National Institutes of Health
Data Standards in Clinical Trials
19 October 2012

“Global Clinical Research Standards
from Protocol through Analysis/Reporting”

Rebecca Kush, PhD
President and CEO, CDISC
The “S” Word!

What is a standard?

• A reference to quality.
• An average cut of beef.
• In the world of data and technology, there are ‘so many to choose from’! And, there are many types.
  ▪ A standard is NOT proprietary.
  ▪ A standard is NOT a “one-off”.
  ▪ True standards are broadly adopted; they do NOT inhibit creativity, rather encourage innovation.
Who Needs Standards?

USB 2.0 Specification

Red Book, IEC 908

ATM Machine - VISA
The Research Landscape

- CAMD, TransCelerate, GSK, DataSphere and CEO Roundtable on Cancer, Medtronaics, One Mind for Research

- “Data Sharing” is a ‘hot topic’. (IOM 4-5 October)
  - Data liquidity, transparency, data liberation, disclosure
  - Privacy, security, protection, portable consent
  - Meta-analysis, pooling of data, risk of being ‘blind-sided’, repeatability of published results, ‘open science’, CER, summary data vs. raw data, clean vs. ‘scruffy’ data, data mining
  - Incentives/dis-incentives, especially for researchers
  - Variability in interpretation of ‘Data Sharing’ (e.g. requirements on NIH projects)
  - Research data is a ‘public good’

- European Medicines Agency has been informed by EU Committee: “Clinical trial data is not commercial confidential information.”

"Data are like children; you like your own best and you don't like strangers to play with them.“  Hans Joerg Eichler, EMA
We should make sure we are using the information wisely, that it is accurate and we can find it…. We owe it to the patients who agree to participate in research studies and share their data.

“One has to simply examine the phenomenon taking place in the various ‘PatientsLikeMe’ web-based communities to gain a glimpse of what a world of shared patient data looks like. Daily entries by tens of thousands of individuals indicate the drive some people possess for sharing data with others.”

Terry, S.F., Terry, P.F. “Power to the People: Participant Ownership of Clinical Trial Data” Science Translational Medicine, Feb 2011
The Research Landscape (II)

• How to we make the research results available in a timely manner?

• How to we make the data useful? How should we best share?

• How do we ensure accuracy, integrity and repeatability of scientific results?
Road to Clinical Quality

- Build quality into the system – up front
- Train and educate research teams/sites/reviewers
- Collect only the data that are needed
- Clearly define the data and specify requirements
- Standardize! (data structures, processes)
- Reduce the number of times data are “handled”
- Plan data quality throughout lifecycle (post market)

Anticipated ‘by-products’ of these steps will be to improve quality, increase efficiency and lower costs

Source: Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision making: Workshop Report, 2000
Common Data Elements (CDEs)

- A CDE is a CRF Question and the associated responses/valid values
- Common Data Element C19984 (NCI Thesaurus)
  Data terms or concepts that have been determined to be identical between projects or contexts.
- Common data element. A structured item characterized by a stem and response options together with a history of usage that can be standardized for research purposes across studies conducted by and for NIH. NOTE: The mark up or tagging facilitates document indexing, search and retrieval, and provides standard conventions for insertion of codes (CDISC Glossary)
- Common data elements (CDEs) are annotations that are collected in a uniform manner across multiple institutions, derived from their broader set of DEs, that allow sharing of data in a standardized format and are defined in detail using a metadata dictionary. (One Mind for Research Position Paper)  

DE = Locally derived, institution- or organization-specific standardized metadata structure.
Figure 1. Organizations Actively Involved in the Development of CDEs and Data Curation

One Mind for Research: Position Paper V1.0: Surveying and Navigating the CDE Landscape, October 2012

(accessible via the CDISC eJournal www.cdisc.org/Resources)
What can be done now?

Agree on a single definition for CDE?

There is not a ‘right’ or a ‘wrong’ standard – it is a matter of consensus building and adoption. Can we agree on a core set of “Standard”/REFERENCE Data Elements and build upon that together?

There is ONE Standards Developing Organization (SDO) focusing on clinical research standards. Can the CDISC work form a foundation?

*Strength through Collaboration* is an essential component.
Overview

- Global, open, multi-disciplinary, vendor-neutral, non-profit standards developing organization (SDO)

- Liaison A Status with ISO TC 215
- Charter agreement with HL7 (2001-2012)
- Leader of Joint Initiative Council (JIC) for Global Harmonization of Standards
- ANSI-led ISO TAG member and contributor

- 501(c)(3) charitable non-profit organization
- Founded 1997 as volunteer group; incorporated 2000
- Multidisciplinary, global member support (~300 member organizations: academia, biopharma, service and technology providers and others)
- Active Coordinating Committees
  - Europe, Japan, China, Korea
- 20 User Networks around world
- >> 90 countries in participant database and/or downloading CDISC standards
The CDISC Vision: informing patient care and safety through higher quality medical research.

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

CDISC Standards are freely available via the website www.cdisc.org
CDISC is known for bringing together the expertise of thousands of individuals from around the world toward productive collaboration to develop clinical research standards.

CDISC – Key Partnerships/Collaborations (Examples)

- Translational Research Informatics Institute (TRI) Kobe, Japan
  - Use of CDISC in research projects by academia funded by TRI.

- IMI = European Union and EFPIA; > 250 IMI consortia academics/SMEs are CDISC Members. Default is for IMI projects to use CDISC if available, If not, partner in developing new standard.

- Controlled Terminology
  - CAMD (AD, PD)
  - CPTTR (TB)
  - …TA Standards

- CV, TB, HL7 CIC Workgroup

- Innovative Medicines Initiative (IMI)

- National Cancer Institute

- Enterprise Vocabulary Services (EVS)

- CRITICAL PATH INSTITUTE
  - collaborate · innovate · accelerate

- FAST Coalition for Accelerating Standards and Therapies

- Duke Medicine

- DCRI

- CTRI
Global Standards for Clinical Research (Protocol-driven Research; Protocol → Reporting)

Harmonized through BRIDG Model**
Controlled Terminology (NCI-EVS)
Semantics/Glossary

Protocol
- Study Design
- Eligibility
- Registration
- Schedule
(PR Model)

Case Report Forms (CRF) (CDASH)
- Study Data

Lab Data
(LAB and PGx)

Tabulated CRF data (SDTM)
- Study Data
- Lab Data
- Study Design

Analysis Datasets
(ADaM)

FDA Critical Path Initiative

FDA eSubmissions Analysis and Reporting

CDASH

** CDISC and HL7 Standard → ISO/CEN

*Transport: CDISC ODM, SASXPT
Clinical or Medical Research (Definition)

Definition used for work with HIT Standards Panel, 2009

Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects.

- epidemiologic and behavioral studies
- outcomes research
- health services research
- research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies
- does not include in vitro studies using human tissues not linked to a living individual.

For the purpose of this course, studies with animals are also addressed.

Clinical Research is GLOBAL
Glossary

CDISC Clinical Research Glossary

Version 8.0

Glossary Terms


abbreviation. A set of letters that are drawn from a word or a sequence of words and that are used for brevity in place of the full word or phrase. NOTE: An abbreviation is NOT pronounced as a word, but each letter is read in sequence (e.g., NIH). Compare to acronym.

absorption. The process by which medications reach the bloodstream when administered orally or intravenously, for example, through nasal membranes. See also ADME (pharmacokinetics).

acronym. 1. A word formed from the beginning letters (e.g., ANSI) or a combination of syllables and letters (e.g., MedDRA) of a name or phrase. 2. The short set of letters that identify a clinical study protocol. NOTE: An acronym is usually pronounced as a word, not by speaking each letter individually. Compare to abbreviation.

action letter. An official communication from FDA to an NDA sponsor announcing an agency decision. See also approval letter, approvable letter, not-approvable letter.

activation. Enabling an eClinical trial system to capture data; usually used for EDC systems.

admission criteria. Basis for selecting target population for a clinical trial. Subjects must be screened to ensure that their characteristics match a list of admission criteria and that none of their characteristics match any single one of the exclusion criteria set up for the study. See also inclusion criteria, exclusion criteria.

CDISC Glossary Project

Arthur Gertel, Project Leader
Glossary Project Core Team:
Patricia Beers Block, Liaison from the Office of Science & Health, FDA, Helene M. Gawrylewski, Johnson and Johnson PRD; Arthur Gertel, Beardsworth Consulting; Stephen A. Raymond, PHT Corporation; Theresa Quinn, Lockheed Martin; Erin Mahlbradt, PhD, Lockheed Martin.

Orientation: The following Glossary Project of CDISC, which seeks to harmonize definitions (including acronyms, abbreviations, and initials) used in the various standards initiatives undertaken by CDISC in clinical research. The purpose of the CDISC Glossary is also to serve the community of clinical researchers by selecting and defining terms pertaining to clinical research, particularly eClinical investigations, sponsored by the pharmaceutical industry or a federal agency. The Glossary is publicly accessible on the CDISC Web site (CDISC.org), where comments on the Glossary are welcomed.

Note that this CDISC Glossary is NOT comprehensive for all words bearing on human health, medicine, or laboratory methods. The Glossary includes references and links to other glossaries such as regulatory dictionaries and to health-related controlled terminologies that are known to be useful in conducting clinical research, including the CDISC Terminology Project.

Glossary terms are organized alphabetically by first word according to the opinion of the Glossary Project Team concerning most common usage in clinical research. Thus “source document verification” would appear under “source,” not “verification.” The Glossary follows the practice of preceding certain terms with the letter “e” to denote that they pertain to electronic or Web implementation. Each term in the Glossary has the following conventions concerning content and order of presentation:

Term. The word or phrase being defined is followed by a period. Only proper nouns are capitalized.

Definition. Multiple meanings of the same term are numbered 1., 2., 3., etc.

Note: Comments including usage or domain knowledge related to a term may follow the definition.

Source(s). The sources for definitions are cited (see “Reference Citations”) in square brackets. Where the definition has been altered by CDISC, the citation states “modified from.” Where the definition has been drawn by CDISC from text that is not itself a definition, the citation states “after” or “from.” Where no source is listed, the definition is from CDISC.

Related terms. Some definitions offer synonyms (See), comments, or related terms (See also or Compare to) to sharpen or expand upon the definition.
Acronyms, Abbreviations, and Initials

Version 8.0

AAAS American Association for the Advancement of Science

ACRPI Changed its name to ICR—Institute of Clinical Research (UK)

AAABB American Association of Blood Banks

ACT Applied Clinical Trials magazine

AAADA Abbreviated Antibiotic Drug Application (FDA) (used primarily for generics)

ACTG AIDS Clinical Trials Group (NIH/D) (2011)

AAMC Association of American Medical Colleges

ACTU AIDS Clinical Trials Unit (NIH)

AAPS American Association of Pharmaceutical Scientists

ADaM Analysis Data Model (a CDISC standard)

ABPI Association of the British Pharmaceutical Industry

ADE Adverse Drug Event; Adverse Drug Effect

ACCP American College of Clinical Pharmacology

ADME absorption, distribution, metabolism, and excretion (used to describe pharmacokinetic processes)

ACDM Association for Clinical Data Management (UK)

ADR adverse drug reaction

ACE angiotensin-converting enzyme

AE adverse event

ACIL A national trade association representing independent, commercial scientific, and engineering firms

AGISS ADRD Early Drug Response (early drug detection) systems

ACPU Association of Clinical Pharmacology Units

AETW Early Experience (FDA)

ACRA Associate Commissioner for Regulatory Affairs (FDA)

AEUG Unany/desirable event

ACRP Association of Clinical Research Professionals (formerly Associates in Clinical Pharmacology, ACP)

AES/ACSP Association of Ehrlich-Schwarz/Adams (ACSP)

AEUG Unany/desirable event

ACUT Association of Clinical Trials (US)

AFMR American Federation for Medical Research, formerly the American Federation for Clinical Research (AFCR)

ANDA Abbreviated New Drug Application (for a generic drug)

ANOVA analysis of variance (statistics)

ANSI American National Standards Institute

AOAC Association of Official Analytical Chemists

APB Association Pharmaceutique Belge (Belgium)

APHA American Pharmacists Association

API active pharmaceutical ingredient

APPP Academy of Pharmaceutical Physicians and Investigators

ARCS Association of Regulatory & Clinical Scientists (Australia)

ARO academic research organization

ASAP administrative systems automation project (FDA)

ASCII American Standard Code for Information Interchange (computer files)
Protocol Representation – Hierarchy

Sample: Sections, Sub-sections, Elements

Document Type
Clinical Trial Protocol

General Information
Protocol Identification

Prototype Title
Protocol Short Title
Protocol Identification Number

Protocol Contact Information
Sponsor
Sponsor Status
<table>
<thead>
<tr>
<th>Protocol Section</th>
<th>CRF Development</th>
<th>Data Collection</th>
<th>Data Analysis</th>
<th>Report or eSubmission</th>
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<tr>
<td>Statistical Analysis Plan</td>
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<td>Appendices, etc.</td>
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<td>Appendices, etc.</td>
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Information Re-Use
Improved Quality and Efficiency

PR Version 1.0

CDASH CRFs

SDTM Data

ADaM Datasets

20
Basic Concepts of CDASH

- Minimal ‘core’ dataset for clinical research
- Required for global research per GCPs and regulations
- Standardize the questions/fields on core CRFs
- Standardize the variables and harmonize with SDTM (CDASH is a subset of SDTM)
- Collect data using standard CDISC controlled terminology (NCI-EVS) that maps into SDTM
- Implementation help
  - Best Practice recommendations
  - Implementation recommendations
CDASH Project Snapshot

- Streamlines data collection at investigative sites - addresses Critical Path Opportunity #45
- Continuation of ACRO’s Initiative
- Started October 2006
- Supported by a collaborative group of 17 organizations
- Initial Core Team of 16 members managed
  - 11 working groups
  - Each with 8-40 volunteers
- 16 (+2) Safety data domains developed
- Consolidated document posted for public review in May 2008
- Received over 1800 comments from 46 companies, institutions and agencies.
- All 3 ICH regions were represented in the public comment process
  - US
  - Europe
  - Japan
- Harmonized with analogous NCI CRFs
CDISC CDASH Initiative
Initiated 2006; V1 Published
October 2008
= Core Minimum Dataset Common
Across Research Protocols

- 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)

Clinical Data Acquisition Standards
Harmonization:
Basic Data Collection Fields for Case Report Forms
Prepared by the CDISC CDASH Core and Domain Teams

Revision History

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<th>Date</th>
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18 Domains
(including common timing and variable tables)
### Demographics

**Birth Date**
- **BD-01**
- **BD-02**

**Sex**
- **SEX**
  - [ ] FEMALE
  - [ ] MALE

**Ethnicity**
- **ETHNIC**
  - [ ] NOT HISPANIC OR LATINO
  - [ ] HISPANIC OR LATINO
  - [ ] NOT REPORTED
  - [ ] UNKNOWN

**Race**
- **RACE**
  - [ ] BLACK OR AFRICAN AMERICAN
  - [ ] AMERICAN INDIAN OR ALASKA NATIVE
  - [ ] ASIAN
  - [ ] NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
  - [ ] WHITE
  - [ ] OTHER

**Specify Other**
- [ ] RACOTH

Conformant to CDASH rules
CDISC Operational Data Model

- Transport Standard (XML)
  - Developed to carry case report form data
  - Carries complete audit trail information (21CFR11)
  - Supports electronic signatures
  - Archives electronic data without need to archive original system at sites
  - Can automate generation of eCRFs
  - Enables remote monitoring or auditing
  - Facilitates exchange of data between different technologies that are ODM (supports features common to all CDM and EDC systems)
ODM & Audit Trail

Who

Why

When

What

ItemData

AuditRecord

DateTimeStamp

UserRef

LocationRef

ReasonForChange

Signature

SignatureRef

DateTimeStamp

MeasurementUnitRef

Annotation

Flag

Comment

CDISC 2012

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CDISC – End to End

**CDASH (eCRFs)**

**Protocol**

**ODM**

**Data Capture**

**ODM**

**Database**

**SDTM**

**Analysis**

**ADaM**

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**CDASH (eCRFs)**

**Protocol**

**ODM**

**Data Capture**

**ODM**

**Database**

**SDTM**

**Analysis**

**ADaM**

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**CDASH (eCRFs)**

**Protocol**

**ODM**

**Data Capture**

**ODM**

**Database**

**SDTM**

**Analysis**

**ADaM**

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**CDASH (eCRFs)**

**Protocol**

**ODM**

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**ADaM**

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**CDASH (eCRFs)**

**Protocol**

**ODM**

**Data Capture**

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**ADaM**
Gartner-PhRMA-CDISC Project

• Business Case for using CDISC standards

• Summary:
  ▪ **Using CDISC standards can save significant time and cost, especially when implemented in the early stages of the study**
  ▪ Opportunities for an additional impact on clinical research
    • Increased data quality
    • Data Integration / enhanced re-usability
    • Facilitates data exchange with partners
    • Enable software tools
    • Improve team communication
    • Facilitate regulatory reviews and audits
BRIDG (Biomedical Integrated Domain Group Model)

• **BRIDG Purpose:**
  A collaborative effort to produce a shared view of the semantics that collectively define a shared domain-of-interest, i.e. protocol-driven research
  - Harmonizes the CDISC standards and other similar standards
  - Links research and healthcare

• **Core Stakeholders:**
  - [CDISC](#)
  - [National Cancer Institute](#)
  - [FDA](#)
  - [HL7](#)

• **Global Standard:** Currently, CDISC and HL7 Standard, on the path to becoming an ISO/CEN Standard through Joint Initiative Council for Global Harmonization of Standards (JIC)
Patient Value: Quality of Healthcare, Safety

Produces a standard core research dataset; Enables 21CFR11-compliant interoperability and eSource
Integrating Workflow: EHRs and Clinical Research, Quality, Safety and Public Health

Public Health
- H1N1 Outbreak Reports to CDC (+ biosurveillance demo)

Safety
- ASTER Project @ Harvard to FDA: AE Reporting 34 min to < 1 min and rate increased dramatically
- Hamamatsu Med School CPOE and EMR to PMDA in Japan

Quality
- Clinical Research using CCD and CDASH:
  - G. Pompidou Univ Hospital in Paris
  - Greenway EHR Georgia, U.S.
  - Outcome; Genzyme Registries

Possibility to Harmonize Value Sets between Quality Measures and Research

CDISC Retrieve Form for Data Capture (RFD) = key common workflow integration profile (easy for EHRs to implement)
ASTER (AE Reporting from EHRs)
30 Ambulatory care physicians at Harvard and Brigham and Women’s with Pfizer, CDISC, CRIX
Nov 08 – Jun 09, > 200 Reports Sent to FDA

Physician Reporting:
* 91% of participating physicians had submitted no ADE reports in the prior year
* During the study, participants reported an average of approximately 5 reports in a 3 month time period
* All participants reported at least 1 AD
* Process: Time to report decreased from ~35 min to < 1 min

Source: Michael Ibara, Pfizer
CDISC – Providing Additional Value 2010 and 2011 Interchange Survey

Additional Value

- Standards-All 33%
- Collaboration 23%
- Development of Research & Tools 20%
- Developing Additional Standards 19%
- Training 5%

* Development and advancement of CDISC standards tools and research projects
  • Development of ‘all’ of the standards/additional standards (total = 52%)
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CDISC Therapeutic Area Standards

- Protocol
- Form Setup & Config
- Data Capture
- Data Mgmt
- Analysis
- Submission and/or Reporting
- Review

Protocol → CDASH → SDTM and ADaM

Therapeutic Data Elements (TB, Cardiology, Oncology, Neurological Disorders, Diabetes, PKD)

Controlled Terminology
Critical Terminology Services

CDISC

TD Standards
SDTM, CDASH, SEND

IQA Standards; CTR
SPL, RPS, ICSR

NCI Thesaurus
Standards and ‘Tools’ Needed

• 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 (e.g. SHARE = Shared Health and Research Electronic Library)

Key purposes:

a) Develop therapeutic area standards & others faster
b) Make current standards more accessible and useful
Desired Criteria for Standards to Facilitate Clinical Research

- Fit for Purpose (MU)
- Global
- Based upon Good Clinical Practices (GCP), ICH Guidelines, and applicable Regulations
- Harmonized and semantically consistent
- Developed through a recognized standards development process (by SDO)
- Consensus-based (multidisciplinary contributions)
  - not proprietary or redundant
  - not ‘right’ or ‘wrong’, but widely adopted
- Platform-independent; encourage innovation
- Support interoperability/link with healthcare
“All too many observations lie isolated and forgotten on personal hard drives and CDs, trapped by technical, legal and cultural barriers.”

Nature, September 2009
CDISC is more than Standards!

Enablers
- Quality Improvement
- Process Redesign
- Standards-inspired Innovation

Strength through collaboration
- Speed
- Workflow Integration
- Resource Savings
Research findings to inform healthcare decisions

Information from healthcare (private, aggregated) to enable research

**Healthcare**
- Quality healthcare
- Informed decisions
- Personalized medicine
- Patient safety and privacy
- Public health
- Improved therapies
- Efficiencies/reduced costs

**Research**
- Discovery of new therapies
- Understanding diseases
- Testing/comparing therapies (CER)
- Assessing efficacy
- Monitoring safety
- Understanding responses (genomics, biomarkers)
- Public health/quality evaluations
- Post-marketing surveillance

Currently Inefficient cycle
Quantifying the Value of Standards

- Cycle Time (and Cost) Savings -

Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.