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

Last Updated on Dec 5, 2013 by SHufnagel@tiag.net, report editor

Edmond Scientific subcontractor to Veterans Health Administration/

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

The latest version of this working-draft report is available at:

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

EXECUTIVE SUMMARY

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.
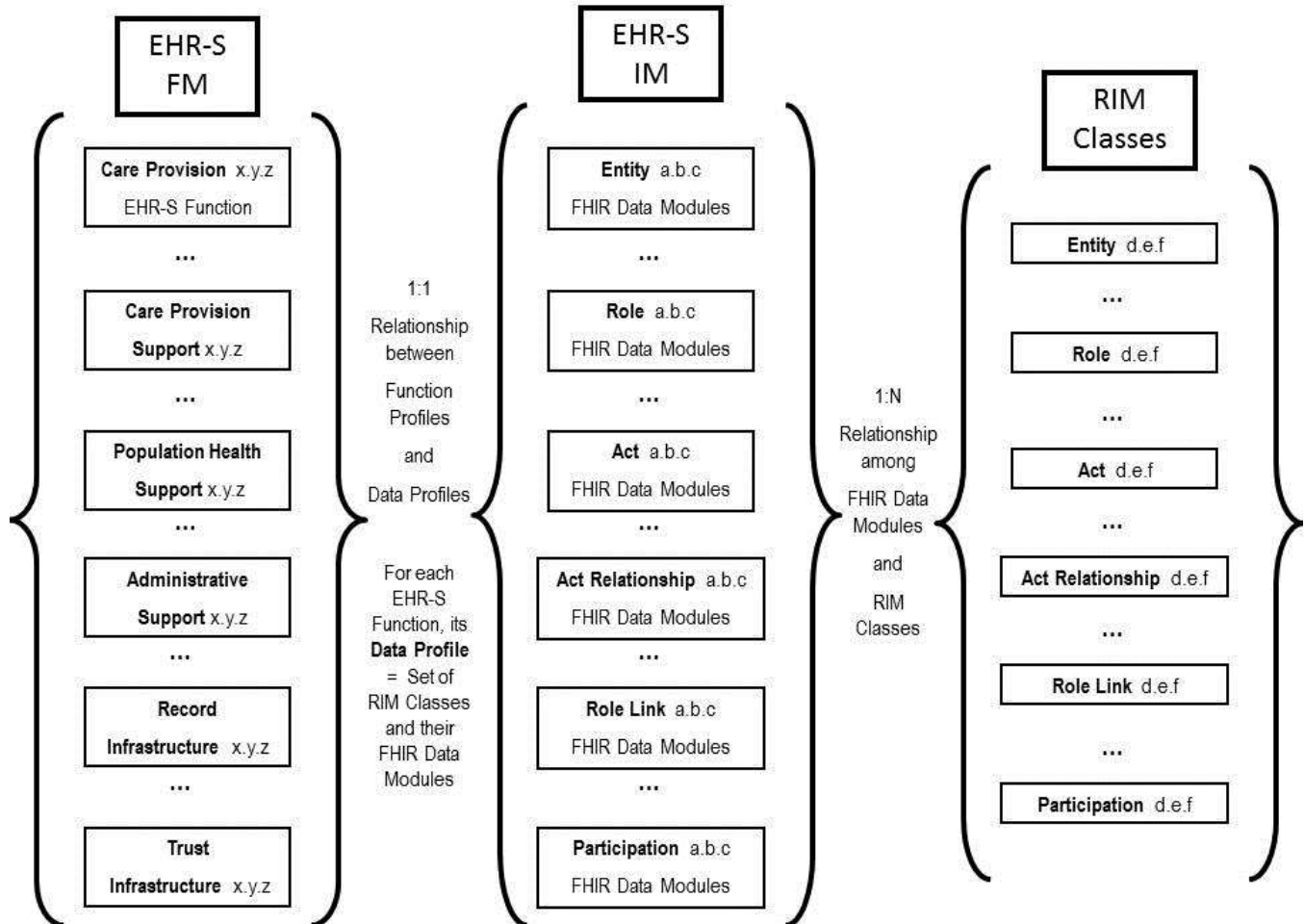

Figure 1 FHIR within Release-3 EHR-S Function-and-Information Model Conceptual-Architecture

GOAL: 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. The Work Group creates and promotes appropriate and necessary standards, including:

- Functional and Information Requirements for Electronic Health Records (EHR) and systems (EHRS),
- Functional and Information Requirements for Personal Health Records (PHR) and systems (PHRS),
- Definition of a high-level framework to support the interoperability requirements and life cycles, and
- Identification of existing and emerging information requirements and other HL7 artifacts.
- An objective of the EHR Interoperability WG team, under the System Function and Information Model (EHR-S FIM r3.0) HL7-project, is to create a clear, complete, concise, correct, consistent and easy-to-use EHR-S FIM r3.0 from the 2014 EHR-S FM r2.0; where, release-3 is HL7 ballot-publishable from Sparx Systems Enterprise-Architect tool. EHR-S FIM r3 is 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 VA negative ballot.
  - VA voted negative against the EHR-S FM r2.0 ballot; because in-part, it was considered inconsistent, non-intuitive and hard to navigate.
- A second objective of the EHR Interoperability WG is producing a Meaningful Use profile for EHR-S FM r2.0.
- The objective of the Resource Management Evidentiary Support (RM-ES) project team 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.

PROJECTS AND SUB-WORKGROUPS

- HL7 List Server Registration: http://www.hl7.org/myhl7/managelistservs.cfm
- Hl7 Work-Group Call-Schedule: http://www.hl7.org/concalls/default.aspx
- EHR WG – Plenary   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
      ix) CPS.9 Support Care Coordination & Reporting
   c) **Population Health Support**
      i) POP.1 Support for Health Maintenance, Preventive Care and Wellness
      ii) POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population
      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
      ii) AS.2 Manage Patient Demographics, Location and Synchronization
      iii) AS.3 Manage Personal Health Record Interaction
      iv) AS.4 Manage Communication
      v) AS.5 Manage Clinical Workflow Tasking

MONTHLY SUMMARIES

(Reverse Chronological Order)

LEGEND

1) Capitalized and Underlined nouns and adjectives are concepts, which should be in the EHR-S FM data dictionary; and, they should also correspond to ISO 13940 Continuity-of-Care "CONTsys" concepts. See www.skmtglossary.org for standard healthcare data-dictionary / glossary.
2) **Blue terms** are recommended terms to be added to the conformance criteria.
3) **Red terms** are recommended terms to be removed from the conformance criteria.
4) Highlighted Yellow Sections are issues and/or new material for the main EHR WG to-review and to-comment-on.

November 2013 Summary

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

16   can be finalized in January 2014. The EHR WG has also been updating the EHR-S FM release-2
17   add-on to the Sparx EA-tool to support the creation of profiles.
18 2) **PHR WG** is waiting on the PHR FM Release-2 ISO ballot-comments, which close 3-Dec-2013 and
19   will be reconciled during December-and-January; where, the HL7 release-2 ballot-comments have
20   already been reconciled.
21 3) **EHR RMES WG** is discussing release authorization within the S&I Framework esMd group; where,
22   esMD is analyzing the situation where healthcare-payers frequently request that providers submit
23   additional medical-documentation for a specific claim, to support claims processing and other
24   administrative functions, such as the identification of improper payments. Currently, Medicare
25   Review Contractors request approximately 2 million medical documents per year by mailing a paper
26   request letter via US Postal Service to healthcare providers. Until recently, providers had only two
27   options for submitting the requested records: 1) mail paper or 2) send a fax. The manual paper
28   process is costly, time consuming and can delay proper claims processing on both the senders' and
29   receivers' end.
30 4) **EHR Usability WG** is collecting issues and mitigations into a reference library, which can be the
31   basis of integrating usability into the release-3 EHR-S FIM.
32 5) **EHR Interoperability WG** focused on the May-2014 Meaningful-Use Profile for the EHR-S FM
33   release-2 and preparation for release-3:2016; where, the November release-3 focus was to define
34   Reference-Models for Concept-of-Operations, Function Information-and-Conformance-Criteria:
35   a) Figure 3 EHR-S Reference-Model (RM) Framework
36   b) Figure 2 EHR Concept-of-Operations (CONOPS) Model
37   c) Figure 4 EHR-S RM System-Actions Sub-Types aka Verb-Hierarchy
38   d) Figure 5 EHR-S RM Data Sub-Types aka Conceptual Information-Model
39   e) Figure 6 Conformance-Criteria are Scenario-Threads through the Reference-Model
40   f) Figure 7 EHR-S CP.6.2#01 Immunization-Management
41   g) Figure 9 EHR-S FIM-FHIR-FHIM Requirements-Specifications
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Figure 2 EHR Concept-of-Operations (CONOPS) Model

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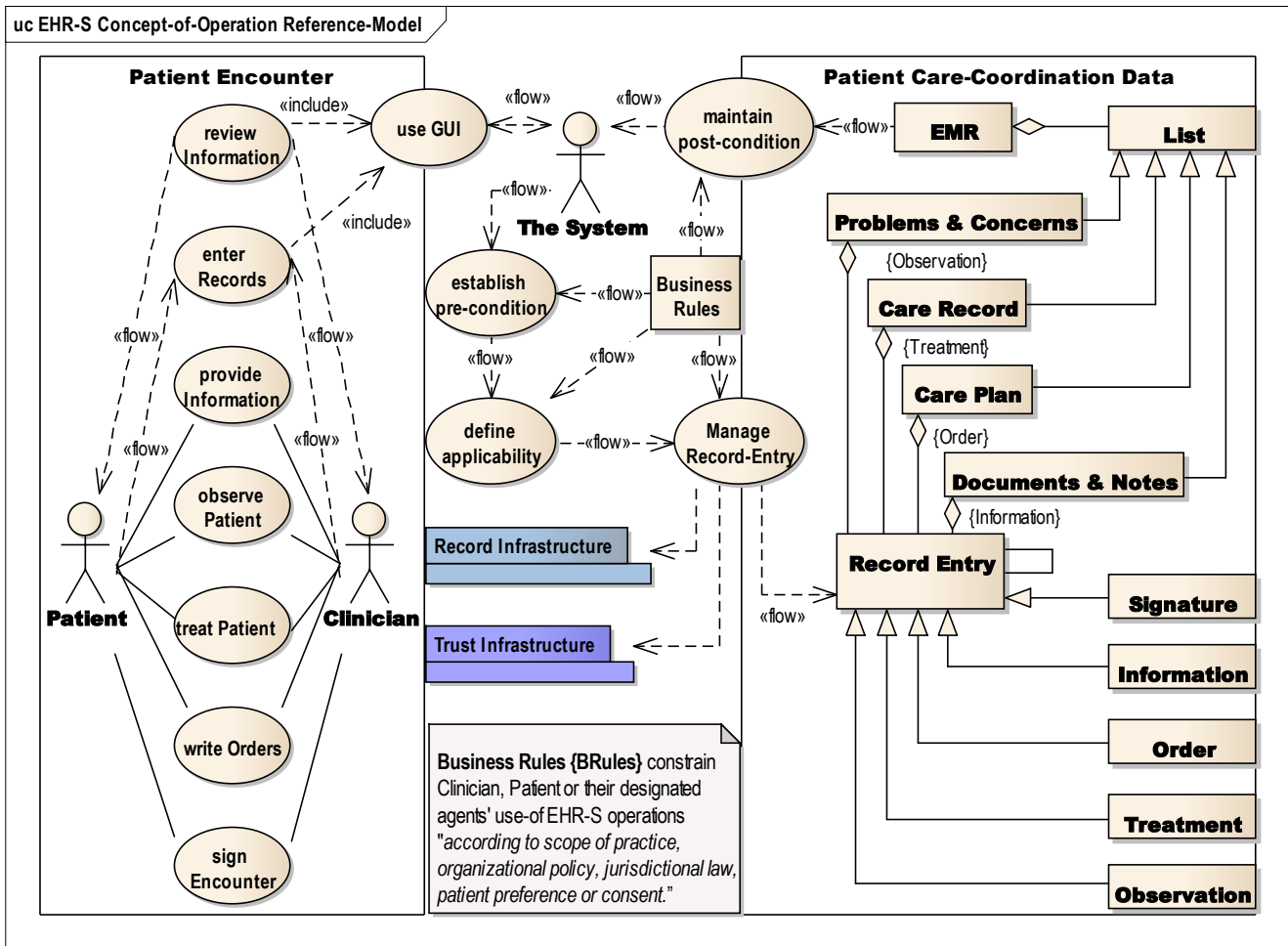
47 **EHR-S Concept-of-Operations Use-Case**

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

51 • where, the System, based on Business Rules,
52   • *establishes pre-conditions to trigger information flow*
53   • *determines (SHALL/SHOULD/MAY) applicability for the System to-provide-the ability or directly manage*
54   • *maintains post-conditions*
55 • The Clinician-or-Patient can
56   • *review* the Patient EMR (Electronic Medical Record) and associated Information
57   • *observe and treat* the Patient, *write* Orders *and document* the Encounter
58   • *provide* patient Information and educational-Information
59   • *enter* EMR Records and associated Information; where,
60   • Record Entries are Orders, Treatments, Observations and associated Information
61   • Lists are Care-Plans, Care-Records, Problems-and-Concerns, Documents & Notes
62   • *sign* Encounter by the Clinician(s) and possibly by the Patient

63 • Conformance Criteria are Scenario threads-of-execution through the Use-Case or Model.

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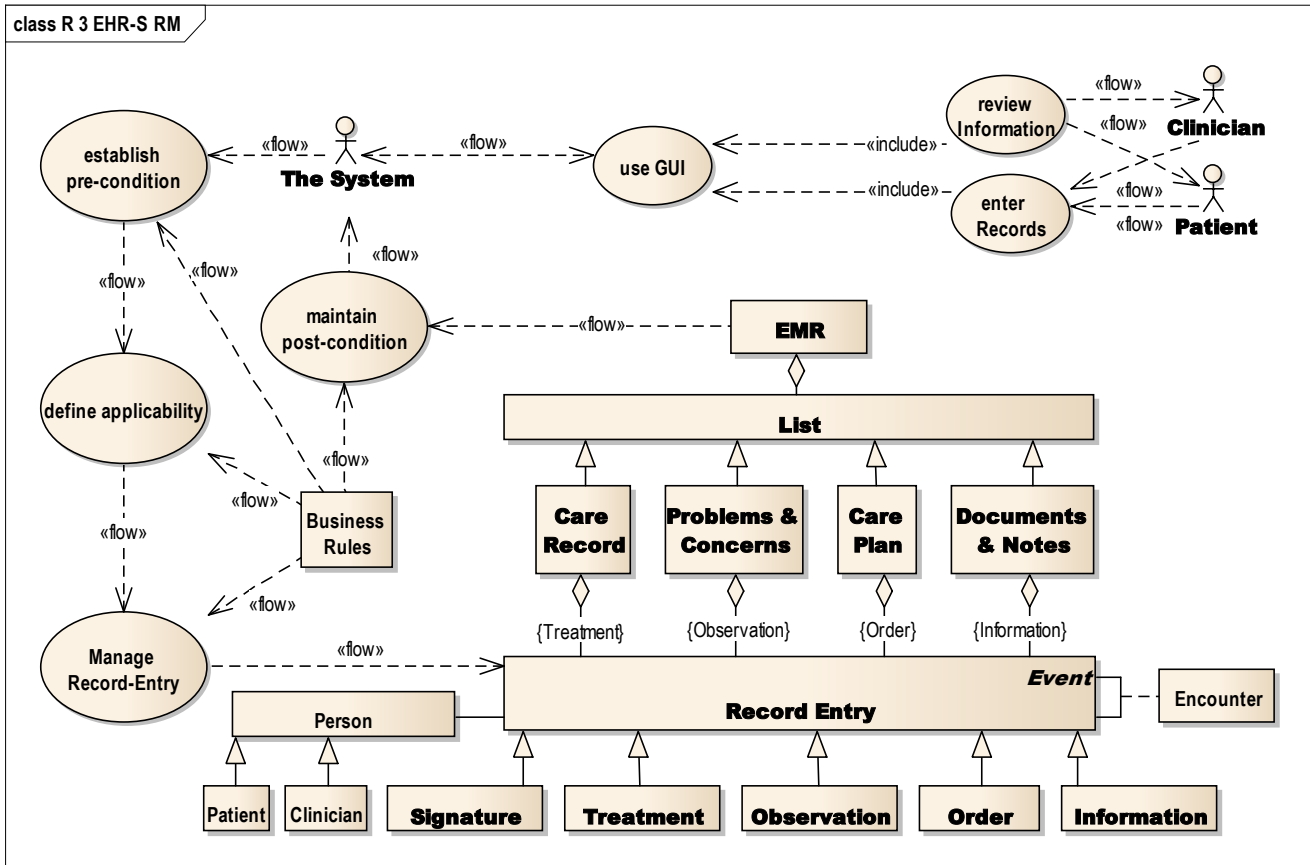
Figure 3 EHR-S Reference-Model (RM) Framework Based-on CONOPS

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

68   1. Establishes pre-conditions
69   2. Defines applicability (The System SHALL/SHOULD/MAY provides-the-ability or directly)
70   3. **Structures significant-relationships among EHR-S Record-Entries**
71   – defined-by EHR-S Action-and-Information Conceptual-Models; where,
72   – EHR-S RM is based-on a functional-use-case constrained hierarchical-lexicon of
73   • nouns (Data-Entities) and noun qualifiers (Data-hierarchy or Sub-Types),
74   • verbs (Actions) and verb qualifiers (Action-hierarchy or Sub-Types) with
75   • conditions {Business Rules based on laws, policies, preferences}; where,
76   – Conformance Criteria (CC) are scenario-threads through the reference use-case & model.
77   4. **Defines Conformance-Criteria syntax-and-semantics; where,**
78   – Functions and their profiles constrain the Verb sub-types, Noun sub-types and Conditions
79   – Functions can-be linked-to Information Exchanges (IEs),
80   – IEs can-be linked-to implementation standards-technologies-paradigms-and-patterns.
81   5. Maintains post-conditions
82 • According to the Organization for the Advancement of Structured Information Standards (**OASIS**) a reference model is "an abstract framework
83   for understanding significant relationships among the entities of some environment, and for the development of consistent standards or
84   specifications supporting that environment. A reference model is based on a small number of unifying concepts and may be used as a basis for
85   education and explaining standards to a non-specialist. A reference model is not directly tied to any standards, technologies or other concrete

86 implementation details, but it does seek to provide a common semantics that can be used unambiguously across and between different
87 implementations."
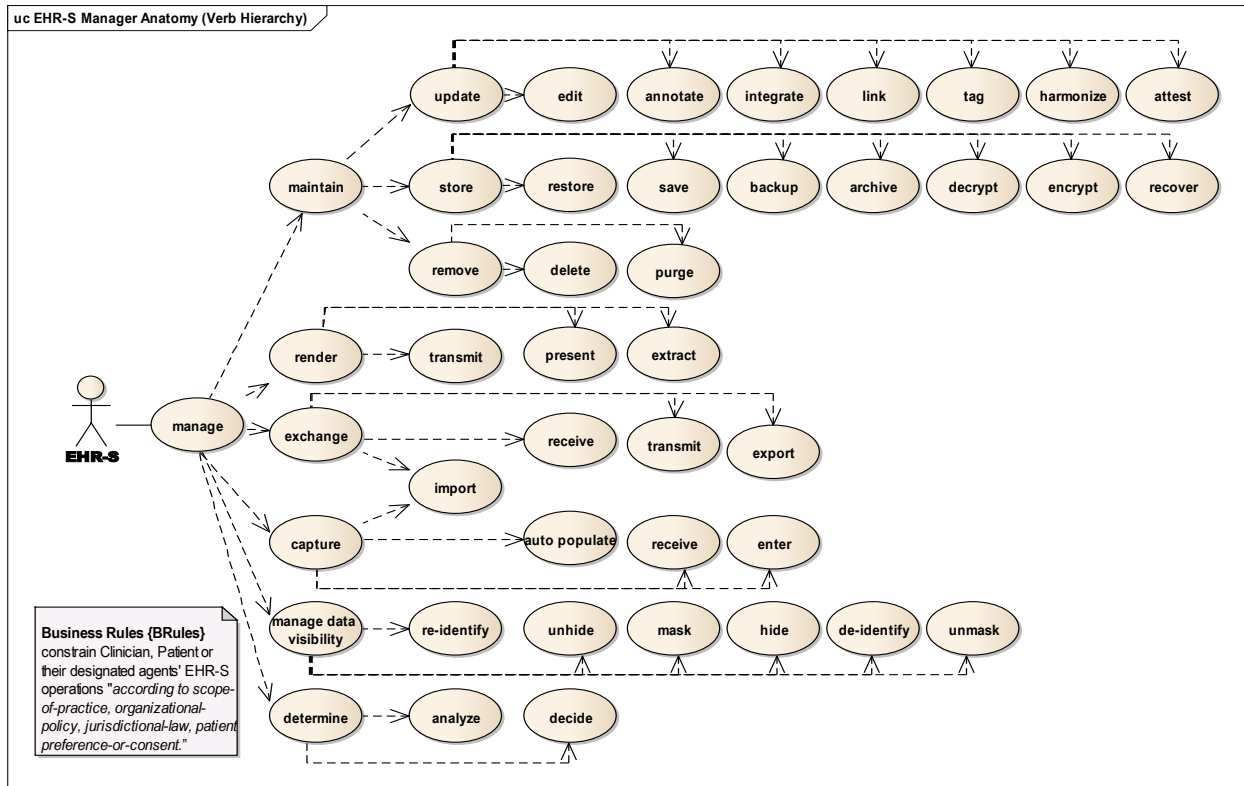
Figure 4 EHR-S RM System-Actions Sub-Types aka Verb-Hierarchy
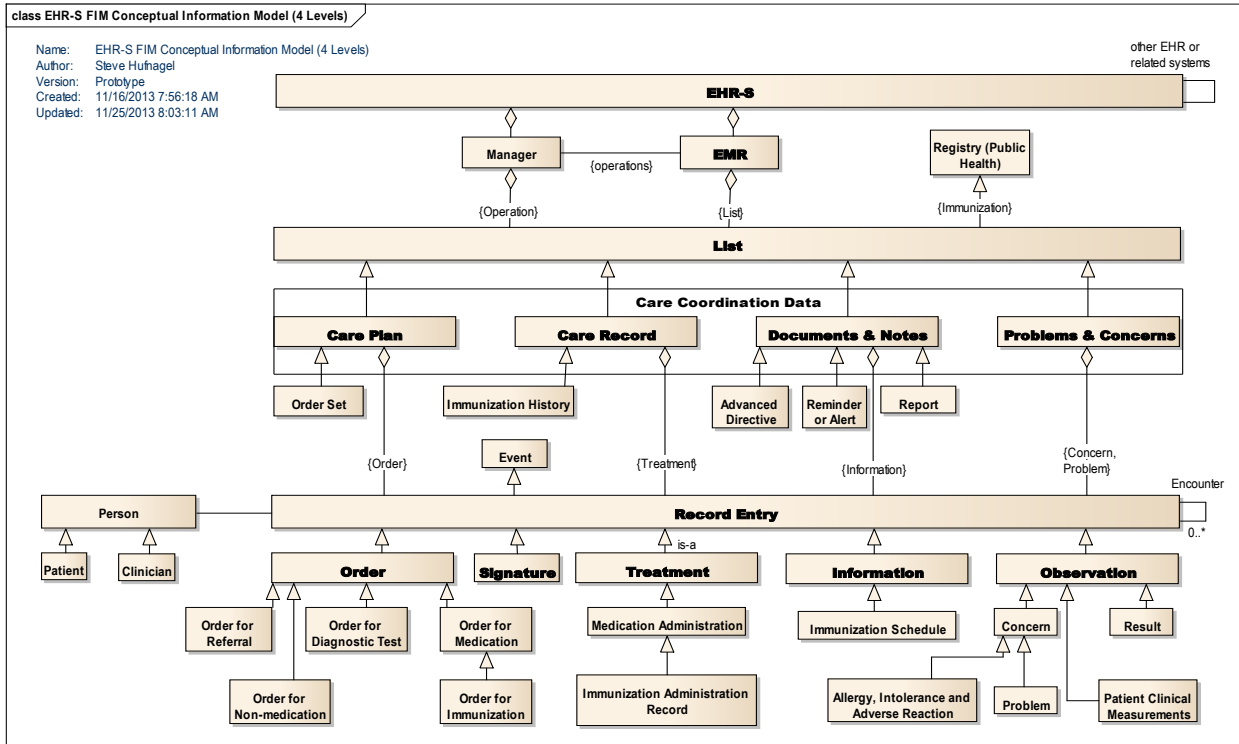
Figure 5 EHR-S RM Data Sub-Types aka Conceptual Information-Model
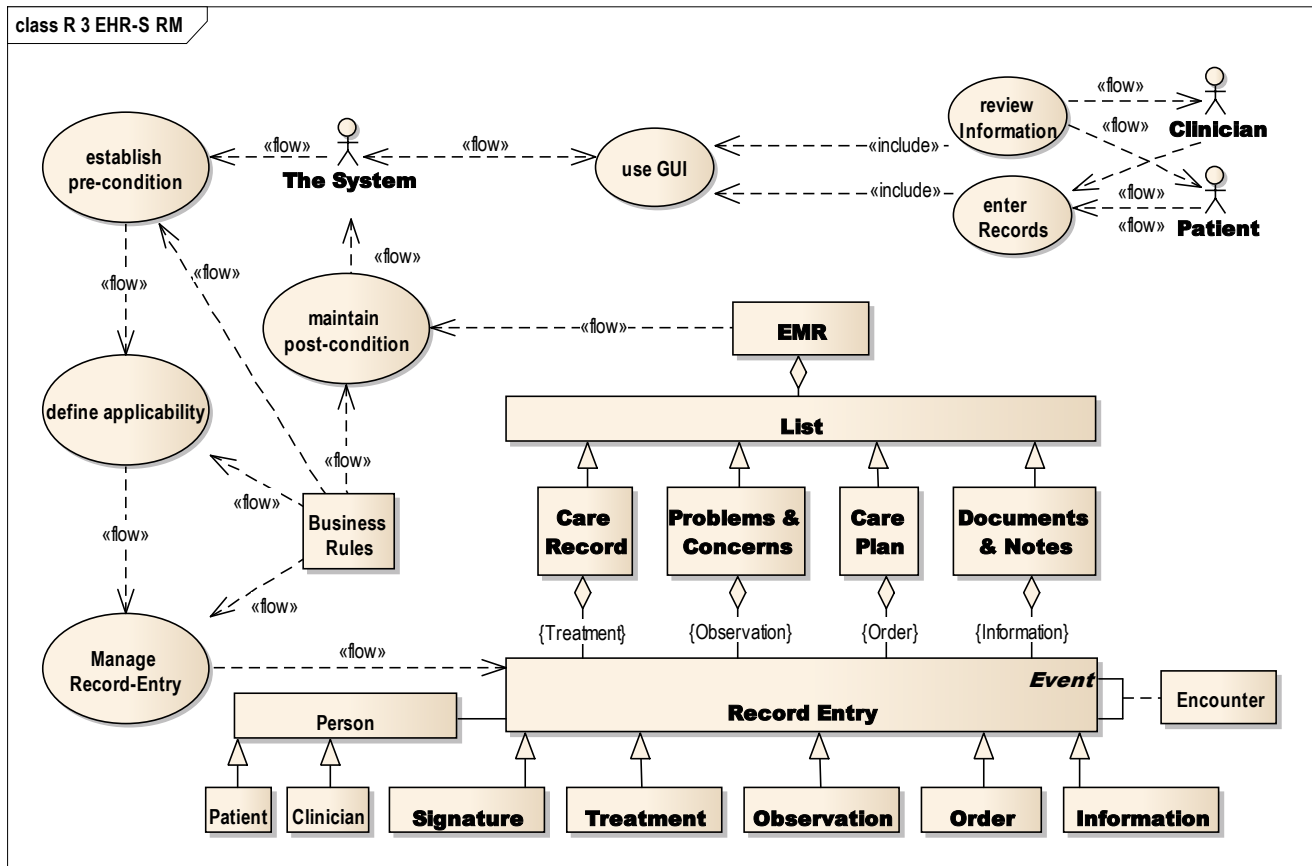
Figure 6 Conformance-Criteria are Scenario-Threads through the Reference-Model

Second, Conformance-Criteria are scenario threads through the Reference Model (RM)

- **SF Invariant-condition** (context)
    - System Identifier (EHR or PHR)
    - System Function (SF) Identifier
    - Profile Identifier
- **SF CC Identifier** (Number)
- **SF CC Pre-condition** (trigger)
    - Pre-condition is a verb-clause.
    - After a Human-Action or System-Action; then,
- **SF CC Applicability**
    - The System SHALL, SHOULD or MAY
        - "provide-the-ability-to"
        - "directly"
- **SF CC System-Action Bindings**
    - Operation linked-to Data-Type; where, conditionally,
    - the *System-Actions depends-on* other-SF
    - Data-Type are *associated-with* other Data-Types
    - Information Exchange(s) are *linked-to*

113	• International Interoperability-Standards (e.g., FHIR)
114	• Realm Interoperability-Specifications (e.g., FHIM)
115	• Implementation Guides (e.g., Consolidated CDA)
116	• Behavioral Interoperability-Specifications (e.g., IHE)
117	• Service Level Agreement (e.g., local workflow)
118	• **SF CC Post-Condition** (expected-outcome)
119	– Post-condition is a subordinate-clause.
120	– "where, the System-Actions are …"
121	• **SF CC See Also**
122	– Supporting or related SFs (e.g., Infrastructure)

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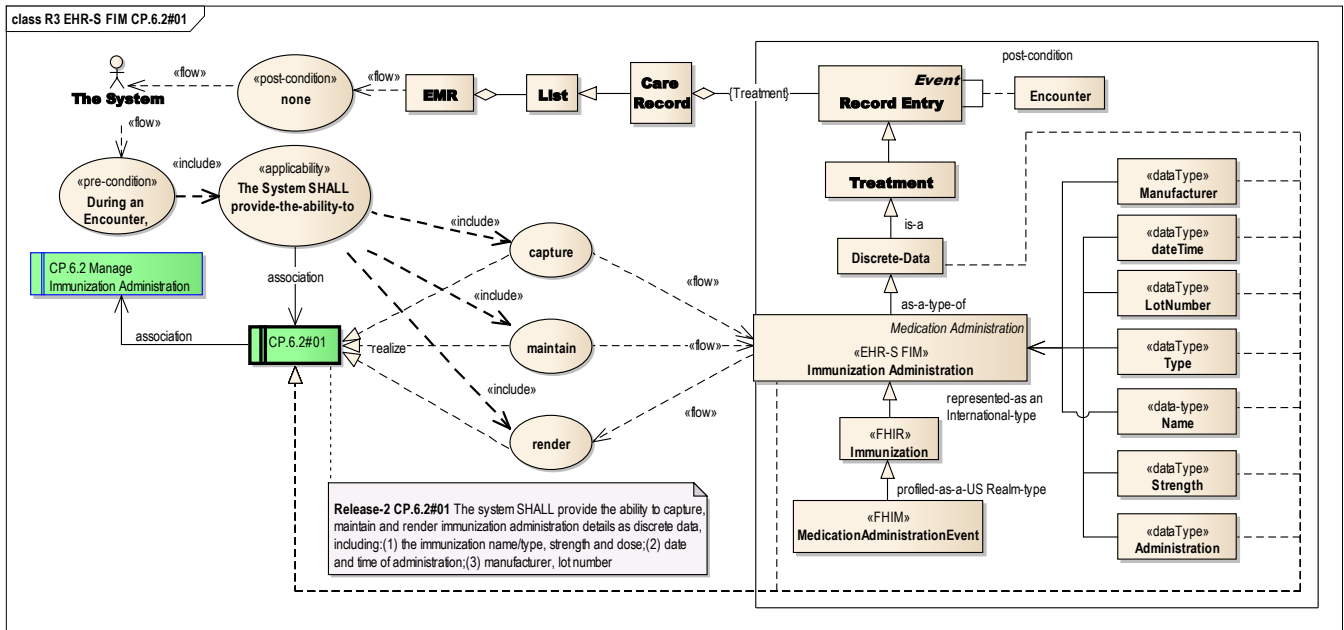
Figure 7 EHR-S CP.6.2#01 Immunization-Management Conformance-Criteria "Scenario"

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126 **Release 3 EHR-S CC Description CP.6.2#01 Immunization-Management**

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

128 Immunization Administration; where,

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

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

131   – manufacturer, lot number

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

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

134   • AdverseReaction and other Observations,

135   • Patient , Practitioner, Organization, Location;

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

137   Immunization and related Domains.

uc EHR-S FM R3 CP.6.2 Refined System-Actions

Name: EHR-S FM R3 CP.6.2 Refined System-Actions
Author: Steve Hufnagel
Version: Prototype
Created: 11/29/2013 11:44:53 AM
Updated: 12/5/2013 6:55:22 AM
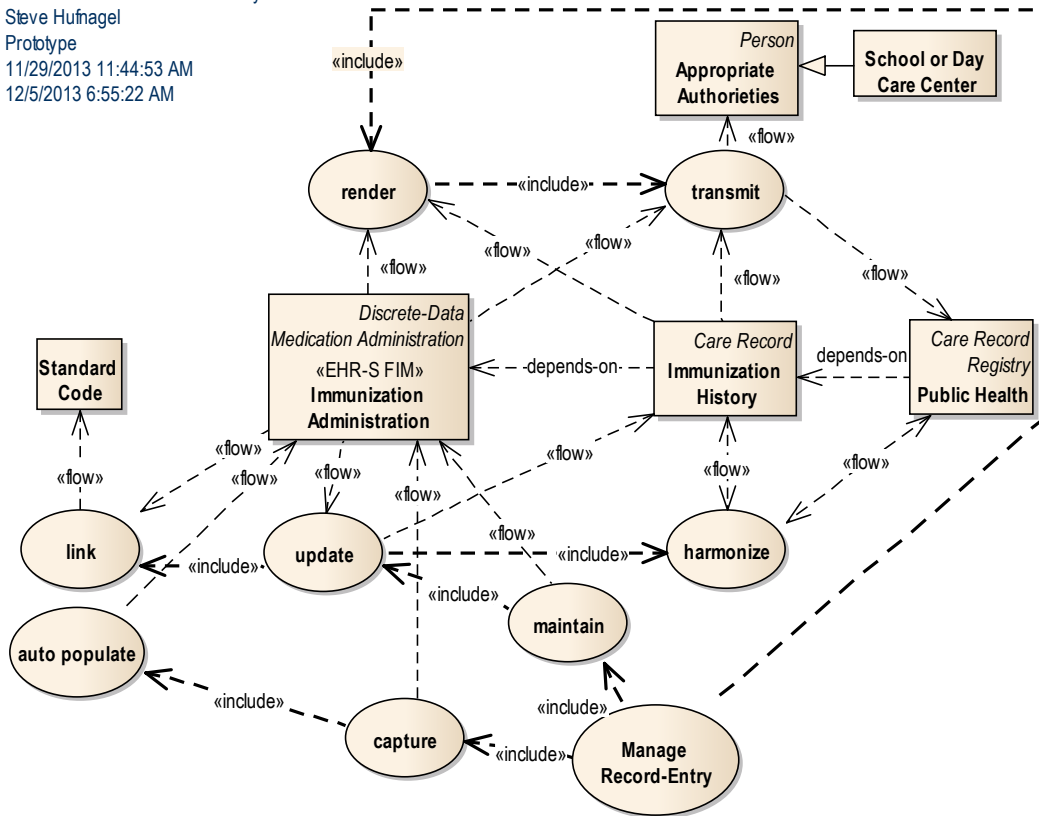
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139 **Figure 8 CP6.2 Immunization-Management System-Actions Use-Case**

class FHIR-FHIM High-Level Specification for Allergy, Intolerance and Adverse Reaction

The EHR-S FIM release-3 objective is for an analyst-or-architect to use the EA-tool to
1. Create a <u>use case</u> 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

«EHR-S FIM»
Allergy, Intolerance & Adverse Reaction

FHIR International Specifications

«FHIR»
AllergyIntolerance

«FHIR»
Symptom

«FHIR»
AdverseReaction

«FHIR»
Exposure

FHIR-FHIM US-Realm-Profile Specifications

«Observation»
IntoleranceConditionEntry

«Observation»
AdverseReactionReportingEvent

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141   **Figure 9 EHR-S FIM-FHIR-FHIM Requirements-Specifications**

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143   <mark>CONCLUSION: **EHR or PHR System Functions**</mark> are defined-by

144   1) **Use-Cases** of System-Actions, which can be UML modelled; where, Use-Case/UML nouns-and-verbs
145   define a lexicon-of
146   a) System-Action-types verb-hierarchy and
147   b) Record-Entry-types data-model; where,

148   2) **Conformance-Criteria** are System-Action Scenario-threads through the Use-Case; where, Scenario-
149   Context is defined by
150   a) pre-condition triggers,
151   b) applicability of
152   i)   SHOULD/SHALL/MAY plus
153   ii) "provide-the-ability-to" or "directly"
154   c) post-condition Business-Rules, according-to scope-of-practice, organizational-policy, jurisdictional-law,
155   and patient-preferences; where,

156   3) **Information-Exchanges** are defined-by Conformance-Criteria Scenarios mapped to
157   a) **FHIR** (Fast Healthcare Interoperability Resource) representative of the Internaltional-Realm,
158   b) **FHIM** (Federal Health Information Model) representative of US-Realm FHIR-profiles,

159   c) **IHE** behavioral-protocals, refined by,

160   i) **local-workflow** behavioral-protocols and associated

161   ii) **Key Performance Parameters** (KPPs); thereby,

162 4) **Profiles** are specified by sets-of System-Functions and their further-constrained context; where,

163 5) **Interoperability-Specifications** can then be generate for Profiles.

164

165 ==ACTION==: HL7 Board approve EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRS-FIM

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167 # October 2013 Summary

168 For details see http://wiki.hl7.org/images/d/d9/HL7_EHR-WG_Summary-Presentation_2013-10-31-Final.pdf

169

170 ## 2013-10-29 (Tu) 3-4 PM ET EHR WG

171 1) Gary Dickinson returned from the ISO meeting in Sydney, Australia and reported that

172   a) **ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1** is under ballot to be

173   consistent with HL7 EHR-S FM r2. Ballot comments are due by December 2013

174   b) **Health informatics - Electronic Health Record Communication (EN 13606)** European Standard is being updated

175   to define a rigorous and stable information architecture for the communicating part or all of the Electronic Health

176   Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components

177   that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed

178   objects:

179   i) Stan Huff and Thomas Beal are updating sections 2 and 3 to be consistent with the CIMI initiative.

180   ii) EHR-S FM and ISO EN 13606 lifecycle events should be made consistent

181   c) *Nicholas* Oughtibridghe, UK National Health Service http://systems.hscic.gov.uk/ , is updating the CONTsys

182   http://www.contsys.net/ European Standard EN 13940 "Health Informatics - System of concepts to support continuity

183   of care". This standard has now been passed by CEN to the ISO Technical Committee 215 to be further developed

184   as a multi-part International Standard as well as a European Standard, with a broadened scope that beyond basic

185   concepts, also includes process-related ones. Inquiries should be made to nicholas.oughtibridge@nhs.net

186   i) EHR-S FIM r3.0 should be made consistent with EN 13940.

187   d) HL7 has been invited to comment on EN 13606 and EN 13940; where, John Quinn is distributing the drafts to

188   interested reviewers.

189 2) Don Mon notes that the NIST Report 7804 ("Technical Evaluation, Testing, and Validation of the Usability of Electronic

190   Health Record", February 2012) is "chock full" of information related to functional requirements.

191 3) Anneke and William Grossen and Michael van der Zel are upgrading the EHR-S FM r2 model, which is hosted

192   in Sparx Enterprise Architect to support the creation of profiles, using the tool.

193   a) Project contact is John Ritter; johnritter1@verizon.net

194   b) For information, go to EHR-S FM Profile Tool Project Wiki ,

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196 ## 2013-10-29 (Tu) 2-3PM ET EHR Interoperability WG Technical-Summary

197 1) **2013-10-29 RI.1.1.1 Originate and Retain Record Entry** was analyzed

198   a) Conformance Criteria (CCs) were restructured into

199   i) pre-condition, EHR-S manager(s) (actions, entities), post-condition (see separate RI.1.1.xlsx spread sheet)

200 2) **COMMENTS / OBSERVATIONS**:

201   a) **ACTION**: Let's prototype CP.6.2 and RI.1.1.1 for EHR WG comment-and-review" [Gary]

202   b) "We should introduce managers and Data Models" [Gary]   see "Notional Description (Scenario)" below

203   c) RecordEvent DateTime should include Occurred-DataTime, Reported-DataTime, Entered-DataTime [Gary]

204   d) EHR-S contains sets-of (Record, Event, Signature), organized-into encounters, lists, documents. [Gary & Steve]

205   3) **RI.1.1.1 Notional Description (Scenario)**: The Record Entry Manager can *Capture, Create, Copy, Record,*

206   *Transcribe*, *Identify, Link, Tag, Encode, Mirror, Integrate* Record-Entry structured-data or unstructured-data and link-

207   to associated Event-Metadata and Signature; where,

208   4) The **pre-condition** "for each Record Entry"

209   a) If the system is down, the Record Information (Action instance-and-context) SHALL be recordable.

210   5) The **post-conditions** "for each Record Entry"

211   a) The record entry SHALL corresponds to an external Action instance-and-context,

212   b) RI.1.1#01 The system SHALL conform to function RI.1.2.1 (Manage Record Entries) as the final step to conclude each Record Lifecycle Event

213   in RI.1.1 (Record Lifecycle) and all child functions.

214   c) If the system was down; then, the Record Information SHALL be Transcribed into a Record Entry; where

215   i) *Transcribed* Record Entry should be *Integrated*

216   d) Record Entry SHALL have a unique Instance-Identifier

217   e) Record Entry SHALL be structured-or-unstructured

218   f) Record Entry may be *Copied* from another Record Entry; where,

219   i) *Copied* Record Entry should be linked to the source's Event-Metadata

220   g) Record Entry SHALL be linked to the Signature-Event of the Origination Entry-Author

221   h) Unstructured Record Entry may be tagged

222   i) Record Entry may be a standard-based Data Object

223   j) Record Entry may *Mirror* a standard-based Data Object

224   k) Event Date-Times should include time of event: occurrence, reported, record-entry

225   l) Record Entry should be managed according to scope of practice, organizational policy and/or jurisdictional law.

226   6) **QUESTIONS / ISSUES / ACTIONS**:

227   a) **ISSUE (consistency)**: When a function defines a context (Create record), should it be consistently be stated as a CC

228   pre-condition (trigger) or implicitly be assumed [Steve].

229   b) **ISSUE**: What is the scope of a Record Entry?

230   i) Is it an encounter record?

231   ii) Is it a Data Module (e.g., FHIR Immunization data module)?

232   iii) Is it a Data Element?

233   c) **ISSUE**: Guideline to use/distinguish EHR-S FM verb-hierarchy vs. EHR-S FM Lifecycle-event verbs?

234   d) **ACTION**: Entity (concept nouns) need to be consistently used and defined in a data dictionary.

235   e) **ACTION**: Manager Operations (e.g., verbs) need to be defined is a data dictionary

236   i) **ISSUE**: What does it mean to *Integrate* Record Entries?

237   f) **ACTION**: UML Model of the Function's Entities and Manager(s) needs to be done (√ done for RI.1.1.1 below)

238   g) **ACTION**: Do a similar analysis-document for CP.6.2 (Immunization Management)

239   h) **ACTION**: Model-and-map FHIR to CP.6.2 and RI.1.1.1

240   i) **ACTION**: Model-and-map CONTsys Entities (concept-nouns) to CP.6.2 and RI.1.1.1

241   j) **INITIAL CONCLUSION & ISSUE:** Building an UML Model of Managers and Data-Modules and creating a structured

242   notional scenario for each function appears to be an effective way to make the overall model consistent; but,

243   i) Maintaining **traceability** from Function and UML class model operations and attributes (Managers & Data

244   Module elements) will be important as changes in structure of the EHR-S FM conformance criteria occur.

245   ii) Additionally, we need to develop the data dictionary and CONTsys mapping

246   iii) Initial thoughts suggest that this can best be done with an enormous Excel Workbook and set of worksheets.

247   (1) **Workbook 1:** UML Model Class attributes & operations mapped-to EHR-S FM r2.0 Functions and CCs

248   **(a)**   **This is the primary r2 Function-model to UML-model traceability**

249   **(i)**   (Column "A"): <u>Class Name</u>

250   **(ii)**   (Column "B"): <u>Class</u> attributes mapped-to EHR-S FM r2.0 LOCAL CC#

251   **(iii)** (Column "C"): <u>Class</u> *operations* mapped-to EHR-S FM r2.0 LOCAL CC#

252   **(iv)** (Row 1) EHR FM r2 Function # and LOCAL Conformance Criteria (CC) #

253   (b)   Excel row-column Intersections coded with Shall, should, may (S, s. m)

254   (c)   Function # CC # linked-to full Function Name and CC in separate workbook

255   (d)   Excel functions and classes roll-ups   to simplify model use

256   (e)   Excel EHR-S FM r2.0 5-sections roll-ups   to simplify model use

257   **(2) Workbook 2** UML Model Class attributes & operations mapped to EHR-S FIM r3.0 Functions and CCs

258   **(a)**   **This is the primary r3 Function-model to UML-model traceability**

259   **(i)**   (Column "A"): <u>Class Name</u>

260   **(ii)** (Column "B"): <u>Class</u> attributes mapped-to EHR-S FM r3.0 LOCAL CC#

261   **(iii)** (Column "C"): <u>Class</u> *operations* mapped-to EHR-S FM r3.0 LOCAL CC#

262   **(iv)** (Row 1): EHR FIM r3.0 UNIVERSAL Conformance Criteria #

263   **(3) Workbook 3** EHR-S FM r2.0 Functions and LOCAL Conformance Criteria (CC)

264   **(a)**   **This is the full r2 model**

265   **(i)**   (Column "A"): **<u>EHR-S FM</u> Function #**

266   **(ii)** (Column "B"): **<u>EHR-S FM</u> Function Statement**

267   **(iii)** (Column "C"): **<u>EHR-S FM</u> CC #**

268   **(iv)** (Column "D"): **<u>EHR-S FM</u> CC Statement**

269   **(4) Workbook 4** EHR-S FIM R3.0 Functions and UNIVERSAL Conformance Criteria (CC)

270   **(a)**   **This is the full r3 model**

271   **(i)**   (Column "A"): **<u>EHR-S FM</u> Function #**

272   **(ii)** (Column "B"): **<u>EHR-S FM</u> Function Statement**

273   **(iii)** (Column "C"): **<u>EHR-S FM</u> CC #**

274   **(iv)** (Column "D"): **<u>EHR-S FM</u> CC Statement**

275   **(5) Workbook 5** EHR-S FM r2.0 Functions and CCs mapped-to EHR-S FIM r3.0 Functions and CCs

276   **(a)**   **This is the primary r2 to r3 traceability**

277   **(i)**   (Column "A"): EHR FIM r3 Function # and UNIVERSAL Conformance Criteria (CC) #

278   **(ii)** (Row 1): EHR FM r2 Function # and LOCAL Conformance Criteria (CC) #

279   **(6) Workbook 6** Master Data Dictionary (MDD) (If we use FHIR or FHIM; then, MDD is already done by FHIR & FHIM teams)

280   **(i)**   (Column "A"): <u>Class Name</u>

281   **(ii)** (Column "B"): <u>Class</u> attributes

282   **(iii)** (Column "C"): <u>Class</u> *operations*

283   **(iv)** (Column "D"): Data Dictionary Definition

284   **(7) Workbook 7** EHR-S FM UML-Model mapped-to FHIR (optional)

285   **(8) Workbook 8** EHR-S FM UML-Model mapped-to FHIM (Federal Health Information Model) (optional)

286   **(9) Workbook 9** FHIR mapped-to FHIM (Federal Health Information Model) (optional)

287   **(10) Workbook 10** EHR-S FM UML Model mapped-to FHIR (optional)
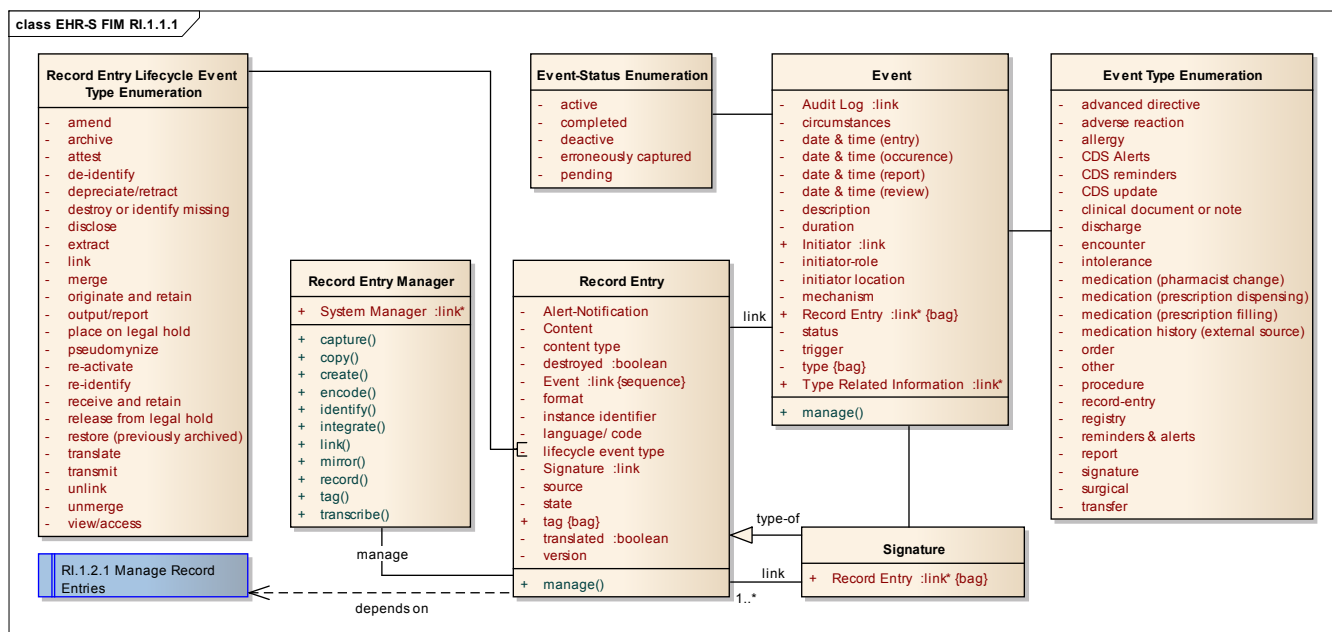
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Figure 10 EHR-S RI.1.1.1 Originate and Retain Record Entry (Logical Data and Manager View)

INTERIM CONCLUSION 1: So far, in the EHR-S FM Resource Infrastructure (RI) section, we have only looked at the RI.1.1.1 function; yet, in Figure 10 EHR-S RI.1.1.1 Originate and Retain Record Entry (Logical Data and Manager View) we can see that the concepts of a common <u>Event</u>, <u>Record Entry</u> and <u>Record Entry Manager</u> are emerging; where, the <u>Record Entry Manager</u> can **Capture, Create, Copy, Record, Transcribe**, **Identify, Link, Tag, Encode, Mirror, Integrate** <u>Record-Entry</u> structured-data or unstructured-data and link-to associated <u>Event-Metadata</u> and <u>Signature</u>. This shows the advantage of creating an EHR-S <u>Function</u> and <u>Information</u> Model, which defines a consistent-set of data-modules (e.g., classes) and managers, which are associated with appropriate EHR-S Functions.

<div align="center">

Telecom Discussion 18 October 2013

</div>

1) EHR-S FM r2.0 Meaningful Use Profile methodology was presented for new attendees ny Hetty Khan.
2) Julie Roberts and Hetty Khan iare taking the 50 test procedures from HHS on MU2 and mapping back to the r2 FM functions.

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Telecom Discussion 11 October 2013

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4) Gary Dickinson returned from the ISO meeting in Sydney, Australia and reported that
   a) **ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1** is under ballot to be consistent with HL7 EHR-S FM r2. Ballot comments are due by December 2013
   b) **Health informatics - Electronic Health Record Communication (EN 13606)** European Standard is being updated to define a rigorous and stable information architecture for the communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:
      i) Stan Huff and Thomas Beal are updating sections 2 and 3 to be consistent with the CIMI initiative.
      ii) EHR-S FM and ISO EN 13606 lifecycle events should be made consistent

317   c) *Nicholas* Oughtibridghe, UK National Health Service http://systems.hscic.gov.uk/ , is updating the CONTsys
318   http://www.contsys.net/ European Standard EN 13940 "Health Informatics - System of concepts to support continuity
319   of care". This standard has now been passed by CEN to the ISO Technical Committee 215 to be further developed
320   as a multi-part International Standard as well as a European Standard, with a broadened scope that beyond basic
321   concepts, also includes process-related ones. Inquiries should be made to nicholas.oughtibridge@nhs.net
322   i) EHR-S FIM r3.0 should be made consistent with EN 13940.
323   5) HL7 has been invited to comment on EN 13606 and EN 13940; where, John Quinn is distributing the drafts to interested
324   reviewers.

2013-10-29 (Tu) 2-3 PM ET EHR Interoperability WG, Topic: EHR-S FIM r3.0

327   1) **2013-10-15 CP.6.2 Immunization Management** was analyzed
328   2) **Objective**: Create a clear, complete, concise, correct and consistent EHR-S Function and Information Model (**EHR-S FIM**
329   r3.0) from EHR-S FM r2.0, which is HL7 ballot-publishable from Sparx Systems Enterprise Architect tool.
330   a) Conformance Criteria (CCs) were restructured into
331   i) pre-condition, EHR-S manager(s) (actions, entities), post-condition (see separate CP.6.2.xlsx spread sheet)
332   b) **COMMENTS / OBSERVATIONS**:
333   i) **ACTION**: Let's prototype RI.1.1.1 for comparison of CCs in a different section of the model [Steve]
334   3) **CP.6.2 Notional Description (Scenario):** The System Manager can *Capture, Auto-populate, Maintain, Render,*
335   *Transmit, Exchange, Harmonize, Update, Determine* Immunization Administrations, Events, Schedules, Plans and
336   Educational Materials; where,
337   a) The **pre-condition** "The System provides the capability to"
338   i) SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization
339   administration (e.g., vital signs).
340   ii) SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
341   iii) SHALL conform to function CP.1.6 (Manage Immunization List).
342   iv) SHALL *Capture* an Immunization Administration; where, an Immunization Administration Record Entry contains details as discrete data,
343   including:
344   (1) immunization name/type, series, strength and dose
345   (2) date and time of administration
346   (3) manufacturer, lot number, expiration date
347   (4) route and site of administration
348   (5) administering provider
349   (6) observations, reactions and complications
350   (7) reason immunization not given
351   v) SHALL *Determine* and *Render* Required Immunizations; where, Required Immunizations includes when they are due, based on widely
352   accepted immunization schedules, when *Rendering* encounter information.
353   vi) SHALL *Maintain* a Patient specific Immunization Schedule.
354   vii) SHALL *Render* a Patient's Immunization Administration History upon request from appropriate authorities such as schools or day-care
355   centers.
356   viii) SHALL *Render* an Immunization Order as written (e.g., exact clinician order language or as mandated - such as by a public health
357   requirement), when rendering administration information.
358   ix) SHALL *Determine* due-and-overdue Immunization Orders including earliest through latest date ranges and *Render* a Immunization
359   Order Notification according to organizational policy and/or jurisdictional law.
360   x) SHALL *Render* a Patient Immunization Administration Educational Information regarding the administration (e.g., Vaccine Information
361   Statement (VIS)).
362   xi) SHALL *Capture* that Patient Immunization Administration Educational Information (e.g., VIS) was provided at the time of immunization
363   administration.
364   xii) SHOULD *Update* Patient's Immunization Administration History at the time of capturing an immunization administration.
365   xiii) SHOULD *Capture*, in an Immunization Administration discrete-field, an Allergy/Adverse Reaction to a Specific Immunization
366   Administration.
367   xiv) SHOULD *Link* Standard Codes (e.g., NDC, LOINC, SNOMED or CPT) with discrete data-elements associated with an Immunization
368   Administration.

369 xv) SHOULD **Transmit** required Patient Immunization Administration information to a public health immunization registry according to scope
370 of practice, organizational policy and/or jurisdictional law.
371 xvi) SHOULD **Exchange** Patient Immunization Administration History with public health immunization registries according to scope of
372 practice, organizational policy and/or jurisdictional law.
373 xvii) SHOULD **Harmonize** Patient Immunization Administration History with a public health immunization registry according to scope of
374 practice, organizational policy and/or jurisdictional law.
375 xviii) SHOULD **Capture** and **Render** Patient Immunization Administration History from a public health immunization registry.
376 xix) SHOULD Capture that Patient Immunization Administration Educational Information (e.g., VIS) including to whom the information was
377 provided and the date/ time that it was provided.
378 xx) SHOULD **Capture** and **Maintain** immunization refusal reasons as discrete data.
379 xxi) SHOULD **Capture** Patient-Immunization Administration-Preferences regarding receipt of immunization (e.g., refusal of certain vaccines)
380 at time of immunization administration.
381 xxii) MAY auto-populate the immunization administration record as a by-product of **Verification** of Administering Provider, Patient, Medication,
382 (dose, route) and Time.

383 b) The **post-conditions** "The System provides the ability to"
384   i) SHALL be managed according to scope of practice, organizational policy and/or jurisdictional law.

385 4) **QUESTIONS / ISSUES / ACTIONS**:
386   a) **ISSUE**: It is important to separate the system capabilities vs. policies, which may change.
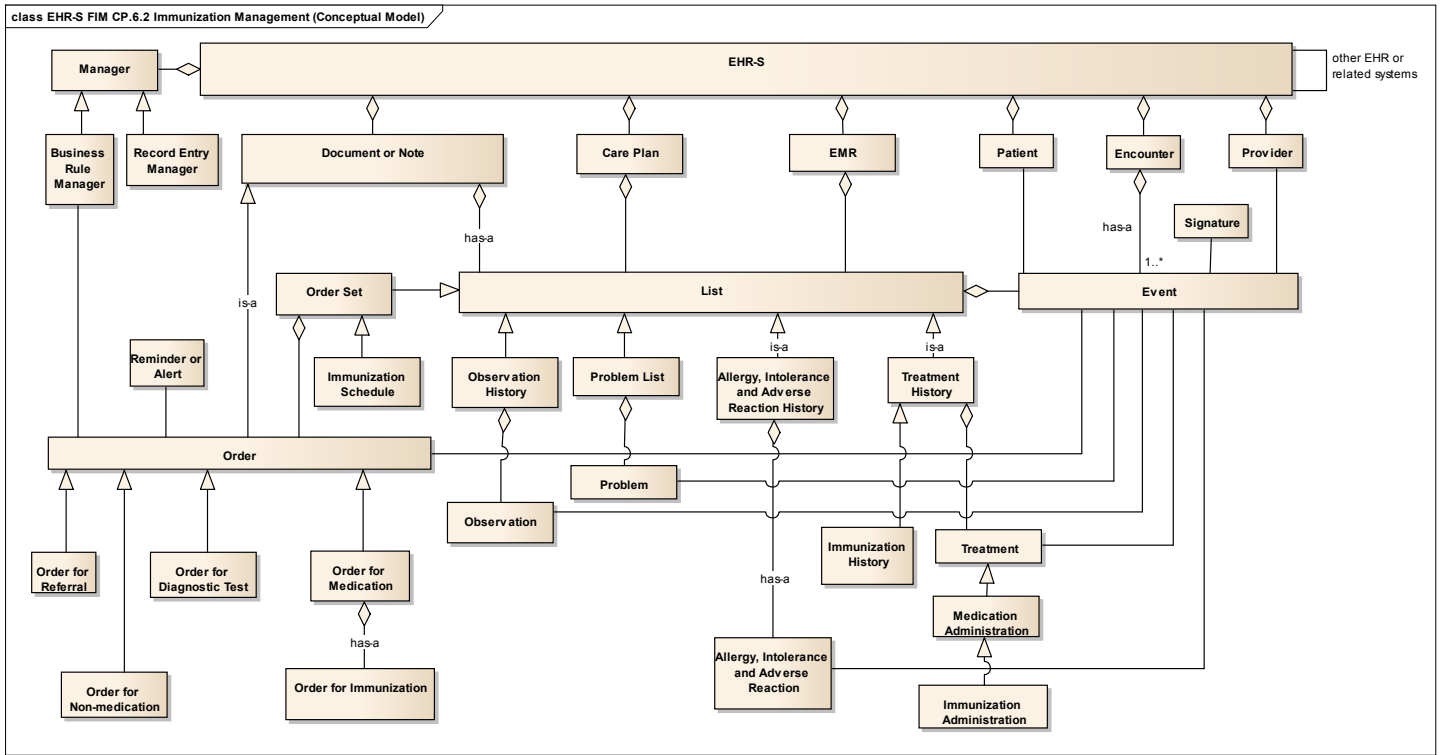
387
388 **Figure 11 EHR-S Conceptual View for CP.6.2 Immunization Management**

389 **INTERIM CONCLUSION 2**: In the CP section, we have looked at medication management, orders
390 management and Immunization management. We can see that Figure 11 EHR-S Conceptual View for CP.6.2
391 Immunization Management is generally applicable for all of the Care Provisioning (CP) section of the EHR-S FM;
392 where, minor element additions and modifications will likely occur as we analyze the rest of the CP section; but,
393 we can already see an 80% to 90% view.

394

395 **INTERIM CONCLUSION 3**: So far, in the EHR-S FM Care Provision (CP) section, we have only modeled the
396 medication management, orders management and Immunization management functions; yet, in Figure 12

397 CP.6.2 Immunization Management (Logical Data and Manager View) we can see that substantially more
398 immunization-applicable data-elements are available than were defined by CP.6.2 alone. This shows the
399 consistency-advantage of creating an EHR-S Function-and-Information Model, which defines a consistent-set of
400 data-modules (e.g., classes) and associates them with appropriate EHR-S Functions.

401

402 We can also see a high level EHR System defined as a set of Patients, Providers, External Partners, Encounters,
403 EMRs, Care Plans, Lists , Managers, Documents and Notes; where, the EHR-S Manager can **Capture, Auto-**
404 **populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine** the RI.1.1 Record Entry content, which
405 in CP.6.2 is Immunization Administrations,   Events, Schedules, Plans and Educational Materials. Because of the ad-hoc
406 nature of the EHR-S FM r2.0 creation, we cannot be sure that the attributes or operations for any class are fully populated until
407 the entire EHR-S FM r2.0 has been modeled.

408
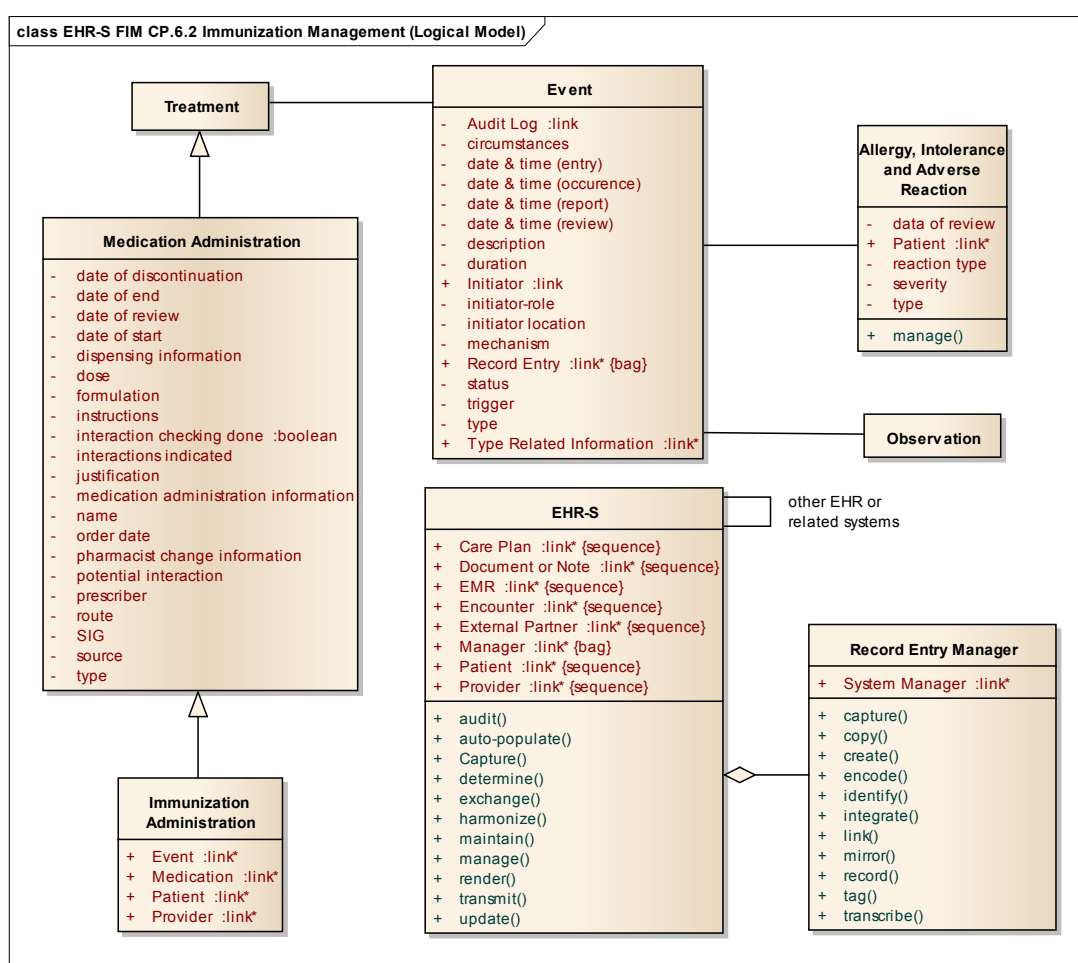
410 **Figure 12 CP.6.2 Immunization Management (Logical Data and Manager View)**

411

412 **September 2013**

413 **See "CIMI and HL7 Trip Report",** Cambridge, MA, 20-26 September 2013, Stephen Hufnagel,
414 SHufnagel@tiag.net, dated 3 October 2013