



**Announcement of Joint Initiative Council  
HL7 Ballot Opening for September 2009 –  
Pharmacovigilance – Structure and Data Elements  
for Individual Case Safety Reports**

**August 14, 2010**

Dear Voter,

Health Level Seven® is conducting a special ballot of the proposed draft standard identified below in coordination with a Joint Initiative Council ballot of the same material. This is in accordance with the ISO/CEN/HL7 SDO Joint Initiative Project of the Joint Initiative on SDO Global Health Informatics Standardization. For more information on the JIC and its members, please visit <http://www.global-e-health-standards.org/>.

It is important to note that the JIC member organizations are balloting the same material and coordinating their ballot periods; however, each individual Standard Developing Organization (SDO) is conducting its ballot in accordance with its policies and procedures. Thus, the ISO ballot of this material is done in accordance with ISO rules and the HL7 ballot is done in accordance with HL7 rules. In this instance, HL7 is coordinating its ballot period to close at the same time as the ISO TC 215 ballot. Please note that if you are a member of more than one participating SDO you may have more than one ballot comment and response, one for each specific membership.

The standards described in this document are based on or associated with the following standards classification:

- Health Informatics: Pharmacovigilance – Structure and Data Elements for Individual Case Safety Report (ICSR)

Final Draft International Standard (F-DIS) ballots require a two-month ballot period and this JIC ballot is scheduled to run from July 15 through September 13, 2010. The purpose of this HL7 ballot is to capture comments on the proposed draft standards from the HL7 community. Because HL7 ballots are generally thirty days, the HL7 ballot has been scheduled to close in conjunction with the JIC ballot, that is, on September 13, 2010.

After the September 13 ballot deadline, the resulting HL7 ballot comments will be jointly addressed by the members of ISO/TC215 and the HL7 Patient Safety WG.

## **Ballot Open/Close Dates**

The ballot pools in this document will open and close for voting on the following dates:

***Ballot Open Date: August 14, 2010***

***Ballot Close Date: September 15, 2010***

## **Original Consensus Group Ballots**

According to HL7 rules governing subsequent Normative ballots of the same material (GOM 14.03.04 – Establishing the Consensus Group), the pools identified in this announcement are limited to the members of the original consensus groups (that is, those voters who voted either affirmative or negative) and those members of the original pool who abstained. These pools are closed to further enrollment.

## **Health Informatics – Pharmacovigilance**

The **Patient Safety Work Group** announces the opening of ballot pools for the following items:

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

- ***Health Informatics – Pharmacovigilance – Individual Case Safety Report, Part 1: the framework for adverse event reporting (2<sup>nd</sup> Normative ballot)***

This project will develop a standardized specification of the data elements and exchange format needed for transmission of Individual Case Safety Reports for adverse events that may occur upon the administration of one or more products to a patient regardless of source and destination. This work is based on two existing work efforts: ISO/TC 215 / SC WG6 N 545 and HL7 Version 3 Standard: Individual Case Safety Reporting, Release 2.

The JIC (HL7/ISO/CEN) balloting of Individual Case Safety Report Standard in May 2009 led to intensive review, and a range of substantial and substantive changes. The goal behind revision of the document has been to address issues brought up in the ISO/HL7 ballot, to include the outcome of further analysis, and to address known requirements from efforts to use the ICSR and related standards. Since the initial ballot of this material, the following changes of note have been made:

- "ControlActEvent" has been added as a class associated to "InvestigationEvent" and "RelatedInvestigation" (formerly "RelatedReport"); the goal is to clearly differentiate between an investigation of a product problem or "AE", and its report.
- A reporting organization is captured as a scoper of the assigned entity role instead of as a player. This corresponds to the preferred HL7 modeling style.
- The structure for managing reporting persons and organizations has been rearranged. The association between organization and department is now captured with an "assignedEntity" role. The association between an organization and the place it is located in (country) is now captured with a "locatedEntity" role.
- Information about the qualifications of the reporter is now captured with a "QualifiedEntity" role.
- Prior Submissions are now included as earlier reports of an investigation – using the control act class.

- Case Seriousness and Reporting Criteria observations are now supported within the Investigation Characteristic class. This class is also supported for Related Investigations
- Allowing the reporter to indicate that their identity not be disclosed to the manufacturer is now captured with confidentiality codes in Related Report and in Control Act (instead of by using the "ConsentEventCriterion" act)
- Information about reactions has been moved to the "ProductReportingRelevantInformation" model. Instead of the triggering reaction being associated to the organization, there is now a component association to adverse event assessment, product defect assessment, and observation classes. The assessment classes are used to indicate whether an event is an AE, a product problem or both.
- Reaction Relatedness has been renamed "Causality Assessment". It is associated with Act Reference classes to provide a link to product use (replacing implicated act), and adverse event or defect reference (new) it is now possible to provide causality analysis for a product problem.
- The Investigative Subject role used to link affected parties to the investigation has been replaced by "Primary Role". This makes it possible to indicate whether the affected party is a patient, a clinical trial subject, or an investigation subject.
- The Research Study Enrollment CMET that allows capture of clinical trial information is being supplemented by explicit classes to do the same thing – but more compactly.
- The Product Reporting Relevant Information model has been changed to make it more like its spiritual parent "clinical statement". The changes include: a) pulling "process" out of the class names, b) removing the intervention characterization (now it is an observation), and the action taken (now it is an act) classes, c) using the "ServiceDeliveryLocation" CMET to capture location information.
- The internal ICSR model R\_Product has been replaced with a very similar CMET from the Common Product Model domain (this facilitates harmonization with SPL and addresses ISO ballot comments.) The major change is that the entry point for the model is now the Instance Of Kind role in place of Manufactured Product. That is to say, it is expected that the report will always be fundamentally about a product instance or the use of a specific product instance. At the same time a substantial amount of new content has been added to the CMET.
- The following changes which appear in the Common Product Model CMET are worth mentioning: a) If there are multiple organizations involved in the product's lifecycle, the relationship between them can be captured, b) composite/ingredient, and group/member associations can now be captured among product and device instances and these associations can be linked to product acts (could capture assembly operations for example)
- Information on product evaluations, as is done for devices, has been moved from the Product model to the base model.
- As a general note, it should be recognized that a number of the element names within the XML schema has changed. In some cases, the order of elements has changed as well.

HL7 Unique Ballot Id: JIC\_ICSR\_AER\_R1\_N2\_2010SEP

**Important Note:** ISO identifies this project as "**ISO/DIS 27953-1.2: Health Informatics – Pharmacovigilance – Individual Case Safety Report, Part 1: The Framework for Adverse Event Reporting**".

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

- ***Health Informatics – Pharmacovigilance – Individual Case Safety Report, Part 2: Human pharmaceutical reporting requirements for ICSR (2<sup>nd</sup> Normative ballot)***

This project will develop a standardized ISO conformance specification of the data elements and exchange format needed for regulatory transmission of Individual Case Safety Reports for adverse events that may occur upon the administration of one or more products to a patient regardless of source and destination. This work is based upon the revised E2B guideline from the International Conference on Harmonization (ICH), and, additionally, the two work efforts: ISO/TC 215 / SC WG6 N 545 and HL7 Version 3 Standard: Individual Case Safety Reporting, Release 2. . Since the initial ballot of this material, the following changes of note have been made:

- "ControlActEvent" has been added as a class associated to "InvestigationEvent" and "RelatedInvestigation" (formerly "RelatedReport"); the goal is to clearly differentiate between an investigation of a product problem or "AE", and its report.
- A reporting organization is captured as a scoper of the assigned entity role instead of as a player. This corresponds to the preferred HL7 modeling style.
- The structure for managing reporting persons and organizations has been rearranged. The association between organization and department is now captured with an "assignedEntity" role. The association between an organization and the place it is located in (country) is now captured with a "locatedEntity" role.
- Information about the qualifications of the reporter is now captured with a "QualifiedEntity" role.
- Prior Submissions are now included as earlier reports of an investigation – using the control act class.
- Case Seriousness and Reporting Criteria observations are now supported within the Investigation Characteristic class. This class is also supported for Related Investigations
- Allowing the reporter to indicate that their identity not be disclosed to the manufacturer is now captured with confidentiality codes in Related Report and in Control Act (instead of by using the "ConsentEventCriterion" act)
- Information about reactions has been moved to the "ProductReportingRelevantInformation" model. Instead of the triggering reaction being associated to the organization, there is now a component association to adverse event assessment, product defect assessment, and observation classes. The assessment classes are used to indicate whether an event is an AE, a product problem or both.
- Reaction Relatedness has been renamed "Causality Assessment". It is associated with Act Reference classes to provide a link to product use (replacing implicated act), and adverse event or defect reference (new) it is now possible to provide causality analysis for a product problem.
- The Investigative Subject role used to link affected parties to the investigation has been replaced by "Primary Role". This makes it possible to indicate

- The Research Study Enrollment CMET that allows capture of clinical trial information is being supplemented by explicit classes to do the same thing – but more compactly.
- The Product Reporting Relevant Information model has been changed to make it more like its spiritual parent "clinical statement". The changes include: a) pulling "process" out of the class names, b) removing the intervention characterization (now it is an observation), and the action taken (now it is an act) classes, c) using the "ServiceDeliveryLocation" CMET to capture location information.
- The internal ICSR model R\_Product has been replaced with a very similar CMET from the Common Product Model domain (this facilitates harmonization with SPL and addresses ISO ballot comments.) The major change is that the entry point for the model is now the Instance Of Kind role in place of Manufactured Product. That is to say, it is expected that the report will always be fundamentally about a product instance or the use of a specific product instance. At the same time a substantial amount of new content has been added to the CMET.
- The following changes which appear in the Common Product Model CMET are worth mentioning: a) If there are multiple organizations involved in the product's lifecycle, the relationship between them can be captured, b) composite/ingredient, and group/member associations can now be captured among product and device instances and these associations can be linked to product acts (could capture assembly operations for example)
- Information on product evaluations, as is done for devices, has been moved from the Product model to the base model.
- As a general note, it should be recognized that a number of the element names within the XML schema has changed. In some cases, the order of elements has changed as well.

This set of changes only applies to Part 2 – Human Pharmaceutical Reporting.

This companion ballot has been created as a strict subset of ICSR Part 1 to highlight the particular requirements of human pharmaceutical reporting, and to be consistent in scope with the specifications created by the International Committee on Harmonization (ICH). The following changes are worth noting:

- All of the expected components of a topic within the HL7 V3 ballot package have been added. In the first ballot, Part only contained specialized RMIMs, HMDs, and message types created by editing the Part 1 artifacts. Now, the topic includes its own storyboards, interactions, trigger events, RMIMs, HMDs, and message types. Note, while the RMIM Is capable of standing on its own as a balloted document, it has been constructed so that the ensuing message types use the same element names (in the XML schema) as does the Part 1 message types.
- The first ballot contained a tabular cross-reference between the ICH E2BR specification and the HL7 ICSR. This has been removed. Conceptually, that cross-reference has been replaced by a sample XML message consistent with the ICSR schema that shows the mapping between the two specifications. However, the sample message is not included in the ballot.

HL7 Unique Ballot Id: JIC\_ICSR\_HPRR4ICSR\_R1\_N2\_2010SEP

**Important Note:** ISO identifies this project as "**ISO/DIS 27953-2.2: Health Informatics – Pharmacovigilance – Individual Case Safety Report, Part 2: Human pharmaceutical reporting requirements for ICSR**".

## **Balloting 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 web server.

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.

Comments resulting from this ballot will be discussed and reconciled by the ISO/TC 215, Health Informatics, WG 6, Pharmacy and medicines business, and the HL7 Regulated Clinical Research Information Management Work Group.

### **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: <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 any problems with the ballot desktop, joining, or voting, please contact the HL7 Director of Technical Services at [webmaster@HL7.org](mailto:webmaster@HL7.org) before the closing of the ballot.

## **Important Notes**

**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 2010 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.