December 2013
EHR Work-Group (EHR WG)

Last Updated on Dec 18, 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 versions of EHR WG Presentations-and-Reports are available at:

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

EXECUTIVE SUMMARY
HL7 EHR-S and PHR-S FIM Release-3

This executive-summary specifically addresses EHR-S and PHR-S FIM capabilities and/or trends, which impact the VA, DOD and IPO "EHR Modernization" mission needs.
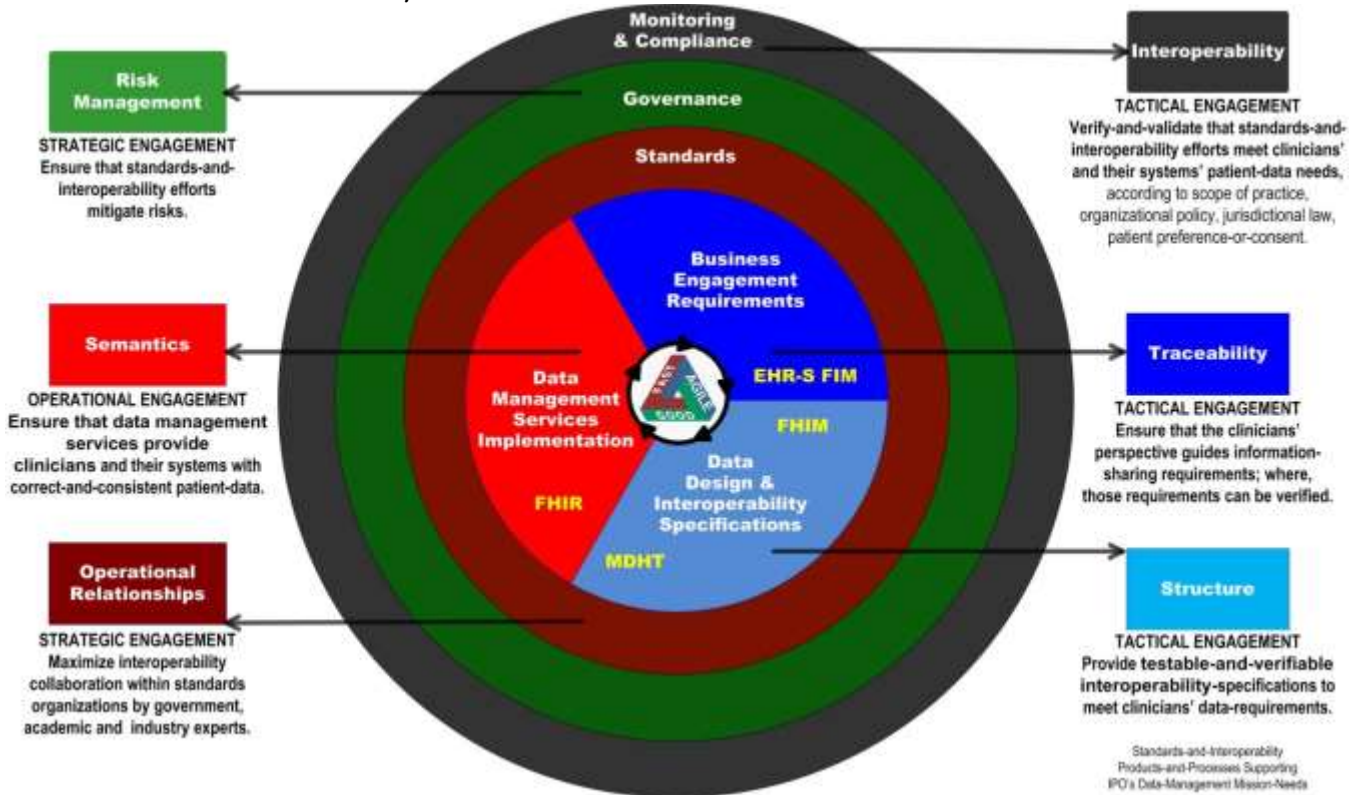

Figure 1 EHR and PHR System Data-Management Mission-Needs

INTRODUCTION: HL7 EHR-S FIM (Function–and-Information Model) release-3 PSS (Project Scope Statement) #688 was approved in January 2012; where, '2017 EHR-S and PHR-S FIM release-3 (r3) follows an agile-process to formally-structure EHR functional-requirements and add data requirements-specifications to the '2014 release-2 EHR-S and PHR-S FM. Additionally, reusable business-process use-case, scenario and interoperability-specification capabilities, Meaningful-Use stage-2 criteria, International **FHIR** (Fast Healthcare Interoperability Resources) and US Realm **FHIM** (Federal Health Information Model) are being incorporated into the EHR-S and PHR-S FIM Reference Model; where,

- EHR-S FIM capabilities are resident in the Sparx EA (Enterprise Architect) tool.
- HL7 EHR-S and PHR-S FIM r3 is being designed to directly support the Figure 1 EHR and PHR System Data-Management Mission-Needs.

The *purpose* of this report is to document the release-3 FIM Mission-Needs-Statement[1], EHR-S and PHW-S FIM development and related projects[2]; where monthly report-content is refined; until ultimately, EHR-S and PHR-S FIM profile requirements-specifications can be generated by the EHR-S FIM tool as a demonstration of the release-3 FIM "Easy-Button" Interoperability-Specification report-generation capability. All EHR WG release-3 FIM working-draft documents are published at http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG.

LEGEND:

1) Capitalized and Underlined nouns-and-adjectives are Record-Entry 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 Electronic Health Record (**EHR**) Work Group (**WG**) 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 EHR Interoperability WG 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**
   o create a clear, complete, concise, correct, consistent and easy-to-use; because,
   o **HL7 ballot-publishable from the Sparx Systems Enterprise-Architect tool**
   o **targeted for 3-to-5 years from now; because,**
     ▪ **joint ISO-HL7 ballots are very challenging to manage and**

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[1] The EHR-S FIM **MNS** (Mission Needs Statement) identifies "EHR-S Modernization" lifecycle-needs,
- that are optimally-satisfied by the EHR-S FIM tool-and-processes;
- where, the EHR-S Modernization lifecycle includes requirements-specifications, acquisition or development, test and certification and sustainment phases;
- where, EHR-S Modernization processes include data-related management, monitoring-and-compliance, governance, requirements-outreach, doctrine, organization, training, materiel, leadership-and-education, personnel-and-facilities (DOTMLPF).

[2] EHR-S FIM Related-profile-projects include:
1. RMES (Resource Management and Evidentiary Support)
2. MU2 (Meaningful Use stage 2)
3. Usability
4. PHR (Personal Health Record)

- **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 EHR Interoperability WG is to produce a Meaningful Use profile for EHR-S FM r2 and r3.
- 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.
- The *objective* of the EHR Usability Project 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

An EHR/PHR **Concept-of-Operation** (CONOPS) was defined-and-refined into a System **Reference-Model** (RM)**;** where,

1) **System Functions** are defined-by **Use-Cases**; 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) **Requirements** Conformance-Criteria are defined-by use-case scenarios; where,
   Scenarios define **business-context** and **subject-verb-object-terminology bindings**; where,
3) **Business-Context** defines pre, post and invariant conditions; where,
   a) **pre-condition** are triggers, followed by
   b) **applicability**; where,
      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 manage-hierarchy verb applies and
         (2) a use-case constrained data-model noun 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, profiled-with
   b) **FHIM** (Federal Health Information Model) specifications, for the US-Realm, bound to
      - **Terminology value-sets**,
   c) **IHE information-exchange behavioral-protocols** refined by,
      - **SLA** and **DURSA** *(Service-level-agreement and 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.

The **benefit** of this formally-specified **Concept-of-Operation** (CONOPS) and **Reference Model** (RM) is a clear, complete, concise, correct and consistent Function-and-Information Model (FIM), profiles and resultant Interoperability-Specifications (ISs).

ACTIONS

Release-3 EHR-S and PHR-S FIM
Table 1 Plan-of-Actions & Milestones Dashboard

POA&M Task	#	Start	Done	POC	Status-Risks-Mitigations
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,	3	pending			

POA&M Task	#	Start	Done	POC	Status-Risks-Mitigations
Preventive Care and Wellness					
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-Related Identifiers	1	pending			
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 RI.1.1.2 Record Entry Create	25	12-2012	inactive	GD, SH	√ 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
      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
      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, Allergy Intolerance, CarePlan, Family History, 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
- **DFD** Data Flow Diagram
- **EA** Enterprise Architect
- **EHR-S** EHR System
- **EHR-S FIM** EHR-S Function-and-Information Model
- **FHA** US Federal Health Architecture
- **FHIM** US Federal Health Information Model
- **FHIR** Fast Healthcare Interoperability Resources
- **FIM** EHR-S Function and Information Model
- **FIM(MU)** EHR-S FIM Meaningful Use profile

- **FM** Function Model
- **FY** Fiscal Year
- **IHE** Integrating *the* Healthcare Enterprise
- **IM** Information Model
- **MDHT** Model Driven Health 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
- **SDLC** Software Development Lifecycle
- **WBS** Work Breakdown Structure
- **WG** Work Group

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MONTHLY SUMMARIES

(Reverse Chronological Order)

1   December 2013

In December, EHR Interoperability WG focused on

1) *Developing* the Table 1 Plan-of-Actions & Milestones Dashboard.

2) *Demonstrating* FIM r3 EA tool generation of Immunization Mgmt. Interoperability-Specification

3) *Refining* November-2013 models into grammatically-correct use-case and scenario "lexical" model; where, they are developed in Conceptual, Semantic, Syntactic, and Lexical stages; where, each stage is relatively easy-to-understand.

    a. The Conceptual Level is when a user is working on an interactive EHR or PHR system and develops a mental-model; where, the user enters-in input to the system, and the system generates output based on that input. The conceptual level identifies the set of familiar task-oriented system-objects and system-actions the user needs to know about in order to use the system; where, the conceptual model in in terms of objects, relations between objects, actions on objects, attributes of objects and the context in which tasks are done.

    b. The Semantic level describes the meanings between the input and output; where, the Semantic Level documents the Information-Exchange (IE) semantic-specification for each system-action identified in the EHR-or-PHR System-Function Use-Case Model, plus any other actions and constraints which are needed. The IE semantic-specification includes a description of the function, including its Information-and-terminology Model, transport protocol, and potential operational context-and-conditions.

    c. The Syntactic level is a set of rules to create a sentence (e.g., EHR-S and PHR-s FIM Reference Model), which will give a set of system conformance criteria to complete a particular system function; where, the syntactic level identifies the use-case sequence of system "manage" action verbs plus Record-Entry type subjects and objects. A conformance-criteria scenario is a system-function sequence represented by the FIM reference-model grammar. The conformance-criteria scenarios define the set of rules for combining EHR and PHR Record-Entries into a system-function use-case. The output will include spatial and temporal factors, such as those specified in IHE profiles, FHIR, FHIM, CDC implementation guides, Consolidated CDA implementation guides, etc.

    d. The Lexical level deals with Information Exchange (IE) dependencies to specify the exact syntax; where, there are nine key lexical interoperability factors.
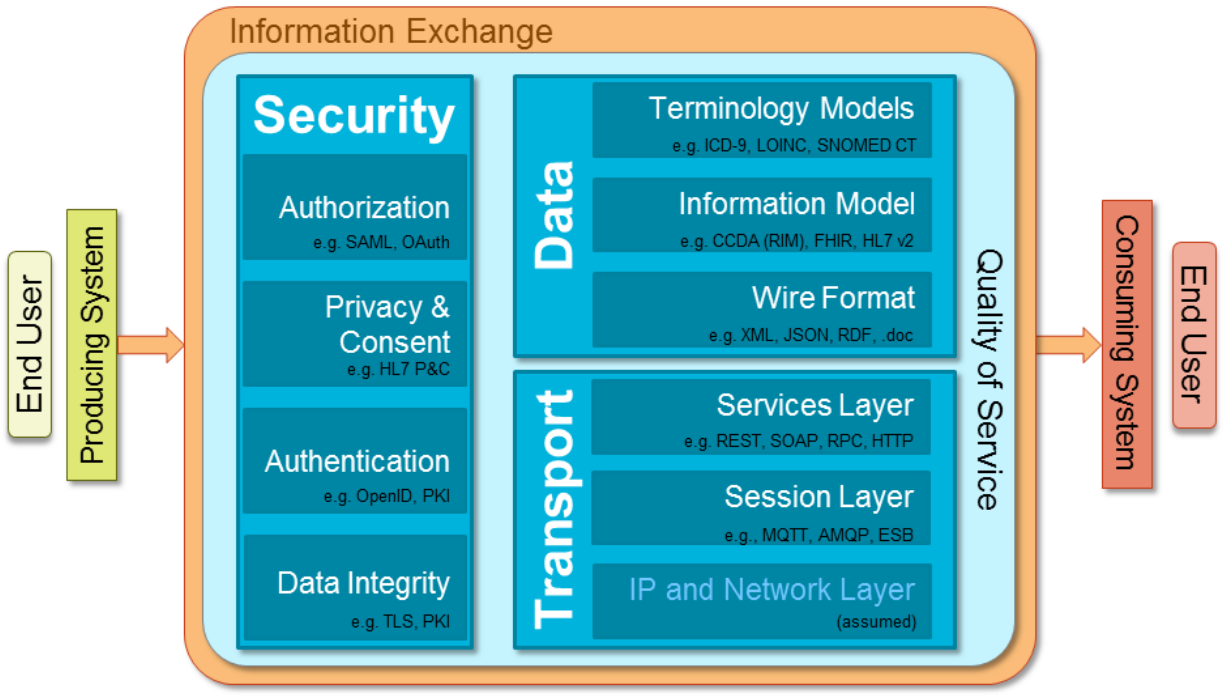
Figure 2 Information-Exchange Model [3]

Figure 2 Information-Exchange Model identifies the three key technical areas and nine factors of consideration required in an Information Exchange Interoperability Specification (**IS**):

1. **Data Content -** The information being communicated between parties, in terms of syntax, semantics, and vocabulary. An IS could allow access to stored data directly (e.g., via a Retrieve, Locate, Update Service (**RLUS**) API, or data derived as the result of processing and transformation (e.g., message, service, or document).
2. **Transport -** How the payload and related items (such as requests, confirmations, subscriptions, and error messages) are moving, inclusive of the technical means, services offered, communication sessions, and transmitting protocols
3. **Security -** How the communication is protected, how parties are positively identified, and determination and enforcement of rights to information.

Generally, Information Exchange Requirements (**IERs**) contain:
- **Need-line Identifier or Description** indicating that one operational node depends on another for service(s) or information and specifies the direction in which the service(s) or information flows; where, a need-line may represent many information exchanges or service dependencies.
- **IER Name and/or Identifier** facilitating IER traceability across the architecture
- **Information Element Content**, including Content name or identifier, Scope, Accuracy, Language, etc.
- **Producer** including Sending Operational (Op) Node Name and Identifier Sending Op Activity Name and Identifier
- **Consumer** including Receiving Op Node Name and Identifier Receiving Op Activity Name and Identifier

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- **Nature of Transaction**, including Mission Scenario task exchange Type (CCD, encounter summary), Triggering Event, Interoperability Level, Required Criticality, applicable standards
- **Performance Attributes**, such as periodicity, timeliness, maximum latency.
- **Information Assurance**, such as Access Control, Availability, Sensitivity, Confidentiality, Dissemination Control, Integrity
- **Security**, such as Accountability, Protection (Type Name, Duration, Date), Classification/Sensitivity, classification caveat, such as VIP, duty type etc.

Scope, Application, and Limitations: This lexical modeling approach creates a top-down framework, which is easy-and-convenient for analysts-and-developers; where, it allows the analysts/developer/implementer user to move from a real-world concept analysis to a system implementation. The System <u>Record-Entries</u> and *manage* system-action concepts-and-functions required to design and implement the EHR and PHR system are modelled and transcribed by use-cases and scenarios. Then the designer can consider how the EHR and PHR concepts-and-functions are expressed at the system information-exchanges. For each function, the use-case and its scenario model direct the analyst, developer and tester to requirements-specifications for the sequence of system-actions that need to be carried out to support a user's functional task, such as immunization management.

CONCLUSION: EHR and PHR System Function-and-Information Model's ultimate success will come from the methodological power resident in the EHR-S & PHR-S FIM tool's virtuosity of expression; where, it is from this methodological context -- combining the methodologies of discovery, invention, and design that the FIM Tool lays down the foundation for an analyst, developer or tester to break down each problem into the conceptual, syntactic, semantic and lexical areas of concentration for modular pieces.

2 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:
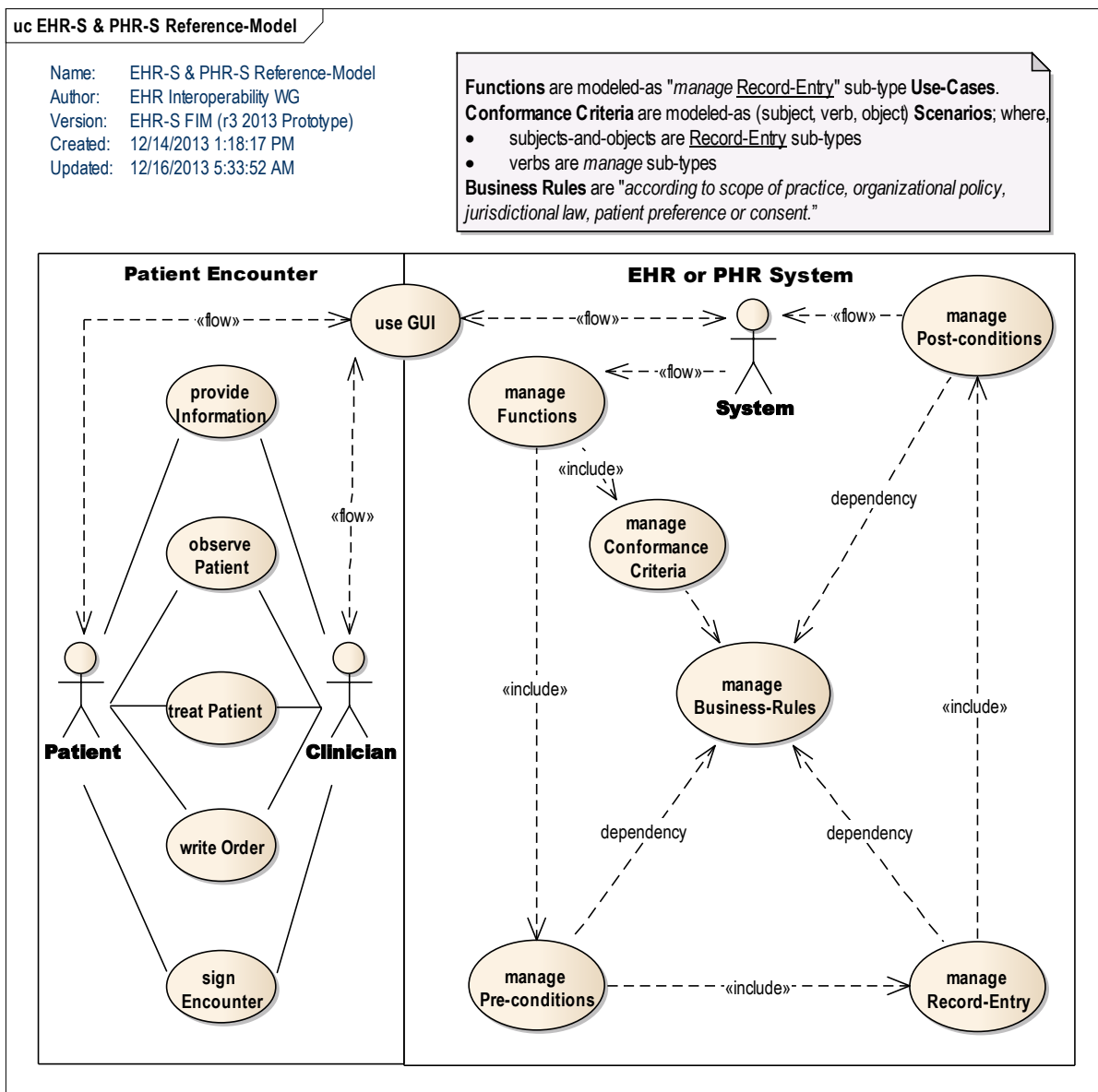
119

Figure 3 EHR-S and PHR-S Reference Model (RM)

120
121
122

123   The **EHR-S and PHR-S Reference Model**[4] [based-on OASIS RM] includes Functions and their Conformance-Criteria; where,

124   1.   Functions are modelled as "*manage* Record-Entry" **Use-Cases**; where, use-cases contain multiple CCs.

125   2.   Conformance-Criteria (CC) are modelled as individual "*manage* Record-Entry" **Scenarios**

126   3.   Clinicians and Patient have Encounters; where, they *use* System-GUIs (Graphical-User-Interface); such that,

127   a.   The Clinicians, Patients or their designated agent may

128   b.   *review* the Patient EMR (Electronic Medical Record) and other types of Information

129   c.   *Observe, treat, write Orders and document* the Patient-Encounter

130   d.   *provide Patient-Information* and Educational-Information

---

[4] 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."

131   e.   *sign* <u>Encounters</u>

132   4. Systems Functions include *manage* <u>Record-Entry</u> Conformance Criteria (CC); where,

133   a. CC Pre-Condition Business-Rules manage entering-data-flows and data-context

134   b. CC Data-management Business-Rules manage applicability

135   • (The System SHALL/SHOULD/MAY "provide-the-ability to *manage*" or "directly-*manage*")

136   c. CC Post-Condition Business-Rules manage exiting-data-flows and data-use

137   d. CC Business-Rules are in-accordance-with

138   scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences.

139

140 **Conformance Criteria Syntax:** A **System-Function (SF) Use-Case** is a constrained-scope and refined-detail System

141 Reference-Model; where, **SF Conformance-Criteria** are System-Action scenario-threads through the SF Use-Case Model containing:

142 1) **SF Invariant-condition** (context)

143   a) System Identifier (EHR or PHR)

144   b) System Function (SF) Identifier

145   c) Profile Identifier

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

147 3) **SF CC Pre-condition** (trigger)

148   a) Pre-condition is a verb-clause.

149   b) After a Human-Action or System-Action; then,

150 4) **SF CC Applicability**

151   a) The System SHALL, SHOULD or MAY

152   i) "provide-the-ability-to*"*

153   ii) "directly"

154 5) **SF CC System-Action Bindings**

155   a) Operation linked-to Data-Type; where, conditionally,

156   b) the *System-Actions depends-on* other-SF

157   c) Data-Type are *associated-with* other Data-Types

158   d) Information Exchange(s) are *linked-to*

159   i)   International Interoperability-Standards (e.g., FHIR)

160   ii)   Realm Interoperability-Specifications (e.g., FHIM)

161   iii) Implementation Guides (e.g., Consolidated CDA)

162   iv) Behavioral Interoperability-Specifications (e.g., IHE)

163   v)   Service Level Agreement (e.g., local workflow)

164 6) **SF CC Post-Condition** (expected-outcome)

165   a) Post-condition is a subordinate-clause.

166   b) "where, the System-Actions are …"

167 7) **SF CC See Also**

168   a) Supporting or related SFs (e.g., Infrastructure)

169   ==ISSUE==: Michael van der Zel suggests we consider using generalization rather-than <<include>> dependency within the verb hierarchy
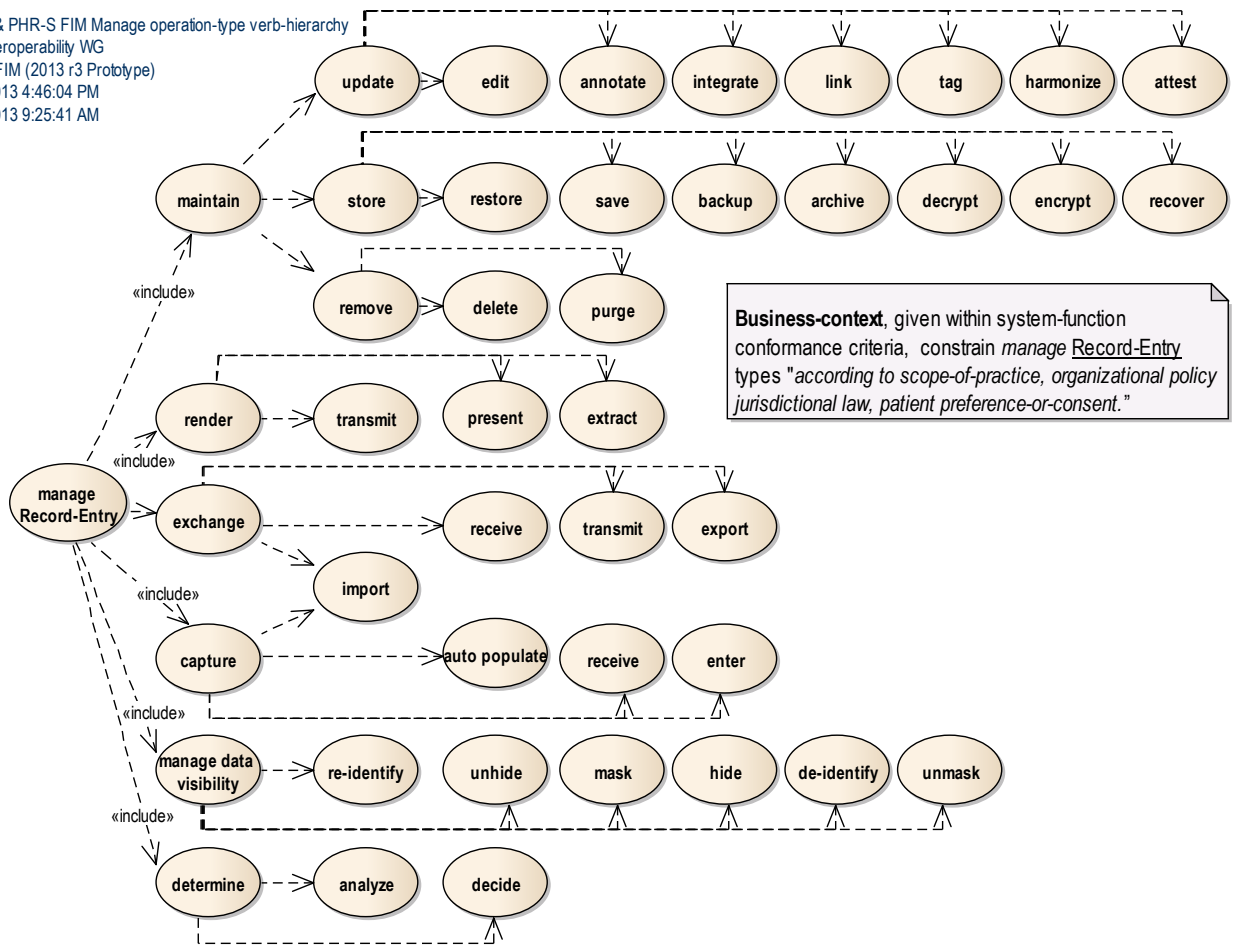
Figure 4 EHR-S and PHR-S FIM Operation-Type Verb-Hierarchy RM

ISSUE: Gora Datta suggests we consider using aggregation within the Record-Entry Data-Types model, for simplicity
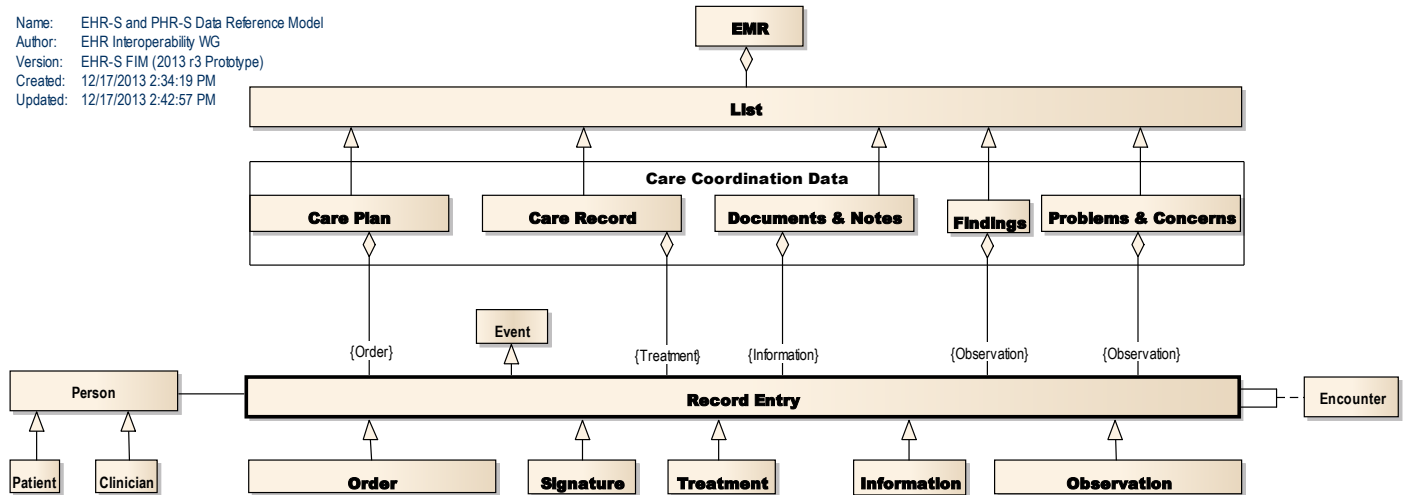

Figure 5 EHR-S and PHR-S FIM Record-Entry Data-Types RM

uc CP.6.2 Use-Case

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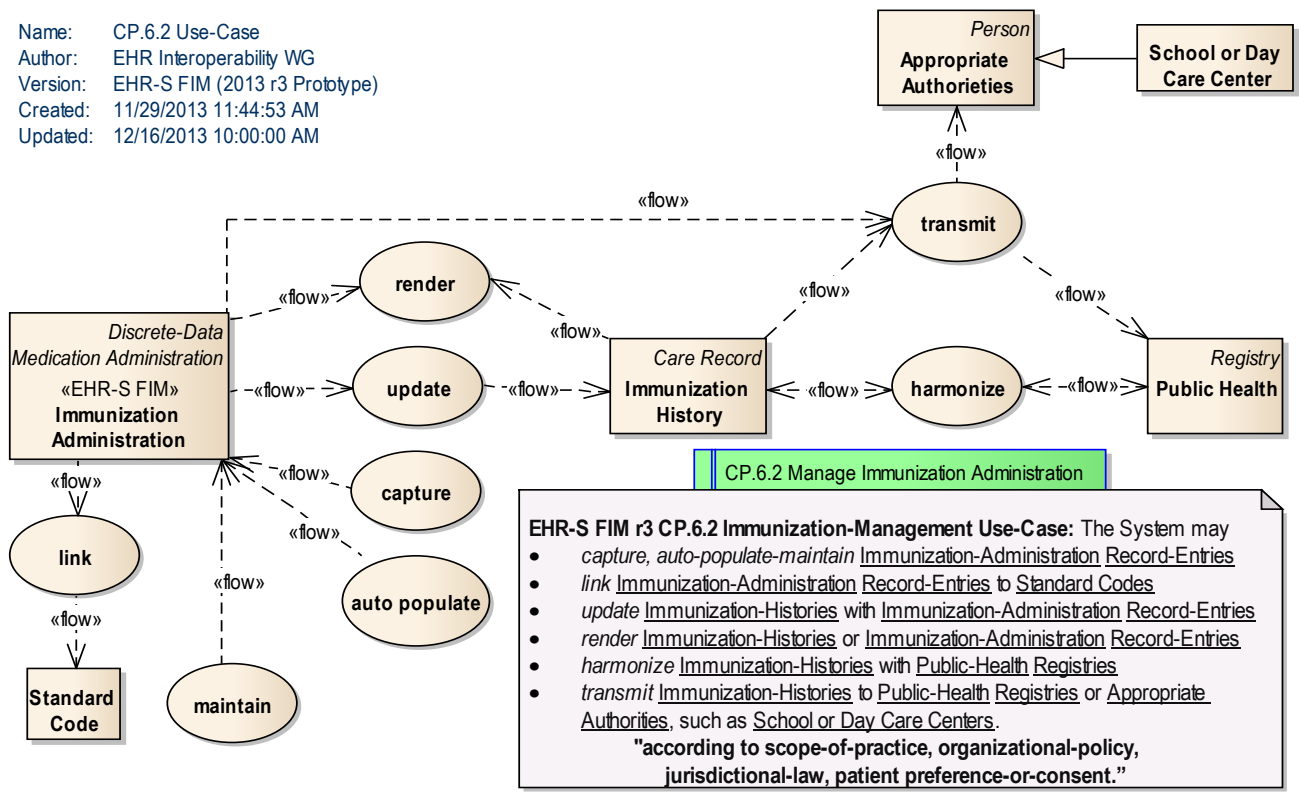Updated: 12/16/2013 10:00:00 AM

CP.6.2 Manage Immunization Administration

EHR-S FIM r3 CP.6.2 Immunization-Management Use-Case: The System may
- *capture, auto-populate-maintain* Immunization-Administration Record-Entries
- *link* Immunization-Administration Record-Entries to Standard Codes
- *update* Immunization-Histories with Immunization-Administration Record-Entries
- *render* Immunization-Histories or Immunization-Administration Record-Entries
- *harmonize* Immunization-Histories with Public-Health Registries
- *transmit* Immunization-Histories to Public-Health Registries or Appropriate Authorities, such as School or Day Care Centers.
"according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent."

177
178   **Figure 6 Example CP.6.2 Immunization-Management Use-Case**
179   The Release-3 EHR System Immunization-Management Function Use-Case includes

180   1) **A Clinician *uses* the EHR-S, during an Encounter, to**
181   a) *review* EMR, Alerts-and-Notifications
182   b) *enter* Observations, Treatments, Orders and associated Documents and Notes
183   c) *sign* the Encounter
184   d) **Immunization Management involves the following:**
185   i) **System-Actions:** *auto-populate, capture, determine, exchange, harmonize, link, maintain, manage, render,*
186   *transmit, update; where,*
187   (1) Immunization-Administration is
188   (a) *linked* with Standard-Codes
189   (b) *transmitted* to Population Health Registries
190   (c) *auto-populated as* a by-product of verification of Administering-Provider, Patient, Medication, Dose,
191   Route and Time.
192   (2) Immunization-History is
193   (a) Updated-with the Immunization-Administration Record-Entries
194   (b) *harmonized* with Public-Health Registries
195   (c) *rendered* and *transmitted; where,*
196   (i) transmitted to Appropriate Authorities (e.g., Schools and Day Care Centers);
197   ii) **Data:** Immunization-Administration, Immunization-History, Public-Health Registry
198   iii) **Associated Data:** Alerts-and-Notification, Allergy-Intolerance-or-Adverse-Event, Patient-Clinical-
199   Measurement, Patient-Directive, Immunization-Schedule, **Patient**-Educational-Information, Signature.
200   e) Where all System-Actions are "according to scope-of-practice, organizational-policy, jurisdictional-law, patient
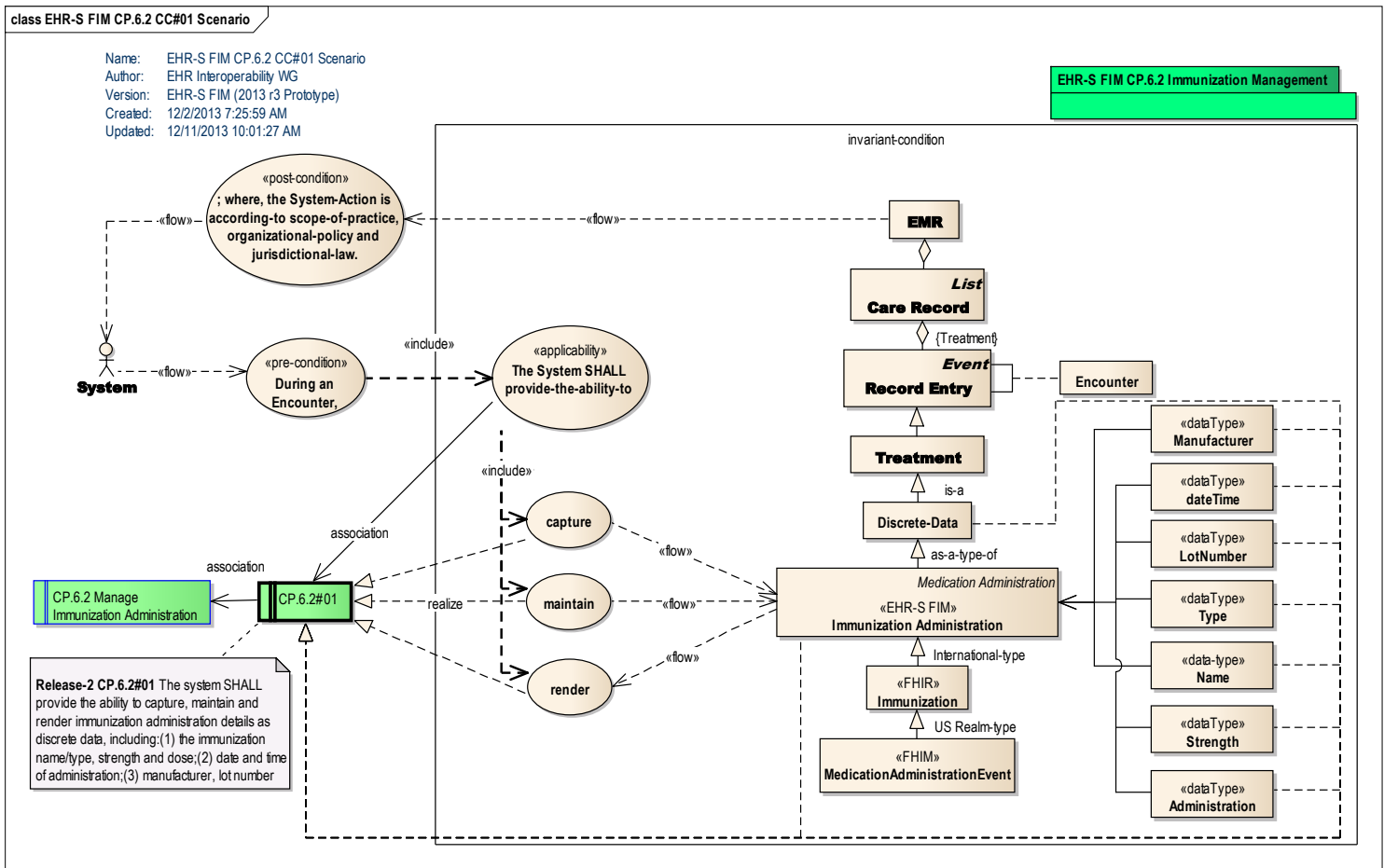201   preference-or-consent."

202

Figure 7 Example CP.6.2 CC#01 Immunization-Management Scenario

206 CP.6.2#01 During an <u>Encounter</u>, the system SHALL provide-the-ability-to *capture, maintain and render* Immunization
207 Administration; where,

- 208 • Treatment <u>Record-Entry</u> details are as discrete-data, including
  - 209 – immunization name/type, strength and dose; date-and-time of administration;
  - 210 – manufacturer, lot number
- 211 • <u>Immunization Administration</u> can be realized-by <u>FHIR</u>; where,
  - 212 – <u>Immunization-Administration</u> is then associated with the following resources:
    - 213 • AdverseReaction and other Observations,
    - 214 • Patient , Practitioner, Organization, Location;
- 215 • <u>Immunization-Administration</u> can be realized-by FHIR-profiles based-on the US Realm FHIM <u>Immunization</u> and
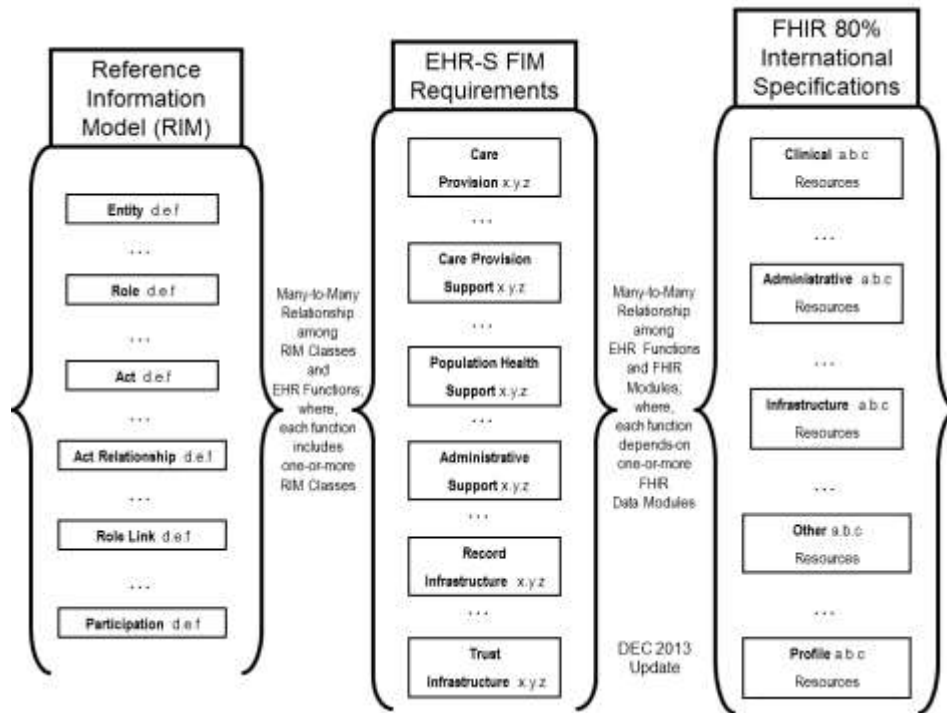 216 related Domains.

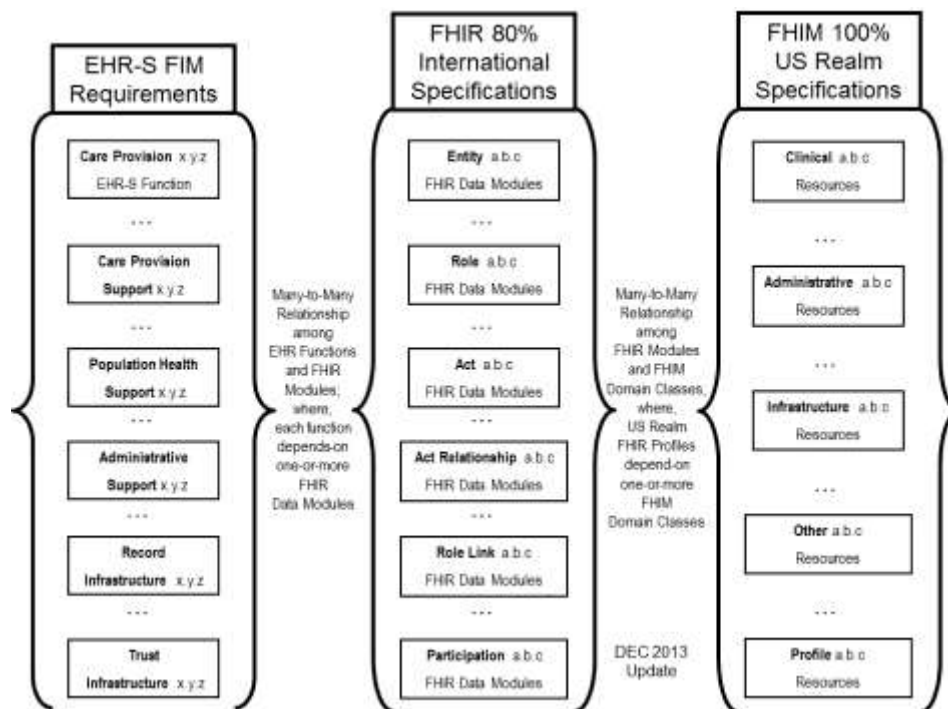**Figure 8 HL7 EHR-S FIM release-3 Relationship with HL7 RIM-and-FHIR [5]**

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

class FHIR Specification for Allergy, Intolerance and Adverse Reaction

Name: FHIR Specification for Allergy, Intolerance and Adverse Reaction
Author: EHR Interoperability WG
Version: EHR-S FIM (2013 r3 Prototype)
Created: 11/5/2013 4:25:17 AM
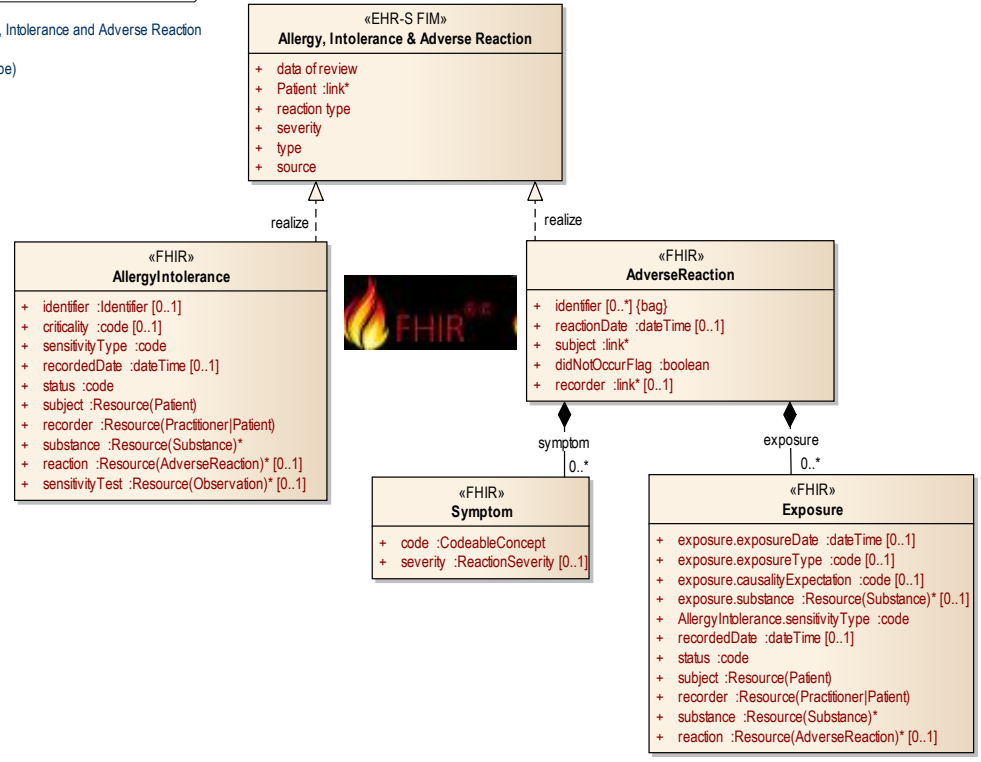Updated: 12/6/2013 6:04:37 PM

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

+ data of review
+ Patient :link*
+ reaction type
+ severity
+ type
+ source

realize

«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]

«FHIR»
AdverseReaction

+ identifier [0..*] {bag}
+ reactionDate :dateTime [0..1]
+ subject :link*
+ didNotOccurFlag :boolean
+ recorder :link* [0..1]

symptom
0..*

exposure
0..*

«FHIR»
Symptom

+ code :CodeableConcept
+ severity :ReactionSeverity [0..1]

«FHIR»
Exposure

+ exposure.exposureDate :dateTime [0..1]
+ exposure.exposureType :code [0..1]
+ exposure.causalityExpectation :code [0..1]
+ exposure.substance :Resource(Substance)* [0..1]
+ AllergyIntolerance.sensitivityType :code
+ recordedDate :dateTime [0..1]
+ status :code
+ subject :Resource(Patient)
+ recorder :Resource(Practitioner|Patient)
+ substance :Resource(Substance)*
+ reaction :Resource(AdverseReaction)* [0..1]

223
224

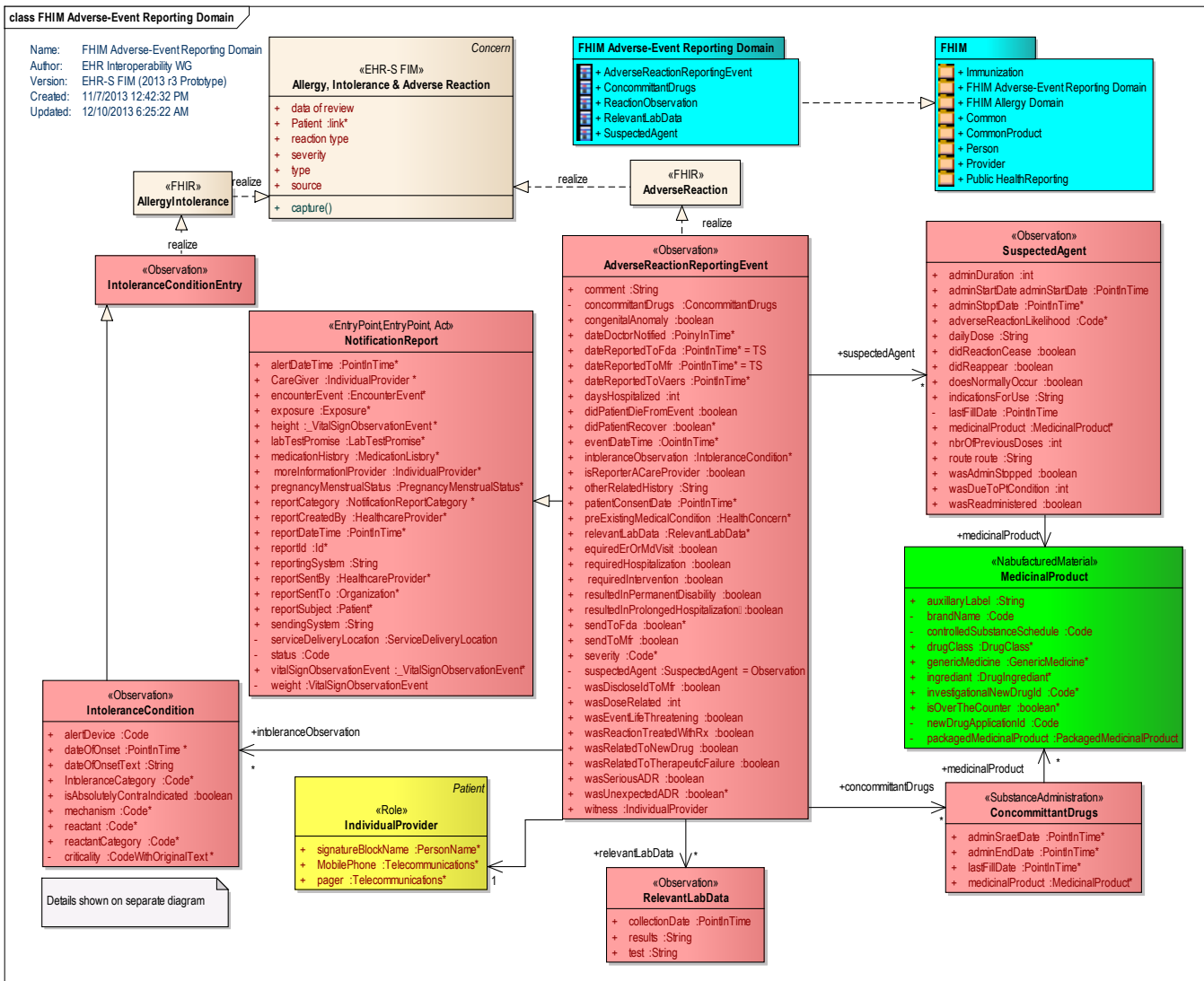**Figure 10 Example EHR-S FIM-FHIR Requirements-Specifications**

Figure 11 Example EHR-S FIM-FHIR-FHIM Requirements-Specifications

NOVEMBER ISSUES-ACTIONS

1. EHR-S FIM IP license.
2. EHR-S FIM home page should be is www.hl7.org/EHRSFIM
3. **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
4. **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
5. **Call-for-Participation** in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (Reference Model), where, Six 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