“Harmonizing Standards Initiatives: An Overview of Collaborative Standards Initiatives for Clinical Research and Healthcare”

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Outline

• Introduction
• Data Standards: The foundation of interoperability in information interchange
  – Standards for healthcare – HL7, ISO
  – Standards for clinical research – CDISC
  – Linking healthcare and clinical research through standards

• The Biomedical Research Integrated Domain Group (BRIDG) Model: A domain analysis model for Biomedical Research
  – What is BRIDG?
  – BRIDG stakeholders (CDISC, HL7, NCI, FDA)
  – BRIDG status
  – BRIDG implementations

• CDISC and HL7 Collaborations
  – Regulated Clinical Research Information Management (RCRIM) Technical Committee
  – Protocol Representation Group
  – Other projects and initiatives linking healthcare and clinical research
Introduction
“Research on the quality of care reveals a health care system that falls short in its ability to translate knowledge into practice, and to apply new technology safely and appropriately.”

“Much of the potential of IT to improve quality is predicated on the automation of at least some types of clinical data.”

- Application of promising IT applications/tools
- Glean knowledge from patient care
- Enable research on outcomes
- Identification of best practices

One of the key barriers to automation of clinical data is the need for standards.

Crossing the Quality Chasm, IOM, 2001
Integration & Interoperability (Standards)

Streamlined Processes

Adoption of Technology

Faster Access to Better Information

Improved Quality; Patient Safety
Role of Standards Organizations Towards this Goal

Integration & Interoperability (Standards)

Streamlined Processes

Adoption of Technology

Faster Access to Better Information

Improved Quality; Patient Safety
Clinical Research Trends

• Clinical research is becoming increasingly “global”
  – India, China, Latin America, Singapore…
  – Percentage of subjects from ex-US/EU is increasing; those from US/EU is decreasing

• FDA BIMO initiative to address a ‘quality system’

• Initiatives to improve safety monitoring

• Healthcare IT initiatives; use of EHRs and need for interoperability

• Need for transparency of clinical research information through publicly accessible registries and databases

  • Incentive for electronic clinical trials; eSource data
  • Important role of data interchange standards in all of the above
“We have not thought enough about health IT as a cost-effective form of therapy. Yet, the best evidence is that when used as intended, health IT saves lives and saves money.”

- A recent study showed that
  - clinical information is frequently unavailable in primary care;
  - this missing information can be harmful to patients;
  - clinical information was less likely to be missing in practices that had electronic health records.

Dr. David Brailer, HIMSS, 17 February 2005
“The same EHR systems critical for improving patient care can also help accelerate clinical research and its impact on practice and improve pharmaceutical safety (pharmacovigilance) and biosurveillance for public health...dual use of EHR systems that could reduce total system costs.”

Slide Courtesy Meredith Nahm
HL7 Overview & Standards for Healthcare
Health Level Seven: Operations

• The world’s leading standard for the electronic interchange of healthcare information
  – 28 Global affiliates
  – 21 years of operation
  – 2500 members
• Charter Agreement for standards harmonization with ISO & CEN
• American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO)
• Acknowledged by the US Department of Health and Human Services (HHS) as the standard for healthcare information exchange
• Liaison A status with ISO TC 215
• Charter agreement with CDISC since 2001
Health Level Seven: Mission

• HL7 provides *interoperable standards* that improve care delivery, optimize workflow, reduce ambiguity, and enhance *knowledge transfer* among all of our stakeholders, including healthcare providers, government agencies, the vendor community, *fellow SDOs* and patients.

• In all of our transactions we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability practicality or *our willingness to put the needs of our stakeholders first.*
Health Level Seven: Functions

• Enables *interoperability* of health information
• Creates standards for the exchange, management and integration of healthcare information
• Develops *specifications*
  – Reference Information Model (RIM)
  – Messaging standards that enable disparate healthcare applications to exchange key sets of clinical and administrative data
  – Clinical Document Architecture
Interchange vs. Interoperability

- **interoperability**: ability of two or more systems or components to exchange information and to use the information that has been exchanged.

Requirements for Semantic Interoperability

- **Model**: The definition of each element of data, and its relationship to all of the other elements and
- **Terminology**: Vocabulary used to represent the data elements, including the definitions, and relationships within the terminology
HL7 Reference Information Model

- Cornerstone for Version 3
- The set of concepts, attributes, and relationships needed to describe any aspect of healthcare
- Supports clinical care, administrative events, financial activities, & research
- Defines a set of datatypes and their relationship to vocabularies
US Healthcare Standards

• Messaging standards
  – HL7 – Clinical data
  – X12 – Financial data, HIPAA-mandated transactions
  – DICOM – Images
  – IEEE – Bedside instruments

• Terminology standards
  – LOINC – Logical observation identifier names and codes
  – Drugs – RxNorm, NDF-RT
  – Billing – CPT, ICD-9CM
  – Clinical – UMLS, SNOMED and others
UK Healthcare Standards

• Messaging standards
  – HL7 - Clinical data
  – DICOM – Images
  – IEEE – Bedside instruments

• Terminology standards
  – Drugs – SNOMED
  – Billing – ICD
  – Clinical – SNOMED, READ codes
HL7 Messaging Standards

• Multiple standards jointly developed by CDISC & the HL7 RCRIM Technical Committee
• HL7 Lab standard
  – First HL7 version 3 standard
• Structured Product Label
  – Release 3 approved by FDA in January 2007 as a mechanism for exchanging medication information
• Clinical Statement Pattern
Clinical Document Architecture

- In development since 1996
- An XML-based *markup standard* used to specify the encoding, structure and semantics of clinical documents
- Creates *XML Style sheets*, which convert XML into a human-readable clinical document
- Uses Clinical Statement Pattern
Clinical Document Architecture: Application & Adoption

- CDA can be used independently of HL7 v3 messages (including v2 and other messages)
- CDA release 2 supports SNOMED & LOINC and can incorporate other documents (DICOM)
- CCD (Continuity of Care Documents) incorporates the ASTM CCR into the CDA architecture
Implementation Guides

- In the UK
  - NHS CFH MIM for England, BT MIM for London, Retinal Screening MIM
- Other international affiliates have similar
- IHE PCC (Patient Care Coordination)
- HL7.org balloted
  - CCD, PHR transfer, Operation Note, others…
HL7 Development Framework (HDF)
HL7 Development Framework (2)

Figure 1-3. Message Development Models
CDISC Overview & Standards for Clinical Research
CDISC Snapshot

- Global, open, multi-disciplinary non-profit organization
  - Founded in 1997; incorporated in 2000
  - Liaison A Status with ISO TC 215
  - Charter agreement with HL7 since 2001
  - Over 200 member organizations
  - Active Coordinating Committees
    - Europe
    - Japan
  - Additional activities
    - Australia
    - India, China
    - S. America

- Established industry standards to support the electronic acquisition, exchange, submission and archiving of data to support regulated clinical research
What's New

CDISC Webinar on Defining CRF Standards
22 January 2007
12:00 pm CST
For details and registration, click here
(Posted 1/10/06)

CDISC: An Overview
London, Brussels, and Madrid
For more details, click here
(Posted 1/10/06)

CDISC Boston Area User Network Meeting
16 February 2007, 9:30 am
The CDISC models are the products of contributions from numerous organizations, functional groups, and individuals; they do not have a sole source.

**Consensus building**
- Involves different disciplines within the industry
- Involves ‘consolidating’ existing models, review comments and testing
- Takes time, but results in widely accepted models

Freely available on the CDISC website ([www.cdisc.org](http://www.cdisc.org))
CDISC Standards Development Process (COP-001)

Stage I: Standard Definition/Team Initiation

- Need for Specific Standard(s) Identified (any stakeholder)
- Proposal to Board of Directors (via Ops)
  - Review per strategy, budget priorities
    - Approved
    - Not Approved
  - Team Leader ID and Team Formation (multidisciplinary) (Ops)
  - Working Plan (timelines, deliverables communication mech., resources req’d) (Team)

Stage II: Standards Development/Review/V 1.0 Release

- Consensus (Initial) Version
- Harmonized Version
  - TLC Review
  - External Focused Review
  - Comments addressed
- Review Version
  - Public Review
  - Released (Production) Version 1.0

Stage III: Education & Support

- Educational Programs (EDU, Ops)
- Respond To Comments And Questions

Stage IV: Standards Update & Maintenance

- Annual Review of Released Version (comments, chg reqsts, tests, plans) (Team)
- Working Plan (timelines, deliverables, communication mech., resources req’d) (Team)
  - Consensus (Revised) Version
    - TLC Review
    - Optional
    - Ex Focused Review
    - Harmonized Version
  - New Released (Production) Version
    - Public Review as needed
    - Note: Occasional bug fix releases may be issued as needed with team review only.
CDISC Standards Development Process (COP-001)

Primary Stages

Stage I: Standard Definition/Approval
Multidisciplinary Team Initiation; Working Plan Development

Stage II: Standards Development-Consensus Model;
Reviews by External Focused Group and Open Public;
Harmonization and Testing throughout; V1.0 Release

Stage III: Education & Support

Stage IV: Standards Update & Maintenance
Data Flow Using CDISC

Protocol Representation

- Trial Design (SDTM) Analysis Plan

Clinical Trial Protocol

ODM XML

(e)Source Document

Clinical (CRF or eCRF) Trial Data (defined by SDTM)

ODM XML

Patient Info

ODM XML

Administrative, Tracking, Lab Acquisition Info

CRF, Analysis Data

ODM XML Define.xml

Integrated Reports

- SDTM Data, Analysis Data, Metadata

Reporting and/or Regulatory Submissions

= ODM (transport)

= SDTM and Analysis Data (content)

= Protocol information (content)

= Source data (other than SDTM/CRF data)
<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
<th>Implementation Version Release Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDTM, SEND</td>
<td>Ready for regulatory submission of CRT; Over 12,000 downloads as of early 2008</td>
<td>2004*</td>
</tr>
<tr>
<td>ODM</td>
<td>CDISC Transport Standard for acquisition, exchange, submission (define.xml) archive</td>
<td>2001*</td>
</tr>
<tr>
<td>Define.xml</td>
<td>Case Report Tabulation Data Definition Specification</td>
<td>2005*</td>
</tr>
<tr>
<td>LAB</td>
<td>Content standard – available for transfer of clinical lab data to sponsors</td>
<td>2002</td>
</tr>
<tr>
<td>ADaM</td>
<td>General Considerations document and examples of datasets for submission</td>
<td>2004</td>
</tr>
<tr>
<td>Protocol</td>
<td>Collaborative effort to develop machine-readable standard protocol with data layer</td>
<td>In progress-due in 2008</td>
</tr>
<tr>
<td>Representation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Terminology</td>
<td>Developing standard terminology to support all CDISC standards</td>
<td>2006 (Pkg1 &amp; 2A)</td>
</tr>
<tr>
<td>Codelist</td>
<td></td>
<td>Pkg 2B in progress</td>
</tr>
<tr>
<td>CDASH</td>
<td>Data acquisition (CRF) standards</td>
<td>In progress-due by Q3 2008</td>
</tr>
</tbody>
</table>

* Specification referenced in FDA Final Guidance
Study Data Tabulation Model (SDTM)

Interventions
- Exposure
- ConMeds
- Subst Use

Findings
- Labs
- InclExcl
- Vitals
- SubjChar
- PhysExam
- ECG
- QS
- PG
- MB

Events
- AE
- Disp.
- MedHist
### 6.3.4 PHYSICAL EXAMINATION — PE

pe.xpt, Physical Examination — Findings, Version 3.1.2, July 25, 2007. One record per body system or abnormality per visit per subject, Tabulation

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Type</th>
<th>Controlled Terms or Format</th>
<th>Role</th>
<th>CDISC Notes</th>
<th>Core</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDYID</td>
<td>Study Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Unique identifier for a study.</td>
<td>Req</td>
<td>SDTMIG 2.4.4</td>
</tr>
<tr>
<td>DOMAIN</td>
<td>Domain Abbreviation</td>
<td>Char</td>
<td>PE</td>
<td>Identifier</td>
<td>Two-character abbreviation for the domain.</td>
<td>Req</td>
<td>SDTMIG 4.1.2.2, Appendix C2</td>
</tr>
<tr>
<td>USUBJID</td>
<td>Unique Subject Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.</td>
<td>Req</td>
<td>SDTMIG 4.1.2.3</td>
</tr>
<tr>
<td>PESEQ</td>
<td>Sequence Number</td>
<td>Num</td>
<td></td>
<td>Identifier</td>
<td>Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.</td>
<td>Req</td>
<td>SDTMIG 2.4.4</td>
</tr>
<tr>
<td>PEGRPID</td>
<td>Group ID</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Used to tie together a block of related records in a single domain for a subject.</td>
<td>Perm</td>
<td>SDTMIG 2.4.4</td>
</tr>
<tr>
<td>PESPID</td>
<td>Sponsor-Defined Identifier</td>
<td>Char</td>
<td></td>
<td>Identifier</td>
<td>Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor’s operational database. Example: Line number on a CRF.</td>
<td>Perm</td>
<td>SDTMIG 2.4.6</td>
</tr>
<tr>
<td>PETESTCD</td>
<td>Body System Examined Short Name</td>
<td>Char</td>
<td>*</td>
<td>Topic</td>
<td>Short name of the measurement, test, or examination described in PETEST. It can be used as a column name when converting a dataset from a vertical to a horizontal format. The value in PETESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., ‘1TEST’). PETESTCD cannot contain characters other than letters, numbers, or underscores.</td>
<td>Req</td>
<td>SDTMIG 2.4.3, SDTMIG 4.1.1.9, SDTMIG 4.1.2.1</td>
</tr>
<tr>
<td>PETEST</td>
<td>Body System Examined</td>
<td>Char</td>
<td>*</td>
<td>Synonym Qualifier</td>
<td>Verbatim term part of the body examined. The value in PETEST cannot be longer than 40 characters. Examples: CARDIOVASCULAR and RESPIRATORY. For subject-level exam, value should be 'PHYSICAL EXAMINATION'.</td>
<td>Req</td>
<td>SDTMIG 2.4.3, SDTMIG 4.1.2.1, SDTMIG 4.1.2.4</td>
</tr>
<tr>
<td>PECAT</td>
<td>Category for Examination</td>
<td>Char</td>
<td>*</td>
<td>Grouping Qualifier</td>
<td>Used to define a category of examination. Examples: GENERAL, NEUROLOGICAL.</td>
<td>Perm</td>
<td>SDTMIG 2.4.3, SDTMIG 4.1.2.6</td>
</tr>
<tr>
<td>PESCAT</td>
<td>Subcategory for Examination</td>
<td>Char</td>
<td>*</td>
<td>Grouping Qualifier</td>
<td>A further categorization of the examination. Used if needed to add further detail to PECAT.</td>
<td>Perm</td>
<td>SDTMIG 2.4.3, SDTMIG 4.1.2.6</td>
</tr>
<tr>
<td>PEORRES</td>
<td>Verbatim Examination Finding</td>
<td>Char</td>
<td></td>
<td>Result Qualifier</td>
<td>Text description of any abnormal findings. If the examination was completed and there were no abnormal findings, the value should be NORMAL. If the examination was not performed on a particular body system, or at the subject level, then the value should be null, and NOT DONE should appear in PESTAT.</td>
<td>Exp</td>
<td>SDTMIG 2.4.3, SDTMIG 4.1.3.6, SDTMIG 4.1.5.1</td>
</tr>
</tbody>
</table>
The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments be provided in an electronic format that FDA can process, review, and archive. The proposal would also require the use of standardized data structure, terminology, and code sets contained in current FDA guidance (the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium) to allow for more efficient and comprehensive data review.
Trial Design Model (TDM)

Example Trial 1: Three Arms

- **Placebo**
  - Screen
  - Run-in
  - Placebo

- **A**
  - Screen
  - Run-in
  - Drug A

- **B**
  - Screen
  - Run-in
  - Drug B

Randomization
Analysis Data Model (ADaM)

- Compared to SDTM, analysis datasets are restructured and contain additional information (derived variables, flags, comments, etc.)

- Describes
  - key principles
  - conventions for standard analysis variables
  - provides an example of a key subject-level analysis file

- Describes metadata specific for Analysis Datasets
  - Analysis dataset metadata
  - Analysis variable metadata
  - Analysis results metadata
CDISC Clinical Laboratory (LAB) Model

- Content Model for Clinical Research Laboratory Data
- Four Implementation Options
  - ASCII
  - SAS
  - ODM XML
  - HL7 V3 Message
- LOINC Codes
- NCI incorporated within caBIG LAB solutions
CDISC Operational Data Model
Top Level ODM Schema
CDISC ODM & Audit Trail

Slide courtesy Dave Iberson-Hurst, Assero
FDA ODM Pilot

- HHS—Food and Drug Administration (FDA)
- [Docket No. 2007N—0064] *(posted 13 March 07)*
- Electronic Case Report Form Submission; Notice of Pilot Project
- **SUMMARY:** The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Food and Drug Administration (FDA) are seeking sponsors interested in participating in a pilot project to test the submission of case report form (CRF) data provided electronically in extensible markup language (XML) based on the Operational Data Model (ODM) developed by the Clinical Data Interchange Standards Consortium (CDISC). This pilot will test the ability of a new data format to support all review activity, which our current submission is incapable of doing…..
Increasing Usage of CDISC Standards

Source: Tufts Survey 2007
• **Mission:** To develop a set of ‘content standards’ (element name, definition, metadata) for a core set of global data collection fields that will support clinical research studies.

• **Scope:** The initial scope will be the ‘safety data/domains’ to support clinical trials.

• Initiated **Collaborative Group** to provide strategic direction and ensure organized, global strategy and resources (16 organizations).

• **Project Leader:** Rhonda Facile (rfacile@cdisc.org)
CM – Basic Data Collection Elements

SDTM Data Variables

CMSEQ
CMGRPID
CMSPID
CMTRT
CMODIFY
CMDECODE
CMCAT
CMSCAT
CMOCCUR
CMSTAT
CMREASND
CMINDC
CMCLAS
CMCLASCD
CMDOSE
CMDOSTXT
CMDOSU

CMTRT
CMINDC
CMSTDTC
CMSTRF
CMENDTC
CMENRF
CMROUTE

CDASH Basic Data Collection (CRF) Elements

CMTRT
CMINDC
CMSTDTC
CMSTRF
CMENDTC
CMENRF
CMROUTE

DRAFT SET
## CDASH Project Update

### 16 DOMAINS

|---------------------------------|---------------------------------|-------------------|-------------------------|-----------------------------------|------------------------|-----------------------------|------------------------------|
CDISC Business Case (Gartner, PhRMA) – Summary Findings

• CDISC standards can significantly improve processes, thus saving time and cost*
  – ~ 60% of the non-subject participation time
  – 70-90% (~ half the value) in the start-up stage

• CDISC standards have additional benefits for clinical research
  – *Increase data quality*
  – *Enable data integration, enhancing re-usability in ‘knowledge’ warehouses to improve science, marketing and safety surveillance*
  – *Streamline data interchange among partners*
  – *Facilitate review of regulatory submissions*
  – *Enable integration of data from disparate tools/technologies*
  – *Improve communication among project team members*

*Note: Actual savings will vary per company and study, depending on baselines.*
Vision – Medical Innovation

Collect Data Once, (Various Sources)

“Rolling Warehouse” Multiple Downstream Uses

CDISC Standards
Real-time Integration

EDC
EHR
ECG
X-RAY
LAB

Regulatory Authority

Sponsor
Public Registries and IRBs
CRO or Partner

Data Sources

CDISC Standards
Real-time Integration
Collect Data Once, (Various Sources)

“Rolling Warehouse” Multiple Downstream Uses
The mission of CDISC is to…

develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.
Data Flow Using CDISC Standard Linking Clinical Research and Healthcare

Electronic Health Record

- Clinical Trial Data
- Patient Info
- HL7 and/or ODM XML

Protocol Representation

- Trial Design (SDTM) Analysis Plan
- Clinical Trial Protocol

(e)Source Document

- Clinical (CRF or eCRF) Trial Data (defined by SDTM)

Operational & Analysis Databases

- CRF, Analysis Data
- Administrative, Tracking, Lab Acquisition Info
- ODM XML

ODM XML Define.xml

Integrated Reports

- SDTM Data, Analysis Data, Metadata

Regulatory Submissions

- Source data (other than SDTM/CRF data)
- = Protocol information (content)
- = SDTM and Analysis Data (content)
- = ODM (transport)
Towards interoperability…..

HL7 Reference Information Model (RIM) V3
Designed for healthcare

Clinical Research Domain Model (BRIDG)

CDISC Models
A clinical research domain analysis model (UML) initiated by CDISC, **BRIDGing**
- Organizations (CDISC, HL7, FDA, NCI)
- Standards
- Research and Healthcare

Towards **semantic interoperability; a Portal to Healthcare**

Open source; Collaborative Project
- See BRIDG Model on CDISC website
  or [www.bridgmodel.org](http://www.bridgmodel.org)

*Biomedical Research Integrated Domain Group (BRIDG) Model*
The BRIDG Model
Agenda – Section II

- History
- Purpose and Scope
- Governance
- Release 2.0
  - What’s In
  - What’s Coming
  - The Model
- Questions and Answers
What is BRIDG?
Biomedical Research Integrated Domain Group

• A formal model
• A communication bridge
• An open community of stakeholders
• The semantic foundation for application and message development
Definitions

• **Syntax**
  – Structure, not meaning
    • The dog eats red meat.
    • The dog drinks blue sky.

• **Semantics**
  – Meaning, not (necessarily tied to one) structure
    • The dog eats red meat.
    • Red meat was eaten by the dog.

• **Interoperability**
  – The ability of two or more systems or components to exchange information and to use the information that has been exchanged.

*Source: Charlie Mead*
The Pillars of Interoperability

*Necessary but not necessarily sufficient*

- Common model across all domains of interest
  - Foundation of rigorously defined data types
  - Methodology for interfacing with controlled vocabularies
  - Formal process and tools for defining interchange structures

Source: Charlie Mead
What is a Domain Analysis Model (DAM)?

- An implementation-independent view of the Problem Space from the Domain Expert’s perspective
  - A DAM must be readable by ‘the domain expert on the street’
  - A DAM defines ‘what’ (static and dynamic aspects)
  - A design model defines ‘how’

- The most important feature is that it separates the semantics of analysis (“the Problem Space”) from those of design (“the Solution Space”) – “what” vs “how”

- The term is somewhat overloaded
  - Doug Rosenberg: static structures of a larger ‘implementation-independent representation of the problem to be solved’
  - HL7 HDF: ‘implementation-independent representation of the problem to be solved’ (i.e. includes both static and dynamic views of the Problem)

Source: Charlie Mead
What’s in a DAM?

- **Minimum components**
  - **Static View**
    - UML class diagram
      - Concepts, Attributes, Relationships
    - Complete, unambiguous documentation (**GLOSSARY**)
    - Appropriate partitioning of sub-domains and layers of abstraction (Packages)
    - Exemplar Instance Diagrams (if necessary)
  - **Dynamic View**
    - Storyboards
    - UML Activity Diagram representations of Storyboards
    - State diagrams of suitably ‘interesting’ static classes
    - Interaction diagrams (if necessary)
  - In the end, if the model’s collective view unambiguously specify the Problem’s semantics (dynamic and static), the ‘correct’ views have been constructed
    - “There are no correct models; some models are helpful.”

Source: Charlie Mead
Talking About a Domain

• Domain Experts have a “mental map” of the Problem Space
  – Noam Chomsky “Syntactic Structures” (1957)
    • Deletion (filtered/missing details)
    • Distortion (incorrect or modified details)
    • Generalization (abstractions via rules, beliefs, principles)
    • Distortion and Generalization share…
      – … Inappropriate/incorrect use of universal qualifiers
        » All/Everyone/Always/Never/Nobody/None

“The Map is not the Territory”
-- Alford Korzybski, Bertrand Russell

Source: Charlie Mead
Talking About a Domain

- **Deletion** – “They use the system to borrow books.”
  - Challenge: “Who uses the system to borrow books?”
  - Response: “Library members, librarians, other libraries.”

- **Distortion** – “Borrowers can’t borrow another book until all overdue books are been returned.”
  - Challenge: “Are there any circumstances where a borrower *can* borrow a book before all overdue books are returned?”
  - Response: “Yes, two circumstances….”

- **Generalization** – “Everyone must have a ticket to borrow books.”
  - Challenge: “Are there any system users that can borrow books without a ticket?”
  - Response: “Librarians and other libraries have a different type of ticket.”
What Problem(s) Does a DAM Solve?

• The Communications conundrum
  – Experts know about the problem but don’t understand how to build robust solutions
  – Technologists understand how to build robust solutions but don’t understand the intricacies of the problem that the solution must support
  – Any implementation (i.e. solution) is a compromise of the original problem statement
    • Compromises must be chosen wisely
      – should be based on a deep understanding of the problem and a dialogue between Problem Space and Solution Space Experts

Source: Charlie Mead
What Problems Does a DAM Create?

- Analysis Paralysis
  - Useless diagrams
  - Endless discussions
  - No real Product of Value

- **KEY POINT:** Building a DAM is a complex activity that is executed within a larger ‘technology development process framework’

- Analysis Paralysis occurs when building a DAM is done within the traditional *Waterfall* process
  - highly *ineffective* in enabling solutions to complex problems

- Building a DAM is highly *effective* when applied within an *iterative, incremental* process framework

Source: Charlie Mead
The Communication Pyramid

- Free-text Documents
- Structured Documents
- ad hoc Drawings
- Non-standard Graphics
- Standardized Models (UML)

Abstraction:
- Problem Space (Implementation-Independent)
- Solution Space (Implementation-Specific)

Source: Charlie Mead
What Problems Does a DAM Create?

- Analysis Paralysis
  - Useless diagrams
  - Endless discussions
  - No real Product of Value
- Analysis Paralysis occurs when building a DAM is done within the traditional *Waterfall* process
  - highly *ineffective* in enabling solutions to complex problems
- Building a DAM is highly *effective* when applied within an *iterative, incremental* process framework
- KEY POINT: Building a DAM is a complex activity that is executed within a larger ‘technology development process framework’
The Unified Process
(Iterative/Incremental, Risk-Focused, Architecture-Centric)
BRIDG Scope

Protocol-driven research and its associated regulatory artifacts,

i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, or device on a human, animal, or other biologic subject or substance plus all associated regulatory artifacts required for or derived from this effort.
How did BRIDG get started?

- **CDISC**: In early 2004, CDISC started constructing a Domain Analysis Model to support harmonization of their standards for clinical research as well as with the Health Level Seven (HL7) healthcare standard.

- **NCI**: In late 2004, NCI's Cancer Biomedical Informatics Grid (caBIG™) initiative joined the CDISC BRIDG efforts to construct a structured protocol representation for its Clinical Trials Management Systems (CTMS) Workspace, in order to further interoperability among clinical trials research in cancer.

- **HL7**: In 2005, the BRIDG model was adopted by the HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee as the RCRIM Domain Analysis Model.

- **FDA**: In 2007, the US Food and Drug Administration included BRIDG in their draft 5 year PDUFA IV IT Plan as a foundation for several projects.
CDISC Mission

The mission of CDISC is to develop and support global, platform-independent data standards that *enable information system interoperability* to improve medical research and related areas of healthcare.
NCI’s caBIG Project and BRIDG

• BRIDG used for Application Development

• CTMSi Project: Proof of Concept

• BRIDG is fundamental part of the CTMS WS software development process
RCRIM’s use of BRIDG

- All HL7 messages developed by RCRIM will be represented in BRIDG
FDA’s Use of BRIDG

- Several FDA projects, including the CDISC HL7 message, will be based on the BRIDG semantics.
BRIDG Governance
Current Organization of the BRIDG project – BRIDG Advisory Board

- **BRIDG Advisory Board**
  - Representation from the current stakeholders
  - Helps to set priorities and identify resources

Source: Doug Fridsma
Current Organization of the BRIDG THC

- **Technical Harmonization Committee (THC)**
  - Responsible for ongoing model maintenance
  - Harmonizes subdomain projects into the main model

Source: Doug Fridsma
BRIDG Release 2
What’s in Release 2.0?

- **New Semantic Content**: Adverse Events, Person / Organization, Cancer Central Clinical Patient Registry
- **Policy Changes**
  - Release schedule: 1-2 per year
  - Mapping documents: Maintained by project teams
- **Model Structure Changes**
  - Evolution of pillar structure
  - Modification of BRIDG backbone
- **Model Support Features**
  - Use of HL7 Abstract Datatype Specification R2
  - BRIDG to RIM mapping
  - Framework for assigning value sets
- **Infrastructure Enhancements**
  - FAQ on website
## What’s In BRIDG?

<table>
<thead>
<tr>
<th>Project</th>
<th>Stakeholder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Data Tabulation Model (SDTM)</td>
<td>CDISC</td>
</tr>
<tr>
<td>Regulated Product Submission (RPS)</td>
<td>FDA/HL7 RCRIM</td>
</tr>
<tr>
<td>Patient Study Calendar (PSC)</td>
<td>NCI</td>
</tr>
<tr>
<td>Trial Design Model (TDM)</td>
<td>CDISC</td>
</tr>
<tr>
<td>caXchange/LabHub</td>
<td>NCI/HL7 RCRIM TC/CDISC</td>
</tr>
<tr>
<td>Clinical Trial Object Model (CTOM)</td>
<td>NCI</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>CDISC, NCI, NIH, US Federal Gov’t, FDA</td>
</tr>
<tr>
<td>Player / Scoper for Person and Org</td>
<td>NCI, CDISC</td>
</tr>
<tr>
<td>Patient Registry</td>
<td>NCI</td>
</tr>
</tbody>
</table>

New in R2.0
What’s Coming Next in 2008 and beyond

• New Content: Clinical Trial Registry and Protocol Abstraction, more to be determined

• Infrastructure Enhancements
BRIDG Scope

Protocol-driven research and its associated regulatory artifacts,

i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, or device on a human, animal, or other biologic subject or substance plus all associated regulatory artifacts required for or derived from this effort.
The BRIDG Model
Release 2.0 Important Components

• Project Documentation and Release Notes

• Model
  – Unified Modeling Language (UML)
  – Backbone
  – Views
Project Documentation & Release Notes

BRIDG Model
http://www.bridgmodel.org

Release 1.1 Documentation Package

Biomedical Research Integrated Domain Group (BRIDG)

prepared by

BRIDG Technical Harmonization Committee (THC)

Becky Angeles (SMBio-NCI)
Julie Evans (CDISC HL7 RCEIM)
Smita Hastik (NemPro-NCI RHEIM)
Chandra Moed (Rozit Allen Hamburg-NCI HL7 RCEIM)
Wendy Ver Hoef (SMBio-NCI)

http://www.bridgmodel.org

22 October 2007

www.bridgmodel.org
Unified Modeling Language

• Used in the BRIDG model

• The industry-standard language for specifying, visualizing, constructing, and documenting the requirements of software systems

• The BRIDG model uses these UML diagrams:
  – Class diagrams
  – Instance diagrams
  – Activity diagrams
UML Class Diagrams

• **class** – a concept of primary importance the domain-of-interest, depicted as a rectangle labeled with the concept’s name

• **attribute** (including datatype specification) – a descriptive feature of a class, depicted as being contained within the class

• **relationship** – one of several types of “lines” between classes
Class diagram example

- **Person**
  - name: string

- **Employee**
  - ::Person
  - name: string

- **Company**
  - name: string

**Relationships**
- Employee works for / employs 1..* Person
- Person works for / employs 1..* Company

**Class and Attribute**
- class
- attribute

**Multiplicity**
- 1..*
The BRIDG Backbone Classes

- Person
- Organization
- Material
- StudyProtocol
- Documentation
- Activity
- ActivityRelationship
- ObservationResult
- ObservationResultRelationship
The BRIDG Backbone – Part 1

Name: View 5 - BRIDG Backbone - Part 1
Package: BRIDG Release 1.0 – Static Classes
Version: 1.0
Author: BRIDG THC
The BRIDG Backbone – Part 2

[Diagram of BRIDG Backbone – Part 2]
The Pillars of Interoperability

*Necessary but not necessarily sufficient*

- Common model across all domains of interest
  - Foundation of rigorously defined data types
- Methodology for interfacing with controlled vocabularies
- Formal process and tools for defining interchange structures

*Source: Charlie Mead, MD, HL7*
Foundation of rigorously defined data types

- Simple vs Complex (or Abstract)
- Simple: Character, String, Text, Numeric

- Plans to use HL7 Abstract Data Type Specification R2, which will soon become an ISO standard
Datatypes: Simple vs Complex

```plaintext
class DatatypeExampleForPresentation

  Document

  StudyProtocol

  + blindedIndicator: BL
  + blindingSchemaCode: CD
  + confidentialityCode: CD
  + diseaseCode: SET<CD>
  + intentCode: CD
  + monitorCode: CD
  + multiInstitutionIndicator: BL
  + phaseCode: CD
  + populationDescription: ST
  + randomizationModeCode: CD
  + randomizedIndicator: BL
  + subjectTypeCode: CD

::Document

  + bibliographicDesignation: ST
  + identifier: SET<II>
  + languageCode: CD
  + revision: ST
  + statusCode: CD
  + statusDateRange: IVL<TS>
  + subtypeCode: SET<CD>
  + summaryDescription: ST
  + synopsis: ST
  + text: ST
  + title: ST
  + typeCode: CD
  + universalResourceLocator: ST
```

**Complex Data Types::CD**

- code: string
- codeSystem: string
- codeSystemName: string
- codeSystemVersion: string
- displayName: string
- originalText: string
- qualifier: string
- translation: SET<CD>
Interfacing with Controlled Vocabularies

• Plans to move BRIDG semantics into a controlled environment such as NCI’s EVS / caDSR
• BRIDG controlled vocabulary should integrate with existing stakeholder vocabulary
BRIDG: Concluding Thoughts

• We expect that BRIDG will transition more at the beginning and then stabilize

• The BRIDG user community will determine the quality and usefulness of the model

Thanks to members of the BRIDG THC: Charlie Mead, Smita Hastak, Becky Angeles, Wendy Ver Hoef, Doug Fridsma, Steve Sandberg
Collaborations and Alliances
• Shared Purposes
  – To improve the quality of public health
  – To have one overarching standard model for interoperability between healthcare and clinical research information systems

• Working Relationships
  – Regulated Clinical Research Information Management (RCRIM) Technical Committee
    • CDISC, FDA, NCI, others bring clinical research domain expertise to HL7 through RCRIM and other groups
  – Formal relationship - Associate Charter Agreement (MOU) between CDISC and HL7 – since 2001
    • Organizational Memberships and Collaborations
    • Outreach Committee for Clinical Research (OCCR)
    • Commitment to harmonize the HL7 and CDISC standards
RCRIM Overview / History

• RCRIM – Regulated Clinical Research Information Management (Technical Committee, now Working Group – name change)

• Formed as Clinical Trial Special Interest Group (CT-SIT) in 2001, then became RCRIM TC in 2002 (joint effort between CDISC, FDA, HL7 and pharma industry)

• Mission
  – This committee supports the HL7 mission to create and promote its standards by developing standards to improve or enhance information management during research and regulatory evaluation of the safety and efficacy of therapeutic products or procedures worldwide.

• RCRIM Sponsors the Patient Safety Special Interest Group (PSSIG) and the Pharmacogenomics SIG (PGxSIG)
RCRIM and HL7

- RCRIM is one of 28 active HL7 Technical Committees
- RCRIM provides expertise in the following domains:
  - Public Health
  - Regulated Products
  - Regulated Studies
- Initial focus within Clinical Research domain
- RCRIM beginning to outreach to other domains and technical committees (e.g. EHR)
RCRIM-Sponsored Standards

- **Domain: Public Health**
  - Individual Case Safety Report (ICSR)
  - Generic Incident Notification (GIN)

- **Domain: Regulated Products**
  - Structured Product Labeling (SPL)
  - Regulated Product Submission (RPS)

- **Domain: Regulated Studies**
  - Annotated ECG (aECG)
  - Clinical Trial Laboratory (CT Lab)
  - Stability Study
RCRIM Project Portfolio

- Clinical Trial Registries
- Protocol Representation
- Clinical Genomics
- BRIDG (Domain Analysis Model)
- RCRIM Vocabulary
- SPL (Structured Product Labeling)
- RPS (Regulated Product Submission)
Specific Collaborative Projects

- BRIDG
- Protocol Representation
- Terminology
- CDISC Content to HL7 Message
- Linking EHRs and Clinical Research
- OCCR
Protocol Representation will identify standard elements of a clinical trial protocol that can be further elucidated and codified to facilitate study design, regulatory compliance, project management, trial conduct and data interchange among consumers and systems. This work will be based upon the needs of protocol consumers, which may include regulatory authorities, IRBs, statisticians, project managers, site personnel and users of any downstream systems for the management of clinical trial information.

Project Objective(s): Publication of a standard, machine-readable model for protocol representation that will enable interchange of this data among systems and stakeholders.
Protocol Representation (PR) Group

A volunteer organization of domain experts representing the stakeholders of the biopharmaceutical industry, NCI/NIH, and FDA with specific expertise in developing and/or conducting regulated clinical trials with regulated protocols.

• PR Group is both:
  – A CDISC team
  – A Project Team of the Health Level 7 (HL7) Regulated Clinical Research and Information Management (RCRIM) Technical Committee
3.1. Summary of Study Design

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

Not very Useful!

Source: Cara Willoughby
3.1. Summary of Study Design

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

Source: Kristin O’Connor
A Document Example: Structuring Information by “Meta” Information

<table>
<thead>
<tr>
<th>“Meta” Information about Content</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject age description</td>
<td>Age 18 years of age or older</td>
</tr>
<tr>
<td>Configuration</td>
<td>Parallel group trial</td>
</tr>
<tr>
<td>Population disease description</td>
<td>Stage I or II hypertensive patients</td>
</tr>
<tr>
<td>Degree of blind</td>
<td>Double-blind</td>
</tr>
</tbody>
</table>

Much More Useful!
Protocol Representation – Hierarchy

Sample: Sections, Sub-sections, Elements

- Document Type
  - Clinical Trial Protocol

- General Information
  - Protocol Identification
    - Protocol Title
    - Protocol Short Title
    - Protocol Identification Number

- Protocol Contact Information
  - Sponsor
    - Sponsor Status
Approach: Assumptions and Decisions (sample)

• Elements must be defined in a glossary, since the industry uses multiple definitions for the majority of protocol elements
  – CDISC Glossary
    • Applied Clinical Trials, Dec 2006
• The model must be flexible to accommodate any protocol-based research.
Approach: Assumptions and Decisions (sample - cont’d)

- Identify core set of elements initially, and expand with further details, as needed
  - Initial set of elements based on ICH E6 & ICH E3 documents, which focus on efficacy and safety trials, but can be applied to other types of studies.
    - ICH E6
      - Basis for the development and organization of the PR Element Spreadsheet
    - ICH E3
      - Terms & definitions
    - EUDRACT (EMEA)
      - Key words and Protocol description
  - WHO and clinicaltrials.gov Clinical Trial Registry
  - Specific topics (e.g. IRB, SAP-E9)
Terminology/Vocabulary

- Formalized CDISC Terminology Initiative in 2005
- Primary Objective: to define and support the controlled terminology needs of the CDISC models across the clinical trial continuum (SDTM → CDASH)
- Terminology Initiative comprised of 60+ team members (Global Sponsors, Regulatory, Academia, CROs, etc...) distributed across 4 project teams
- Key partnership with US National Cancer Institute Enterprise Vocabulary Services (NCI EVS)
- Combined HL7 RCRIM Vocabulary & CDISC Terminology teams to ensure common development; also now working with ISO and ICH
“Standard” Controlled Terminology

Global Pharma & CROs

FDA & Academia

International SDOs

Vocabulary Developers

Health Level Seven
(RCRIM TC)
Data Collection & Mgmt

Analyses & Reporting

Integrated Report/eSub

CDISC SDTM Study Summary (subset of CTR)

Structured Eligibility Criteria

CDISC Trial Design Part I
(arms, elements, visits)

CDISC Trial Design Part II
Planned assessments & interventions
(NCI Study Calendar)

CDISC Statistical Analysis Plan

Other Protocol Template Sections and Attachments

Clinical Trial Tracking, Summary, Registry

Structured Eligibility Criteria

CDISC Trial Design Part I
(arms, elements, visits)

CDISC Trial Design Part II
Planned assessments & interventions
(NCI Study Calendar)

CDISC Statistical Analysis Plan

Analysis Dataset Metadata

CRF Data
(AE data)
LAB Data
Genomics Data
ECG
SAE Reports

CDISC Study Data Tabulation Model (SDTM)
(CRF data and other, inc. SEND)

CDISC ADaM (analysis datasets)

Report and/or Submission Preparation

Report Template Content, etc
From FDA 5-yr IT Plan
“Standards should be extended to facilitate data collection at investigative sites”

Percent Agree

<table>
<thead>
<tr>
<th>Region</th>
<th>BioPharma</th>
<th>CRO</th>
</tr>
</thead>
<tbody>
<tr>
<td>W. Europe</td>
<td>94%</td>
<td>91%</td>
</tr>
<tr>
<td>N. America</td>
<td>93%</td>
<td>91%</td>
</tr>
<tr>
<td>Japan, Other</td>
<td>89%</td>
<td>91%</td>
</tr>
</tbody>
</table>

International: Sponsors (n=89): 51% Europe; 22% Japan; 27% Latin America, Other
Service Providers (n=46): 73% Europe; 5% Japan; 22% Latin America, Other

* N. America: Sponsors: (n=211)
Service Providers: (n=146)
eSource Data Interchange (eSDI) Initiative

- CDISC requested by FDA to lead initiative as neutral, non-profit global organization

- **Purpose of eSDI Initiative**
  - *to facilitate the use of electronic technology in the context of existing regulations for the collection of eSource data in clinical trials for regulatory submission by leveraging the power of the CDISC standards, in particular the Operational Data Model (ODM).*
  - **Note:** eSource pertains to eDiaries, ePRO, eDCI, Electronic Health Records...
eSource Data Interchange (eSDI) Initiative

• **Overarching goals:**
  – to make it easier for physicians to conduct clinical research,
  – collecting data only once in an industry standard format for multiple downstream uses, and thereby
  – to improve data quality and patient safety

• **Product (2 year development process)**
  – Version 1.0 document posted at [www.cdisc.org](http://www.cdisc.org)

Presentations and Publications
• Leverages healthcare (HL7 CDA) and research (CDISC) data interchange standards; tool interoperability
• Facilitates investigator workflow; eliminates transcription steps
• Complies with 21CFR11 and HIPAA feasible
• Enables online monitoring
CDISC Initiative: Healthcare Link

An industry initiative that has successfully demonstrated clinical information interoperability between physician clinical systems (EHR) and pharmaceutical clinical trials systems based on open standards.
- Duke Clinical Research Institute, CDISC, Novartis, Merck, J&J, Microsoft.

Next Step: Development and Demonstration of an Integration Profile called Retrieve Form for Data Capture (RFD)

Co-sponsored by Integrating the Healthcare Enterprise (IHE), the New Directions Life Sciences Interoperability demonstrations employ the RFD to enable data integration between systems. (Project Leader: Landen Bain, lbain@cdisc.org)
EHR-CR Project

“Roadmap” to Connecting Healthcare and Research Data

www.EHRCR.org
Project Sponsors & Participants

Sponsors:

- eClinical Forum
- PhRMA

Gold level partners:

- Procter & Gamble
- Pfizer
- Eli Lilly & Company
- PhRMA

Global Participants:

- Astellas US, LLC
- Bayer Healthcare
- Boehringer Ingelheim Pharmaceuticals
- Bristol Myers Squib
- Cerner Corporation
- ClinPhone Inc.
- Eli Lilly & Company
- FDA
- Glaxo SmithKline
- Hoffman La Roche
- Lundbeck Pharmaceuticals
- Millennium Pharmaceuticals, Inc.
- NIH / Cancer Research Foundation
- Northrop Grumman Health Solutions
- Novartis
- Nycomed GmbH
- Orion Pharma
- Pfizer
- Procter & Gamble Pharmaceuticals

In Cooperation and Consultation With:

- HL7 EHR Technical Committee
- EuroRec Q-Rec
- CDISC
**Manage Unstructured Health Record Information**

**Statement:** Create, capture, and maintain unstructured health record information.

**Description:**
The EHR/CR system must allow for unstructured health record information such as to provide the investigator with the ability to comment on other data that is represented in structured format. We are recommending the use of CDISC/CDASH data formats which allows for unstructured data in the investigator comments area only. It is not recommended that data other than comments be handled in unstructured format. Images, ECGs, etc should be used by the site to make a diagnostic or assessment that should be translated into numeric values or codes for clinical research. Investigators must be careful to only use free text in areas allowed for by CDASH comments so as to not lead the sponsor to review all comments for detecting SAEs which would put them at risk of seeing patient-identifying information.

**New Conformance Criteria for Clinical Research**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The system SHALL capture unstructured health record information as part of the patient EHR.</td>
</tr>
<tr>
<td>2.</td>
<td>The system SHALL retrieve unstructured health record information as part of the patient EHR.</td>
</tr>
<tr>
<td>3.</td>
<td>The system SHALL provide the ability to update unstructured health record information.</td>
</tr>
<tr>
<td>4.</td>
<td>The system SHALL conform to function IN.2.1 (Data Retention, Availability and Destruction) to provide the ability to inactivate, obsolete, or destroy unstructured health record information.</td>
</tr>
<tr>
<td>5.</td>
<td>The system SHALL provide the ability to mask Personal Health Identifiers (PHI) from the unstructured data that is also used for clinical research.</td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
</tr>
<tr>
<td>--------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Jan 04, 2008</td>
<td>Submit Project Scope Statement</td>
</tr>
<tr>
<td>Jan 11, 2008</td>
<td>Register EHR/CR Profile on NIST Web Site</td>
</tr>
<tr>
<td>January 16, 2008</td>
<td>Present the intent to go to Ballot in Spring of 2008 to the EHR and RCRIM TCs</td>
</tr>
<tr>
<td>February 17, 2008</td>
<td>Notification of Intent to Ballot (NIB) Deadline</td>
</tr>
<tr>
<td>February 24, 2008</td>
<td>Initial Content Deadline</td>
</tr>
<tr>
<td>March 16, 2008</td>
<td>Final Content Deadline</td>
</tr>
<tr>
<td>March 24 – April 28, 2008</td>
<td>Ballot Period (30 Days)</td>
</tr>
</tbody>
</table>
• Outreach Committee for Clinical Research (OCCR)
  – HL7 Board-appointed Committee
  – Chair: Ed Helton (Vice Chair: Becky Kush)
  – Current Members: Randy Levin, Ed Tripp, Ed Hammond, Chuck Jaffe, Ross Martin, Bron Kisler, Bob Birmingham, Robert DiLaura
  – Goal to expand HL7 efforts to reach more individuals interested in clinical research and healthcare, particularly through educational opportunities
OCCR Meeting of 15 Jan 08 (next one 7 May)

- OCCR wishes to expand membership to other organizations, e.g. NCI, CTSAs, NIH, Japanese groups, European groups (e.g. EMEA), AMIA, eCR Forum, others

- Three educational events in 2008
  - HL7 Summit
  - CDISC European Interchange
  - CDISC International Interchange

- Proposed Manuscript emphasizing the importance of collaboration among standards development organizations (outlined)

Note: Have now added Japan, China and India in 2008.
Information and Contacts

- For standards and additional information:
  - See www.cdisc.org and www.hl7.org

- Charles Jaffe: cjaffe@hl7.org
- Charlie McCay: Charlie@ramseysystems.co.uk
- Julie Evans: jevans@cdisc.org
- Rebecca Kush: rkush@cdisc.org