December 2013
EHR Work-Group (EHR WG)
Cumulative FY14 Summary-Report

Last Updated on Dec 10, 2013 by SHufnagel@tiag.net, facilitator

Edmond Scientific subcontractor to Veterans Health Administration/

Health Informatics/ Office of Informatics & Analytics/ Knowledge Based Systems

The complete-and-latest version of the Summary-Report is available at:

http://wiki.hl7.org/images/0/0a/Hufnagel_-_FY2014_HL7-EHR-WG_Summary-Report.pdf

EXECUTIVE SUMMARY
Release-3 EHR-S and PHR-S FIM

This executive-summary and report specifically address potential EHR impacts and/or EHR trends, which are important for the VA, IPO and DOD to-be aware-of.
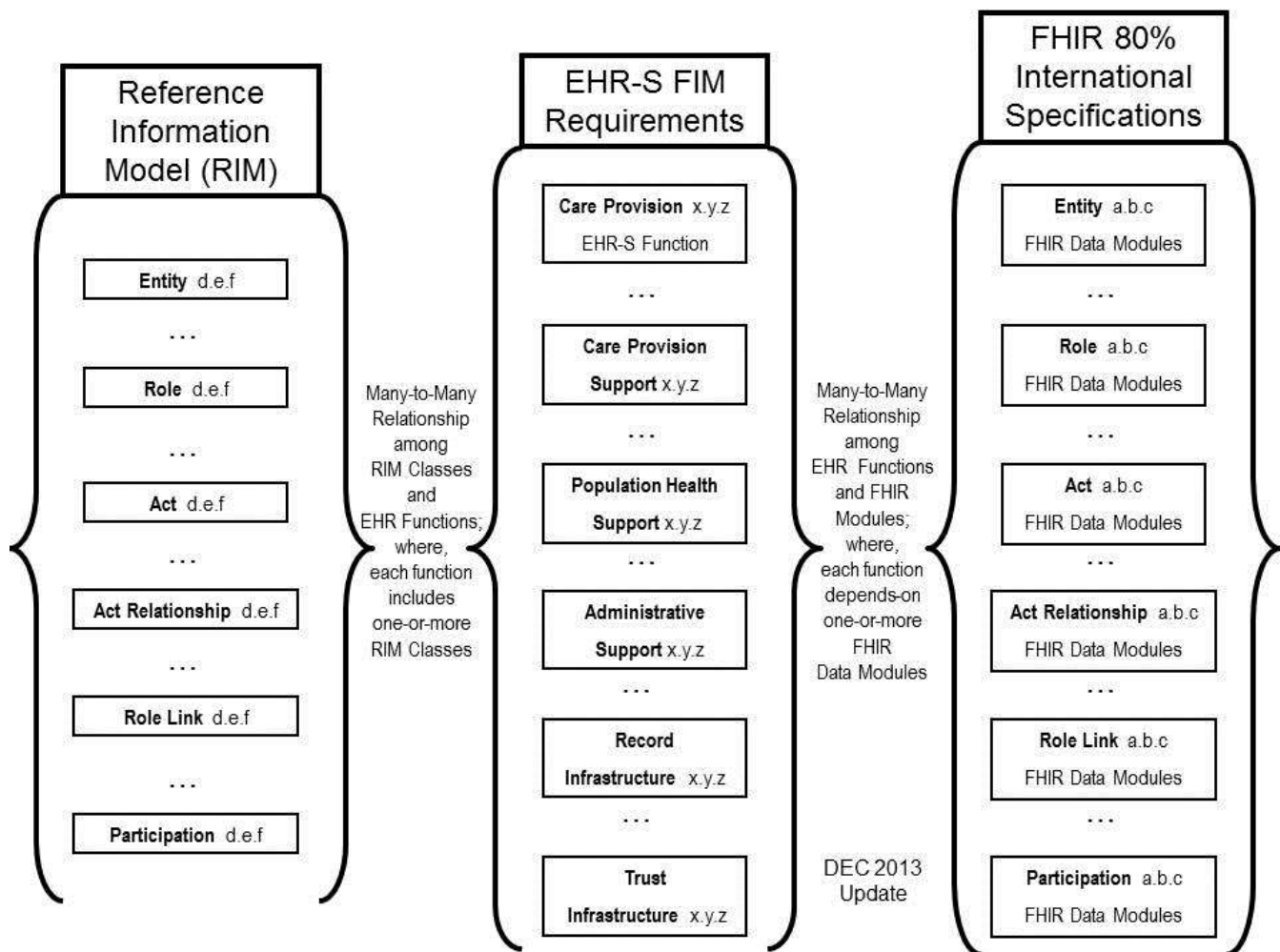

Figure 1 HL7 EHR-S FIM release-3 Relationship with HL7 RIM-and-FHIR [Jan 2012 PSS #688]

INTRODUCTION: the *purpose* of this report is to document the EHR-and-PHR System release-3 Function–and-Information-Model (FIM) development and related projects; where, EHR-S FIM release-3 restructures and adds an information model to the release-2 EHR-S FM. An agile approach is being followed, where monthly report-content is refined; until ultimately, the report can be generated by the Sparx Enterprise Architect tool as a demonstration of the release-3 FIM "Easy-Button" Interoperability-Specification (IS) report-generation capability. All EHR WG release-3 FIM working-draft documentation is published at http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG.

LEGEND:

1) <u>Capitalized and Underlined</u> nouns-and-adjectives are <u>Record-Entry</u> data-types aka data-model, which should be in the EHR-S FM data dictionary; and, *italicized* verbs are *manage* sub-types aka verb-hierarchy. See www.skmtglossary.org for standard healthcare data-dictionary / glossary.
2) **Blue-Bold words** are recommended -additions to original text.
3) **Red-Bold words** are recommended-deletions from the original text.
4) <mark>Highlighted Yellow words</mark> are issues-Actions and/or important new material for the main EHR WG to-review.

GOAL: The *goal* of the <u>Electronic Health Record (**EHR**) Work Group (**WG**)</u> is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability. The Work Group creates and promotes appropriate and necessary standards. EHR WG *objectives* include:

1) Functional-and-Information Requirements**-Specifications** for Electronic Health Records (EHR) and systems (**EHR-S**),
2) Functional-and-Information Requirements**-Specifications** for Personal Health Records (PHR) and systems (**PHR-S**),
3) Definition of a high-level framework to support the interoperability requirements-**specifications** and life cycles, and
4) Identification of existing and emerging information **interoperability**-requirements and **related HL7 artifacts**.

- A Jan 2012 Project #688 System Function-and-Information Model release-3 (**EHR-S FIM r3**) *objective* of the<u> EHR Interoperability WG</u> is an **UML-specified EHR/PHR Concept-of-Operations (CONOPS), Reference Model (RM), set-of Function Use-Cases with Conformance-Criteria Scenarios; where, EHR-S FIM r3 is to-be**
  - create a clear, complete, concise, correct, consistent and easy-to-use; because,
  - **HL7 ballot-publishable from the Sparx Systems Enterprise-Architect tool**
  - **targeted for 3-to-5 years from now; because,**
    - **joint ISO-HL7 ballots are very challenging to manage and**
    - **sufficient-time is needed to address the structural issues identified by the EHR-S FM r2 ballot; where, VA voted negative, due to inconsistency, non-intuitiveness and unnecessary-complexity/non-usability.**
- A *second-objective* of the <u>EHR Interoperability WG</u> is to produce a Meaningful Use profile for EHR-S FM r2 and r3.
- The *objective* of the <u>Resource Management Evidentiary Support (RM-ES) project team</u> is to provide expertise to the EHR work group, other standards groups and the healthcare industry on records management, compliance, and data/record integrity for, EHR systems and related to EHR governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.
- The *objective* of the <u>EHR Usability Project</u> is to translate existing, well established usability guidelines and health information management principles into functional conformance-criteria in the EHR-S FM standard.

SITUATION
EHR-S and PHR-S FIM '2016 Release-3 Preparation

The **benefit** of a formally specified EHR-and-PHR **Concept-of-Operation** (CONOPS) and **Reference Model** (RM) is a clear, complete, concise, correct and consistent Function-and-Information Model (FIM) and resultant Interoperability-Specifications (ISs). An EHR/PHR CONOPS was defined; and than, it was refined into a System **Reference-Model** (RM)**;** where,

1) **System Functions** are defined-by **Use-Case**; where,
   a) System-operations are verbs refined into a "*manage* verb-hierarchy" aka operation-type model,
   b) System-entities are subject-and-object nouns refined into a "Record-Entry data-model" aka data-type model
   c) Terminology value-sets are bound-to discrete-data-elements within each Record-Entry.
2) **Conformance Criteria** are defined-by scenarios within each use-case; where, scenarios contain business-context and subject-verb-object-terminology bindings; where,
3) **Business-Context** is defined-by
   a) pre-condition triggers,
   b) applicability of
      i) "The System SHOULD or SHALL or MAY"
      ii) "provide-the-ability-to-*manage* Record-Entries" or "directly-*manage* Record-Entries," where,
         (1) a use-case constrained verb-hierarchy applies and
         (2) a use-case constrained data-model applies; where,
   c) post-condition Business-Rules are
      "according-to scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences."
4) **Information-Exchanges** are defined-by scenarios mapped to
   a) **FHIR** (Fast Healthcare Interoperability Resource) specifications, for the International-Realm,
   b) **FHIM** (Federal Health Information Model) specifications, for the US-Realm, bound to
   c) **Terminology value-sets**,
   d) **IHE information-exchange behavioral-protocols**, which may-be refined-or-replaced by,
      • **SLA** and **DURSA** (Service-level-agreement Data-Use-and-Reciprocal-Support-Agreement) *and*
      • **KPPs** (Key Performance Parameters).
      • **Cost** estimation factors
5) **EHR-S/PHR-S Profiles** are defined-by a set-of System-Function Use-Cases, with further constrained scenario' Applicability, business-context and subject-verb-object-terminology bindings.
6) **Interoperability-Specifications** are generated with the FIM r3 reporting-tool.

ACTIONS

1. **HL7 Board approval** of EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRSFIM
2. **FHIR WG Coordination** to integrate EHR-S FIM-FHIR into a joint Sparx Enterprise Architect (EA) model; where, EA can generate integrated EHR-S FIM-FHIR International-Realm interoperability requirements-specifications
3. **FHIM Team Coordination** to integrate EHR-S FIM-FHIR-FHIM into a joint Sparx Enterprise Architect (EA) model; where EA can generate integrated EHR-S FIM-FHIR-FHIM US-Realm interoperability requirements-specifications
4. **Call-for-Participation** in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (Reference Model), where, 6 Full Time Equivalent (FTE) level-of-effort is estimated (2-FTEs per-year for three-years) Calls every-Tuesday, 1PM ET, + 1-770-657-9270, PC 510269# and please joint EHR Interoperability ListServer

Release-3 EHR-S and PHR-S FIM
Plan-of-Actions & Milestones Dashboard

POA&M Task	#	Start	Done	POC	Comment
CONOPS		12-2013	12-2013	SH. GD	Potential for minor changes in the future
Reference Model		06-2013	12-2013	SH, GD	Potential for minor changes in the future
manage operation-type			05-2013	EHRWG	Verb-Hierarchy was part of r2 ballot
Record-Entry data-types		01-2012	active	SH, GD	Data-Model to-be refined for each function
www.HL7.org/EHRSFIM		01-2014		EHRWG	**ISSUE**: Open IP approval by board
FHIR Integration		01-2014		EHRWG	**ISSUE**: Integrated or linked models?
FHIM Integration		01-2014		EHRWG	**ISSUE**: Integrated or linked models?
EHR-S FIM r3 Resources	6	01-2014		EHRWG	**ISSUE**: 6 FTEs for EHR-S & PHR-S FIM r3
Other work (Pub., FHIR, FHIM)		pending	1-2017	EHRWG	1 FTE
EHR-S specific work		pending	1-2017	EHRWG	1 FTE
PHR-S specific work		pending	1-2017	EHRWG	1 FTE
EHR-S and PHR-S FM Modelling specific	143	1-2014	1-2017	Interop	3 FTEs = 1 week-per- function (143)
Care Provision	37				
CP.1 Manage Clinical History	9	pending			
CP.2 Render Externally Sourced Information	2	pending			
CP.3 Manage Clinical Documentation	6	pending			
CP.4 Manage Orders	7	01-2012	inactive	SH, GD	√ 2012 prototype → Todo wrt RM
CP.5 Manage Results	2	01-2012	inactive	SH, GD	√ 2012 prototype → Todo wrt RM
CP.6 Manage Treatment Administration CP.6.1 Medication Management CP.6.2 Immunization Management	3	O1-2012 10-2013	inactive active	SH, GD	√ 2012 prototype → Todo wrt RM √ Use case done, CCs in progress
CP.7 Manage Future Care	3	pending			
CP.8 Manage Patient Education & Communication	2	pending			
CP.9 Manage Care Coordination & Reporting	3	pending			
Care Provision Support	67				
CPS.1 Record Management	14	pending			
CPS.2 Support Externally Sourced Information	9	pending			
CPS.3 Support Clinical Documentation	13	pending			
CPS.4 Support Orders	10	pending			
CPS.5 Support for Results	1	pending			
CPS.6 Support Treatment Administration	5	pending			
CPS.7 Support Future Care	2	pending			
CPS.8 Support Patient Education & Communication	7	pending			
CPS.9 Support Care Coordination & Reporting	6	pending			
Population Health Support	17				
POP.1 Support for Health Maintenance, Preventive Care and Wellness	3	pending			
POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population	1	pending			
POP.3 Support for Notification and Response	1	pending			
POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health	1	pending			
POP.5 Donor Management Support	1	pending			
POP.6 Measurement, Analysis, Research and Reports	6	pending			
POP.7 Public Health Related Updates	1	pending			
POP.8 De-Identified Data Request Management	1	pending			
POP.9 Support Consistent Healthcare Management of Patient Groups or Populations	1	pending			
POP.10 Manage Population Health Study -	1	pending			

POA&M Task	#	Start	Done	POC	Comment
Related Identifiers					
Administration Support	22				
AS.1 Manage Provider Information	8	pending			
AS.2 Manage Patient Demographics, Location and Synchronization	1	pending			
AS.3 Manage Personal Health Record Interaction	3	pending			
AS.4 Manage Communication	5	pending			
AS.5 Manage Clinical Workflow Tasking	5	pending			
AS.6 Manage Resource Availability	7	pending			
AS.7 Support Encounter/Episode of Care Management	6	pending			
AS.8 Manage Information Access for Supplemental Use	6	pending			
AS.9 Manage Administrative Transaction Processing	6	pending			
Trust Infrastructure					
TI.1 Security	25	01-2012	Inactive	GD, SH	√ 2012 prototype → Todo wrt RM
TI.2 Audit	1	01-2012	inactive	GD, SH	√ 2012 prototype → Todo wrt RM
TI.3 Registry and Directory Services	1	pending			
TI.4 Standard Terminology and Terminology Services	1	pending			
TI.5 Standards-Based Interoperability	6	pending			
TI.6 Business Rules Management	1	pending			
TI.7 Workflow Management	1	pending			
TI.8 Database Backup and Recovery	1	pending			
TI.9 System Management Operations and Performance	1	pending			
Record Infrastructure					
RI.1 Record Lifecycle and Lifespan	25		inactive	GD, SH	
RI.1.1.2 Record Entry Create		12-2012			√ 2012 prototype → Todo wrt RM
RI.2 Record Synchronization	1	pending			
RI.3 Record Archive and Restore	1	pending			

WORKGROUP AND PROJECT LOGISTICS

- HL7 List Server Registration: http://www.hl7.org/myhl7/managelistservs.cfm
- Hl7 Workgroup Call-Schedule: http://www.hl7.org/concalls/default.aspx
- EHR WG Wiki: http://wiki.hl7.org/index.php?title=EHR

Health Level Seven – Electronic Health Record Work Group
Weekly Teleconference Schedule
Revised: 20 November 2013

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

- **EHR CCD to Blue Button Tool Project Wiki** - This project defined the conversion of an HL7 Continuity of Care Document (CCD) to the Blue Button format via an XSLT style sheet tool.
  Project contact: Lenel James and Keith Boone. List Service: EHRTeamCCD@lists.hl7.org

- **EHR-S FM Profile Tool Project Wiki** – This project, sponsored by the HL7 Tooling Workgroup, will produce a (web-based and/or desktop) tool to create EHR-S FM profiles (starting with the EHR-S FM R2), with enforced profiling rules, and exports as documents, support for and XML interchange format for reuse across profile tool instances or for use in other tools. Project contact: John Ritter; johnritter1@verizon.net

- **EHR Usability Project Wiki** This project has been launched to translate existing, well established usability guidelines and health information management principles into functional criteria in the EHR System Functional Model (EHR-S FM) standard.
  Project contact: John Ritter, Don Mon, Mitra Rocca and Walter Suarez
  List Service: ehrwgusability@lists.hl7.org

- **PHR Project Wiki** The HL7 Personal Health Record System Functional Model provides a reference list of functions that may be present in a Personal Health Record System (PHRS).
  Project contact: John Ritter; johnritter1@verizon.net

- **Diabetes Data Strategy Project Wiki** The scope for this project is to focus on the minimum data set and data standards in EHR systems for diabetes assessment in children in outpatient clinic settings, based on clinical and business requirements. Project contact: Don Mon; donmon@rti.org

REFERENCE INFORMATION

1) **Common Clinical informatics standards:**
   a) **SNOMED CT** for problems, smoking status
   b) **DICOM** for radiology
   c) **LOINC** for laboratory anatomical pathology , **LOINC** taxonomy for document types for inpatient notes
   d) **RxNorm** for pharmacy
   e) **CVX** and **MVX** for immunology
   f) **HITSP C32, HL7 CCD** and **CCDA-CCD** for VLER Health data
   g) **ICD9 CPT4/HCPCS** ICD9PCS for TRICARE billing data.
   h) **ICD-10** and **SNOMED CT** for outpatient visits, **ICD-10** and **LOINC** for admissions encounter data
   i) **CPT4** and **HCPCS** for procedures
   j) **PDA-F** for scanned paper reports
   k) **CDC** value set race codes for demographics
   l) **UCUM** for units of lab measures
   m) **NUCC** Health provider taxonomy for provider types

2) **Common technical standards:**
   a) **CTS** or Common Terminology Service
   b) **FHIR** or Fast Healthcare Interoperability Resource with RESTful API.
   c) **CDS** or Clinical Decision Support API
   d) **CCDA** is Consolidated CDA
   e) **VPR** or Virtual Patient Record
   f) **RDF** or Resource Description Framework for semantic web applications
   g) **RLUS** or Retrieve Locate Update Service for heterogeneous database facades
   h) **JSON** or JavaScript Object Notation
   i) **WS*** or Web Service Standards

3) **EHR-S FM r2.0 Perspectives**
   a) **Care Provision**
      i) CP.1 Manage Clinical History
      ii) CP.2 Render Externally Sourced Information
      iii) CP.3 Manage Clinical Documentation
      iv) CP.4 Manage Orders
      v) CP.5 Manage Results
      vi) CP.6 Manage Treatment Administration
      vii) CP.7 Manage Future Care
      viii) CP.8 Manage Patient Education & Communication
      ix) CP.9 Manage Care Coordination & Reporting
   b) **Care Provision Support**
      i) CPS.1 Record Management
      ii) CPS.2 Support Externally Sourced Information
      iii) CPS.3 Support Clinical Documentation
      iv) CPS.4 Support Orders
      v) CPS.5 Support for Results
      vi) CPS.6 Support Treatment Administration
      vii) CPS.7 Support Future Care
      viii) CPS.8 Support Patient Education & Communication
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   c) **Population Health Support**
      i) POP.1 Support for Health Maintenance, Preventive Care and Wellness
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      iii) POP.3 Support for Notification and Response
      iv) POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health
      v) POP.5 Donor Management Support
      vi) POP.6 Measurement, Analysis, Research and Reports
      vii) POP.7 Public Health Related Updates
      viii) POP.8 De-Identified Data Request Management
      ix) POP.9 Support Consistent Healthcare Management of Patient Groups or Populations
      x) POP.10 Manage Population Health Study -Related Identifiers
   d) **Administration Support**
      i) AS.1 Manage Provider Information
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      iii) AS.3 Manage Personal Health Record Interaction
      iv) AS.4 Manage Communication
      v) AS.5 Manage Clinical Workflow Tasking
      vi) AS.6 Manage Resource Availability
      vii) AS.7 Support Encounter/Episode of Care Management
      viii) AS.8 Manage Information Access for Supplemental Use
      ix) AS.9 Manage Administrative Transaction Processing
   e) **Trust Infrastructure**
      i) TI.1 Security
      ii) TI.2 Audit
      iii) TI.3 Registry and Directory Services
      iv) TI.4 Standard Terminology and Terminology Services
      v) TI.5 Standards-Based Interoperability
      vi) TI.6 Business Rules Management
      vii) TI.7 Workflow Management
      viii) TI.8 Database Backup and Recovery
      ix) TI.9 System Management Operations and Performance
   f) Record Infrastructure
      i) RI.1 Record Lifecycle and Lifespan
      ii) RI.2 Record Synchronization
      iii) RI.3 Record Archive and Restore

4) **FHIR (Fast Healthcare Interoperability Resources)**
   a) FHIR Data Dictionary is at:
   http://www.hl7.org/implement/standards/fhir/
   b) **FHIR Administrative**
      i) Attribution: Patient, RelatedPerson, Practitioner, Organization
      ii) Resources: Device, Location, Substance, Group
      iii) Workflow Management: Encounter, Alert, Supply, Order, OrderResponse
      iv) Financial: Coverage
   c) **FHIR Clinical**
      i) General: AdverseReaction, AllergyIntolerance, CarePlan, FamilyHistory, Condition, Procedure, Questionnaire
      ii) Medications: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense, MedicationStatement, Immunization, ImmunizationProfile
      iii) Diagnostic: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
      iv) Device Interaction: DeviceCapabilities, DeviceLog, DeviceObservation
   d) **FHIR Infrastructure**
      i) Support: List, Media, Other, DocumentReference, (Binary)
      ii) Audit: Provenance, SecurityEvent
      iii) Exchange: Document, Message, OperationOutcome, Query
      iv) Conformance: Conformance, ValueSet, Profile

e) Acronyms

- **aka** also known as
- **CC** EHR-S FIM Conformance Criteria
- **CDA** Clinical Document Architecture
- **DD** Data Dictionary
- **CIM** Conceptual Information Model
- **CP** Care Provision
- **CPS** Care Provisioning Support
- **EA** Enterprise Architect
- **EHR-S** EHR System
- **EHR-S FIM** EHR-S Function-and-Information Model
- **FHA** US Federal Health Architecture
- **FHIM** US Federal Health Information Model
- **FHIR** Fast Healthcare Interoperability Resources
- **FIM** EHR-S Function and Information Model
- **FIM(MU)** EHR-S FIM Meaningful Use profile

- **FM** Function Model
- **FY** Fiscal Year
- **IHE** Integrating *the* Healthcare Enterprise
- **IM** Information Model
- **MDHT** Model Driven Health Tools
- **MU** US Meaningful Use objectives-and-criteria
- **ONC** US Office of the National-Coordinator
- **OHT** Open Health Tools
- **POA&M** Plan of Actions and Milestones
- **R 2/3** Release 2 or 3
- **RI** Resource Infrastructure
- **RIM** HL7 Reference Information Model
- **S&I** ONC Standards & Interoperability Framework
- **WBS** Work Breakdown Structure
- **WG** Work Group

1

MONTHLY SUMMARIES
(Reverse Chronological Order)

1   November 2013

For details see http://wiki.hl7.org/images/8/83/HL7_EHR-WG_Summary-Presentation_November_2013.pdf

1) **EHR WG** is waiting on the EHR-S FM Release-2 ISO ballot comments; where, the HL7 release-2 ballot-comments have already been reconciled. The ISO ballot closes on 3-Dec-2013; and then, the ISO-ballot-comments can be reconciled during December-and-January and EHR-S FM release-2 can be finalized in January 2014. The EHR WG has also been updating the EHR-S FM release-2 add-on to the Sparx EA-tool to support the creation of profiles.

2) **PHR WG** is waiting on the PHR FM Release-2 ISO ballot-comments, which close 3-Dec-2013 and will be reconciled during December-and-January; where, the HL7 release-2 ballot-comments have already been reconciled.

3) **EHR RMES WG** is discussing release authorization within the S&I Framework esMd group; where, esMD is analyzing the situation where healthcare-payers frequently request that providers submit additional medical-documentation for a specific claim, to support claims processing and other administrative functions, such as the identification of improper payments. Currently, Medicare Review Contractors request approximately 2 million medical documents per year by mailing a paper request letter via US Postal Service to healthcare providers. Until recently, providers had only two options for submitting the requested records: 1) mail paper or 2) send a fax. The manual paper process is costly, time consuming and can delay proper claims processing on both the senders' and receivers' end.

4) **EHR Usability WG** is collecting issues and mitigations into a reference library, which can be the basis of integrating usability into the release-3 EHR-S FIM.

5) **EHR Interoperability WG** focused on the May-2014 Meaningful-Use Profile for the EHR-S FM release-2 and preparation for release-3:2016; where, the November release-3 focus was to define Reference-Models for Concept-of-Operations, Function Information-and-Conformance-Criteria:
   - Figure 1 HL7 EHR-S FIM release-3 Relationship with HL7 RIM-and-FHIR [Jan 2012 PSS#688]
   - Figure 2 EHR/PHR Concept-of-Operations (CONOPS)
   - Figure 3 EHR-S/PHR-S RM
   - Figure 4 EHR/PHR-RM Operation-Types Model (Verb-Hierarchy
   - Figure 5 EHR/PHR-RM Data-Types Model
   - Figure 6 CP.6.2 Immunization-Management Use-Case
   - Figure 7 CP.6.2#01 Immunization-Management Conformance-Criteria
   - Figure 8 EHR-S FIM-FHIR-FHIM Requirements-Specification Relationship
   - Figure 9 Example EHR-S FIM-FHIR Requirements-Specifications
   - Figure 10 Example EHR-S FIM-FHIR-FHIM Requirements-Specification

42
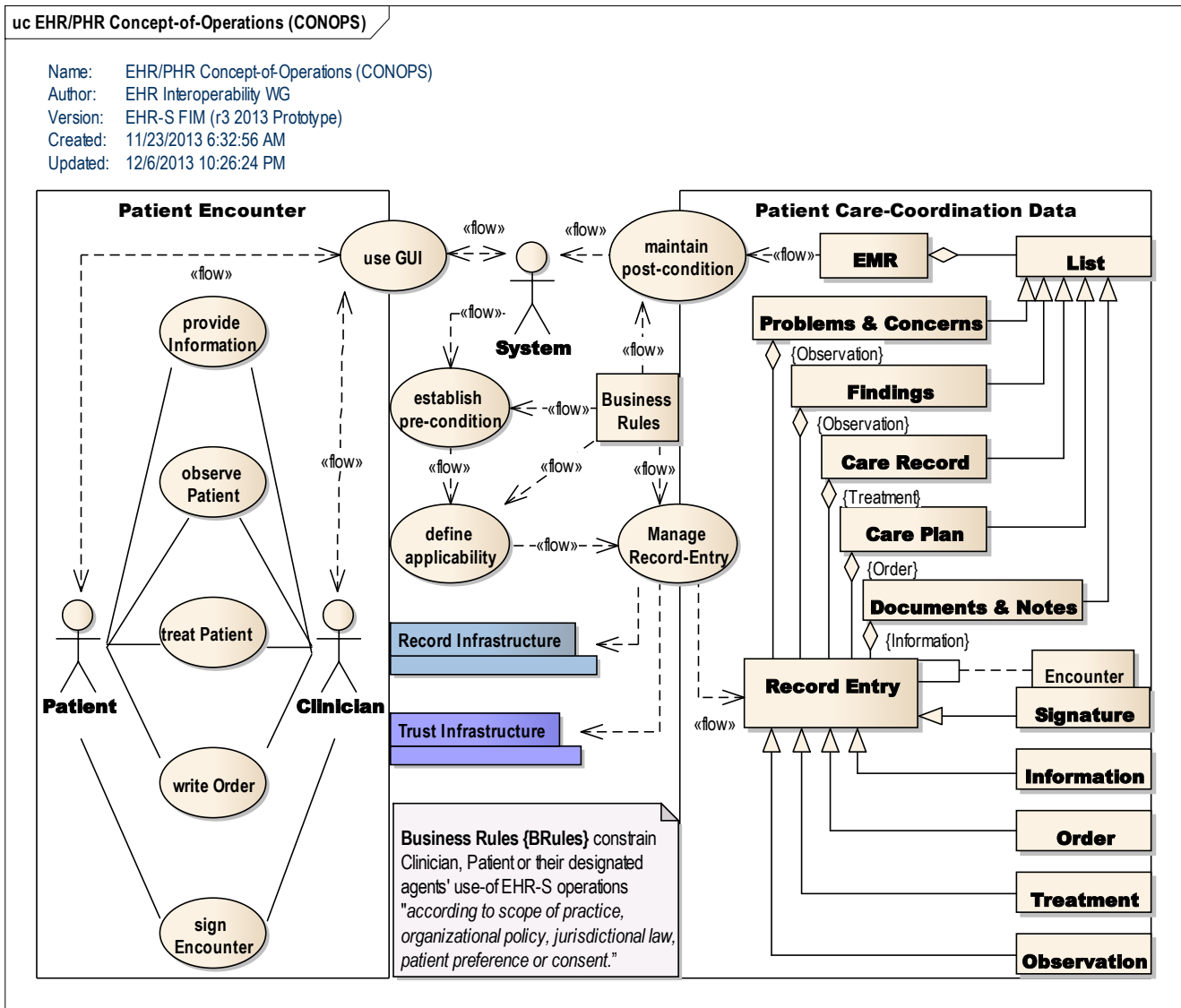
Figure 2 EHR/PHR Concept-of-Operations (CONOPS)

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44
45
46 **EHR-S Concept-of-Operations (CONOPS) Use-Case** A <u>Clinician</u> and <u>Patient</u> and/or their designated <u>Agents</u> have

47 <u>Encounters</u>; where, they *use* a System <u>GUI</u> (Graphical-User-Interface) to *manage* <u>Record-Entries</u> and <u>EMRs</u> (Electronic

48 Medical Records); where,

49 • The <u>System</u>, based-on <u>Business Rules</u>,

50 • *establishes pre-conditions to trigger information flow*

51 • *determines (SHALL/SHOULD/MAY) applicability for the System to-provide-the ability-to-manage or directly-manage*

52 • *maintains post-conditions* in accordance with

53 • scope-of-practice, organizational-policy,

54 • jurisdictional-law, and patient-preferences.

55 • The <u>Clinician</u>, <u>Patient</u> (or their designated agent) can

56 • *review* the <u>Patient</u> <u>EMR</u> (Electronic Medical Record) and associated <u>Information</u>

57 • *observe and treat the* <u>Patient</u>, *write* <u>Orders</u>, *document* the <u>Encounter</u>, *provide* <u>Information</u>

58 • *provide* patient-<u>Information</u> and educational-<u>Information</u>
59 • *enter* EMR <u>Records</u> and associated <u>Information</u>; where,
60 • <u>Record Entries</u> are <u>Orders</u>, <u>Treatments</u>, <u>Observations</u> and associated <u>Information</u>
61 • <u>Lists</u> are <u>Care-Plans</u>, <u>Care-Records</u>, <u>Findings</u>, <u>Problems-and-Concerns</u>, <u>Documents & Notes</u>
62 • *sign* <u>Encounter</u> by the Clinician(s) and/or the Patient
63 • Conformance-Criteria are Scenario threads-of-execution through the Use-Case or Model.
64
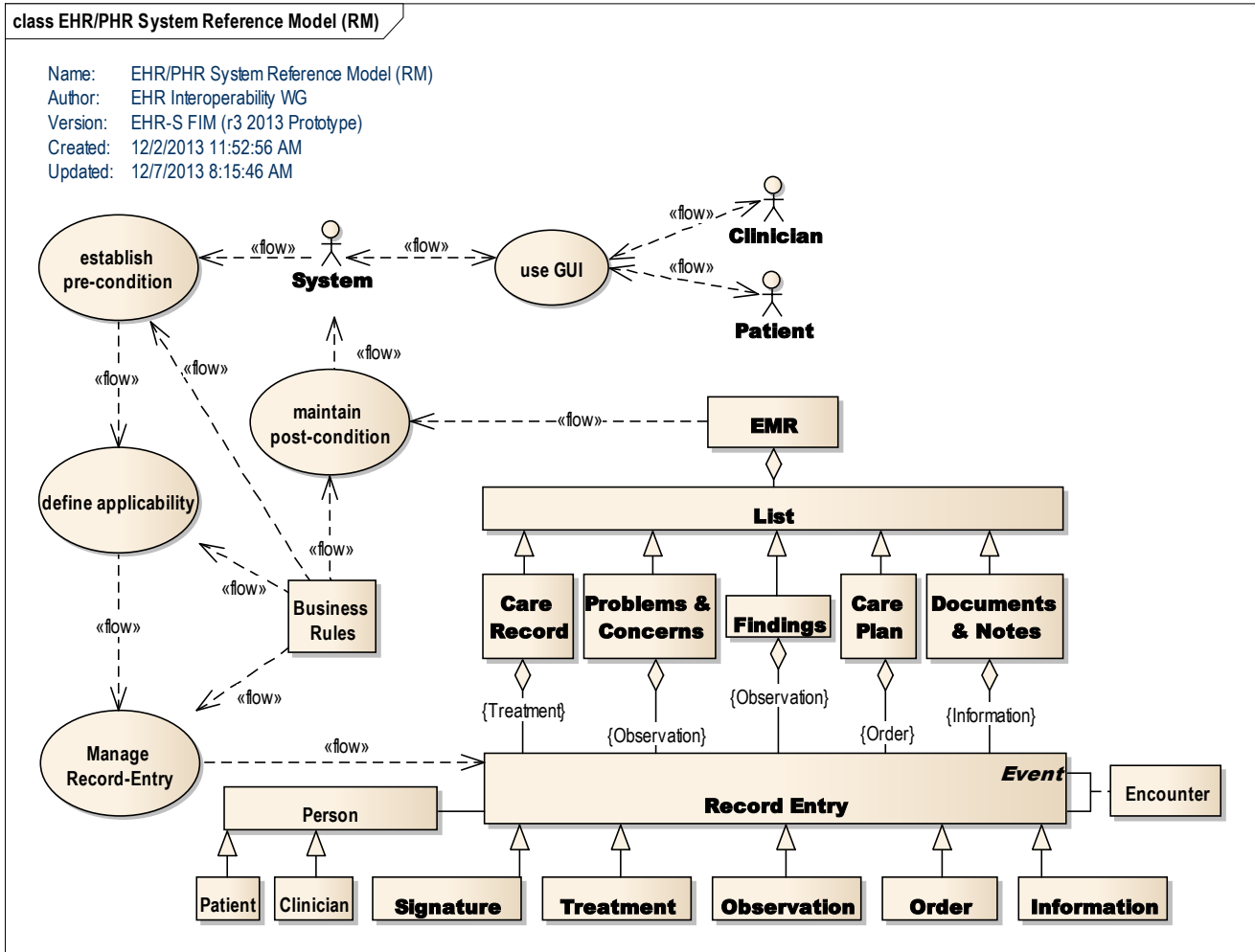
Figure 3 EHR-S/PHR-S RM

67 **The EHR Reference-Model (RM)[1] [based-on OASIS RM definition]**

68 1. Establishes pre-conditions

69 2. Defines applicability (The System SHALL/SHOULD/MAY "provide-the-ability to *manage*" or "directly-*manage*")

70 3. Structures **<u>Record-Entry</u>** relationships

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[1] 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."

71		–	defined-by system operation-and-data models; where,
72		–	EHR/PHR system RM is based-on a functional-use-case constrained <u>hierarchical-lexicon</u> of
73			• <u>nouns</u> (<u>Record-Entry</u> data-types) and <u>noun qualifiers</u>,
74			• <u>verbs</u> (*manage* operation-types) and <u>verb qualifiers</u> with
75			• <u>conditions</u> {Business Rules based on laws, policies, preferences}; where,
76		–	Conformance Criteria (CC) are use-case <u>scenario-threads</u> (context and subject-verb-object bindings).

77   4.   **Defines Conformance-Criteria syntax-and-semantics; where,**
78   –   Function Conformance-Criteria and their profiles constrain the *manage* sub-types, <u>Record-Entry</u> sub-types
79   –   Functions can-be linked-to Information Exchanges (IEs),
80   –   IEs can-be linked-to implementation standards-technologies-paradigms-and-patterns (e.g., FHIR, FHIM, IHE).

81   5.   Maintains post-conditions; where,

82

83   A **System-Function (SF) Use-Case** is a constrained-scope and refined-detail System Reference-Model; where,

84   **SF Conformance-Criteria** are System-Action scenario-threads through the SF Use-Case Model containing:

85   1)   **SF Invariant-condition** (context)
86   a)   System Identifier (EHR or PHR)
87   b)   System Function (SF) Identifier
88   c)   Profile Identifier

89   2)   **SF CC Identifier** (Number)

90   3)   **SF CC Pre-condition** (trigger)
91   a)   Pre-condition is a verb-clause.
92   b)   After a Human-Action or System-Action; then,

93   4)   **SF CC Applicability**
94   a)   The System SHALL, SHOULD or MAY
95   i)   "provide-the-ability-to"
96   ii)   "directly"

97   5)   **SF CC System-Action Bindings**
98   a)   Operation linked-to Data-Type; where, conditionally,
99   b)   the *System-Actions depends-on* other-SF
100   c)   Data-Type are *associated-with* other Data-Types
101   d)   Information Exchange(s) are *linked-to*
102   i)   International Interoperability-Standards (e.g., FHIR)
103   ii)   Realm Interoperability-Specifications (e.g., FHIM)
104   iii)   Implementation Guides (e.g., Consolidated CDA)
105   iv)   Behavioral Interoperability-Specifications (e.g., IHE)
106   v)   Service Level Agreement (e.g., local workflow)

107   6)   **SF CC Post-Condition** (expected-outcome)
108   a)   Post-condition is a subordinate-clause.
109   b)   "where, the System-Actions are …"

110   7)   **SF CC See Also**
111   a)   Supporting or related SFs (e.g., Infrastructure)

112
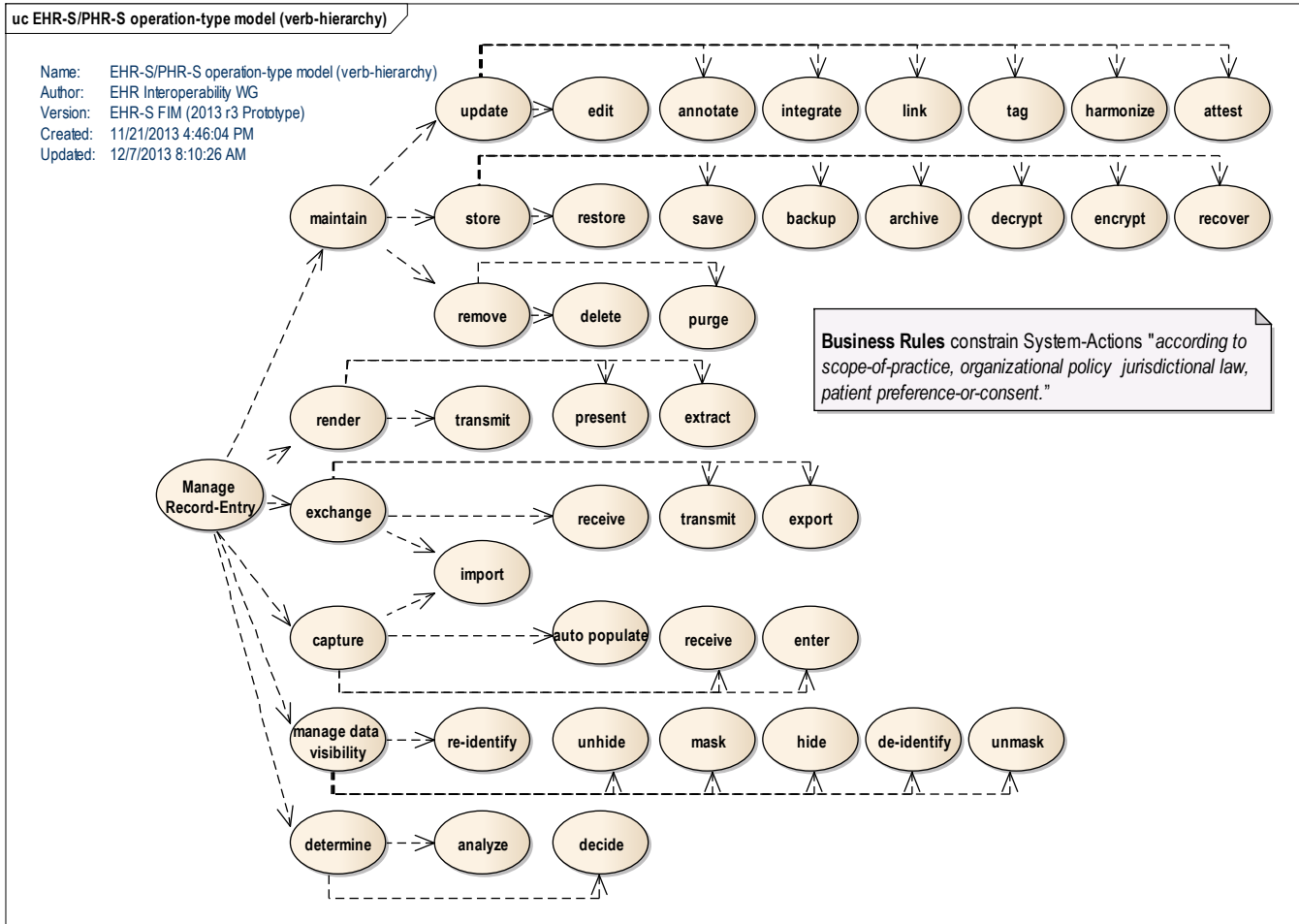
Figure 4 EHR/PHR-RM Operation-Types Model (Verb-Hierarchy)

Figure 5 EHR/PHR-RM Data-Types Model

uc CP.6.2 Immunization Management Use-Case

Name: CP.6.2 Immunization Management Use-Case
Author: EHR Interoperability WG
Version: EHR-S FIM (2013 r3 Prototype)
Created: 11/29/2013 11:44:53 AM
Updated: 12/9/2013 6:03:46 AM
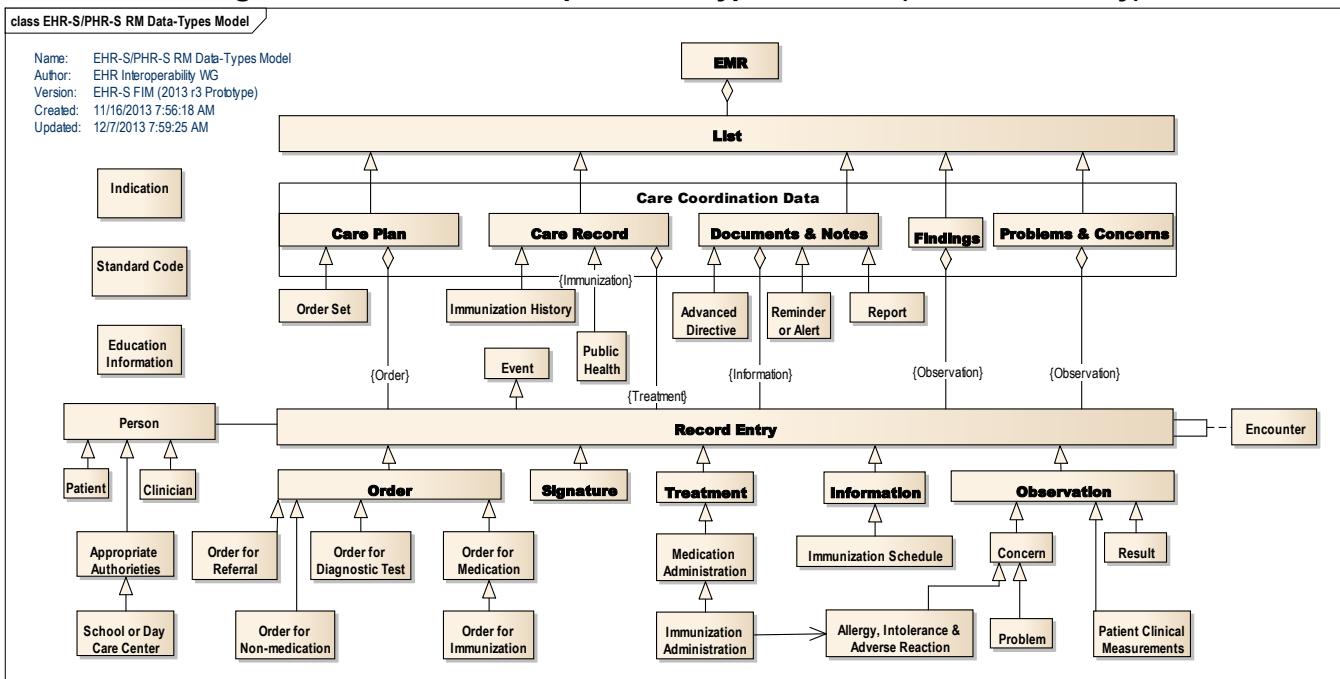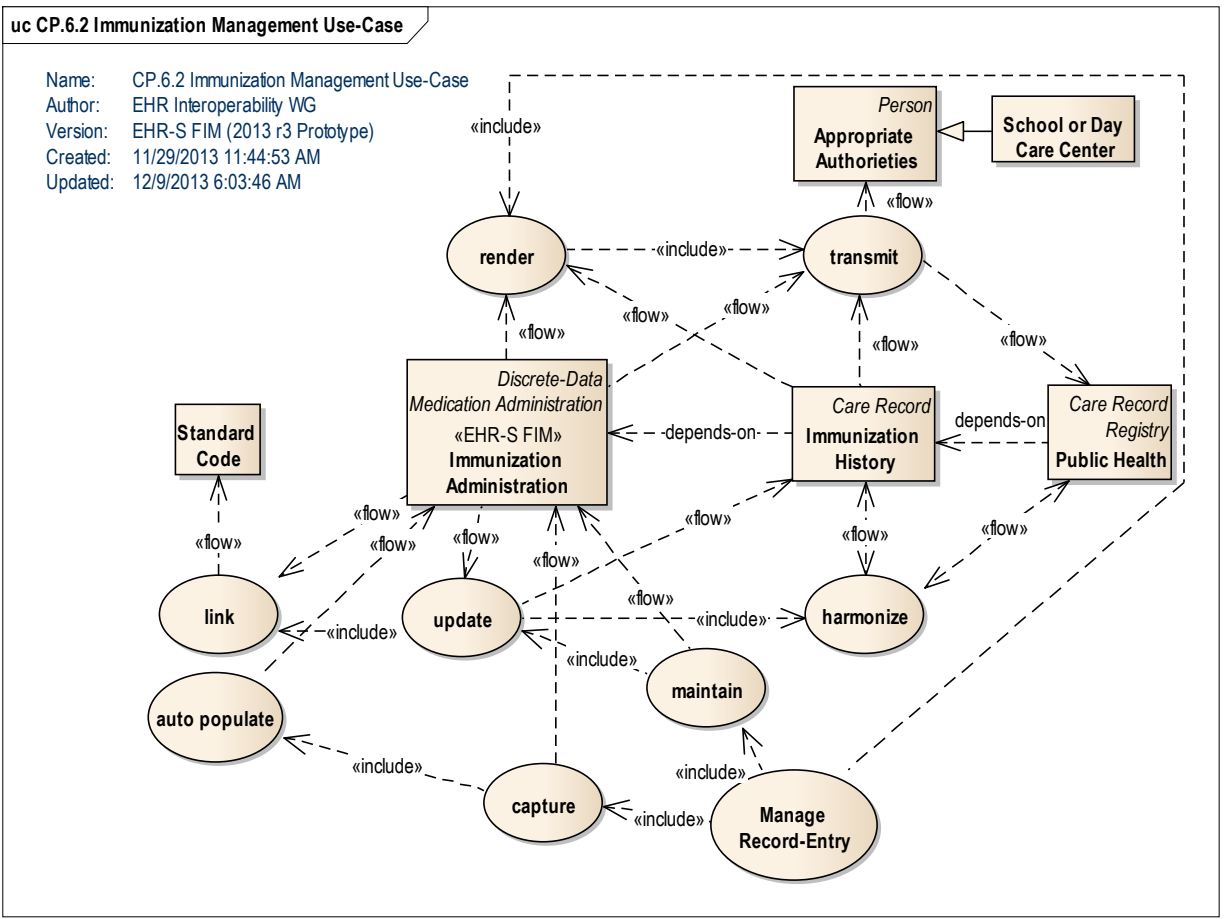
Figure 6 CP.6.2 Immunization-Management Use-Case

The Release-3 EHR System Immunization-Management Function Use-Case includes

1) **A Clinician *uses* the EHR-S, during an Encounter, to**
   a) *review* EMR, Alerts-and-Notifications
   b) *enter* Observations, Treatments, Orders and associated Documents and Notes
   c) *sign* the Encounter
   d) **Immunization Management involves the following:**
      i) **System-Actions:** *auto-populate, capture, determine, exchange, harmonize, link, maintain, manage, render, transmit, update; where,*
         (1) Immunization-Administration is
            (a) *linked* with Standard-Codes
            (b) *transmitted* to Population Health Registries
            (c) *auto-populated as* a by-product of verification of Administering-Provider, Patient, Medication, Dose, Route and Time.
         (2) Immunization-History is
            (a) Updated-with the Immunization-Administration Record-Entries
            (b) *harmonized* with Public-Health Registries
            (c) *rendered* and *transmitted; where,*
               (i) transmitted to Appropriate Authorities (e.g., Schools and Day Care Centers);

137   ii) **Data:** Immunization-Administration, Immunization-History, Public-Health Registry

138   iii) **Associated Data**: Alerts-and-Notification, Allergy-Intolerance-or-Adverse-Event, Patient-Clinical-

139   Measurement, Patient-Directive, Immunization-Schedule, **Patient**-Educational-Information,

140   Signature.

141 e) Where all System-Actions are "according to scope-of-practice, organizational-policy, jurisdictional-law,

142   patient preference-or-consent."

143
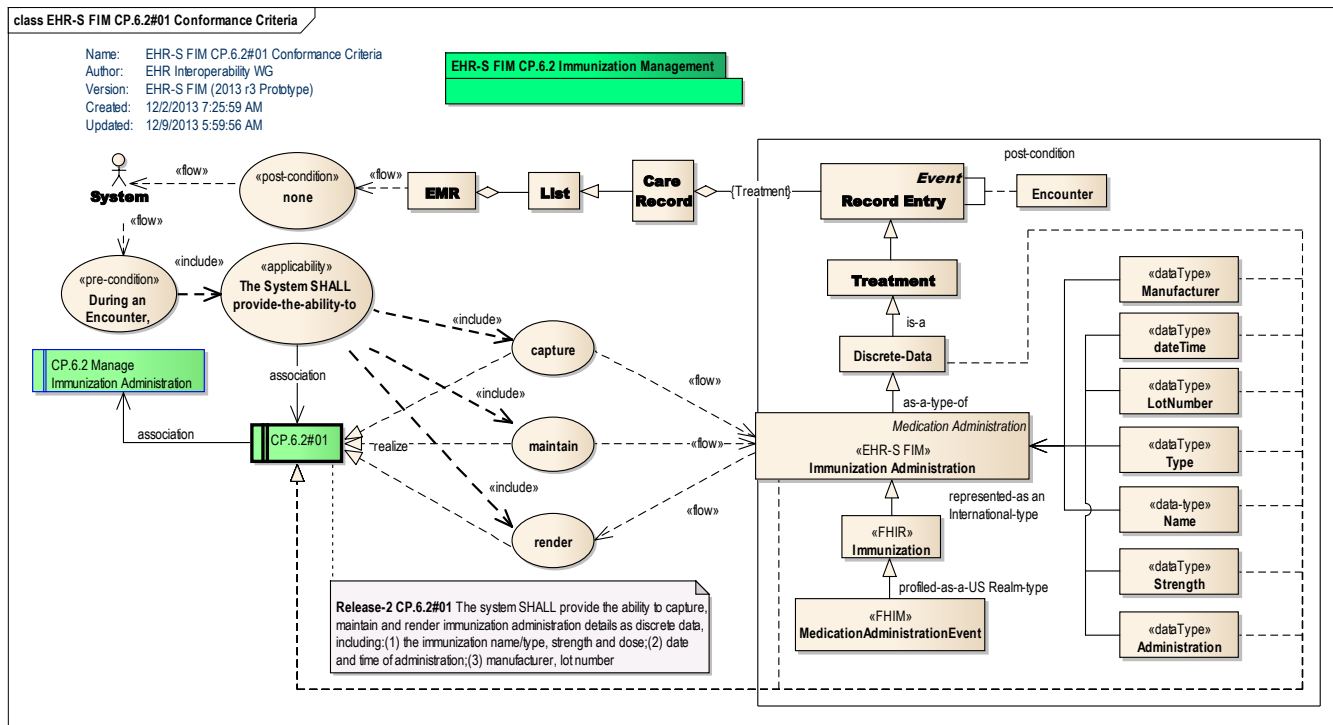
Figure 7 CP.6.2#01 Immunization-Management Conformance-Criteria

146

147 CP.6.2#01 During an Encounter, the system SHALL provide-the-ability-to *capture, maintain and render*

148 Immunization Administration; where,

149   • Treatment Record-Entry details are as discrete-data, including

150   – immunization name/type, strength and dose; date-and-time of administration;

151   –   manufacturer, lot number

152   • Immunization Administration can be realized-by FHIR; where,

153   – Immunization-Administration is then associated with the following resources:

154   • AdverseReaction and other Observations,

155   • Patient , Practitioner, Organization, Location;

156   • Immunization-Administration can be realized-by FHIR-profiles based-on the US Realm FHIM

157   Immunization and related Domains.

158

159
160   **Figure 8 EHR-S FIM-FHIR-FHIM Requirements-Specification Relationship**

161
162   **Figure 9 Example EHR-S FIM-FHIR Requirements-Specifications**

class FHIM Adverse-Event Reporting Domain

Name: FHIM Adverse-Event Reporting Domain
Author: EHR Interoperability WG
Version: EHR-S FIM (2013 r3 Prototype)
Created: 11/7/2013 12:42:32 PM
Updated: 12/10/2013 6:25:22 AM

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

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

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

«FHIR» AllergyIntolerance

«FHIR» AdverseReaction

«Observation» IntoleranceConditionEntry

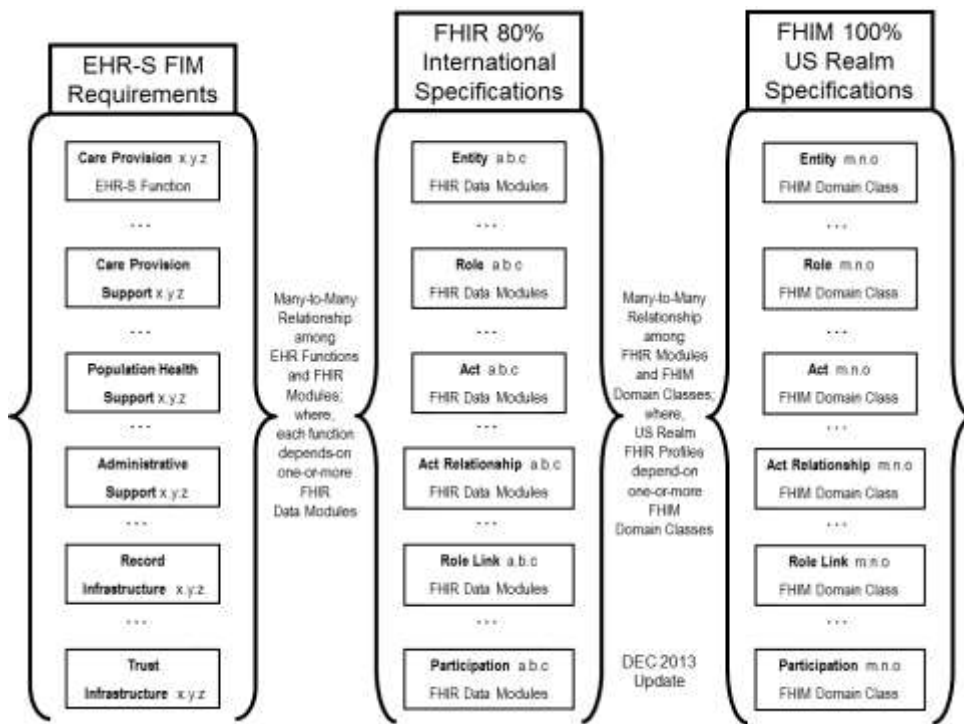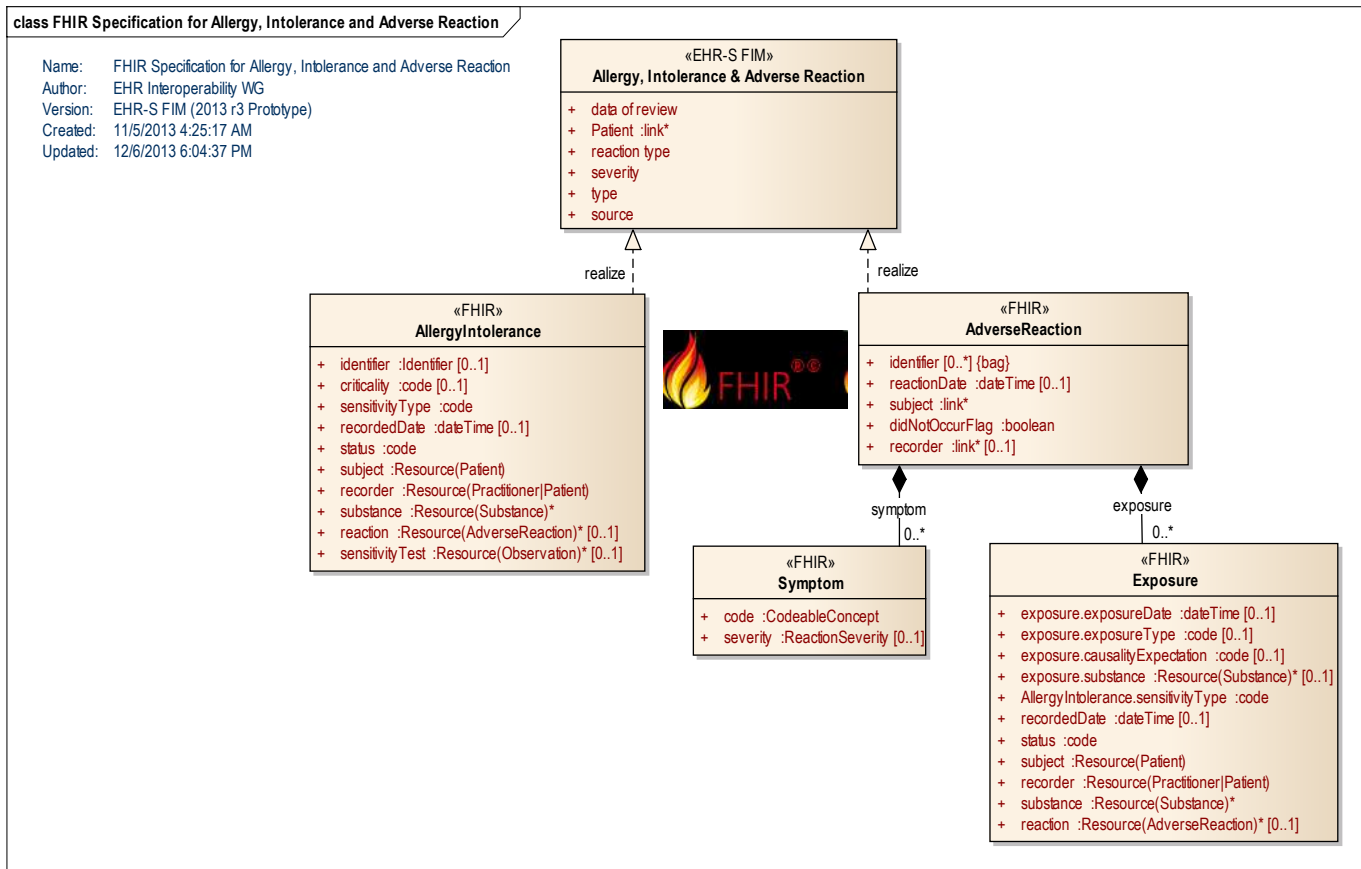**«EntryPoint,EntryPoint, Act»**
NotificationReport
+ alertDateTime :PointInTime*
+ CareGiver :IndividualProvider *
+ encounterEvent :EncounterEvent*
+ exposure :Exposure*
+ height :_VitalSignObservationEvent *
+ labTestPromise :LabTestPromise*
+ medicationHistory :MedicationListory*
+ moreInformationProvider :IndividualProvider*
+ pregnancyMenstrualStatus :PregnancyMenstrualStatus*
+ reportCategory :NotificationReportCategory *
+ reportCreatedBy :HealthcareProvider*
+ reportDateTime :PointInTime*
+ reportId :Id*
+ reportingSystem :String
+ reportSentBy :HealthcareProvider*
+ reportSentTo :Organization*
+ reportSubject :Patient*
+ sendingSystem :String
- serviceDeliveryLocation :ServiceDeliveryLocation
- status :Code
+ vitalSignObservationEvent :_VitalSignObservationEvent*
+ weight :VitalSignObservationEvent

«Observation»
AdverseReactionReportingEvent
+ comment :String
- concommittantDrugs :ConcommittantDrugs
+ congenitalAnomaly :boolean
+ dateDoctorNotified :PoinyInTime*
+ dateReportedToFda :PointInTime* = TS
+ dateReportedToMfr :PointInTime* = TS
+ dateReportedToVaers :PointInTime*
+ daysHospitalized :int
+ didPatientDieFromEvent :boolean
+ didPatientRecover :boolean*
+ eventDateTime :OointInTime*
+ intoleranceObservation :IntoleranceCondition*
+ isReporterACareProvider :boolean
+ otherRelatedHistory :String
+ patientConsentDate :PointInTime*
+ preExistingMedicalCondition :HealthConcern*
+ relevantLabData :RelevantLabData*
+ equiredErOrMdVisit :boolean
+ requiredHospitalization :boolean
+ requiredIntervention :boolean
+ resultedInPermanentDisability :boolean
+ resultedInProlongedHospitalization :boolean
+ sendToFda :boolean*
+ sendToMfr :boolean
+ severity :Code*
- suspectedAgent :SuspectedAgent = Observation
+ wasDiscloseIdToMfr :boolean
+ wasDoseRelated :int
+ wasEventLifeThreatening :boolean
+ wasReactionTreatedWithRx :boolean
+ wasRelatedToNewDrug :boolean
+ wasRelatedToTherapeuticFailure :boolean
+ wasSeriousADR :boolean
+ wasUnexpectedADR :boolean*
+ witness :IndividualProvider

«Observation»
SuspectedAgent
+ adminDuration :int
+ adminStartDate adminStartDate :PointInTime
+ adminStoptDate :PointInTime*
+ adverseReactionLikelihood :Code*
+ dailyDose :String
+ didReactionCease :boolean
+ didReappear :boolean
+ doesNormallyOccur :boolean
+ indicationsForUse :String
- lastFillDate :PointInTime
+ medicinalProduct :MedicinalProduct*
+ nbrOfPreviousDoses :int
+ route route :String
+ wasAdminStopped :boolean
+ wasDueToPtCondition :int
+ wasReadministered :boolean

+suspectedAgent

+medicinalProduct

«NabufacturedMaterial»
MedicinalProduct
+ auxillaryLabel :String
- brandName :Code
- controlledSubstanceSchedule :Code
+ drugClass :DrugClass*
+ genericMedicine :GenericMedicine *
+ ingrediant :DrugIngrediant*
+ investigationalNewDrugId :Code*
+ isOverTheCounter :boolean*
- newDrugApplicationId :Code
- packagedMedicinalProduct :PackagedMedicinalProduct

«Observation»
IntoleranceCondition
+ alertDevice :Code
+ dateOfOnset :PointInTime *
+ dateOfOnsetText :String
+ IntoleranceCategory :Code*
+ isAbsolutelyContraIndicated :boolean
+ mechanism :Code*
+ reactant :Code*
+ reactantCategory :Code*
- criticality :CodeWithOriginalText *

+intoleranceObservation

Details shown on separate diagram

«Role» *Patient*
IndividualProvider
+ signatureBlockName :PersonName*
+ MobilePhone :Telecommunications*
+ pager :Telecommunications*

+relevantLabData

«Observation»
RelevantLabData
+ collectionDate :PointInTime
+ results :String
+ test :String

+concommittantDrugs

+medicinalProduct

«SubstanceAdministration»
ConcommittantDrugs
+ adminSraelDate :PointInTime*
+ adminEndDate :PointInTime*
+ lastFillDate :PointInTime*
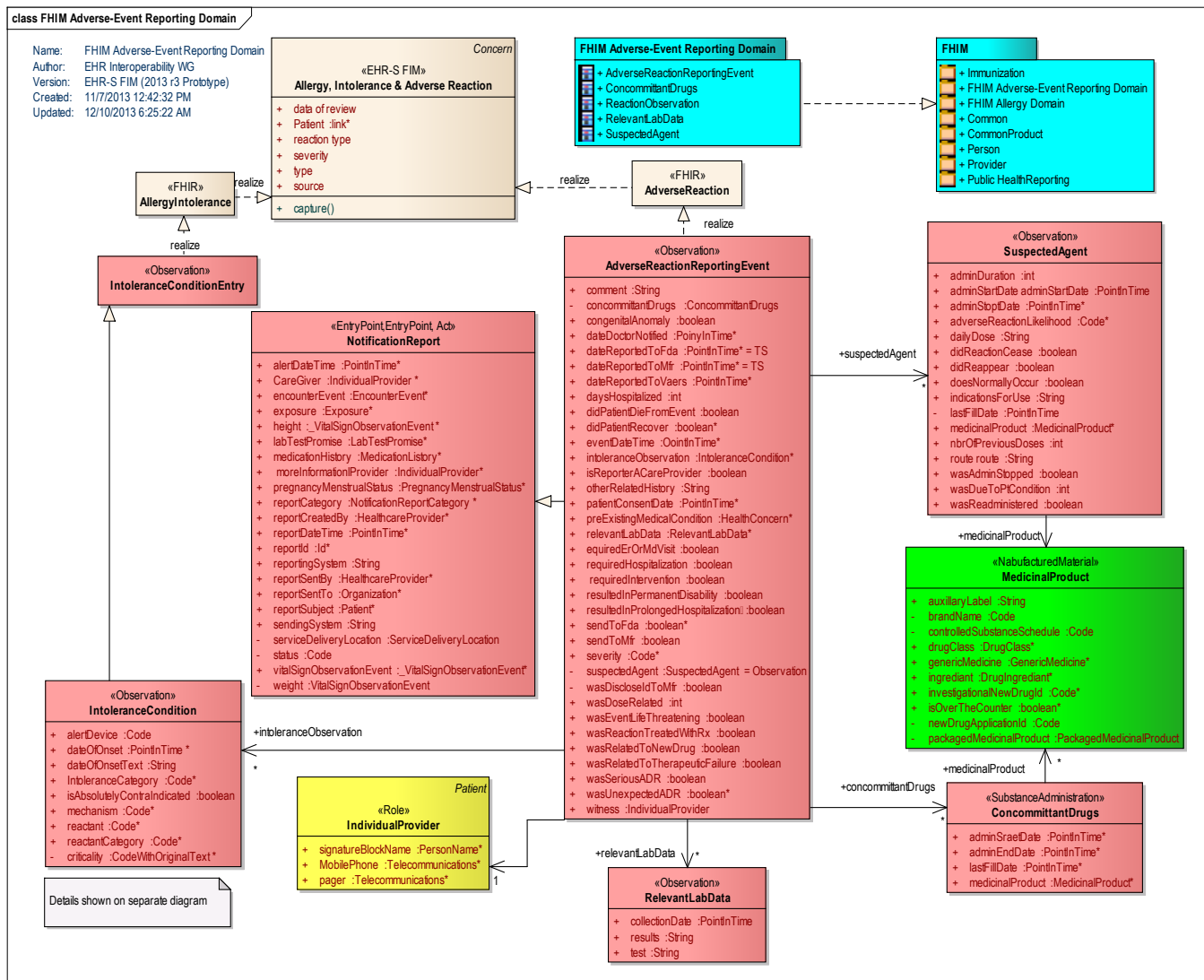+ medicinalProduct :MedicinalProduct*

Figure 10 Example EHR-S FIM-FHIR-FHIM Requirements-Specification

CURRENT ISSUES-ACTIONS

5. **HL7 Board approval** of EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRSFIM
6. **FHIR WG Coordination** to integrate EHR-S FIM-FHIR into a joint Sparx Enterprise Architect (EA) model; where, EA can generate integrated EHR-S FIM-FHIR International-Realm interoperability requirements-specifications
7. **FHIM Team Coordination** to integrate EHR-S FIM-FHIR-FHIM into a joint Sparx Enterprise Architect (EA) model; where EA can generate integrated EHR-S FIM-FHIR-FHIM US-Realm interoperability requirements-specifications
8. **Call-for-Participation** in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (ReferenSce Model), where,