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.

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 FIM. Additionally, reusable business-process use-case, scenario and interoperability-specification capabilities, Meaningful-Use stage-2 criteria, implementation paradigms, such as V2 and V3 messaging, CCDA, SOA RLUS, 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-Needs¹ (see Figure 1), EHR-S and PHR-S FIM development and related projects²; where following an agile methodology, 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) Highlighted Yellow words 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

¹ The EHR-S FIM MNS (Mission Needs Statement) identifies “EHR-S Modernization” lifecycle-needs, that are optimally-defined 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 Managementand Evidentary 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 Release-3 Preparation**

An EHR/PHR Concept-of-Operation (CONOPS) is 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 appropriate implementation-paradigms, such as
   a) **HL7 V2 and V3 message, RIM and CDA, SOA RLUS standards and related DAMS**
   b) **FHIR (Fast Healthcare Interoperability Resource) specifications, for the International-Realm, profiled-with**
   c) **FHIM (Federal Health Information Model) specifications, for the US-Realm, bound to**
      - **Terminology value-sets**, 
      d) **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.

7) The Immunization Management Prototype was completed in December and a report and presentation are being prepared for the January 2014 Workgroup meeting in San Antonio see [http://wiki.hl7.org/images/0/0d/HL7_EHR-S_FIM_Release-3_Prototype_Immunization-Management_Use-Case_Information-Models_and_Scenarios.pdf](http://wiki.hl7.org/images/0/0d/HL7_EHR-S_FIM_Release-3_Prototype_Immunization-Management_Use-Case_Information-Models_and_Scenarios.pdf)
The benefit of this formally-specified **Concept-of-Operation** (CONOPS) and **Reference Model** (RM) approach is a clear, complete, concise, correct and consistent EHR-S and PHR-S Function-and-Information Model (FIM), profiles and resultant Interoperability-Specifications (ISs); where, ISs include appropriate implementation-paradigm specifications (V2 or V3 messaging, CDA, FHIR profiles, RLUS Data Services).

## OPEN ISSUES & ACTIONS

1. **HL7 IP license** vs. need for convenient access to EHR-S FIM versions-and-profiles.
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. **FIM Team Coordination** to integrate EHR-S FIM-FHIR-FIM into a joint Sparx Enterprise Architect (EA) model; where,
   EA can generate integrated EHR-S FIM-FHIR-FIM US-Realm interoperability requirements-specifications
5. **Call-for-Participation** in EHR-S and PHR-S FIM r3 based on a common 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 join EHR Interoperability ListServer

## Release-3 EHR-S and PHR-S FIM

**Table 1 Plan-of-Actions & Milestones Dashboard**

<table>
<thead>
<tr>
<th>POA&amp;M Task</th>
<th>#</th>
<th>Start</th>
<th>Done</th>
<th>POC</th>
<th>Status-Risks-Mitigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONOPS</td>
<td>1</td>
<td>12-2013</td>
<td>12-2013</td>
<td>SH, GD</td>
<td>Potential for minor changes in the future</td>
</tr>
<tr>
<td>Reference Model</td>
<td>0</td>
<td>06-2013</td>
<td>12-2013</td>
<td>SH, GD</td>
<td>Potential for minor changes in the future</td>
</tr>
<tr>
<td>Manage operation-type</td>
<td>0</td>
<td>05-2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record-Entry data-types</td>
<td>0</td>
<td>01-2012</td>
<td>active</td>
<td>EHRWG</td>
<td>Verb-Hierarchy was part of r2 ballot</td>
</tr>
<tr>
<td>HL7 IP for EHR-S FIM</td>
<td>0</td>
<td>01-2014</td>
<td>active</td>
<td>EHRWG</td>
<td>ISSUE: Board approval needed</td>
</tr>
<tr>
<td>wwww.HL7.org/EHR</td>
<td>0</td>
<td>12-2013</td>
<td>active</td>
<td>EHRWG</td>
<td>ISSUE: PSS approval needed</td>
</tr>
<tr>
<td>Implementation Paradigm Integration</td>
<td>0</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>ISSUE: Integrated or linked models?</td>
</tr>
<tr>
<td>V2 and V3 messaging, CCDA, RLUS API</td>
<td>0</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>RECOMMENDATION: linked</td>
</tr>
<tr>
<td>FHIR</td>
<td>0</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>ISSUE: shared governance (CCB &amp; CM)?</td>
</tr>
<tr>
<td>FIM</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care Provision</td>
<td>37</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:1 Manage Clinical History</td>
<td>9</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:2 Render Externally Sourced Information</td>
<td>2</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:3 Manage Clinical Documentation</td>
<td>6</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:4 Manage Orders</td>
<td>7</td>
<td>01-2012</td>
<td>Inactive</td>
<td>SH, GD</td>
<td>^ 2012 protocol pe -&gt; Todo wrt RM</td>
</tr>
<tr>
<td>CP:5 Manage Results</td>
<td>2</td>
<td>01-2012</td>
<td>Inactive</td>
<td>SH, GD</td>
<td>^ 2012 protocol pe -&gt; Todo wrt RM</td>
</tr>
<tr>
<td>CP:6 Manage Treatment Administration</td>
<td>3</td>
<td>01-2012</td>
<td>Inactive</td>
<td>SH, GD</td>
<td>^ 2012 protocol pe -&gt; Todo wrt RM</td>
</tr>
<tr>
<td>CP:6.1 Medication Management</td>
<td>0</td>
<td>01-2013</td>
<td></td>
<td></td>
<td>^ Use case done, CCs in progress</td>
</tr>
<tr>
<td>CP:6.2 Immunization Management</td>
<td>10</td>
<td>01-2013</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:7 Manage Future Care</td>
<td>3</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:8 Manage Patient Education &amp; Communication</td>
<td>2</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP:9 Manage Care Coordination &amp; Reporting</td>
<td>3</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care Provision Support</td>
<td>67</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS:1 Record Management</td>
<td>14</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS:2 Support Externally Sourced Information</td>
<td>9</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS:3 Support Clinical Documentation</td>
<td>13</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS:4 Support Orders</td>
<td>10</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS:5 Support for Results</td>
<td>1</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS:6 Support Treatment Administration</td>
<td>5</td>
<td></td>
<td>pending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POA&amp;M Task</td>
<td>#</td>
<td>Start</td>
<td>Done</td>
<td>POC</td>
<td>Status-Risks-Mitigations</td>
</tr>
<tr>
<td>------------</td>
<td>-----</td>
<td>-------</td>
<td>------</td>
<td>-----</td>
<td>-------------------------</td>
</tr>
<tr>
<td>CPS.7 Support Future Care</td>
<td>2</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.8 Support Patient Education &amp; Communication</td>
<td>7</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.9 Support Care Coordination &amp; Reporting</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Population Health Support</strong></td>
<td>17</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.1 Support for Health Maintenance, Preventive Care and Wellness</td>
<td>3</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.3 Support for Notification and Response</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.5 Donor Management Support</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.6 Measurement, Analysis, Research and Reports</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.7 Public Health Related Updates</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.8 De-Identified Data Request Management</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.9 Support Consistent Healthcare Management of Patient Groups or Populations</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.10 Manage Population Health Study-Related Identifiers</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Administration Support</strong></td>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.1 Manage Provider Information</td>
<td>8</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.2 Manage Patient Demographics, Location and Synchronization</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.3 Manage Personal Health Record Interaction</td>
<td>3</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.4 Manage Communication</td>
<td>5</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.5 Manage Clinical Workflow Tasking</td>
<td>5</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.6 Manage Resource Availability</td>
<td>7</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.7 Support Encounter/Episode of Care Management</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.8 Manage Information Access for Supplemental Use</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.9 Manage Administrative Transaction Processing</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Trust Infrastructure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.1 Security</td>
<td>25</td>
<td>01-2012</td>
<td>Inactive</td>
<td>GD, SH</td>
<td>√ 2012 prototy pe → Todo w r RM</td>
</tr>
<tr>
<td>TI.2 Audit</td>
<td>1</td>
<td>01-2012</td>
<td>Inactive</td>
<td>GD, SH</td>
<td>√ 2012 prototy pe → Todo w r RM</td>
</tr>
<tr>
<td>TI.3 Registry and Directory Services</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.4 Standard Terminology and Terminology Services</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.5 Standards-Based Interoperability</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.6 Business Rules Management</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.7 Workflow Management</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.8 Database Backup and Recovery</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TI.9 System Management Operations and Performance</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Record Infrastructure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI.1 Record Lifecycle and Lifespan</td>
<td>25</td>
<td>12-2012</td>
<td>Inactive</td>
<td>GD, SH</td>
<td>√ 2012 prototy pe → Todo w r RM</td>
</tr>
<tr>
<td>RI.1.1.2 Record Entry Create</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI.2 Record Synchronization</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI.3 Record Archive and Restore</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
WORKGROUP AND PROJECT LOGISTICS

- HL7 Workgroup Call-Schedule: [http://www.hl7.org/concalls/default.aspx](http://www.hl7.org/concalls/default.aspx)

<table>
<thead>
<tr>
<th>Day</th>
<th>Time US ET</th>
<th>Activity</th>
<th>Lead(s)</th>
<th>Dial-In</th>
<th>Screen Sharing</th>
<th>List Server</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td>1200</td>
<td>Records Management/ Evidentiary Support</td>
<td>Warner, Gelerz</td>
<td>1-877-868-4493 Code 927 002 088#</td>
<td>Link</td>
<td>EHR Legal</td>
</tr>
<tr>
<td></td>
<td>1300</td>
<td>EHRS FM Release 3 Planning</td>
<td>Hufnagel, Dickinson</td>
<td>1-770-557-9270, Passcode 510269#</td>
<td>Link</td>
<td>EHR Interop</td>
</tr>
<tr>
<td>Tues</td>
<td>1400</td>
<td>Meaningful Use Functional Profile</td>
<td>Datta, Dickinson</td>
<td>1-770-557-9270, Passcode 510269#</td>
<td>Link</td>
<td>EHR Interop</td>
</tr>
<tr>
<td></td>
<td>1600</td>
<td>FULL EHR WG</td>
<td>Co-Chairs</td>
<td>1-770-557-9270, Passcode 510269#</td>
<td>Link</td>
<td>EHR WG</td>
</tr>
<tr>
<td>Wed</td>
<td>1200</td>
<td>Personal Health Record WG</td>
<td>Ritter, Dickinson, Dooh</td>
<td>1-770-557-9270, Passcode 510269#</td>
<td>TBA</td>
<td>EHR PHR</td>
</tr>
<tr>
<td></td>
<td>1300</td>
<td>EHR System Usability WG</td>
<td>Mon, Ritter, Rocca, Gardner</td>
<td>1-770-557-9270, Passcode 510269#</td>
<td>Link</td>
<td>EHR Usability</td>
</tr>
<tr>
<td>Thur</td>
<td>Open</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fri</td>
<td>0930</td>
<td>EHR WG Co-Chairs</td>
<td>Co-Chairs</td>
<td>1-770-557-9270, Passcode 510269#</td>
<td>TBA</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- **EHR CCD to Blue Button Tool 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** is sponsored by the HL7 Tooling Workgroup and is producing 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** was 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 WG** provides a reference list of functions that may be present in a Personal Health Record System (PHR-S). Project contact: John Ritter; johnritter1@verizon.net

- **Diabetes Data Strategy Project** focus is 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

- **EHR Interoperability WG** has two active projects
- **EHR-S FM Meaningful Use profile**
- **EHR-S FIM Release-3** preparation is restructuring release-2; where, the benefit of this formally specified EA tool-based Concept-of-Operation and Reference Model is a clear, complete, concise, correct and consistent EHR-S and PHR-S Function-and-Information Model, profiles and resultant Interoperability-Specifications (ISs); where, ISs include appropriate implementation-paradigm specifications (V2 or V3 messaging, CDA, FHIR profiles, web-services, RLUS Data Services).
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 CCDACA-CCD for VLER Health data
   g) ICD9/CPT4/HCPCS ICD9PCSC 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) CCDCA 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
   g) 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, 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, Security Event
         iii) Exchange: Document, Message, OperationOutcome, Query
         iv) Conformance: Conformance, ValueSet, Profile
5) **Acronyms**

- aka also known as
- ABSI American National Standards Institute
- ASC X12 Accredited Standards Committee X12 of ANSI
- CC EHR-S FIM Conformance Criteria
- CCB Change Control Board
- CDA Clinical Document Architecture
- CCDA Consolidated Clinical Document Architecture
- CIM Conceptual Information Model
- CIMI Common Informatics Modeling Initiative
- CM Change Management
- DD Data Dictionary
- CDM Conceptual Information Model
- CP Care Provision
- CPS Care Provisioning Support
- DFD Data Flow Diagram
- DMBOK Data Management Book of Knowledge
- 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 Function and Information Model
- FIM (MU) FIM Meaningful Use profile
- FM Function Model
- FY Fiscal Year
- IHE Integrating the Healthcare Enterprise
- IHTSDO International Health Terminology SDO
- IM Information Model
- IV&V Independent Verification and Validation
- MDHT Model Driven Health Tools
- MU US Meaningful Use objectives-and-criteria
- NIEM National Information Exchange Model
- OMG Object Management Group SDO
- ONC US Office of the National-Coordinator
- OHT Open Health Tools
- POA&M Plan of Actions and Milestones
- QA Quality Assurance
- 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
- SDO Standards Development Organization
- WBS Work Breakdown Structure
- WG Work Group
MONTHLY SUMMARIES
(Reverse Chronological Order)

1 December 2013

Executive Summary (extensively updated)

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; where, the Work Group and its projects create-and-promote appropriate-and-necessary standards. HL7 Project Scope Statement (PSS) #688 is for ISO/HL7 10781 r3:2017 EHR-S FIM; where, EHR-S Function- and-Information Model Release-3 is planned for '2017 ballot. This report demonstrates 1-function of 150-functions remaining to-be done over the next three-years.

The vision is to restructure the '2014 EHR-S FM Release-2 into clear, complete, concise, correct, consistent and easy-to-use functions and conformance criteria within the '2017 UML-modeled EHR-S FIM Release-3 Easy-Button tool; where, the EHR-S FIM Enterprise Architect (EA) platform is capable-of managing specific-profiles (e.g., personal health record, behavioral health, long-term care, emergency department, inpatient, outpatient or individual-system); where, profile reports or web-sites can be automatically-generated, which include:
1. Functional use-case entities, system-actions information-exchanges, conformance-criteria scenarios, according-to patient-preference, situation, scope-of practice, organizational-policy and jurisdictional-law
2. Interoperability-specifications, including selectable implementation paradigms
3. Requirements lifecycle-traceability and configuration-baselines.
4. Implementation-paradigm profile-additions; such as, those for messages, CDA documents, web-services, interface behavioral-specifications and realm-specific data-models with terminology-bindings can be added to produce a fully-qualified exchange-architecture, of system Information-Exchanges (IEs) and implementable-and-testable Interoperability-Specifications (ISSs); where, this document contains an "Allergy, Intolerance and Adverse Reaction" related HL7-International Fast Healthcare Interoperability Resources (FHIRs) and US-realms Federal Healthcare Information Model (FHIM) classes examples to show how implementation-profile additions are included.

The Linguistic-kiss Methodology hierarchically-constrains the UML-modeled EHR-S lexicon-of entities, actions and information-flows into function document-sections and sub-sections modeled-as use-case paragraphs of user-story scenario-sentences; where, these scenario-sentences are also known as conformance-criteria (CCs). As an example, the Immunization-Management function's use-case has 23 CC user-story scenarios, which can be further constrained according-to patient-preference, situation, scope-of practice, organizational-policy and jurisdictional-law.

The "Easy-Button tool" is an EHR-informatics knowledge-repository and force-multiplier, which institutionalizes informatics-wisdom; where, it empowers users to efficiently-and-effectively reuse informatics-knowledge in EHR-related areas such as:
- Business requirements, use-cases, user-story scenarios;
- Platform-independent (logical) architectural design-specifications
- Platform-specific (implementable) development, test and certification ISSs, profiles, and guides.
The benefit of the recommended methodology-and-technology is that high-quality and low-cost EHR-S FIM profiled web-sites and reports can be generated in hours-or-days by one-person; where formerly, weeks-or-months were required by an integrated product team. Initial results may still require subject-matter-expert verification-and-validation (V&V) to identify special-needs and gaps; where, a capability approach proposal can be developed as-the-basis-of both strategic gap-mitigation and tactical investment-and-execution planning.

The benefit of using Sparx Enterprise Architect (EA) as the underlying EHR-S FIM "Easy-Button" platform is the built-in support for enterprise-wide, full-lifecycle, model-driven, architecture-and-design solutions for visualizing, analyzing, simulating, testing and maintaining EHR-related systems, software, processes and architectures; where, EA is a collaborative team-based modeling, design, management-and-documentation tool based on UML 2.4.1. EA's Standard XML Metadata Interchange (XMI) export capability allows the use of other tools, such as IBM's Rational Software/System Architect.

The estimated cost to bring the EHR-S FIM "Easy-Button" vision to fruition is 3-FTEs allocated for 2-years; where, 6-total FTEs = 2-weeks per-function * 150 functions = 5-hours per conformance criteria (CC) * 2500 CC. And, adding specific implementation-paradigm capabilities requires additional resources.

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 requirements-specifications
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 into 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-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 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.

**Figure 2 Information-Exchange Model**

- **Security**
  - Authorization (e.g., SAML, OAuth)
  - Privacy & Consent (e.g., HIPAA)
  - Authentication (e.g., OpenID, PKI)
  - Data Integrity (e.g., TLS, PKI)

- **Data**
  - Terminology Models (e.g., CDA, LOINC, SNOMED CT)
  - Information Model (e.g., CCDA, RIM, FHIR, HL7 v2)
  - Wire Format (e.g., XML, JSON, RDF, msg)

- **Transport**
  - Services Layer (e.g., REST, SOAP, RPC, HTTP)
  - Session Layer (e.g., MQTT, AMQP, ESB)
  - IP and Network Layer (assumed)

- **End User**
  - Producing System

- **End User**
  - Consuming System

**Standards cited are for illustration purposes only**

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

- **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 (TypeName, 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 analyst/developer/implementer user to move from a real-world concept analysis to a system implementation. The System Record-Entries 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

---

3 “VA-DOD Health Architecture Alignment Recommendations” made to the HARB, July 2013, MITRE Authors: Dr. Mark A. Kramer, Kevin Gunn, Sponsor: Department of Veterans’ Affairs, Contract No.: VA791-P-0042, Project No.: 40134028-DA
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 their specific problem into the conceptual, syntactic, semantic and lexical areas.

---

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."

5 As a rule of thumb, FHIR uses an 80/20 rule; where, elements should be included in a resource if they are catered-for/used by 80% of the implementing systems; and where FHIR profiles define the 20% of specific-implementation elements.