



- [January Working Group Meeting TSC Report from the TSC Chair](#)
- [Domain Experts Steering Division Update—Work Group Health](#)
- [Services Aware Enterprise Architecture Framework \(SAEAF\) Version 200902](#)
- [TSC Updates Since the January Working Group Meeting](#)
- [Version 3 Editing Project: Continuing to Smooth the Path to Interoperability With World Wide Collaboration](#)
- [Financial Management MITA Project](#)
- [Annotated ECG: Five Years Later](#)
- [Direction and Correction of Vocabulary Content Errors](#)



January Working Group Meeting TSC Report from the TSC Chair

By Charlie McCay

Chair, TSC

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The Orlando Working Group Meeting was the first WGM for Lynn Laakso, the new Technical Steering Committee Project Manager. Lynn has allowed the TSC (http://hl7tsc.org/wiki/index.php?title=Main_Page) to take on more substantial planning work and is helping to make all the activities within the working group more visible.

A new Enterprise Architecture Implementation Project (EA-IP, Project Insight ID: 469 (http://wiki.hl7.org/index.php?title=EA_IP [login: wiki, password: wikiwiki]) was set up by the TSC during the working group meeting to manage the rollout of the new HL7 Enterprise Architecture work being undertaken by the Architectural review Board (http://wiki.hl7.org/index.php?title=Architecture_Board [login:

wiki, password: wikiwiki]). The successful adoption of the Enterprise Architecture is a major objective for HL7 and a good deal of thought and effort was put into getting this project off to a good start.

Work increasing the visibility of HL7 projects has progressed over the last three months, with the searchable project list (<http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm>) being available from the HL7.org home page (<http://www.hl7.org>) and also as an excel spreadsheet (http://newgforge.hl7.nscee.edu/frs/?group_id=52) for those who want to do their own analysis.

Work is also underway to ensure that work group activity documents (minutes and agendas) are easier to find; that committees have Mission and Charter documents that reflect their activity; and that three-year plans are available so everyone can share common expectations as to what the work groups will produce.

A new set of activities led by John Quinn, HL7 CTO (Project Insight ID: 413), will ensure that we have a set of market-facing descriptions of the HL7 product set, and a process in place to maintain these descriptions. This should dramatically reduce the difficulty that newcomers have finding what offerings from HL7 are relevant to them. This work will complement the activities of the HL7 Marketing Council and market positioning work being led by Chuck Jaffe, HL7 CEO.

There is a final “visibility” initiative to make the work of the TSC and CTO more transparent (Project Insight ID: 452 http://hl7t3f.org/wiki/index.php?title=TSC_Visibility_2009) This includes publishing the roles and responsibilities for the CTO, TSC chair and TSC project manager; a work plan for the year; and the period until the next WGM. As part of this effort, the TSC and CTO activities will be managed in clearly defined projects.

Both the TSC and the Board spent time discussing how to more effectively deliver National Initiatives, particularly the new US administration’s intended large investment in healthcare IT. There will continue to be active planning in this year, to ensure that HL7 can deliver the standards that are needed, and is viewed as capable of delivering such standards.

This will clearly involve working with other standards organizations, both internationally and in the US. The CEO and CTO have been proactive in establishing the Memorandum of Understanding (MOU) agreements for other collaborations that will help ensure that HL7 can provide its members with a gateway into a coherent set of standards that meet the needs of its members. The TSC work to make projects, products, and work groups more visible is also being extended so that work across organizations can be coordinated and reused.



Domain Experts Steering Division Update—Work Group Health

By Austin Kreisler and Ed Tripp

Domain Experts Steering Division Representatives

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The movement of HL7 to adopt a strategic roadmap for the organization in order to assist in focusing the organization's resources and efforts to the greatest benefit of its members requires knowledge concerning both the conditions that impact the effectiveness of each group (strengths, weaknesses, opportunities and threats or SWOTs), and the planned activities for the work groups in the near and long term (up to three years).

SWOTs and three-year plans provide input to the HL7 roadmap at both ends of the process. The roadmap provides the high-level strategies that guide the decisions and activities of the organization as a whole. SWOTs assist the Board of Directors in evaluating major obstacles to productivity that the work groups have identified as well as the organizational strengths upon which the overarching strategies should be built. Thus, SWOTs allow for the focusing of HL7s strategies to best take advantage of the strengths and opportunities and to mitigate weaknesses and threats.

Three-year plans are used in the preparation and evaluation of organizational strategies, as well as to assess the alignment of proposed work group projects with the published strategies of the working group. Thus, proposed projects that do not fit into any of the currently accepted strategies would be deemed out of scope for the organization, but could be considered for inclusion in future strategic initiatives when the roadmap is updated.

SWOTs and three-year plans provide both the input and focus of the needs of HL7s primary constituencies, i.e. the membership doing the actual work of standards development and the consumers of the HL7 work products. By integrating these documents along with the high-level business strategies of the organization, HL7 is able to focus its limited resources in the most productive manner, while still providing a high level of value to stakeholders in the health community.



Services Aware Enterprise Architecture Framework (SAEAF) Version 200902

Submitted by Tony Julian

ArB member

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The HL7 Architecture review Board (ArB) has finished the first peer review of the Services Aware Enterprise Architecture Framework (SAEAF) document. The disposition of the comments may be found at:

http://wiki.hl7.org/index.php?title=SAEAF_Peer_Review (login: wiki, password: wikiwiki)

The next release of the SAEAF slide decks will be posted on or about March 15, 2009. Interested parties may download the four slide decks at

http://hl7projects.hl7.nscce.edu/frs/?group_id=64

The papers (there will be one paper per deck) will be the rewrite of the SAEAF, but they will mirror the decks very closely. For example, no images should be in the papers that are not in the decks, and no concepts should appear in the papers that are not already discussed in the decks (though there might be elaboration or examples in the papers).

Peer review will be available via Gforge Tracker. All peer review is due by April 14, 2009. The ArB will review the peer review April 15-17, 2009 in conjunction with the Harmonization meeting.



TSC Updates Since the January Working Group Meeting

By Lynn Laakso

HL7 TSC Project Manager

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Approved Projects

- The ACS Cardiology DAM, Release 2 (TSC Issue 827 – Status = Closed; Project Insight ID= 216)
- Pre-planning (phase 0) for The Enterprise Architecture Implementation Project (EA IP) for the Architecture Rollout of the SAEAF (TSC Issue #747 – Status = Open; Project Insight ID:469)

- The Enterprise Architecture Implementation Project (EA IP) Phase 1 (TSC Tracker # 747, Project Insight ID=469)
- Project Approval (revised scope statement), Datatypes transfer from InM to Mnm: TSC Tracker # 879 – Status = Closed; Project Insight ID=455)
- EHR System Design Reference Model project (TSC Issue 858 – Status = Closed; Project Insight ID= 444)
- Clinical Genomics Gene Expression Data (TSC Issue 875 – Status = Closed; Project Insight ID= 333)
- Public Health Case Reporting Implementation Guide for CDA R2 Level 3 by SD/PHER (TSC Issue 876 – Status = Closed; Project Insight ID= 457)
- Electronic Laboratory Reporting to Public Health IG by PHER/OO (TSC Issue 884 – Status = Closed; Project Insight ID= 448)
- Patient Administration - Project Proposal on Scheduling CMET (TSC Issue 915 – Status = Closed; Project Insight ID=459)
- Orders & Observations - Project Proposal on Common Product Model (TSC Issue 916 – Status=Closed; Project Insight ID=456)
- PHER - Version 2.5.1 Implementation Guide for Immunization Messaging (TSC Issue 918 – Status=Closed; Project Insight ID=458)

Ballot Cycle Related Approvals

In accordance with the GOM, the TSC approves ballot cycle documents, ballot levels, etc.

On the February 16, 2009 call, the TSC approved the following:

- Re-affirmation of the CCOW V1.5 document, to be balloted for comment only, to extend ANSI approval past its five-year mark. (TSC Tracker # 888, Project Insight ID=467)
- Re-affirmation of the RCRIM Version 3 Standards: Regulated Studies; Annotated ECG, Release 1, to be balloted for comment only, to extend ANSI approval past its five-year mark. (TSC Tracker # 888, Project Insight ID=462)
- Modification of one (1) existing title: RCRIM CDISC Content to Message – Study Participation (Project Insight ID=405)

DSTU Publication Approvals

The following documents were approved as Draft Standards for Trial Use (DSTU) and will be available on the HL7 DSTU comment site (<http://www.hl7.org/dstucomments/index.cfm>).

- eStability DSTU (TSC Tracker #865 – State=Closed)

Other Approvals

- The Dissolution Request of the Laboratory Work Group, merging into O&O, was approved
- The confirmation of John Koisch as co-chair of the Architecture Board (ArB) was approved

- The TSC reviewed and approved updates to ArB membership: Patrick Loyd, Dale Nelson, Wendell Ocasio, replacing Nancy Orvis, Ying Jing Bao and Mead Walker
- The TSC reviewed and approved the interpretation of balloting rules regarding the submission of negative votes without comment on informative ballots as using the same rules as for normative ballots; that is, a negative vote without comment is discounted. See also disposition of votes for members of consensus groups whose organizational or individual memberships expired at the end of December (TSC Issue # 854 – Status = Closed)
- The TSC reviewed and clarified the interpretation of process in the changing of a project's scope, to say, "When scope is changed in a project an adjusted Project Scope Statement will be approved by the sponsoring WG (s) and the SD, and provided to the TSC using the same time line and deadlines as submissions for new projects". (TSC Issue 748 – Status=Closed)
- The TSC approved updates to its Mission and Charter, Decision Making Practices, and Communications Plan. These updates include minor revisions to the Mission and Charter to better reflect the TSC responsibility between Work Groups and for formation, change, and dissolution of Work Groups. The DMPs were updated to follow the new DMP template available to all Work Groups on the HL7.org web site at <http://www.hl7.org/Library/decisionmaking/Generic%20HL7%20WG%20DMP%20v2.0%20Template.doc>. The Communications Plan added a section on "Who does the TSC communicate with" that also describes the purpose and value of that communication.

Version 3 Editing Project: Continuing to Smooth the Path to Interoperability With World Wide Collaboration

By Sarah Ryan and Jay Lyle

HL7 Version 3 Technical Editors

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The Version 3 editing project, begun in 2007, will complete its core document work in 2009. The project has now finished the RIM and Data Types R1/R2. Perhaps, though, the most visible document of this current cycle is the revision of the Core Principles, which entailed team work on three continents.

Working with Modeling & Methodology (MnM), Infrastructure & Messaging (InM) and Vocabulary, the editing project's objectives have been to ensure that documents written by different people at different times are coherent and consistent. In making mechanical and stylistic changes, the group was also able to identify and then clarify issues with methodology.

Since the last published update in the fall newsletter, the editing project has finished the RIM, collaborating with the MnM Work Group. Edits were presented to and approved by work group members, and then were reviewed for quality by newly elected board member Stan Huff. The revised material will be included in the upcoming normative ballot for general membership comment.

The Data Type work focused on “release two,” in both the abstract and ISO editions. The editors worked iteratively with InM co-chair Graham Grieve; the ISO version is being submitted to ISO for approval. The Data Types materials are included within the spring ballot for review.

The Core Principles document is a partnership between MnM, InM, and Vocabulary. The document articulates the foundations of Version 3. The version in the spring ballot work is in its second version. The edited and updated material is targeted for the 2009 normative ballot.

The writing team – led by Jobst Landgrebe, Ted Klein and Woody Beeler – has meticulously reviewed and expanded upon existing copy. The Version 3 editors helped in the coordination of new composition and made suggestions for updating areas where further clarification was needed. A long-term concern voiced by the membership in general has been the lack of coordinated documentation from the Vocabulary Work Group; this effort addresses both issues.

The project is now finishing up this round of deliverables. The editing team is Ockham Information Services (Jay Lyle and Sarah Ryan, with the assistance of Abdul Malik Shakir and Harold Solbrig). Ockham invites comments: please send them to Jay Lyle at jlyle@ockhamis.com.



Financial Management MITA Project

By Mary Kay McDaniel

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The Medicaid Information Technology Architecture (MITA) Project is sponsored by the Financial Management Workgroup (FM). This “project” is one component in the overarching US MITA Initiative developed by the Centers for Medicaid and Medicare Services (CMS).

CMS and Medicaid administrators recognize the lack of a comprehensive view of the Medicaid world and that existing Medicaid Management Information Systems (MMIS) are not capable of keeping pace with a rapidly changing health care environment. Medicaid recipients come from a variety of backgrounds with many, and in some cases, highly complex care coordination needs. Clinical information to make decisions has been difficult to obtain and share among the agencies responsible (Medicare, Medicaid, State Programs, Mental Health Programs, Commercial Insurance, Indian Health Services, etc.) or across state lines due to independent systems, different state laws, and a lack of data standards.

The MITA is a CMS Medicaid re-tooling effort. MITA is:

- A *Plan* to transform Medicaid
 - Built on business models that support the business vision and mission
- An *Architecture Framework*
 - Web-based, patient-centric, interoperable system based on industry

- IT standards
 - Enterprise-oriented, rather than organization or system
 - Data shared across boundaries using standard-based methods
 - Provides basis for HIT/E, EHR, eRx, PHR
 - Identifies reusable capabilities
 - Technology neutral
- A collaborative *Process*
 - Each Medicaid program may build IT solutions based on standards, models and processes contained within the MITA Framework that have been developed with the help of all states and the IT industry

The HL7 MITA Project volunteers are:

- Modeling the first of 79 Medicaid Business Processes (UML depictions)
- Developing an Information Model, using the MITA Development Framework (MDF, US Realm) based on the HL7 Development Framework (HDF), with all Version 3 artifacts
- Reviewing business process information interactions. Where message standards are available and/or mandated, those standards will be recommended. Where no standards and/or mandate exist, HL7 messages will be developed following HL7 processes
- Supporting the maintenance, refresh, and new development of FM models in three topic areas: Account and Billing; Claims and Reimbursement; and Policy/Program Coverage and Benefits.
 - Supporting the maintenance, refresh, and new development of affiliated work groups, including Patient Administration, especially with respect to Provider and Client Enrollment; Provider, Service Delivery, and Client/Patient Registries; and Scheduling, Admissions, and Encounters
- Supporting Community Based Collaborative Care for Privacy Policy and Consent Directive topic; and artifacts supportive of community based services and long-term care

Additional information regarding the MITA can be found at:

<http://www.cms.hhs.gov/MedicaidInfoTechArch/>

The HL7 FM MITA Project wiki with all work in process is located at:

<http://mita.wikispaces.com/>



Annotated ECG: Five Years Later

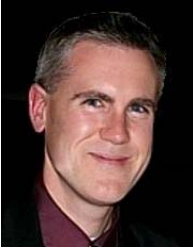
By Ed Tripp

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And

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The HL7 Version 3 Standard: Regulated Studies - Annotated ECG, Release 1 became a normative standard in May of 2004. As we near the fifth anniversary of this message, we would like to provide an update on its implementation and use.

The FDA continues to be concerned about evaluating non-cardiac drugs for negative cardiac effects, such as a prolonged QT interval on an electrocardiogram (ECG). Before this initiative, sponsors were submitting ECG findings tabulations (e.g. QT interval measurements) with their applications. However, the FDA could not systematically evaluate the ECG waveforms and the measurement locations the findings came from. Most (if not all) ECGs were collected on paper and were not electronically retained. In response to the FDA's need, HL7's Regulated Clinical Research Information Management (RCRIM) Work Group created the Annotated ECG (aECG) standard.

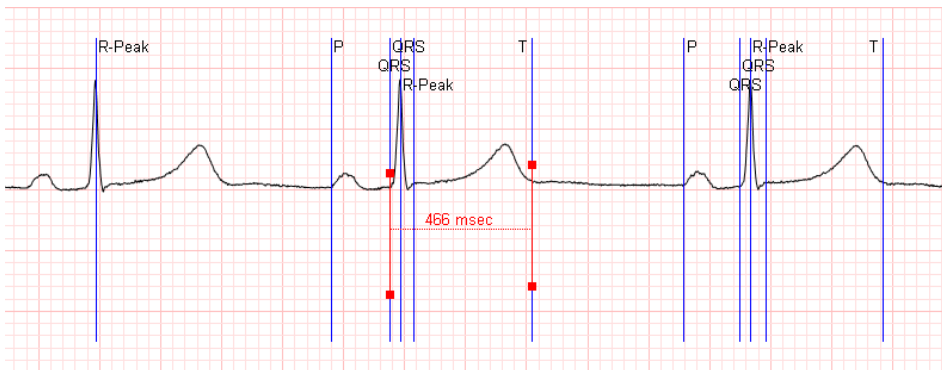


Figure 1 - QT interval measurement

Following the development of the standard, the E-Scribe ECG Warehouse (www.ecgwarehouse.com) was created for the collection and storage of protocol driven annotated ECGs. The E-Scribe ECG Warehouse, a public-private collaboration with the FDA, provides tools for annotated ECG review, scoring and warehousing. Sponsors and central laboratories upload annotated ECG datasets supporting new drug applications to FDA into the E-Scribe ECG Warehouse to facilitate regulatory review using the toolset provided within the warehouse. The data upload process features a validation step to verify that all annotated ECGs adhere to the HL7 annotated ECG standard.

Today there are more than three million annotated ECGs stored within the E-Scribe

ECG Warehouse. They represent the largest collection of standardized ECGs in the world. The FDA hopes to mine this vast collection of ECGs to accelerate the investigation of improved biomarkers and to better characterize the cardiac safety of new drugs.

HL7 Annotated ECG is now the most widely adopted ECG standard in the world. All device manufacturers and software companies working with ECGs and the pharmaceutical industry support this format. Although it is optimized for drug trials but lacking in some general healthcare features, areas in Europe have been able to use it to transfer ECG waveforms between different vendors' information systems.

HL7 Annotated ECG is one of the earliest and most widely adopted parts of Version 3. The FDA considers the Annotated ECG initiative a huge success and uses it as a model for future work with SDOs.

Happy fifth Anniversary to Annotated ECG, and congratulations to FDA, HL7 and the RCRIM Work Group!



Direction and Correction of Vocabulary Content Errors

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Representative
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During the week of February 8, 2009, several reports surfaced about value set "errors" in the published Vocabulary content. They arose from disparate sources, but in almost every instance from someone who was attempting to implement Version 3 standards. More detailed investigation revealed four sets of problems, three of which were inadvertently introduced while processing either "vocabulary cleanup" or harmonized updates, and a fourth arose because a change approved at a Harmonization Meeting affected legacy software in the RMIM Designer (in Visio). (More detail on all of these can be [found on the Wiki.](#))

The first two errors also caused concomitant errors in the vocabulary core schema (voc.xsd) that is "included" in every other Version 3 schema. In turn, this caused validation errors to appear incorrectly for otherwise valid message instances. Fortunately, retained documentation from harmonization and "cleanup" activities allowed full identification of the source of the errors and the steps needed to correct them.

All errors were corrected in release 2.25.2 of the RIM Repository. Current releases can be [downloaded from Gforge](#). Further, the impact on the RMIM Designer (in Visio) has led to an updated version of that software that uses the much more reliable MIF-representation of the HL7 Vocabulary Content. This is being released

[from Gforge](#) as BETA Release 4.4.0. Needless to say, these occurrences will lead to improvement in the way that vocabulary changes, once made, are validated.

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