CDISC Standards: Current and Future

CDISC Japan Interchange
Tokyo, Japan
20 July 2010

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Clinical Research Standards (Content)  
(Protocol-driven Research; Protocol → Reporting)
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Transport: CDISCand/or HL7
# CDISC Protocol Representation Model

## V 1.0 Now Available!

### Protocol Section
- Info for Trial Registration
- Eligibility Criteria
- Study Design: Arms, Epochs
- Study Design: Planned Events
- Statistical Analysis Plan
- Appendices, etc.

### CRF Development
- CDASH CRFs

### Data Collection
- Data Collection
- Data Tabulation

### Data Analysis
- Data Analysis
- ADaM Datasets

### Report or eSubmission
- Study Summary
- Eligibility Criteria
- Study Design: Arms, Epochs
- Study Design: Planned Events
- SDTM Data

### Information Re-Use
- Improved Quality and Efficiency

### SDTM

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**CDISC Protocol Representation Model V 1.0**

**CDASH CRFs**

**Data Collection**

**Data Analysis**

**SDTM Data**

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**CDISC**

**PR Version 1.0**

**Information Re-Use**

**Improved Quality and Efficiency**

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**Study Design:**
- Arms, Epochs

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**SDTM**

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**Appendices, etc.**
Domain-Friendly, Subdomain-Specific Business Models

Separate EA/XMI 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)
Protocol Representation Model
Early Implementations

- Population of Clinical Trial Registries
  (EudraCT, clinicaltrials.gov, WHO International Clinical Trials Registry)
- Identification of patients for research studies
  (eligibility criteria)
- Study Design extension of CDISC ODM
- Study Design for SDTM
- Workflow automation for EHRs (visit scheduling)
- Protocol tracking; clinical trial management
CDISC CDASH
Published 3 October 2008

18 Domains (including common timing and variable tables)
- Adverse Events (AE)
- Concomitant Medication (CM)
- Demographics (DM)
- Subject Characteristics (SC)
- Inclusion/Exclusion Criteria (IE)
- Medical History (MH)
- Substance Use (SU)
- Physical Exam (PE)
- Vital Signs (VS), Disposition (DS)
- Drug Accountability (DA)
- Exposure (EX)
- Protocol Deviations (DV)
- Comments (CO)
- Lab (LB), ECG (EG)

Implementation Guide in progress: due Q2 2010
ODM CRF examples: in review now
CDISC Operational Data Model (ODM)

- Transport Standard
  - Carries case report form data
  - Can automate generation of eCRFs
  - Carries complete audit trail information (21CFR11)
  - Allows for remote monitoring or auditing
  - Supports electronic signatures
  - Archives electronic data without need to archive original system at sites; standard archive format
  - Enables exchange of standard data (e.g. CDASH) between different systems/tools, thus paving the path for SDTM-based eSubmissions
CDASH CRFs

ODM Sample: Demographics

Terminology and Value Sets match SDTM
ODM Trial Design Model Extension

- Trial Summary and Parameters
- Inclusion/Exclusion Criteria
- Structural Elements: Arms, Epochs, Cells, Segments
- Activities
  - Workflows between Activities
  - Timings between Activities
Data Flow Using CDISC

- Protocol Representation
  - Trial Design (PRM, SDTM)
  - Analysis Plan

- Clinical Trial Protocol

- ODM XML

- Clinical (CDASH) Trial Data (defined by SDTM)

- Patient Info

- (e)Source Document

- Administrative, Tracking, Lab Acquisition Info

- CRF, Analysis Data

- Operational & Analysis Databases

- ODM XML Define.xml

- Integrated Reports
  - SDTM Data, Analysis Data, Metadata

- Reporting and/or Regulatory Submissions

- = ODM (transport)

- = CDASH, SDTM and Analysis Data (content)

- = Protocol information (content)

- = Source data (other than SDTM/CRF data)
SDTM & CDASH Domains

Interventions
- Con Meds
- Exposure
- Substance Use

Events
- Adverse Events
- Disposition
- Medical History
- Deviations
- Clinical Events

Findings
- ECG
- Incl/Excl Exceptions
- Labs
- Physical Exam
- Questionnaire
- Subject Characteristics
- Vital Signs
- Drug Accountability
- Microbiology Spec.
- PK Concentrations
- Microbiology Suscept.
- PK Parameters
- Findings About

Special Purpose
- Demographics
- Comments
- Subject Elements
- Subject Visits

Relationships
- SUPPQUAL
- RELREC

Trial Design
- Trial Elements
- Trial Arms
- Trial Visits
- Trial Incl/Excl
- Trial Summary
CDISC Standards End-to-End…

- CDISC Standards support the ‘safety domains’
- Issue with where to put ‘efficacy’ data
- CDISC members and FDA have requested these to augment existing CDISC standards
- Need efficacy domains and controlled terminology (codelists)
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.
2009
BRIDG R3.0
PR Model

2010
SDTM CDASH ADaM LAB

2011
THERAPEUTIC AREA (Efficacy) STANDARDS

2012
SHARE

Shared Health and Research Electronic Library (SHARE)
Data Flow Using CDISC Standard Linking Clinical Research and Healthcare

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

- **Protocol Representation**
  - Trial Design (PRM, SDTM) Analysis Plan

- **Clinical Trial Protocol**
  - (e)Source Document

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

- **ODM XML**
  - Define.xml

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

Legend:
- Orange: ODM (transport)
- Green: SDTM and Analysis Data (content)
- Purple: Protocol information (content)
- Light Green: Source data (other than SDTM/CRF data)
“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
  - CDASH, eSource, EHRs

*Focus for 2010: Use CDISC from the start:
CDASH, Protocol Representation Model, eSource/EHRs*
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 2004~ 2006)
  - Version 1.0 document posted at [www.cdisc.org](http://www.cdisc.org)
  - Presentations and Publications
  - Includes 12 Requirements for eSource
  - Also includes Scenarios, Checklists for PIs, Sponsors…

**NOTE:** European Medicines Agency – Document for GCP Auditors cites these 12 requirements
Standards: To Streamline Workflow from Protocol through Reporting and to Ensure Useful Data, with Integrity and Meaning for Patients and anyone in Clinical Research.
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.