HL7 RIM
An introduction for Non-technical Professionals

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Let’s talk about

- CDISC, HL7, FDA and how it fits together
- Key concepts of HL7 V3 methodology
- HL7 Reference Information model
Why do we talk about HL7?

As of January 1, 2008 CDER only accepts electronic submissions in the eCTD format. To facilitate the transition to the CTD format FDA will start accepting CTD submissions based on the RPS standard for a limited set of submissions. These submissions have been part of a paper submission with the electronic.

SDTM version 3.1.1 submissions are accepted by FDA. A draft implementation guide for SDTM 3.1.2 is currently under review by CDISC and FDA. CDISC and CDISC are in the process of forming a communications team that will ensure SDTM meets FDA’s scientific requirements.

CDISC - HL7 Project - The FDA plans to transition to HL7 exchange messages for submission of all study data. This initiative is based on the outcomes of the CDISC Content HL7 Message Exploratory Project. The objective of the Exploratory Project was to:

- Harmonize the SDTM into the BRIDG model (see below).
- To identify HL7 exchange message content for submission to a regulatory authority that addresses: a) study summary (clinical trial registry), b) eligibility criteria, c) trial design (including parts I and II: arms, elements visits, planned assessments, and planned intervention(s)), d) statistical analysis plan, e) collected data/study data tabulations and f) derived data/analytics datasets, all of which are currently defined by the CDISC standard.

- CDISC Content to Message Project initiative was approved by the HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee 11/2007.

The FDA is proposing the development of four messages that map to content areas identified above:

- Study Design
- Study Participation
- Subject Data
- Individual Case Safety Reporting (ICSR)

This project also includes the completion of the BRIDG Model.

Message development is underway in HL7. Plan is to go to Dstu (draft standard for trial use) ballot at the end of 3rd Quarter 2008 and to test the messages as part of the Janus phase 3 pilot (see Janus Initiative). Additional milestones:

- 3rd Quarter, 2008
  - HL7 DSTU Ballot
- 2008 – 2009
  - Testing
- 3rd Quarter, 2009
  - HL7 Normative Ballot
- 2009-2012
  - FDA accepts both CDISC-HL7 XML and SAS transport files
- 2013 and Beyond
  - FDA accepts only CDISC-HL7 XML
Development, User Acceptance Testing, and Adoption

FDA first attempts to identify an existing standard that will meet the business need. Standards that adhere to the principles described previously. If a standard is not already being developed, FDA identifies and works with a well recognized Organization (SDO), when appropriate to develop and adopt a standard. Priority is on consensus-based standards recognized by the American National Standards Institute (ANSI) such as the International Organization for Standardization (ISO), Health Level Seven (HL7) and National Council for Prescription Drug Programs (NCPDP).

For new health information exchange standards, the FDA works within HL7. The FDA also encourages other stakeholders, such as the healthcare community, Clinical Data Interchange Standards Consortium (CDISC), International Conference on Harmonization (ICH), other government agencies, and international regulatory bodies to participate in the development process.
Recent FDA announcement (September 2013)

Source: http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm
HL7 versions and models and abbreviations

- V2
- V3
  - Internationalization & localization
  - Key concepts
    - Unified Modeling Language (UML)
    - Reference Information Model (RIM)
    - Domain Message Information Model (D-MIM)
    - Refined Message Information Model (R-MIM)
    - Hierarchical Message Description (HMD)
    - Message type
HL7 model – do you feel dizzy?
Nice toy or?
HL7 RIM stands for

- Reference Information Model
- HL7 – „Metadata model“ for all other models
- HL7 creates / defines and sends „messages“
Green - Entity

- Person A
- Person B
- Organisation
- Device
- Material
- Creature
- Animal

Represents the physical things and beings that are of interest to and take part in health care
Yellow - Role

- Patient
- Investigator
- Nurse
- CEO

Establishes the roles that entities play as they participate in health care acts
Blue - Participation

- Hospitalizer
- Author
- „Destination“
Object

Expresses the context for an act in terms such as who performed it, for whom it was done, where it was done, etc.
Red - Act

- Procedure
- Transport
- Episode
- Financial activities
- Monitoring
- Observation

Represents the actions that are executed and must be documented as health care is managed and provided.
2 help „colors“
A first example

PERSON A → PATIENT → “Object to investigate” → ANAMNESE

PERSON B → PHYSICIAN → INVESTIGATOR
Play with them....
Domain experts describe their communication scenario / message:

Storyboard:

- "A pregnant woman was transferred from her local gynecologist in the hospital for further investigation as possible disturbance of growth are expected."

Roles:
- Person
- Role
- Act
- Organisation
- Participation

Observations:
- pregnant woman
- transferred
- hospital
- local gynecologist
- investigation
- disturbance of growth
- further
Modelling with Tools

- good way to explain the 'things' – even understandable for domain experts
Design the model
D-MIM vs. R-MIM

- D=Domain
- R=Refined
- Special subset/categories of interaction
- And further, special form (CMET-Common Message Element Types) for further re-use (ex. Patient)
Attributes and Cardinality Codes in Act, Entity and Role

- **ClassCode (in Act, Entity, Role)**
  - Represents the exact class or concept intended, whether or not that class is represented as a class in the RIM hierarchy

- **MoodCode (in Act) and DeterminerCode (in Entity)**
  - An attribute that distinguishes whether the class represents an instance or a kind of Act or Entity. If the class is a specialization of Act then moodCode further delineates the instance as an occurrence of intent

- **Code (in Act, Entity, Role)**
  - Provides further classification within a particular classCode value such as a particular type of observation within the observation class
  - Examples: taskCode, typeCode,
Attributes and Cardinality (2)
Codes in Participation, ActRelationship and RoleLink

- `typeCode` (in Participation, ActRelationship and RoleLink)
  - Represents a variety of concepts (different forms of participation / different kinds of relationships between acts)
  - `typeCode` is the attribute for this distinctions for each of these classes.
Daily example for mood code

- Proposal (PRP)
  - „Why you are not clean up your room?“

- Order (ORD)
  - „Clean your room!“

- Intent (INT)
  - „I swear, I will clean my room“

- Event (EVN)
  - „My room is clean!“

- Definition (DEF)
  - „Clean the room means: toys on the right place, bed is ok, always fun 😊

- Event Criterion (EVN.CRT)
  - „You want an ice cream, clean up your room.“
In Clinical:

- DEF - Definition of an X-Ray
- EVN - Visit executed
- APT – Visit planned
- ....
There is much more ....

- ... but would extend „an introduction“

- Things like:
  - Trigger and application role
  - More status codes / transition statuses / state machines
  - „Hundreds“ of class attributes
    - Ex: Financial transaction
      - creditExchangeRateQuantity
    - Person
      - maritalStatus
      - raceCode
  - HL7 Data types
    - DataValue = ANY
    - Boolean = BL ....
HL7 Lab (CDISC) model = „One message“
4.6.1  CTLab Test Result Abnormality Assessment Request (PORT_IN030002UV)

**Description**

Structured Name: Ctlabthree Event Test Result Abnormality Assessment Request

This interaction supports communication of clinical trial laboratory test results to an assessment service for evaluae Response (PORT_IN030003UV) interaction, which would transport the original clinical trial laboratory test result data.

<table>
<thead>
<tr>
<th>Trigger Event</th>
<th>Agreed TransmissionCriterion Attained - CT</th>
<th>PORT_TE010001UV01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmission Wrapper</td>
<td>Send Message Payload</td>
<td>MCCI_MT000100UV01</td>
</tr>
<tr>
<td>Control Act Wrapper</td>
<td>Trigger Event Control Act</td>
<td>MKAL_MT700201UV01</td>
</tr>
<tr>
<td>Message Type</td>
<td>CT Laboratory Observation Periodic Report</td>
<td>PORT_MT300003UV</td>
</tr>
</tbody>
</table>

**Receiver Responsibilities**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Trigger Event</th>
<th>Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiate the abnormality assessment response, in order to transmit the preliminary assessment outcome data.</td>
<td>PORT_TE010001UV01</td>
<td>PORT_IN030002UV</td>
</tr>
</tbody>
</table>

**Sending and Receiving Roles**

<table>
<thead>
<tr>
<th>Sender</th>
<th>ClinicalTrial Observation Order Global Racer</th>
<th>PORT_AB020002UV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiver</td>
<td>Abnormality Assessment Observation Fulfiller</td>
<td>PORT_AB030003UV</td>
</tr>
</tbody>
</table>

4.6.2  CTLaboratory Periodic Report to Sponsor/Agent (PORT_IN030001UV)

**Description**

Structured Name: Ctlabthree Event Periodic Report To Sponsor/agent

This interaction is used by the central laboratory responsible for the laboratory data, to communicate clinical trial

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**Sending and Receiving Roles**

<table>
<thead>
<tr>
<th>Sender</th>
<th>CTLaboratory Observation Event Global Informer</th>
<th>PORT_AB030001UV01</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiver</td>
<td>ClinicalTrial Observation Event Global Tracker</td>
<td>PORT_AB030004UV</td>
</tr>
</tbody>
</table>
Ballot sites: example CDISC lab model

2009

2011

today

Source: www.hl7.org