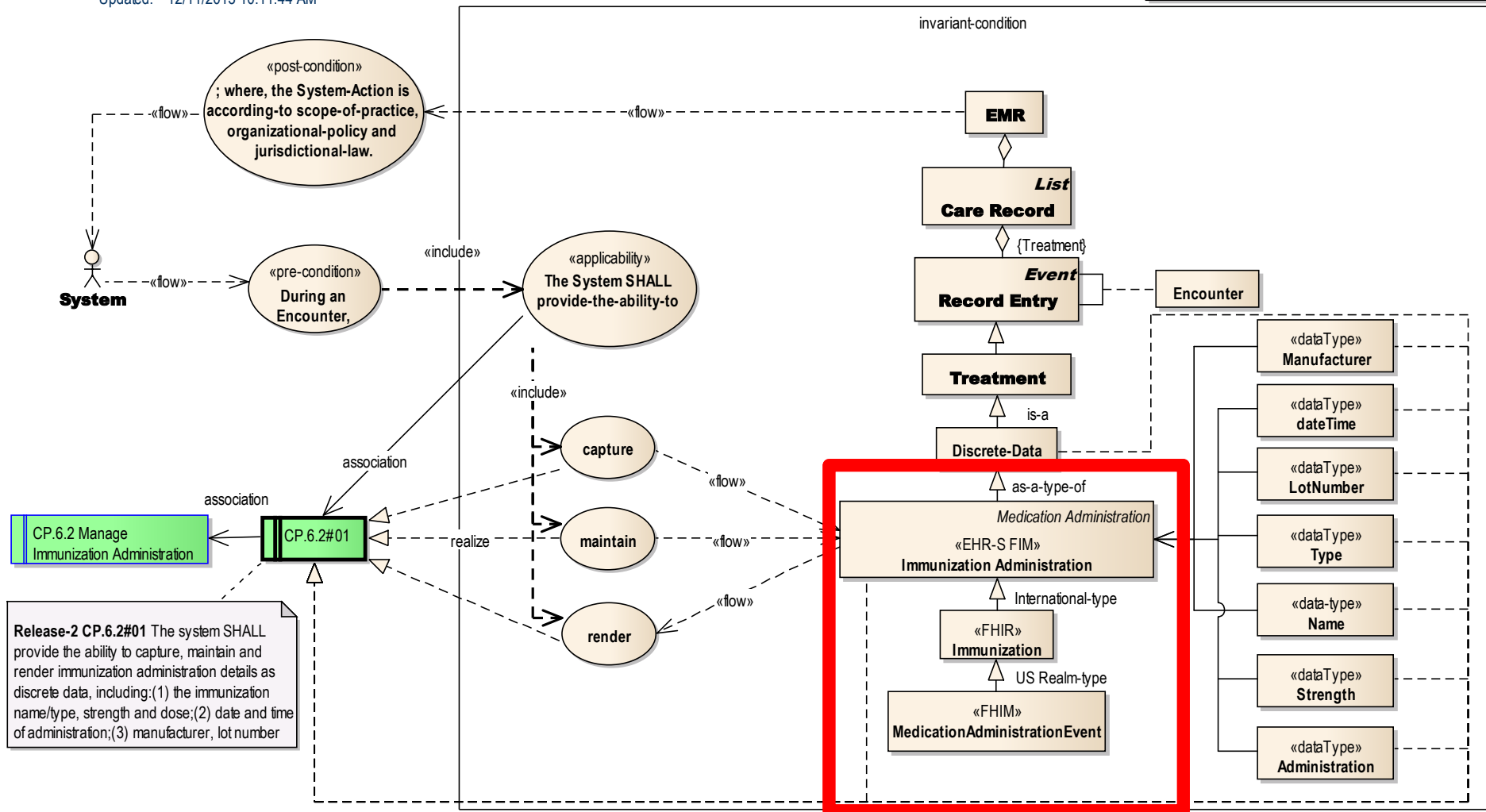
CP.6.2 CC#01 Immunization Management



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

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 Version: EHR-S FIM (2013 r3 Prototype)
 Created: 12/2/2013 7:25:59 AM
 Updated: 12/11/2013 10:11:44 AM

EHR-S FIM CP.6.2 Immunization Management



■ EHR-S & PHR-S FIM r3 Scenario

CP.6.2 CC#01 Immunization Management



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 & 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

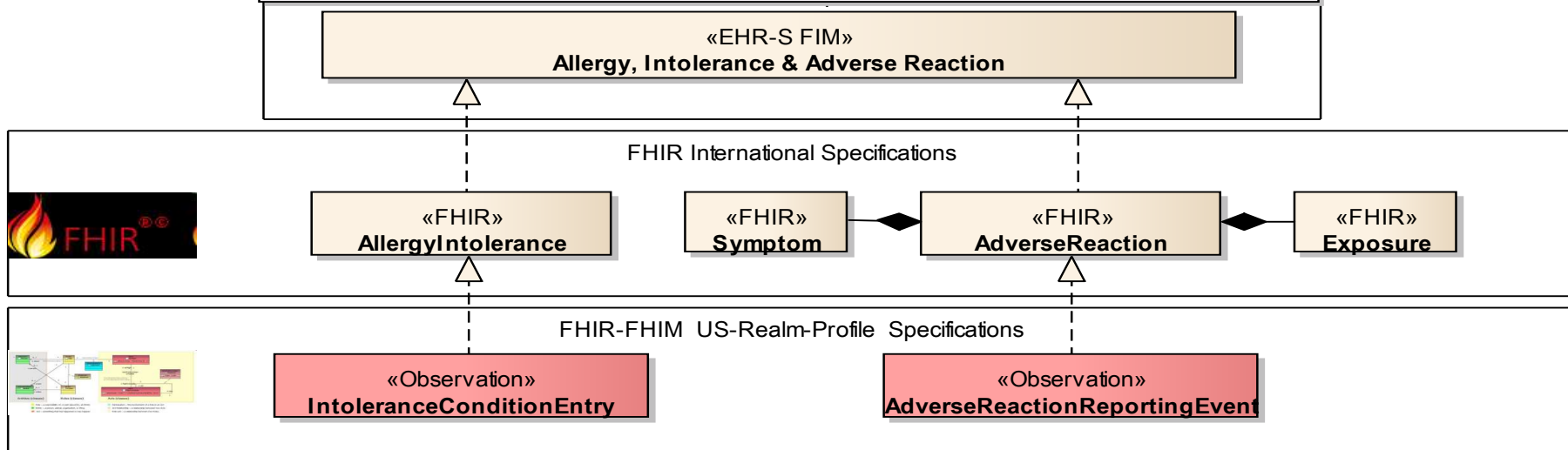
CM ISSUE: Should EHR-S FIM map at Data-Module or Data-Element Level?

- 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



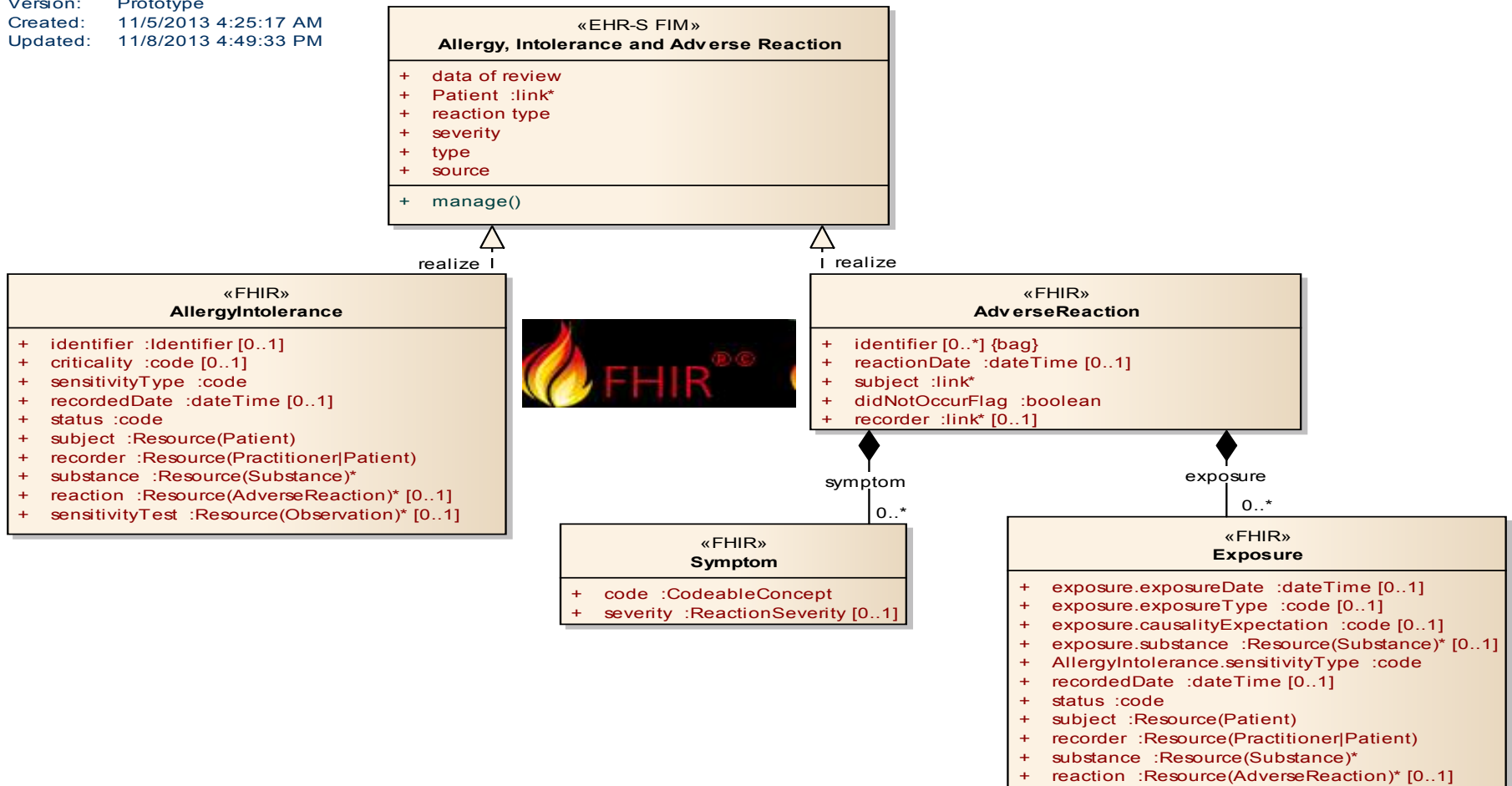
Prototype

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



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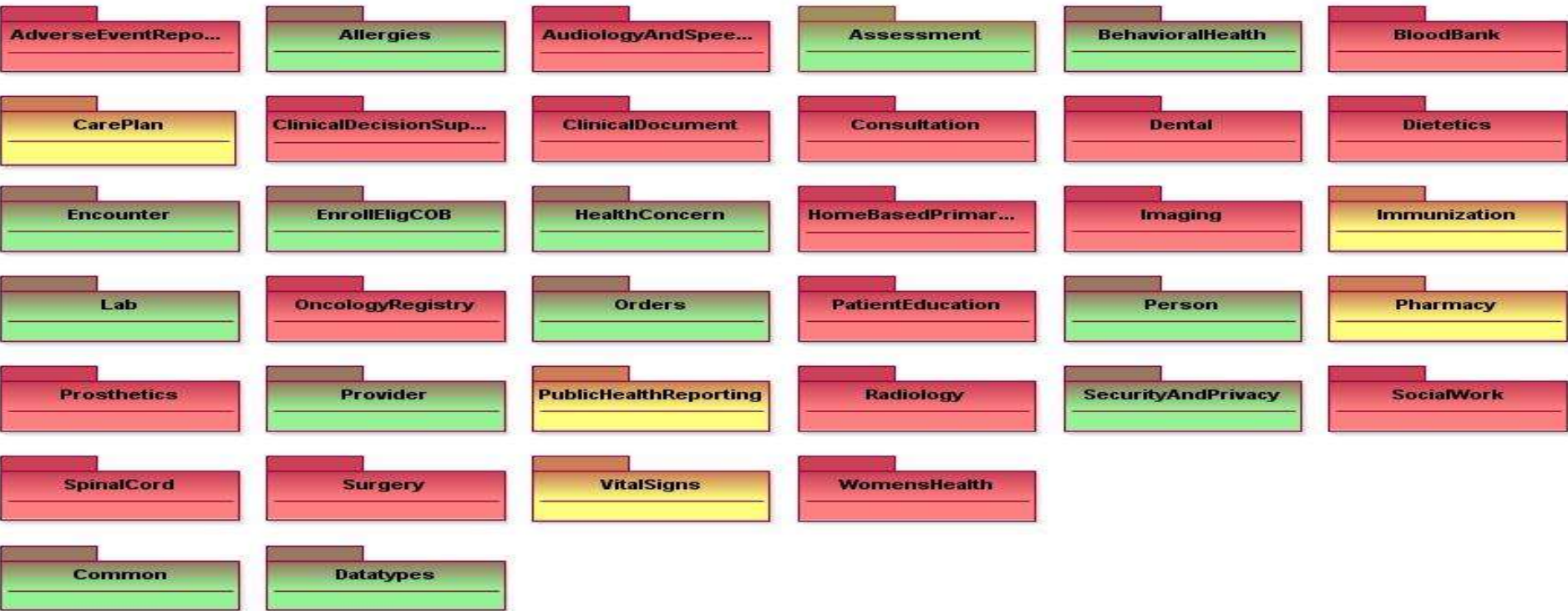
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http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

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

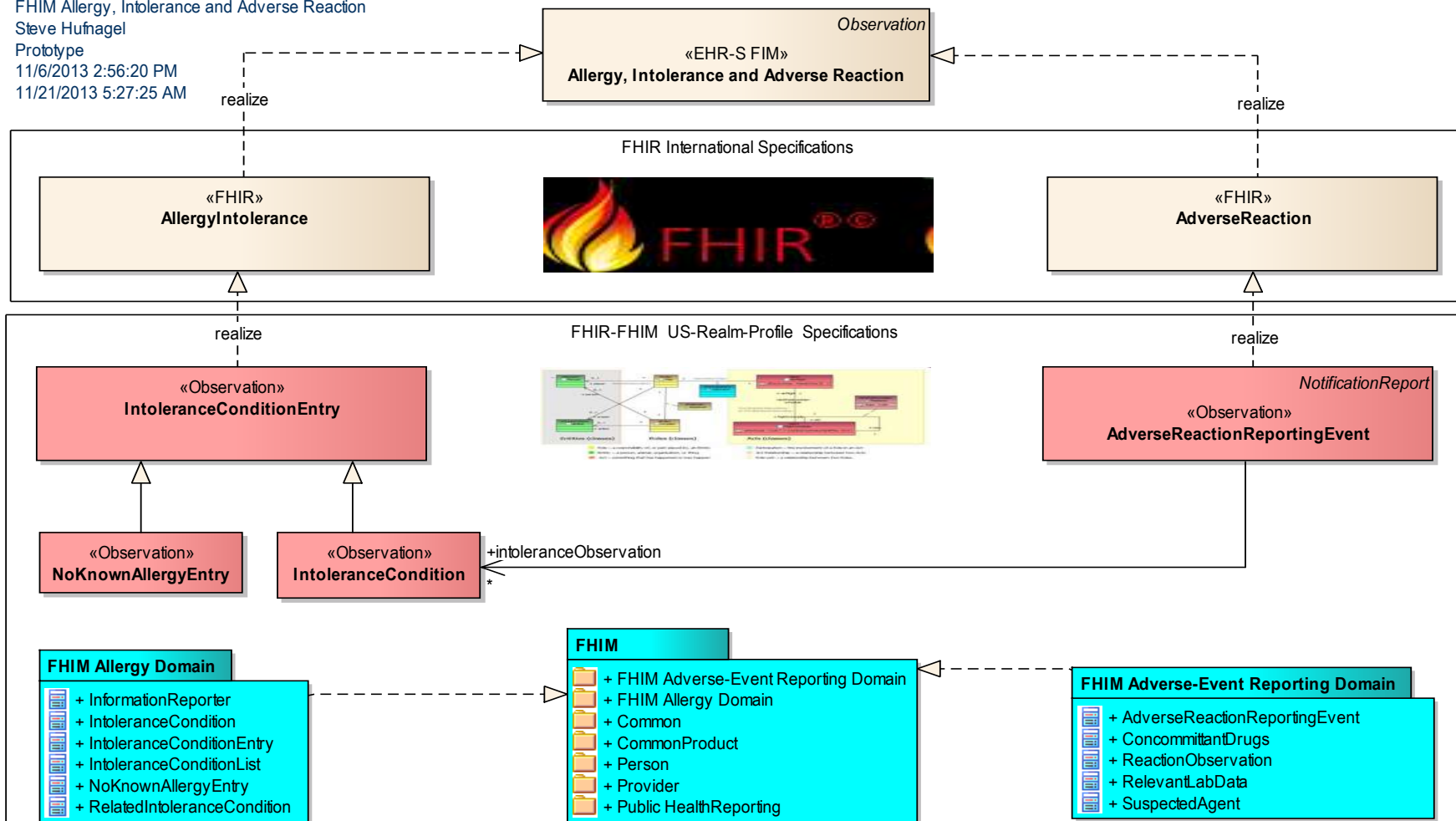
Unchanged from the VHIM

Color Key

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

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 Updated: 11/21/2013 5:27:25 AM

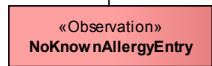
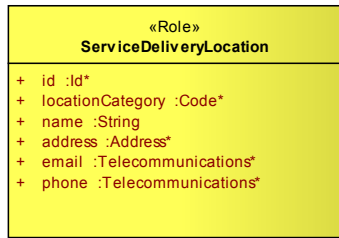
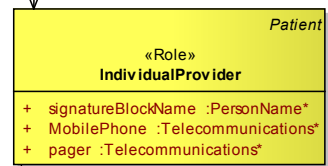
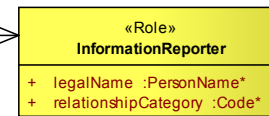
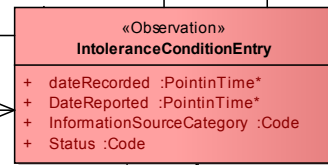
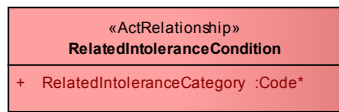
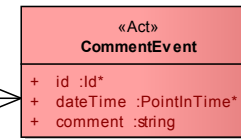
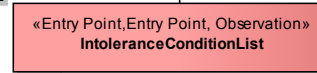
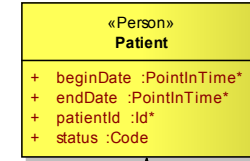
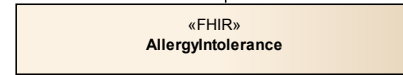
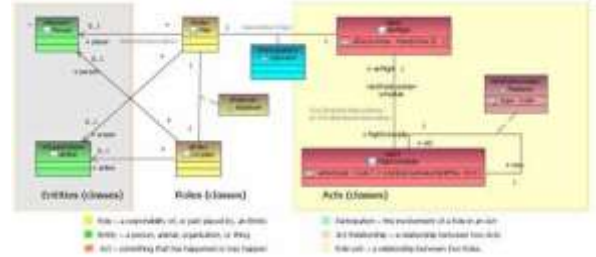
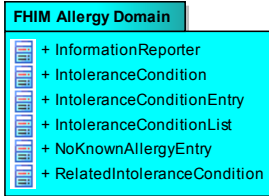
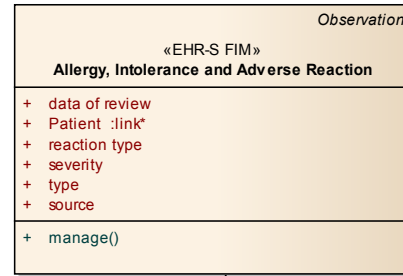


Prototype

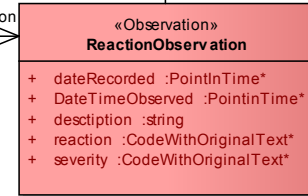
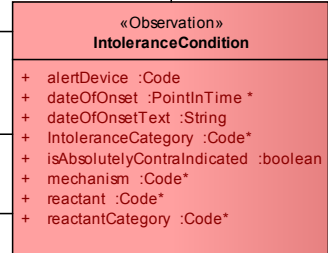
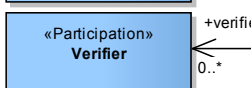
FHIM-Detailed Allergy & Intolerance Specification

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



May need to know drug allergies and no known food allergies entries



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.

■ 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 web site for browsing & feedback.