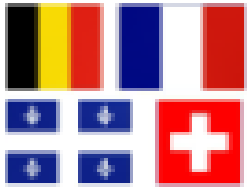

GROUPE DES UTILISATEURS FRANCOPHONES
DES STANDARDS CDISC, Paris, 2 février 2016

CDISC en 2016: Avancement des projets et orientations pour le futur

Pierre-Yves Lastic
Chief Privacy Officer, Sanofi
Past-Chair of the Board, CDISC

Strength *through Collaboration*

CDISC

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The Clinical Data Interchange Standards Consortium

- Global, open, multi-disciplinary, vendor-neutral, non-profit standards developing organization (SDO)
- 501(c)(3) charitable non-profit Founded 1997, incorporated 2000
- Member-supported (>380 academia, biopharma, service provider organizations)
- Associations with ISO TC 215 (Liaison A), HL7, Global Joint Initiative Council (JIC), IHE, NCI-EVS, CFAST, IMI, PhUSE, others
- Coordinating Committees in Europe, China, Japan, Asia-Pacific
- Standards users from > 90 countries
- Standards freely available

***The CDISC Vision:** Informing patient care and safety through higher quality medical research*

CDISC Board of Directors- 2016

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Board Meeting Topics

- Committee Reports and Recommendations
  - Financial Oversight Committee
  - Governance
  - Technical Advisory Committee
  - Strategy Committee
  - Fund Development Committee
- Operations Update; CDISC Roadmap
- SHARE Business Model Discussions/Decisions
- CDISC Strategic Goals→Operational Goals

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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

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CDISC Roadmap 2015-2017

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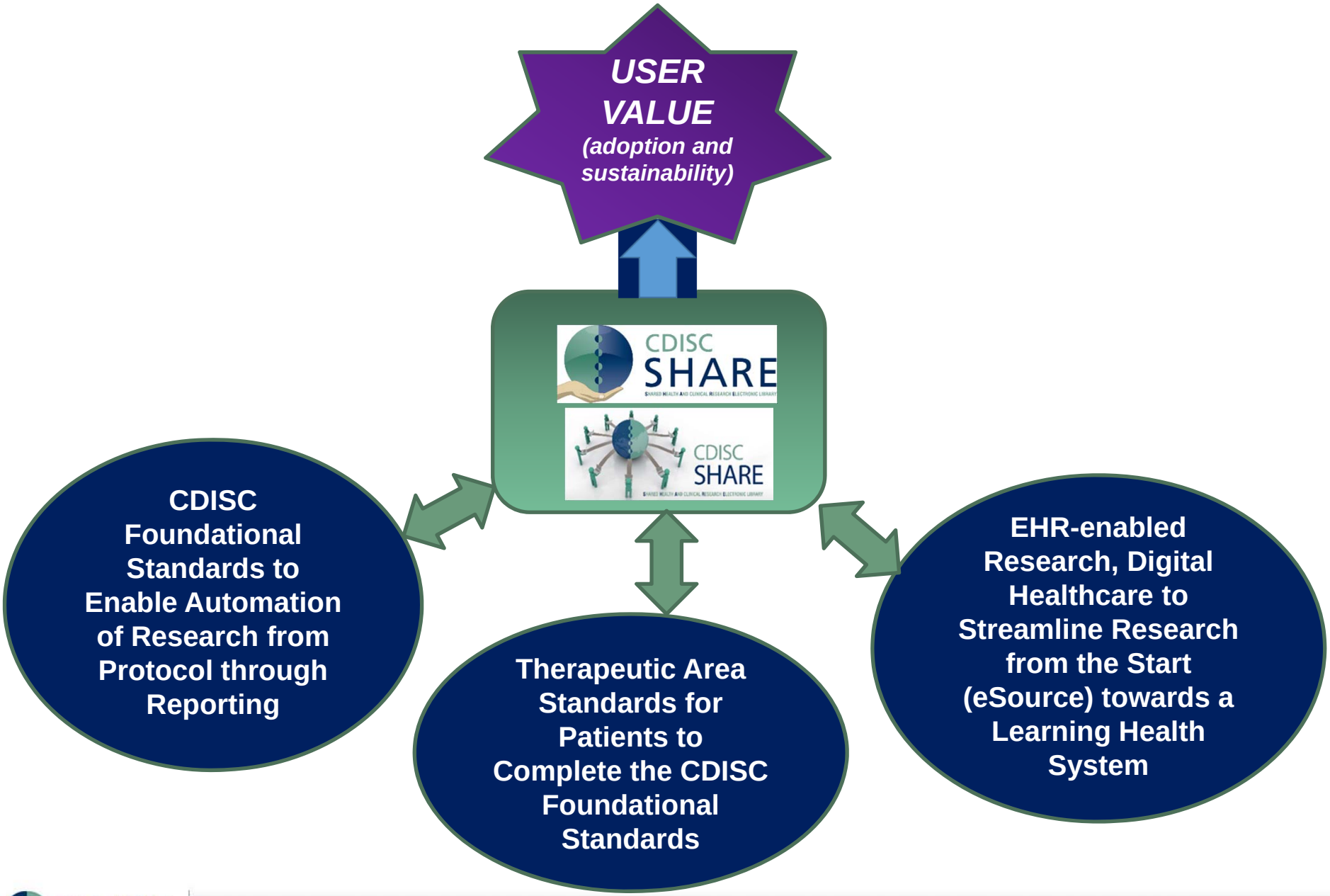
USER VALUE
(adoption and sustainability)
CDISC SHARE
CDISC SHARE
CDISC Foundational Standards to Enable Automation of Research from Protocol through Reporting
Therapeutic Area Standards for Patients to Complete the CDISC Foundational Standards
EHR-enabled Research, Digital Healthcare to Streamline Research from the Start (eSource) towards a Learning Health System

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Strategic Goal #1

Foundational Standards
SDTM, CDASH, ADaM, Controlled Terminology, Protocol, Glossary, XML Technologies to Streamline Research Data Flow from Beginning to End, Healthcare Link, Regulatory Submissions, Data Sharing, etc.

CDISC Foundational standards are at the core of CDISC to streamline research from protocol and data collection through analysis and reporting.

- **Harmonize CDISC standards from beginning to end.**
- **Align with Therapeutic Area Standards and leverage SHARE.**
- **Improve the Controlled Terminology process and transparency.**
- **Facilitate implementation of the CDISC Protocol Standards.**
- **Address CDISC validation rules internationally.**
- **Update Foundational Standards to support CDISC Healthcare Link.**
- **Create a new Version of the CDISC Glossary.**

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Strategic Goal #1

CFAST

Towards Beginning to End Automation→ SHARE-generated Therapeutic Area Stndards (Prostate Cancer); PMDA Input & FDA TA Specifications
Initiate 1-2 Oncology TA Standards and Others in Pipeline
Protocol, CDASH and ADaM for other TAs

CDISC Therapeutic Area Standards complement the Foundational Standards such that they apply to specific therapeutic areas.

- **Begin to develop 'complete' research standards, including Foundational, Therapeutic Area (TA) augmentations and Controlled Terminology from Protocol through SDTM/ADaM.**
- **Use SHARE to build TA standards from the start, re-using prior TAs; Prostate Cancer is the first use case.**
- **Modularize the TA standards, including specifications for the FDA Standards Catalog.**
- **Support the development of additional TAs, including those by developed entirely volunteer teams.**

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Strategic Goal #1

Adoption

Education, Survey and Implementation Calls; SHARE Roll-out; IntraChange, Interchanges, CFAST TA Standards Workshops, Summit, New Messaging & Publications

The broader the adoption of CDISC Standards globally, the more valuable they will become--- accelerating the research process by facilitating protocol development, data collection, data aggregation, reporting or submission of data and data sharing.

- **Provide CDISC Education: online, webinars, classroom, private.**
- **Hold CDISC Interchanges, IntraChange and TA Workshops.**
- **Complete surveys and 'Listening Tours' to understand implementation issues with CDISC standards.**
- **Expand collaboration/alliances to support SHARE, TA standards.**
- **Enhance member relations, CDISC Advisory Council.**
- **Improve CDISC Communications and leverage new messaging.**

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Strategic Goal #2

Healthcare Link
Complete ACC Registry Project; Launch eSource HCL Projects
To provide direct links between healthcare and research

The CDISC Healthcare Link Initiative is designed to streamline clinical research by using eSource data (from electronic health records, eDiaries and other eSource tools) to:

a) enable the entry of data once for multiple purposes,
b) to make it easier for clinicians and patients to participate in research,
c) to improve data quality and patient safety.

- **Deliver on project for EHRs to streamline the population of registries.**
- **Support the use of EHRs for clinical research (E2C and more) by academia and biopharma, working with FDA on lessons learned.**
- **Initiate eSource Stakeholders Group.**
- **Gather metrics and communicate on these processes/ROI.**

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Strategic Goal #3

SHARE
Support "Beginning to End" for TA Standards and Modular Publication;
Support Healthcare Link and eSource Projects;
Demonstrate and Publish on Value

SHARE is a global, accessible electronic library that enables precise and standardised data element definitions that can be used in applications and studies to improve biomedical research and its link with healthcare.

- **Deliver all CDISC standards electronically in various formats.**
- **Deliver TA standards electronically in modules.**
- **Leverage SHARE to develop TA standards faster.**
- **Leverage SHARE for Healthcare Link projects.**
- **Harmonize standards beginning to end, including protocol.**
- **Enable interfaces to automate use of SHARE content.**
- **Collaborate on additional SHARE content.**

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Foundational Standards
SDTM, CDASH, ADaM, Controlled Terminology,
Protocol, Glossary, XML Technologies
to Streamline Research Data Flow from Beginning to End, Healthcare Link,
Regulatory Submissions, Data Sharing, etc.

CFAST
Towards Beginning to End Automation→ SHARE-generated TA (PrCa) -
PMDA Input & FDA TA Specs;
Initiate 1-2 Oncology TA standards and Others in Pipeline

Adoption
Education, Survey and Implementation Calls; SHARE Roll-out;
IntraChange, Interchanges, CFAST TA Standards Workshops, Summit,
New Messaging & Publications

Healthcare Link
Complete ACC Registry Project; Launch eSource HCL Projects
To provide direct links between healthcare and research

SHARE
Support "Beginning to End" for TA Standards and Modular Publication;
Support Healthcare Link and eSource Projects;
Demonstrate and Publish Value

By 2017 there will be global, open standards available electronically through SHARE to streamline research, from protocol through reporting for all major disease areas in support of a learning health system.

CDISC

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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.

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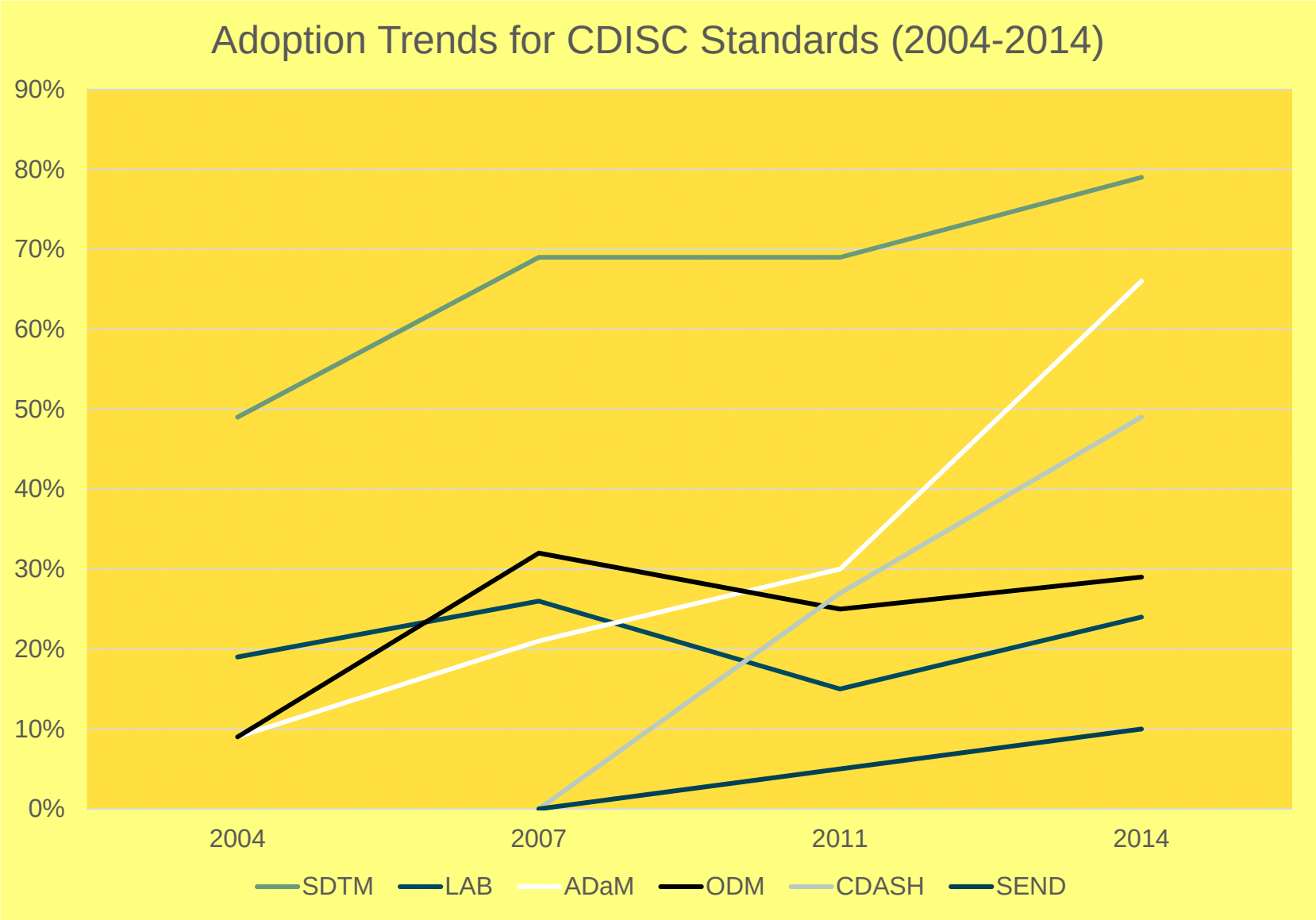

2014 Data from recent Tufts CSDD Survey

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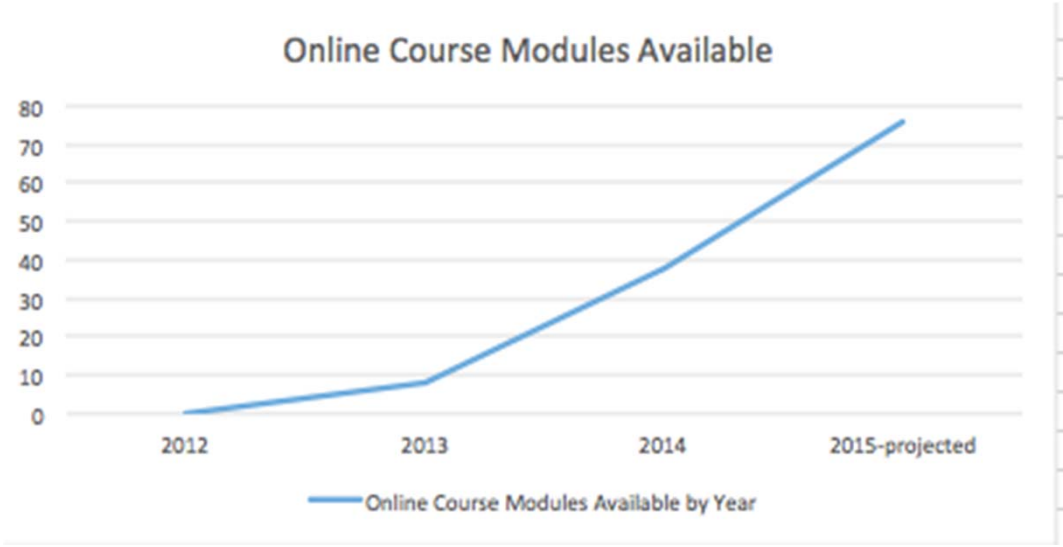
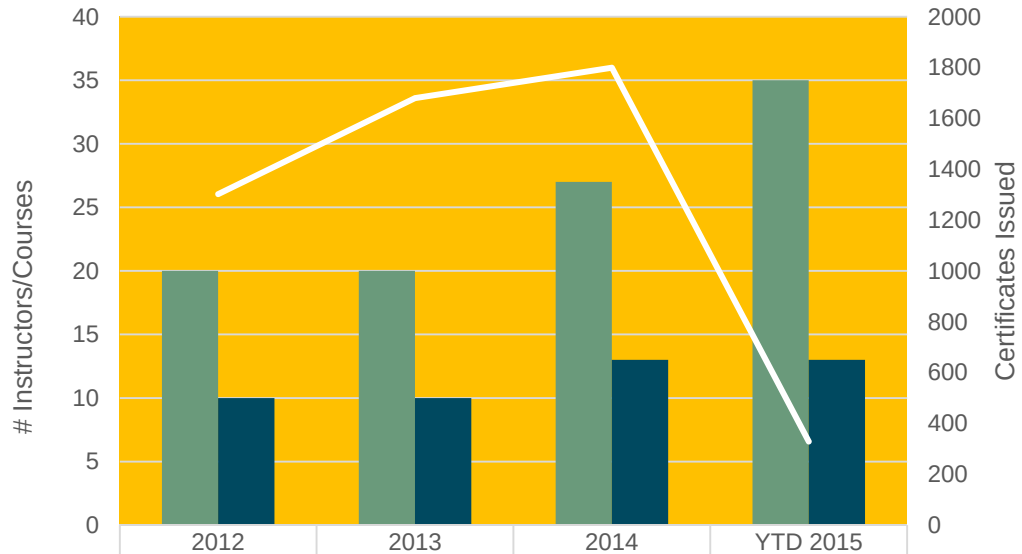
Education Metrics 2012-2015



Classroom Courses



	2012	2013	2014	YTD 2015
Total Number of Instructors	20	20	27	35
Courses Offered	10	10	13	13
Certificates Issued/Individuals Trained	1302	1680	1799	329

CDISC

Public Courses in Paris, France

Follow CDISC Today

Sanofi
1 Avenue Pierre Brossolette
Chilly-Mazarin 91385
France

Course Information:
Name: 2-day SDTM Theory and Application
Date/Time: 7-8 Mar 2016; 09:00-17:00
Instructor: Niels Both
Course Language: English

Cowboy Up!

An Evening of Live Music Collaborating for PTS & Mental Health Research

03 March 2016
Austin, Texas

2016 CDISC Japan Interchange

30 May – 03 June 2016
Tokyo, Japan

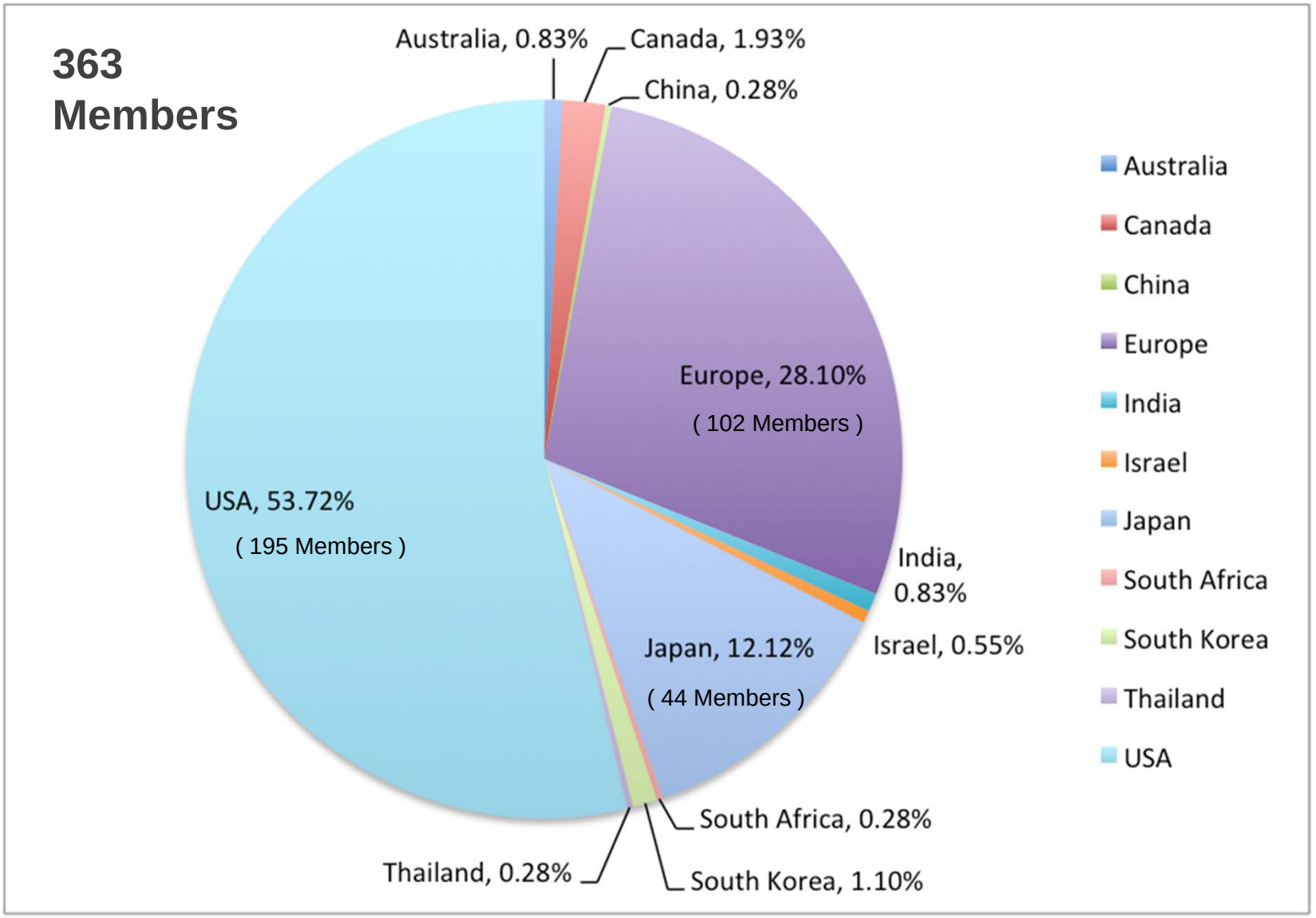
2016 CDISC Europe Interchange

25 – 29 April 2016
Vienna, Austria

Save the Date!

International Interchange
26-29 September 2016
Bethesda, MD

Members by Country



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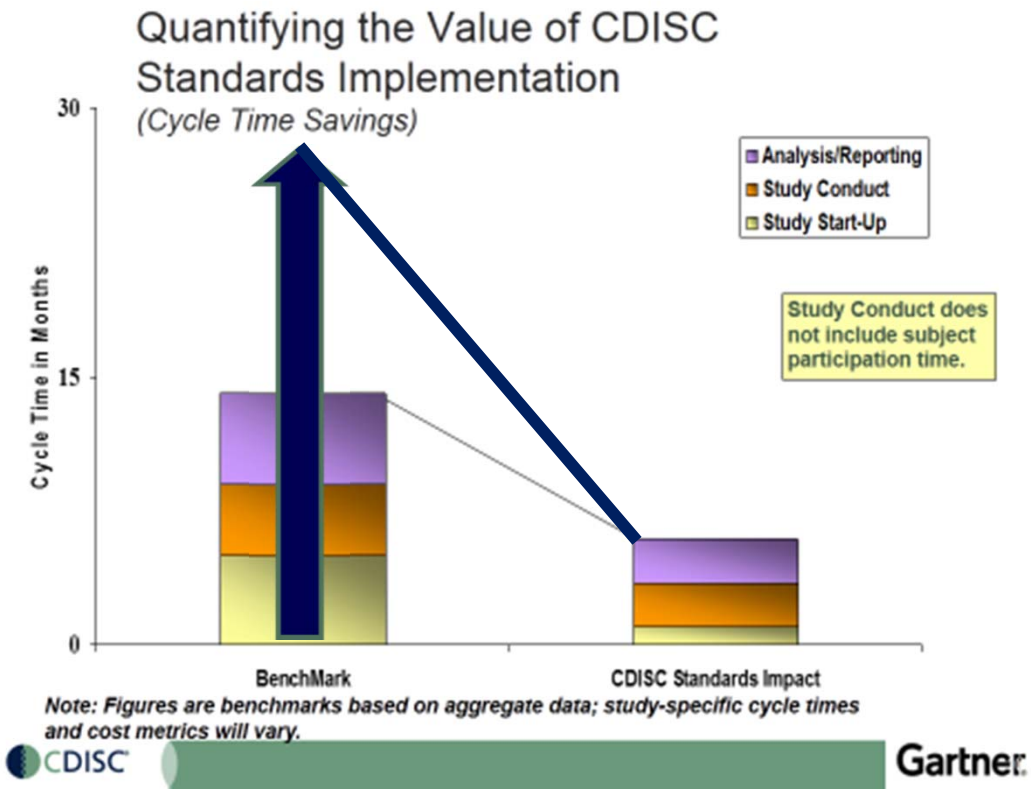
The Value of Using Standards from the Start



2007 CDISC Business Case

2014 Business Case

Current Landscape 2014

- Study Complexity
- # Datapoints
- Data Management
- Time/Resources
- Cost of Research

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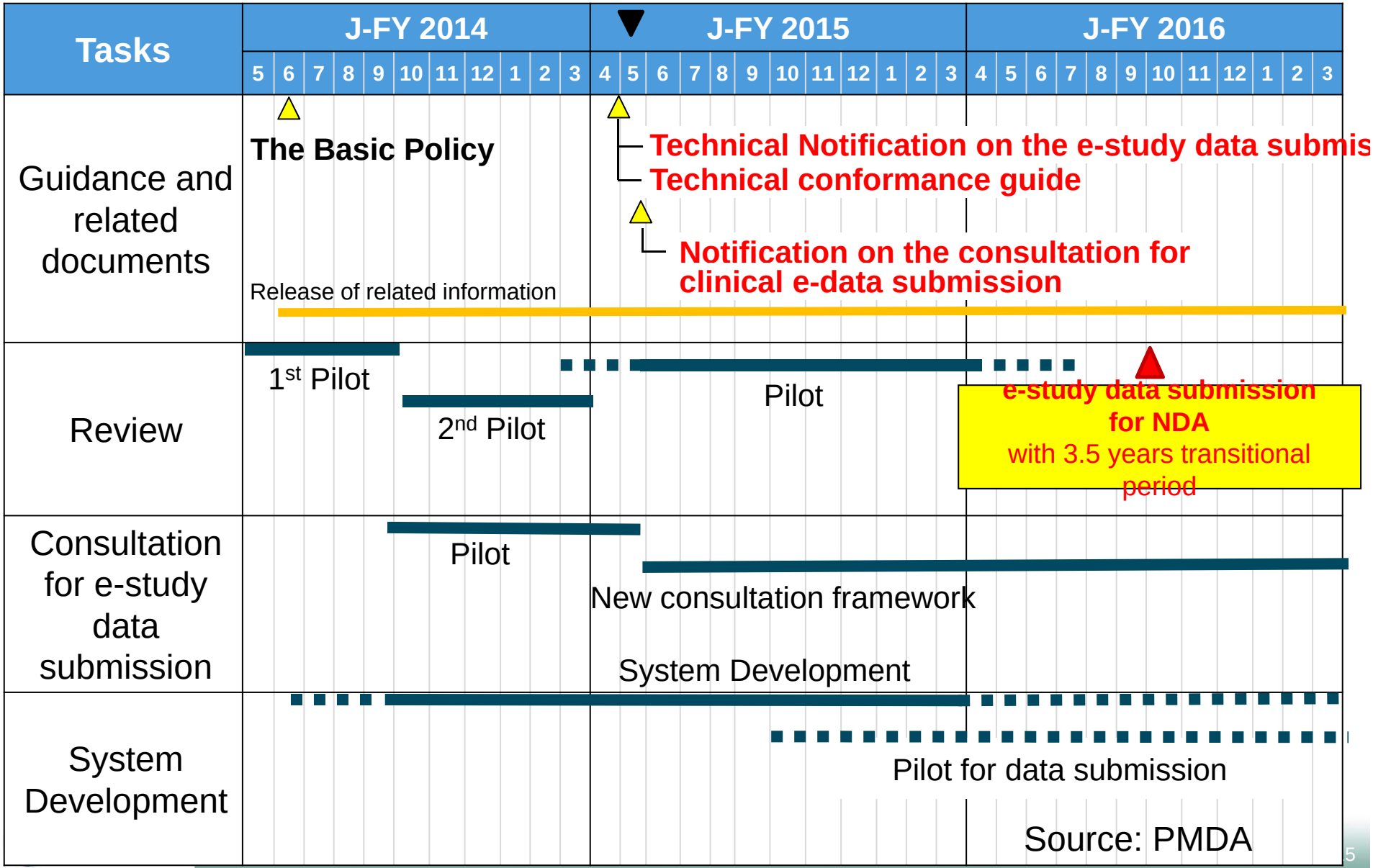
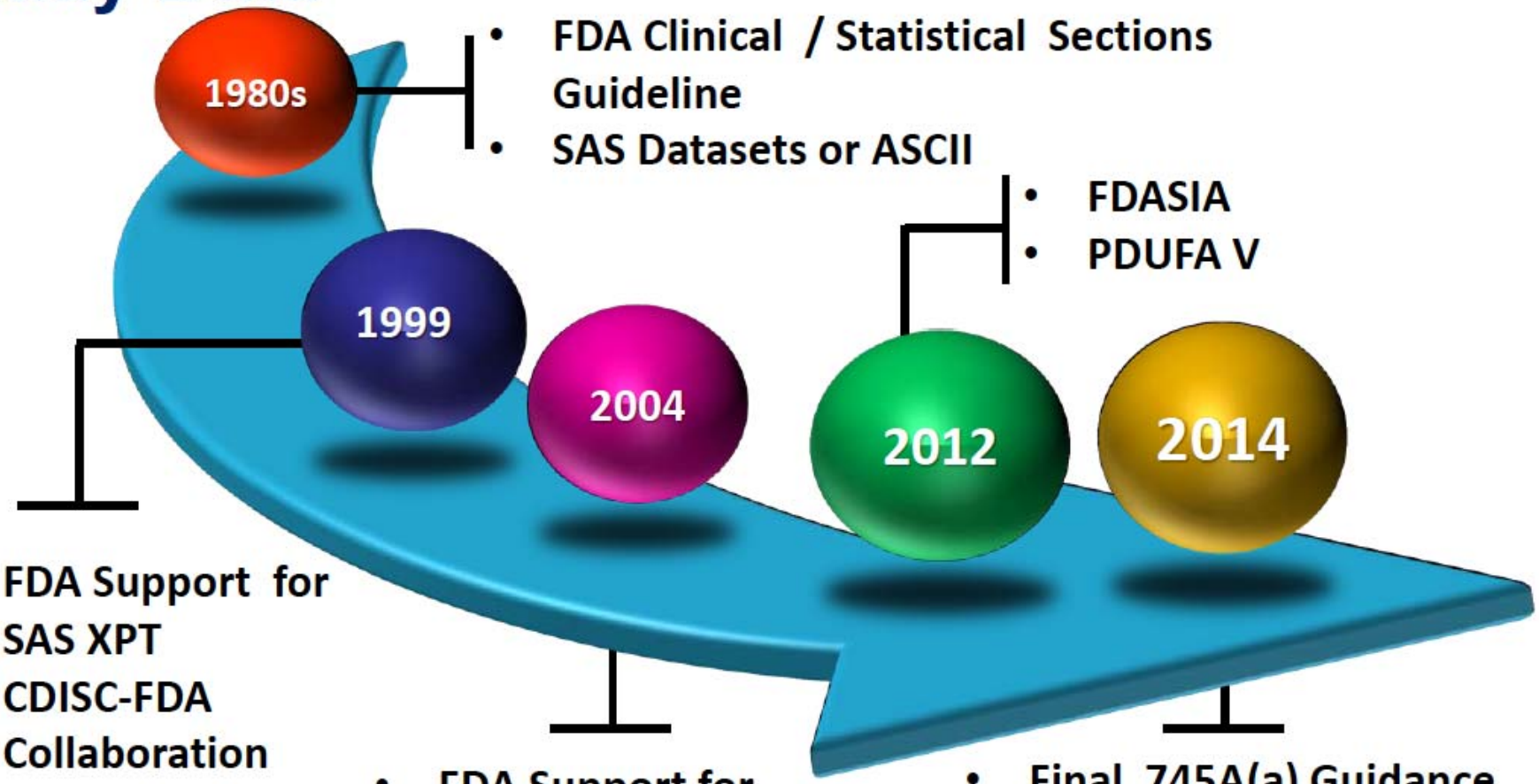
Timeline for Establishment of the Framework for Electronic Study Data Utilization in PMDA



U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Path to Electronic Standardized Study Data



- FDA Clinical / Statistical Sections Guideline
- SAS Datasets or ASCII

- FDASIA
- PDUFA V

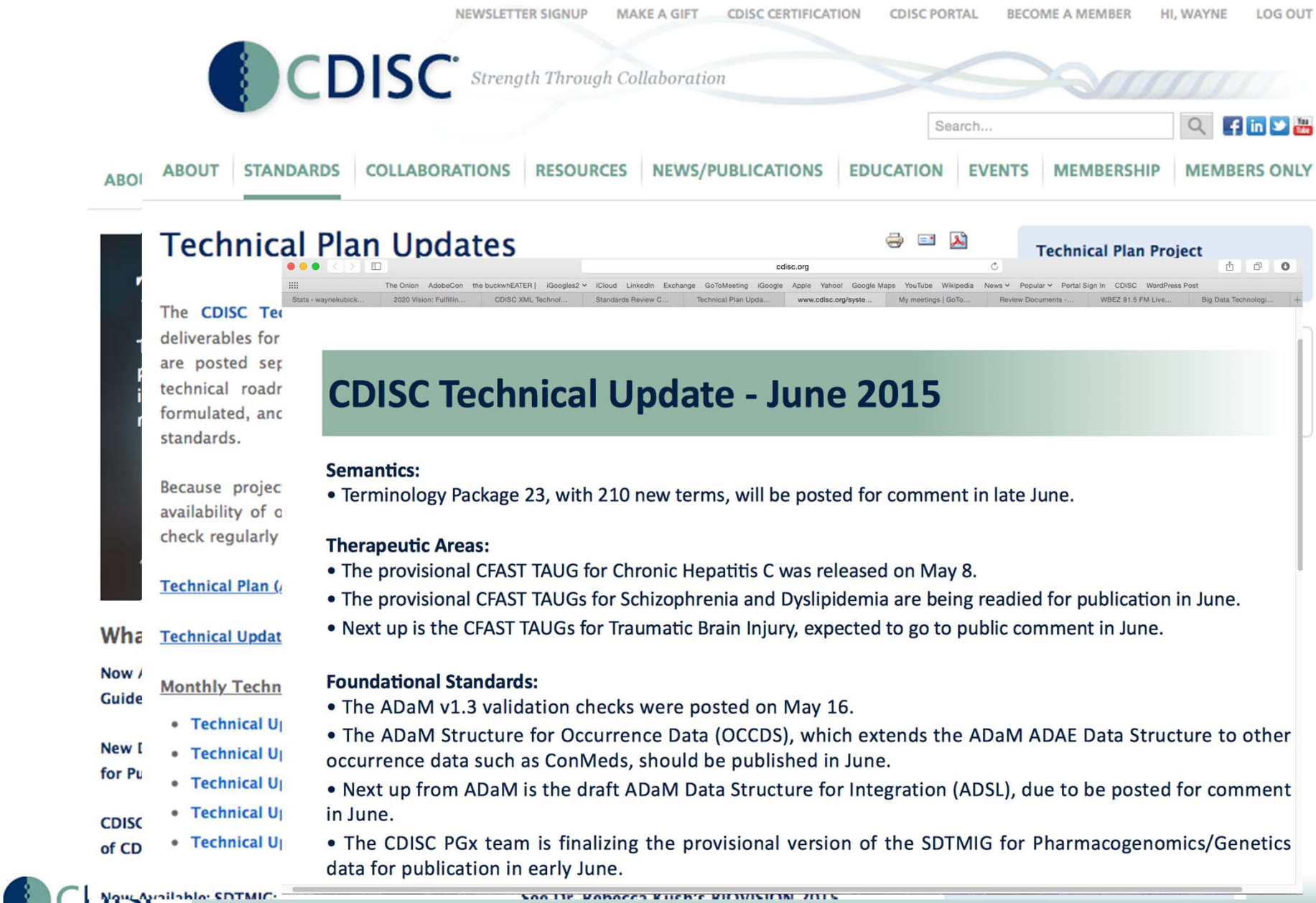
- FDA Support for SAS XPT
- CDISC-FDA Collaboration

- FDA Support for CDISC Submissions

- Final 745A(a) Guidance
- Final eStudy Data Guidance
- Tech Conformance Guide

Source: FDA

Keeping up with CDISC Standards



CFAST Therapeutic-Area Data Standards:

It's about Patients, People!

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CFAST Program

- Launched in 2012 by partners CDISC and C-Path
- SAC initiated in 2013
- Asthma Pilot completed November 2013 included:
  - Enhanced development process*
  - Introduced new roles*
  - TA User Guide content & layout*
  - Concept modeling using concept maps*
  - Metadata displays*
  - SDTM
- Goal is to expand content to developing concept level “Beginning to End” Biomedical Concepts

(* new aspects)

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Working Principles

- Focus on **Core** concepts that apply to all phases of clinical trials in a specific TA
  - Minimal Valuable Product (MVP) for 1st versions
- Minimize text, where possible
  - Focus on explaining concept maps, metadata and examples
- Use SHARE eco-system tools, where possible
  - As tools become available, use them to develop concept metadata
- Re-use existing content to assemble TA packages

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Published Standards

Standards Available for Download!

http://www.cdisc.org/therapeutic

CDISC Standards

CDISC Standards specify **how** to structure the data to support efficient data sharing for regulated clinical trials

CDISC Standards **Do Not** specify what data should be collected or how to conduct clinical trial protocols, assessments or endpoints.

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Program Overview – January 2016

Therapeutic Area	Charter Approved	Check of Concepts Completed	Posted for Internal Review	Posted for Public Review	Projected Publication
Breast Cancer v1	Oct 14	Oct 14	Mar 15	Nov 15	*Q116*
COPD v1	Sep 14	Dec 14	Jul 15	Nov 15	*Q116*
Diabetic Kidney Disease v1	May 15	Aug 15	Jan	Feb	*Q216*
Tuberculosis v2	Apr 15	Apr 15	Sep 15	Oct 15	*Q116*
Rheumatoid Arthritis v1	Jun 15	Oct 15	Jan	Mar	*Q216*
CV Imaging v1	May 15	Jul 15	Dec 15	Feb	Q216
Prostate Cancer v1	Nov 15	Jan			Q316
Major Depressive Disorder (Bi-Polar, General Anxiety Disorder)	Dec 15	Feb			Q316
Kidney Transplant	Jan	Feb			Q316
Colorectal Cancer v1	Q116				Q416
Vaccines*				Q116	Q216
Ebola*	Sep 15	Q116			Q316
Malaria*	Oct 15	Q116			Q316
Nutritional Standards*	Mar 15	Q116	Q216	Q316	Q416
Cardiovascular Concepts in Traditional Chinese Medicine*	Q116	Q216			Q416

Upcoming Publications 1Q–2Q 2016:

- *COPD*
- *Breast Cancer*
- *Diabetic Kidney Disease*
- *Tuberculosis v2*
- *Rheumatoid Arthritis*
- *CV Imaging*

Stage 0 – Scoping , Stage 1 – Concept Modeling, Stage 2 – Standards Development, Stage 3a – Internal Review, Stage 3b – Public Review, Stage 3c – Publication

Key| Stage completed | Stage ongoing | All months reflect when stage is, or is projected to be, completed.

*Project duration depends on volunteer resource variability

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CFAST Pipeline

CFAST Therapeutic Area Standards Project Pipeline as of September 2015

2012-2015 Published	2015 to be Published	2015 In-Process or Planned Starts	2016 Planned Starts
Asthma v1	Traumatic Brain Injury[4]	Diabetic Kidney Disease [2]	*Oncology-Lung [2,5]*
Alzheimer's v2	Oncology - Breast Cancer[2]	Rheumatoid Arthritis[2]	*Psoriasis*
Multiple Sclerosis v1	COPD	Tuberculosis v2	*Duchenne Muscular Dystrophy [1, 2]*
Diabetes v1[2]	Diabetes ADaM Supplement	CV Imaging (Echo)[4]	*Clostridium difficile associated diarrhea (CDAD)[1,3]*
Cardiovascular Endpoints v1[4]	Virology v2 (Viral Resistance)	Oncology - Prostate[3]	*Post--Menopausal Osteoporosis [2]*
QT Studies		Major Depressive Disorder[4]	*Skin and Skin Structure Infections [1,2]*
Influenza		Generalized Anxiety Disorder	
Hepatitis C[2]		Bipolar [1]	
Schizophrenia[4]		*Solid Organ Transplantation - Kidney[2] (Q4 Start)*	
Dyslipidemia[2]		*Oncology-colorectal[3] (Q4 Start)*	

Projects in *Italics* are candidates to be scheduled and subject to change
[1]Indicates Project Proposal Summary and Approval Pending
[2]Indicates FDA recommendations project completed
[3]Indicates FDA recommendations project planned or in process
[4]Indicates CDE inputs or domain analysis models from third party (e.g., DCRI)
[5]Indicates high NCI Priority

http://www.cdisc.org/system/files/all/CFAST_ProjectPipeline.pdf

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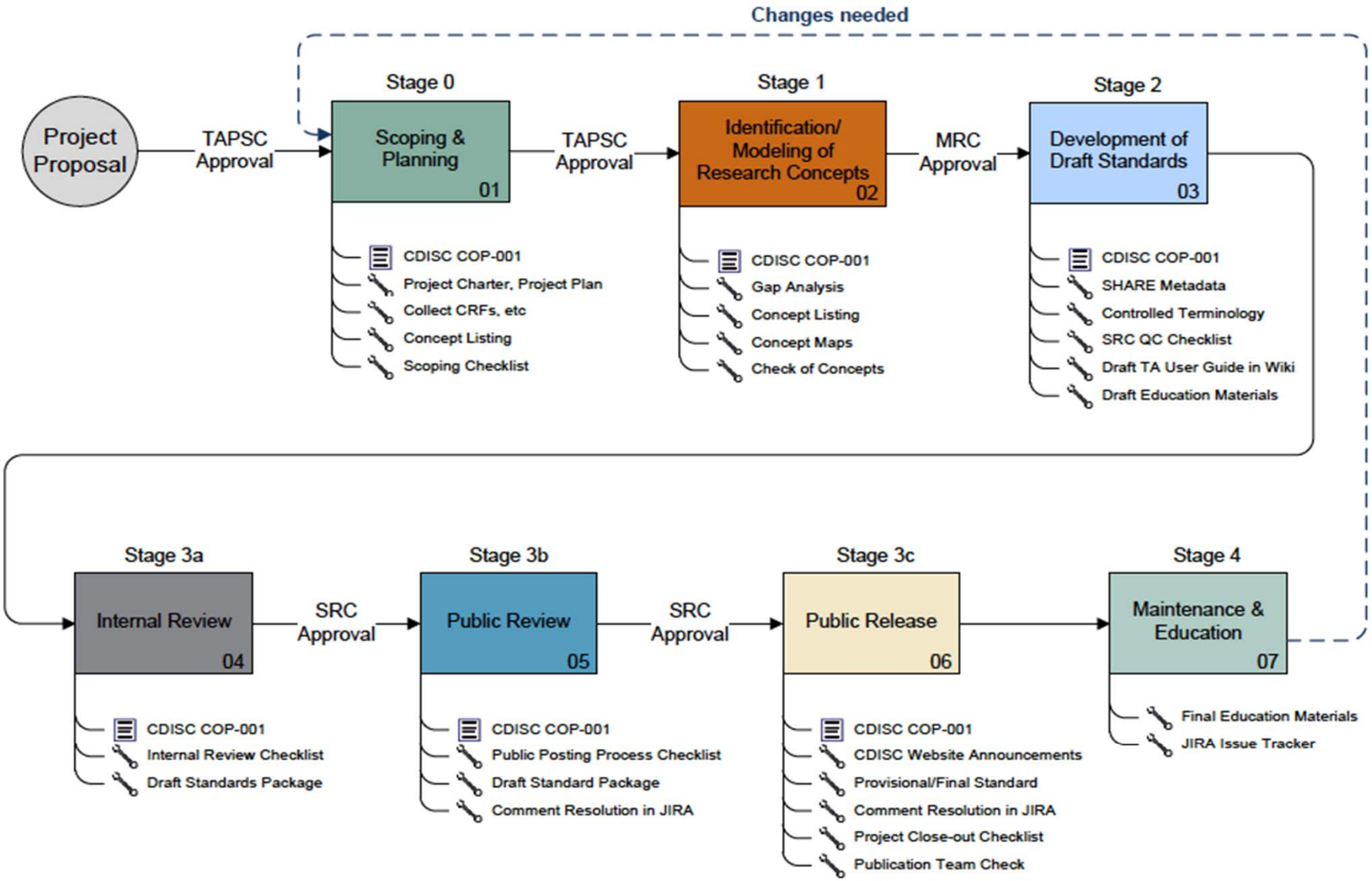
CDISC TA Standards Development Process

High Level



TAPSC = Therapeutic Area Program Steering Committee
MRC = Modeling Review Committee
SRC= Standards Review Council

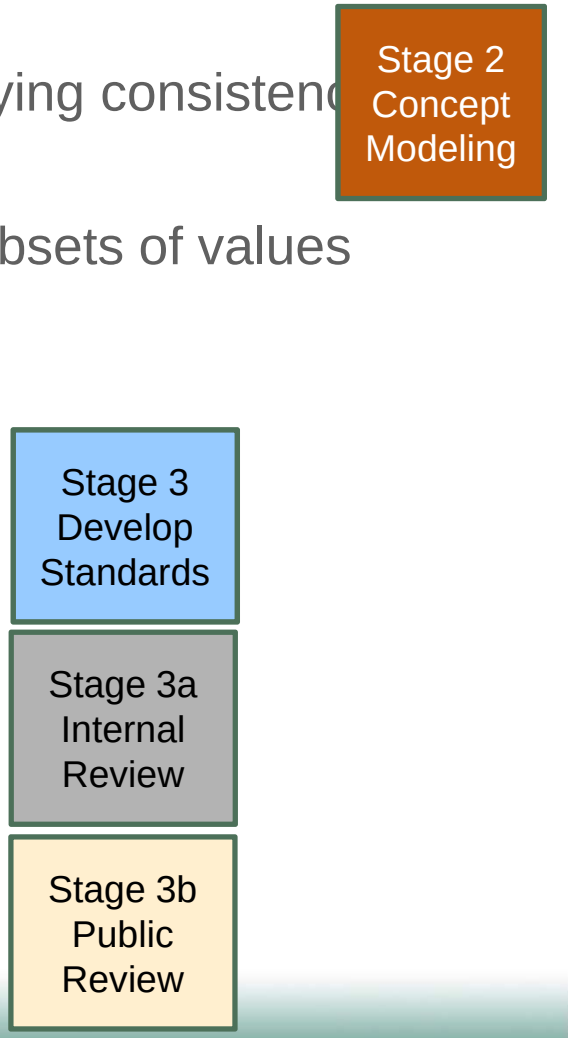
Process for developing content

- Set scope
  - Enough to be useful
  - Not too much to achieve in 10-12 months
  - Identify regulatory and clinical guidelines
- Involve clinicians
- Start with system-independent concept maps
  - Where does the data come from?
  - What are the data items and what do they mean?
  - How are the data items related?

Stage 1
Scoping

Process for developing content

- Develop “biomedical concept” metadata
  - Based on the BRIDG model to provide underlying consistenc
  - Includes CDASH and SDTM metadata
  - Includes controlled terminology values and subsets of values
- Develop implementation examples
- Create TA User Guide Modules
- CDISC review process
  - “Internal” cross-team review
  - Public Review



Beginning to End Coverage

- The first CDISC TA standard (TB, 2012) was a supplement to the SDTM Implementation Guide
  - Organized by SDTM domain
  - No mention of any other standard
- CFAST TA projects expanded to other standards
  - Asthma: SDTM, prototype biomedical concept metadata
  - Diabetes: added CDASH examples
  - QT Studies: included ADaM examples
  - Schizophrenia: includes trial design examples

Adding depth

- Biomedical concept metadata: a small package of relevant variables and terminology for a particular research concept (e.g., a particular test)
  - CDASH prompt/question text
  - SDTM domain, test/test code
  - Applicable variables
  - Computational method, if applicable (e.g., BMI)
  - Subset of relevant controlled terminology
- To be curated in SHARE metadata repository

TA User Guide Contents - Example SDTM metadata

- Introduction
- A list of patient directed resources on the Indication
- SDTM domains
- SDTM Metadata Examples

Rows 1-4: Show examples of oral Glucose administration for two subjects at each of two different visits. The date and time of the start and end of the glucose administration was collected.

ag.xpt

Row	STUDYID	DOMAIN	USUBJID	AGSEQ	AGTRT	AGCAT	AGPRESP	AGOCCUR	AGDOSE	AGDOSU	AGROUTE
1	XYZ	AG	XYZ-001-001	1	GLUCOSE	ORAL GLUCOSE TOLERANCE TEST	Y	Y	75	G	ORAL
2	XYZ	AG	XYZ-001-001	2	GLUCOSE	ORAL GLUCOSE TOLERANCE TEST	Y	Y	75	G	ORAL
3	XYZ	AG	XYZ-001-002	1	GLUCOSE	ORAL GLUCOSE TOLERANCE TEST	Y	Y	75	G	ORAL
4	XYZ	AG	XYZ-001-002	2	GLUCOSE	ORAL GLUCOSE TOLERANCE TEST	Y	Y	75	G	ORAL

Row	VISIT	AGDTC	AGSTDTC	AGENDTC
1 (cont)	VISIT 1	2008-05-01	2008-05-01T08:50	2008-05-01T08:53
2 (cont)	VISIT 5	2008-08-01	2008-08-01T07:30	2008-08-01T07:33
3 (cont)	VISIT 1	2008-06-07	2008-06-07T08:30	2008-06-07T08:35
4 (cont)	VISIT 5	2008-09-01	2008-09-01T08:00	2008-09-01T08:05

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TA User Guide Contents – Concept Maps

- Illustrates relationships among concepts and attributes
- Facilitates understanding (semantic interoperability) among functions involved in standards development

Self-Monitoring Blood Glucose (SMBG) – example

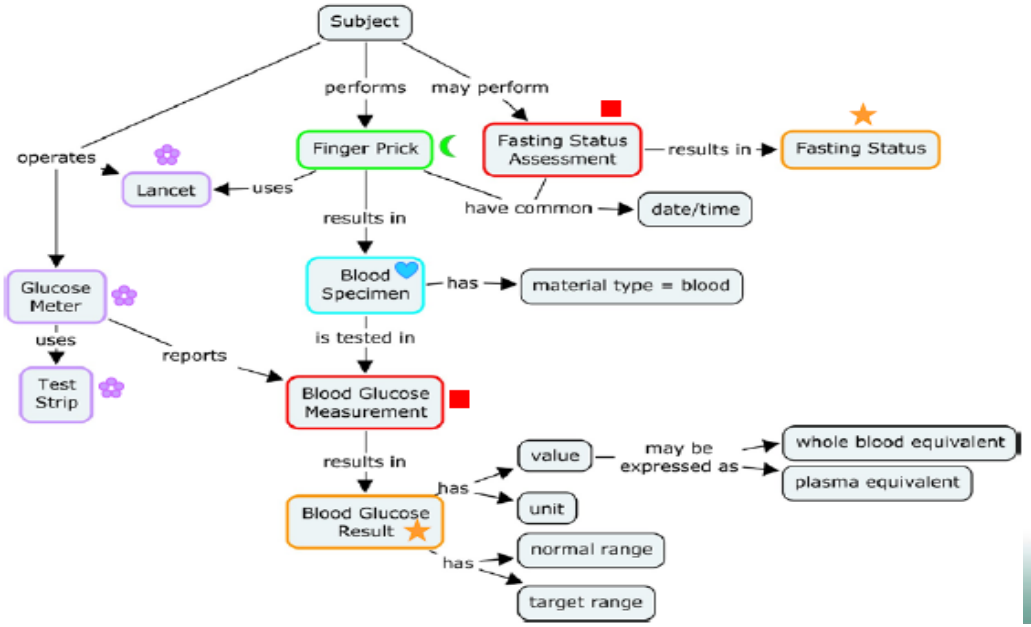

Diagram 2: Self-Monitoring Blood Glucose
Glucose measurements typically performed by subjects with diabetes are indicated. The glucose meter device requires a whole blood sample, but the glucose reading may be read as either a whole blood equivalent or a plasma equivalent.

TA User Guide Contents – CDASH Annotated CRFs

CDASH Annotated CRF example – Hypoglycemia

CETERM = Hypoglycemic Event
CECAT = HYPO EVENTS

Any Hypoglycemic Events Experienced?	No Yes (If yes complete for each event) CEYN
Sponsor Defined ID CESPID	001
Date/Time of Event CESTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) CESTDAT CESTTIM
When Did the Hypoglycemic Event Occur?	Between Bedtime and Waking Between Waking and Bedtime FAORRES when OBJ= Hypoglycemic Event and FATEST= "When Did the Hypoglycemic Event Occur?"
In the Opinion of the Investigator Was This an Adverse Event?	No Yes WASAEYN
Was a Glucose Measurement Obtained at the Time of the Event? LBSTAT	No Yes (If yes enter result and unit below) LBPERF
	- - - - Glucose Result LBORRES mg/dL mmol/L LBORRESU
Last Study Medication Taken	----------Name/Reference EXTRT
EXSTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) EXSTDAT EXSTTIM
	- - - dose EXDOSE - - - units EXDOSU EXDSTXT
Last Concomitant Diabetic Medication Taken	----------Name/Reference CMTRT
CMSTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) CMSTDAT CMSTTIM
	- - - dose CMDOSE - - - units CMDOSU CMDSTXT
Date/Time of Last Meal MLSTDTC	-- --- ---- (DD-MMM-YYYY) - -:- - (24 hour clock) MLSTDAT MLSTTIM

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TA User Guide Contents - CDASH (CRF) Metadata

CDASH CRF Metadata for Hypogycemia

Question Text	Prompt	CDASH Variable Name	CDASH Core	SDTM Variable Name	SDTM Core	Case Report Form completion instructions	Mapping Instructions	Implementation Instructions
Any Hypoglycemic Events Experienced?	Any Hypoglycemic Events Experienced?	CEYN	O	N/A	N/A	Indicate whether or not any hypoglycemic events occurred	This variable does not map to SDTM	Primary intent/purpose of field is to help with data cleaning and monitoring
Sponsor Defined ID		CESPID	HR	CESPID	Perm			Can be pre-populated Row or Sequence Number to Identify Event (SPID)
Date/Time of Event		CESTDAT CESTTIM	HR	CESTDTC	Exp	Record start date using DD-MMM-YYYY format. Record time using a 24 hour clock.	For SDTM-based dataset, SDTM IG variable ECSTDTC is derived by concatenating CDASH Start Date (CESTDAT) and Time (CESTTIM if time is collected) and converting to ISO 8601 format. For more detail see the CDASH v1.1 Best Practice section This field does not map directly into SDTM.	CDASH recommends the unambiguous format DD-MMM-YYYY where "DD" is a 2-digit numeric value for day, "MMM" is a 3-character letter abbreviation for month, and "YYYY" is a 4-digit numeric value for year.
Hypoglycemic Term		NA	O	CETERM	Req			Not typically entered by an investigative site. May appear as a label or header on the case report form.
When Did the Hypoglycemic Event Occur?		FAORRES	HR	FAORRES	Exp	Record the time period during which the hypoglycemic event occurred	FAORRES when OBJ= Hypoglycemic Event, and FATEST= "When Did the Hypoglycemic Event Occur?"	Recommend response choices: "Between Bedtime and Waking" and "Between Waking and Bedtime".

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CDISC SHARE Metadata Example

CM and Treatment Naïve

BRIDG-based concept variable	Value(s)	Attribute	SDTM variable	
MEDCRIT.DefinedDrug.classCode.DSET<CD>.item.code	*from drug dictionary*	Pre-specified class	in CMCAT	Block for pre-specified properties of kind of medication on which question or data collection is focused
MEDCRIT.DefinedDrug.classCode.DSET<CD>.item.displayName.value	*from drug dictionary*			
MEDCRIT.DefinedDrug.classCode.DSET<CD>.item.originalText.value	*free text*			
MEDCRIT.DefinedDrug.code.CD.code	*from drug dictionary*	Pre-specifieddrug	CMTRT	
MEDCRIT.DefinedDrug.code.CD.displayName.value	*from drug dictionary*			
MEDCRIT.DefinedDrug.code.CD.originalText.value	*free text*			
MEDCRIT.DefinedDrug.formCode.CD.code	*from codelist C66726*	Pre-specified dose form	in CMCAT	
MEDCRIT.DefinedDrug.formCode.CD.displayName.value	*from codelist C66726*			
MEDCRIT.DefinedDrug.formCode.CD.originalText.value	*free text*			
MEDCRIT.DefinedDrug.description.ST.value	*free text*	Pre-specified description	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.code	*from codelist C66729*	Pre-specified route of adminstration	in CMCAT	Block for pre-specified properties of kind of medication administration on which question or data collection is focused
ADMINCRIT.DefinedSubstanceAdministration.routeOfAdministrationCode.CD.displayName.value	*from codelist C66729*			
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.code	*from codelist C74456*	Pre-specified target site	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.displayName.value	*from codelist C74456*			
ADMINCRIT.DefinedSubstanceAdministration.targetAnatomicSiteCode.CD.originalText.value	*free text*			
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.code	*from codelist C74456*	Pre-specified site of administration	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.displayName.value	*from codelist C74456*			
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteCode.CD.originalText.value	*free text*			
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.code	C25228, C25229		in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.approachAnatomicSiteLateralityCode.CD.displayName.value	RIGHT, LEFT			
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.code	*sponsor codelist*	Pre-specified indication	in CMCAT	
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.displayName.value	*sponsor codelist*			
ADMINCRIT.DefinedSubstanceAdministration.reasonCode.DSET<CD>.item.originalText.value	*free text*			
CMQ_O.DefinedObservation.focalDuration.PQ.value	SDTM uses ISO8601			Block for pre-

Shows BRIDG basis and detailed values

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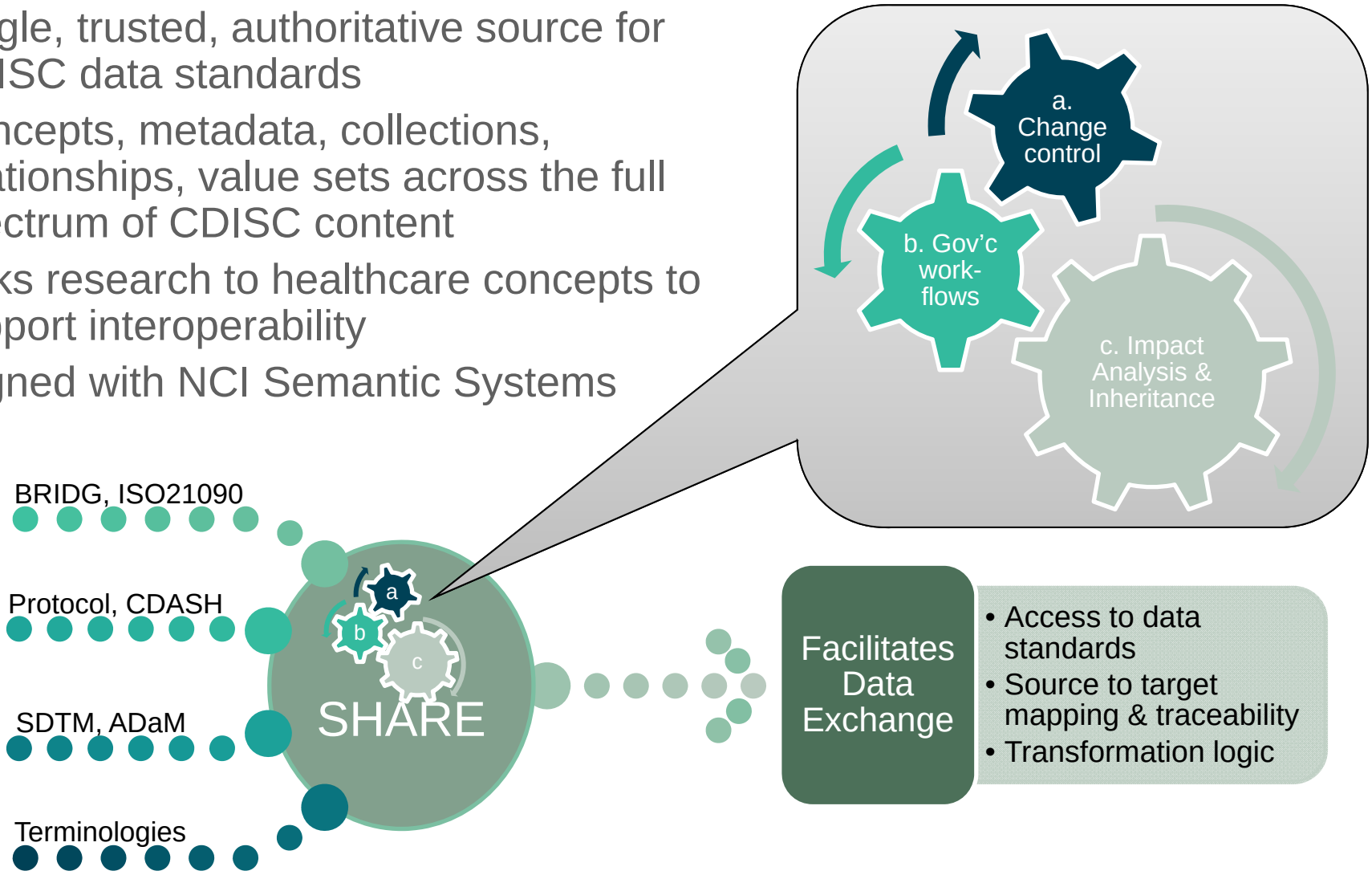
CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

- Single, trusted, authoritative source for CDISC data standards
- Concepts, metadata, collections, relationships, value sets across the full spectrum of CDISC content
- Links research to healthcare concepts to support interoperability
- Aligned with NCI Semantic Systems



Adapted from Source by Sue Dubman, Sanofi-Aventis

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SHARE Video

http://www.youtube.com/watch?v=gCyVdvgVpY8&feature=youtu.be

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TA Standards Specification for FDA & User Guides Modularized Content

Non-Normative

- TA User Guides
  - **For data managers, programmers, others..**
  - Includes:
    - Implementation instructions
    - Concept maps and explanations
    - Examples
      - SDTM, Controlled Terminology and other standards
    - Appendices
      - Glossary
      - Known issues
      - References
      - Team list
      - IP policy

Normative

- TA Specifications
  - **For FDA data standards catalogue**
  - Includes:
    - New domains/variables specifications
      - Domain tables
      - New variables
        - » Standard and Non-Standard
    - SDTM Rules
    - Controlled Terminology
    - Known issues
    - Evolve to Biomedical Concept Metadata tables – over time

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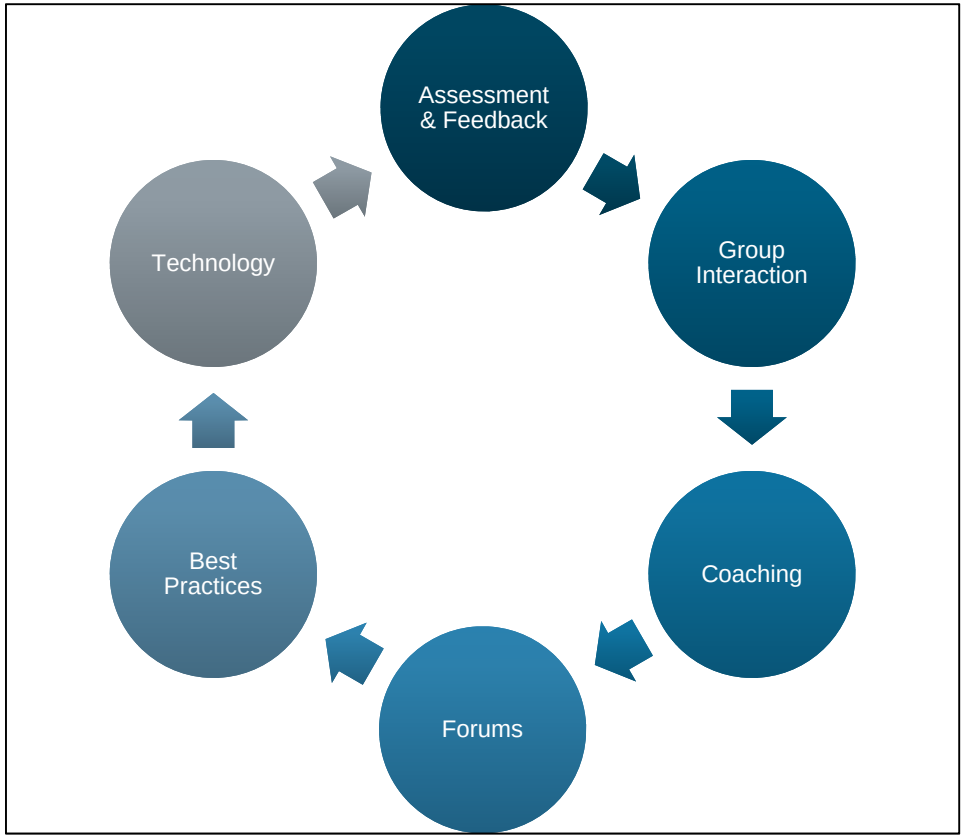
CDISC's Culture of Learning

- Assessment & Feedback
  - Lessons Learned
  - Does it work/not work?
  - Make needed changes
- Group Interaction
  - Use of dialogue & skillful discussion to draw out group intelligence that is greater than the sum of individual member's talent.
- Coaching
  - Modeling Expert
  - CDISC Experts, SRC, etc.
- Forums
  - Concept Modeling
  - Metadata Development
- Best Practices
  - Process documentation
  - Tools, Checklists, etc
- Leverage Technology
  - CDISC SHARE



(Adapted from Peter Senge, The Dance of Change: The Challenges of Sustaining Momentum in Learning Organizations, Doubleday, New York, 1999)

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Lessons Learned

- TA standards development will drive/are driving development of most CDISC standards
- Attention to project scope is essential
- Point to reference material, don’t repeat it
- Smaller, experienced resourced teams
  - Focused clinical input
  - Large review community input at Internal and Public Review

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Path Forward

- Streamlining & Modularizing TA User Guides
  - focus on “Core” information
- Use Pre-populated templates, where possible
- Produce Normative Specifications for all TA User Guides for FDA
- Update Published TA User Guides (point versions) to remove draft domains
  - Create an area on the wiki where those draft SDTM domains and other proposed changes can be maintained.
- Extract examples from older TA User Guides and loading them into SHARE.
- Continually observe what works & what doesn’t

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How to get Involved

- Join a TA working group
- Comment on draft standard at the Internal Review and/or Public Review
- Attend the Interchange
- Participate in the CDISC Fellow program

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CDISC Fellows Program

CDISC Fellows:

- Actively participate in the development of CDISC standards on a near full-time basis for a fixed period of time (nominally one year)
- Develop proficiency in the development, use and maintenance of standards
- Acquire knowledge that can be leveraged internally by sponsoring companies
- Provide ongoing part-time expertise
  - as a reviewer or other participant to the CDISC collaboration community

http://www.cdisc.org/cdisc-fellows-program

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CDISC Fellows Class of 2015-2016

- Mikenlette Avent, UCB
- Cliff Reinhardt, UCB
- Dany Guerendo, STATProg Inc.
- Kapila Patel, InventiveHealth
- Dr. Helen Sile, FDA*
- Sharon Powell, Independent*
- Sandeep Savant, InventiveHealth*
- Junchao Chen, Shanghai University of TCM*
- Anayansi Van Der Berg, RA eClinical Solutions*
- Ruiling Peng, Beijing Improve-Quality Technology Ltd. Co.
- Phillip Ho, Rundo Int Pharmaceutical Research & Development Co.
- Qingna (Joy) Li, Xiyuan, Hospital, China Academy of Chinese Medical Sciences

*not pictured

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CDISC Strategic Goals 2015-2017

#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.

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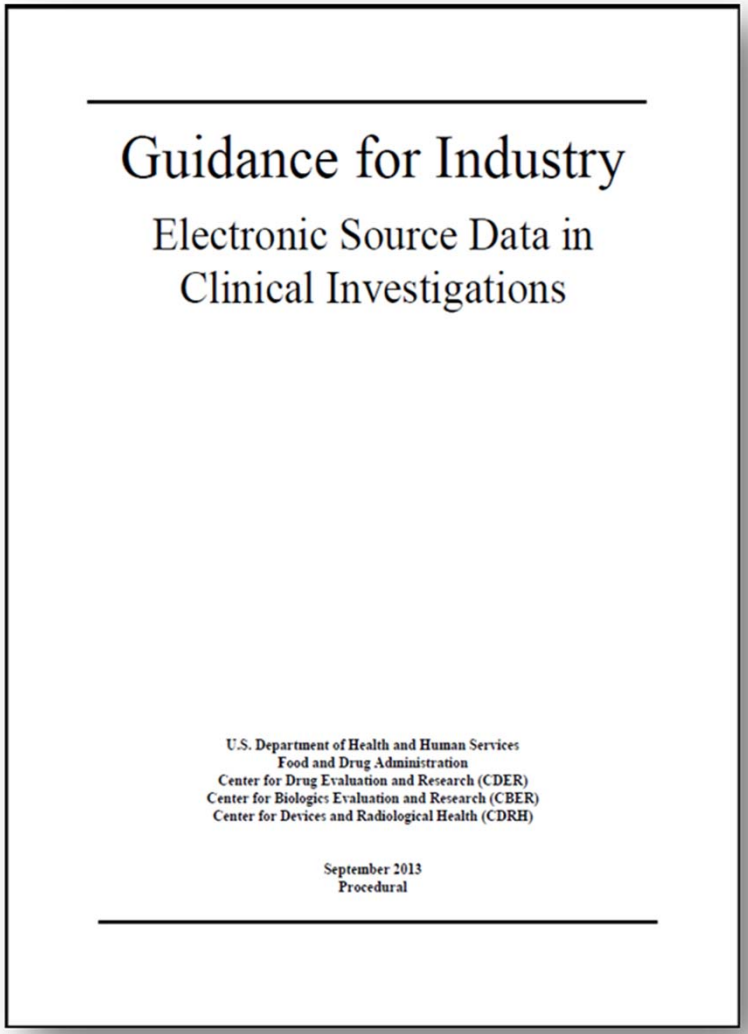
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 June 2010
EMA/INS/GCP/454280/2010
GCP Inspectors Working Group (GCP IWG)
Date for coming into effect 01 August 2010

Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials

References

2. CDISC (Clinical Data Interchange Standards Consortium) Clinical Research **Glossary Version 8.0**, DECEMBER 2009
http://www.cdisc.org/stuff/contentmgr/files/0/be650811feb46f381f0af41ca40ade2e/misc/cdisc_2009_glossary.pdf.
3. **CDISC e-source standard requirements-CDISC** (Clinical Data Interchange Standards Consortium) Version 1.0 20 November 2006.



eSource = data entered electronically first, i.e.EHRs, eDiaries….

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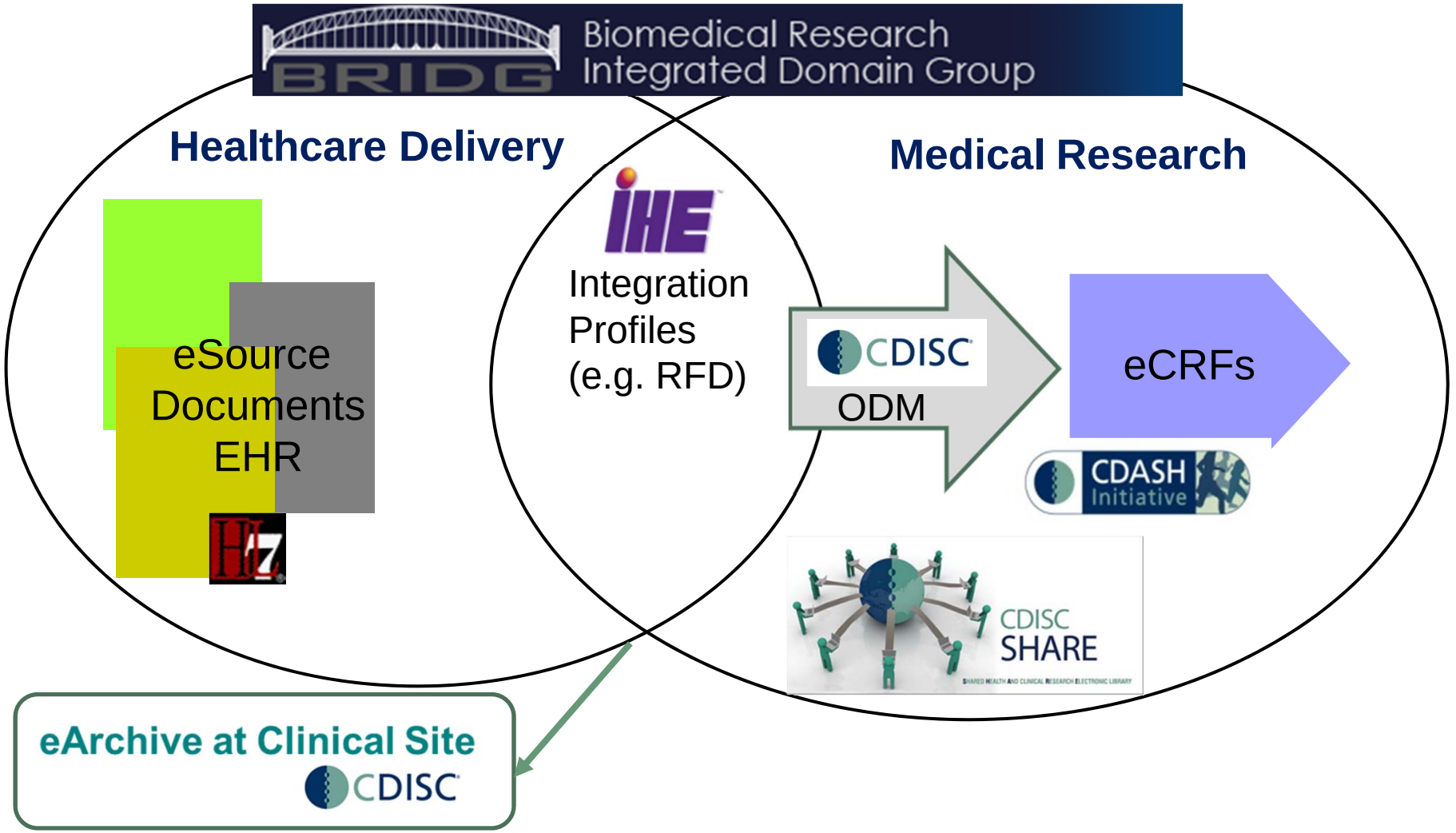
Synergistic Standards Available



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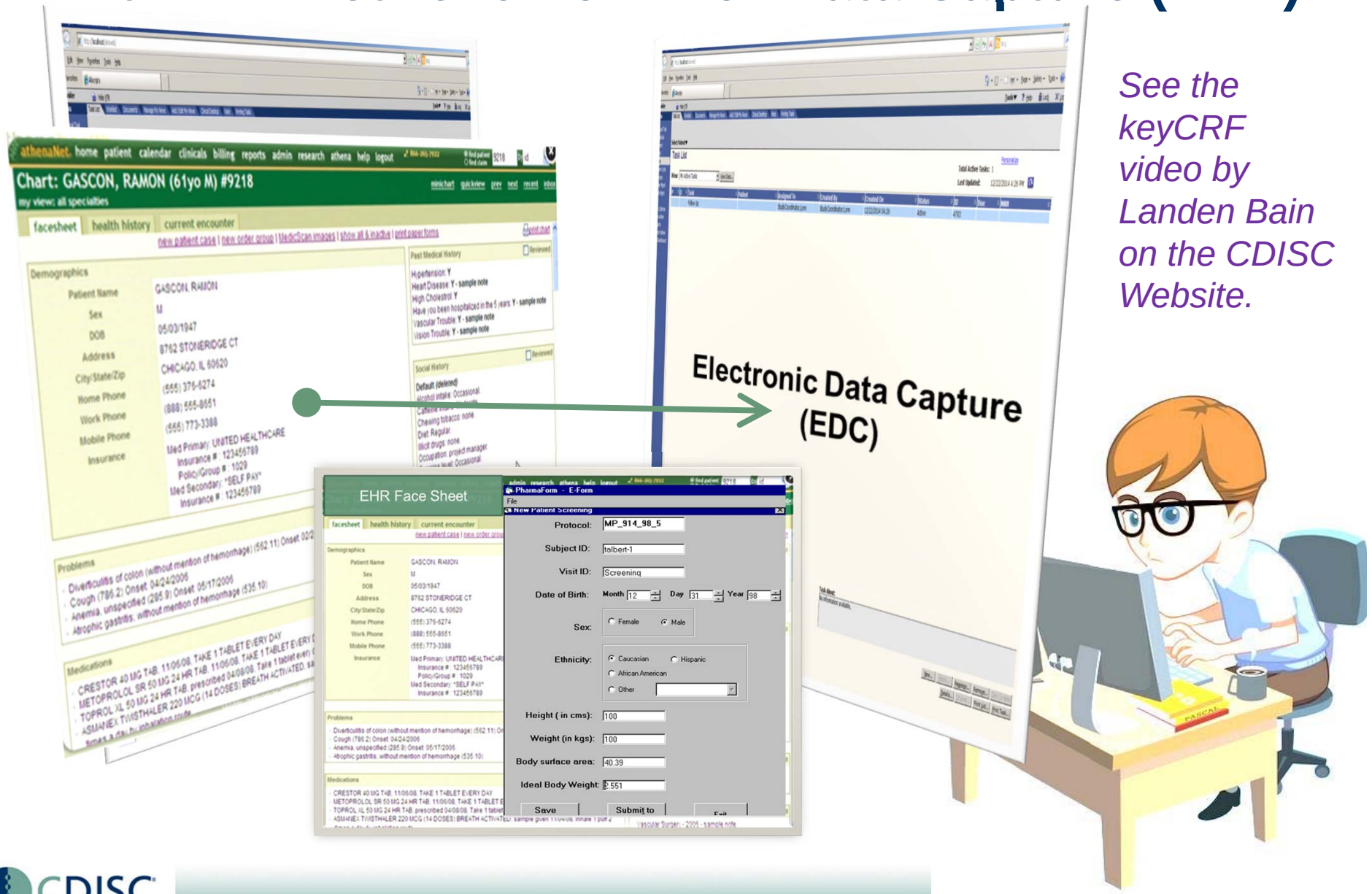
EHR to Electronic Data Capture (CDASH) with IHE Retrieve Form for Data Capture (RFD)



See the keyCRF video by Landen Bain on the CDISC Website.

CDISC

“We owe it to patients who participate in research to use their data wisely.”

Innovative Medicines Initiative

The NEW ENGLAND JOURNAL of MEDICINE

Fostering Responsible Data Sharing through Standards

Rebecca Kush, Ph.D., and Michel Goldman, M.D., Ph.D.

Children with muscular dystrophy and their families make sacrifices to engage in clinical research studies, providing valuable data they expect will contribute to the discovery of a cure, although they know it may not be found in time to help them. This message was emphasized at a recent meeting organized by the Institute of Medi-

treatment of Alzheimer's disease have led several companies to begin collaboratively developing innovative study designs requiring extensive data sharing.

Unfortunately, the diverse ways in which data are collected and reported in clinical studies make it difficult or impossible to query across data sets, pool and share data, or integrate data for

metadata, such confusion is inevitable. Units and other metadata are critical in medical research as well. Standard data and metadata formats are required for efficient aggregation of patient-level data, trustworthy statistical analyses, and accurately informed clinical decisions. When such standards are not implemented by all parties at the

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eSource Stakeholders Group

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+1.316.558.0160
avadakin@cdisc.org

FOR IMMEDIATE RELEASE

CDISC to Convene eSource Stakeholders Group to Encourage Use of EHRs for Research

Austin, TX – 14 January 2016 – The Clinical Data Interchange Standards Consortium (CDISC) announced today the establishment of the "eSource Stakeholders Group," an open, inclusive forum which will provide coordination and focus to the increasing community of stakeholders interested in realizing the benefits of using eSource, also known as electronic source data, in clinical trials and meeting regulatory requirements for eSource data, provenance and electronic records. This news follows the FDA's announcement in June 2015 encouraging organizations to propose demonstration projects, the September 2013 FDA Guidance encouraging the use of electronic source data in the conduct of clinical investigations, and, most recently, the updated Electronic Health Record (EHR) eSource webpage on the FDA-CDER website.

"The use of electronic health records has the potential to foster efficiency and further innovation in regulated clinical research," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "Demonstration projects that test and evaluate the performance of end-to-end EHR-to-EDC single-point data capture approaches are an important source of information as we collectively work to ensure the quality of data from electronic source to electronic regulatory submission."

CDISC Strategic Goals 2015-2017

#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.

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CDISC SHARE

What is SHARE?

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SHARE Team Still Accepting Volunteers

The SHARE Team is accepting new volunteers to our growing list of participants. There are a number of sub-teams that are either underway or planning to start in the near future. A current **list of sub-**

--Public Review--

ADaM Integration-IADSL v1 Draft
Comments due 10 July 2015

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CDISC SHARE Video
SHARE Requirements (pdf)
2013 International Interchange SHARE Presentation (pdf)

SHARE Through the Eyes of a Child

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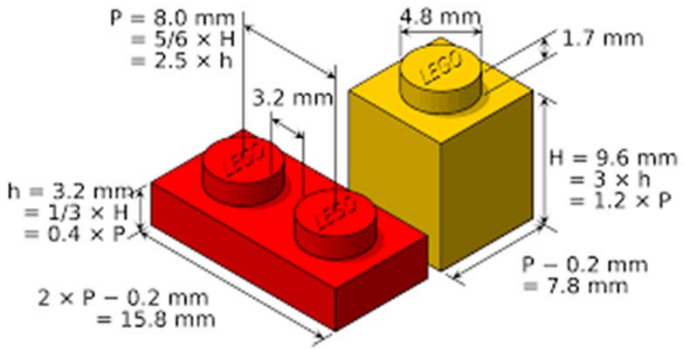
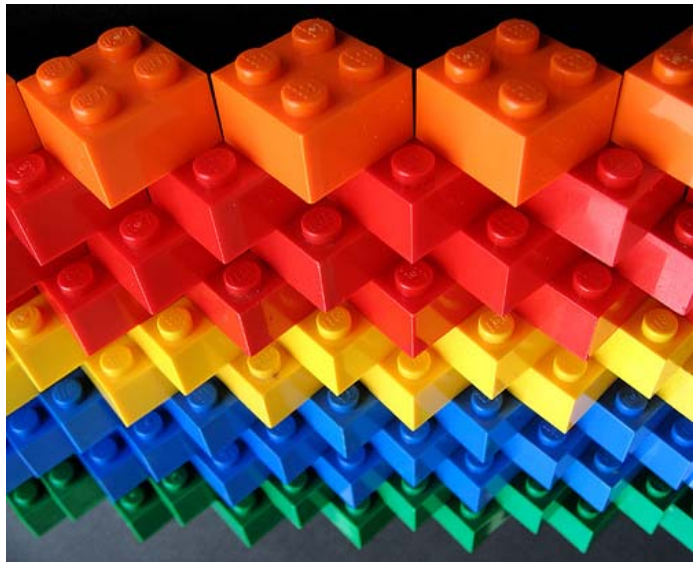
A World Without Data Standards

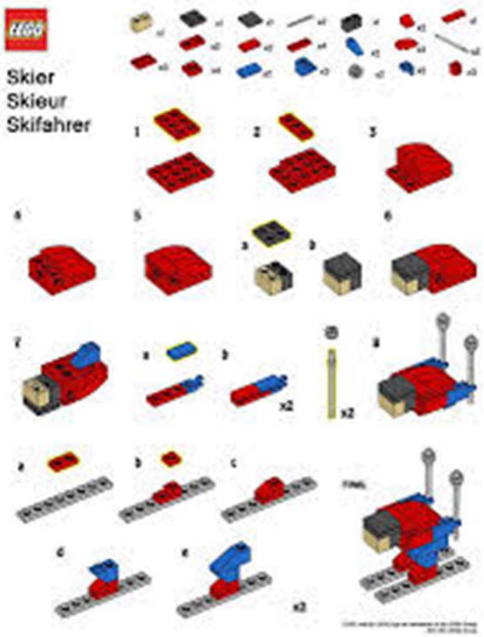
© CDISC 2015

Elements, Metadata, Terminology



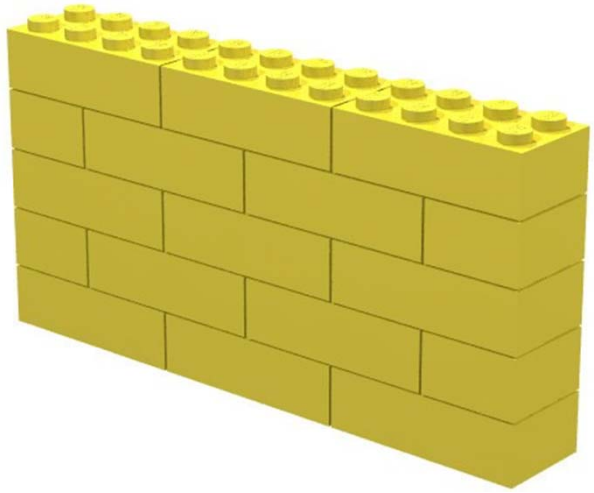


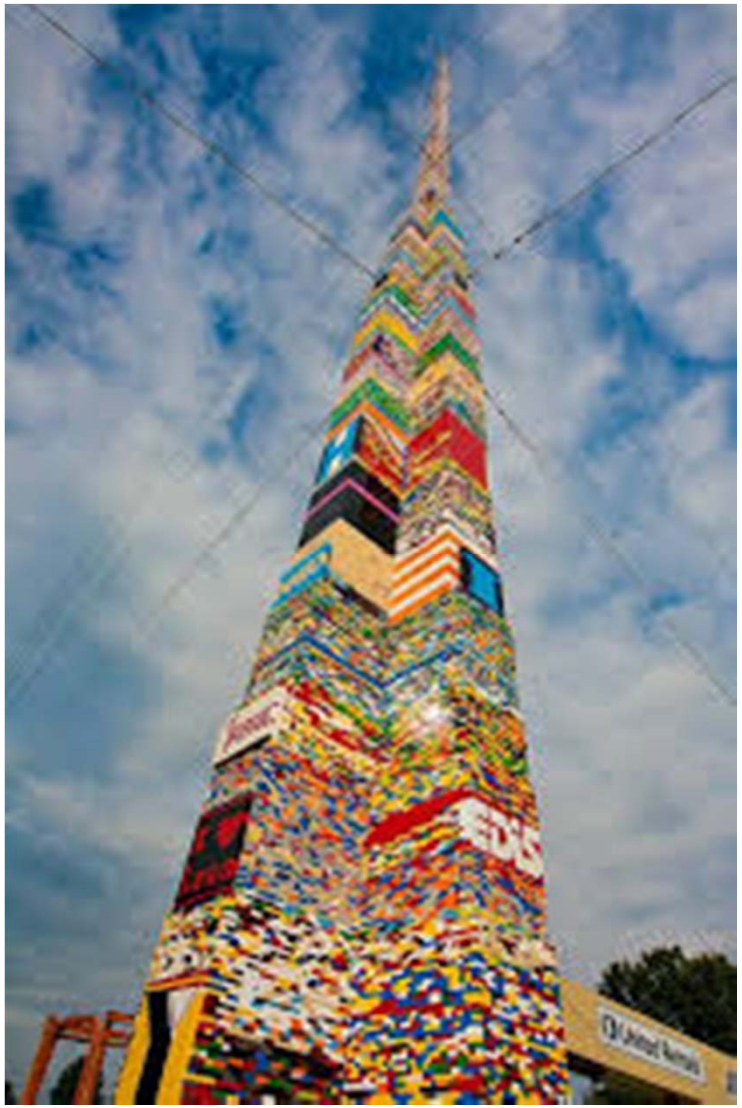
User Guides / Solution Kits



© CDISC 2015

Research Concepts





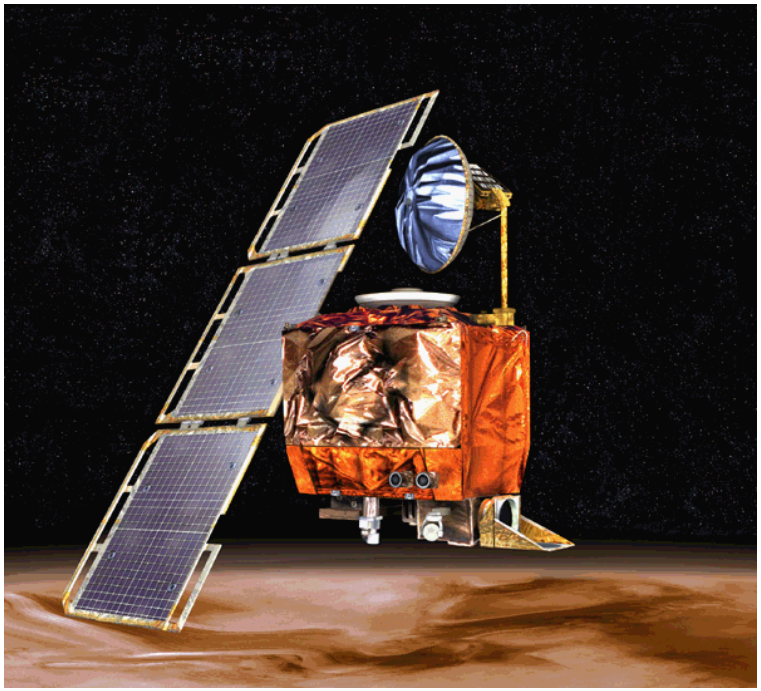
Begin with the End in Mind: How Important is Concept or Value-Level Metadata?

Event	Time	D	S	F
Begin	9/23/99 02:01:00	121,900,000	12,300	143.878
End	9/23/99 02:17:23		9,840	

Event	Time	D	S	F
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

Source: Dave Christiansen

In this case $125,000,000: Mars Climate Orbiter



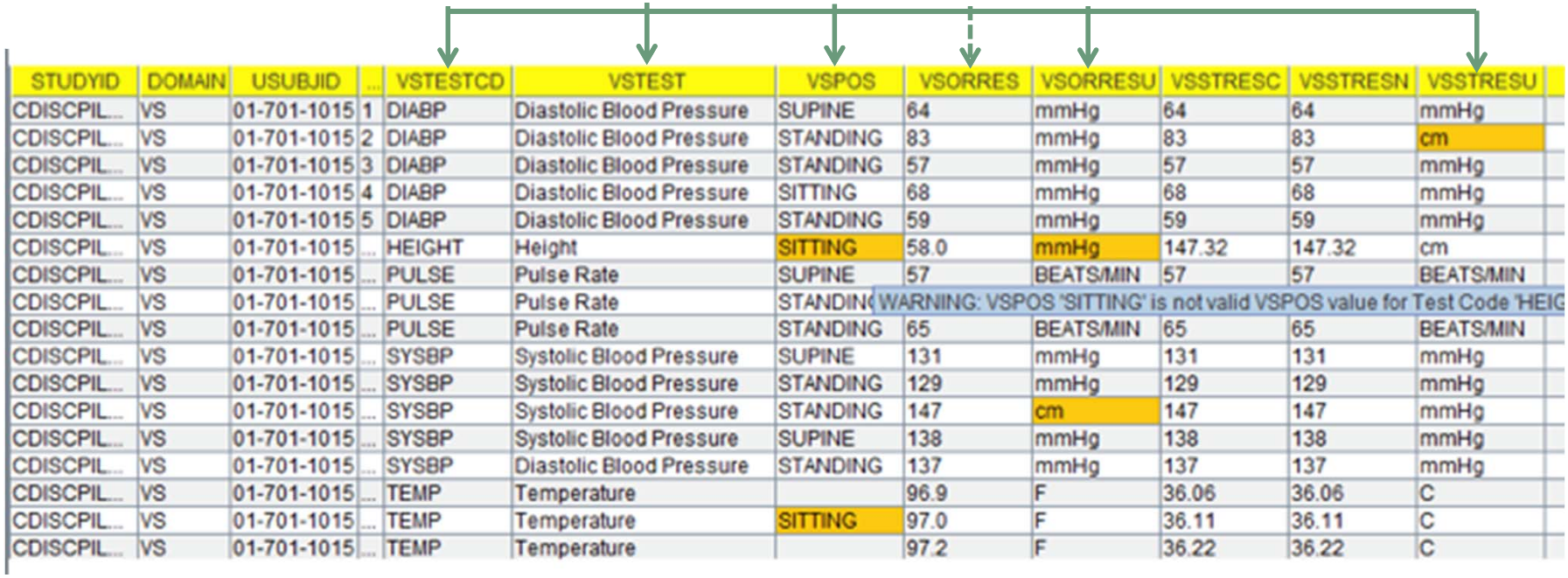
Mars Orbit Insertion Burn	M/D/Y HH:MM:SS PDT (Earth Receive Time, 10 min. 49 sec. Delay)	Distance (miles)	Speed (miles/hr)	Force (Pounds)
Begin	9/23/99 02:01:00	121,900,000	12,300	143.878
End	9/23/99 02:17:23		9,840	
Mars Orbit Insertion Burn	**YYYYMMDD EDT (Earth Receive Time, 10 min. 49 sec. Delay)**	**Distance (km)**	**Speed (km/sec)**	**Force (Newtons)**
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

Source: Dave Christiansen

© CDISC 2015

Research Concepts

Metadata set Components



STUDYID	DOMAIN	USUBJID	...	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
CDISCPIL...	VS	01-701-1015	1	DIABP	Diastolic Blood Pressure	SUPINE	64	mmHg	64	64	mmHg
CDISCPIL...	VS	01-701-1015	2	DIABP	Diastolic Blood Pressure	STANDING	83	mmHg	83	83	cm
CDISCPIL...	VS	01-701-1015	3	DIABP	Diastolic Blood Pressure	STANDING	57	mmHg	57	57	mmHg
CDISCPIL...	VS	01-701-1015	4	DIABP	Diastolic Blood Pressure	SITTING	68	mmHg	68	68	mmHg
CDISCPIL...	VS	01-701-1015	5	DIABP	Diastolic Blood Pressure	STANDING	59	mmHg	59	59	mmHg
CDISCPIL...	VS	01-701-1015	...	HEIGHT	Height	SITTING	58.0	mmHg	147.32	147.32	cm
CDISCPIL...	VS	01-701-1015	...	PULSE	Pulse Rate	SUPINE	57	BEATS/MIN	57	57	BEATS/MIN
CDISCPIL...	VS	01-701-1015	...	PULSE	Pulse Rate	STANDIN(	WARNING: VSPOS 'SITTING' is not valid VSPOS value for Test Code 'HEIG				
CDISCPIL...	VS	01-701-1015	...	PULSE	Pulse Rate	STANDING	65	BEATS/MIN	65	65	BEATS/MIN
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	SUPINE	131	mmHg	131	131	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	STANDING	129	mmHg	129	129	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	STANDING	147	cm	147	147	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Systolic Blood Pressure	SUPINE	138	mmHg	138	138	mmHg
CDISCPIL...	VS	01-701-1015	...	SYSBP	Diastolic Blood Pressure	STANDING	137	mmHg	137	137	mmHg
CDISCPIL...	VS	01-701-1015	...	TEMP	Temperature		96.9	F	36.06	36.06	C
CDISCPIL...	VS	01-701-1015	...	TEMP	Temperature	SITTING	97.0	F	36.11	36.11	C
CDISCPIL...	VS	01-701-1015	...	TEMP	Temperature		97.2	F	36.22	36.22	C

Source: Jozef Aerts (Adapted)

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A Voyage Through Visit Dates

What is the visit name?	Visit	VISIT	PlannedActivity.name*	A clinical encounter that encompasses planned and unplanned trial inventions, procedures, and assessments that may be performed on a subject.	When applicable (e.g., on paper CRFs), record the visit name.	This is typically pre-printed/pre-populated. *See the BRIDG model for complete path.
What is the visit number?	Visit Number	VISITNUM	PlannedSubjectActivityGroup.sequenceNumber	A number assigned to a clinical encounter.	When applicable (e.g., on paper CRFs), record the	This is typically pre-printed/pre-populated. ay be used to onological order counters.
What is the visit date?	Visit Date				format (DD-MON-YYYY).	collected are e should be collected some way. This may be done once for the visit using VISDAT or may be done at the CRF level using the domain-specific DAT field

CDASH: 15-APR-2015

VISITNUM	Visit Numb				Exp
VISIT	Visit Name			r. ISITDY.	Perm
VISITDY	Planned Stu			C in Demographics.	Perm
QSDTC	Date/Time of Finding	Char	ISO 8601	Timing	Date of questionnaire.	Exp

SDTM: 2015-04-15

ADT	Analysis Date	Num		Perm	The date associated with AVAL and/or AVALC in numeric format.	
AVISIT					ISIT), derived visit , Endpoint, etc.), or have to map to cord, but it does not	

ADaM: Integer with Format

SHARE and End-to-End Standards

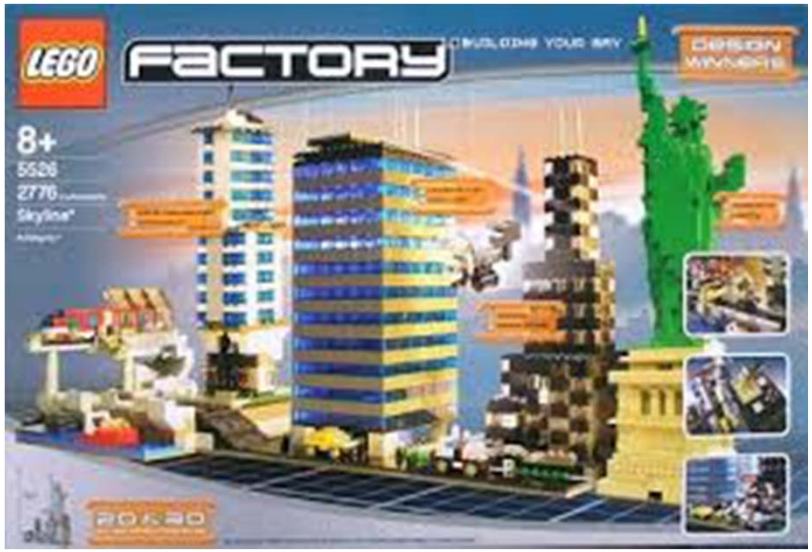
PEF

Each Visit

VS CRF Questions

RS Domain Records

△ ADEFF BDS
From Baseline



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--Public Review--

ADaM Integration-IADSL v1 Draft
Comments due 10 July 2015

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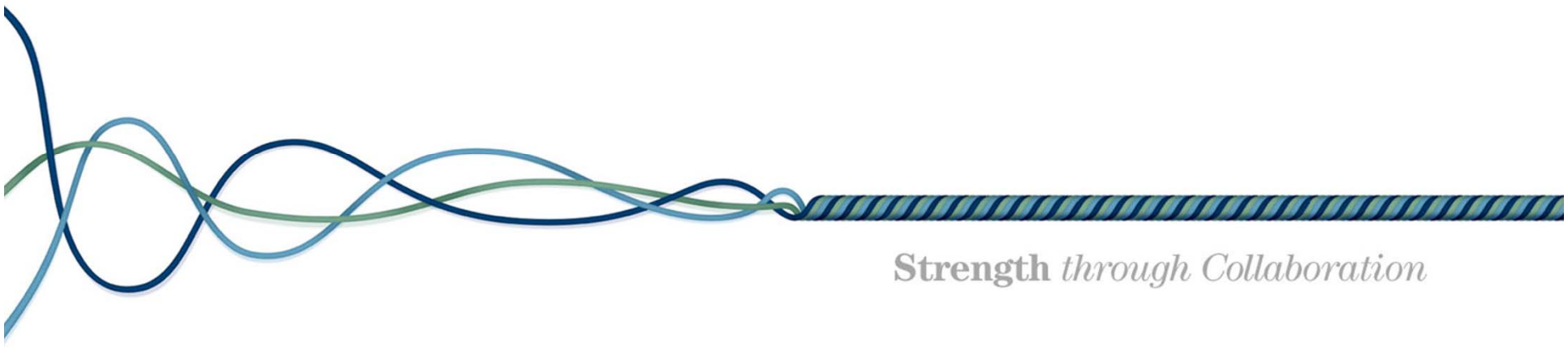
What is SHARE?



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Shared Health and Research Electronic Library (SHARE)

SHARE is a global electronic repository.

With SHARE, you can:

- Develop, integrate and access CDISC standards metadata in electronic format.
- Dramatically improve quality, reusability and integration across CDISC standards and controlled terminologies.
- Improve interoperability with healthcare.

SHARE is a prerequisite for standards-based automation, which is key to ROI from standards implementation

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eSHARE Content TODAY

eSHARE Content

- Foundational standards:
  - SDTM-IG 3.1.2, 3.1.3, 3.2, 3.3
  - CDASH 1.1
  - SEND-IG 3.0, 3.1
  - ADaM 2.1
- Medical Device standards
- Therapeutic Area Standards
- Controlled Terminology

eSHARE Formats

- ODM 1.3.2
- Define-XML v1.0
- Define-XML v2.0
- CSV
- Excel
- RDF/OWL
- Bundles

All standards will be loaded into SHARE prior to public review

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SHARE and Therapeutic Area Standards Development

TA Standards Available:

- Asthma
- Alzheimer's
- Virology
- Cardiovascular
- Diabetes
- Influenza
- Multiple Sclerosis
- QT
- Dyslipidemia
- CHCV

Future: TA Standards

- Specification documents generated from SHARE
- Metadata
  - CDASH, SDTM, & ADaM
- Examples
- Rules
- Biomedical Concepts
- Diff files
- Annotations

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What Can SHARE Do for *ME?*

© CDISC 2015

eSHARE Downloads Page

CDASH			eSHARE Standards Catalog	
Date Posted	**Content**	**Version**	**Type**	**Download Files**
CDASH 1.1				
2014-06-02	CDASH	1.1	Metadata	ODM v1.3.2 | CSV | Excel
2014-06-02	CDASH + CT	1.1+2013-12	Bundle	ODM | Excel
2014-06-02	CDASH	1.1	Document	PDF
2014-06-02	CDASH UG	1.1	Document	PDF
CDASH Terminology				
2015-04-10	CDASH Terminology	2015-03	Metadata	ODM v1.3.1 | RDF | Excel | Define-XML v2.0 | Diff
2014-10-17	CDASH Terminology	2014-09	Metadata	ODM v1.3.1 | RDF | Excel | Define-XML v1.0 | Define-XML v2.0
2014-10-17	CDASH Terminology	2014-03	Metadata	ODM v1.3.1 | RDF | Excel | Define-XML v1.0 | Define-XML v2.0
2014-06-02	CDASH Terminology	2013-12	Metadata	ODM v1.3.1 | RDF | Excel | Define-XML v1.0 | Define-XML v2.0
CDASH To SDTM Map				
2015-02-02	CDASH To SDTM Map	1.1 to 3.1.2	For Review	Excel

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eSHARE Content: *For Review & Experimental*

TAUG

Date Posted	Content	Version	Type	Download Files
Asthma 1.0				
2015-03-23	Asthma TA	1.0	For Review (Experimental)	**Asthma TAUG Metadata Bundle**
2015-04-28	Asthma TA	1.0 (Draft)	For Review	**Asthma TAUG Metadata**
2015-04-28	Alzheimer's TA	1.0 (Draft)	For Review	**Alzheimer's TAUG Metadata**
2015-04-28	SDTM UG	1.0 (Draft)	For Review	**Virology TAUG Metadata**
2015-05-05	Cardiovascular TA	1.0 (Draft)	For Review	**Cardiovascular TAUG Metadata**

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SHARE Tomorrow

- RDF
- Loaded Define-XML v2.0
- Biomedical Concepts
- Example repository
- Validation rules
- keyCRF / E2C content
- Controlled Terminology subsets
- SHARE API
- Standards governance workflow
- Standards request capture and process

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Early Evidence of Success

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Baseline Findings before SHARE

- Time component: “To update metadata through the manual process, **it takes an average of an hour per domain** depending on how many variables need to be added, and how many labels and descriptions need to be added.”

- Effort of QC: “This time [average of one hour] does not account for the occurrence of human error, for further QC to make sure all of the new domains and variables have been added, or for the time it takes to update old domains based on changes in the standard.”

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Early Examples of Demonstrated Value

- "Before the variables of the SDTM-IG were published electronically in eSHARE, it took me all my evenings during two weeks to copy and paste the information from a new SDTM-IG into my SDTM-ETL mapping software. After the variables were published in eSHARE as a worksheet, it took me just 2 hours.”

- "Once CDISC publishes the variables of the SDTM-IG as a Define-XML template, it will take me 2 minutes."

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That’s Exciting! Do I Have Access?

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CDISC Membership Benefits

eSHARE Access for Gold and Platinum CDISC Member Organizations

- ***New*** Access to eSHARE
- ***New*** ALL CDISC Standards
  - (Provisional and Final)
  - Foundational Standards
  - Terminology
  - Therapeutic Area Standards
  - Clinical Outcome Assessments and Questionnaires

SHARE is also Accessible to Academic Researchers

- ALL Formats, including Excel, XML, RDF, Define-XML, ODM, PDF, CSV
- Access to Members Only Area for all employees of member organizations
- Monthly Members Only Mini-Training Webinars on industry hot topics
- 20% Discounts on CDISC Training Courses and Events
- Opportunity to be a CDISC Registered Solution Provider; RSPs serve as subject matter resources to organizations who want to implement CDISC standards
- Opportunity for your database to be Operational Data Model (ODM) certified to improve the quality of metadata and data interchange throughout the clinical development process
- Enroll in the CDISC Licensed Training Program which allows your staff to become authorized instructors to do in-house training on CDISC standards
- Receipt of personalized Gold Member plaque

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Where is eSHARE?

- eSHARE exists as part of the CDISC web site
- Access to eSHARE can be found on CDISC.org under Members Only
  - http://www.cdisc.org
  - Select "MEMBERS ONLY"
  - Select "eSHARE Downloads"
- Or, by loading eSHARE directly
  - http://cdisc.org/eshare-downloads
- The eSHARE catalog is located at:
  - http://cdisc.org/cdisc-share

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How to Access eSHARE?

- Go to the CDISC web site and logon
  - Create your account if you haven't already
  - Use your corporate email account
  - http://cdisc.org
- Go to the eSHARE page using the URL
  - http://cdisc.org/eshare-downloads
- Agree to the EULA – End User License Agreement
  - Required the first time you access eSHARE

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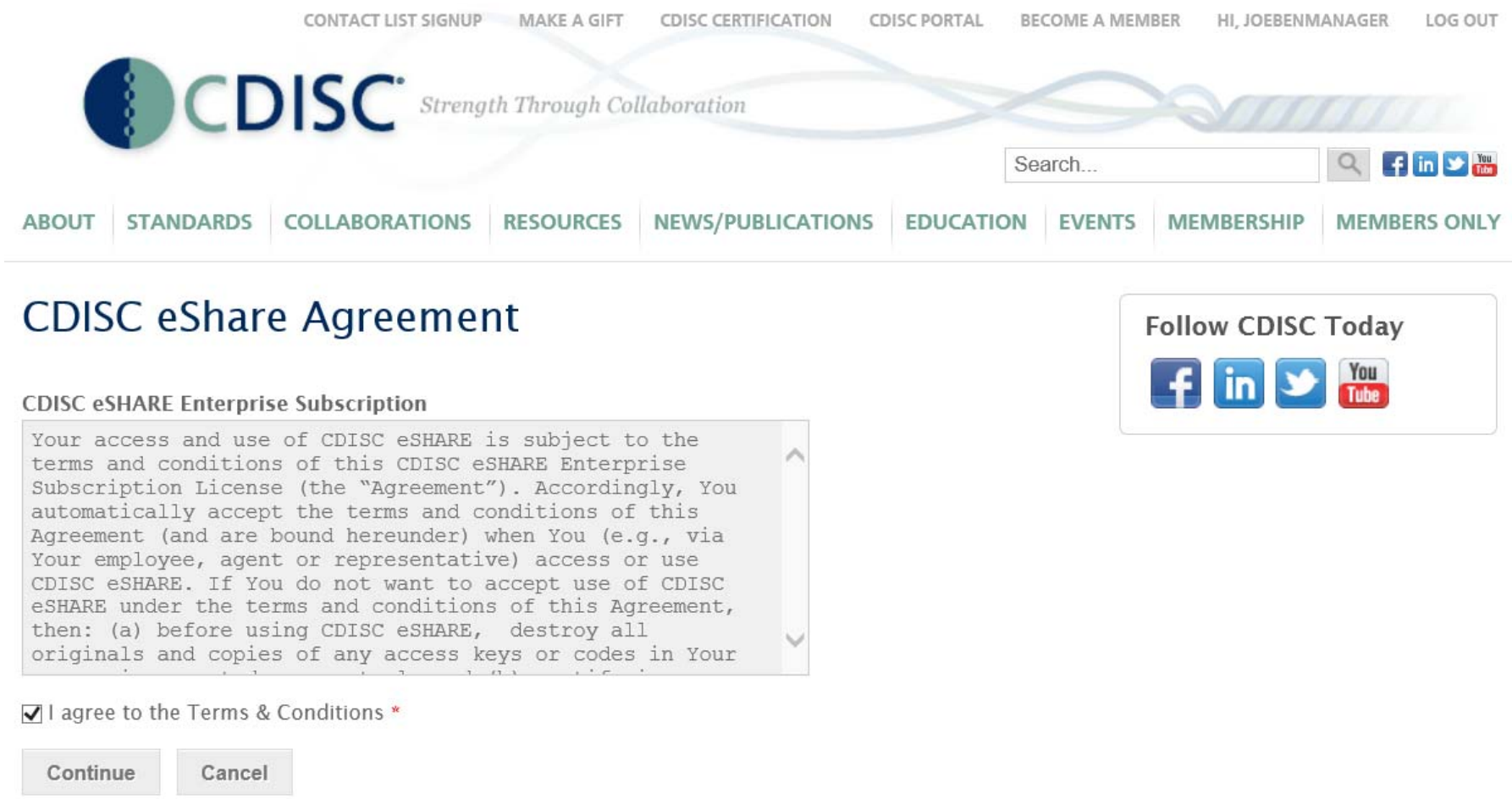
eSHARE End-User License Agreement



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I’d Like to be Involved!

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eSHARE Requests for Feedback

- Requests for specific content not currently published on eSHARE, or feedback on current content

- Feedback on how to change or improve existing content
  - Create a JIRA issue
    - Jira.cdisc.org
    - SHARE project
  - Email me: shume@cdisc.org

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Keep up with eSHARE News

- Periodically check the website
  - http://cdisc.org/cdisc-share
- CDISC Newsletter
- Follow our Social Media:
  - Twitter: follow @CDISC, @cdiscSHARE, @swhume
  - LinkedIn Group: CDISC
  - CDISC Facebook Group
- SHARE space on the CDISC Wiki
  - http://wiki.cdisc.org
- Sam's blog on SHARE topics
  - http://mungingmetadata.blogspot.com/

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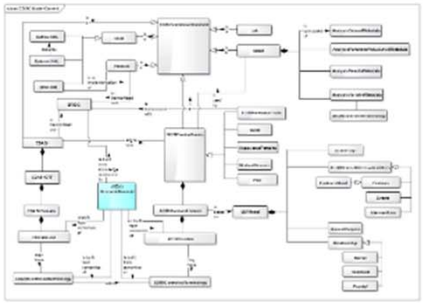
CDISC Wiki Spaces People Polls Calendars Browse Create

SHARE

SHARE Home

Edit Watch Share Tools

Added by Max Kanevsky, last edited by Julie Chason on May 05, 2015 (view change)



Quick Links

SHARE R3 Progress Report for Q2

SHARE page at CDISC website

eSHARE Downloads (CDISC Platinum Members)

FAQ

Blog

Volunteer for CDISC

Sub-Team Roster

How To: Log SHARE Review Comments in CDISC JIRA

Metadata Listing (Domain Catalog, SUPPQUAL Listing)

SHARE Wiki

Planning

R2 Milestones

SHARE Release 3

Wish List

CDISC Standards: Content and Meeting Notes

SDTM

SEND

ADaM

Therapeutic Area User Guides

Research Concepts

- RC Pilots

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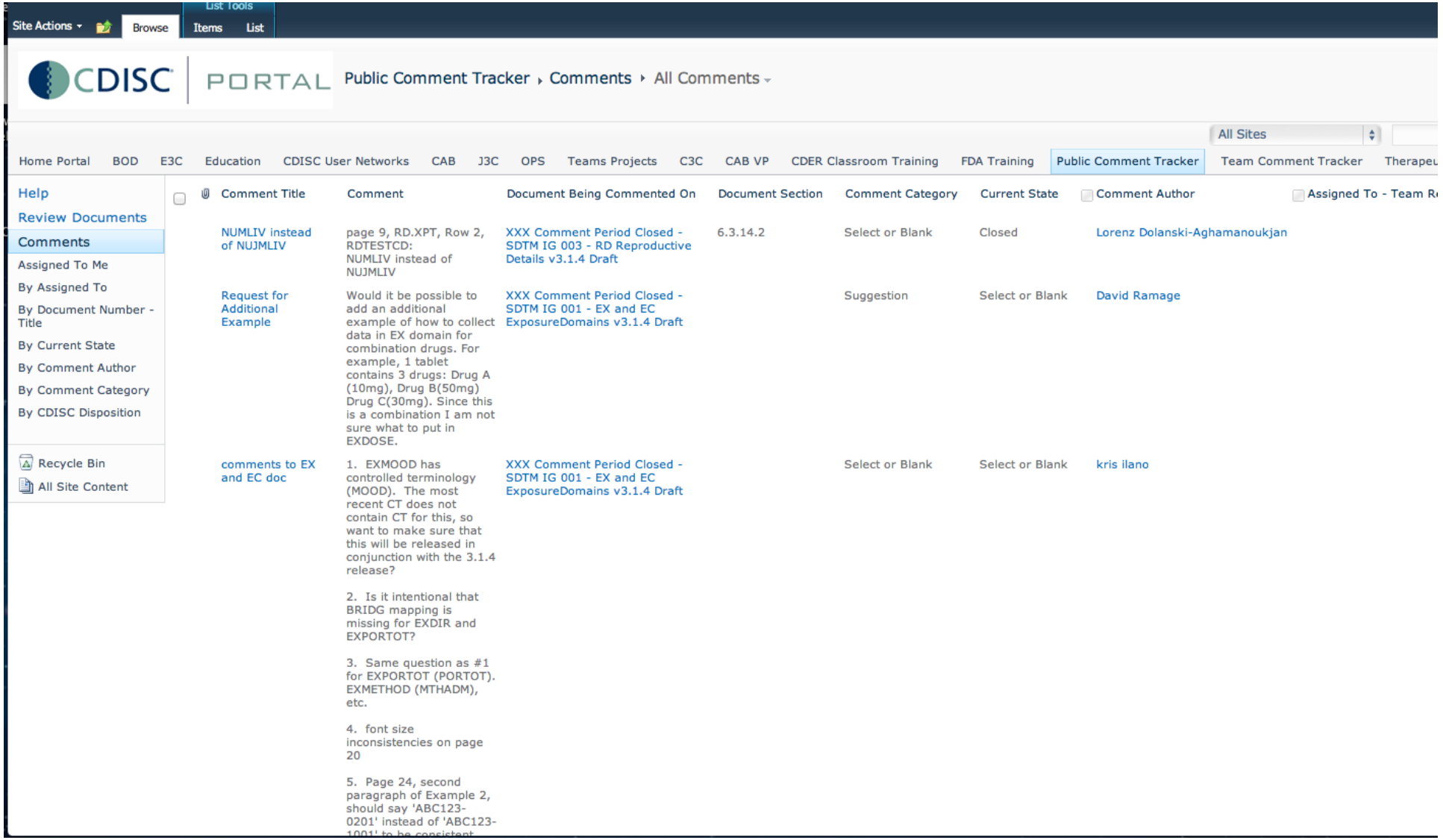
Public Comment Tracker – CDISC Needs You!



CDISC Wiki Spaces People Calendars Create

Dashboard

Welcome to CDISC Wiki

CDISC Wiki contains information relevant to CDISC standards and the activities of CDISC standards development teams. Please get involved and add your voice to the CDISC Community toward the advancement and increased use of CDISC standards worldwide. Volunteer Today!

2014 CDISC INTRAChange 25-27 February

2014 CDISC INTRAChange 25-27 February Home

2 Added by Amy Palmer, last edited by Wayne Kubick on Apr 02, 2014 (view change)

2014 CDISC Winter IntraChange: *Learn, Meet, Interact*

Final IntraChange Agenda and Rooms

Spaces Pages Network

Site Spaces

- 2014 CDISC INTRAChange 25-27 February
- Asthma
- CDASH
- CFAST
- CFAST TAPSC
- Define.xml

Popular | All Updates | Favourite Spaces | Network

Gary Walker
SDTM Rule Discussion Items
Updated 17 minutes ago (view change)

Alana St. Clair
2014-03-24 Terminology - CFAST PM Meeting Notes
Updated about an hour ago (view change)

John Glover
Re: CFAST TA Program Status Table
John updated notes section for LLD. 4 clinical experts to 3 and DB search date from 17Mar14 to week of 31Mar14.
Commented about 4 hours ago
CFAST TA Program Status Table
Updated about 4 hours ago (view change)

Anthony Chow
Installing SOA Rich Clients
Updated Mar 29, 2014 (view change)

Alana St. Clair
2014-03-25 Meeting Notes
Task marked complete
Updated Mar 29, 2014 (view change)
Volunteer Coordination Home

Annual Public Report

CONTACT LIST SIGNUP MAKE A GIFT

CDISC Strength Through Collaboration

ABOUT | STANDARDS | COLLABORATIONS | RESOURCES

Public Courses in Paris, France

Sanofi
1 Avenue Pierre Brossolette
Chilly-Mazarin 91385
France

Course Information:
Name: 2-day SDTM Theory and Application
Date/Time: 7-8 Mar 2016; 09:00-17:00
Instructor: Niels Both
Course Language: English

Name: 1/2-day ADaM Primer
Date/Time: 9 Mar 2016, 13:00-17:00
Instructor: Niels Both
Course Language: English

Name: 1-day ADaM Theory and Application
Date/Time: 10 Mar 2016; 09:00-17:00
Instructor: Niels Both
Course Language: English

Name: 1-day Define-XML
Date/Time: 11 Mar 2016; 09:00-17:00
Instructor: Jozef Aerts
Course Language: English

Register by 6 Feb 2016 to avoid late registration fees

Registration for Payment by Credit Card
Registration for Payment by Invoice
Course Fees

Hosted by:

SANOFI

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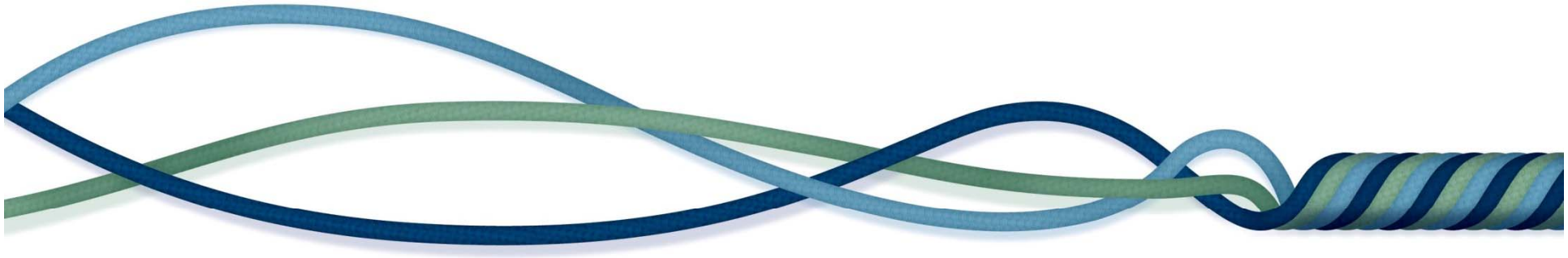
Merci pour votre attention!

pierre-yves.lastic@sanofi.com



Strength *through collaboration.*

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