CDISC & HL7
The Strategy of Cooperation

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Data Flow Using CDISC Standard Linking Clinical Research and Healthcare

- **Electronic Health Record**
  - Patient Info
  - Clinical Trial Data

- **HL7 or ODM XML**
  - Clinical Trial Data

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

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

- **Analysis**
  - Data

- **Metadata**

- **Integrated Reports**
  - SDTM Data, Analysis Data, Metadata

- **Regulatory Submissions**

- **Operational & Analysis Databases**
  - Administrative, Tracking, Lab Acquisition Info

- **ODM XML Define.xml**

Legend:
- Orange = ODM (transport)
- Green = SDTM and Analysis Data (content)
- Purple = Protocol information (content)
- Light Green = Source data (other than SDTM/CRF data)
• 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 (co-chaired by FDA, HL7, CDISC) [CDISC, FDA, NCI bring clinical research domain expertise to HL7 through RCRIM and other groups]
  – Renewed Associate Charter between CDISC and HL7
  – Organizational Memberships and Collaborations
  – Outreach Committee for Clinical Research (OCCR)
  – Commitment to harmonize the HL7 and CDISC standards
Interchange Standards: Long-term Desired Outcomes

• A holistic approach to standards, facilitating data interchange from sites through regulatory submission, utilizing XML
• Standards for data acquisition supporting the population of a cross-trial warehouse within FDA
• HL7-CDISC models harmonized to yield value for both clinical research and healthcare – sharing of information between EMR and clinical trials
• Global adoption of CDISC data standards

CDISC Meeting with FDA Commissioner, April 2003
Initiatives Towards the CDISC Mission

• Single Source Proof-of-Concept
  – Objective: Leverage standards to demonstrate how data can be entered once for multiple uses (healthcare and clinical research) to facilitate clinical research for investigative sites

• eSource Data Interchange Group
  – Objective: Produce a document that will align multiple factors in the current regulatory environment to encourage the use of eSource data collection and industry data standards to facilitate clinical research for investigators, sponsors and other stakeholders.
  – FDA encouraged initiation of eSDI; four liaisons.
An industry initiative that has successfully demonstrated clinical information interoperability between physician clinical systems and pharmaceutical clinical trials systems based on open standards.

Data are collected once and subsequently rendered into multiple formats/systems using CDISC and HL7 standards – streamlines workflow.

Single Source creates one “source record” for medical data collection regardless of purpose (patient care or research).

Single Source opens the door for semantic interoperability
• Leverages healthcare (HL7) and research (CDISC) data interchange standards; tool interoperability
• Facilitates investigator workflow; eliminates transcription steps
• Compliance with 21CFR11 and HIPAA feasible
• Enables online monitoring
Integrating the Healthcare Enterprise (IHE)

Retrieve Form for Data Capture (RFD)
A Profile to link Electronic Health Records (EHR) to Clinical Research Electronic Data Capture (EDC) Systems

Landen Bain
CDISC Liaison to Healthcare
Parallel Universes
Healthcare Data and Clinical Research Data Live in Parallel Universes

- Multiple data sources and data types
- HL7 V2.x a pervasive standard
- Electronic medical records assembled from multiple sources
- Clinicians want to see everything they can get
- Data are organized around the patient

- Carefully controlled data
- Each trial’s data independent
- CDISC the emerging standard
- Data flows from sites to CROs to sponsors to FDA
- Bio-statisticians tightly control what is gathered
- Data are organized around a trial
“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.”

Courtesy Meredith Nahm
More Initiatives Towards the CDISC Mission

• Collaborations with NCI, FDA and HL7
  – ANSI-accredited HL7 V3 RIM implementation of CDISC LAB Model
  – CDISC ODM Mapped to the HL7 RIM
  – eData Collection Instrument (eCRF) message based on ODM in development at NCI
  – Terminology Standards
  – Protocol Representation Standards
  – CRIX; Janus Implementation (FDA’s cross-trial database design)
  – Biomedical Research Integrated Domain Group (BRIDG) Model
The BRIDG Model
(a.k.a. PSM, DSAM, DAM)

- **Vision**: Create a domain analysis model for the clinical research domain to harmonize clinical research standards among each other and to harmonize standards between clinical research and healthcare.

- **A Key Goal**: Define a structured computable protocol representation that supports the entire life-cycle of clinical trials protocol to achieve syntactic and semantic interoperability.

- **Milestones**:
  - January 2004 - *Initiated by CDISC Board*, with HL7 RIM expertise and leadership from Dr. Charlie Mead; followed HL7 Development Framework (HDF).
  - *Contributions of resources from NCI, HL7 RCRIM, FDA, CDISC, NIH and others* collaborated to create the Biomedical Research Integrated Domain Group (BRIDG) model.
  - January 2005 – *Adopted by HL7 RCRIM* as Clinical Research Domain Analysis Model and posted on open source website.
  - February 2005 – *CDISC ODM mapped to HL7 RIM* (collaborative effort among CDISC, NCI, HL7).
caBIG will facilitate sharing of infrastructure, applications, and data

Source: S. Dubman, NCI, Oct 2004
Relevant caBIG Goals

- Establish and/or adopt standards for semantic and syntactic interoperability to facilitate data and tools sharing and access across the caBIG community
- Guide new tools development towards applying these standards
- Providing guidelines for existing custom and vendor solutions to become caBIG compatible
  - caBIG guidelines can be found at: http://cabig.nci.nih.gov

Source: S. Dubman, NCI, Oct 2004

Fall 2004 – NCI caBIG identified “best of breed” models in the CDISC standards and HL7 messages

Christo Andonyadis, NCICB
Smita Hastak, ScenPro, Inc.
Why BRIDG?

• One common, shared data exchange standard to:
  – Reduce costs; eliminate duplication of effort
  – Facilitate data sharing
  – Help to speed delivery of innovative solutions to the patient based on research
  – Improve the efficiency and timeliness of data reporting
  – Enhance patient safety during clinical trials
  – Improve the shared care of patients
Structured Clinical Trial Protocol Development Path

- Protocol Elements
- Definitions For Elements
- Code Lists Terminology
- Modeling Information (e.g. cardinality)

HL7 Development Framework → XML Schema

Human and Machine-Executable Protocol (possible template)

- Element Re-use-Clinical Documents*
- Review or Management Tools*
- Cross-trial Databases Warehouses‡
- Protocol Authoring Tools
- Data Collection Tools (eSource eCRF)

PR Group and Reviewers → HL7 Modeling → HL7 Balloting → Implementation/Tools

* e.g. Planned vs. Actual; Project Status
‡ e.g. Regulatory, Pharma Company, IRB
° e.g. Study Reports, PI Brochures
Structured Protocol

Single Source

eSource

Single Source

ePatient Record → HL7 → Study Database

HL7 CDISC

Study Database
Towards interoperability.....

HL7 Reference Information Model (RIM) V3
Designed for healthcare

Clinical Research Domain Model (BRIDG)

CDISC Models
Vision: End-to-End Seamless Integration; Semantic Interoperability

Open Data Model - XML based, CDISC compliant

Source: Dave Iberson-Hurst
More Initiatives Towards the CDISC Mission

• Support NIH Roadmap Grants for networking research sites

• Participate in WHO Clinical Trial Registry Platform Project – a global registry for all interventional trials

• Participate in national HIT initiatives (ONCHIT, CCHIT, HITSP) – use case committees, HITSP Board
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Becky Kush, PhD
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