



HL7 Ballots

Voting Made Easy

Presented by Ed Tripp

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Introduction

- This presentation will cover the HL7 ballot process and how to participate in the balloting.
- At the end of this presentation you should be able to:
 1. Understand the types of ballots
 2. Access and navigate the ballot website
 3. Access and navigate the ballot material
 4. Submit your comments on a ballot package



Training Outline

- Section 1: Understanding the HL7 Ballot Types
 - In this section you will learn about the four types of ballots that you may participate in.
- Section 2: The Ballot Desktop
 - In this section you will learn how to navigate the ballot desktop and join in a ballot pool
- Section 3: Ballot Materials
 - In this section you will learn how to locate the desired ballot material and navigate through it.
- Section 4: Voting
 - In this section you will learn how to cast a vote and upload comments.



Section 1: Understanding the HL7 Ballot Types

- Objectives
 - Understand what types of material are balloted.
 - Understand what types of ballots exist and the differences



Section 1: Understanding HL7 Ballot Types

- Work Groups in HL7 manage projects that produce products (standards materials)
- Before balloting, you should determine the product you will be reviewing
- The project scope statement describes the type of material that is being developed for the project.
- The Project Name, ID and Products section will tell you what product(s) are being developed.

Health Level Seven, Inc.
Project Scope Statement

Template Usage Information:

- Replace RED text with appropriate content; do not change the name/format/font of the template sections
- To check a box, double click on the box then select the 'Checked' Radio Button under the 'Default Value' heading
- For assistance in completing each section, refer to [Appendix A](#)
- The Project Approval Process is documented in [Appendix B](#)
- For FAQs (Frequently Asked Questions), refer to [Appendix C](#)
- Submit template change requests to PMO@HL7.org

1. Project Name, ID and Products

The name should be concise, based on the objective and unique among all other projects the group takes on.
Project Insight: Enter into 'Project Name' and 'Product Type'.
[Click here to go to Appendix A for more information regarding this section.](#)

Enter the name of the project here.

☐ Non Product Project (Educ, Marketing, Elec. Services, etc.)

☐ Arden Syntax

☐ Clinical Context Object Workgroup (CCOW)

☐ Domain Analysis Model (DAM)

☐ Electronic Health Record (EHR)

☐ V2 Messages - Administrative

☐ V2 Messages - Clinical

☐ V2 Messages - Departmental

☐ V2 Messages - Infrastructure

☐ V3 Documents - Administrative (e.g. SPL)

☐ V3 Documents - Clinical (e.g. CDA)

☐ V3 Documents - Knowledge

☐ V3 Foundation - RIM

☐ V3 Foundation - Vocabulary Domains & Value Sets

☐ V3 Messages - Administrative

☐ V3 Messages - Clinical

☐ V3 Messages - Departmental

☐ V3 Messages - Infrastructure

☐ V3 Rules - GELLO

☐ V3 Services - Java Services (ITS Work Group)

☐ V3 Services - Web Services

☐ New Product Definition

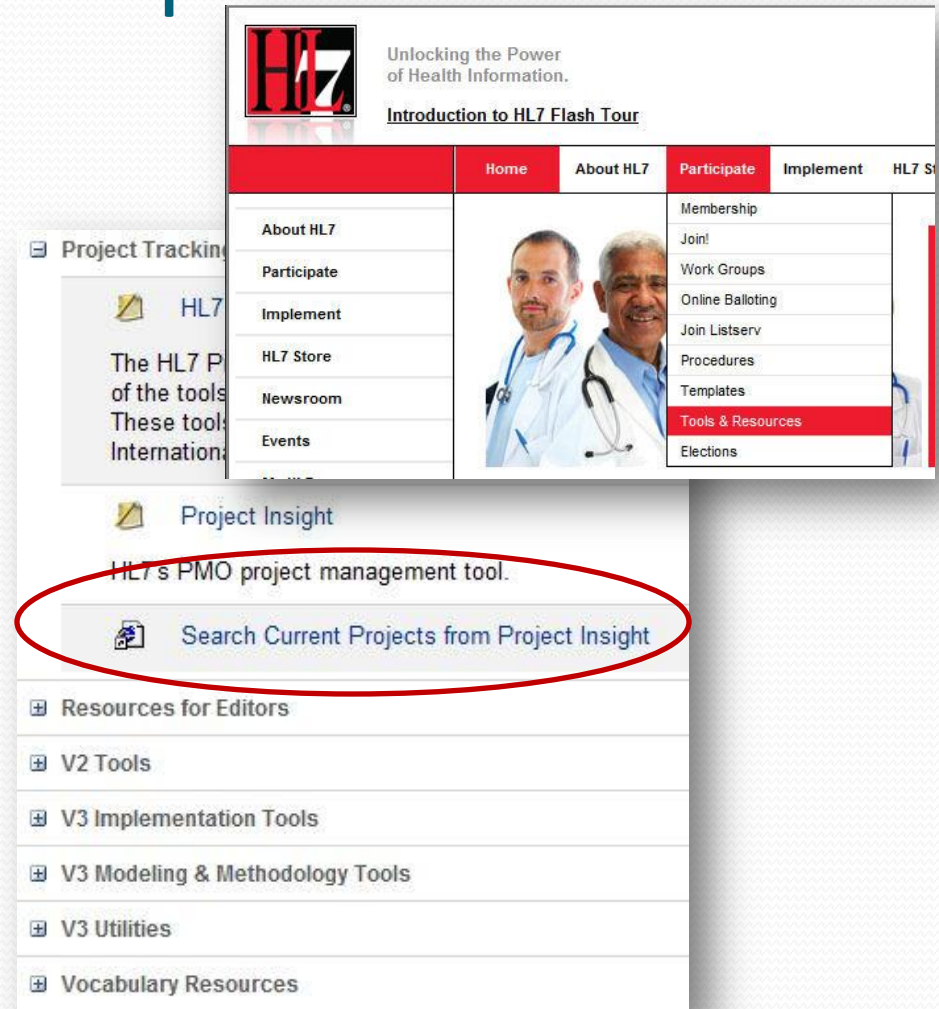
Project ID:

An ID will be assigned by Project Insight



Finding the Project Scope Statement

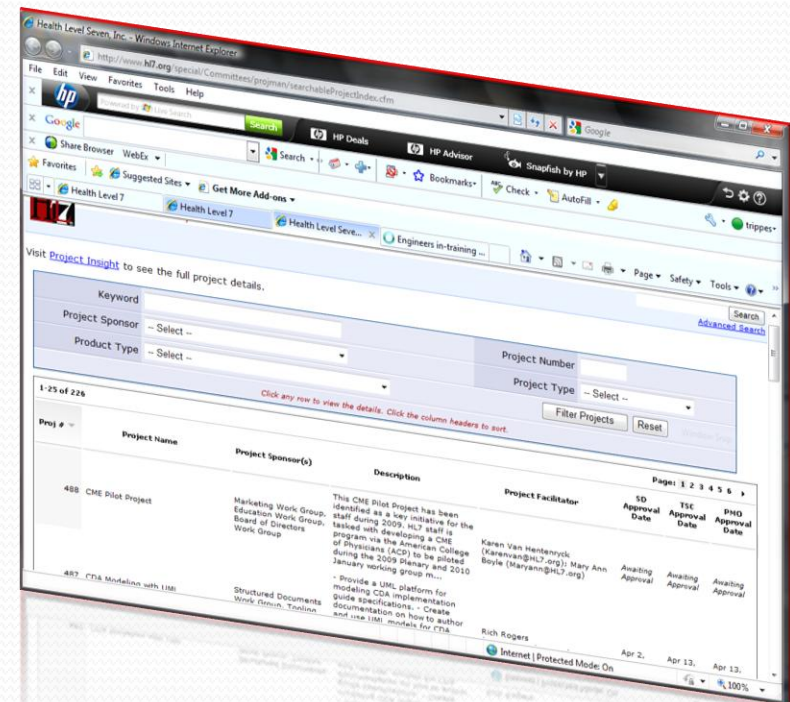
- To find a project scope statement, navigate to the HL7 website at www.hl7.org
- Open **Tools and Resources**
- Click on **Search Current Projects from Project Insight**





Search Project Insight

- The link takes you to the Project Insight Search page.
- You can search projects by:
 - Keyword - word or phrase associated with the project
 - Sponsor (Work Group) – Workgroup owning the project
 - Product Type – List on slide 10
 - Project Number – assigned from Project Management Office
 - Project Type – Ballot level or contract work





Find the Project Summary

- Once you have performed a search click on the **project name** to pull up the project summary page

Health Level Seven, Inc. - Windows Internet Explorer

http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?sortBy=&sortDirection=8

File Edit View Favorites Tools Help

hp HP Deals HP Advisor Snapfish by HP

Google Search

Share Browser WebEx

Health Level 7 Health Level 7 Health Level Seven Login

visit [Project Insight](#) to see the full project details.

Keyword Project Number

Project Sponsor RCRIM Work Group Project Type -- Select --

Product Type -- Select -- Filter Projects Reset

Click any row to view the details. Click the column headers to sort.

1-8 of 8 Page: 1

Proj #	Project Name	Project Sponsor(s)	Description	Project Facilitator	SD Approval Date	TSC Approval Date	PMO Approval Date
462	Annotated ECG, Release 1 ANSI reaffirmation	RCRIM Work Group	Ballot the current Annotated ECG, Release 1 standard 'for comment only' to reaffirm its suitability as an ANSI standard.	Ed Tripp edward.tripp@estripp.com	Feb 18, 2009	Feb 27, 2009	Feb 27, 2009
372	Clinical Trial Registration and Results (CTRR)	RCRIM Work Group	This project will be focused on the development and maintenance of an HL7 V3 message in support of the global data exchange requirements brought about by the increasing number of national, regional, global and organizational clinical trial registries and ...	Ed Helton - helton2@mail.nih.gov; Tracy Beck - becktj@lilly	Dec 8, 2008	Dec 15, 2008	Dec 30, 2008
325	Medical Product and Device Listing	RCRIM Work Group	This project will develop a standardized specification of the data elements and exchange format for the transmission of information that uniquely and certainly identifies a medical product or device, wherever authorized for marketing, for the purposes of...	Ed Tripp	Feb 20, 2008	Jun 2, 2008	Jun 2, 2008

Internet | Protected Mode: On 100%



Project Summary

- Scrolling through the project summary, you can find the product and project type. This information will be useful in accessing the ballot material.

Project Type	Ballot - Normative		
Product Type	V3 Messages-Clinical		
Objectives / Deliverables	<ol style="list-style-type: none">1. Utilize the BCRIM BRIDG model in the analysis process and extend, as needed, to meet trial registry and result database requirements2. Develop an initial standard to meet the requirements of trial registration and basic results reporting3. Extend the initial standard to meet the requirements of expanded results reporting4. Establish a roadmap for evolving the standard into an ISO-approved, global exchange standard		
	Project Definition and Approvals	December 2008	
	Project Kick-off	January 2009	
	Draft Standard for Trial Use Ballot	April 2009	
	Pilot DSTU	May 2009 to TBD	



Types of Products

- Arden Syntax
- Clinical Context Object Workgroup (CCOW)
- Domain Analysis Model (DAM)
- Electronic Health Record (EHR)
- V₂ Messages
 - Administrative
 - Clinical
 - Departmental
 - Infrastructure
- V₃ Documents
 - Administrative (e.g. SPL)
 - Clinical (e.g. CDA)
 - Knowledge
- V₃ Foundation
 - RIM
 - Vocab Domains & Value Sets
- V₃ Messages
 - Administrative
 - Clinical
 - Departmental
 - Infrastructure
- V₃ Rules – GELLO
- V₃ Services
 - Java Services (ITS Work Group)
 - Web Services

V₃ messages ballot materials are located at the V₃ Ballot site or can be downloaded where other material is usually downloaded as a stand alone package.



Types of Ballots

- There are four basic types of ballots
 - N – Normative
 - I – Informative
 - D – Draft Standard for Trial Use
 - O – Comment
- The following slides will define each of these ballot types.

Note:
Letter designations
are used at the
ballot sight to
indicate ballot level



Normative

- A normative ballot is intended to process and validate those specifications intended for submission to ANSI for consideration as American National Standards.
- The normative ballot process shall adhere to the tenets of *ANSI Essential Requirements: Due process requirements for American National Standards*.
- Under normal circumstances the subject matter of a normative ballot will have at some point been subjected to a review ballot; however, there are a number of scenarios where material may need to move directly to normative ballot, such as the need to respond to government mandate or to resolve a critical issue raised by a stakeholder or noted in an existing American National Standard.



Participation in Normative Ballot

- An initial normative ballot shall be open to all interested and materially affected parties; however, quorum shall be defined relative to the number of HL7 members in the ballot pool.
 - HL7 shall assess an administrative fee for the processing, handling, and shipping of the ballot package for nonmembers.
 - Members can join the ballot pool up to two weeks from the close of the ballot.
 - Quorum for balloting consists of 60% of the HL7 members in the ballot pool. Non members are not counted in establishment of quorum.
- Those registrants who do not return a ballot shall not be included in the consensus group and shall not participate in any subsequent normative ballot of the same content



Normative Ballot Approval

- A 75% affirmative response of the combined affirmative and negative votes cast shall be required for approval with not less than 60% of the ballot pool returning ballots and representative of at least 60% of the HL7 members participating in the ballot pool.
- All statements accompanying affirmative ballots shall be considered by the appropriate Work Group.
- 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.
 - Negative ballots not accompanied by comments shall not be considered.
- A comment resulting in a substantive change shall necessitate a subsequent normative ballot of the same content.
 - Substantive change is any change that alters the information content of a message, the circumstances under which it would be sent, or the interpretation of its content.



Informative

- An Informative Document is the product of a Work Group that is not currently deemed normative, but nonetheless is intended for general publication. It explains or supports the structure of the specifications, or provides detailed information regarding the interpretation or implementation of an HL7 Specification.
- A Work Group may declare an informative document as US Realm-specific in that its function is to constrain a specification for implementation in the United States of America (USA).



Participation in Informative Ballot

- Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the ballot closing date.
- For US Realm Specific material, the Work Group may request that the review group be restricted to current individual members or representatives of current organizational members whose primary address or place of business is in the USA.
- There is no quorum required for an informative document.



Informative Ballot Approval

- The informative document shall be considered approved if, following ballot review, sixty percent (60%) of the combined affirmative and negative votes cast are affirmative.
- At the close of the ballot the responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the informative document. While not on a par with a normative reconciliation package, the results of the Work Group's consideration of the comments submitted shall be posted to the Ballot Desktop.



Draft Standard for Trial Use (DSTU)

- DSTU is used to provide the basis for proof of concept pilot projects and objective assessment of the viability of implementation of the proposed standard.



Participation in DSTU Ballot

- Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the ballot closing date.
- The minimum review group shall be ten current individual members or individuals representing at least three current organizational members.
- Reviewers are encouraged to provide constructive comments for improving the content or language of the subject matter under review.



DSTU Ballot Approval

- The proposed draft standard shall be considered approved if sixty percent (60%) of the combined affirmative and negative votes cast by the review group are affirmative.
- Upon approval the proposed draft standard, shall be released for publication as a DSTU for a period up to two years.
- At the close of the review ballot the responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the proposed draft standard. While not on a par with a normative reconciliation package, the results of the Work Group's consideration of the comments submitted shall be posted to the Ballot Desktop.



For Comment Only

- A Work Group may submit proposed content or requirements documents, such as a Domain Analysis Model (DAM), to comment-only review. The intent is to gather input from members outside of the Work Group on the viability and clarity of the proposed content or requirements document. The review of proposed content or requirements documents does not seek a vote, per se, but will capture all comments.
- A ballot to reaffirm an HL7 American National Standard (ANS) shall be submitted to a Comment-only Ballot to allow interested parties to express their opinion by supporting reaffirmation, suggesting revisions to update the ANS, or providing reasons to withdraw the ANS.



Participation in For Comment Ballot

- Members shall indicate their interest by enrolling in the review group via the HL7 Ballot Desktop during the enrollment period which shall end one week prior to the review closing date.
- Nonmembers who wish to be part of the comment-only review group may do so at no cost, but must register their intent with HL7 Headquarters during the stated enrollment period by mail, telephone, or email.
- There is no minimum review group.
- At the close of the comment-only review period the responsible Work Group shall consider all comments with the intent of improving the quality and clarity of the submitted content before submission to a subsequent ballot.
- The Work Group shall post the results of their consideration of the comments submitted to the HL7 Ballot Desktop.



Section 1: Wrap-up

- There are over twenty (20) product types in HL7.
 - Those voting should understand the product type that is being balloted.
 - Product type is found in Project Insight
 - Ballot materials will either be found on the V3 ballot website or presented for download.
- There are four types of ballots
 - Normative
 - Informative
 - DSTU
 - Comment



Ballot Type Summary

	Quorum	Approval
Normative	60% HL7 Members	75%
Informative	N/A	60%
DSTU	10 HL7 Members	60%
Comment	N/A	N/A



Section 2: The Ballot Desktop

<http://www.hl7.org/ctl.cfm?action=ballots.home>

- Objectives
 - Learn how to join in a ballot pool
 - Learn how to navigate the ballot desktop





Locating the Ballot Desktop

- The link below will take you directly to the Ballot Desktop

<http://www.hl7.org/ctl.cfm?action=ballots.home>

- You can also get there from the HL7 Home Page. Find the link to **Online Balloting** and follow the links to the Ballot Desktop.





Section 2: Desktop Home Page



The screenshot shows the HL7 Desktop Home Page. At the top right, there are navigation links: "What's New", "Ballots", "Events", and "Help". Below these, there are links for "HL7 Home Page", "Member Login", and "Contact Us". On the left side, there is a large HL7 logo and a "Home" button. A large black arrow points from the "Home" button towards the "Member Login" link. The main content area has a heading "Welcome to HL7" and a paragraph of text. Below this, there are two sections: "Old vs. New" and "Security".

Welcome to HL7

Welcome to the new HL7 Web Site. Currently this site is in Beta Development with the exception of the on-line Balloting. Now that the framework for the new site is in place we will be adding features and functions throughout the coming year. We would like to bring your attention to a few noteworthy features and functions.

Old vs. New

First and foremost, the old web site is still up and running so don't be afraid to use it. Currently, only balloting has moved and will no longer be updated in the old site. We'll keep you updated on the home page until we have a majority of the old site moved so check back here often for the time being. As always, if you have any problems with the site, feel free to contact the [Webmaster](#). Here at HL7 Headquarters we are working hard to build a better environment in which to support the collaboration needed for the hard working groups of participants and volunteer to inform, educate and produce the high quality standards that we have all come to expect from HL7.

Security

The foundation for security in new HL7 site is driven by a completely different mechanism so it is required that you login. Basic information about you and your login are saved to your desktop in the form of a cookie. The information it stores is cryptic being a series of numbers and nothing more and it is that information that will recognize you on subsequent visits. The Member Login link is always present at the top of the website so if you encounter any

- When you link to the ballot desktop members should log in at the home page using your HL7 User ID and Password.



Navigate to the Ballot Page



- Click on the **Ballots** Tab to navigate to the Ballots Page.
- Then from the list of ballot cycles on the left, click on the **current ballot cycle** (the top link)



Join the Ballot Pools

HL7

What's New | Ballots | Events | Help

HL7 Home Page | Member Logout | Contact Us | Welcome **Edw**

Home | Ballots | Ballot Desktop | Join a Pool | Remove yourself from a Pool

Choose a Ballot Cycle

Click the time period below to review a ballot cycle and your participation in it.

The Cycles are ordered descending so the topmost cycle is the most current.

- ▶ [May 2009 Ballot cycle](#)
- ▶ [January 2009 Ballot Cycle](#)
- ▶ [September 2008 Ballot Cycle](#)
- ▶ [May 2008 Ballot Cycle](#)
- ▶ [January 2008 Ballot Cycle](#)
- ▶ [November 2007 Ballot Cycle](#)
- ▶ [September 2007 Ballot Cycle](#)
- ▶ [May 2007 Ballot Cycle](#)
- ▶ [January 2007 Ballot Cycle](#)
- ▶ [September 2006 Ballot Cycle](#)
- ▶ [May 2006 Ballot Cycle](#)
- ▶ [January 2006 Ballot Cycle](#)

Balloting

Ballot Desktop

May 2009 Ballot cycle

2009MAY , Mar 19, 2009 - Apr 30, 2009

Announcement Documents:

- ▶ [Announcement of Joint HL7 ISO Ballot of EHR Functional Model for March 2009 \(pdf , 46.1 kb \)](#)
- ▶ [Formation of Reaffirmation Review Groups for May 2009 Ballot Cycle \(pdf , 51.5 kb \)](#)
- ▶ [Formation of Ballot Pools for May 2009 Ballot Cycle \(pdf , 133.9 kb \)](#)
- ▶ [Correction to Announcement of Joint HL7 ISO DIS Ballot of V3 ICSR \(pdf , 62 kb \)](#)
- ▶ [Paid Participation in HL7 Ballots Instructions \(pdf , 89.5 kb \)](#)
- ▶ [Announcement of Joint HL7 ISO Ballot of EHR Functional Model for March 2009 \(pdf , 45.3 kb \)](#)
- ▶ [Announcement of Ballot Openings for May 2009 Ballot Cycle \(pdf , 134.3 kb \)](#)
- ▶ [Seeking Interested Members to Help Us Fulfill Balance of Interest for Normative Ballots - May 2009 Ballot Cycle \(htm , 8.6 kb \)](#)

Your Desktop

The Ballot Desktop lets review all the ballotable documents available in given cycle. When a cycle is active, you can vote, review your votes, view ballot materials, and review announcements.

▶ [Join Ballot Pools](#)

As long as a pool is still open, you can remove yourself from it. Once in which you have vote closed, you cannot remove yourself but will be precluded with other options.

- Click on the **Join a Pool** link to select the ballots you wish to participate in.
- On the Join a Pool Page, Select from the list of all open ballots



Ballot Pools Display



Ballot Document Pools in which you ARE Participating						
⚠ All ballots close on their specified close date at midnight, US Eastern Time Zone.						
R. Pkg Name	Lvl.	Ballot Document	Open	Close	Vote	Cmnt
HL7 Version 3 Standard: Common Product Model CMETs, Release 9	D2	(link to site)	Aug 11, 2009	Sep 14, 2009	No Return	
HL7 Version 3 Standard: Reference Information Model, Release 2	N2	(link to site)	Aug 11, 2009	Sep 14, 2009	No Return	
HL7 Version 3 Standard: Regulated Studies; CDISC Content to Message - Study Design, Release 1	D2	(link to site)	Aug 11, 2009	Sep 14, 2009	No Return	

- After selection of ballot pools, the desktop will display ballot pools in which you are participating
- It is a good idea to join ballot pools near the time they open so that when it is time to cast a ballot they are all listed at the top of the page.



Ballot Pools Display

[Ballot Cycle \(pdf , 28.2 kb \)](#) [Seeking Interested Members to Help Us Fulfill Balance of Interest for Normative Ballots - September 2009 Ballot Cycle \(htm , 11.4 kb \)](#)

Ballot Document Pools in which you ARE Participating

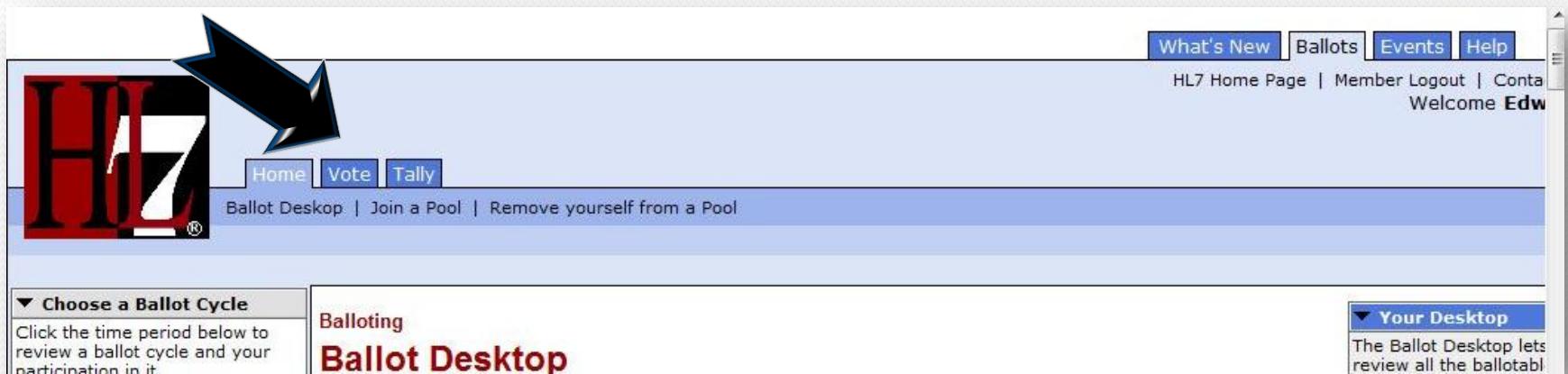
 **All ballots close on their specified close date at midnight, US Eastern Time Zone.**

R. Pkg Name	Lvl.	Ballot Document	Open	Close	Vote	Cmnt
HL7 Version 3 Standard: Common Product Model CMETs, Release 9	D2	 (link to site)	Aug 11, 2009	Sep 14, 2009	No Return	

- The desktop displays the following
 - Name of the ballot (displayed is HL7 Version 3 Standard: Common Product Model CMETs, Release 9)
 - Level of Ballot (displayed is D2: DSTU second ballot)
 - Ballot Document (this is either a ballot package for download or a link)
 - Open and close dates
 - Your vote
 - Comments (consolidated comments after a ballot has closed)



Ballot Desktop Vote Tab



- The **Vote** tab at the top of the page takes you to a listing of those ballots you are participating in. This where you will submit your vote and comments.



Ballot Desktop Tally Tab

Home | Vote | Tally

Home | Return to Ballot Desktop

Balloting Tally

May 2009 Ballot cycle

2009MAY , Mar 19, 2009 - Apr 30, 2009

Announcement Documents: [Announcement of Joint HL7 ISO Ballot of EHR Functional Model for March 2009 \(pdf , 46.1 kb \)](#) [Formation of Reaffirmation Review Groups for May 2009 Ballot Cycle \(pdf , 51.5 kb \)](#) [Formation of Ballot Pools for May 2009 Ballot Cycle \(pdf , 133.9 kb \)](#) [Correction to Announcement of Joint HL7 ISO DIS Ballot of V3 ICSR \(pdf , 62 kb \)](#) [Paid Participation in HL7 Ballots Instructions \(pdf , 89.5 kb \)](#) [Announcement of Joint HL7 ISO Ballot of EHR Functional Model for March 2009 \(pdf , 45.3 kb \)](#) [Announcement of Ballot Openings for May 2009 Ballot Cycle \(pdf , 134.3 kb \)](#) [Seeking Interested Members to Help Us Fulfill Balance of Interest for Normative Ballots - May 2009 Ballot Cycle \(htm , 8.6 kb \)](#)

To review the Tally details and interact with participants as well as perform various reconciliation functions, click the document pool from the list provided.

R. Pkg. Name	Lvl.	Aff.	Neg.	Abst.	NV	TotP.	Q.	A.
Joint ISO Ballot - HL7 EHR System Functional Model, Release 1.1	N1	64	10	7	27	108	75.00%	56
Entity Identification Service (EIS), Release 1	O1	62	17	26	16	121	86.78%	0

Tally Legend

- **Lvl.** = Ballot Level
- **Aff.** = Affirmative Votes
- **Neg.** = Negative Votes
- **Abst.** = Abstaining
- **NV** = No vote Returned
- **TotP.** = Total Participants
- **Q.** = Quorum
- **A.** = Affirmatives Required for Approval

Quorum and Approval values in this color mean that required values have been achieved.


Calculating Quorum

- Normative Ballots: 60%

- The **Tally** tab displays the ballot level and voting tallies for Affirmative, Negative, Abstentions, No Vote, Total Pool, Quorum and Number of Affirmatives required for approval



Ballot Desktop Tally Tab



Home | **Vote** | Tally

Tally Home | Return to Ballot Desktop

HL7 Home Page | Member Login | Non-Member Login | Contact Us

Printer Friendly Version

Balloting
Ballot Tally Details

Tally Legend
Calculating Quorum

HL7 Version 3 Domain Analysis Model: Regulated Studies; CDISC Content to Message - Study Design, Release 1
V3DAM_CDISC2MSG_SDS_R1_I1_2009MAY

Review Informative 1
Mar 30, 2009 - Apr 30, 2009

Announcement Documents: [Announcement of Joint HL7 ISO Ballot of EHR Functional Model for March 2009 \(pdf , 46.1 kb \)](#) [Formation of Reaffirmation Review Groups for May 2009 Ballot Cycle \(pdf , 51.5 kb \)](#) [Formation of Ballot Pools for May 2009 Ballot Cycle \(pdf , 133.9 kb \)](#) [Correction to Announcement of Joint HL7 ISO DIS Ballot of V3 ICSR \(pdf , 62 kb \)](#) [Paid Participation in HL7 Ballots Instructions \(pdf , 89.5 kb \)](#) [Announcement of Joint HL7 ISO Ballot of EHR Functional Model for March 2009 \(pdf , 45.3 kb \)](#) [Announcement of Ballot Openings for May 2009 Ballot Cycle \(pdf , 134.3 kb \)](#) [Seeking Interested Members to Help Us Fulfill Balance of Interest for Normative Ballots - May 2009 Ballot Cycle \(htm , 8.6 kb \)](#)

Ballot Content: [Ballot Site](#)

	Aff.	Neg.	Abst.	NV
Affiliate	0	0	9	1
Consultant	2	0	6	0
General Int.	13	0	8	1
Payor	0	0	0	0
Pharmaceutical	25	9	3	4
Provider	1	1	25	2
Vendor	5	1	12	4
Totals	46	11	63	12
% of Votes	34.85%	8.33%	47.73%	9.09%
Quorum				90.91%
Approval				35

Participants
Please note that any Entries for HL7 Headquarters Staff are not included in the final tally.
If you want to see details on your votes, use your [Ballot Desktop](#) and click on your vote.

of

- Clicking on the **name of the ballot** takes you to the ballot tally details for that ballot. At the top of the page a summary table displays.



Ballot Desktop Tally Tab

Participants

Please note that any Entries for HL7 Headquarters Staff are not included in the final tally.
If you want to see details on your votes, use your [Ballot Desktop](#) and click on your vote.

Name	Firm	Type	Vote	Cmnt?	Upld?	# of Evnts	Entry Date
Tripp, Edward	Edward S Tripp and Associates, Inc.	Pharmaceutical	Negative	No	<u>Yes</u>		Apr 29, 2009

- Scroll down the page and you will find listings for each member's vote.
- Member in the pool has a **Vote** recorded as Affirmative, Negative, Abstain, or No Return. Negative votes are highlighted in red to make them easy to locate.
- The Comment (**Cmnt?**) field indicates if any text-based comments were made when the ballot was submitted for this specification.
- The Upload (**Upld?**) field indicates if there was a ballot spreadsheet uploaded. **Note: The ballot spreadsheet will be covered in section 4 of this material**
- **# of Evnts** = Number of times a negative voter has been contacted for withdrawal purposes



Section 2: Wrap-up

- The ballot desktop is located at:
<http://www.hl7.org/ctl.cfm?action=ballots.home>
- The ballot desktop is the central site where you can
 - Join ballot pools
 - Locate Ballot material
 - Cast a vote
 - Examine voting tallies
 - Examine comments from voters
- The tabs at the top of the page allow you to navigate between the [Home Page](#), [Voting Page](#) and [Tally Page](#)







Section 3: Understanding the HL7 Ballot Materials

- Objectives
 - Learn how to locate the desired ballot material
 - Learn how to navigate the ballot material.



Where are the Materials?

<http://www.hl7.org/ctl.cfm?action=ballots.home>

R. Pkg	Name	Lvl.	Ballot Document	Signup Close Date	Ballot Open	Ballot Close	Cmn
	Entity Identification Service (EIS), Release 1	O1	 (link to site)	Apr 23, 2009		9	
	HL7 Clinical Context Management Specification Version 1.5	O1	 (49.5 kb)	Apr 23, 2009			
	HL7 Implementation Guidance for Unique Object Identifiers (OIDs), Release 1	I2	 (384.1 kb)	Apr 23, 2009			

On the ballot website

Downloadable as a document

Downloadable as a zip package

The downloadable materials have the documents or material for consideration, so we will next learn about the ballot website



The Ballot Site

<http://www.hl7.org/v3ballot/html/welcome/introduction/index.htm>

The screenshot shows the HL7 v3 May 2009 Ballot Site. The header features the HL7 logo and the text "May 2009 v3". The main content area is titled "Dear Members" and includes a welcome message from the HL7 Board of Directors. Three blue callout boxes highlight key features: "Link to the ballot site" points to the "Link to HL7 Version 3.0 May 2009 Ballot Site" link; "Special List Service to receive updates and issues" points to the "Receive notices on Ballot Patch and Issues for Version 3 ballots by clicking here" link; and "Page to download all or some of the ballot to your local computer" points to the "Link to Downloads Page" link. The bottom of the page contains copyright information and a list of updates.

Link to the ballot site

Special List Service to receive updates and issues

Page to download all or some of the ballot to your local computer

Link to HL7 Version 3.0 May 2009 Ballot Site

Receive notices on Ballot Patch and Issues for Version 3 ballots by [clicking here](#) and signing up for the v3ballotupdate list service.

Link to Downloads Page

Allows for the download of various ballot segments or the entire ballot site in various formats.

HL7® Version 3 Standard, © Health Level Seven®, Inc. All Rights Reserved. HL7 and Health Level Seven are registered trademarks of Health Level Seven.

- The vocabulary schema is now based solely on defined value sets, whereas previously there were concept domains and auto-generated value sets involved.
- The constraints for the structural attributes ("classCode" in three RIM classes, "typeCode" in three RIM classes) are now based solely on defined value sets, whereas previously there were concept domains and auto-generated value sets involved.

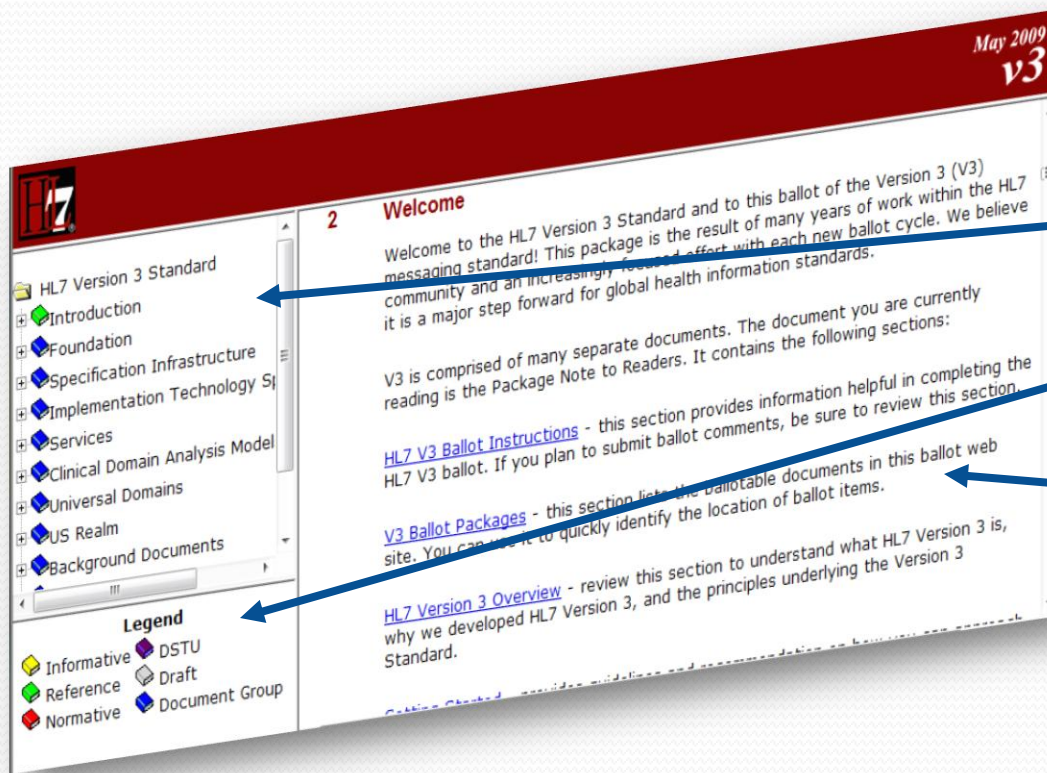


Special List Service

- To keep you continually apprised of any updates or patches to the ballot site, HL7 instituted a special list service to which you may subscribe.
- You can only sign up through the ballot web page by clicking on the link presented
- On the linked page, you will need to sign-in (if you have a list service ID, or create one if you do not)
 - go to the Publishing header
 - select the v3ballotupdates list
 - Only HL7 staff are permitted to post messages to this list



The V3 Ballot Site



The page is divided into 3 frames.







On the upper left hand side is the navigation pane or backbone.

At the bottom left is the legend

On the right hand side is the content



The Legend

Icon	Description
	Yellow identifies an informative document. Informative documents are balloted according to a procedure outlined by HL7. While calling for consensus, the ballot procedure for informative documents is not as stringent as that for normative documents. Information documents are not submitted to ANSI for approval.
	Green identifies a reference document. Reference documents are not balloted and are included with the ballot material to assist with understanding and comprehension. The Glossary, for example, is a reference document.
	Red identifies a normative document. Normative documents are balloted according to procedures that adhere to ANSI's procedures. Normative documents must pass a full normative level ballot. Normative documents, once they've passed ballot, are submitted to ANSI for approval.
	Blue identifies a group of documents that fall into one or more of the categories listed above. Many of the domain documents are grouped together under a blue section heading. This is simply an easy way to group documents.
	Gray identifies a draft only document. Ultimately, this document may become normative, informative or reference but at the time of balloting, a gray book means that this document or document group will be draft only and not ballotable.
	Purple identifies a normative document that is (or will be) Draft Standard for Trial Use (DSTU).



Finding ballot material

- Although you can navigate all of the V3 site using the navigation frame, HL7 provides a quick reference means to locate ballot material.
- In section **2 Welcome** click on the link to V3 ballot packages

[V3 Ballot Packages](#) - this section lists the ballotable documents in this ballot web site. You can use it to quickly identify the location of ballot items.

- This link will take you to a section of the standard that contains a listing of all ballot (see picture on next slide)



Ballot Packages

4 V3 Packages

4.1 Ballotable Documents in this V3 Ballot Package

The following material contains the content for the distinct ballot groups in different stages of Informative, Draft Standard for Trial Use (DSTU), and Normative ballot in this cycle that you may find in this V3 ballot standard:

4.1.1 Foundation Documents

- [Core Principles and Properties of Version 3 Models, Release 1](#)
- [Data Types — Abstract Specification, Release 2](#)
- [Reference Information Model, Release 2](#)
- [Using SNOMED CT, Release 1](#)

4.1.2 Specification Infrastructure, Implementation Technology Specification and Services Documents

- [Common Terminology Services, Release 2](#)
- [Entity Identification Service \(EIS\), Release 1](#)

4.1.3 Domain Analysis Models

- [Study Participation Domain Analysis Model \(CDISC Content to Message\), Release 1](#)
Note: This DAM is located with the Regulated Studies Domain under Universal Domains.

4.1.4 Universal Domain Documents

- [Blood, Tissue and Organ; Donation Topic, Release 1](#)
- [Care Provision; Care Composition, Release 1](#)
- [Care Provision; Clinical Document, Release 1](#)
- [Care Provision; Health Concern, Release 1](#)

Links on this page will take you directly to the material that is being balloted

Example



The Domain Material

- The link from the Ballot Packages page takes you to the top level of the applicable domain. For example, if we choose **Regulated Studies; Study Participation (CDISC Content to Message), Release 1**, we are linked to the top level of the **Regulated Studies** domain
- Each Domain has a table of contents as shown on the right
- Scroll down the table of contents to find the Topic of interest

Table of Contents	
Hide Revision Marks	
Preface	
i Notes to Readers	
ii Changes from Previous Release	
iii Message Design Element Navigation	
1	Overview
1.1	Introduction & Scope
1.2	Domain Message Information Models
2.	AnnotatedECG Topic
2.1	Storyboards
2.2	Application Roles
2.3	Refined Message Information Models
2.4	Hierarchical Message Descriptions
2.A	Implementation Guide
3.	Clinical Research Filtered Query Service Release 1 Topic
4.	CTLaboratory, Release 2 Topic
4.1	Storyboards
4.2	Application Roles
4.3	Trigger Events
4.4	Refined Message Information Models



The Topic

- Each Topic has a table of contents that will assist you in finding key items
- The topic can be read by scrolling through the text.
- As you read the Topic, make note of any areas of concern or recommended changes
- In some topics you will find additional downloadable files such as a PDF of an implementation guide.

● 9 Study Participation Topic

HL7 DSTU
Ballot

HL7 CDISC3MSG SP, R1
HL7 Version 3 Standard: CDISC Content to Message - Study Participation, Release 1
DSTU Ballot 1 - May 2009

[Hide Revision Marks](#)

[Return to Domain Table of Contents](#)

Content Last Edited: 2009-02-26T11:51:09

- 9.1 [Storyboards](#)
- 9.2 [Application Roles](#)
- 9.3 [Trigger Events](#)
- 9.4 [Refined Message Information Models](#)
- 9.5 [Hierarchical Message Descriptions](#)
- 9.6 [Interactions](#)

Introduction

Introduction

The study participation message answers the question who is involved in one particular study (i.e., two studies would have two different study participation messages).

The Study Participation message is intended to inform the agency about all experimental units, investigators, and other relevant entities that are involved in the conduct of an individual study. A study in this context is any investigation performed to support the safety, effectiveness, or quality of a medical product. As such, the experimental unit of a study can be a human, other nonhuman living subjects, parts of nonhuman living subjects, groups of nonhuman living subjects, or the medical product itself. This information is often provided:

1. At the start of the study
2. As part of a subsequent update on that study
3. As part of the final study report

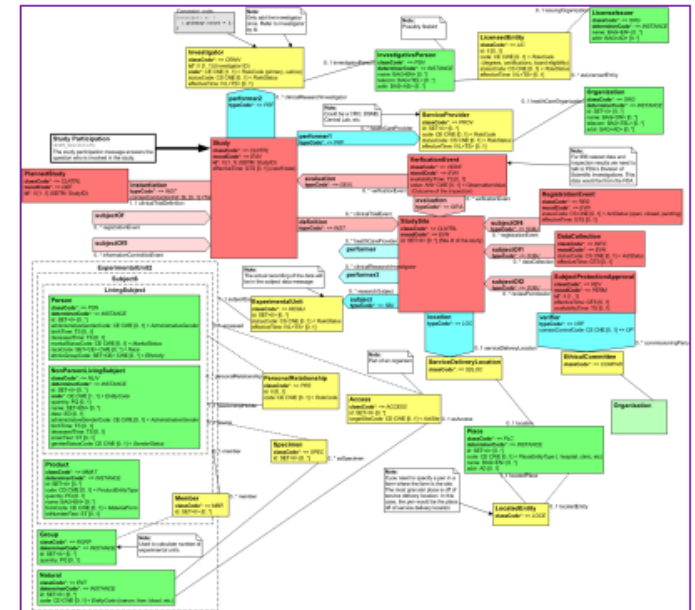
At each of the above time points the message could contain some or all of the following information:

Refined Message Information Models

- Messages and common message element types (CMETs) being balloted will contain a Refined Message Information Model or RMIM. There is additional functionality that will help you review this material.
- Click on the thumbnail and the model opens in a new window

9.4.1 Study Participation RMIM (PORT_RM100001UV01)

Diagram



[Click thumbnail above to open larger graphic in a new window](#)

Navigating the RMIM

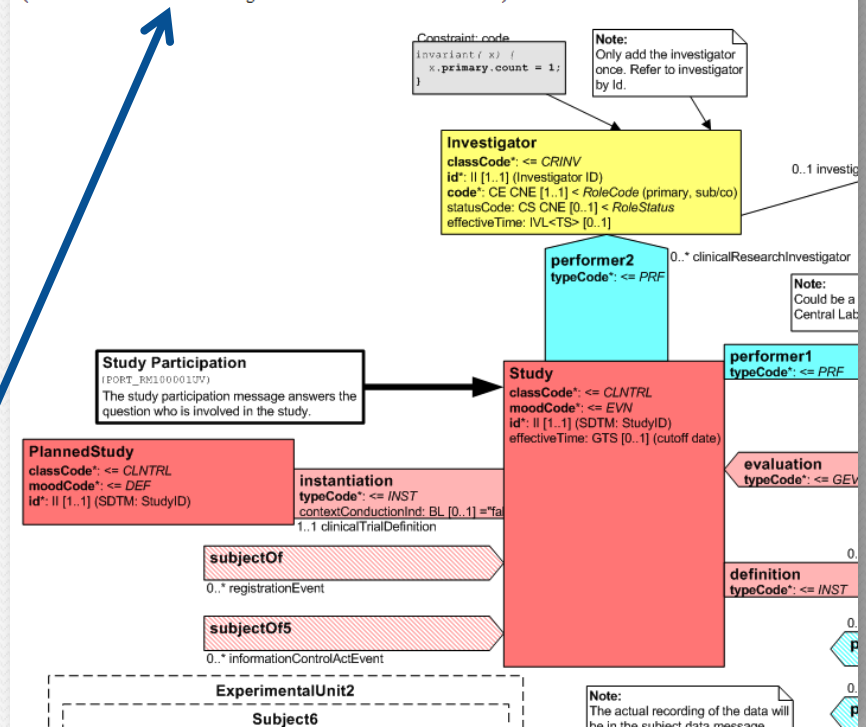
- The graphics within this diagram are linked to a table.
- Clicking on a box (Study for example) will open up the table within the browser to display class and attribute information.
- If you do not want a linked diagram you can link go a pure graphic rendition

Study Participation (PORT_RM100001UV)

Date: 2009-03-20 13:47:05

[Link to graphic without hyper-links.](#)

(IE 5 will shrink this to fit on single screen to serve as an over-view.)





The Table View

PORT_HD100001UV Study Participation	(Link to Excel View) Derived from RIM: PORT_RM100001UV
Study	Design Comments: A collector of performed activities in a study including a description of the actual number of study subjects and the start and end dates of enrollment. A performed study occurs after a planned study has been approved for execution. Detailed information about the planned study plan or protocol is collected in the study design message
classCode [1..1] (M) Observation (CS) {CNE:V: ActClassClinicalTrial , root= "CLNTRL"}	
moodCode [1..1] (M) Observation (CS) {CNE:V: ActMoodEventOccurrence , root= "EVN"}	
id [1..1] (M) Observation (II)	Design Comments: The identifier of the performed study. This id will be used when updating information about the performed study.
effectiveTime [0..1] Observation (GTS)	Design Comments: The cutoff date. The report the data is as of.

- The table provides detailed information about the data types along with class and attribute information. The classes and attributes are linked to the Reference Information Model (RIM) to provide additional information
- If you wish to work in Excel there is a link at the top of the page



Excel View

PORT_HD100001UV [Read-Only] [Compatibility Mode]											
No	Element Name (Link to tabular view)	Card	Mand	Conf	Rim	Source	of Message Element Type	Src	Domain	CS	U
	Study Participation	Common message for PORT_HD100001UV									
1	Study Participation	..				Observation	Study	N			
2	classCode	1..1	M	R		Observation	CS	D	V:ActClassClinicalTrial	CNE	
3	moodCode	1..1	M	R		Observation	CS	D	V:ActMoodEventOccurrence	CNE	
4	id	1..1	M	R		Observation	II	D			
5	effectiveTime	0..1				Observation	GTS	D			
6	Performer1	0..*					SET<Performer1>	U			
7	Performer2	0..*					SET<Performer2>	U			
8	definition	0..*				ActRelationship	SET<Definition1>	N			
9	typeCode	1..1	M	R		ActRelationship	CS	D	V:ActRelationshipInstantiatesI	CNE	
10	studySite	1..1				Observation	StudySite	N			
11	classCode	1..1	M	R		Observation	CS	D	V:ActClassClinicalTrial	CNE	
12	moodCode	1..1	M	R		Observation	CS	D	V:ActMoodEventOccurrence	CNE	
13	id	0..*				Observation	SET<II>	D			
14	subject	0..*				Participation	SET<Subject1>	N			
15	typeCode	1..1	M	R		Participation	CS	D	V:ParticipationTargetSubject	CNE	
16	experimentalUnit	1..1				Role	ExperimentalUnit	N			
17	classCode	1..1	M	R		Role	CS	D	V:RoleClassResearchSubject	CNE	
18	id	0..*				Role	SET<II>	D			
19	statusCode	0..1				Role	CS	D	D:RoleStatus	CNE	
20	effectiveTime	0..1				Role	IVL<TS>	D			

Here is the same information from the previous slide displayed in the Excel file.



Downloading the Ballot

- As previously mentioned the front page of the ballot site has a link to a download page.
- If you decide to download the ballot it is recommended that you download the full sight.
- It is recommended that you download over a high speed connection due to the size of the download (May 2009 was 315 Megabytes)
- When you unzip the files you download, create a central "root" directory on your hard drive to which you will then extract the zip file contents.
- It is recommended you set up a directory named based on the ballot you are reviewing, for example, "C:\HL7V3BALLOT_2009MAY".
- Once extracted, find the file named INDEX.HTM and use this to launch the ballot.



Section 3: Wrap-up

- Ballot material is provided as either a download document, zip file or from the ballot website.
- It is recommended you sign up for the ballot list service to be notified of ballot issues or patches.
- For V3 standards the ballot site provides quick links to Domains that contain topics for ballot.
- Keep notes as you review the ballot so that you can provide comments on the material.



Section 4: Voting

- Objectives
 - Understand the type of vote you can cast.
 - Understand how to fill out the ballot spreadsheet



Types of Votes

- The voting tab of the ballot desktop allows you to cast the following votes.
 - Affirmative – This may include affirmative comments or suggestions.
 - Abstain – no vote but wish to remain in the ballot pool for future balloting on the standard
 - Negative – This must include comments. Negative votes with no comments are not counted as valid votes.

Note: some voters refer to comments from other voters “See comments from John Doe” If there are no comments from that voter the negative ballot is not counted as a valid ballot.



Ballot Comment Spreadsheet

- It is important to utilize the Ballot Comment Spreadsheet for making comments on a ballot. This allows for automatic consolidation of all comments so that the work group can manage reconciliation in an effective and timely manner.
- The ballot comment spreadsheet can be downloaded from the Ballot Desktop
- If you download all comment spreadsheets in the single zip file provided you can locate the correct spreadsheet based on the name of the spreadsheet file.
 - The spreadsheet will be named ballotComment_BallotName
 - Example [BallotComment_EHR_FM_R1_1_N1_2009MAY](#) is the Ballot Comment Spreadsheet for the EHR Functional Model Release 1 Normative 1 for May 2009



Filling out the spreadsheet

- The spreadsheet has the following tabs
 - Submitter
 - Ballot
 - Instructions
 - Instructions Continued
 - Format Guidelines
 - Setup
- You fill in your information and comments on the submitter and ballot tabs.



The Submitter Tab

BALLOT TITLE:	HL7 EHR System Functional Functional Model (EHR_FUNCMODEL_R1_1_N1_2009MAY) - 1st Normative Ballot
BALLOT CYCLE:	May-09
SUBMITTED BY NAME:	
SUBMITTED BY EMAIL:	
SUBMITTED BY PHONE:	
SUBMITTED BY ORGANIZATION (if applicable):	
SUBMISSION DATE:	
SUBMITTED BY IDENTIFIER:	

1. Verify that the Ballot Title is the correct title for the ballot you are commenting on
2. Fill in your name in the [Submitted by Name:](#) field
3. Fill in your e-mail address in the [Submitted by email:](#) field
4. Fill in your phone number in the [Submitted by Phone:](#) field
5. If you are representing an HL7 member organization different than your employer, fill out [Submitted by Organization:](#) field
6. Fill in the [Submission Date:](#) field with the date of your vote.
7. Pick your vote ([Affirmative](#), [Negative](#) or [Abstain](#)) from the drop down



Entering Comments

- Click on the [Enter Ballot Comments \(Line Items\)](#) link below the submitter information
- Do not alter the first column labeled [Number](#)
- Enter each comment in its own row
- Under [Ballot Committee](#) select the committee managing the ballot from the drop down list
- Select the type of [Artifact](#) the comment applies to from the list shown in the table on the right

HD	Hierarchical Message Definition
AR	Application Roles
RM	Refined Message Information Model
IN	Interaction
TE	Trigger Event
MT	Message Type
DM	Domain Message Information Model
ST	Storyboard
??	Other



Entering Comments Continued

- Enter the **Artifact ID** in the fourth column.
- Next fill in **Section** in the sixth column.

EXAMPLE:

9.4.1 Study Participation RMIM (PORT_RM100001UV01)

Artifact is RM

Artifact ID is PORT_RM100001UV01

Section is 9.4.1



Vote and Type

- For each comment select the vote and type from the drop down in column eight
 - Neg-Mj: Negative Vote with Reason - Major.
 - Use this in situations where the content of the material is non-functional, incomplete or requires correction before final publication.
 - All Neg-Mj votes in normative ballots must be resolved by the work group.
 - Neg-Mi: Negative Vote with Reason- Minor.
 - Use this when the comment needs to be resolved, but is not as significant as a negative major.
 - A-S: Affirmative Vote with Comment -Suggestion.
 - Use this if the work group is to consider a suggestion such as additional background information or justification for a particular solution.
 - A-T: Affirm Vote with Comment - Typo..
 - If the material contains a typo such as a misspelled word, enter A-T.
 - A-C: Affirm Vote with Comment
 - A-Q: Affirm Vote with Question



Commenting

- If appropriate, copy and paste the existing ballot material into the **Existing Wording** column
- Enter your desired change into the **Proposed Wording** column
- In the **Comments** column enter any rationale for the change
- In the **In Person Resolution Required?**, select yes to indicate that you would appreciate discussing particular comments in person during a Committee Meeting.
- Save the spreadsheet



Voting and Uploading

HL7 Version 3 Standard: Regulated Studies; CDISC Content to Message - Subject Current Vote
Data, Release 1 **No Return**

<input checked="" type="radio"/> No Return <input type="radio"/> Affirmative <input type="radio"/> Negative <input type="radio"/> Abstain	You may change your vote as often as you like until the ballot closes. A Negative vote requires a comment or file upload.
--	---

Vote Comment:

Remember you must supply a ballot comment if you are voting negatively on this document

Comment

Upload:

☐ **I have read and agree to abide by the stipulations governing affirmative and negative votes.**

Stipulations Governing Affirmative and Negative Votes

- On the Ballot Desktop select the Vote tab
- Scroll to the voting block for the standard you wish to vote on
- Select the type of vote from the radio button
- If you have a comment spreadsheet, press the upload button and select the file you previously saved.
 - Be sure to verify you are uploading the correct file for the ballot
- Read the disclaimer at the bottom of the page and check it off.
- Press submit to cast your ballot



Section 4: Wrap-up

- You may cast an Affirmative, Negative or Abstain vote for any standards in ballot pools you are participating
 - Affirmative votes may have comments of an affirmative nature (Comment, Suggestion, Typo or Questions)
 - Negative votes must have one or more negative comments (Negative Vote with Reason – Major or Minor)
- You are strongly encouraged to enter comments using the BallotComment spreadsheets
 - The process of reconciling ballots is greatly facilitated by use of the spreadsheet



Final Comment

- The HL7 ballot process is a consensus process that allows for constructive contribution to standards through the ballot process.
- Comments are encouraged and when given in a constructive manor strengthen the standards
- Balloting is not difficult but it can be time consuming. Ballots are open for about four weeks to allow for sufficient time to review the material



The End