



## ANNOUNCEMENT OF FORMATION OF BALLOT POOLS FOR JANUARY 2012 BALLOT CYCLE

**November 4, 2011**

Health Level Seven International® invites you to take part in the formation of ballot groups for the upcoming January 2012 ballot cycle. The candidate standards and other documents described in this announcement are expected to ballot prior to HL7's January 2012 Working Group Meeting (WGM). Comments received in response to these ballots will be addressed at that WGM running January 15-20, in San Antonio, TX.

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### **Ballot Overview**

#### **Ballot Open/Close Dates**

Most ballot pools in this document will open and close for voting on the following dates. Exceptions for a specific pool are listed with that pool.

***Ballot Open Date: Monday, December 5, 2011***

***Ballot Close Date: Monday, January 9, 2012***

#### **Ballot Pool Enrollment Period**

Ballot pool enrollment will be available from a date at least two weeks preceding the ballot pool opening date and will continue until one week before ballot pool close. While the exact dates are dependent upon individual pool ballot open and close dates, in general the signup period dates are as follows:

***Ballot Pool Sign-Up Open Date: Monday, November 21, 2011 (no later than)***

***Ballot Pool Sign-Up Close Date: Monday, January 2, 2012***

Please be aware that these dates may not be accurate for all ballot pools. To sign up, point your browser to <http://www.hl7.org/ctl.cfm?action=ballots.home>. **Important Note:**

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**Ballot pool signup will close one (1) week** before the ballot close date. This is also the final date non-members can sign up for Non-Member Participation in the ballot.

### **Ballot Listing**

This section details the candidate/draft standards and other documents that HL7 intends to ballot before the upcoming May WGM. Please note that the following details about specific items are subject to review by the HL7 Technical Steering Committee:

- Approval of all projects initiating any ballot item
- Approval of titles for new candidate and draft standards and other documents
- Approval of new candidate Draft Standards for Trial Use
- Approval of ballot level for those items moving directly to Normative ballot

Any changes from the initial details in this announcement will be identified in the ballot announcement document released when the September 2011 ballot cycle opens.

In addition, please be aware that some of the listed ballot pools are closed to additional enrollment. Original consensus group ballots are subsequent ballots of material previously balloted at the normative level and are usually limited to the members of the original consensus group, as stipulated in the HL7 Governance and Operations Manual (GOM), section 14.03.04 – Establishing the Consensus Group. Accordingly, these ballot pools are closed to sign up on the HL7 Ballot Desktop. The affected pools are identified in this document. For complete details on original consensus group ballots, please refer to the indicated section of the HL7 GOM.

### **Standards Classifications**

These items are based on or associated with the following standards or other classifications:

- Arden Syntax
- Clinical Document Architecture (CDA®), Release 2
- Electronic Health Records
- Health Level Seven International Governance
- Service Aware Interoperability Framework
- Version 2 Messaging
- Version 3 Messaging
- Version 3 Specifications, Infrastructure and Foundation

A section is devoted to each of the standards classifications below.

### **Ballot Listings by Classification**

#### **Arden Syntax**

The **Arden Syntax Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

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- ***Health Level Seven Arden Syntax for Medical Logic Systems, Version 2.9 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [734](#)***  
Arden Syntax is a formalism for representation of procedural clinical knowledge for use in clinical decision support systems. Version 2.9 will extend version 2.8 through the inclusion of new and overloading of extant operators to facilitate fuzzy logic as well as a more detailed and fine-grained alternate XML representation for the Arden Syntax.  
Unique Ballot ID: ARDEN\_V29\_N1\_2012JAN

### *Clinical Document Architecture (CDA®), Release 2*

The **Clinical Genomics Work Group** announces the formation of a ballot group for the following item:

- ***HL7 Implementation Guide for CDA® Release 2: Genetic Testing Reports, Release 1 (4<sup>th</sup> Comment Only Ballot) – Project Insight ID: [460](#)***  
This is another ballot cycle of the CDA® Implementation Guide for a Genetic Testing Report (GTR). This CDA IG provides a format for genetic testing reports. It is a Universal specification and thus is supposed to serve both research and clinical environments as well as address various types of genetic testings, e.g., genetic variations, cytogenetics, gene expression, etc. Changes from the last ballot version will be summarized in an addendum to the GTR IG.  
Unique Ballot ID: CDAR2\_IG\_GENTESTRPT\_R1\_O4\_2012JAN

The **Regulated Clinical Research Information Management and Structured Documents Work Groups** announce the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Implementation Guide for CDA® Release 2: Exchange of Clinical Trial Subject Data; Patient Narratives, Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [822](#)***  
This implementation guide describes how to implement the exchange of patient narratives gathered during clinical trials and is based on the now-withdrawn Version 3 Regulated Studies: Subject Data DSTU. A patient narrative is a summary document describing a study subject's experience during a clinical trial and is documented by the investigative site. The narrative integrates the information on all serious events, outcomes of serious adverse events, withdrawals, deaths, and causes of death, autopsy reports, concomitant conditions and procedures, etc. into a single narrative.  
Unique Ballot ID: CDAR2\_IG\_EXCTSD\_PATNARR\_R1\_D1\_2012JAN

The **Structured Documents Work Group** announces the formation of a ballot group for the following item:

[Alternate ballot open date pending Technical Steering Committee approval.]

***Alternate ballot open date: December 9, 2011***

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- ***HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, Release 1 – US Realm (1<sup>st</sup> DSTU Update Ballot) – Project Insight ID: [210](#)***

The purpose of this document is to describe constraints on CDA Release 2 Header and Body elements for Quality Reporting Documents. Quality Reporting Document Architecture (QRDA) is a document format that will provide a standard structure with which to report quality measure data to organizations that will analyze and interpret the data that is received. Updates to this document include enhancements to the QRDA Category I report based on feedback received through the 2009 DSTU testing, and expansion of the QRDA Category III to advance to DSTU status.

Unique Ballot ID: CDAR2\_QRDA\_R1\_U1\_2012JAN

### *Electronic Health Records*

The **Electronic Health Records Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 EHR-System Functional Profile for Health Information Exchange Metadata, Release 1 – US Realm (1<sup>st</sup> Informative Ballot) – Project Insight ID: [819](#)***

The scope of this project is to create a US Realm EHR Functional Profile describing the functions for an EHR system to support metadata required for patient demographics, provenance (source and type of data), and security and privacy in support of health information exchange.

Unique Ballot ID: EHR\_FP\_HIEM\_R1\_I1\_2012JAN

### *Health Level Seven International Governance*

The **HL7 Board of Directors** announces the formation of a ballot group for the following item:

- ***Proposed 2013 HL7 Strategic Initiatives and Criteria (1<sup>st</sup> Comment Only Ballot) – Project Insight ID: [808](#)***

The Strategic Initiatives document represents HL7's approved strategic initiatives for 2012. HL7 members and non members are invited to submit suggested revisions to the SI document as input to preparing the organization's 2013 strategic initiatives. Any and all comments are welcome and will be vetted by the Strategic Initiatives committee and then taken to the HL7 Board of Directors for approval. The 2012 Strategic Initiatives were developed based on feedback from last year's for comments ballot. The six strategic initiatives from the 2011 plan have been compressed into three strategic initiatives.

Unique Ballot ID: HL7\_SI2013\_R1\_O1\_2012JAN

The **Project Services Work Group** announces the formation of a ballot group for the following item:

- ***Introducing New Processes to HL7, Release 1 (1<sup>st</sup> Comment Only Ballot) – Project Insight ID: [818](#)***

HL7 has a well defined methodology for producing standards, but the method to introduce new processes and move them to adoption and deployment throughout

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the HL7 organization is more obscure/ad hoc. Project Services drafted a proposed process, working with the Services Aware Interoperability Framework Architecture Program (SAIF AP) and the Technical Steering Committee (TSC). The new process defined in the document "Introducing New Processes to HL7" is being balloted to validate the process it defines. This new process will apply to new process artifacts impacting more than one Work Group/Committee, and existing processes with "significant change." Steering Division chairs will provide guidance on "significant change."

Unique Ballot ID: HL7\_INTNEWPROC\_R1\_O1\_2012JAN

### Service-Aware Interoperability Framework

The **Architectural Review Board** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Service-Aware Interoperability Framework: Canonical Definition, Release 2 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [807](#)***

The Service Aware Interoperability Framework (SAIF) provides consistency between all artifacts, enables a standardized approach to Enterprise Architecture development and implementation, and a way to measure the consistency. SAIF is the framework that is required to rationalize interoperability of standards. SAIF is an architecture for achieving interoperability, but it is not a whole-solution design for enterprise architecture management. This document describes a canonical form of Service Aware Interoperability Framework (SAIF) which can be adapted to an organization's implementation requirements thorough the production of a SAIF implementation guide. Since the publication of the Release 1 version, measurements of conformity and consistency have been added and terms have been harmonized and added to the glossary.

Unique Ballot ID: SAIF\_CANON\_R2\_D1\_2012JAN

### Version 2 Messaging

The **Clinical Decision Support** and **Orders and Observations Work Groups** announce the formation of a ballot group for the following item:

[Ballot level pending Technical Steering Committee approval.]

- ***HL7 Version 2 Implementation Guide: Implementing the Virtual Medical Record for Clinical Decision Support (vMR-CDS), Release 1 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [184](#)***

A Virtual Medical Record (vMR) is a data model for representing the data that are analyzed and/or produced by clinical decision support (CDS) engines. The goal of this project is to define HL7 vMR data models capable of supporting scalable, interoperable CDS. The specification undergoing ballot consists of a guide for implementing the vMR using HL7 v2 messages. It is derived from the vMR Domain Analysis Model (DAM). Since the initial ballot in May 2010, this specification has been adapted to take into account the updated vMR Domain Analysis Model, which was adopted in September 2011.

Unique Ballot ID: V2IG\_CDS\_VMR\_R1\_I3\_2012JAN

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The **Clinical Genomics Work Group** announces the formation of ballot groups for the following items:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Version 2 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetic Model, Release 1 - US Realm (1<sup>st</sup> Informative Ballot) – Project Insight ID: [663](#)***

This IG covers transmission of results for chromosome analysis, including both traditional and molecular chromosome analysis. Currently, this data is reported in narrative form and warrants development of a structured data model in order to make it available for clinical decision support, outcomes analysis, and other secondary usage, as well as support linkage to knowledge bases enabling clinical interpretations to remain up-to-date. This implementation guide is based on the HL7 2.5.1 Laboratory Reporting guide. This work extends this standard for the reporting of cytogenetic test results from a laboratory into the EHR. There have been no substantive changes since the last comment only ballot of this material in September 2011.

Unique Ballot ID: V2IG\_CG\_CYTOGEN\_R1\_I1\_2012JAN

- ***HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2 – US Realm (1<sup>st</sup> Informative Ballot) – Project Insight ID: [692](#)***

This implementation guide extends release one, continuing to address the need to report structured genetic test results into the EHR, using well adopted standards and in a manner that is consistent with Clinical Genomics Variation model. Pilot projects have reported the need to support emerging testing platforms and use cases. Release 2 contains support for large genotyping tests (e.g. tumor profiling), test definition, coded references (e.g. articles in PubMed, records in OMIM).

Unique Ballot ID: V2IG\_CG\_LOINCGENVAR\_R2\_I1\_2012JAN

The **Implementable Technology Specifications Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***XML Encoding Rules for Version 2 Messages, Release 2 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [825](#)***

This standard describes the rules for the encoding of HL7 v2.x messages in XML for transmission. This document supersedes Release 1 and contains additional specifications to accommodate new features introduced beginning HL7 Version 2.3.1, for example the use of choices within message structures. This document is valid for all v2.x versions which have passed ballot up to and including v2.7.

Unique Ballot ID: HL7\_V2\_XML\_R2\_N1\_2012JAN

The **Orders and Observations Work Group** announces the formation of ballot groups for the following items:



[Ballot pending Technical Steering Committee approval.]

- ***HL7 Version 2.5.1 Implementation Guide: Orders and Observations; EHR-Laboratory Interoperability and Connectivity Specification (ELINCS) for Orders, Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [827](#)***  
The EHR-Laboratory Interoperability and Connectivity Specification (ELINCS) Orders Implementation Guide is an HL7 V2.5.1-based messaging specification intended to provide implementers of electronic laboratory order interfaces between ambulatory electronic health record (EHR) systems and clinical laboratories with clear, standards-based guidance on how to format and populate the relevant order messages. This specification focuses exclusively on the electronic ordering of ambulatory clinical lab tests in the ambulatory setting for the US realm. Electronic ordering for other tasks and contexts is outside the scope of the ELINCS Orders specification at this time, including messaging for ordering tests within the clinical lab, ordering inpatient lab tests, ordering lab tests outside of the US Realm, and for special-purpose ordering such as radiology test orders and referral orders (i.e. "send-out" tests) placed between labs. This specification assumes that electronic orders are transmitted from an EHR system to a specific, known lab. It does not address the concept of order queues, clearing houses, or other transport-level mechanisms and protocols that may be used to transfer or hold orders for later retrieval by a lab selected to perform the lab service. The EHR-Laboratory Interoperability and Connectivity Specification (ELINCS) Orders Implementation Guide is an This is a constraint on the HL7 V2.5.1-based messaging specification intended to provide implementers of electronic laboratory order interfaces between ambulatory electronic health record (EHR) systems and clinical laboratories with clear, standards-based guidance on how to format and populate the relevant order messages.  
Unique Ballot ID: V251\_IG\_EHRLABSPEC4ORD\_R1\_D1\_2012JAN

[Ballot level pending Technical Steering Committee approval.]

- ***HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [792](#)***  
This implementation guide focuses on the transmission of lab results from an ambulatory lab to an ambulatory EHR. The guide combines key capabilities that were introduced in the existing HL7 lab results guides, including a number of enhancements that exists in neither of those. The entire implementation guide went through a rigorous review with changes in all sections of the document. Consequently, all sections are within the scope of the ballot.  
Unique Ballot ID: V251\_IG\_SIF\_LABRESULTS\_R1\_D1\_2012JAN

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 2.7.1 Messaging Standard (2<sup>nd</sup> Normative Ballot) – Project Insight ID: [793](#)***  
V2.7.1 provides a number of updates necessary to support the US S&I Framework initiative to develop a Laboratory Results Interface in support of upcoming Meaningful Use stages. The scope of the ballot is focused on changes made to Chapter 2B, Chapter 4, and Chapter 7. They include:
  - enhancements to new definitions for conditional statements under conformance
  - definitional fixes to OBR.13 and OBR.54 in chapters 4 and 7

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Unique Ballot ID: V271\_N2\_2012JAN

The **Public Health and Emergency Response Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Version 2.5.1 Implementation Guide: Vital Records Birth and Fetal Death Reporting, Release 1 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [816](#)***

The V2.5.1 Vital Records Birth and Fetal Death Reporting Implementation Guide is an initial effort to provide an Implementation Guide for transmitting live birth and fetal death related information from a clinical setting to the vital records electronic registration system. This is the first cycle for this IG: Reporting Birth and Fetal Death Information from the EHR to Vital Records as a DSTU ballot. Unique Ballot ID: V251\_IG\_VR\_BAFDRPT\_R1\_D1\_2012JAN

### Version 3 Messaging

The **Clinical Interoperability Council Work Group** announces the formation of a ballot group for the following item:

- ***HL7 Version 3 Domain Analysis Model: Cardiology, Release 2 (2<sup>nd</sup> Informative Ballot) – Project Insight ID: [726](#)***

The scope of this project is to extend the initial release of this Domain Analysis Model (DAM) (V3\_CD\_ACSDAM\_R1\_I1\_2008MAY) approved in the May 2008 ballot. The initial scope was tightly constrained to core activities in the diagnosis and treatment of Acute Coronary Syndromes; this next phase will broaden the initial scope and significantly extend the clinical content more broadly in the Cardiovascular ACS domain. Release 2 of the ACS CV DAM will include clinical data elements associated with each of the activities in the patient care process including, but not limited to, the following use cases: cardiac case summary for patient care, secondary reporting for evaluating compliance with patient care guidelines and clinical trials with cardiovascular event endpoints. This follow up to the September 2011 ballot is to address the many ballot comments received.

Unique Ballot ID: V3\_DAM\_ACS\_R2\_I2\_2012JAN

The **Patient Administration Work Group** announces the formation of ballot groups for the following items:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Version 3 Domain Analysis Model: Patient Administration; Interdependent Registries, Release 1 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [725](#)***

Industry experience shows that real world applications require different types of registries to work together. The challenge for HL7 is to revise and extend the existing standards to support this interdependency. This document will ballot a Domain Analysis Model that describes information and behavior requirements to meet real world use cases. The goal of this DAM is to revise and extend the following existing standards to support this interdependency:

- Person topic (DSTU in Patient Administration domain)



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- Patient topic (DSTU in Patient Administration domain)
- Service Delivery Location (DSTU in Patient Administration domain)
- Provider topic (Normative R1 in Personnel Management domain)
- Organization topic (Normative R1 in Personnel Management domain)
- Healthcare, Community Services and Provider Directory (Normative R1 in Services domain)
- Entity Identification Service (Normative R1 in Services domain)
- Real Time Location System topic (Normative R1 in Registries domain)

The current HL7 registry standards follow somewhat different design patterns and implement incomplete dynamic models. In addition, the project needs to consider industry requirements for new registry standards such as Health Service Registry, Health Program Registry and Application/Device Registry. This ballot will incorporate concerns and suggested updates from the comment only ballot in May 2011.

Unique Ballot ID: V3\_PA\_INTREG\_R1\_D1\_2012JAN

[Ballot level pending Technical Steering Committee approval.]

- ***HL7 Version 3 Standard: Patient Administration; Patient Encounter, Release 1 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [736](#)***

This document proposes a significant revision to the current HL7 V3 patient encounter messaging DSTU. The current nine encounter-related topics are combined into a single Patient Encounter topic. The standard is simplified by eliminating constraints that are not appropriate for the universal standard. The document also implements a number of changes requested by implementers. The changes from the current DSTU include the following:

- The standard is reduced from nine topics to a single topic;
- The number of message types is reduced from 33 to 11;
- The number of trigger events is reduced from 49 to 20;
- Value constraints on structural attributes are changed from multi-value code sets to single code values where appropriate;
- Context conduction is revised to use the new vocabulary-based context conduction; and,

New query parameters are added.

There have been no substantive changes to this material since the DSTU ballot in May 2011.

Unique Ballot ID: V3\_PA\_R2\_ENCOUNTER\_R1\_N1\_2012JAN

The **Pharmacy Work Group** announces the formation of ballot groups for the following items:

- ***HL7 Version 3 Standard: Identification of Medicinal Products – Creation and Maintenance Messages, Release 1 (3<sup>rd</sup> DSTU Ballot) – Project Insight ID: [501](#)***

This ballot relates to the joint ISO and HL7 Identification of Medicinal Products (IDMP) project for creation and maintenance messages. IDMP is a JIC project to establish an ISO standard for identification of medicinal products at several levels (ISO-FDIS 11238, 11239, 11240, 11615 and 11616). These standards describe an information model, but not the business processes that use the information, nor an implementation of the information model that can be used by regulators,

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pharmaceutical companies and others who wish to implement the standards. ISO FDIS IDMP standards as follow:

- 11615 unique identification and exchange of regulated medicinal product information
- 11616 Unique identification and exchange of regulated pharmaceutical product information
- 11238 Substances
- 11239 Pharmaceutical dose forms, units of presentation and routes of administration
- 11240 Units of Measurement.

Unique Ballot ID: V3\_IDMP\_CMM\_R1\_D3\_2012JAN

[Original Consensus Group Ballot; closed to additional enrollment.]

- ***HL7 Version 3 Standard: Pharmacy; Medication Knowledge-Base Query, Release 1 (7<sup>th</sup> Normative Ballot) – Project Insight ID: [189](#)***

This topic covers the issuing of queries to medication knowledge-base applications for such information as medication composition, characteristics, and dosage instructions. Based on comments received in the September 2011 ballot, a non-backwards-compatible correction is being made to our Query model to handle the relationship of the parameters in a more correct manner.

Unique Ballot ID: V3\_RX\_MKBQ\_R1\_N7\_2012JAN

The **Public Health and Emergency Response Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Domain Analysis Model: Immunization, Release 1 (1<sup>st</sup> Informative Ballot) – Project Insight ID: [310](#)***

The Immunization Domain Analysis Model is a document that is intended to paint a picture of the domain around immunization. This includes the types of immunization data important in clinical medicine and public health, the interactions between health information systems regarding immunization which support these efforts. It seeks to provide a framework to support HL7 efforts in messaging, documents and services. The Domain Analysis Model document was balloted for comment in May 2011. The document being balloted has been adjusted to accommodate the suggestions from that ballot. This includes new and updated story boards, new and updated actors and updated use cases. In addition, this document includes class diagrams, activity diagrams and sequence diagrams to round out the picture.

Unique Ballot ID: V3DAM\_IZ\_R1\_I1\_2012JAN

The **Regulated Clinical Research Information Management Work Group** announces the formation of ballot groups for the following items:

- ***HL7 Version 3 Standard: Regulated Product Submission, Release 2 (2<sup>nd</sup> DSTU Update Ballot) – Project Insight ID: [539](#)***

The RPS Release 2 project goal is to extend the existing HL7 V3 Regulated Product Submission Standard, Release 1 with new requirements from ICH and ICH regional parties as an update to the current RPS R2 DSTU. The project will

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enhance the existing RPS Release 1 standard ultimately intended to yield a global standard. RPS Release 2 will extend the existing Release 1 through the inclusion of the ICH requirements for the management of drug product submissions in eCTD format. Additionally this release includes enhancements to support:

- European procedure types and modes and the recent European Variation legislation changes,
- Japanese health authority (PMDA) requirements for shinsei, shinki or ichihen in the RPS concepts of Application and Submission,
- The ability to define and reuse documents as a single file or as a collection of files (e.g., study and study components),
- The definition of product has been reduced to a set of essential components, and
- A product category has been added to further support Japanese review procedures.

Since the first DSTU Update ballot in September 2011, storyboards have received some minor edits, alignment with CPM has been achieved, and all attributes that can be fixed are now fixed.

Unique Ballot ID: V3\_RP\_R2\_U2\_2012JAN

- ***HL7 Version 3 Standard: Regulated Studies; Clinical Research Filtered Query (CRFQ) Service Functional Model (SFM), Release 1 (1<sup>st</sup> DSTU Update Ballot) – Project Insight ID: [541](#)***

The document is the Draft Standard for Trial Use of the Service Functional Model for Clinical Research Filtered Query. There have been no changes since the last version of this document from May 2008

Unique Ballot ID: V3\_CRFQSFM\_R1\_U1\_2012JAN

The **Security Work Group** announces the formation of a ballot group for the following item:

- ***HL7 Version 3 Domain Analysis Model: Security, Release 1 (1<sup>st</sup> Informative Ballot) – Project Insight ID: [529](#)***

This project intends to create a single Domain Analysis Model (DAM) integrating both security access control and privacy information models. The additions to the Composite Security and Privacy Domain Analysis Model, which passed ballot in May 2010 as DSTU, are intended to clarify how Confidentiality Codes are associated with policies, managed, assigned by senders and complied with by receivers. Use cases for managing, assigning and complying with Confidentiality Codes are integrated into the current DAM as described in the project scope statement for the Refactor Confidentiality Code Project #798:

<http://www.hl7.org/special/committees/projman/searchableprojectindex.cfm?action=edit&ProjectNumber=798>.

Unique Ballot ID: V3DAM\_SECURITY\_R1\_I1\_2012JAN

The **Structured Documents** and **Public Health and Emergency Response Work Groups** announce the formation of ballot groups for the following items:

[Ballot and alternate ballot open date pending Technical Steering Committee approval.]

***Alternate ballot open date: December 9, 2011***

- ***HL7 Version 3 Implementation Guide: Health Quality Measure Format (HQMF), Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [756](#)***  
The Health Quality Measure Format (HQMF) Implementation Guide includes a domain analysis model, the content required to measure quality. The content is the Quality Data Model (QDM) a consensus model of National Quality Forum (NQF). QDM lists information needs of quality measure and clinical decision support developers and is tested in retooling 113+ quality measures in HQMF. Included are CDA and RIM templates developed for each QDM elements and constraints and conventions and attributes used. Use of comparators is also included. The HQMF standard enables specification of measures to achieve the goal of repurposing existing clinical data.  
Unique Ballot ID: V3\_IG\_HQMF\_R1\_D1\_2012JAN

[Ballot and alternate ballot open date pending Technical Steering Committee approval.]

***Alternate ballot open date: December 9, 2011***

- ***HL7 Version 3 Standard: Representation of the Health Quality Measures Format (eMeasure), Release 1 (1<sup>st</sup> DSTU Update Ballot) – Project Insight ID: [508](#)***  
The Health Quality Measures Format (HQMF) formally defines a quality measure (data elements, logic, definitions, etc) to support consistent and unambiguous interpretation. Quality measures encoded in the HQMF format are referred to as "eMeasures". Quality measure developers can encode their measures in this format so that they can be consumed by provider organizations, who will then be able to use the formal definitions to, for instance, query their EHR data stores. HQMF has been applied to a large number of clinical quality measures. This process has identified opportunities for further enhancing the standard.  
Unique Ballot ID: V3\_HQMF\_R1\_U1\_2012JAN

***Version 3 Specifications, Infrastructure and Foundation***

The **Services Oriented Architecture Work Group** announces the formation of a ballot group for the following item:

[Ballot level pending Technical Steering Committee approval.]

- ***Resource Location and Updating Service (RLUS), Release 1 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [268](#)***  
The Retrieve, Locate, and Updating Service (RLUS) Service Functional Model specification provides a set of capabilities through which information systems can access and manage information resources. RLUS realizes, at its core, a basic set of CRUD capabilities plus location for health information resources management and, simply, standardizes the way in which the resources are exposed and consumed independently from the nature of the resources. HL7 Service Functional Models (SFMs) specify the functional requirements of a service. This work is complemented by a Service Technical Model (STM) specification, such as the complementary OMG's Retrieve, Locate, and Update Service (RLUS) Specification which specifies the technical requirements of a service. This document reflects a refresh of what had been the DSTU document to bring it into alignment with the subsequently-adopted OMG RLUS complementary

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specification. The internal reference model (Platform Independent Model - PIM) and supporting language have been adjusted to align with lessons-learned from implementation experience of the work. Detailed errata are available on the project working site.

Unique Ballot ID: V3\_RLUS\_R1\_N1\_2012JAN

The **Templates Work Group** announces the formation of a ballot group for the following item:

[Ballot pending Technical Steering Committee approval.]

- ***HL7 Templates Registry Business Process Requirements Analysis, Release 1 (1<sup>st</sup> Comment Only Ballot) – Project Insight ID: [829](#)***

Extensive changes to the initial draft have been suggested at the September 2011 HL7 WG meeting, and in online and conference call discussions within the Templates WG, and need to be integrated into this updated version. The revised document will seek clarification of all business requirements including: roles and responsibilities; varying levels of registrations and approval requirements by the different types of users of the registry. In particular, this includes role definitions for template suppliers, template information consumers, and template registry management as well as communication/feedback requirements/responsibilities among all role types.

Unique Ballot ID: HL7\_TEMPLREGREQAN\_R1\_O1\_2012JAN

### **Ballot Procedure**

#### **General Guidelines**

The membership is reminded that ANSI rules dictate that all individuals who were in a normative ballot pool **MUST** be included in the initial ballot pool when the same document goes out for a subsequent normative ballot. Thus, if a document is going out for a 2<sup>nd</sup> normative ballot, all individuals who were active in the ballot pool (casting either an affirmative, negative or abstain) for the 1<sup>st</sup> normative ballot are automatically subscribed as members for the subsequent normative ballot.

HL7 will conduct these ballots according to its procedure for electronic balloting. Individuals who sign up for the ballot group will not receive a paper copy of the document or a paper ballot. Instead, they will be notified by e-mail when the ballot package is available. They will download the document from the HL7 web server and will enter their votes and comments using the HL7 Ballot Desktop.

If a member of the ballot group does not have access to the technology being used, or if the person can demonstrate that using the electronic process creates a substantial hardship, he/she may request a paper copy of the ballot package and/or vote using a paper ballot. Because of the extra expense and time delays associated with paper ballots, HL7 does not intend to provide the alternative of using paper to members who have access to the technologies and have no substantial hardship associated with their use.

#### **Voting**

HL7 members and others who are materially affected by any of the proposed standards and wish to participate in these ballots must join the respective ballot

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groups. This can be accomplished by logging on to the Ballot Desktop at the following URL: <http://www.HL7.org/ctl.cfm?action=ballots.home>. Alternately, members can call the HL7 office at (734) 677-7777 and request that the Ballot Group Declaration Form be faxed or mailed to them.

With the exceptions noted above, all voting related activity – joining ballot pools, downloading or reviewing ballot content, uploading comments and voting – is done through the Ballot Desktop. In addition, non-members wishing to take part in this or any HL7 ballot must use the Ballot Desktop to register. Those non-members wishing to use this option are referred to the Paid Participation in HL7 Ballots Instructions posted on the HL7 Ballot Desktop.

All ballot dates are inclusive: votes cannot be cast before the beginning date or after the ending date of a ballot pool. Please note that all times are tracked in the Eastern Time Zone (US). If you have problems with the ballot desktop, joining, or voting, please contact the HL7 Director of Technical Publications ([ballotmanager@hl7.org](mailto:ballotmanager@hl7.org)) or Director of Technical Services ([webmaster@HL7.org](mailto:webmaster@HL7.org)) before the closing of the ballot.

**Negative Votes on Normative Ballots:** Members are reminded of the following rules from the HL7 GOM regarding the submission of negative votes on normative ballots:

- 14.06.03.01 Submission of Comments – Statements accompanying negative ballots should be submitted as an attachment to the ballot and clearly reference the particular ballot item(s) to which it pertains.
- 14.06.03.02 No Comments or Inappropriate Comments – Negative ballots not accompanied by comments or accompanied by inappropriate comments or comments of no relevance to the ballot proposal shall not be considered. Such ballots will be recorded as a “negative without comment” for the purposes of establishing a quorum and reporting to ANSI. However, these ballots shall not be factored into the numerical requirements for consensus. No effort shall be made to solicit comments from the submitter of a negative without comment.

### Important Notes

**IMPORTANT NOTE on Balloting Rules:** Due to changes in the past several cycles in the HL7 Governance and Operations Manual (GOM), the rules under which balloting takes place have changed slightly. These changes can be summarized as follows:

- The definition for the Consensus Group for Subsequent Normative Ballots of the Same Content (GOM: 14.03.04) has changed. The consensus group for subsequent ballots "shall consist of those individuals, members or nonmembers, who submitted a ballot by the close of the ballot response period; whether affirmative, negative, or abstain." For complete details, please refer to the indicated section.
- As a reminder, the quorum and approval levels stipulated in the GOM will apply to all ballot pools. They are as follows:
  - Informative Ballots – No quorum requirement; 60% affirmative votes for approval.



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- DSTU Ballots – No quorum requirement; 60% affirmative votes for approval.
- Normative Ballots – Minimum 10 HL7 members in ballot pool; 60% returning votes for quorum; 75% affirmative votes for approval.
- Comment Only Ballots – No quorum requirement.

**Reconciliation Rules:** The balloting of all items listed in this announcement is contingent upon completion of the appropriate ballot reconciliation activities as indicated the HL7 GOM sections 13, for Review ballots, and 14, for Normative ballots.

**Unique Ballot IDs:** Each ballot document has a unique Ballot ID that can be found following its descriptive text. In addition, updated ballot comment spreadsheets will be available on the balloting website at the time the ballots open.

### Help

**ISSUE – Ballot Pools Not Displayed:** If you navigate to the Ballot Desktop and it does not correctly display the ballot pools you have previously signed up for, please click the “September 2011 Ballot Cycle” link in the left-hand navigation pane. This will resolve 90% of users’ issues.

**ISSUE – Ballot Pools Not Open for Enrollment:** When enrolling in ballot pools, you may notice that some pools are not available for enrollment. This is either because the enrollment period for that ballot has closed, or that ballot is a subsequent normative ballot and is limited to the original consensus group of that ballot.

**IMPORTANT:** Should you have issues voting, it is important that you contact us before the close of the ballot. Communications received after a ballot has closed cannot be honored.

**OTHER ISSUES -** Should you have any other issues logging in to the Ballot Desktop, signing up for ballot pools or voting, please contact Don Lloyd (dlloyd@HL7.org), Technical Publications Manager, or Michael Kingery (mkingery@HL7.org), HL7 Webmaster.

Appendix A – Listing of Ballots by Ballot Level for January 2012 Ballot Cycle

Normative Ballots

- ***Health Level Seven Arden Syntax for Medical Logic Systems, Version 2.9 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [734](#)***  
Unique Ballot ID: ARDEN\_V29\_N1\_2012JAN
- ***HL7 Version 2.7.1 Messaging Standard (2<sup>nd</sup> Normative Ballot) – Project Insight ID: [793](#)***  
Unique Ballot ID: V271\_N2\_2012JAN
- ***HL7 Version 3 Standard: Patient Administration; Patient Encounter, Release 1 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [736](#)***  
Unique Ballot ID: V3\_PA\_R2\_ENCOUNTER\_R1\_N1\_2012JAN
- ***HL7 Version 3 Standard: Pharmacy; Medication Knowledge-Base Query, Release 1 (7<sup>th</sup> Normative Ballot) – Project Insight ID: [189](#)***  
Unique Ballot ID: V3\_RX\_MKBQ\_R1\_N7\_2012JAN
- ***Resource Location and Updating Service (RLUS), Release 1 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [268](#)***  
Unique Ballot ID: V3\_RLUS\_R1\_N1\_2012JAN
- ***XML Encoding Rules for Version 2 Messages, Release 2 (1<sup>st</sup> Normative Ballot) – Project Insight ID: [825](#)***  
Unique Ballot ID: HL7\_V2\_XML\_R2\_N1\_2012JAN

Informative Ballots

- ***HL7 Domain Analysis Model: Immunization, Release 1 (1<sup>st</sup> Informative Ballot) – Project Insight ID: [310](#)***  
Unique Ballot ID: V3DAM\_IZ\_R1\_I1\_2012JAN
- ***HL7 EHR-System Functional Profile for Health Information Exchange Metadata, Release 1 – US Realm (1<sup>st</sup> Informative Ballot) – Project Insight ID: [819](#)***  
Unique Ballot ID: EHR\_FP\_HIEM\_R1\_I1\_2012JAN
- ***HL7 Version 2 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetic Model, Release 1 - US Realm (1<sup>st</sup> Informative Ballot) – Project Insight ID: [663](#)***  
Unique Ballot ID: V2IG\_CG\_CYTOGEN\_R1\_I1\_2012JAN
- ***HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 2 – US Realm (1<sup>st</sup> Informative Ballot) – Project Insight ID: [692](#)***  
Unique Ballot ID: V2IG\_CG\_LOINCGENVAR\_R2\_I1\_2012JAN

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- ***HL7 Version 3 Domain Analysis Model: Cardiology, Release 2 (2<sup>nd</sup> Informative Ballot) – Project Insight ID: [726](#)***  
Unique Ballot ID: V3\_DAM\_ACS\_R2\_I2\_2012JAN
- ***HL7 Version 3 Domain Analysis Model: Security, Release 1 (1<sup>st</sup> Informative Ballot) – Project Insight ID: [529](#)***  
Unique Ballot ID: V3DAM\_SECURITY\_R1\_I1\_2012JAN

### DSTU Ballots

- ***HL7 Implementation Guide for CDA® Release 2: Exchange of Clinical Trial Subject Data; Patient Narratives, Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [822](#)***  
Unique Ballot ID: CDAR2\_IG\_EXCTSD\_PATNARR\_R1\_D1\_2012JAN
- ***HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, Release 1 – US Realm (1<sup>st</sup> DSTU Update Ballot) – Project Insight ID: [210](#)***  
Unique Ballot ID: CDAR2\_QRDA\_R1\_U1\_2012JAN
- ***HL7 Service-Aware Interoperability Framework: Canonical Definition, Release 2 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [807](#)***  
Unique Ballot ID: SAIF\_CANON\_R2\_D1\_2012JAN
- ***HL7 Version 2 Implementation Guide: Implementing the Virtual Medical Record for Clinical Decision Support (vMR-CDS), Release 1 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [184](#)***  
Unique Ballot ID: V2IG\_CDS\_VMR\_R1\_I3\_2012JAN
- ***HL7 Version 2.5.1 Implementation Guide: Orders and Observations; EHR-Laboratory Interoperability and Connectivity Specification (ELINCS) for Orders, Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [827](#)***  
Unique Ballot ID: V251\_IG\_EHRLABSPEC4ORD\_R1\_D1\_2012JAN
- ***HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [792](#)***  
Unique Ballot ID: V251\_IG\_SIF\_LABRESULTS\_R1\_D1\_2012JAN
- ***HL7 Version 2.5.1 Implementation Guide: Vital Records Birth and Fetal Death Reporting, Release 1 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [816](#)***  
Unique Ballot ID: V251\_IG\_VR\_BAFDRPT\_R1\_D1\_2012JAN
- ***HL7 Version 3 Domain Analysis Model: Patient Administration; Interdependent Registries, Release 1 (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [725](#)***  
Unique Ballot ID: V3\_PA\_INTREG\_R1\_D1\_2012JAN
- ***HL7 Version 3 Implementation Guide: Health Quality Measure Format (HQMF), Release 1 – US Realm (1<sup>st</sup> DSTU Ballot) – Project Insight ID: [756](#)***  
Unique Ballot ID: V3\_IG\_HQMF\_R1\_D1\_2012JAN

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- ***HL7 Version 3 Standard: Identification of Medicinal Products – Creation and Maintenance Messages, Release 1 (3<sup>rd</sup> DSTU Ballot) – Project Insight ID: [501](#)***  
Unique Ballot ID: V3\_IDMP\_CMM\_R1\_D3\_2012JAN
- ***HL7 Version 3 Standard: Regulated Product Submission, Release 2 (2<sup>nd</sup> DSTU Update Ballot) – Project Insight ID: [539](#)***  
Unique Ballot ID: V3\_RP\_R2\_U2\_2012JAN
- ***HL7 Version 3 Standard: Regulated Studies; Clinical Research Filtered Query (CRFQ) Service Functional Model (SFM), Release 1 (1<sup>st</sup> DSTU Update Ballot) – Project Insight ID: [541](#)***  
Unique Ballot ID: V3\_CRFQSFM\_R1\_U1\_2012JAN
- ***HL7 Version 3 Standard: Representation of the Health Quality Measures Format (eMeasure), Release 1 (1<sup>st</sup> DSTU Update Ballot) ) – Project Insight ID: [508](#)***  
Unique Ballot ID: V3\_HQMF\_R1\_U1\_2012JAN

### For Comment Only Ballots

- ***HL7 Implementation Guide for CDA® Release 2: Genetic Testing Reports, Release 1 (4<sup>th</sup> Comment Only Ballot) – Project Insight ID: [460](#)***  
Unique Ballot ID: CDAR2\_IG\_GENTESTRPT\_R1\_O4\_2012JAN
- ***HL7 Templates Registry Business Process Requirements Analysis, Release 1 (1<sup>st</sup> Comment Only Ballot) – Project Insight ID: [829](#)***  
Unique Ballot ID: HL7\_TEMPLREGREQAN\_R1\_O1\_2012JAN
- ***Introducing New Processes to HL7, Release 1 (1<sup>st</sup> Comment Only Ballot) – Project Insight ID: [818](#)***  
Unique Ballot ID: HL7\_INTNEWPROC\_R1\_O1\_2012JAN
- ***Proposed 2013 HL7 Strategic Initiatives and Criteria (1<sup>st</sup> Comment Only Ballot) – Project Insight ID: [808](#)***  
Unique Ballot ID: HL7\_SI2013\_R1\_O1\_2012JAN