Key Accomplishments in 2015

The CDISC vision is to inform patient care & safety through higher quality medical research.
CDISC Key Accomplishments 2015

OUTLINE
Part One:  What is CDISC?
Part Two:  Summary of Key CDISC Accomplishments in 2015
Part Three: CDISC Resources for Implementers
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; now a 501(c)3 charitable organization
- Nearly 400 member organizations; 90 countries download
- Coordinating Committees in Europe, Japan, China, Asia-Pacific; ~ 20 user networks; CDISC Europe Foundation
- Alliances with ISO, IHE and HL7
- Robust Education Program (English, Japanese, French, German)
- *Strength through Collaboration drives the progress*
- CDISC Suite of harmonized Clinical Research Standards
  - Streamline research processes and enable data sharing/aggregation
  - Support all types of research from protocol through analysis and reporting
  - Include links to healthcare through EHRs and BRIDG model
CDISC Strategic Goals 2015-2017

#1 Promote and support the continued global adoption of harmonized data standards throughout the clinical research lifecycle by engaging regulatory agencies, research sponsors, academia and other stakeholders through education, advocacy and collaboration.

#2 Implement clinical research standards that are complementary to standards in the broader healthcare ecosystem and thus add value for clinical researchers, healthcare providers and patients.

#3 Leverage the Shared Health And Research Electronic Library (SHARE) and other tools to further expedite the development and facilitate the implementation of harmonized standards for clinical research.

Approved by the CDISC Board of Directors, February 2015
For more information about CDISC, see the Annual Public Report posted at www.cdisc.org

The newest version will be available in May 2016.
Summary of Key CDISC Accomplishments 2015
Key CDISC Accomplishments 2015

• CDISC Membership
  ▪ Increased number of member organizations to 387 (59 new organizations); retention was 93%
  ▪ Improved Members Only Area of the website with additional content

• CDISC Education
  ▪ Trained 10 educators to teach various CDISC courses in Japanese and others in Europe and China are being trained
  ▪ Improved processes and delivery around online training
  ▪ CDISC courses were taught to 2,449 individuals through 172 public and private courses, 14 online training bundles and 170 online training modules in 21 countries.

• International Development/Grant Awards
  ▪ BRIDG 3.2 – ISO Final International Standard
  ▪ Three winning proposals (~ $1M total)
    – Colorectal Cancer Standard (FDA)
    – CFAST Year 3 Extension with C-Path (FDA)
    – eSource (Broad Agency Agreement)
  ▪ New market development, e.g. Devices (interest by CDRH)
Key CDISC Accomplishments 2015 (2)

• Therapeutic Area Standards
  ▪ Seven (7) new TA standards, bringing the total to 25; 77% of the PDUFA V list have been completed or progressed
  ▪ First year of Fellows Program successful (7 Fellows) and second year coming in with 12 Fellows
  ▪ Initiated TA Standards Workshops to support volunteer TA teams
  ▪ Specifications for TA standards (modularization); template approved by FDA for Standards Catalog
  ▪ Continuously improving process, now beginning to leverage SHARE

• CDISC Foundational Standards
  ▪ ADaM – 3 products including Validation Checks
  ▪ Pharmacogenomics (PGx) Domain for SDTM Released
  ▪ First ever RDF/OWL formats
  ▪ BRIDG V4.0 (with genomics) balloted through HL7 and CDISC comment period
  ▪ Support for SHARE mappings and loadings; quarterly releases of Controlled Terminology and Questionnaire Supplements
<table>
<thead>
<tr>
<th>Therapeutic Area Project</th>
<th>Project Manager</th>
<th>Stage 0 Charter Approval</th>
<th>Stage 1 Check of Concepts Completed</th>
<th>Stage 3a Posted for Internal Review</th>
<th>Stage 3b Posted for Public Review</th>
<th>Stage 3c Projected Standards Publication</th>
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<tbody>
<tr>
<td>Traumatic Brain Injury v1</td>
<td>Amy Palmer</td>
<td>Oct 13</td>
<td>Sep 14</td>
<td>Mar</td>
<td>Jul</td>
<td>Q415</td>
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<td>Sep 14</td>
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<td>Jul</td>
<td>Nov</td>
<td>Q415</td>
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<td>SRC Review for Pub: Nov 23</td>
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<td>Aug</td>
<td>Nov</td>
<td>Jan 16</td>
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<td>Oct</td>
<td>Dec</td>
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<td>Prostate Cancer v1</td>
<td>John Owen</td>
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<td>GAD v1</td>
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<td>Triple-</td>
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<tr>
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<td>Scope</td>
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**Upcoming Publications 4Q15/1Q16:**
- **Traumatic Brain Injury** *(Just Published!)*
- **Diabetes ADaM Supplement** *(Published)*
- **COPD**
- **Breast Cancer**
- **Diabetic Kidney Disease**
- **Tuberculosis v2**

**Key:**
- Stage 0 – Scoping
- Stage 1 – Concept Modeling
- Stage 2 – Standards Development
- Stage 3a – Public Review
- Stage 3b – Public Review
- Stage 3c – Publication

Stage ongoing | All months reflect when stage is, or is projected to be, completed.
Key CDISC Accomplishments 2015 (3)

- **Shared Health and Research Electronic Library (SHARE)**
  - Broadened Access - rolled out SHARE to Gold Member Organizations (September) and to Academic Researchers (November)
  - Published ADaM in SHARE
  - Provided end-to-end mappings of CDASH to SDTM and SDTM to ADaM
  - API Pilot – Implementations in Testing
  - RDF Exports for SDTM and CDASH
  - Loaded TA standards and began modularization to support FDA Catalog
  - Began to develop Prostate Cancer Standard from SHARE, leveraging other Oncology standards content

- **Healthcare Link**
  - Mapping of Electronic Health Record patient summary (CCD) to CDASH
  - Registry project for American College of Cardiology
  - eSource Project (BAA grant) Launched
  - Relationship building and focus on quality and elegance of design
Access SHARE Here

A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions that can be used in applications and studies to improve biomedical research and its link with healthcare

From 2009 Stakeholder Analysis (~ 50 organizations interviewed)
Key CDISC Accomplishments 2015 (4)

- CDISC Europe Foundation
  - Continued progress on IMI projects (eTRIKS, BioVacSafe and EHR4CR) and collaborative Publication of Standards Starter Pack for IMI Consortia
  - Clinical Trial Registry XML standard developed and out for public review
  - Meetings with EMA regarding CT Portal and CFAST

- Communications and IT
  - Annual Public Report for 2014 and Quarterly eNewsletters
  - New messaging campaign for clinicians and patient research groups, with new website (www.unlockcures.org)
  - Migrated website to more flexible platform (Drupal) and leveraged Jira for teams and public reviews of standards

- Events
  - Three CDISC Interchanges in Europe, Japan and U.S. brought increased attendance and significant newcomers participation
  - Supported two IntraChanges and outside events, including IOM, DIA, IMI, EBI, PhUSE, SCDM, ACRP, SOCRA

- Financials
  - Hired VP, Finance with international expertise and organizational growth experience
  - Evaluating new software that would significantly improve internal CDISC processes
WHEN CLINICAL DATA SPEAKS THE SAME LANGUAGE, RESEARCH DELIVERS. WHEN DATA TALKS, A WORLD OF CURES CAN BE UNLOCKED

CDISC is in a new era. We all need to ensure that we have a robust plan for sustainability of the organization and maintenance of all of the CDISC standards in SHARE. Demonstrating value, diversification of funding opportunities, implementation support and collaboration will continue to be critical. Communications must be available for technical and non-technical individuals and support from stakeholders is key.

UNLOCKCURES.ORG
Revenue and expenses breakdown
FY 2015

Revenue:
- Total membership: 45%
- Education: 25%
- External Projects: 16%
- Interchanges/Events: 14%
- Healthcare Link: 0%
- Other Income: 0%

Expenses:
- IT/Operations/Finance: 19%
- Healthcare Link: 3%
- Alliances and business developments: 8%
- Interchanges/Events: 10%
- Communication: 5%
- Education: 16%
- Standards Development: 19%
- SHARE: 16%
- Memberships: 4%

Revenue ~ Expenses ($6.4 M)
Key CDISC Accomplishments 2015 (5)

• Additional CDISC Accomplishments in 2015
  ▪ Hired CDISC Executive Director (March)
  ▪ Member surveys (Platinum and Gold) and ‘Listening Tours’ to learn about CDISC Implementation Issues
  ▪ Inclusion of a Research Standards section in the Standards Advisory document developed by the U.S. HHS Office of the National Coordinator
  ▪ Launch of SHARE Steering Committee
  ▪ Leadership of ISO Workgroup and participation in new ISO Model around Standards by Reference
  ▪ Continued hosting of the Learning Health Community
  ▪ New CDISC Roadmap Developed (diagram of core areas on next slide; see CDISC website for the Roadmap)
CDISC Resources Available for Implementers of CDISC Standards and Implementation Managers
CDISC Leadership

Marine Laurent, CPA  
VP, Finance

Nicole Harmon, PhD  
Chief Operating Officer

Rebecca Kush, PhD  
President & CEO

Bron Kisler  
VP, Strategic Alliances

Shannon Labout, CCDM  
VP, Education

Lauren Becnel, PhD  
Director, Bioinformatics and Alliances

Michael Ibara, PharmD  
Head of Digital Healthcare

Rhonda Facile, MS  
VP, Standards Development

Barrie Nelson  
VP, Standards, Terminology and Technical Services

Diane Wold, PhD  
Sr. Director Stds Modeling

Sam Hume, MS  
SHARE and XML Technologies
CDISC 2016 Roadmap
See www.cdisc.org/About CDISC for details.
CDISC Website

- Strategic Goals and Roadmap 2016
- Annual Public Report and eNewsletters
- CDISC Interchanges
- CDISC Education
  - Online Training
  - Public Courses
  - Private Courses
  - Mini Trainings
- CDISC Standards
  - Foundational Standards
  - Therapeutic Area Standards
  - Questionnaires and Terminology (with NCI)
- SHARE
- Videos (SHARE, Healthcare Link Demo, + more!)
- Membership
- Sign Up for CDISC Communications!
Save the Dates!

2016 CDISC Europe Interchange
25 – 29 April 2016
Vienna, Austria

2016 CDISC Japan Interchange
30 May – 03 June 2016
Tokyo, Japan

International Interchange
26-29 September
Bethesda, MD, USA
Online Courses Currently Available (1)

- BRIDG001 Introduction to BRIDG
- BRIDG002 BRIDG Activities
- BRIDG003 Common Sub-Domain
- BRIDG004 Protocol Representation Sub-Domain
- BRIDG005 Study Conduct Sub-Domain
- BRIDG006 Adverse Event Sub-Domain and Statistical Analysis Sub-Domain
- BRIDG007 Data Types
- SDTM001A An Introduction to the SDTM
- SDTM002A SDTM Basics
- SDTM003A Basics of the SDTM IG
- SDTM004A Special Purpose Domains: DM
- SDTM005A General Observation Classes
- SDTM007A Controlled Terminology
- SDTM008A Interventions Domains
- SDTM009A Events Domains
- SDTM010A Findings Domains
- SDTM011A Findings About
- SDTM012A RELREC
- SDTM013A Supplemental Qualifiers
- SDTM014A Creating Custom Domains
- SDTM015A Trial Design
- SDTM016A Special Purpose Domains
- SDTM017A Define-XML
- SDTM018A Conformance, Validation and FDA
- Website001 An Introduction to the CDISC Website
Online Courses Currently Available (2)

- BRIDG008 Constraints and Tags
- BRIDG009 Harmonization and Mapping
- TA001 Overview of TA User Guides
- TA002 Asthma User Guide
- TA0010 Diabetes User Guide
- ADAM001 Introduction to ADaM
- ADaM002 ADaM Traceability, Rules and Best Practices
- CDASH004 Events Domains
- CDASH005 Interventions Domains
- CDASH006 Findings Domains
- CDASH007 Best Practice

Recommendations
- CDASH008 Implementing CDASH in your Data Stream
- CDISC the Future of eClinical with CDISC (Japanese)
- SDTM006A Timing and Grouping Variables
- CDASH V1.1 Bundle
- SDTM V3.1.3 Bundle
- BRIDG V3.2 Bundle
- TA018 Dyslipidemia
- Associated Persons Domains
# 11 Mini Training courses for CDISC Member Organizations – 2015

(Recordings available)

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<thead>
<tr>
<th>Month</th>
<th>Course Title</th>
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<tr>
<td>January</td>
<td>Overview of Define-XML and Dataset-XML</td>
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<tr>
<td>February</td>
<td>Ensuring USUBJID is Unique within an Application</td>
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<td>March</td>
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<tr>
<td>April</td>
<td>Associated Persons IG</td>
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<tr>
<td>May</td>
<td>The Case for Automating Clinical Standards</td>
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<tr>
<td>June</td>
<td>Questionnaire Supplements</td>
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<tr>
<td>July</td>
<td>ADaM Validation Checks</td>
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<td>August</td>
<td>Implementation of Oncology Domains</td>
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<tr>
<td>September</td>
<td>Top Seven CDISC Standards Issues</td>
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<td>October</td>
<td>EPOCH Variable</td>
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<tr>
<td>November</td>
<td>Ophthalmology Domain</td>
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<td>December</td>
<td>SEND</td>
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# Public Webinars – 2015 (recordings available)

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<tr>
<th>Month</th>
<th>February: Schizophrenia User Guide</th>
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<tr>
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<td>SHARE Research Concepts</td>
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<td>March: Dyslipidemia Controlled Terminology (21, 22) Medical Device Standards</td>
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<td>April</td>
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<td>May: CFAST Projects Updates</td>
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<td>CDISC Training Updates</td>
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<td>June: TBI User Guide</td>
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<td>Quarterly Technical Updates</td>
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<td>Virology V2 User Guide</td>
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<td>July: Virology User Guide</td>
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<td>August: ADaM Supplement for Diabetes User Guide</td>
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<td>September</td>
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<td></td>
<td>October: Breast Cancer User Guide</td>
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<td></td>
<td>November: CDISC CTR Standard TB V2 User Guide</td>
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<td>December: Controlled Terminology</td>
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CDISC Fellows Class of 2014-2015

1. Sherwood Barbee, Quintiles
2. Christine Fleeman, UCB
3. Gloria Jones, Johnson & Johnson
4. Ina Assfalg, Boehringer-Ingelheim
5. Tasneem Shahmalak, Theorem
6. Carolyn Famatiga-Fay, Independent
7. Kathy Mellars, Independent*

*not pictured; others listed left to right

To apply for the 2016-17 the CDISC Fellows Program, please contact Alana St. Clair (astclair@cdisc.org) or Rhonda Facile (rfacile@cdisc.org).
CDISC Fellows Class of 2015-2016

1. Mikenlette Avent, UCB
2. Cliff Reinhardt, UCB
3. Dany Guerendo, STATProg Inc.
4. Kapila Patel, InventiveHealth
5. Dr. Helen Sile, FDA*
6. Sharon Powell, Independent*
7. Sandeep Savant, InventiveHealth*
8. Junchao Chen, Shanghai University of TCM*
9. Anayansi Van Der Berg, RA eClinical Solutions*
12. Qingna (Joy) Li, Xiyuan, Hospital, China Academy of Chinese Medical Sciences

*not pictured
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

Standards bring order to complexity.
WHEN CLINICAL RESEARCH IS DONE IN SILOS, WE CAN’T HARVEST CURES.

When we don’t share findings in clinical research, it’s as if billions of dollars get buried. When that happens, we all lose out on finding cures to diseases that affect people we love.