CDISC Global Update

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Don’t Forget to Visit the Demonstrations and Exhibits!
Concurrent Progressions

Global Expansion of CDISC

US → Europe (E3C) → Japan (J3C) → China CC → Korea CC → Australia, India, (UG), Singapore, Brazil

Standards

Idea/Progress → Non-profit → CDISC eSub Stds → BRIDG → eSDI → CDASH → RFD → EHR/CR IS

Collaborations

CDISC → HL7 Agreement → ISO Liaison A → JIC

JIC = Joint Initiative Council (ISO/HL7/CEN/CDISC/IHTSDO)
CDISC – Global Expansion 2009

US → Europe (E3C) → Japan (J3C) → China CC → Korea CC
Australia, India, (UG), Singapore, Brazil

- CDISC Coordinating Committees – Europe (E3C), Japan (J3C), China (C3C)
  - Proposed in India and Korea

- Courses in Europe, China, Japan, Singapore, Australia
  - Virtual learning through CDISC and Harvard Medical School

- Global eHealth Initiative and WHO meetings
  on eHealth Architecture and Global Open Access to Standards

- CDISC Webinar in October: >200 attendees from 21 countries
- CDISC participant database has over 8,000 names
  - Of the 4,000 with countries specified, there are over 60 different ones

- Joint Initiative Council for Global Harmonization of Standards
CDISC Standards - 2009

Idea/Progress → Non-profit → CDISC eSub Stds → BRIDG → eSDI → CDASH → RFD → EHR/CR IS
Clinical Research Standards (Content)
(Protocol-driven Research; Protocol → Reporting)

Integrated Standards (BRIDG R 3) and Controlled Terminology

- Protocol
  - Study Design
  - Eligibility
  - Registration
  - Schedule
- Case Report Forms (CRF) (CDASH)
  - Study Data
- Lab Data (LAB)
- Tabulated CRF data (SDTM)
  - Study Data
  - Lab Data
  - Study Design
  - Schedule
- Analysis Datasets (ADaM)

PR V 1.0
CDASH & ODM
Genomics @ HL7
SDTM 3.1.2
ADaM IG soon

*Transport: CDISC and/or HL7*
A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions (including value sets) that can be used in applications and studies to improve biomedical research and its link with healthcare.

Key purposes: Develop efficacy standards faster and make the CDISC standards more accessible.
“The good and bad about STANDARDS...
There are so many to choose from”

- ‘We need more standards’ – for efficacy!
- ‘Proprietary standards’ – an oxymoron?
- Standards should be global and open, developed and maintained by a Standards Developing Organization (SDO) such as CDISC (working with other SDOs as appropriate).

Focus for 2010: Develop more standards, faster, focusing on content.
The CDISC Mission

To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

Strength through collaboration
Patient Value: Quality of Healthcare, Safety

Research informs healthcare more effectively
Build quality into process at beginning

Site Research Archive

EHR

HITSP IS #158

HL7 CDA CCD

Identified Data

Std. Common Research Data

Study Sponsor
(e.g. ARO, CRO, Vendor, Principal Investigator)

Research Site
(Healthcare Location, Investigator, Site Personnel)

CDISC CDASH

IHE RFD

Research Results, eSubmission Standard Formats

Public Registries, IRB, DSMBs

Reviewers
(e.g. Research Partner, Sponsor, Registry, Regulator, IRB, DSMB)

Scientific Publisher

Regulatory Authority

Department of Health & Human Services
Office of the National Coordinator for Health Information Technology

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ANSI
American National Standards Institute
“Gold Star Ideas”*

a) We’ve learned from other industries that starting with simple standards works well.

b) Keep the standards as minimal as possible to support the business goal.

c) Start immediately rather than waiting for the perfect standard.

• Dr. John Halamka based upon Implementation Workgroup Testimony to the HIT Standards Committee
“Stuff That Works”*

* Song by Guy Clark

- To reap the greatest benefits from CDISC Standards, implement them ‘up front’
  - Build in Quality
  - Mapping at the ‘back end’ is inefficient, costly and fraught with issues

- Ultimate goal is to enter once and use for multiple purposes

Focus for 2010: **Use CDISC from the start:**
CDASH, Protocol Rep Std, HITSP/IS #158
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.
JIC = Joint Initiative Council (ISO/HL7/CEN/CDISC/IHTSDO)

- BRIDG as a JIC Project
- ISO Liaison A – BRIDG R3 as a New Work Item
  - Required support from at least 5 countries
- HL7
  - EHR-CR Functional Profile;
  - Clinical Trial Registry message (based on BRIDG)
  - Clinical Genomics (LAB and SDTM)
  - CDISC CEO – Elected to HL7 Board 2010-2012
- IHTSDO (SNOMED) - MOU
Joint Initiative Council
CDISC Collaborations - 2009

CDISC \rightarrow New\ Content\ Standards;\ Efficacy

- AdvaMed – Device standards

- C-PATH Institute – Coalition Against Major Diseases
  - Parkinson’s Disease
  - Alzheimer’s Disease

- PKD Foundation and Tufts – Polycystic Kidney Disease

- FDA Disease Projects (Continuation of work with DCRI/NIH)
  - TB
  - Cardiovascular

- NCI - Oncology
CDISC – Strength Through Collaboration

- CDISC represents Clinical/Biomedical Research through its collaborations with many different organizations
- CDISC wants to keep its standards open and freely available, which requires memberships and other means of support for CDISC

Focus for 2010: Join CDISC, influence the standards, and spread the word to others. Be involved; communicate.
Browse through the new CDISC website
Twitter
http://twitter.com/CDISC

Blog
http://cdiscblog.wordpress.com/

Newsletter
Sign up on the CDISC website:
www.cdisc.org

Introducing CDISC…
2010 – 3 Messages

• Develop more standards, faster, focusing on **content**
• Use CDISC from the **Start** for the **Most Value**; implement ‘stuff that works’ now
• Join CDISC, influence the standards, and spread the word to others. **Be involved; communicate.**
Knowing is not enough; we must apply.  
Willing is not enough; we must do.  

- Goethe-

To the gracious supporters who ‘apply’ and ‘do’....  
THANK YOU!