



HL7 EHR Work Group (EHR-WG)

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November 26, 2013 Frequently-Updated Working-Draft http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG



EHR Work Group Goal & Objectives

- <u>Electronic Health Record (EHR) Work Group's</u> goal is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability.
 - Functional and Information Requirements for Electronic Health Records (EHR) and systems (EHRS),
 - Functional and Information Requirements for Personal Health Records (PHR) and systems (PHRS),
- EHR Interoperability WG's objectives are
 - 1. to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 in the Sparx Systems Enterprise Architect (EA) tool; where, it addresses the issues identified by the VA negative r2.0 ballot.
 - 2. to produce a Meaningful Use profile for r2.0.
- Resource Management Evidentiary Support (RM-ES) project's objective is to provide expertise on records management, compliance, and data/record integrity and governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.
- EHR Usability WG's objective is developing a usability profile for the EHR-S FM
- PHR-S WG's objective is to maintain a Patient Healthcare System Functional Model (PHR-S FM).

EHR WG Logistics



Schedule: http://www.hl7.org/concalls/default.aspx

List Server: http://www.hl7.org/myhl7/managelistservs.cfm

Health Level Seven - Electronic Health Record Work Group

Weekly Teleconference Schedule

Revised: 20 November 2013

Day	Time US ET	Activity	Lead(s)	Dial-In	Screen Sharing	List Server (for agendas, announcements)	
Mon	1200	Records Management/ Evidentiary Support	Warner, Gelzer	1-877-668-4493 Code 927 002 088#	<u>Link</u>	EHR Legal	
Tues	1300	EHRS FM Release 3 Planning	Hufnagel, Dickinson	1-770-657-9270, Passcode 510269#	<u>Link</u>	EHR Interop	
	1400	Meaningful Use Functional Profile	Datta, Dickinson	1-770-657-9270, Passcode 510269#	<u>Link</u>	EHR Interop	
	1500	FULL EHR WG	Co-Chairs	1-770-657-9270, Passcode 510269#	<u>Link</u>	EHR WG	
Wed	1200	Personal Health Record WG	Ritter, Dickinson, Doo	1-770-657-9270, Passcode 510269#	ТВА	EHR PHR	
	1300	EHR System Usability WG	Mon, Ritter, Rocca, Gartner	1-770-657-9270, Passcode 510269#	<u>Link</u>	EHR Usability	
Thur	Open	Open					
Fri	0930	EHR WG Co-Chairs	Co-Chairs	1-770-657-9270, Passcode 510269#	ТВА	N/A	

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

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

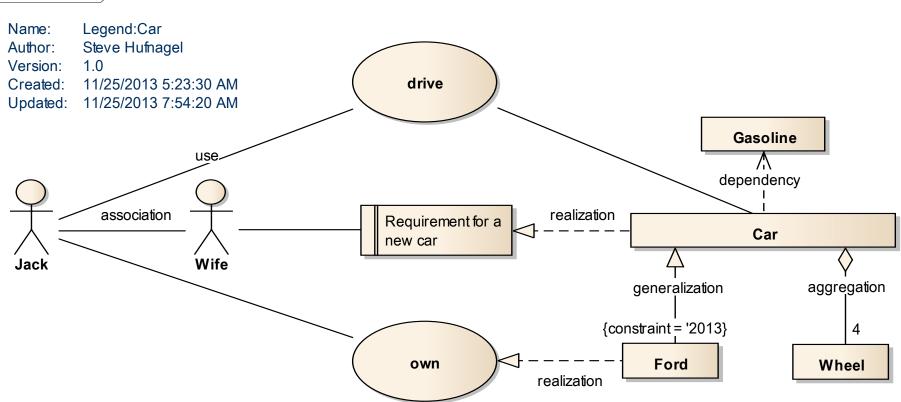
EHR-S FIM Acronyms

•	aka	also known as
•	CC	EHR-S FIM Conformance Criteria
•	CDA	Clinical Document Architecture
•	DD	Data Dictionary
•	CIM	Conceptual Information Model
•	CP	Care Provision
•	CPS	Care Provisioning Support
•	EA	Enterprise Architect
•	EHR-S	EHR System
•	EHR-S F	IM EHR-S Function and Information Model
•	FHA	US Federal Health Architecture
•	FHIM	US Federal Health Information Model
•	FHIR	Fast Healthcare Interoperability Resources
•	FIM	EHR-S Function and Information Model
•	FIM(MU)	EHR-S FIM Meaningful Use profile
•	FM	Function Model
•	FY	Fiscal Year
•	IHE	Integrating the Healthcare Enterprise
•	IM	Information Model
•	MDHT	Model Driven Health Tools
•	MU	US Meaningful Use objectives-and-criteria
•	ONC	US Office of the National-Coordinator
•	OHT	Open Health Tools
•	POA&M	Plan of Actions and Milestones
•	R 2/3	Release 2 or 3
•	RI	Resource Infrastructure
•	RIM	HL7 Reference Information Model
•	S&I	ONC Standards & Interoperability Framework
•	WBS	Work Breakdown Structure
•	WG	Work Group

Legend UML Notation







USE CASE: "Jack drives a car." "Jack owns a '2013 Ford Car."

CLASS: 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's car to be new.

Executive Summary EHR-S FIM r3:2016 Preparation

This executive-summary specifically addresses potential work-group impacts and/or trends, which are important for VA, IPO and DOD awareness.

EHR System Function-and-Information Model (EHR-S FIM)

- Structured, based-on a fully-specified Reference Model (RM) for
 - Clear, complete, concise, correct, consistent and intuitive ease-of-use;
 - Sparx Enterprise Architect (EA) UML-model tool-based; where, release 3 (r3)
 - manages user-activities, system-functions. business-rules, interoperable-data separately; and,
 - Consistent-global r3 Conformance Criteria (CCs) replace ad-hoc-local r2 CCs
 - r3 Infrastructure-section contains previously-separate r2 Record-and-Trust Infrastructure-sections

• EA Tool-generated Interoperability-Specifications based-on Use-Cases

- Use-Cases come-from HITSP & S&I Framework Use-Case Simplification work linked-to
- Requirements, which come-from EHR-S r2.0 Functions' and their restructured CCs linked-to
- International Interoperability-Specifications based-on HL7 FHIR (Fast Healthcare Interoperability Resources)
- US-Realm Interoperability-Specifications based-on FHAFHIM (Federal Health Information Model)
- Behavioral Specifications can be included, based-on IHE or other Protocols.

Executive Summary Conclusions and Recommendations EHR-S FIM r3:2016 Preparation



- 1. EHR-S FIM vision is to become the "Easy Button" for EHR Interoperability Specifications
 - a. Easily-customizable to user-specific profiles.
 - b. Including a US-Realm Meaningful Use (MU) & FHIM profile
 - c. EHR-S FIM r3:2016 within Sparx EA represents a powerful HL7 product; where,
 - i. EA integrates FHIR, FHIM and S&I Framework's Use-Case Simplification, and
 - ii. The EA tool-based EHR-S FIM is consistently governed and configuration-managed
 - iii. The EA tool can generate both a navigable-web-site and printable-report
 - iv. user-specific profiles (e.g., WG project DAMs, DIMs, DCMs).can be supported.
- 2. HL7.org/EHRSFIM web-site should be setup-and-managed by the EHR Interoperability WG
 - a. Supporting peer review, trial-use and stakeholder-contribution during FY14- Alpha & FY15-Beta development.
- 3. EHR-S FIM development, tooling and balloting resources = (estimated) 6-FTE Man-years
 - a. 4 development FTEs + 1 Tooling FTE + 1 Balloting FTE
 - b. A marketing campaign is needed to justify EHR-S FIM r3:2016 resources

Plan-of-Actions and Milestones FY2014Q1 POA&M



EHR-S FIM Release-3:2016 Preparation

October 2013 (Identify processes, tools and issues/risks)	Completed				
Prototype CP.6.2 Immunization Management	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 Scenario-and-Model	22-Nov-13				
 Prototype Use-Case generation of Immunization Interoperability-Specification 	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 <u>www.EHR-S-FIM.org</u> website to get broad peer-review

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Reference Model (RM) Definition EHR-S FIM Release-3:2016 Preparation



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

1. Structures significant-relationships among EHR-S entities

- defined-by EHR-S operational-and-information conceptual-models; where,
- EHR-S RM contains a constrained-lexicon
 - of <u>nouns</u> (Data-Entities) and <u>qualifiers</u> (Data-Types), bound-to
 - verbs (Operations/Tasks) and qualifiers (Operation types) with
 - constraints {Business Rules},
- Conformance Criteria (CC) are threads through the reference model.

2. Common syntax-and-semantics for the EHR-S and PHR-S models

- Where, verbs (Operations), nouns (Data Types), constraints are refined within functions.
- Where, these models are
 - Linked-to implementation standards-technologies-paradigms-or-patterns.
 - Consistent-and-unambiguous across implementations, tests and certifications.
- According to the Organization for the Advancement of Structured Information Standards (OASIS) a reference model is "an abstract framework for understanding significant relationships among the entities of some environment, and for the development of consistent standards or specifications supporting that environment. A reference model is based on a small number of unifying concepts and may be used as a basis for education and explaining standards to a non-specialist. A reference model is not directly tied to any standards, technologies or other concrete implementation details, but it does seek to provide a common semantics that can be used unambiguously across and between different implementations."

INTERNATIONAL

Reference Use-Case EHR-S FM Concept-of-Operations EHR-S FIM Release-3:2016 Preparation

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

- review the <u>Patient EMR</u> (Electronic Medical Record) and associated <u>Information</u>
- Observe and treat the <u>Patient</u>, write-orders and document the <u>Encounter</u>
- Provide patient <u>Information</u> and educational-<u>Information</u>
- Enter EMR Records and associated information
 - Record Entries for Orders, Treatments, Observations and associated Information
 - <u>Record-Entries</u> organized into lists of <u>EMR Care-Plans</u>, <u>Care-Records</u>, <u>Problems-and-Concerns</u>, <u>Documents & Notes</u>
- sign Encounter by the Clinician(s) and possibly by the Patient

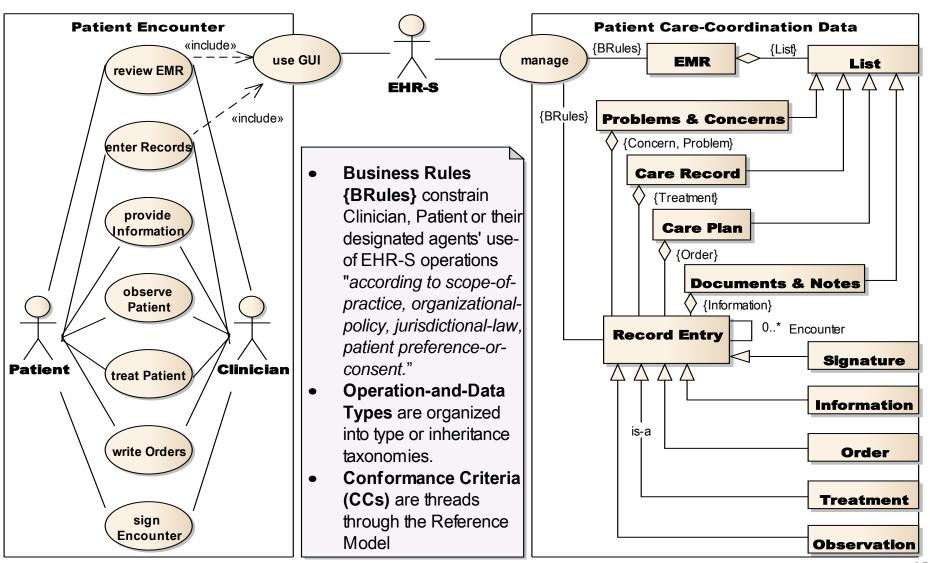
Reference Model (RM) EHR-S FM Concept-of-Operations



Humans and their Actions

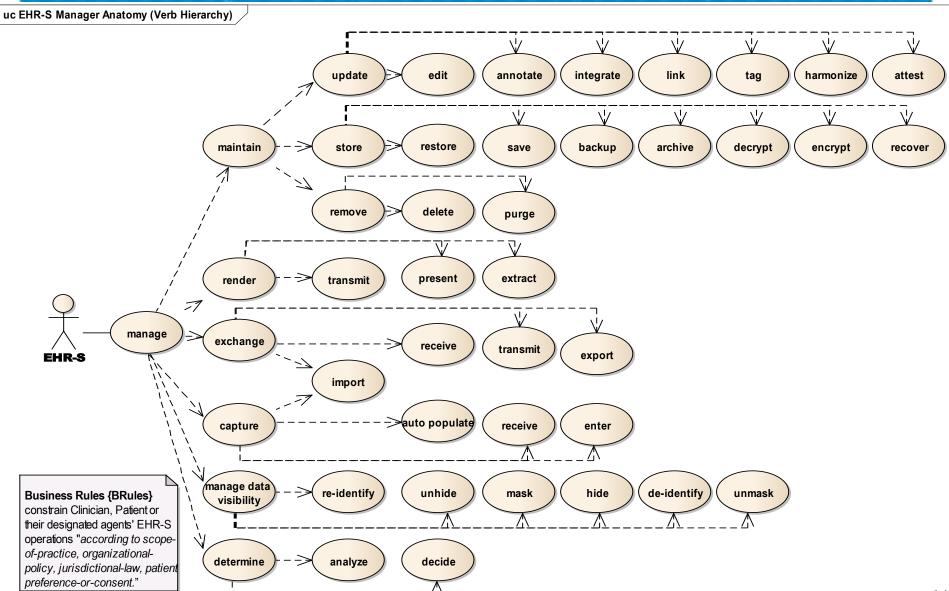
EHR-S Operations

EHR-S Conceptual Information Model



RM Operations Sub-Types aka Verb-Hierarchy

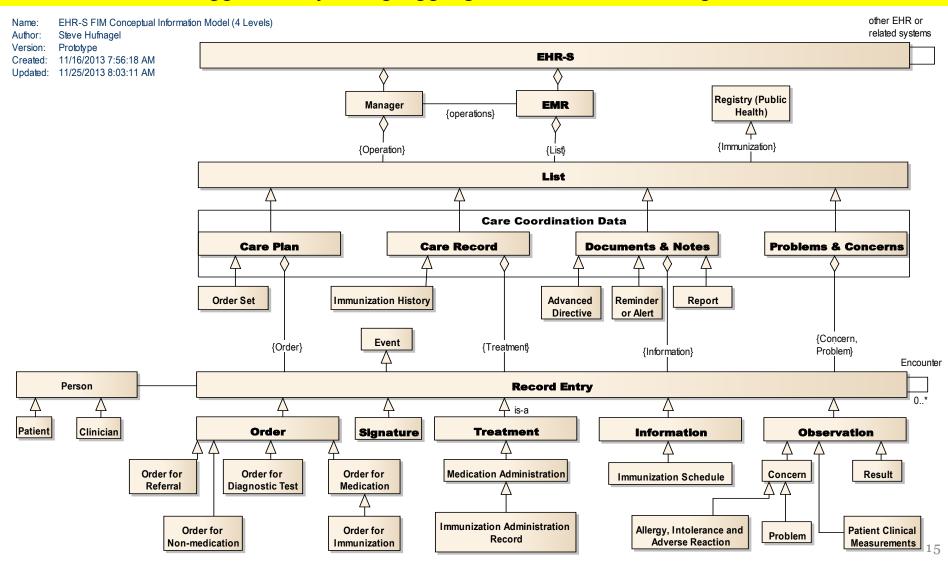




RM Data-Entities Sub-Types aka Information-Model Sub-Types



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



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



Human

Clinician, Patient, Designated Agent

Human Action

- Linked-to Use-Case Actions
- CLINICIAN: Observe, Treat, Write-Orders
- such as Immunization Administration

System

- EHR or PHR

Applicability (SHALL, SHOULD or MAY)

- according to
 - Scope of practice,
 - Organizational policy,
 - · Jurisdictional law,
 - Patient preference or consent."

System Function Constraints

- Invariant-conditions (e.g., context)
- Pre-conditions (e.g., triggers)
- Post- conditions (e.g., goal, outcomes)

System Function Type

- System provides the ability (for a human) to
- Or the system directly does

• **System Function** EHR-S operations linked-to

- EHR-S Data-Type(s) (Immunization, Vital Sign, lab order)
- Information Exchange(s) linked-to
 - International Interoperability-Standards (e.g., FHIR, W3C)
 - <Realm Interoperability-Specifications (e.g., FHIM, HITSP)>
 - <Implementation Guides (e.g., CDC lz., CCDA>
 - <Behavioral Interoperability-Specifications (e.g., IHE)>
 - Service Level Agreement (e.g., local workflow)>

Associations & Dependencies

Supporting components and functions

See Also

Functions with significant common CCs

NOTE: < ... > means optional



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

CP.6.2#01 During an <u>Encounter</u>, the EHR system SHALL provide the ability to capture <u>Immunization Administration</u> details as discrete data-requirements, realized-by <u>FHIR</u> (Fast Healthcare Interoperability Resource) data-specifications; where, the <u>Immunization-Administration</u> <u>Record-Entry</u> is associated with the following resources:

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

In the US Realm, <u>Immunization-Administration</u> and associated resources are realized-by FHIM (Federal Health Information Model) data-specification Domains of:

- Immunization, Adverse Reaction, Allergy and Intolerance, Care-Plan,
- Encounter, Health Concern, Person, Provider, Public Health Reporting, Patient Education, Vital Signs.



Interim Conclusions EHR-S FIM r3.0:2016 Preparation

- We have looked at Medication-and-Immunization Management, Orders-and-Results Management and Record Entry Management; where,
 - The <u>EHR-S RM (reference model)</u> was used to structure EHR-S functions-and-data; where, the function's conformance-criteria lexicon defines the grammar of nouns (entities), qualifiers (data-types), verbs (operations), qualifiers (verb-types) and constraints (conditions/business rules).
- The EHR-S <u>Conceptual Information Model (CIM)</u> and <u>Conceptual Operations Model (COM)</u> 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.

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

- A <u>Clinician</u> uses the EHR-S, during an Encounter, to
 - review EMR
 - Enter Observations, Treatments, Orders, associated Documents and Notes
 - Sign the Encounter
- Immunization Management involves the following:
 - Operation-Types: Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, or Determine applicable Data-Types
 - Data-Types: Immunization-Administrations Treatment-History and Registries,
 (Allergies, Intolerances, Adverse-Events, Patient Clinical-Measurements Observations,
 Problems and Concerns), (Patient Directives, Immunization Schedule-and-Educational
 Documents & Notes), Immunization Care-Plans, Signed Encounters.

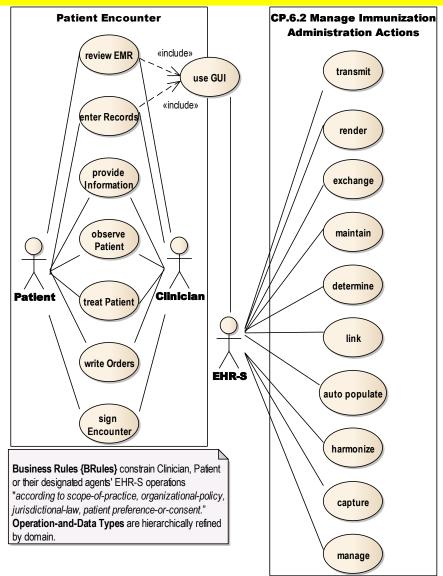
Use-Case Reference-Model CP.6.2 Immunization Management

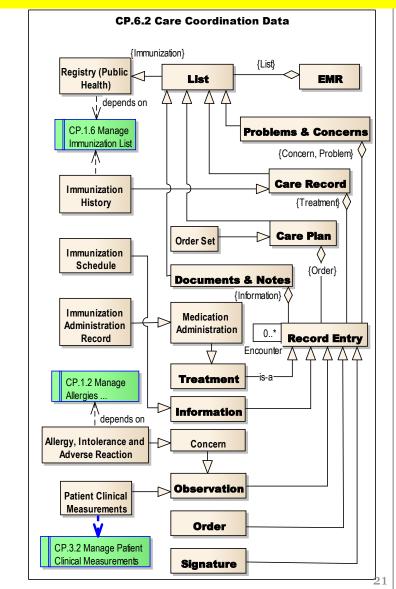


Human and their Actions

CP.6.2 Operations

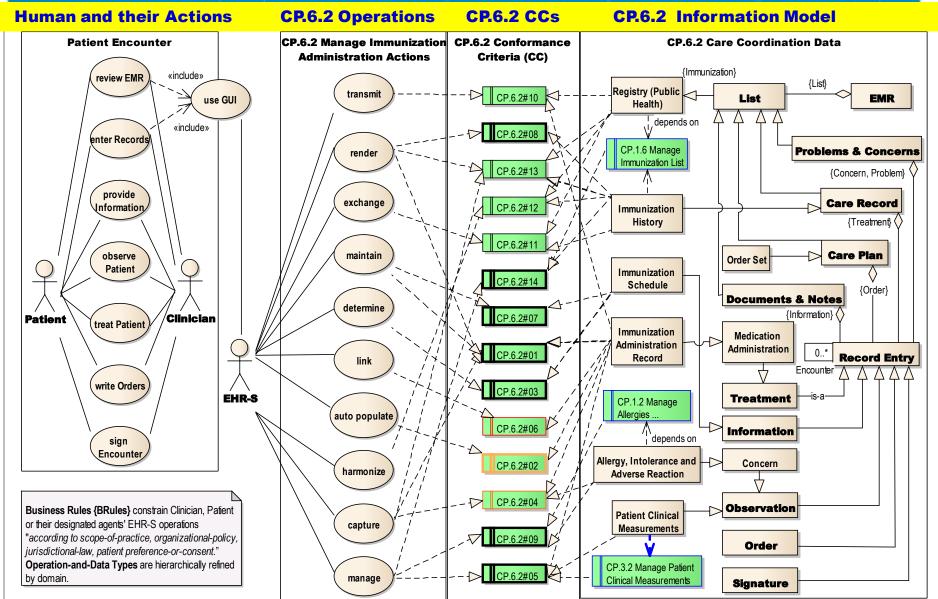
CP.6.2 Information Model





Use-Case CC Traceability-Model CP.6.2 Immunization Management







EHR-S-FM R2.0:2013 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-FM R2.0:2013 Conformance Criteria (CCs) CP.6.2 Immunization Management

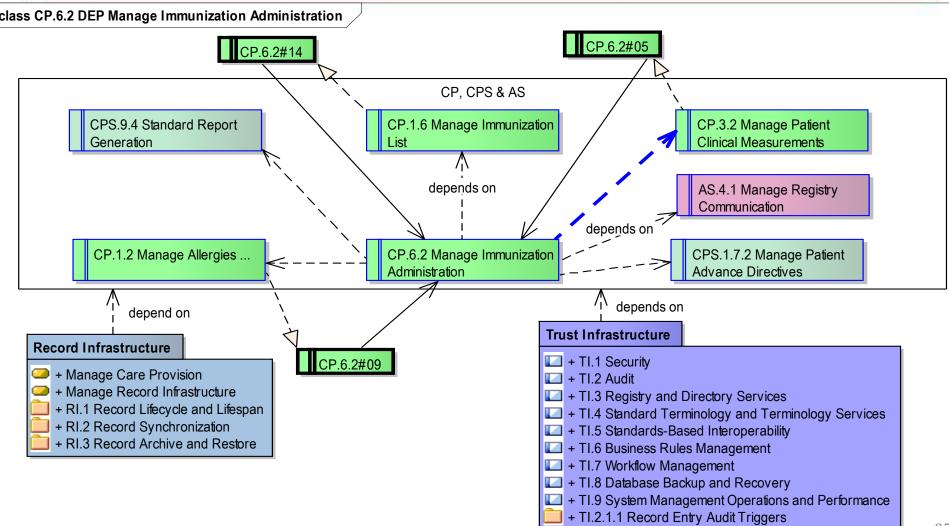


ISSUE: Consistency of Conformance Criteria (CC) across related functions, such as Medication-and-Immunization and Orders-and-Results Management.

- 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.

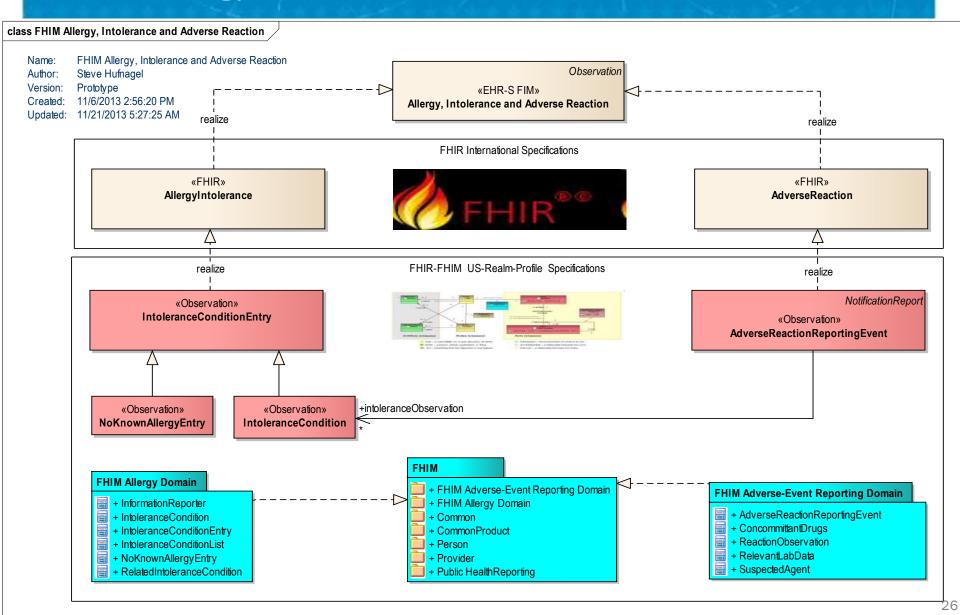
Use-Case Dependencies CP.6.2 Immunization Management





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

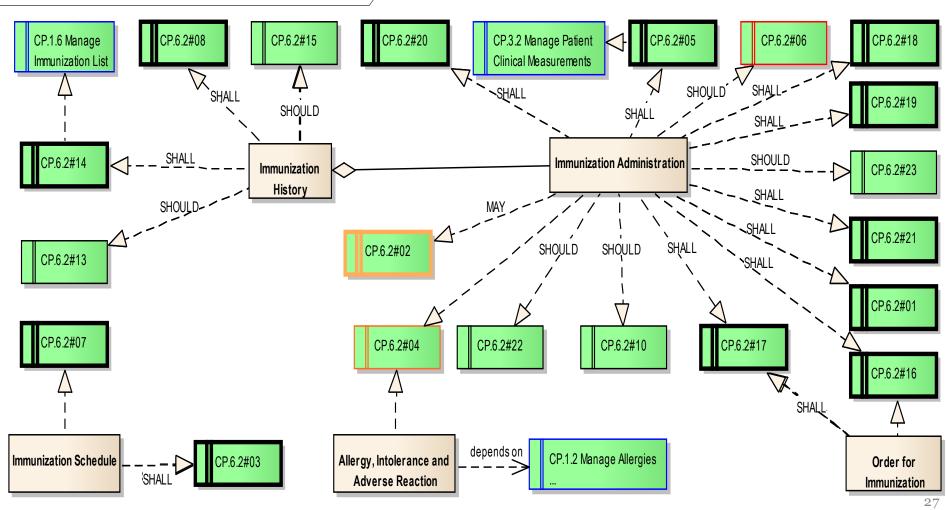






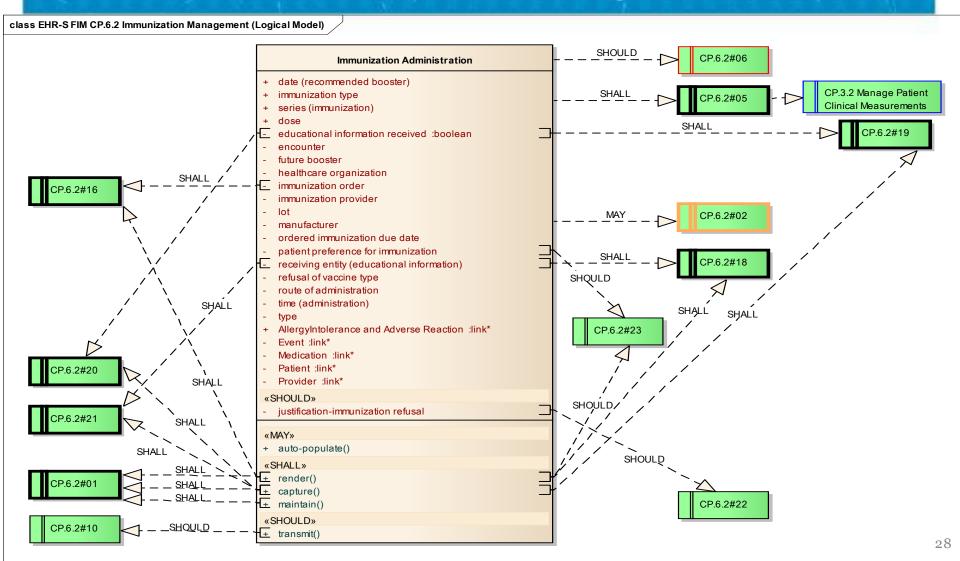
EHR-S-FIM Conceptual Traceability Model CP.6.2 Immunization Management

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



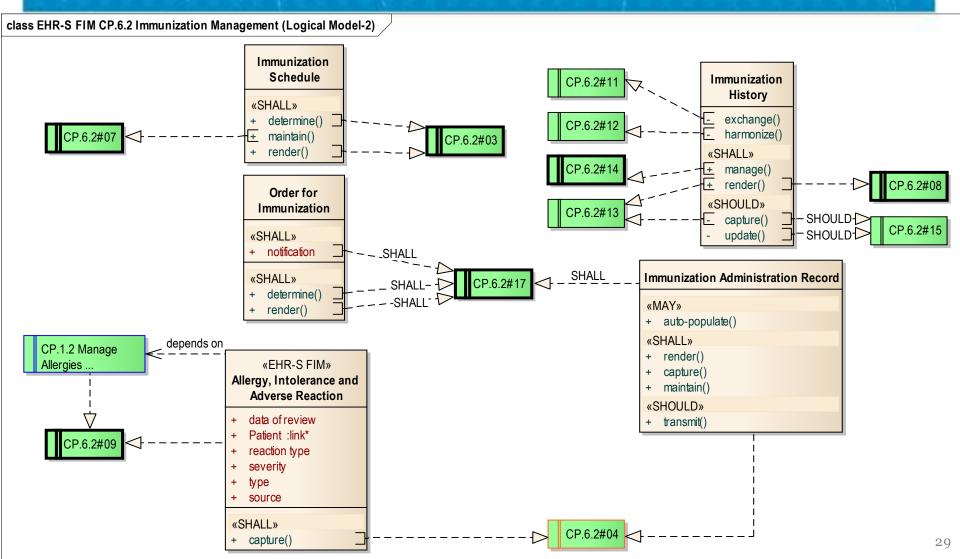


EHR-S FIM Logical Traceability-Model CP.6.2 Immunization Management





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



Interim Conclusion EHR-S FIM CP.6.2 Immunization Management



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



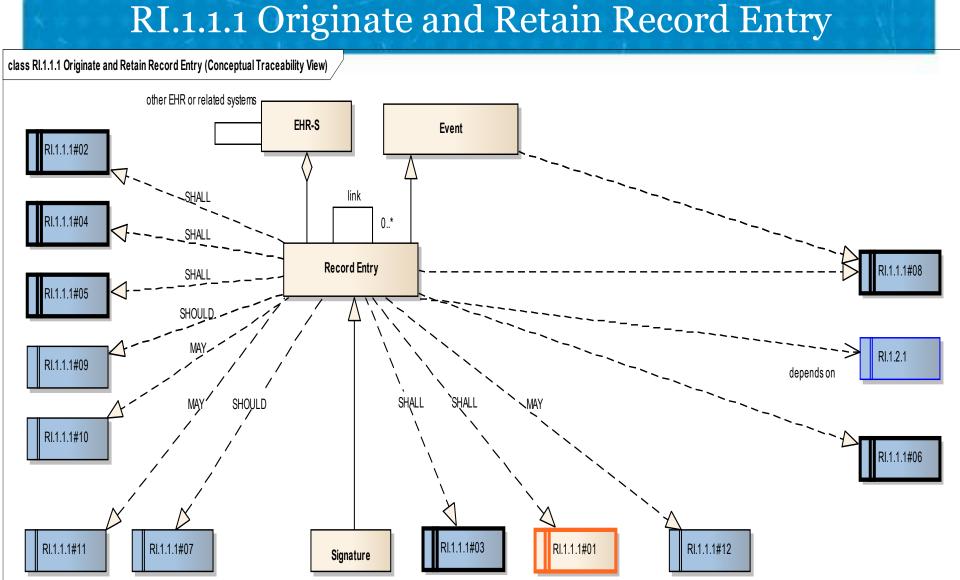


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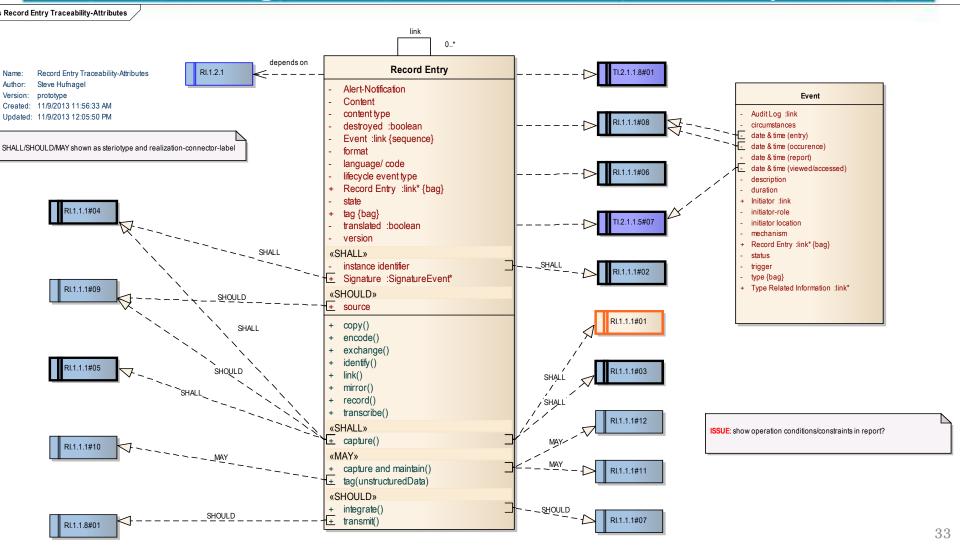
EHR-S FIM Conceptual Information Model (CIM)







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.#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 <u>function TI.2.1.1.1</u> (Originate/Retain Record Entry Audit Trigger), including specified metadata.
- 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.#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

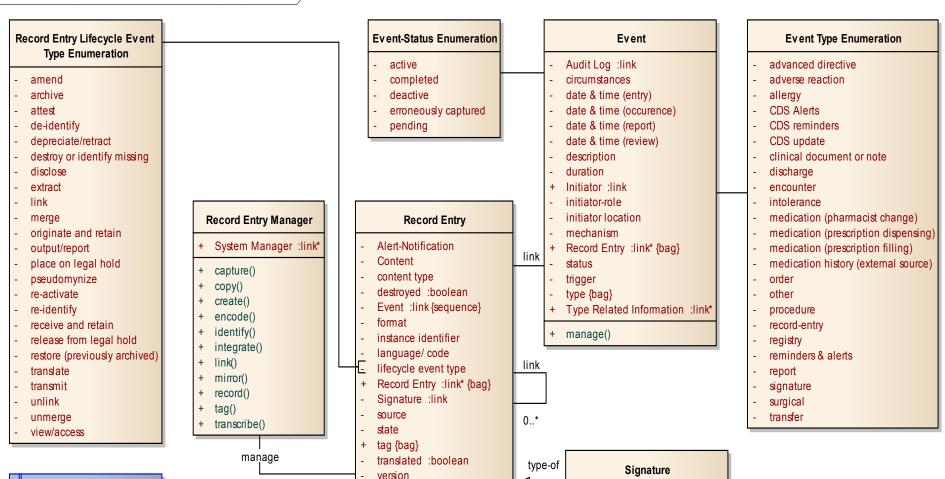
class RI.1.1.1 Originate and Retain Record Entry (Logical View)

+ manage()

depends on

RI.1.2.1 Manage Record

Entries



+ Record Entry :link* {bag}

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

Resultant Description (Notional Scenario)

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

Interim Conclusion EHR-S FIM



RI.1.1.1 Originate and Retain Record Entry

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

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

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- CP.6.2 Immunization-Management Deep-Dive
- RI.1.1.1 Originate-and-Retain Record-Entry Deep-Dive
- EHR-S FIM linked-to FHIR for Allergy, Intolerance and Adverse-Reaction **5**.
- EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
- Traceability

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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]

FHIR-FHIM High-Level Specification for Allergy, Intolerance and Adverse Reaction Name: Author: Steve Hufnagel Version: Prototype The 2016 EHR-S FIM release-3 objective is for an analyst-or-architect to use the EA-tool to Created: 11/7/2013 4:26:03 AM Create a use case from a prescribed lexicon of Entities, Events, Modifiers and Actions; where, Updated: 11/18/2013 9:07:42 AM the lexicon is mapped to applicable EHR System Functions; where, 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 **EHR-S FIM Requirements** «EHR-S FIM» Allergy, Intolerance and Adverse Reaction FHIR International Specifications «FHIR» «FHIR» «FHIR» «FHIR» AllergyIntolerance Symptom AdverseReaction FHIR-FHIM US-Realm-Profile Specifications «Observation» «Observation» IntoleranceConditionEntry AdverseReactionReportingEvent



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

realize

Author: Steve Hufnagel

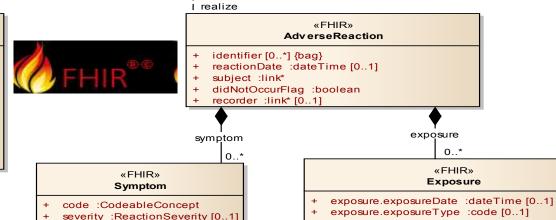
Version: Prototype

Created: 11/5/2013 4:25:17 AM Updated: 11/8/2013 4:49:33 PM

«EHR-S FIM» Allergy, Intolerance and Adverse Reaction + data of review + Patient :link* + reaction type + severity + type + source + manage()

#FHIR* AllergyIntolerance + identifier :Identifier [0..1] + criticality :code [0..1] + sensitivityType :code + recordedDate :dateTime [0..1] + status :code

- + subject :Resource(Patient) + recorder :Resource(Practitioner|Patient)
- + substance :Resource(Substance)*
- + reaction :Resource(AdverseReaction)* [0..1]
- + sensitivityTest :Resource(Observation)* [0..1]



exposure.causalityExpectation :code [0..1] exposure.substance :Resource(Substance)* [0..1] AllergyIntolerance.sensitivityType :code

recorder :Resource(Practitioner|Patient) substance :Resource(Substance)*

reaction :Resource(AdverseReaction)* [0..1]

recordedDate :dateTime [0..1]

subject :Resource(Patient)

status :code



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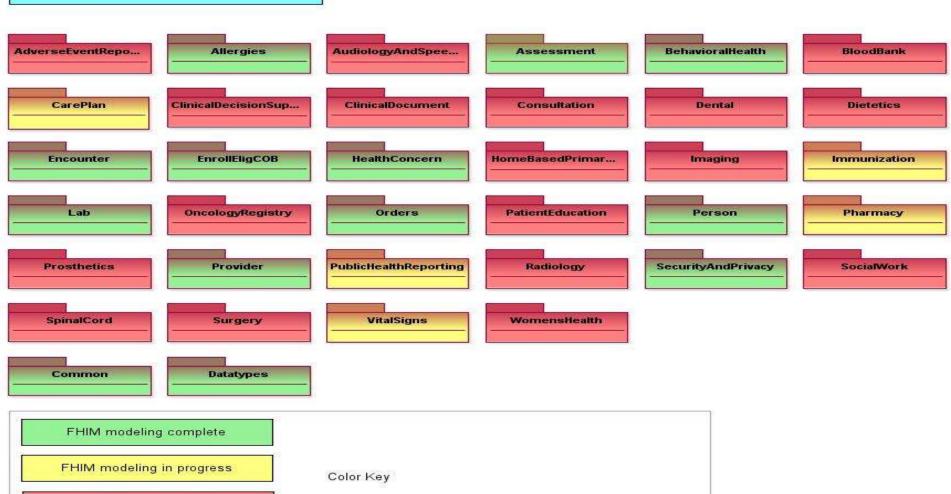
EHR-S FIM Using Federal Health Information Model (FHIM)



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

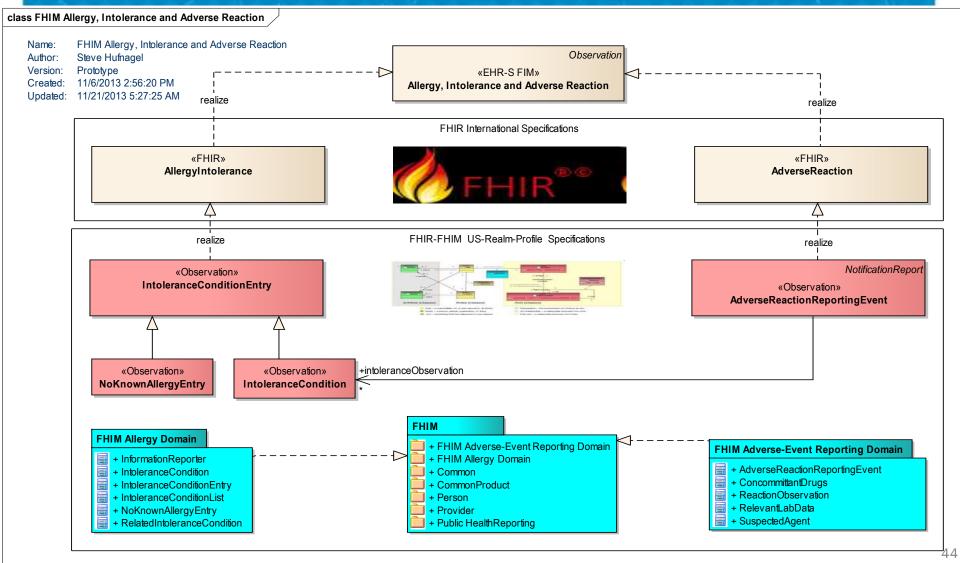
FHA Federal Health Information Model (FHIM)

Unchanged from the VHIM



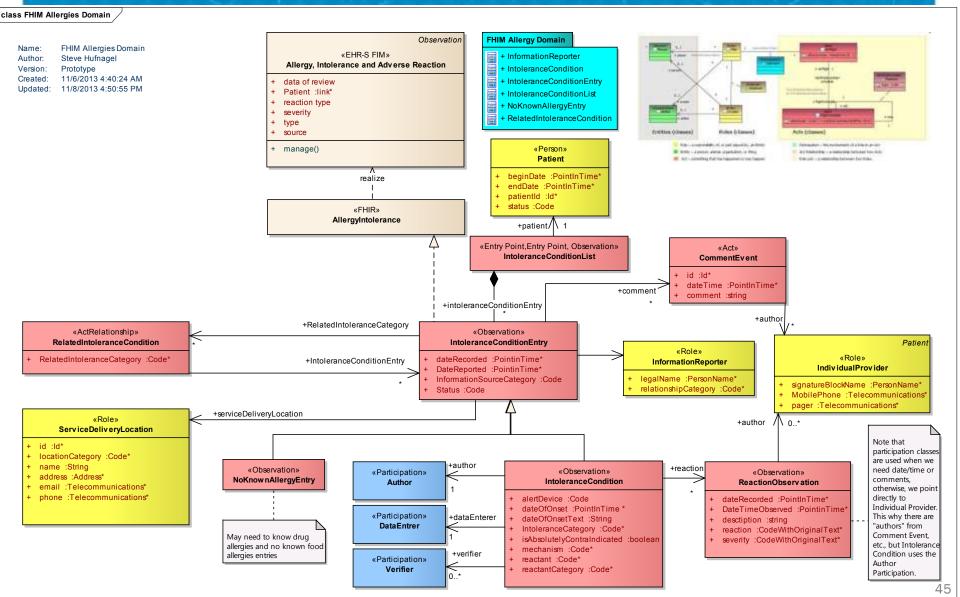


Prototype Allergy, Intolerance & Adverse-Reaction FHIM High-Level US-Realm Specification



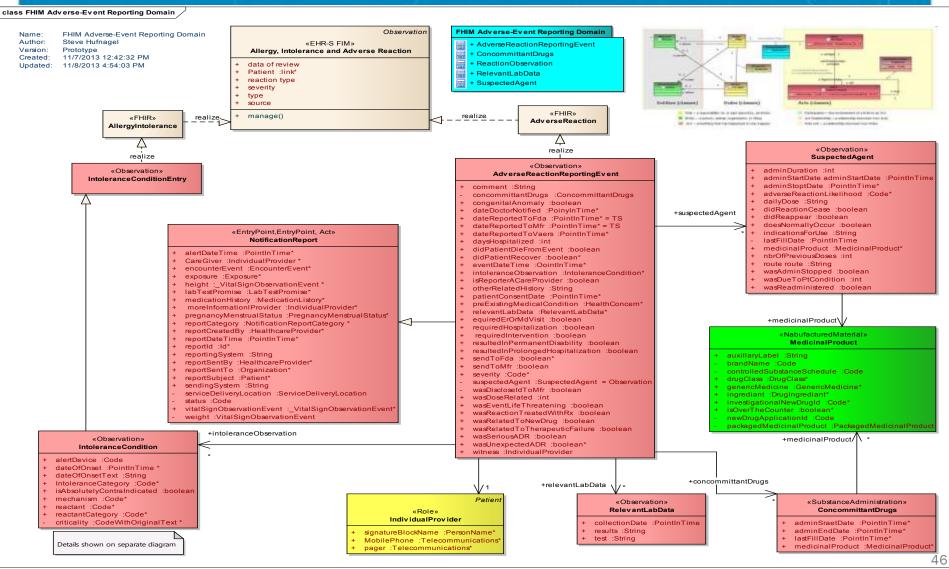
Prototype FHIM-Detailed Allergy & Intolerance Specification







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 <u>International Data-Specifications ("The 80% set")</u>
- FHIM can define the <u>US-FHA FHIR-Profile</u>
- Joint Configuration Management is essential for FIM/FHIR/FHIM consistent
 A FIM-FHIR-FHIM populated UML-Tool (e.g., EA or RSA) can manage
- Requirements from EHR-S FIM
- International Data-Specifications from FHIR
- US-Realm Data-Specifications-Profile from FHIM



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- EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
- **Traceability**

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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 UNIVERSALCC 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.





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	Archive Backup Decrypt Encrypt Recover Restore Save	Annotate Attest Edit Harmonize Integrate Link Tag	Remove Delete Purge	Typ - origin - amen - transks - attest - view/s - outpu - disclo - transk - receiv - de-ide - pseud - re-ide - extrac	access t/report se nit e and retain entify omynize ntify	Event		Export Import Receive Transmit	Analyze	Decide	De-Identify Hide Mask Re-Identify Unhide Unmask
				- destro	y or identify mis piate/retract vate ge		are	elocated	-Entry Lifecycle Events d here for convenience; o they correspond to		

place on legal hold

release from legal hold

50

Verbs in the verbs hierarchy?.