CDISC Standards around the World

Bron Kisler & Rhonda Facile
Genetic Alliance, 9 September 2014
Outline

• Overview of CDISC
• Therapeutic Area Standards
• SHARE Metadata Repository
• Healthcare Link
• Wrap Up / Q&A
What is CDISC?
Clinical Data Interchange Standards Consortium

- Global Standards Development Organization (SDO)
- Founded in 1997 (all volunteers)
- Incorporated in 2000 as a non-profit organization
- Over 320 member organizations
- 90 countries; Coordinating Committees in Europe, Japan, China, Asia-Pacific; 20 user networks
- Robust education program

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

- **Technology Service Provider:** 33%
- **Medical Device:** <1%
- **Pharmaceutical:** 19%
- **CRO:** 26%
- **BioTech:** 5%
- **Consulting:** 6%
- **Government:** 2%
- **Healthcare Provider:** 2%
- **NPO:** 3%
- **Other:** 3%
- **Academic Institution:** 1%
CDISC has established **worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical research data and metadata** to improve data quality and streamline medical and biopharmaceutical product development and research processes

**Consensus-based** development

Standards are **freely available** at [www.cdisc.org](http://www.cdisc.org)

IP Policy ensures **open standards**
Achieving Interoperability

**BRIDG**

**CLINICAL & NON-CLINICAL RESEARCH**

**Protocol**
- PRM Study Design

**Data Collection**
- CDASH
- CDISC-Lab

**Tabulation & Analyses**
- SEND SDTM
- ADaM

**Submission/Publication Reporting**
- SEND SDTM ADaM

**Controlled Terminology**

**THERAPEUTIC AREA STANDARDS & QUESTIONNAIRES**

**CDISC SHARE**

- **Foundational Standards**
- **Data Exchange**
- **Semantics**

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CDISC Around the Globe

- 2000
- 2001
- 2002
- 2008
- 2010
EU - Innovative Medicines Initiative: Joining Forces in the Healthcare Sector

The biggest public/private partnership in Life Science aiming to:

- Make drug R&D processes in Europe more **innovative** and **efficient**
- Enhance Europe’s **competitiveness**
- Address key **societal challenges**

**Features:**

- 1:1 funding, joint decision making
- All EU funds go to SMEs, academia, patient organisations and regulatory agencies
- Large pharmaceutical industry, represented by EFPIA, contributes in-kind

Ann Martin, Principal Scientific Manager, IMI Knowledge Management
CDISC and IMI

• IMI is a member of CDISC
• CDISC and IMI have a Memorandum of Understanding
  • …identify and engage in areas of mutual research interest primarily around IMI Knowledge Management; CDISC education and training
• CDISC established the CDISC Europe Foundation (CEF) to participate in European Commission funded projects
• CDISC is a partner on 3 IMI projects
  • eTRIKS – European Translational Information & Knowledge Management Services, using TranSMART platform
  • EHR4CR – Electronic Health Records for Clinical Research
  • BioVacSafe – Vaccine Safety
3. Electronic data and its method of submission

1) Data standards for submission

Clinical study data subject for submission should be in a format conforming to the standards according to the Clinical Data Interchange Standards Consortium standards (hereinafter referred to as CDISC standards).

Conformity of the electronic submission data to the CDISC standards must be ensured under the responsibility of the applicants.
Study Data Standards for Regulatory Submissions

Position Statement

FDA recognizes the investment made by sponsors over the past decade to develop the expertise and infrastructure to utilize Clinical Data Interchange Standards Consortium (CDISC) [1] standards for study data. The submission of standardized study data enhances a reviewer's ability to more fully understand and characterize the efficacy and safety of a medical product.

The Prescription Drug User Fee Act (PDUFA V) [2] Performance Goals state that FDA will develop guidance for industry on the use of CDISC data standards for the electronic submission of study data in applications. In the near future, FDA will publish guidance that will require study data in conformance to CDISC standards [3].

FDA envisions a semantically interoperable and sustainable submission environment that serves both regulated clinical research and health care. To this end, FDA will continue to research and evaluate, with its stakeholders, potential new approaches to current and emerging data standards. FDA does not foresee the replacement of CDISC standards for study data and will not implement new approaches without public input on the cost and utility of those approaches.

September 13, 2013

http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm368613.htm
• Clinical Terminology Standards: Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through open standards organizations (i.e., CDISC) …
  – … FDA published version 2.0 of the Therapeutic Area Standards Initiative Project Plan June 2014

• …periodically publish final guidance specifying the completed data standards, formats, and terminologies that sponsors must use to submit data in applications.
Therapeutic Area Standards
Formed by CDISC and the Critical Path Institute (C-Path)

A joint initiative to accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health

With the enactment of FDASIA/PDUFA V, FDA recognized the opportunity to work with CFAST, along with the pharmaceutical industry, to develop therapeutic area data standards.

CFAST Steering & Advisory Members:
### Current and Planned CFAST Projects

**CFAST Therapeutic Area Standards Project Pipeline as of June 2014**

<table>
<thead>
<tr>
<th>2012-2013</th>
<th>2014</th>
<th>2015</th>
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<td>Rheumatoid Arthritis</td>
<td>Duchenne Muscular Dystrophy*</td>
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<td>Schizophrenia</td>
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<td>Complicated UTIs*</td>
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<td>Oncology v4*</td>
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<td>Maintenance Update TBD*</td>
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Projects in Italics are candidates to be scheduled and may be subject to change

*Indicates Project Proposal Summary and Approval Pending

### CDISC Therapeutic Area Data Standards (published prior to CFAST):

<table>
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Collaborations & Governance

**CFAST SAC**
Scientific Advisory Committee

- Provides Scientific Advice to TAPSC
- Identifies Risks and Opportunities
- Identifies/Engages Relevant Partners

**CFAST TAPSC**
Therapeutic Area Program Steering Committee

- Prioritizes/Approves Proposals
- Approves Projects & Charters
- Resources & Oversees Projects
• Enhanced development process to address the requirements of TA concept development
• Focus on research and clinical input early in the process
• The use of public database searches
• Attention to medical literature and regulatory guidance (reference management)
• Use of Concept mapping
• Availability of Dedicated resource
• Committed CFAST community
Therapeutic Area Standards – Baseline Content

- Mindmap/model of disease area clinical concepts
- Essential core data elements with definitions, data types (simple & ISO 21090), BRIDG and SDTM mappings
  - Core = most common
- SDTM domains and examples
- Minimum terminology value sets (from code lists) with definitions and C-Codes
- User/Implementation Guide with permissions statements
- CDASH CRFs with SDTM annotations, as appropriate
- ADaM analysis models
CFAST as a Convergence Catalyst

- The process of developing TA concepts has caused a convergence effect

TAUG - Therapeutic Area User Guide
SHARE Metadata Repository
Global electronic repository for developing, integrating and accessing CDISC standards metadata in electronic format.

SHARE should dramatically improve the quality, reusability and integration across CDISC standards and controlled terminologies, and improve interoperability with healthcare.

**SHARE is the foundation for standards-based automation, which is critical to maximizing the Return on Investment of implementing standards**
Research Concepts and Metadata: The Keys to End-to-End Standards
Define Once; Use Many Times

Research Concept-Based Standards Development (e.g., Waist Measurement)

- Defined Observations
- Protocol PRM, SDM-XML
- Performed Observations CRF Collection CDASH
- Performed Results Data Tabulations SDTM
- +Derived Results Analysis Datasets ADaM

Data Reviewers
User Perspectives of SHARE

SHARE

iSHARE
(SHARE Interactive)

Standards Development & Governance

eSHARE
(SHARE Exports)

Accessing Published Standards in a Machine-Readable Format
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<td>3.1.2</td>
<td>IG</td>
<td>PDF</td>
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</table>
CDISC Healthcare Link
CDISC ‘Healthcare Link’ Initiative: Optimizing the Process

Healthcare Delivery

Medical Research

Source Documents
EHR

eSource

(e)CRFs

~1997

Auto Reconciliation for Source Data Verification
Leverage Synergistic Standards

Healthcare Delivery
- eSource Documents
- EHR
- HL7 CCDA

Medical Research
- Integration Profiles (e.g. RFD)
- ODM
- eCRFs

2014
Wrap Up / Q&A
Key Messages

- Standards streamline research processes from eSource through reporting/submission, while allowing innovation and creativity.
- CDISC has a full complement of research standards, from Protocol (and EHRs) through Analysis and Reporting.
- The greatest benefits are reaped when CDISC standards are used from the start of the research project (build quality in at the beginning).
- The therapeutic area standards will augment/complete the CDISC Foundational Standards.
- The best standards result from having the most global input during their development – please join in and get involved with CDISC!
CDISC Communications

• Website Upgraded in June
  www.cdisc.org

• New Business Case to be available September 2014

• YouTube Videos e.g. SHARE
  https://www.youtube.com/watch?v=gCyVdvgVpY8

• Press Releases & Announcements

• eNewsletter-New Format

CDISC 2013 Annual Report

Sign up online to our e-mail list!
Questions?

Strength *through collaboration*...