Monthly Summary Briefing

HL7 EHR Work Group (EHR-WG)

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November 20, 2013 **Frequently-Updated Working-Draft**

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

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

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

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 Work Group Goal & Objectives

- The goal of the Electronic Health Record (EHR) Work Group 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),

- An objective of the EHR Interoperability WG is 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 (e.g., clear, complete, concise, correct , consistent) identified by the VA negative r2.0 ballot.

- A second objective of the EHR Interoperability WG is producing a Meaningful Use profile for r2.0.

- The objective of the Resource Management Evidentiary Support (RM-ES) project 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.

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

EHR WG

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

Meeting	Time (ET)	Relevance
EHR-S FM **Plenary** 770-657-9270, PC 510269#	Every Tuesday 3:00 PM Eastern LiveMeeting https://www.livemeeting.com/cc/cdc/join?id=K3J84M&role=attend	EHR Strategy, liaison with other WGs, ballot reconciliation etc.
EHR Interoperability **EHR-S FIM r3.0** 770-657-9270, PC 510269#	Every Tuesday 1:00 PM Eastern GoTo Meeting https://www3.gotomeeting.com/join/798931918	Directly addressing EHR-S r2.0 Interoperability concern-and-needs
EHR Interoperability **Meaningful-Use** 770-657-9270, PC 510269#	Every Tuesday 2:00 PM Eastern GoTo Meeting https://www3.gotomeeting.com/join/798931918	Directly address ARRA MU2 concern-and-needs
Resource Management and Evidentiary Support Phone: 650-479-3208	Every Monday 12:00 Noon Eastern WebEx Code: 923-467-215, PC1519 https://ahima.wex.com/ahima/j.php?ED=227980377&UID=0&PW=NY2MwOGY1NjI3&RT=MiM3	Directly addressing EHR-S r2.0 RMES concerns-and-needs
PHR-S **Usability** 770-657-9270, PC 510269#	Every Wednesday 12 :00 Noon Eastern Every Wednesday 1 :00 PM Eastern	Blue-Button Usability concerns-and-needs

Plan of Actions and Milestones
FY2014Q1 POA&M
EHR-S FIM Release-3:2016 Preparation

	Completed
October 2013 (Identify processes, tools and issues/risks)	
• 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 EHR-S Reference-Model and Conceptual-Architecture	15-Nov-13
• Prototype S&I Framework's Use Case Simplification for Immunization	in-progress
• Harmonize with ISO/EN 13940 Continuity-of-Care System-of-Concepts	pending
• Harmonize with Electronic Health Record Communication (ISO/EN 13606)	
• Prototype EHR-S FIM Ballot Production process-and-products for prototype	

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

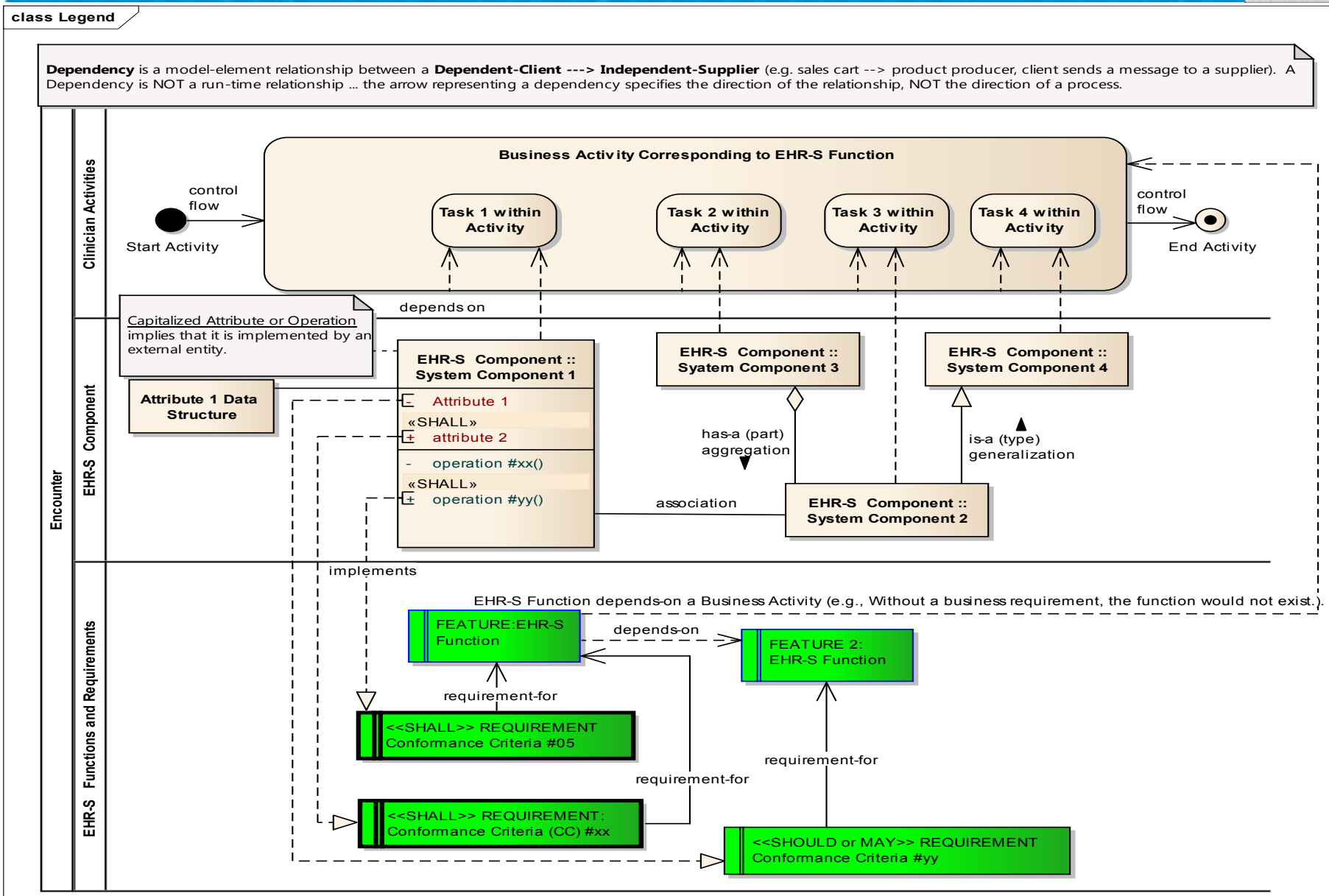
January 2014 – 2016 (Approve & Execute Plan)

- 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

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 profile for MU
- **FM** Function Model
- **FY** Fiscal Year
- **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

EHR-S FIM Legend



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Executive Summary
EHR-S FIM r3:2016

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 Conformance Criteria (CCs) replace ad-hoc-local r2 CCs
    - Single Infrastructure-section contains previously-separate r2 Record-and-Trust Infrastructure-sections
- **EA Tool-generated Interoperability-Specifications based-on Use-Cases**
  - Use-Cases come-from HITSP & S&I Framework Use-Case Simplification work linked-to
  - Requirements, which come-from EHR-S r2.0 Functions' and their restructured CCs linked-to
  - International Interoperability-Specifications based-on HL7 FHIR (Fast Healthcare Interoperability Resources)
  - US-Realm Interoperability-Specifications based-on FHA FHIM (Federal Health Information Model)

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

Interim Conclusions and Recommendations EHR-S FIM r3:2016

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 Governed and Configuration Managed consistently.
      iii. The EA tool can generate both a navigable-web-site and printable-report
      iv. Support user-specific profiles (e.g., WG project DAMs, DIMs, DCMs).
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) 5-FTE Man-years
   a. A marketing campaign is needed to justify EHR-S FIM r3:2016 resources

EHR-S FIM
Reference Model Definition

The EHR-S reference model (RM) is an abstract-framework for structuring significant-relationships among the entities of EHR-S environments based-on consistent EHR-S function-and-information conceptual models; where, EHR-S RM conformance criteria contain a constrained-lexicon of nouns (entities), verbs (operations/tasks), qualifiers (conditions), constraints (policies/rules), which may be used-as requirements-specifications by analysts, developers, implementers, and testers. The EHR-S or PHR-S RM-instance-models provide a common syntax-and-semantics that can be used unambiguously across-and-between different implementations; where, the RM instances may be linked-to specific-implementation standards-technologies-paradigms-or-patterns. [based-on OASIS RM definition]

- 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 FM r2.0:2013 Dimensions and Stakeholders

Care Provision

1. CP.1 Manage Clinical History
2. CP.2 Render Externally Sourced Information
3. CP.3 Manage Clinical Documentation
4. **CP.4 Manage Orders**
5. **CP.5 Manage Results**
6. **CP.6 Manage Treatment Administration**
7. CP.7 Manage Future Care
8. CP.8 Manage Patient Education & Communication
9. CP.9 Manage Care Coordination & Reporting

Care Provision Support

1. CPS.1 Record Management
2. CPS.2 Support Externally Sourced Information
3. CPS.3 Support Clinical Documentation
4. CPS.4 Support Orders
5. CPS.5 Support for Results
6. CPS.6 Support Treatment Administration
7. CPS.7 Support Future Care
8. CPS.8 Support Patient Education & Communication
9. CPS.9 Support Care Coordination & Reporting

Trust Infrastructure

1. TI.1 Security
2. TI.2 Audit
3. TI.3 Registry and Directory Services
4. TI.4 Standard Terminology and Terminology Services
5. TI.5 Standards-Based Interoperability
6. TI.6 Business Rules Management
7. TI.7 Workflow Management
8. TI.8 Database Backup and Recovery
9. TI.9 System Management Operations and Performance

Population Health Support

1. POP.1 Support for Health Maintenance, Preventive Care and Wellness
2. POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population
3. POP.3 Support for Notification and Response
4. POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health
5. POP.5 Donor Management Support
6. POP.6 Measurement, Analysis, Research and Reports
7. POP.7 Public Health Related Updates
8. POP.8 De-Identified Data Request Management
9. POP.9 Support Consistent Healthcare Management of Patient Groups or Populations
10. POP.10 Manage Population Health Study-Related Identifiers

Administration Support

1. AS.1 Manage Provider Information
2. AS.2 Manage Patient Demographics, Location and Synchronization
3. AS.3 Manage Personal Health Record Interaction
4. AS.4 Manage Communication
5. AS.5 Manage Clinical Workflow Tasking
6. AS.6 Manage Resource Availability
7. AS.7 Support Encounter/Episode of Care Management
8. AS.8 Manage Information Access for Supplemental Use
9. AS.9 Manage Administrative Transaction Processing

Record Infrastructure

1. **RI.1 Record Lifecycle and Lifespan**
2. RI.2 Record Synchronization
3. RI.3 Record Archive and Restore

Blue-Bold
indicates Prototype Inclusion

Proposed Restructuring Strategy
EHR-S FIM r3.0: 2016

Release 3.0:2016 – focus on usability and efficiency

Restructure model to make it more intuitive

1. Direct Care
   1. Order Entry/Mgmt./CPOE
   2. Results
   3. Care/Treatment Administration
   4. Decision Support
2. Supportive Care
   1. Administrative Processes
   2. Patient Support/Education
   3. Health Information-and-Data
   4. Reporting & PopHealth Mgmt.
3. Infrastructure (EHR System)
   1. Event and metadata Management
   2. Records Management
   3. Trust Management
   4. List Management
   5. Document manager
   6. Registry manager
   7. Repository manager
   8. Communication and Connectivity Management

EHR-S FIM
Proposed Conformance-Criteria RM

- **System**
  - EHR or PHR
- **Applicability (SHALL, SHOULD or MAY)**
  - according to
    - Scope of practice,
    - Organizational policy,
    - Jurisdictional law,
    - Patient preference or consent."
- **Human Action**
  - Linked-to Use-Case Actions
  - such as Immunization Administration
- **System Function Type**
  - System provides the ability (for a human) to
  - Or the system directly does
- **System Function Constraints**
  - Pre-conditions (e.g., triggers)
  - Post- conditions (e.g., outcomes)
  - Invariant-conditions (e.g., context)
- **System Function**
  - EHR Verb Hierarchy of what the system does, such as manage, maintain, …
- **Data Requirements**
  - Linked-to International FHIR specifications
  - Linked-to US Realm FHIM specifications
- **Associations & Dependencies**
  - Supporting capabilities and functions

EHR-S RM
Conformance-Criteria Example

CP.6.2#01 The EHR system SHALL provide the ability to *capture* Immunization Administration details as discrete data, such as Immunization FHIR; where, the Immunization resource is associated with the following resources:

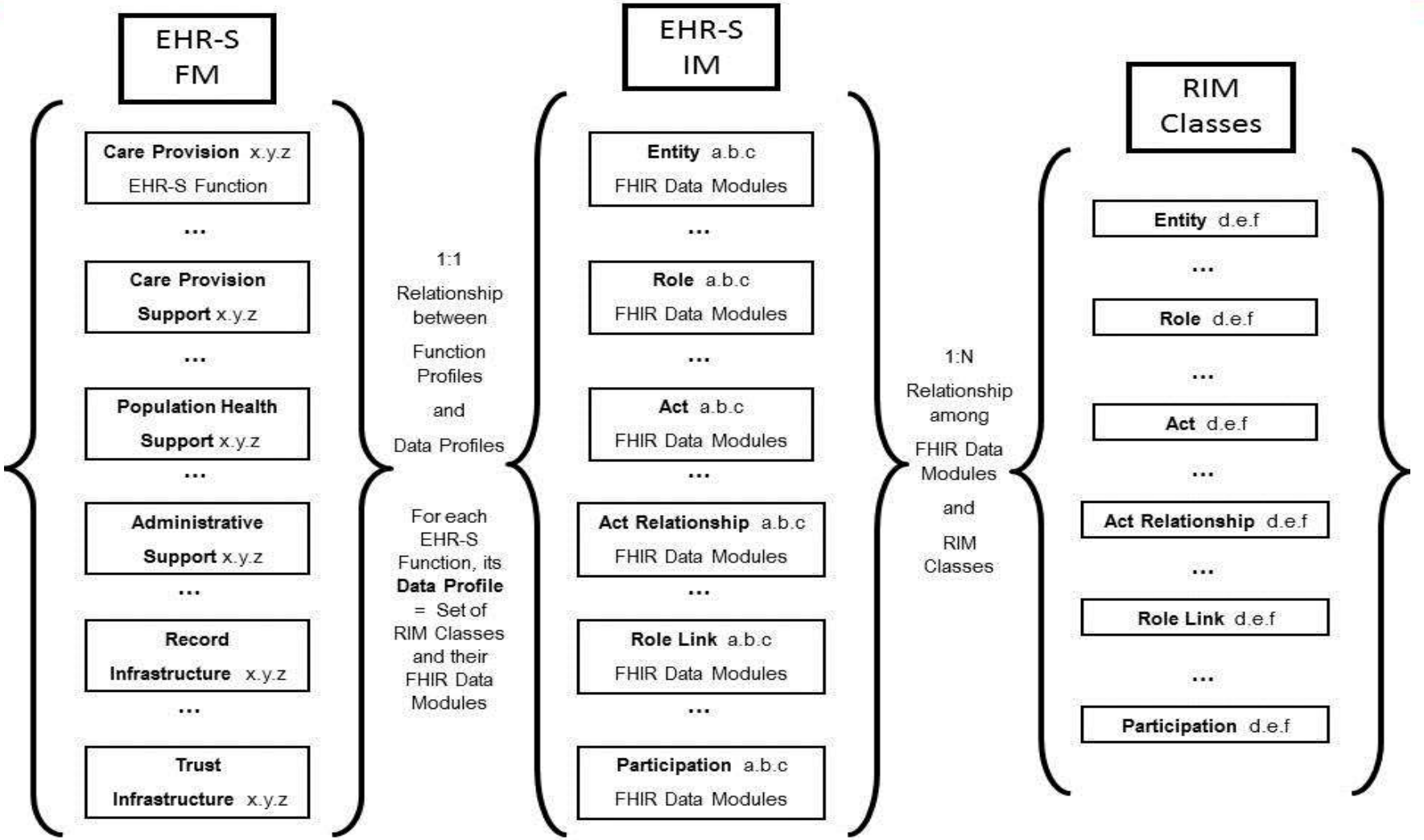
- AdverseReaction
- Patient
- Practitioner
- Organization
- Location
- Observation;

And, within the US Realm, the Immunization and associated resources are expressable by the applicable FHIM Domains of:

- Immunization, Adverse Reaction, Allergy and Intolerance
- Associated with appropriate FHIM classes (e.g., Person, …)

EHR-S RM
Proposed Information-Architecture

by Stephen Hufnagel PhD; where,
RIM is the HL7 reference Information Model, **FHIR** is Fast Healthcare Interoperability Resource



FHIM will also be linked [5-Nov13]

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

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

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Author: Steve Hufnagel
Version: Prototype
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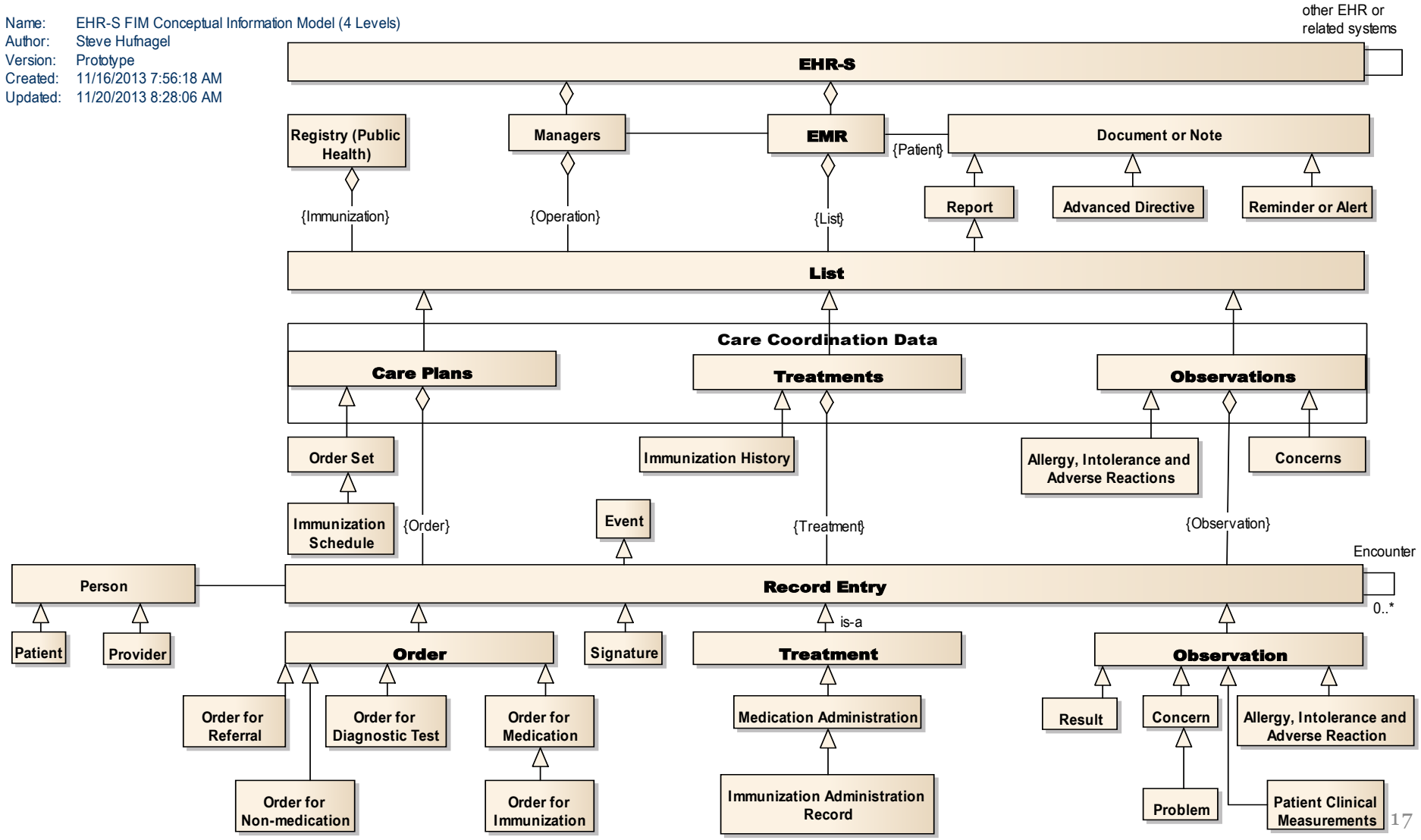
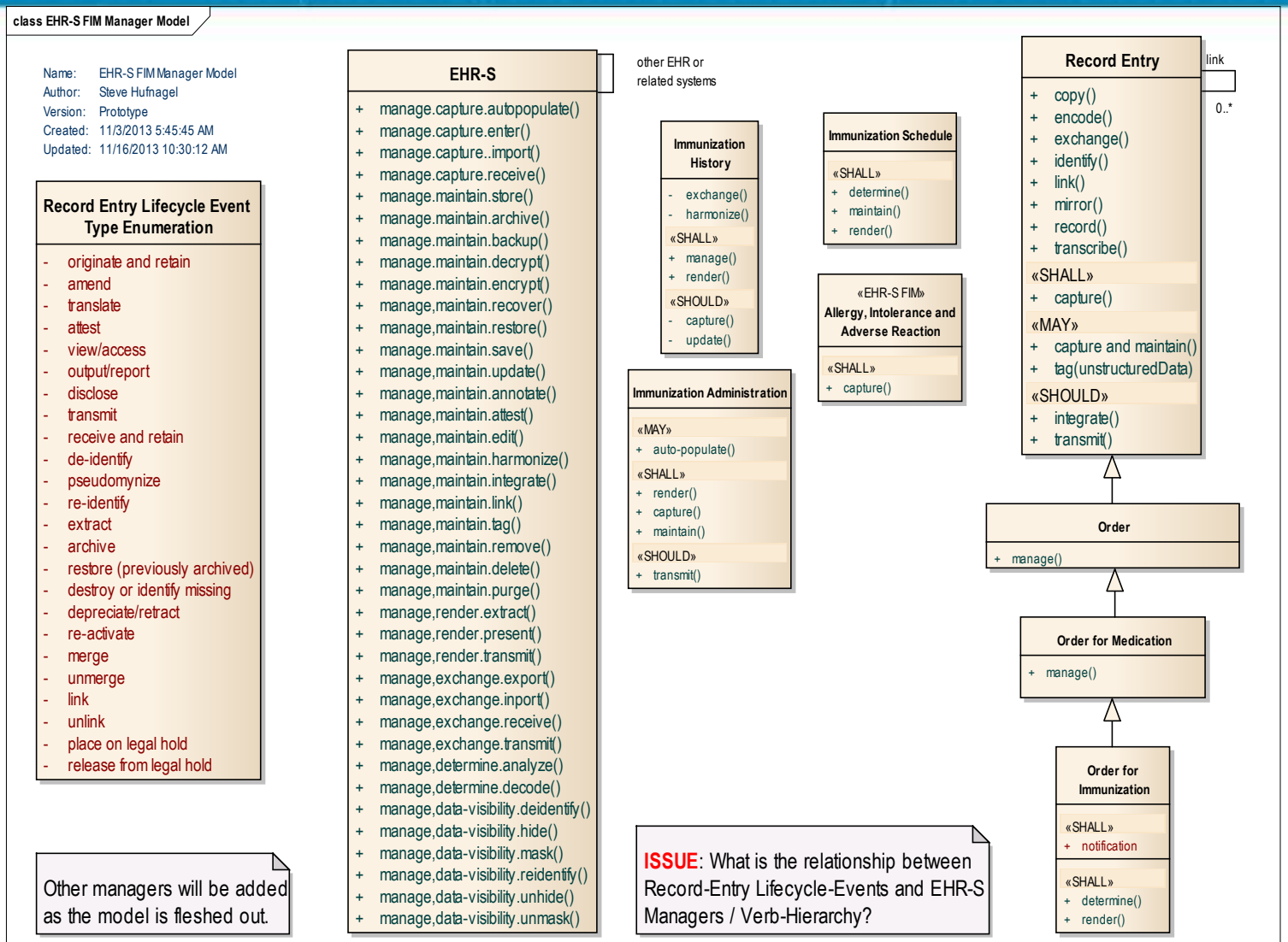
Updated: 11/20/2013 8:28:06 AM



EHR-S FIM Anatomy (Structure) Conceptual Operations (Managers) Model

ISSUE: Consistency of EHR-S Managers (Verb-Hierarchy) & Record Lifecycle Events.



EHR-S FIM Based on Conceptual Information-and-Operations Models

Resultant EHR-S Description (Notional Scenario)

An **EHR system** is composed of a set of EMRs with associated Documents or Notes and their Managers

- Where, each patient's **EMR** contains Care-Coordination-Data Lists (aka histories) of
  - **Treatments** (e.g., immunizations),
  - **Observations** (e.g., allergy-intolerance-and-adverse-reactions), Orders-and-Results and/or
  - **Care-Plans** (e.g., immunization schedule)
- Where, the EHR-S lists are composed of **Record-Entries** for
  - Various types of Orders, Treatments or Observations
  - Which may be grouped into encounters with provider and/or patient signatures
- Where, the EHR-S Managers perform operations
  - Internally on the lists, record-entries or documents and
  - Externally with federated-data Registries-and-Repositories and Ancillary-Service Systems.

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

ss 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: 11/17/2013 1:19:46 PM

Observation
«EHR-S FIM»
Allergy, Intolerance and Adverse Reaction

realize

realize

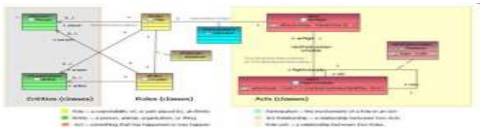
«FHIR»
AllergyIntolerance

«FHIR»
AdverseReaction

realize

realize

«Observation»
IntoleranceConditionEntry



NotificationReport
«Observation»
AdverseReactionReportingEvent

«Observation»
NoKnownAllergyEntry

«Observation»
IntoleranceCondition

+intoleranceObservation
*

FHIM Allergy Domain
+ InformationReporter
+ IntoleranceCondition
+ IntoleranceConditionEntry
+ IntoleranceConditionList
+ NoKnownAllergyEntry
+ RelatedIntoleranceCondition

FHIM
+ FHIM Adverse-Event Reporting Domain
+ FHIM Allergy Domain
+ Common
+ CommonProduct
+ Person
+ Provider
+ Public HealthReporting

FHIM Adverse-Event Reporting Domain
+ AdverseReactionReportingEvent
+ ConcommittantDrugs
+ ReactionObservation
+ RelevantLabData
+ SuspectedAgent

Interim Conclusions
EHR-S FIM r3.0:2016

- We have looked at Medication-and-Immunization Management, Orders-and-Results Management and Record Entry Management.
- The EHR-S RM (reference model) is used to structure EHR-S functions-and-data; where, the function's conformance-criteria lexicon defines the grammar of nouns (entities), 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.

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

1. Introduction and Plan of Actions & Milestones
2. Executive Summary, Reference-Model and Conceptual-Architecture
3. **CP.6.2 Immunization-Management Modeling-Prototype**
4. RI.1.1.1 Originate and Retain Record Entry Modeling-Prototype
5. EHR-S FIM use of FHIR for Allergy, Intolerance and Adverse-Reaction
6. EHR-S FIM use of FHIM for Allergy, Intolerance and Adverse-Reaction
7. Traceability

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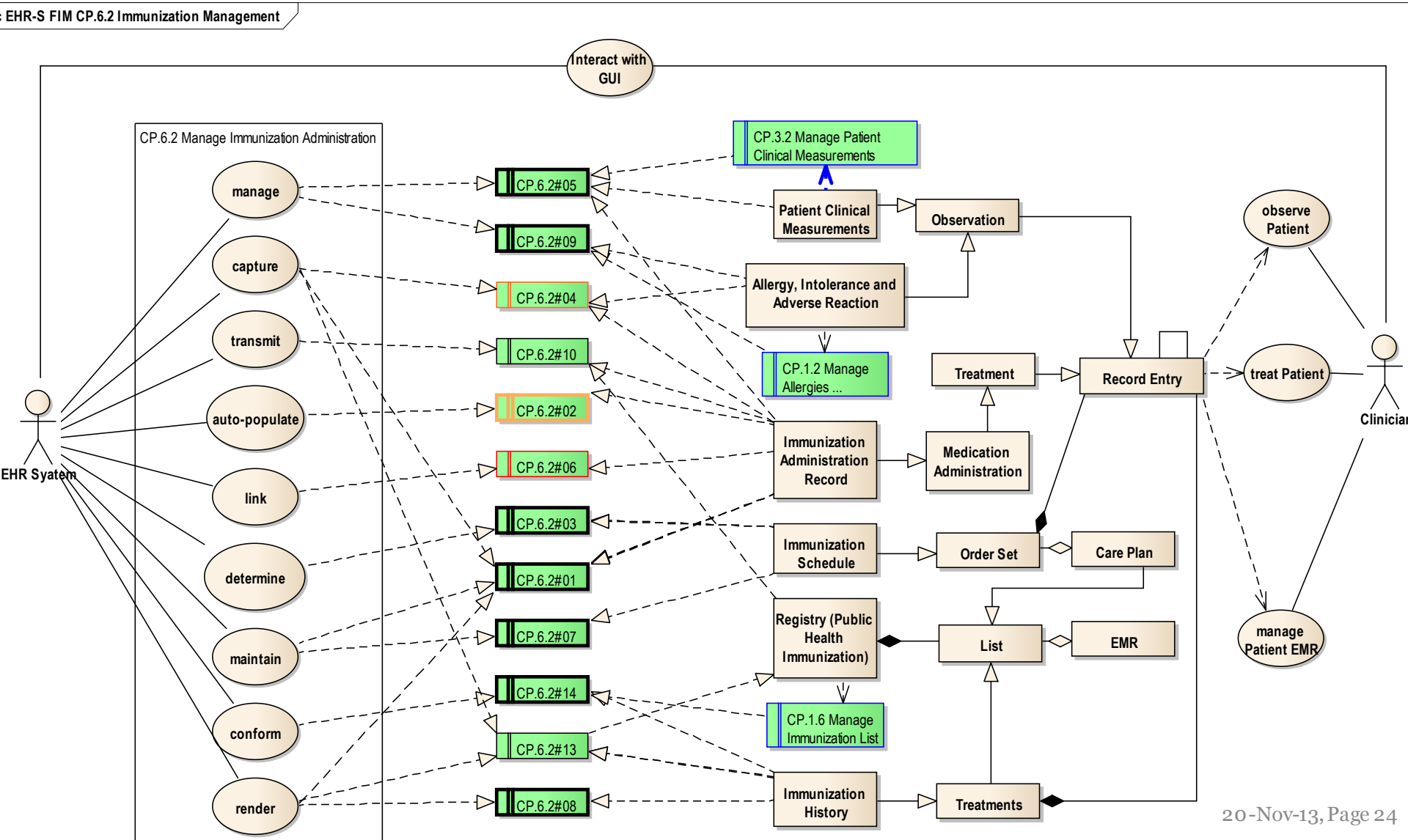
EHR-S FIM
CP.6.2 Immunization Management

Use-Case Description (Notional Scenario)

- A Clinician *reviews* the patient's EMR for Allergies and Intolerances, reviews the Patient's Immunization-Schedule, treats (*immunizes*) the Patient with a Vaccine and *observes* Adverse-Reactions.
- The EHR-S Immunization related managers can
  - *Capture, Auto-populate, Maintain, Render, Transmit, Exchange,*
  - *Harmonize, Update, or Determine*
- The following data-modules:
  - Immunization-Administrations, Allergies, Intolerances, Adverse-Events
  - Events, Schedules, Plans and Educational Materials

EHR-S-FIM Physiology (Function) Use-Case Traceability Analysis

CP.6.2 Immunization Management Conformance Criteria



EHR-S-FIM Anatomy (Structure) Conceptual Information Model (CIM) CP.6.2 Immunization Management

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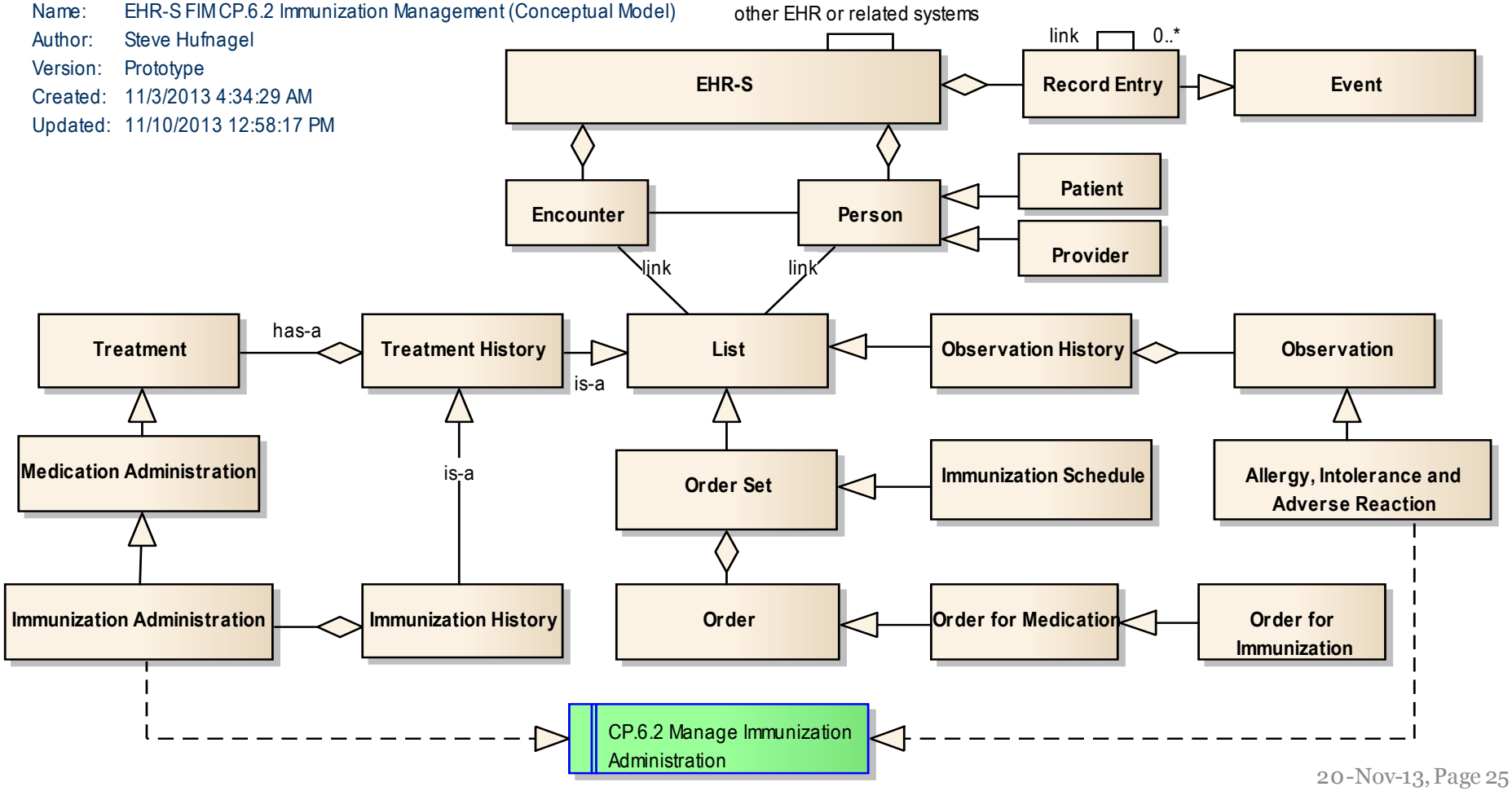
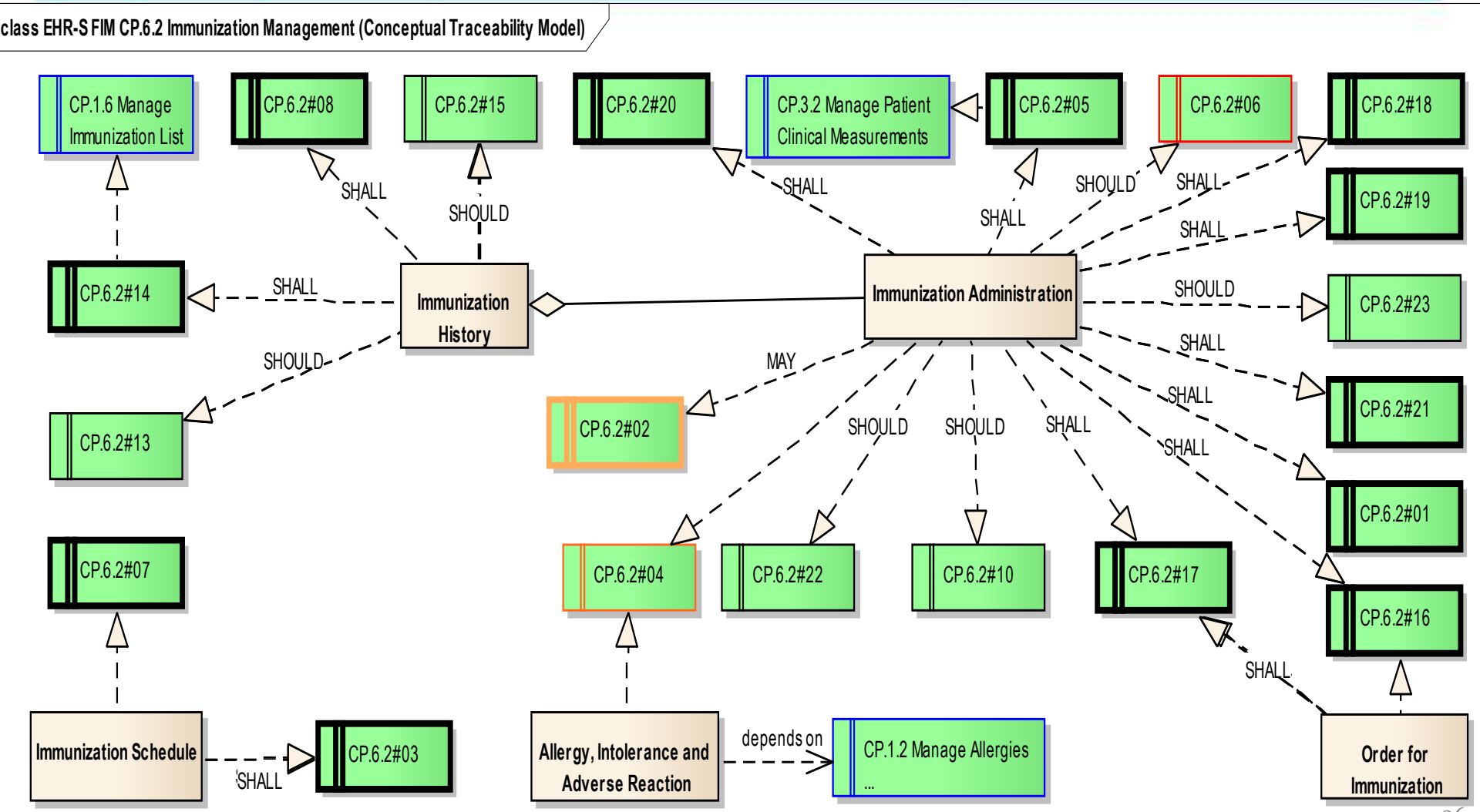
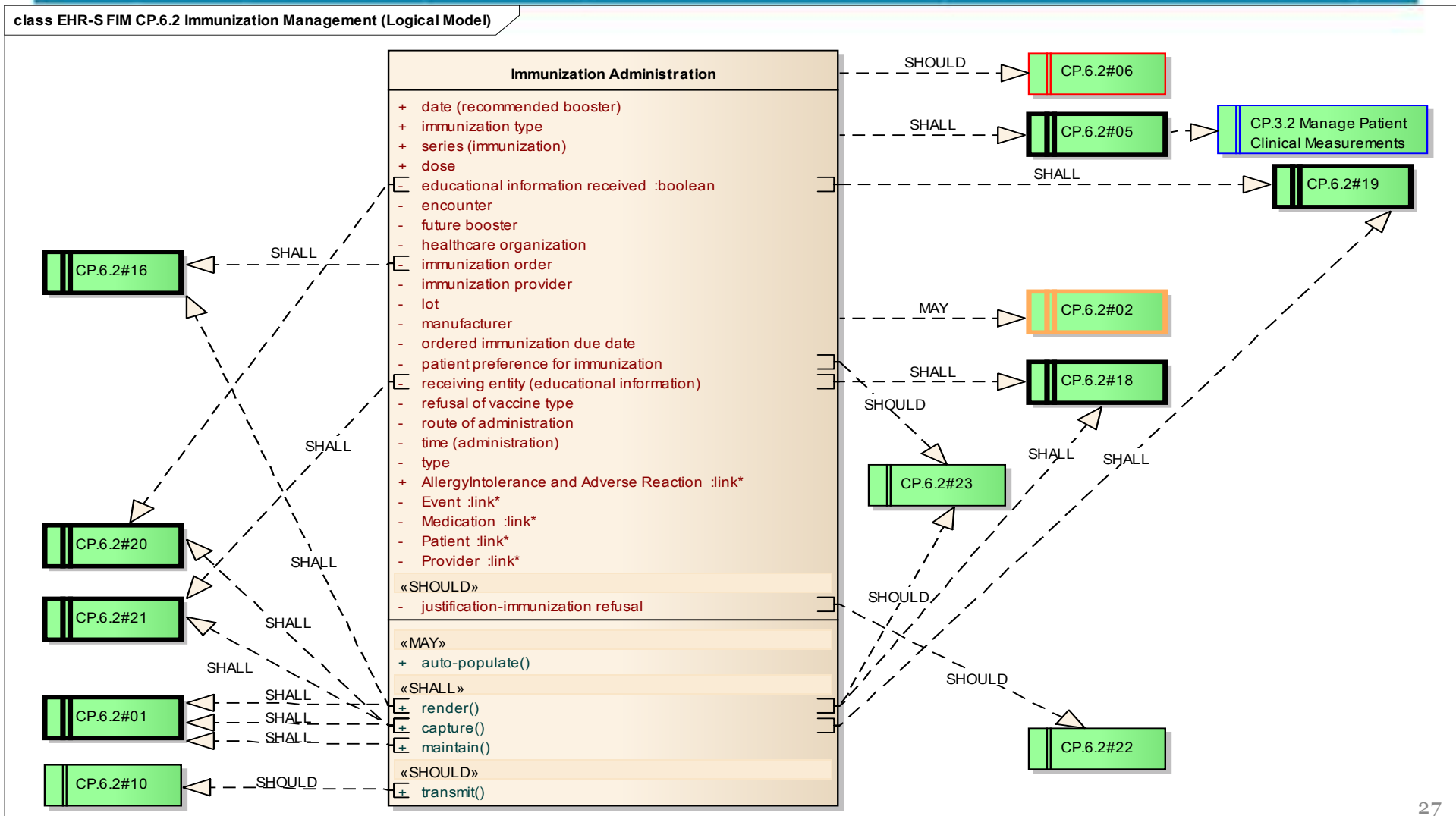


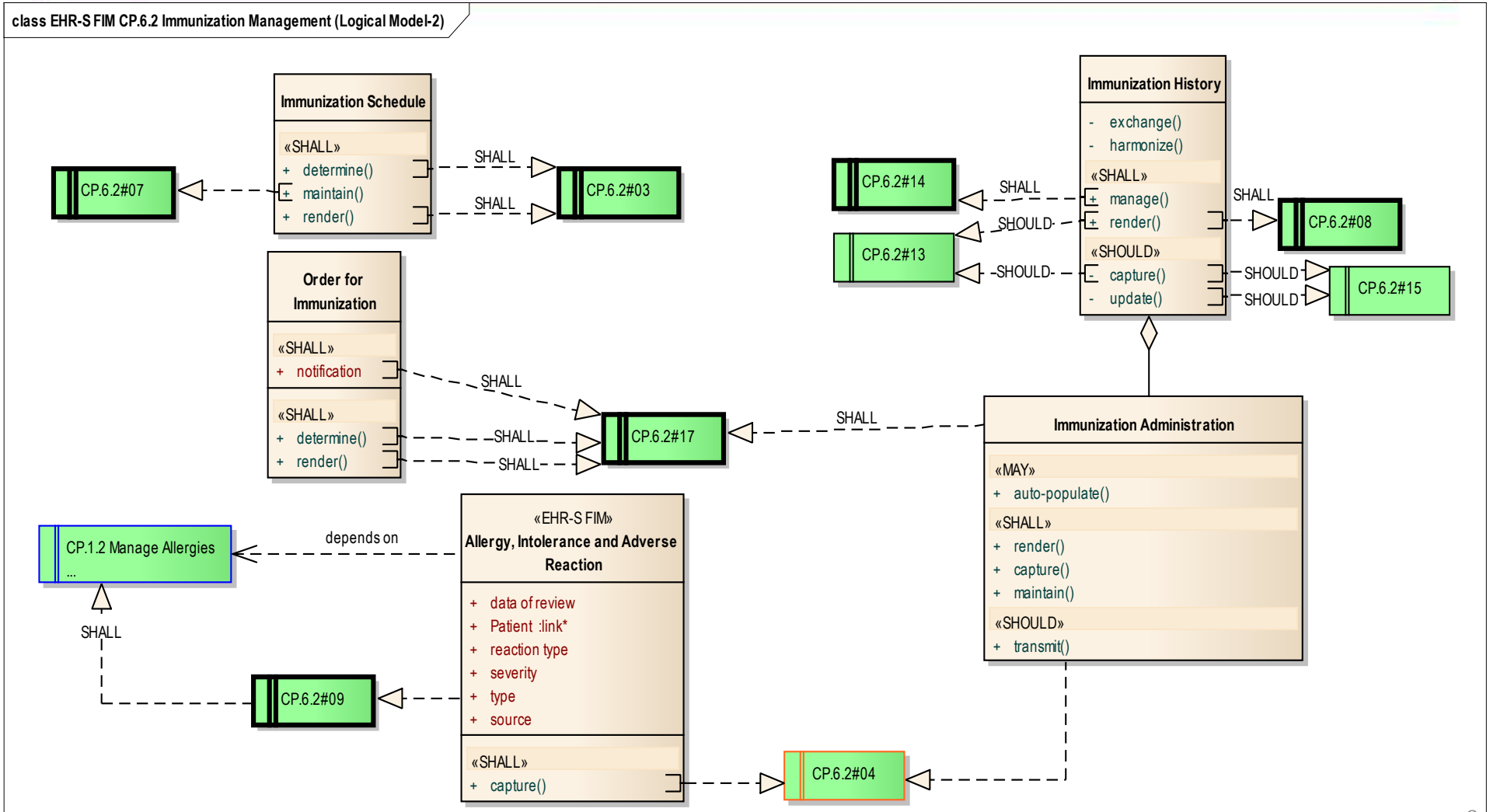
EHR-S-FIM
Traceability Model
CP.6.2 Immunization Management



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



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



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.

EHR-S-FIM
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
CP.6.2 Immunization Management

INTERIM CONCLUSION

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

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

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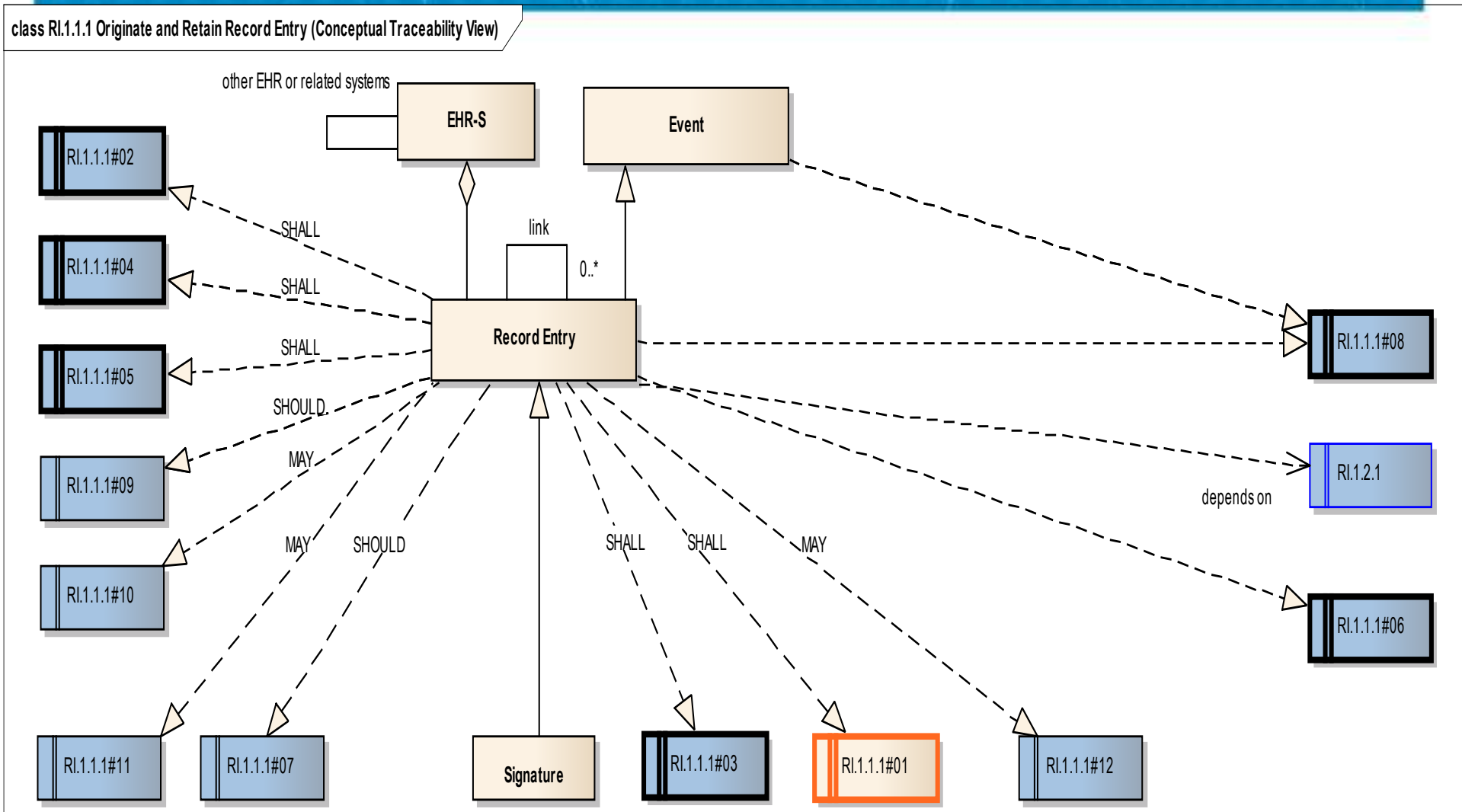
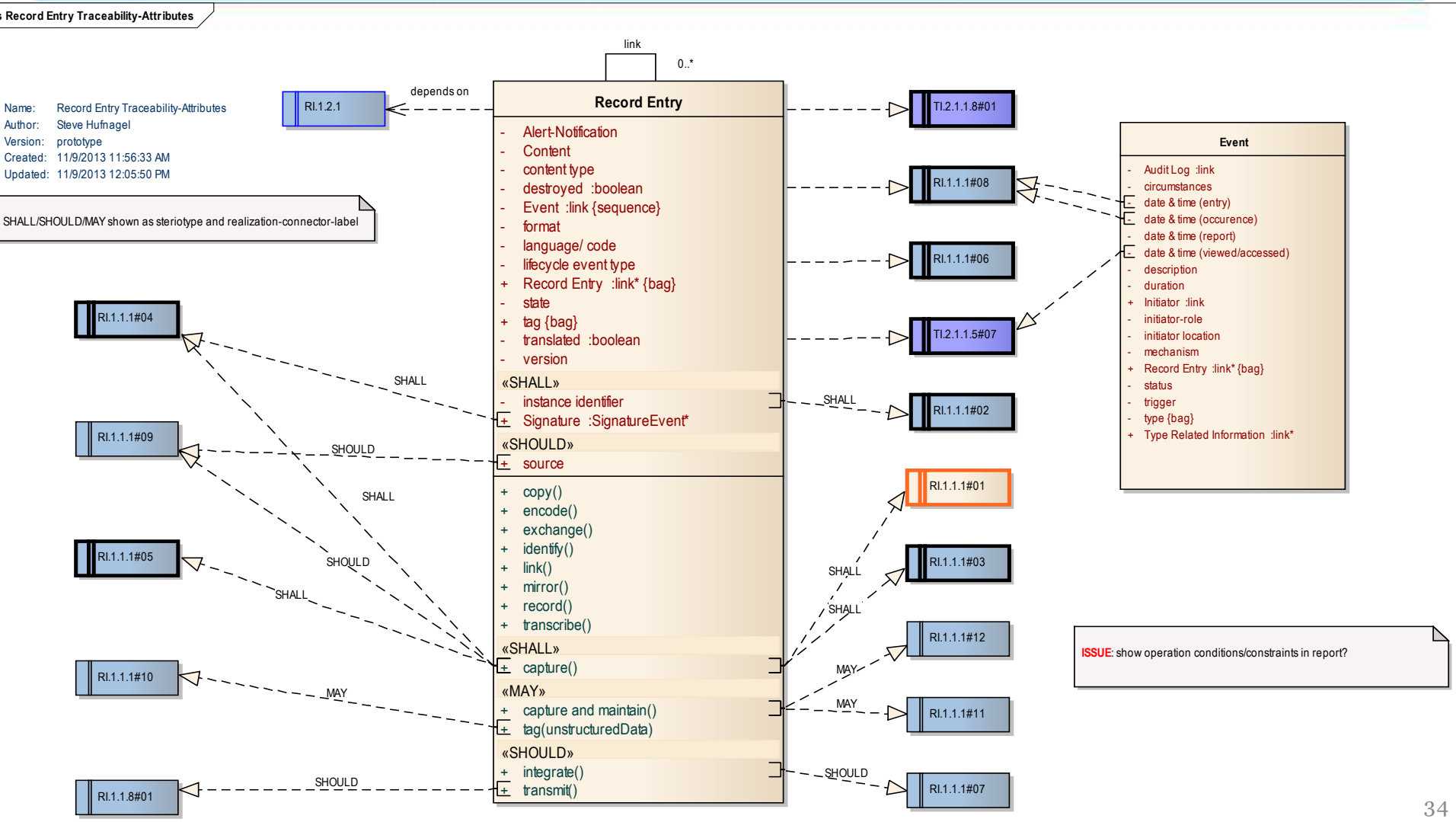
EHR-S FIM
Conceptual Information Model (CIM)
RI.1.1.1 Originate and Retain Record Entry



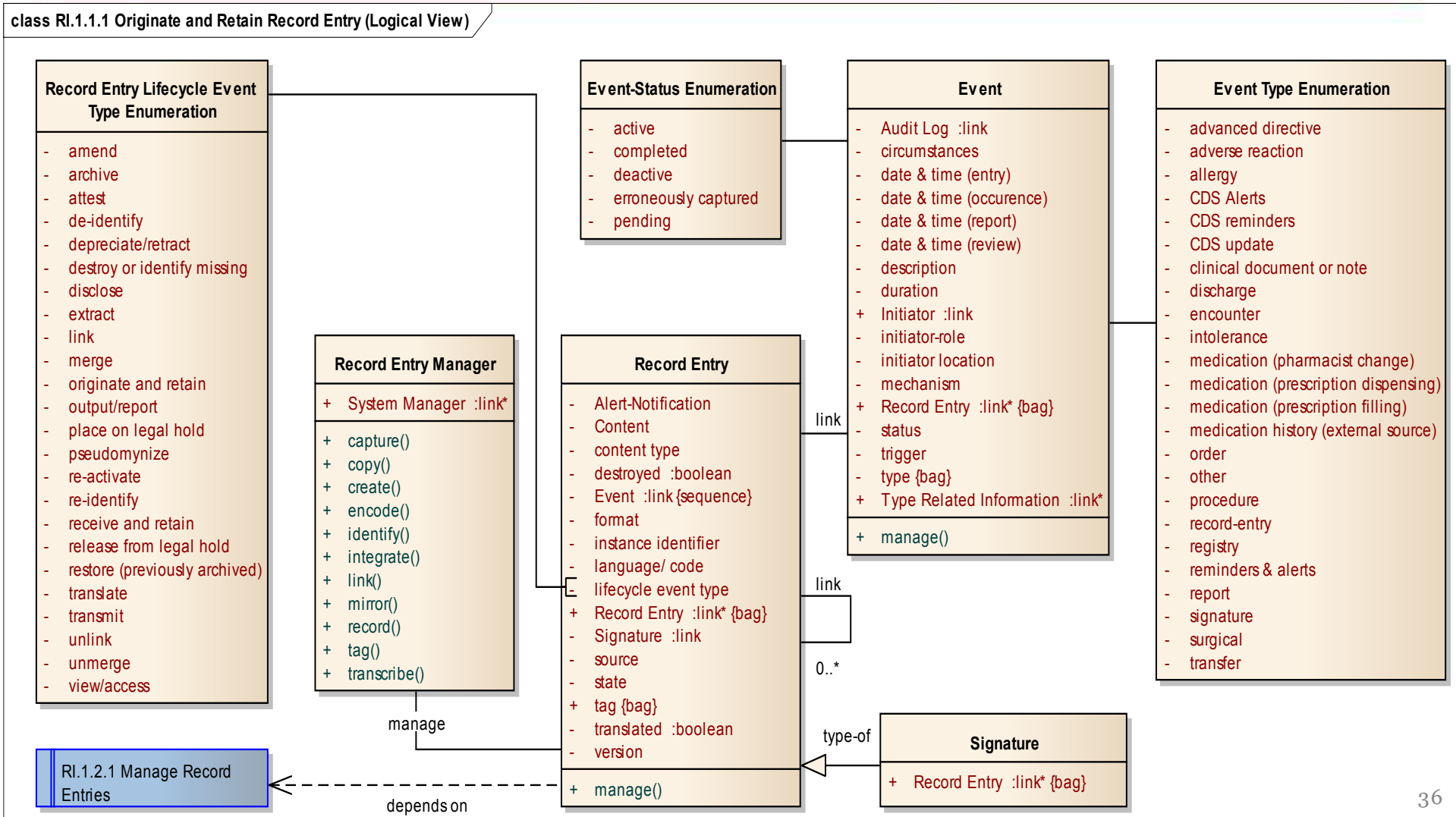
EHR-S FIM
Traceability View
RI.1.1.1 Originate-and-Retain Record Entry



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

1. RI.1.1.1#01 The system **SHALL** provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
2. RI.1.1.1#02 The system **SHALL** capture a unique instance identifier for each Record Entry.
3. RI.1.1.1#03 The system **SHALL** conform to function TI.2.1.1.1 (Originate/Retain Record Entry Audit Trigger), including specified metadata.
4. RI.1.1.1#04 The system **SHALL** capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.
5. RI.1.1.1#05 The system **SHALL** provide the ability to capture both structured and unstructured content in Record Entries.
6. RI.1.1.1#06 The system **SHALL** provide the ability to capture Record Entries from information recorded during system downtime.
7. RI.1.1.1#07 The system SHOULD provide the ability to integrate Record Entries from Information recorded during system downtime.
8. RI.1.1.1#08 The system **SHALL** provide the ability to capture date/time an Action was taken or data was collected if different than date/time of the Record Entry.
9. RI.1.1.1#09 The system SHOULD capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).
10. RI.1.1.1#10 The system MAY provide the ability to tag unstructured Record Entry content to organize it according to need, for example, in a time-related fashion or by application-specific groups (such as photographs, handwritten notes, or auditory sounds)
11. RI.1.1.1#11 The system MAY capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care or other HL7 CDA R2 Document).
12. RI.1.1.1#12 The system MAY capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.

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



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

Resultant Description (Notional Scenario)

- The EHR-S Record-Entry manager can
  - *Capture, Create, Copy, Record, Transcribe*, *Identify,*
  - *Link, Tag, Encode, Mirror, and Integrate*
- Record-Entries as
  - structured or unstructured-data link-to associated
    - Event-Metadata and Signatures.

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

INTERIM CONCLUSION

we have only looked at the RI.1.1.1 function; yet,

- we see that the emergence of common Record-Entries, Events, Record Entries and a Record Entry Manager
- which can *Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate*
  - structured-data or unstructured-data and link-to
  - associated Event-Metadata and Signature.

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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

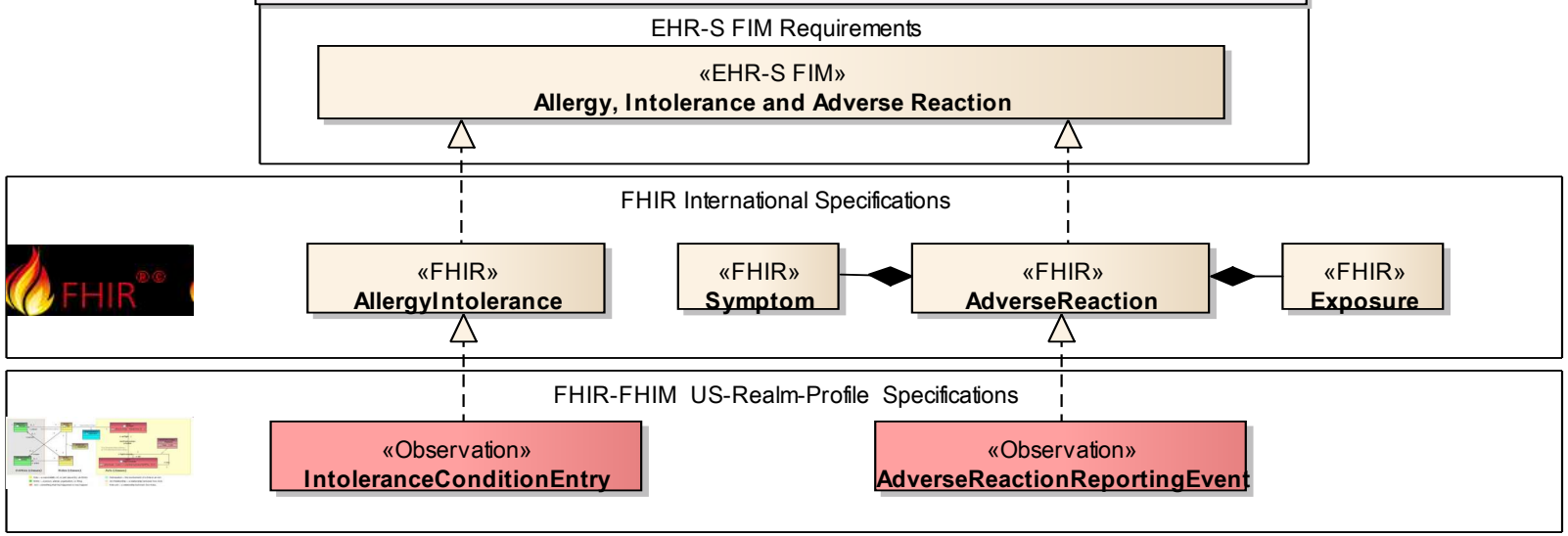
EHR-S FIM Prototype
Allergy, Intolerance & Adverse-Reaction
FIM-FHIR-FHIM Requirements-Specifications

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

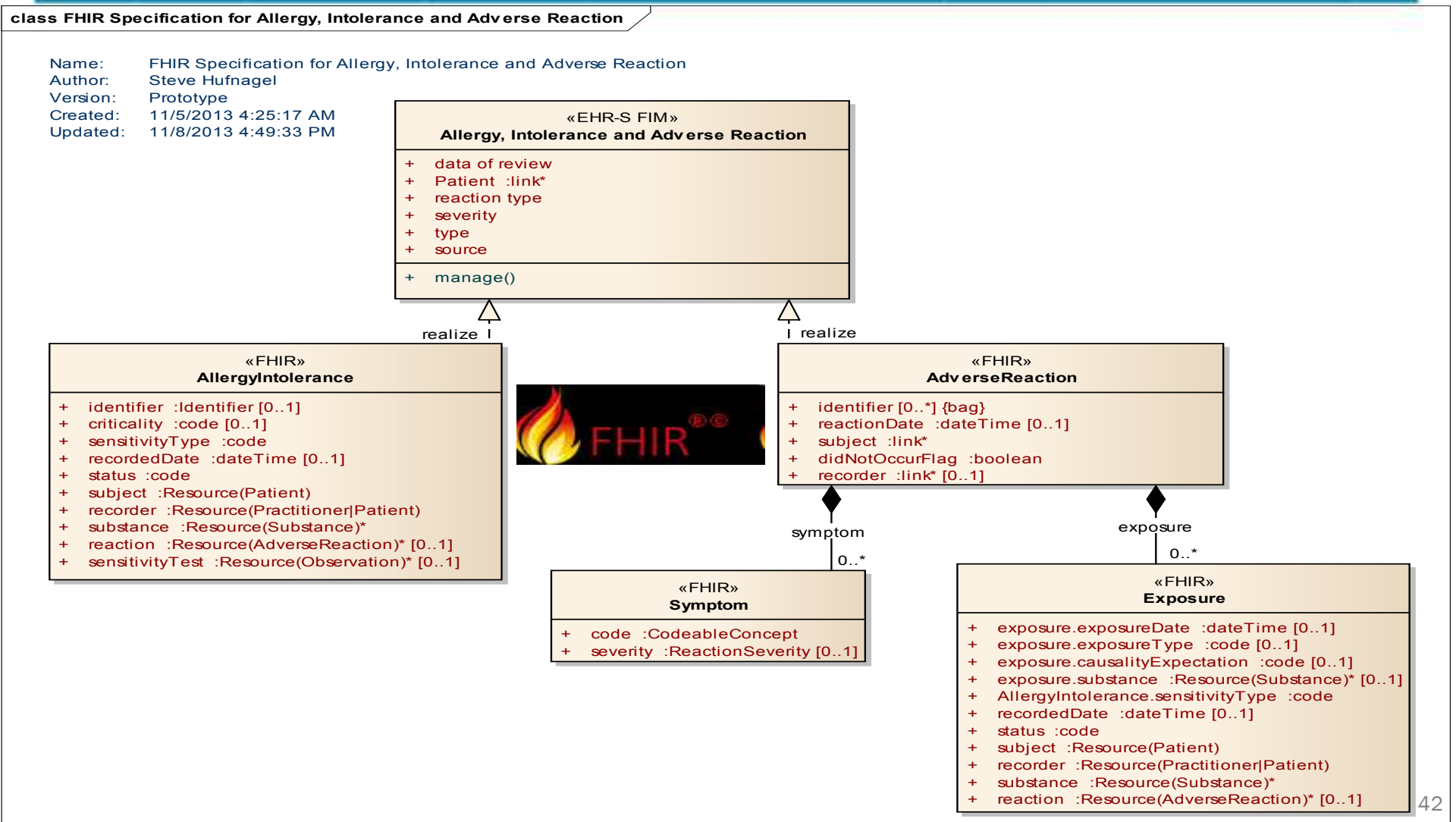
Name: FHIR-FHIM High-Level Specification for Allergy, Intolerance and Adverse Reaction
Author: Steve Hufnagel
Version: Prototype
Created: 11/7/2013 4:26:03 AM
Updated: 11/18/2013 9:07:42 AM

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



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1. Introduction and Plan of Actions & Milestones
2. Executive Summary, Reference-Model and Conceptual-Architecture
3. CP.6.2 Immunization-Management Modeling-Prototype
4. RI.1.1.1 Originate and Retain Record Entry Modeling-Prototype
5. EHR-S FIM use of FHIR for Allergy, Intolerance and Adverse-Reaction
6. **EHR-S FIM use of FHIM for Allergy, Intolerance and Adverse-Reaction**
7. Traceability

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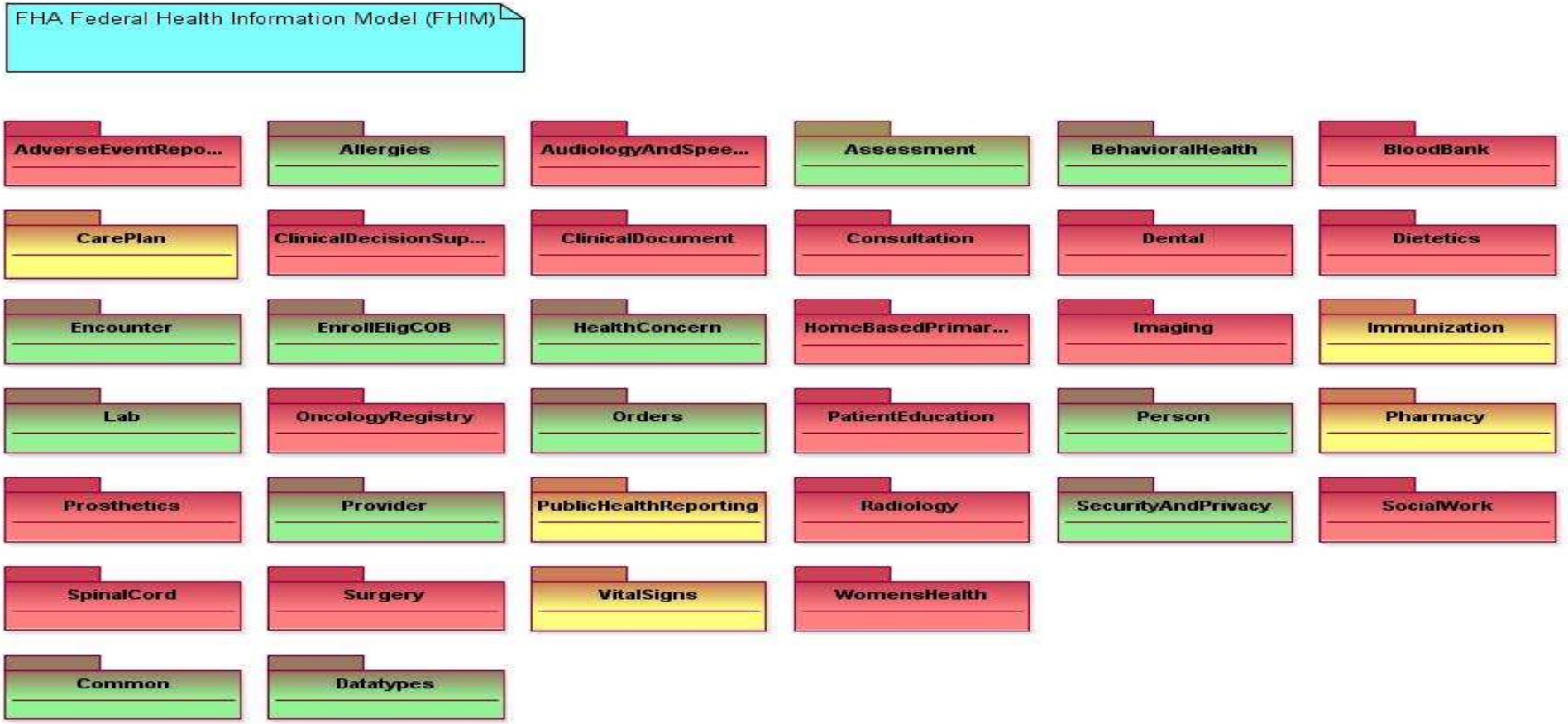
EHR-S FIM Using Federal Health Information Model (FHIM)

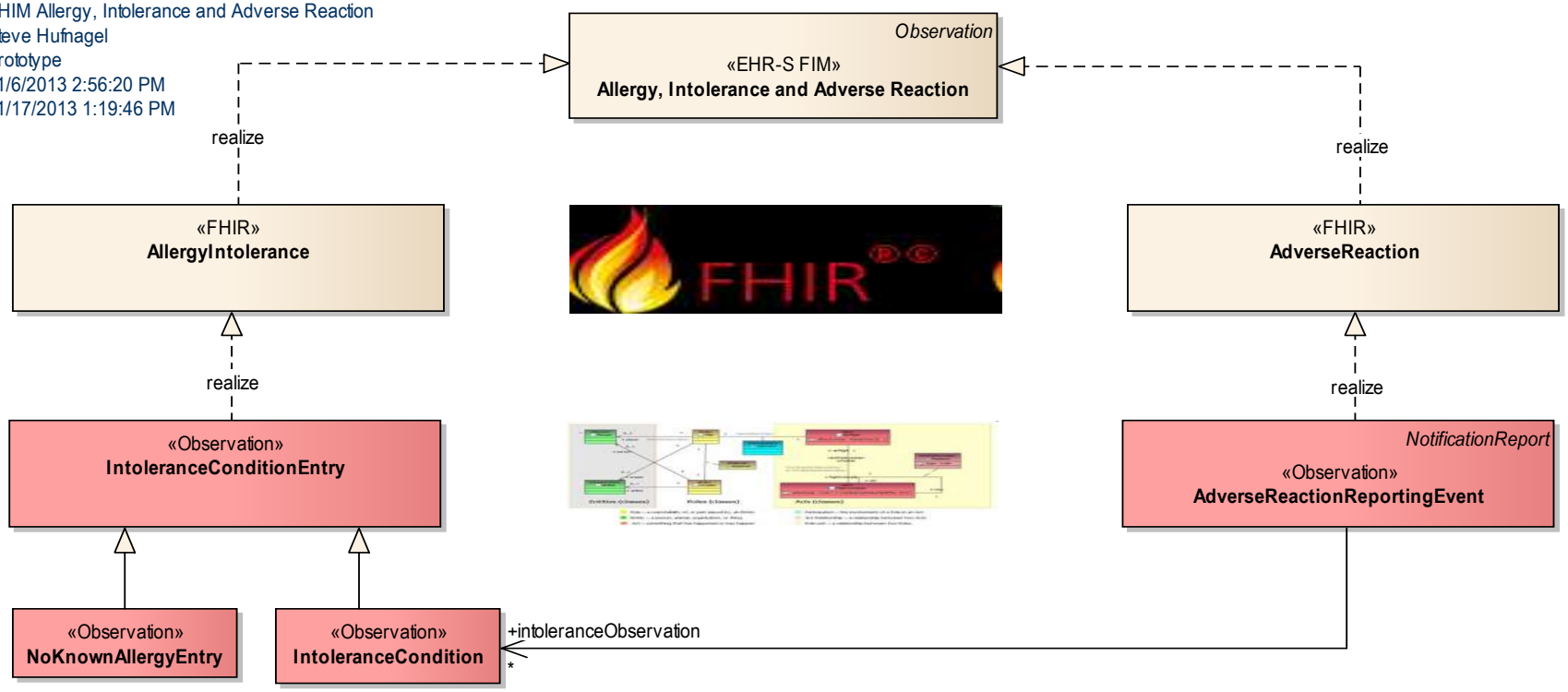
http://www.fhims.org/content/420A62FD03B6_root.html

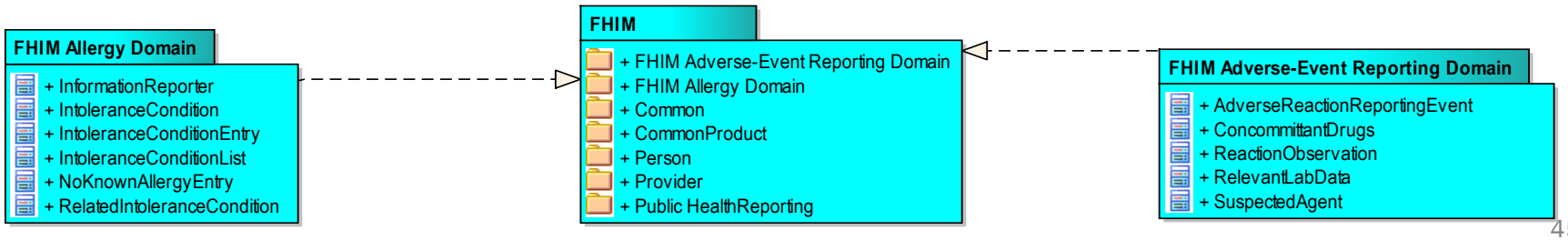


Prototype
Allergy, Intolerance & Adverse-Reaction
FHIM High-Level US-Realm Specification

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: 11/17/2013 1:19:46 PM

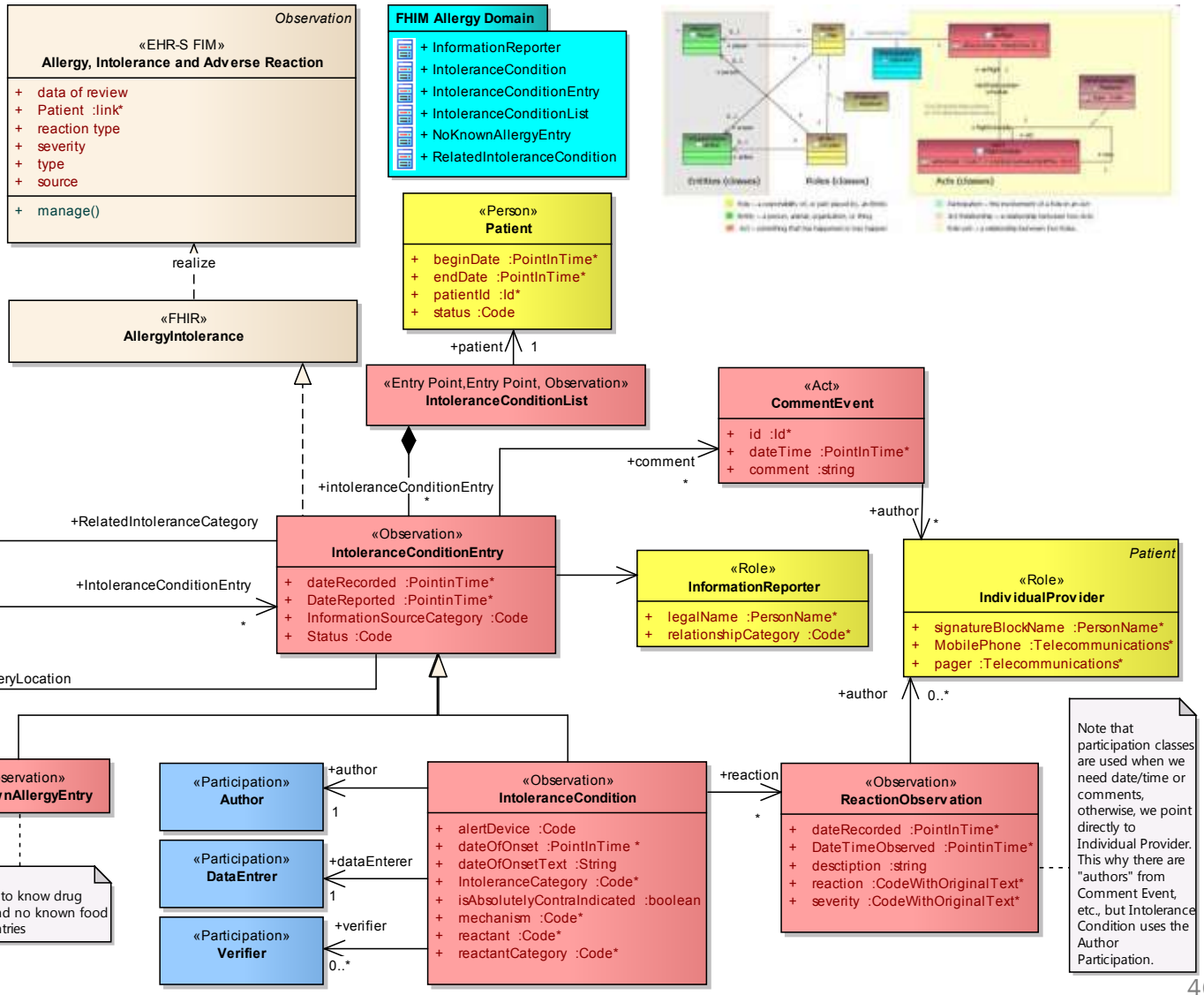




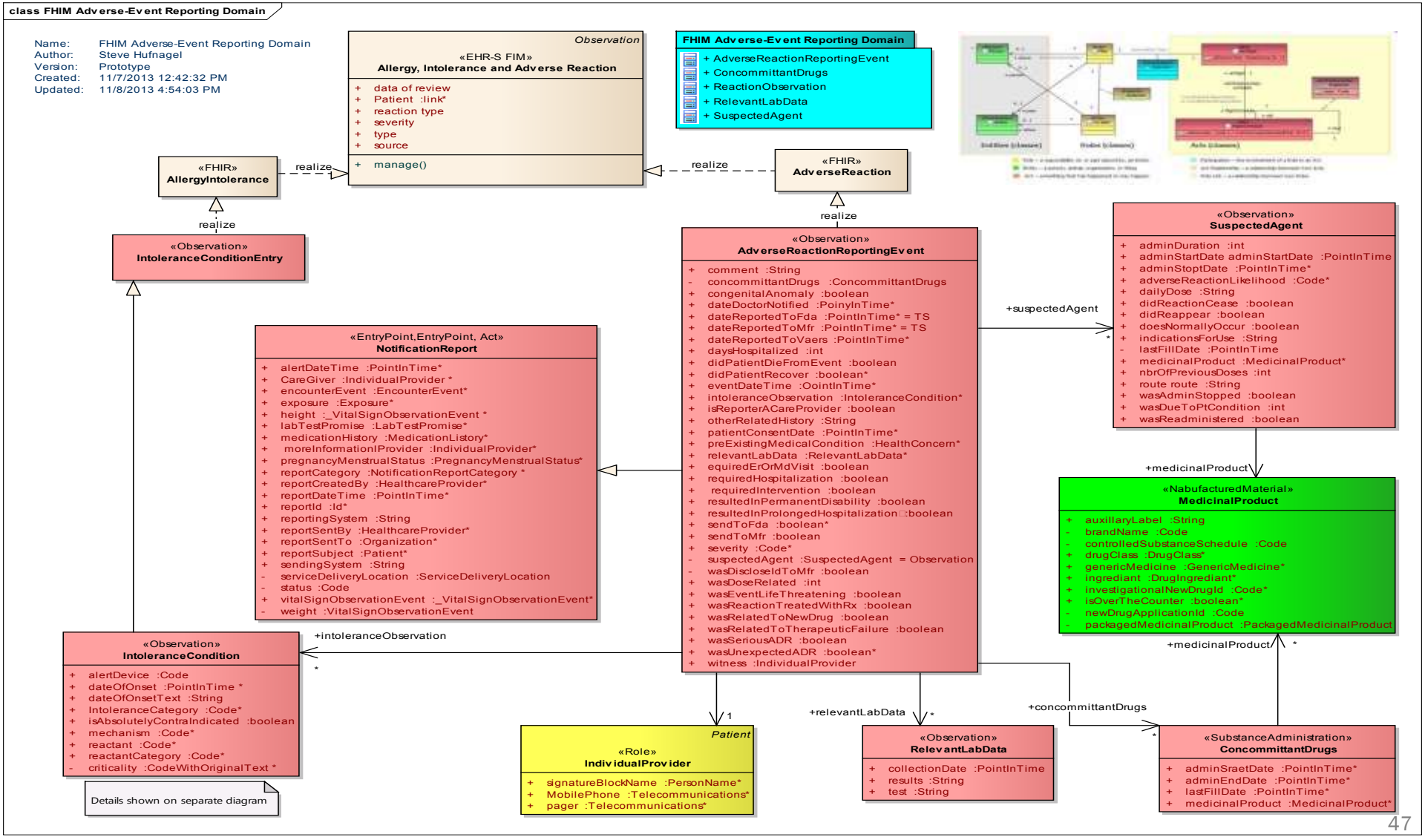
Prototype
FHIM-Detailed Allergy & Intolerance Specification

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



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-Specification**s from FHIR
- **US-Realm Data-Specifications-Profile** from FHIM

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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							

Record Entry Lifecycle Event Type Enumeration

- originate and retain
- amend
- translate
- attest
- view/access
- output/report
- disclose
- transmit
- receive and retain
- de-identify
- pseudomynize
- 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

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