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

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Global, open, multi-disciplinary non-profit organization

- Founded in 1997; incorporated in 2000
- > 240 organizational members (academia, biopharma, service and technology providers, etc)
- Liaison A Status with ISO TC 215
- Charter agreement with HL7 since 2001
- Member of Joint Initiative Council for Global Harmonization of Standards
- Active Coordinating Committees
  - Europe, Japan, China
  - Over 60 countries in participant database

Established industry standards to support the electronic acquisition, exchange, submission and archiving of data to streamline biomedical research
HL7 and CDISC Relationship

- **Formal Charter Agreement**
  - *Original agreement in 2001*
  - *Renewed in 2004, 2007 and 2009*

- Initiated Clinical Trials Special Interest Group (SIG) in 2001, which (along with FDA) was ‘elevated’ to the Regulated Clinical Research Information Management Technical Committee in 2002; CDISC Co-chair position retained since 2002

- Commitment to ‘harmonize’ CDISC standards with HL7
CDISC and the HL7 RIM.....circa 2001

HL7 Reference Information Model (RIM)

CDISC Standards
Potential Standards Harmonization: CDISC-HL7
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

*Biomedical Research Integrated Domain Group (BRIDG) Model*
Domain-Friendly, Subdomain-Specific Business Models

Separate EA/XML file for each subdomain

BRIDG Domain Analysis Model (DAM)

Single Enterprise Comprehensive View
Contains subdomain level tags on classes and attributes to support subdomain-specific names for Layer 1 models

Single EA file with comprehensive and subdomain Views

BRIDG OWL-DL File (semantics)

RIM-Based BRIDG Model
Class and attribute level mappings to the Enterprise Comprehensive View will be captured in the Visio tool. The Visio tool generates mapping reports for documentation.

Equivalent to an HL7 DMIM (HL7 Visio)
CDISC Production Version Standards

The BRIDG Model*

Transport Layer

ODM XML - 2001

HL7 V3

SAS XPT → HL7 XML

Glossary - 2002 and Consistent Terminology

CDASH (CRFs) 2008

LAB 2002

Protocol 2008

SDTM/SEND (CRTs) 2004

ADaM Analysis 2004

ODM XML- 2001

SAS XPT → HL7 XML

HL7 V3
HL7 and CDISC Relationship – cont’d

– All CDISC standards will be modeled and harmonized into BRIDG
– BRIDG is the Domain Analysis Model for the HL7 RCRIM Workgroup
– HL7 collaborates on harmonization of Terminology and in the BRIDG Advisory Board
– BRIDG is being balloted through JIC
HL7 and CDISC Relationship (cont’d)

– CDISC LAB standard is an HL7 accredited message
– CDISC participated in ECG waveform standard
– HL7 Clinical Genomics SIG co-initiated by CDISC and HL7
– Participated in EHR-Clinical Research Functional Profile Development
– CDISC Content to HL7 Messages (sponsored by FDA) – in progress
– Clinical Trial Registry Message – developed in ‘record time’ due to availability of BRIDG
– Interact with other HL7 Workgroups (e.g. Cardiology, Templates, Patient Safety, CIC)
SHARE = Shared Health & Research Electronic Repository
Streamlining Development, Harmonization and Sharing of Reference Data Elements

Reference Repository

New content (disparate definitions)

IHTSDO - SNOMED CT
NCI Metathesaurus (BRIDG, CDISC CT, CDASH)
HL7 Terminology
UCUM, ICD – 9 and 10
MedDRA (subset)

ISO 21090 datatypes

Hosted Platform (LexGrid Wiki)

“Target” Reference Standard

Pilot done with Mayo Clinic, MD Anderson, Genzyme, GSK, Lilly
Currently in Development; Technology Partner NCI

National Cancer Institute

Supported and Monitored Content (Draft Standard)
CDISC and HL7 Relationship (cont’d)

- HL7 – CDISC Tutorial developed by C. Jaffe and R. Kush – presented at CDISC Interchanges in Europe and US by a number of different instructors

- Working with HL7 on joint educational opportunities (e.g. tutorial through CDISC and events in and Japan (exploring China, India)

- HITSP Foundations Committee; EHR-CR IS uses CCD

- Outreach Committee for Clinical Research (OCCR) – HL7 Board Committee

- R. Kush- new HL7 Board Board Member
CDISC operates to advance the continued improvement of public health by enabling efficiencies in medical research and related areas of healthcare.

Strength through collaboration.

As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.