CDISC Controlled Terminology: Let’s Speak the Same Language

CDISC User Network
November 8, 2011

Chris Tolk
Director, Terminology
Agenda

• Overview / Objectives
• Key Drivers
• Terminology Development
• SDTMIG Terminology v3.1.2
• Harmonization Activities
• Terminology Projects 2011
• How to Access Terminology
Terminology Objectives

- Primary Objectives
  - Define and support the terminology needs of CDISC standards starting with SDTM/IG
  - Focus on “standard” terminology codelist development and publication
Guiding Principles (1)

Adopt...Adapt...Develop Philosophy

• Evaluate and/or utilize existing terminology first

• Expand existing vocabularies where incomplete, working with vocabulary developer / owner

• Harmonize across CDISC Models and with pre-existing vocabulary initiatives
Guiding Principles (2)

• Address international needs for global projects and organizations

• Ensure a sustainable “open source” environment and infrastructure for production terminology supporting terminology evolution
NCI EVS Partnership

• Dedicated terminology experts and resources

• CDISC controlled terminology development, harmonization, publication and maintenance

• Established terminology infrastructure and standard operating procedures

• CDISC terms are coded and tagged in *NCI Thesaurus*
CDISC-FDA-NCI EVS Terminology Harmonization

CDISC

SDTMIG v3.1.1
CDASH, SEND

SDTMIG v3.1.1
SDTMIG v3.1.1

SPL
RPS, ICSR

NCI Thesaurus

CDISC

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The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposed rule would require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive. The proposal also would require the use of standardized data structure, terminology, and code sets contained in current FDA guidance (the Study Data Tabulation Model (SDTM) developed by the Clinical Data Interchange Standards Consortium) to allow for more efficient and comprehensive data review.
For terminology standards, the FDA partners with the National Cancer Institute Enterprise Vocabulary Services (EVS). The NCI EVS hosts the FDA terminologies and makes them freely available to the public.

NCI EVS supports FDA vocabulary initiatives

- Structured Product Label (SPL)
- Regulated Product Submission (RPS)
- Individual Case Safety Report (ICSR)
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Terminology Gap Analysis is performed on a standard to identify terminology needs.

- Government Agencies
- Pharma / CROs
- Academia
- International Representative

Identify Team Leader

Form Team
Controlled Terminology Development

Slide courtesy of Rhonda Facile
ADaM Terminology Numbers

Q1 2010

Q1 2011

SEND Terminology Numbers

Q1 2011

Slide Courtesy of Erin Muhlbradt (NCI-EVS)
SDTM Terminology

• ~10,000 production terms across 50 codelists
  – These terms were developed to support SDTMIG v3.1.2, ADaM v2.0 CDASH v1.0 and SEND

• Terminology Request Mechanism
  – Developed and Maintained by NCI EVS
  – Accessed through the CDISC Website with a direct link to NCI EVS

http://www.cancer.gov/cancertopics/terminologyresources/CDISC
2009-2011 Terminology Requests (Total)
Codelist Use

• Code lists that are used for one domain
  – Action Taken with study drug (AE domain)
  – ECG Result (EG domain)
  – Laboratory Test Code and Name (LB domain)

• Code lists that are used across multiple domains
  – Units of Measure (CM, LB, EG)
  – Anatomical Location (AE, PE, VS)
  – Position (EG, VS)
  – Route (CM, EX)
  – No/Yes
POSITION Codelist
(SDMIG /CDASH & Harmonized with HL7)
VSPOS, EGPOS

Standard Terminology Codelist

CDISC Controlled Terminology

- Sitting
- Prone
- Standing
- Supine
- Fowlers
- Semi-Fowlers
- Trendelenburg
- Reverse Trendelenburg
- Right Lateral Decubitus
- Left Lateral Decubitus

Codelist = Value Set = Permissible Values
CDISC Controlled Terminology User guide:

Prepared by the
CDISC Terminology Governance Implementation Sub-Team

Notes to readers
This Terminology User guide is to be used in conjunction with the following CDISC models: PRG (Protocol), SDTM (Study Data Tabulation Model), CDASH (Clinical Data Acquisition Standards Harmonization), ADaM (Analysis Data Model), SEND (Standard for the Exchange of Non-Clinical Data) and ODM (Operational Data Model).
CDISC Controlled Terminology Governance process

Public domain NCI request tool interface

- Change/new request identified
- Multiple code lists
- Request process for multiple code list requests

- NCI Terminology governance team domain
  - Categorize request (New term, change, new code list etc)
  - Verification Grading (I, II, III)
  - Grade I
  - Ongoing New Request process

- Public domain (Posted to CDISC website) - 30 day review window
  - Request accepted
  - Unapproved
  - Approved

- NCI Terminology governance team domain
  - Public Review & Comment
  - TG1 Sub-team

- NCI Terminology governance team domain
  - Version terminology

- Public domain (Posted to CDISC website)
  - Release

Advertise forthcoming change - Newsletter, SOMEWHERE on the CDISC website, send email to TGRM/Leadership/Known interested parties. Create a communication plan (or network) - automated email blast.
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### Code Lists in SDTMIG v3.1.2

**“Controlled Terms or Formats” Column**

<table>
<thead>
<tr>
<th>Variable Name</th>
<th>Variable Label</th>
<th>Controlled Terms or Format</th>
<th>Synonym Qualifier</th>
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<td>Subcategory for Lab Test</td>
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Harmonization - CDISC Models

Data Sources
- Site CRFs
- Laboratories
- Contract Research Organizations
- Development Partners
  - CDASH
  - LAB

Operational
- Database
  - Study Data
  - Audit Trail
  - Metadata
  - ODM

Submission Data
- Datasets
  - CRT/Domain Datasets
  - Analysis Datasets
  - Metadata
  - SDTM, ADaM
  - SEND

Standard Terminology

ODM = Operational Data Model
LAB = Laboratory Data Model
SDM = Submission Data Model
ADaM = Analysis Data Models
SEND = Standard for the Exchange of Non-clinical Data
CDASH = Clinical Data Acquisition Standards Harmonization
Harmonization Activities - Internal

• Support and harmonize terminology with other maturing CDISC standards (e.g., SDTM, SEND, ADaM, CDASH)

• Support and harmonize terminology with new domain development (e.g., Devices, Oncology, Trial Summary Parameters)
Harmonization Activities…other (1)

- FDA Projects (e.g., ICSR, RPS)
- US HITSP Foundation Harmonization Subcommittee: (e.g., Marital Status, Gender, Body Site, Route of Administration)
- ISO Technical Committee 215 WG-6 Identification of Medicinal Products (e.g., Units of Measure, Dose Forms, Routes of Administration)
- Joint Initiative Council (ISO, CDISC, CEN, HL7 and IHTSDO)
Harmonization Activities…other (2)

- C-Path - CAMD
  - Using the SDTM to map existing data for Alzheimer’s

- RTRN
  - Working under a CRNFA to map data from 3 large clinical cardiovascular studies
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Terminology Plans 2011
Therapeutic Area Standards

• FDA Disease Projects
  – TB
  – Cardiovascular

• PKD Foundation
  – Development of efficacy data elements and terminology for Polycystic Kidney Disease

• C-Path
  – Parkinson’s Disease
  – Alzheimer’s Disease

• Pain & Analgesics initiative with Univ. of Rochester

• New FDA Projects
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How to Access CDISC Terminology

• Go to CDISC Website
• Standards & Innovations
• Terminology
CDISC Terminology

The Clinical Data Interchange Standards Consortium (CDISC) is an international, non-profit organization that develops and supports global data standards for medical research. CDISC is working actively with EVS to develop and support controlled terminology in several areas, notably CDISC’s Study Data Tabulation Model (SDTM). SDTM is an international standard for clinical research data, and is approved by the FDA as a standard electronic submission format.

CDISC SDTM and other terminology goes through an extensive process of definition, development, and review before it is declared ready for release. Terminology that has completed this process is tagged as "Production," and now includes some 50 SDTM codelists with about 2,200 terms covering demographics, interventions, findings, events, trial design, units, frequency, and ECG terminology. This terminology is maintained and distributed as part of NCI Thesaurus, and is available for direct download from the CDISC SDTM directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml and pdf formats.

CDISC also leads the Clinical Data Acquisition Standards Harmonization (CDASH) project, which develops clinical research study content standards in collaboration with sixteen partner organizations including NCI. NCI EVS maintains and distributes CDASH controlled terminology as part of NCI Thesaurus. More information is available at CDISC's CDASH Web page. CDASH terminology is a subset of SDTM terminology and is available for direct download from the CDISC CDASH directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml and pdf formats.

CDISC also leads the Analysis Data Model (ADaM) project, which supports efficient generation, replication, review and submission of analysis results from clinical trial data. NCI EVS maintains and distributes ADaM controlled terminology as part of NCI Thesaurus. ADaM terminology is available for direct download from the CDISC ADaM directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml and pdf formats.

CDISC also leads the Standard for the Exchange of Nonclinical Data (SEND) project, which guides the organization, structure and format of standard nonclinical tabulation data sets for interchange between organizations such as sponsors and CROs and for submission to a regulatory authority such as the FDA. NCI EVS maintains and distributes SEND controlled terminology as part of NCI Thesaurus. SEND terminology is available for direct download from the CDISC SEND directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml and pdf formats.

The CDISC New Term Request web page handles suggestions for both new terminology and changes to existing terminology. The CDISC Term Request Tracking Excel spreadsheet helps members of the CDISC community review and comment on all submitted requests.
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Term Suggestion

Contact Information:
- Business Email: *
- Name:
- Business Phone Number:
- Organization:

Privacy Notice: For term submission purposes we request business contact information only, not personal information.

Your business email, and any other business contact information that you enter, will be stored in a publicly-accessible web site in support of CDISC term submission tracking. CDISC personnel may contact you.

Term Information:
- Vocabulary: CDISC Terminology
- Request Type: None
- CDISC Code List: None

Enter Term or Codelist Request Information: *

Note to user: CDASH and SDTM Terminology are the same and are contained within the SDTM codelists in the drop down list.

Additional Information:
- Reason for suggestion and any other additional information:
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<td>CDISC</td>
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Strength *through collaboration.*

If you are interested in contributing to the CDISC Terminology Initiative, please contact me…

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