December 5, 2008

Health Level Seven (HL7) invites you to take part in the formation of ballot groups for the upcoming January 2009 ballot cycle. The candidate standards and other documents described in this announcement are expected to ballot prior to HL7's January 2009 Working Group Meeting (WGM). Comments received in response to these ballots will be addressed at that WGM running January 11-16 in Orlando, FL. Please refer to "Appendix B – Changes from Initial Announcement" for important updates to this document since the initial Announcement of Formation of Ballot Pools.

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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: December 3, 2008
Ballot Close Date: January 5, 2009

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: November 19, 2008
Ballot Pool Sign-Up Close Date: December 29, 2008

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:
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 Paid Participation in the ballot.

Ballot Listing

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

- 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 January 2009 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 limited to the members of the original consensus group, as stipulated in the HL7 Governance and Operations Manual (GOM), section 14.03.04 - Consensus Group for Subsequent Normative Ballots of the Same Content. 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 GOM.

Standards Classifications

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

- Clinical Document Architecture, Release 2
- Electronic Health Records
- Version 2.7 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

Clinical Document Architecture, Release 2

The Structured Documents Work Group announces the formation of ballot groups for the following documents:

Alternate Ballot open date: December 6, 2008


With cooperation from CDC and healthcare associated infections (HAI) software vendors, this project will further develop an implementation guide constraining CDA Release 2. The implementation guide, the initial release of which was approved as a Draft Standard for Trial Use in the January 2008 HL7 ballot cycle, will support electronic submission of HAI data to the CDC’s National Healthcare

Safety Network (NHSN). The current ballot proposal adds the following new forms:
- Urinary tract infections,
- Pneumonia,
- Other infections for which CDC provides case definitions and a reusable custom event form, and
- Process of care measures, namely central line insertion practices (CLIP) and influenza vaccination coverage for healthcare personnel and high risk patients.

Updates to the BSI/SSI and respective denominator reports will also be included. The updated HAI ballot will include:
- Updated vocabulary,
- Harmonization of the findings section with IHE,
- Merging of value sets and OID review.

The NHSN requires specific vocabulary terms that are not always available in the traditional terminology systems. When standard terms are available they will be used by NHSN. In some instances the standard terms, included in the IG, do not capture the full meaning necessary by NHSN so they will be updated to local terms. Many of the HAI reports include a findings organizer to report lab information. In order to keep consistent with other industry standards a harmonization will be done with the appropriate pieces of IHE. As the NHSN vocabulary services have evolved new relationships between terms have emerged. In order to keep consistent with the advancements of NHSN some value sets and code systems, within the IG, will be reassigned. This document has been identified as not backwards compatible.

Unique Ballot Id: CDAR2L3_IG_HAIRPT_R2_D2_2009JAN

Alternate Ballot open date: December 6, 2008
  The project will:
  - Support the development of a CDA IG for patient assessments, including assessments that include functional status; and
  - Submit this CDA IG for balloting as an HL7 DSTU.
  The DSTU will include a Universal Realm Framework and, as an example of implementation of the framework, a full specification for the US Realm Minimum Data Set, 3.0.
  Unique Ballot Id: CDAR2_IG_PA_R1_D1_2009JAN

Alternate Ballot open date: December 6, 2008
  The goal of the Plan-to-Plan Personal Health Record (PHR) Data Transfer Project is to create an HL7 implementation guide that will provide for PHR portability between Health Plans. The project is limited in scope to the payor stakeholder community in the U.S. Realm. However it could be expanded or adapted to include other PHR stakeholders, data transfer beyond the PHR, and the international affiliates. The updated ballot will include:
  - Harmonization with HITSP C32 requirements,
  - Updated vocabularies to standard terminologies,
Additional administrative items, and
A mapping table with the elements required for a P2P exchange.
The harmonization effort with HITSP C32 will include careful review of
vocabularies defined and new constraints for overlapping sections, such as
Problems and Alerts. In the initial ballot the P2PPHR included vocabularies
specific to the insurance sector. As part of the ballot update a review and mapping
to standard terminologies will be done. In order to fully support the P2PPHR
additional administrative items and a mapping table of required elements will be
added. Some of the new fields include:
- Place of service,
- Facility type code, and
- Claim frequency code.
The mapping table in the IG will partner the required elements with XPATH
statements to help new CDA implementers locate where the information is being
sent.
Unique Ballot ID: CDAR2_IG_P2PHRDATATRANS_R1_I2_2009JAN

**Electronic Health Records**

The **Electronic Health Records Work Group** announces the formation of ballot groups for
the following documents:

- **HL7 EHR Clinical Research Functional Profile, Release 1 (1\textsuperscript{st} Normative Ballot)**
The EHR/CR Functional Profile is intended to provide high-level requirements
necessary for using electronic health record data for regulated clinical research,
and to further provide a roadmap towards an evolutionary process of integrating
the environment that provides both patient care and data for clinical research. It is
intended to provide one overall view of the regulatory needs of clinical research
with respect to electronic patient records.
This profile successfully passed Informative Ballot in May, 2008. All ballot
comments were addressed. The submitters of negative comments were contacted,
heard and their concerns were successfully addressed during reconciliation. There
were no substantive changes.
Unique Ballot Id: EHR_CRFP_R1_N1_2009JAN

- **HL7 EHR System Long Term Care Functional Profile, Release 1-US Realm (1\textsuperscript{st} Normative Ballot)**
The LTC EHR-S Functional Profile establishes the functions and conformance
criteria for EHR systems in the nursing home setting for the US Realm. The LTC
EHR-S functional profile was previously balloted within the LTC community
before balloting at HL7 at the informative level.
Substantive changes:
- Addition of a new child function to the summary lists function DC.1.4 - the
new list type would be for medical equipment, orthotics and prosthetics. In the
nursing home setting since a patient's care is managed over a longer period of
time the facility becomes responsible for knowing what devices/equipment are
in place, the maintenance schedule, etc. (and also communicating that info to
subsequent care givers).
Renumbered conformance criteria to assign a unique number to each item
(e.g. changed criteria number as 4a. to 5) and other typo/grammatical updates.
Unique Ballot Id: EHR_LTCFP_R1_N1_2009JAN

Version 2.7 Messaging

The Infrastructure and Messaging, Electronic Health Records, Financial Management,
Implementation/Conformance, Orders and Observations, Patient Administration,
Patient Care, Scheduling and Logistics, Technical Steering Committee and Vocabulary
Work Groups announce the formation of a ballot group for the following candidate
standard:

[Original Consensus Group ballot; closed to additional enrollment. Voters are reminded that
only changes resulting from the previous normative ballot comments are open for review;
comments related to previously balloted material will be found out of scope.]

- **HL7 Messaging Standard Version 2.7: An Application Protocol for Electronic
  Data Exchange in Healthcare Environments (3rd Normative ballot)**
  This ballot is for all V2 chapters to create the HL7 V2.7 standard from Version
  2.6 by applying those proposals that were accepted by the end of the January 2008
  WGM, ruled to be in scope, and found to be possible in the publication
  timeframe. Global changes include:
  - Correction of various typographical and technical errors
  - Correction of examples in various chapters
  CH2, Control, changes include:
  - Fix FHS and BHS segment definitions to be consistent with MSH
  - Fix detected issues with the length changes, including references to the
    truncation separator
  - Correction of various cross references
  - Change component to ST instead of ID and move link to rfc 2046 from 2C
e   to Chapter 2
  - Change CSU datatype to use ST for CSU-17 and CSU-20
  - Correct NA and MA datatype descriptions
  - Make the VID.1 component required instead of optional.
  CH2A, Data Types, changes include but are not limited to:
  - 2.A.90 "5599" is the country code for Guantanamo Bay fix c.len
  CH2B, Conformance, changes include but are not limited to:
  - Several updates correcting section references
  - Wording for Min/Max length examples corrected in 2.B.7.1
  - Wording for explanation of truncation corrected in 2.B.7.3
  - Wording replaced by reference to CH. 2 in 2.B.8.10
  CH2C (NEW), Code Tables, additions include:
  - Editor will make sure that all deprecated/withdrawn data types are
    annotated.
  - 2.C.2.213Update/fixed Table Metadata to have Vocab listed as maintainer
  CH3, Patient Administration, changes include:
  - Mark section 3.3.18 as withdrawn
  - Change message structure in 3.3.43 to A44
  - Corrected note for withdrawal of trigger events in 3.3.36
  - Added clarification to new field PID-40 in 3.4.2
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- Added Adverse Reaction segment grouping in 3.3.60
- Removed information from table for withdrawn fields PID-14 and PID-19 in 3.4.2
- Corrected text for field description in 3.4.7.21

CH4, Orders & Observations, changes include:
- PRT segment for the Patient Group grouping corrected to Patient Group.
- PRT segment added to Patient Group where missing (ack messages)
- Changes to the ORC and OBR segment definitions to make them consistent with regard to placer order number
- Segment groups without names were given name Specimen Observation Group
- "Result ID" replaced by "Observation Group" in names of BR-51 & 52
- Reference to SDM removed from HL7 Table 0411
- PRT segment references to chapter 15 changed to chapter 7

CH4A, Queries, changes include:
- Segment group(s) w/o names will be named
- Message structure for 4.A.13 and 4.A.14 will be reconciled

CH5, Queries, changes include:
- Message structures will be harmonized across the whole chapter

CH6, Financial Management, changes include:
- Datatype changes ST to CX in fields: 6.5.1.38, 6.5.1.39, 6.4.1.42
- Field name change in 6.5.9.12
- Missing definitions added in 6.5.1.43

CH7, Observations, changes include:
- OPU - Message structure fixed to match PRT introduction in 7.3.11
- OBX - Table reference changed to Table 0125 in 7.4.2.2
- PRT – Participation Segment, Condition updated to harmonize with ROL segment in 7.4.4.1
- PRT – Participation Segment, table reference changed to Table 0206 in 7.4.4.2
- PRT – Participation Segment, added conditionality statement in 7.4.4.7
- PRT – Participation Segment, definition that address can repeat and add conditionality statement was clarified in 7.4.4.14/15
- PEX – Product Experience Message, fixes to segment group names in 7.11.1
- Tables 905, 906, 907, and 544 changed to HL7 defined in various sections.

CH8, Master Files, changes include:
- 8.8.8.11 Item Names will be corrected to match attribute table

CH9, Medical Records:
- No Issues

CH10, Scheduling & Logistics, changes include:
- Removal of an empty table

CH11, Patient Referral, changes include:
- Insertion of new Collaborative Care Message

CH12, Patient Care, changes include
- One definitional change and other minor wording changes.

CH13, Clinical Laboratory Automation:
- No Issues

CH14, Application Management:

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- No Issues

CH15, Personnel Management:
- No issues

CH16, eClaims, changes include:
- Wrong sequence number corrected in 16.4.2.21
- Item Name differed from attribute table in16.4.2.22
- Segment groups without a name corrected in 16.3.6, 16.3.10, 16.3.14

CH17, Materials Management, changes include:
- Non-substantive, technical corrections to sequence numbers in three field definitions.

Unique Ballot ID: V27_N3_2009JAN

Version 3 Messaging

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

[Original Consensus Group ballot; closed to additional enrollment. Voters are reminded that only changes resulting from the previous normative ballot comments are open for review; comments related to previously balloted material will be found out of scope.]

- HL7 Version 3 Standard: Clinical Genomics; Genetic Variation, Release 1 (1st For Comment Only Ballot)
  This ballot document stems from industry need. During the DSTU period, the area that has been experimented the most in the Clinical Genomics Domain is the genetic variations area, and therefore it is the first topic we progress to Normative. This is the second iteration of the normative ballot of the topic. Changes stem from reconciling negative comments made in the previous ballot cycle. This document has been identified as backwards compatible.
  Unique Ballot Id: V3_CG_GV_R1_O1_2009JAN

The Community Based Collaborative Care Work Group announces the formation of ballot groups for the following documents:

- HL7 Version 3 Domain Analysis Model: Medical Records; Composite Privacy Consent Directive, Release 2 (1st Informative Ballot)
  This RMIM is based on the normative A_DataConsent CMET and a Consent Directive Grouper class to enable grouping of consent directives. This ballot introduces the following:
  - A Domain Analysis Model that specifies use cases, process flow, information model, business rules, glossary, and business rules associated with privacy policy and individual privacy consent directives.
  The Domain Analysis Model addresses additional use cases (in addition to consent management and query) that have been included since the previous ballot.
  Unique Ballot Id: V3DAM_MR_CPCD_R2_I1_2009JAN
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- **HL7 Version 3 Standard: Medical Records; Composite Privacy Consent Directive, Release 2 (2nd For Comment Only Ballot)**
  This RMIM is based on the normative A_DataConsent CMET and a Consent Directive Grouper class to enable grouping of consent directives. This ballot includes the following:
  - Revisions to the "Composite Privacy Consent Directive, Release 2" based on the comments submitted during the previous "For Comment" ballot.
  Unique Ballot Id: V3_MR_CPCD_R2_O2_2009JAN

The **Financial Management Work Group** announces the formation of ballot groups for the following documents:

- **HL7 Version 3 Standard: Account & Billing CMETs, Release 9 (1st Normative Ballot)**
  This is the first normative ballot of the A_Value Item, A_Benefit, and A_Provider Contract CMETs. There have been no changes to these items since the last ballot.
  Unique Ballot Id: V3_AB_CMET_R9_N1_2009JAN

  The Medicaid Information Technology Architecture (MITA) Unified Modeling Language (UML) Development Framework document is intended to describe a set of notation elements and conventions intended to support the reuse and application of MITA based on domain analysis principles and using UML as the notation. Changes since last cycle include the addition of a MITA Overview Section to frame the context of the materials presented.
  Unique Ballot Id: V3_MITASG_R1_D2_2009JAN

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

- **HL7 Version 3 Standard: Laboratory CMETs, Release 9 (1st Normative Ballot)**
  Two Laboratory Related CMETs are included in this ballot pool:
  - COCT_MT430000 R_LabTestKit universal
  - COCT_MT570000 A_LaboratoryProcessingStep universal
  These two CMETs were previously balloted at committee level, passing without any comments. Laboratory is now balloting these CMETs at the Normative level. No changes have been made since these CMETs passed the previous committee ballots.
  Unique Ballot Id: V3_LAB_CMET_R9_N1_2009JAN

- **HL7 Version 3 Standard: Specimen CMETs, Release 9 (4th Committee Ballot)**
  Three Specimen CMETs are included in this ballot pool:
  - COCT_MT080000 R_Specimen universal
  - COCT_MT080100 R_Specimen minimal
  - COCT_MT080200 R_Specimen lite
  These three CMETs were previously balloted at committee level, and received several negative comments requiring substantive changes. Laboratory is
reballoting these CMETs at the Committee level. The following changes are being made to the Specimen CMETs:
- Remove the "No cycles allowed" constraint
- Rename Additive.Target constraint to Additive.player
- Rename Container.Target constraint to Container.player
- Change ObservationEvent.code and SpecimenCollectionProcess.code from CE to CD data type.
- Remodel IdentifiedHolderContainerOrAdditive class to be consistent with other uses of the IDENT role class in the Specimen CMETs.

Unique Ballot Id: V3_SPEC_CMET_R9_C4_2009JAN

The Orders and Observation Work Group announces the formation of ballot groups for the following documents:

- **HL7 Version 3 Standard: Blood, Tissue, Organ; Donation, Release 1 (4th Committee Ballot)**
  This ballot document includes message standards for the transmission of donor and blood product information between a blood center and other facilities, such as a transfusion service, an off-site donor testing laboratory, a hospital, and/or a plasma manufacturing company, and message standards for recording a request to donate blood, e.g. directed donations or autologous (for self) donations. Changes since the last ballot include minor modifications to the message models to address harmonization issues (with other HL7 v3 Standards) and documentation updates to conform to publishing standards.
  Unique Ballot Id: V3_BTO_DONATION_R1_C4_2009JAN

The Orders and Observation and Pharmacy Work Groups announce the formation of a ballot group for the following document:

- **HL7 Version 3 Standard: Common Clinical Product Model, Release 1 (1st Normative Ballot)**
  This ballot document includes message specifications for the creation of a Common Clinical Product Model, which takes into account all the current product-like models used in V3 messages - for example the Medication Domain Message Information Model (Pharmacy), the Structured Product Labelling document structure, the Individual Case Safety Report message, and Immunization.
  Unique Ballot Id: V3_CCP_R1_N1_2009JAN

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

- **HL7 Version 3 Standard: Patient Administration CMETs, Release 9 (1st Normative Ballot)**
  This pool intends to complete normative balloting of Patient Administration derived CMETs to make them consistent with current Patient Administration DMIM. The following CMETs are included in this ballot:
  - COCT_RM030000UV E_LivingSubject universal
  - COCT_RM030100UV E_NonPersonLivingSubject universal
• COCT_RM030200UV E_Person universal
• COCT_RM050000UV R_Patient universal
• COCT_RM050003UV R_Patient contact
All the CMETs previously passed Committee ballot.
Unique Ballot Id: V3_PA_CMET_R9_N1_2009JAN

• **HL7 Version 3 Standard: Personnel Management; Organization Registry, Release 2 (1st DSTU Ballot)**
Personnel Management Release 1, consisting of the Provider and Organization topics, became a normative standard on October 25, 2005. Work on Release 2 of those topics progressed through Committee 1 ballot in January 2006 followed by For-Comment 1 ballot in May 2006 after which the Personnel Management Technical Committee disbanded. In this project the Patient Administration Work Group will resume work on Release 2 of the Organization topic. Organization Registry Release 2 will address the following requirements:
- Support the use of Accountability History methodology.
- Additions to Organization Candidate Query
- Additions to Add and Update Organization RMIMs
This document has been identified as backwards compatible.
Unique Ballot Id: V3_PM_OR_R1_D1_2009JAN

• **HL7 Version 3 Standard: Personnel Management; Provider Registry, Release 2 (1st DSTU Ballot)**
Personnel Management Release 1, consisting of the Provider and Organization topics, became a normative standard on October 25, 2005. Work on Release 2 of those topics progressed through Committee 1 ballot in January 2006 followed by For-Comment 1 ballot in May 2006 after which the Personnel Management Technical Committee disbanded. In this project the Patient Administration Work Group will resume work on Release 2 of the Provider topic. Provider Registry Release 2 will address the following requirements:
- Support the use of Accountability History methodology
- Add name attribute to QualifiedEntityRole
- Add Organization parameter to Provider Query
This document has been identified as backwards compatible.
Unique Ballot Id: V3_PM_PR_R1_D1_2009JAN

The **Patient Care Group** announces the formation of a ballot group for the following document:

• **HL7 Version 3 Standard: Care Provision; Assessment Scales, Release 2 (1st DSTU Ballot)**
Since the DSTU for assessment scales under care provision care structures new insights in assessment scale representations require an update. In particular nesting for subscales, reference ranges, and referring to additional information supporting the scoring are additions required. Further, the model should accommodate future development and deployment in HL7 v3 of detailed clinical models. The R-MIM will be changed in particular extended with additional classes. The walkthrough will be completed, reusing the existing materials from R1 DSTU, but adding application guidelines.
The Pharmacy Work Group announces the formation of a ballot group for the following document:

- **HL7 Version 3 Standard: Pharmacy; Medication Order, Release 1 (1st Normative Ballot)**
  This document describes messaging to support the prescription (also known as request or order), dispensing (also known as supply) and administration of medications (also known as drugs), in both a Community (e.g. family practice or community pharmacy) and an Institutional (e.g. hospital) setting. These activities may also occur between or across care settings. Note: a hospital can order a drug to be dispensed in a community pharmacy. Attribute Descriptions are being added as are corrections to the model based on the ballot reconciliation.

Unique Ballot Id: V3_RX_MEDORDER_R1_N1_2009JAN

The Public Health/Emergency Response Work Group announces the formation of a ballot group for the following items:

- **HL7 Version 3 Standard: Public Health CMETs, Release 9 (1st Normative Ballot)**
  This ballot pool covers the following public health related CMETs:
  - COCT_MT840000 E_PublicHealthEntity universal
  - COCT_MT840100 E_PublicHealthNonPersonLivingSubject universal
  - COCT_MT840200 E_PublicHealthPerson universal
  - COCT_MT840300 E_PublicHealthVector universal
  - COCT_MT840500 E_PublicHealthPathogen universal
  - COCT_MT841000 E_PublicHealthFomite universal
  - COCT_MT841100 E_PublicHealthMaterial universal
  - COCT_MT841200 E_PublicHealthManufacturedMaterial universal
  - COCT_MT841300 E_PublicHealthPlace universal
  - COCT_MT841400 E_PublicHealthOrganization universal
  - COCT_MT841500 E_PublicHealthPhysicalEntity universal

  These CMETs were previously balloted at normative level. Changes to the E_PublicHealthEntity suite of CMETs include the following:
  - Changes to what entities are allowed to play the Employment Role
  - Fine-tuning attribute level and walkthrough descriptions
  - Changes to what entities are allowed to play the Product related roles
  - Update Act and Role code attributes to use concept domains added in the last round of harmonization

Unique Ballot Id: V3_PH_CMET_R9_N1_2009JAN

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

• **HL7 Version 3 Domain Analysis Model: Public Health; CDISC Content to Message - Study Participation, Release 1 (1st Informative Ballot)**
  This document provides the Domain Analysis Model and associated mappings to BRIDG and to the associated Study Participation message. This is the first ballot of this material.
  Unique Ballot Id: V3DAM_CDISC2MSG_SP_R1_I1_2009JAN

• **HL7 Version 3 Implementation Guide: Drug Stability Reporting (eStability), Release 2 (2nd Informative Ballot)**
  This document describes the basic requirements needed for using the Drug Stability Reporting standard and the requirements needed for submitting information to the Food and Drug Administration (FDA) using the standard. This ballot is constrained to the changes since the last ballot. Changes provide clarification of purpose and one study, one instance. An example of a range for criteria was added, as was the clarification that "passes" is equivalent to "meets requirements". "Aluminum overseal" was added to closure list. Also, additional changes to the model required changes to IG.
  Unique Ballot Id: V3_IG_DSR_R2_I2_2009JAN

  This Implementation Guide (IG) is for the use of the Health Level 7 (HL7) Version 3 Standard: Structured Product Labeling, Release 4. The IG describes the inclusion of Establishment Registration and Drug Listing details resulting from the SPL Schema Release 4.
  Unique Ballot Id: V3IG_SPL_R4_I1_2009JAN

• **HL7 Version 3 Standard: Drug Stability Reporting (eStability), Release 2 (2nd DSTU Ballot)**
  The specification is designed to capture the contents of a stability report to be submitted to a national regulatory agency. At this point, the primary point of reference is current stability reporting within the United States. The scope of a single transaction or message in this specification has been restricted to only include studies with a single set of storage conditions. However, the stability studies that are filed with regulatory authorities are not simply a study with a single set of storage conditions - the studies include a number of storage conditions plus multiple orientations (upright and inverted). This is especially true for injectable/Parenteral products. These more complex situations, that is to say, studies that require multiple storage conditions and or orientations (e.g., accelerated, room temperature, inverted, upright, etc.), will be handled through the submission of multiple linked reports, with each report covering a single storage condition and orientation. Ballot constrained to the changes. Since the last ballot, the following changes have been made:
  - Additional information has been added describing the messages handling of multiple conditions and orientations.
  - The model was spread out separating the role and entity.
  - A shadow class was used for StudySponser.
  - Typographical errors were corrected. Application roles were added on interactions diagram to match application role artifacts in topic.
• Retract was used in place of nullify and withdraw.
• The AssociatedStudy is a ComponentOf StabilityStudy.
• StabilityStudy, StudyOnBatch, and Storage changed class code to ACT.
Unique Ballot ID: V3_DSR_R2_D2_2009JAN

• HL7 Version 3 Standard: Public Health; CDISC Content to Message - Study Design, Release 1 (1st For Comment Only Ballot)
This standard provides information included in a study protocol and protocol amendments including planned interventions, assessments, analyses, eligibility criteria, visits, etc. Planned sequence of events for the study: The standard provides the ability to compare actual subject progress to the study plan. The message is applicable to studies that are performed to determine the quality, safety and efficacy of regulated products.
Unique Ballot Id: V3_CDISC2MSG_SDS_R1_O1_2009JAN

• HL7 Version 3 Standard: Public Health; CDISC Content to Message - Study Participation, Release 1 (1st For Comment Only Ballot)
This standard describes:
  ▪ Who is involved in the conduct of a study,
  ▪ What the roles of the involved parties are,
  ▪ When they are involved, and,
  ▪ Where there involvement is.
This standard applies to studies that are performed to determine the quality, safety and efficacy of regulated products.
Unique Ballot Id: V3_CDISC2MSG_SP_R1_O1_2009JAN

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

[Original Consensus Group ballot; closed to additional enrollment. Voters are reminded that only changes resulting from the previous normative ballot comments are open for review; comments related to previously balloteted material will be found out of scope.]

• HL7 Version 3 Standard: Structured Documents Architecture, Release 1 (2nd Normative Ballot)
In this project the Structured Documents committee will focus on the development of the D-MIM and supporting documentation for structured documents, based on inputs from current HL7 publications and projects. We will coordinate with other SIGs and TCs in HL7, including Pediatrics Data StandardSIG, Government Projects, Decision Support and others to help determine the requirements for the D-MIM. The following changes have been made since the last revision:
  ▪ Added title attribute to document
  ▪ Changed Clone name of ParentDocument
  ▪ Required derived specifications to fix the representation to a specific version of the RIM, Vocab, and Data Types
  ▪ Added optional code attribute to Role participant on the document.
  ▪ Constrained document.moodCode
  ▪ Made generic participant optional
  ▪ Added R_Patient_Universal to Record Target Choice

The Clinical Decision Support Work Group announces the formation of a ballot group for the following document:

  This project will reconcile the current GELLO normative standard with the upcoming version 2.1 of the Object Constraint Language. It will correct some problems with the existing standard, such as the ‘let’ assignment, and will ensure that the GELLO-specific collection operators are incorporated into OCL. The goal is to ensure that the GELLO query expressions can be authored, parsed and executed with the range of existing OCL-compliant tools. Changes:
  - Change ‘let’ assignments to become OCL-compliant, i.e., temporary variable assignments within the context of a single expression
  - Re-implement ‘factory’ keyword as OCL-compliant constructor for initializing complex HL7 data types
  - Update OCL v2.1 with GELLO collection operators
  - Re-define GELLO BNF to ensure execution by OCL-compliant tools
  - Update implementation guide, including publication of GELLO/OCL Primer for educating HL7 members and implementers.
  This document has been identified as not backwards compatible.
  Unique Ballot Id: V3_GELLO_R2_I1_2009JAN

The Modeling and Methodology Work Group announces the formation of a ballot group for the following document:

- **HL7 Version 3 Standard: Reference Information Model, Release 2 (1st For Comment Only Ballot)**
  The Health Level Seven (HL7) Reference Information Model (RIM) is a static model of health and health care information as viewed within the scope of HL7 standards development activities. It is the combined consensus view of information from the perspective of the HL7 working group and the HL7 international affiliates. The RIM is the ultimate source from which all HL7 version 3.0 protocol specification standards draw their information-related content. The HL7 Reference Information Model (RIM) received its first normative ballot in 2003. The RIM is underdeveloped through the HL7 Harmonization Process that accepts proposals for additions and changes to the RIM, formally reviews these and then produces an incremental update. This "continuous maintenance" process results in an updated version about every four months. Since the last time the RIM underwent normative ballot, there have been twenty-one such version releases. The M&M Work Group seeks to complete Normative Voting during 2009, but is opening the ballot presentation with a "For Comment Only." This is undertaken because the HL7 Technical Editing Project has led to restructuring the RIM publication content and we would like a round of comments before opening the Normative voting. This document has been identified as backwards compatible.
Unique Ballot Id: V3_RIM_R2_O1_2009JAN

The **Modeling and Methodology** and **Infrastructure and Messaging Work Groups** announce the formation of a ballot group for the following document:

- **HL7 Version 3 Standard: Core Principles and Properties of Version 3 Models, Release 1 (1st For Comment Only Ballot)**
  
  HL7 Version 3 Standards are founded on three models - Reference Information Model, Data Types and Vocabulary. This specification defines the rules for binding these three models together and for using them in the specification of standards and the implementation of those standards. It will need a companion specification to the three base models and thereby facilitate implementation and development of V3 Standards. The initial, albeit incomplete, document was balloted in May 2008. Subsequently, reconciliation resolutions were voted for all negative ballots. Appropriate updates to the content will be provided for many, but not all of these resolutions. Thus the required reconciliation cannot be "completed" and therefore the updated material is offered as For Comment Only. This document has been identified as backwards compatible.

  Unique Ballot Id: HL7_V3_CPPV3MODELS_R1_O1_2009JAN

### 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 2nd normative ballot, all individuals who were active in the ballot pool (casting either an affirmative, negative or abstain) for the 1st 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 the proposed standard and wish to participate in these ballots must join the respective ballot groups. This can be accomplished by logging on to the Ballot Desktop at the following URL:

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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 any problems with the ballot desktop, joining, or voting, please contact the HL7 Director of Technical Services at 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 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.
- While committee ballots are no longer recognized under the GOM, those ballots previously identified at committee level (i.e.- those balloted at this level in previous ballot cycles) will continue on this track until they achieve approval and/or are deemed ready to advance to a normative ballot.
- 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.
- Committee ballots grandfathered in will be run under the same requirements as Review ballots and, in addition, under the same Review ballot reconciliation guidelines.

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 2008 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 either Don Lloyd (dlloyd@HL7.org), Technical Publications Manager, or Michael Kingery (mkingery@HL7.org), HL7 Webmaster.
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Appendix A – Listing of Ballots by Ballot Level for All September 2008 Cycle Ballots

For Comment Only Ballots

- **HL7 Version 3 Standard: Clinical Genomics; Genetic Variation, Release 1 (2nd Normative Ballot)**
  Unique Ballot Id: V3_CG_GV_R1_O1_2009JAN

- **HL7 Version 3 Standard: Core Principles and Properties of Version 3 Models, Release 1 (1st For Comment Only Ballot)**
  Unique Ballot Id: HL7_V3_CPPV3MODELS_R1_O1_2009JAN

- **HL7 Version 3 Standard: Public Health; CDISC Content to Message - Study Design, Release 1 (1st For Comment Only Ballot)**
  Unique Ballot Id: V3_CDISC2MSG_SDS_R1_O1_2009JAN

- **HL7 Version 3 Standard: Public Health; CDISC Content to Message - Study Participation, Release 1 (1st For Comment Only Ballot)**
  Unique Ballot Id: V3_CDISC2MSG_SP_R1_O1_2009JAN

- **HL7 Version 3 Standard: Reference Information Model, Release 2 (1st For Comment Only Ballot)**
  Unique Ballot Id: V3_RIM_R2_O1_2009JAN

Informative Ballots

  Unique Ballot ID: CDAR2_IG_P2PPHRDATATRANS_R1_I2_2009JAN

- **HL7 Version 3 Domain Analysis Model: Public Health; CDISC Content to Message - Study Participation, Release 1 (1st Informative Ballot)**
  Unique Ballot Id: V3DAM_CDISC2MSG_SP_R1_I1_2009JAN

  Unique Ballot Id: V3_IG_DSR_R2_I2_2009JAN

  Unique Ballot Id: V3IG_SPL_R4_I1_2009JAN

  Unique Ballot Id: V3_GELLO_R2_I1_2009JAN

- **HL7 Version 3 Standard: Medical Records; Composite Privacy Consent Directive, Release 2 (1st Informative Ballot)**
  Unique Ballot Id: V3_MR_CPCD_R2_I1_2009JAN
Draft Standard for Trial Use Ballots

  Unique Ballot Id: CDAR2L3_IG_HAIRPT_R2_D2_2009JAN

  Unique Ballot Id: CDAR2_IG_PA_R1_D1_2009JAN

- **HL7 Version 3 Standard: Care Provision; Assessment Scales, Release 2 (1st DSTU Ballot)**
  Unique Ballot Id: V3_PC_AS_R2_D1_2009JAN

- **HL7 Version 3 Standard: Drug Stability Reporting (eStability), Release 2 (2nd DSTU Ballot)**
  Unique Ballot ID: V3_DSR_R2_D2_2009JAN

- **HL7 Version 3 Standard: Personnel Management; Organization Registry, Release 2 (1st DSTU Ballot)**
  Unique Ballot Id: V3_PM_OR_R1_D1_2009JAN

- **HL7 Version 3 Standard: Personnel Management; Provider Registry, Release 2 (1st DSTU Ballot)**
  Unique Ballot Id: V3_PM_PR_R1_D1_2009JAN

  Unique Ballot Id: V3_MITASG_R1_D2_2009JAN

Committee Ballots (Grandfathered)

- **HL7 Version 3 Standard: Blood, Tissue, Organ; Donation, Release 1 (4th Committee Ballot)**
  Unique Ballot Id: V3_BTO DONATION_R1_C4_2009JAN

- **HL7 Version 3 Standard: Specimen CMETs, Release 9 (4th Committee Ballot)**
  Unique Ballot Id: V3_SPEC_CMET_R9_C4_2009JAN

Normative Ballots

- **HL7 EHR Clinical Research Functional Profile, Release 1 (1st Normative Ballot)**
  Unique Ballot Id: EHR_CRFP_R1_N1_2009JAN

- **HL7 EHR System Long Term Care Functional Profile, Release 1-US Realm (1st Normative Ballot)**
  Unique Ballot Id: EHR_LTCFP_R1_N1_2009JAN
• **HL7 Messaging Standard Version 2.7: An Application Protocol for Electronic Data Exchange in Healthcare Environments (2\textsuperscript{nd} Normative ballot)**
  Unique Ballot ID: V27\_N3\_2009JAN

• **HL7 Version 3 Standard: Account & Billing CMETs, Release 9 (1\textsuperscript{st} Normative Ballot)**
  Unique Ballot Id: V3\_AB\_CMET\_R9\_N1\_2009JAN

• **HL7 Version 3 Standard: Common Clinical Product Model, Release 1 (1\textsuperscript{st} Normative Ballot)**
  Unique Ballot Id: V3\_CCP\_R1\_N1\_2009JAN

• **HL7 Version 3 Standard: Laboratory CMETs, Release 9 (1\textsuperscript{st} Normative Ballot)**
  Unique Ballot Id: V3\_LAB\_CMET\_R9\_N1\_2009JAN

• **HL7 Version 3 Standard: Patient Administration CMETs, Release 9**
  Unique Ballot Id: V3\_PA\_CMET\_R9\_N1\_2009JAN

• **HL7 Version 3 Standard: Public Health CMETs, Release 9**
  Unique Ballot Id: V3\_PH\_CMET\_R9\_N1\_2009JAN

• **HL7 Version 3 Standard: Pharmacy; Medication Order, Release 1 (1\textsuperscript{st} Normative Ballot)**
  Unique Ballot Id: V3\_RX\_MEDORDER\_R1\_N1\_2009JAN

• **HL7 Version 3 Standard: Structured Documents Architecture, Release 1 (2\textsuperscript{nd} Normative Ballot)**
  Unique Ballot Id: V3\_SDA\_R1\_N2\_2009JAN
Appendix B – Changes from Initial Announcement

Items Withdrawn from Balloting

- HL7 Version 3 Standard: Individual Case Safety Reporting, Release 2 (Unique Ballot Id: V3_RR_ICSR_R2_D3_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Version 3 Standard: Observations; Common Observation, Release 1 (Unique Ballot Id: V3_OB_CMNOBS_R1_D1_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Version 3 Standard: Observations; Observation Request, Release 1 (Unique Ballot Id: V3_OB_OBSREQ_R1_D1_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Version 3 Standard: Orders & Observations; Observation CMETs, Release 8 (Unique Ballot Id: V3_OO_OBS_CMET_R8_N1_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Version 3 Domain Analysis Model: Public Health; CDISC Content to Message - Study Design, Release 1 (Unique Ballot Id: V3DAM_CDISC2MSG_SDS_R1_I1_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 1 – US Realm (Unique Ballot Id: V2(CG_LOINC_GENVAR_R1_N1_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Version 3 Standard: Common Terminology Services, Release 2 (Unique Ballot ID: V3_CTS_R2_D1_2009JAN) has been withdrawn from balloting this cycle.
- HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1 (Unique Ballot Id: V3_OIDS_R1_I2_2009JAN) has been withdrawn from balloting this cycle.

Changes to Ballot Level or Iteration

- The HL7 Implementation Guide for CDA Release 2: Plan-to-plan Personal Health Record (PHR) Data Transfer, Release 1 – US Realm ballot level was incorrectly identified as 1st DSTU. The correct ballot level is 2nd Informative. This resulted in a change to the Unique Ballot ID from CDAR2_IG_P2PPHRDATATRANS_R1_D1_2009JAN to CDAR2_IG_P2PPHRDATATRANS_R1_D2_2009JAN.
- Initially, a ballot pool for a first informative ballot of HL7 Version 3 Standard: Medical Records; Composite Privacy Consent Directive, Release 2 was announced. This was incorrect. The listing has been corrected to identify two ballot pools, one for the domain content update of the Composite Privacy Consent Directive (a 2nd Draft for Comment ballot), and a second, new, pool for a Domain Analysis Model related to this material (a 1st Informative ballot). The ballot listing was split to recognize these two pools and this change resulted in a change in the Unique Ballot ID. Initially, the single Unique Ballot ID was V3_MR_CPCD_R2_I1_2009JAN. This has been updated to V3_MR_CPCD_R2_O2_2009JAN for the HL7 Version 3 Standard: Medical Records; Composite Privacy Consent Directive, Release 2 (2nd Draft for
Comment Ballot) pool and V3DAM_MR_CPCD_R2_I1_2009JAN for the HL7 Version 3 Domain Analysis Model: Medical Records; Composite Privacy Consent Directive, Release 2 (1st Informative Ballot) pool.

- The V27 ballot was incorrectly identified as a 2nd Normative ballot. It is the 3rd Normative ballot. This change did not result in a change to the unique ballot id.
- The HL7 Version 3 Standard: Account & Billing CMETs, Release 9 ballot was incorrectly identified as Release 8. This change resulted in a change to the Unique Ballot ID from V3_AB_CMET_R8_N1_2009JAN to V3_AB_CMET_R9_N1_2009JAN.
- The HL7 Version 3 Standard: Clinical Genomics; Genetic Variation, Release 1 ballot level has been changed to 1st For Comment Only Ballot from 2nd Normative Ballot. This change resulted in a change to the Unique Ballot ID from V3_CG_GV_R1_N2_2009JAN to V3_CG_GV_R1_O1_2009JAN.
- The HL7 Version 3 Standard: Laboratory CMETs, Release 9 ballot was incorrectly identified as Release 8. This change resulted in a change to the Unique Ballot ID from V3_LAB_CMET_R8_N1_2009JAN to V3_LAB_CMET_R9_N1_2009JAN.
- The HL7 Version 3 Standard: Patient Administration CMETs, Release 9 ballot was incorrectly identified as Release 8. This change resulted in a change to the Unique Ballot ID from V3_PA_CMET_R8_N1_2009JAN to V3_PA_CMET_R9_N1_2009JAN.
- The HL7 Version 3 Standard: Public Health CMETs, Release 9 ballot was incorrectly identified as Release 8. This change resulted in a change to the Unique Ballot ID from V3_PH_CMET_R8_N1_2009JAN to V3_PH_CMET_R9_N1_2009JAN.
- The HL7 Version 3 Standard: Specimen CMETs, Release 9 ballot was incorrectly identified as Release 8 and also incorrectly identified as a 3rd Committee ballot. This ballot is release 9 and the 4th Committee level ballot of these CMETs. This change resulted in a change to the Unique Ballot ID from V3_SPEC_CMET_R8_C3_2009JAN to V3_SPEC_CMET_R9_C4_2009JAN.

Changes to Ballot Name

- HL7 Version 3 Standard: Medicaid Information Technology Architecture (MITA) Development Framework, Release 1 -US Realm was initially listed with the incomplete name Medicaid Information Technology Architecture (MITA) Development Framework, Release 1 -US Realm. This did not require a change to the Unique Ballot ID.