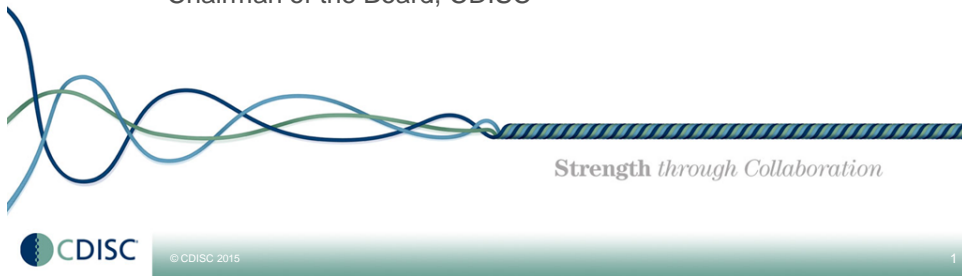




GRUPE DES UTILISATEURS FRANCOPHONES  
DES STANDARDS CDISC, Genève, 28 septembre 2015

## CDISC en 2015: Avancement des projets et orientations pour le futur

**Pierre-Yves Lastic**  
Chief Privacy Officer, Sanofi  
Chairman of the Board, CDISC



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1

## 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 (>300 academia, biopharma, service providers)
- Associations with ISO TC 215 (Liaison A), HL7 Joint Initiative Council, IHE, NCI-EVS, CFAST, IMI, PhUSE, others
- Coordinating Committees in Europe, China, Japan, others
  - Participants from > 90 countries
- Standards freely available.



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



2

## CDISC Board of Directors

### *CDISC Executive Committee:*

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- *Chair-elect:* Dr. David Hardison, Deloitte
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- *Executive Director:* Nicole Harmon, CDISC

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- Nevine Zariffa, Astra Zeneca

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- Jonathan Chainey, F. Hoffmann-La Roche



## Board Meeting Topics

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



# CDISC Strategic Goals 2015-2017

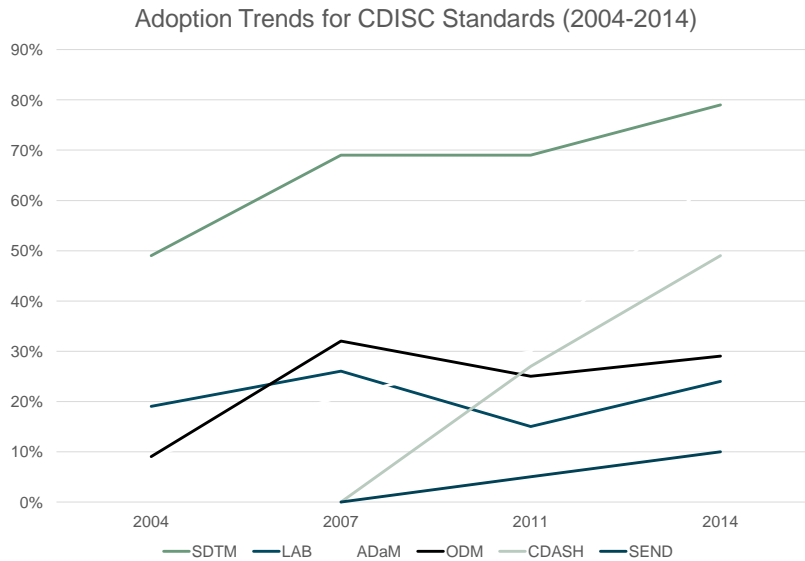
## #1

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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5



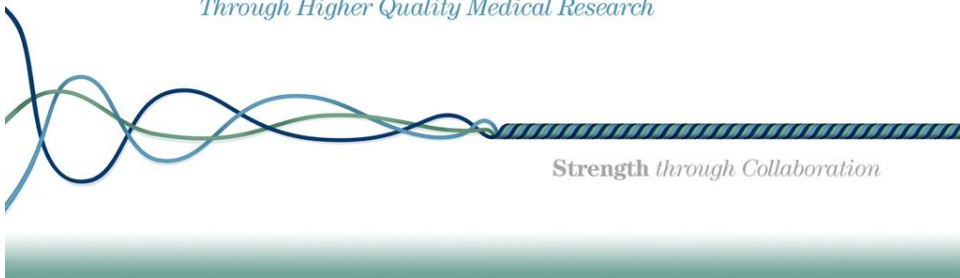
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2014 Data from recent Tufts CSDD Survey



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

*The CDISC Vision is to Inform Patient Care & Safety  
Through Higher Quality Medical Research*



*Strength through Collaboration*

## CDISC Interchanges in 2015



**Europe Interchange**  
Basel, Switzerland  
3-7 May 2015

**Japan Interchange**  
Tokyo, Japan  
22-26 June 2015



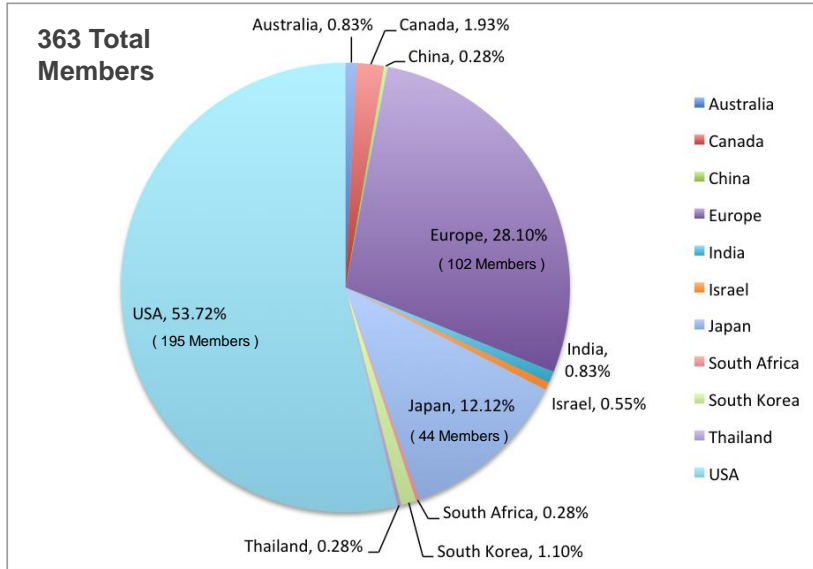
**International Interchange**  
Chicago, Illinois, USA  
9-13 November 2015



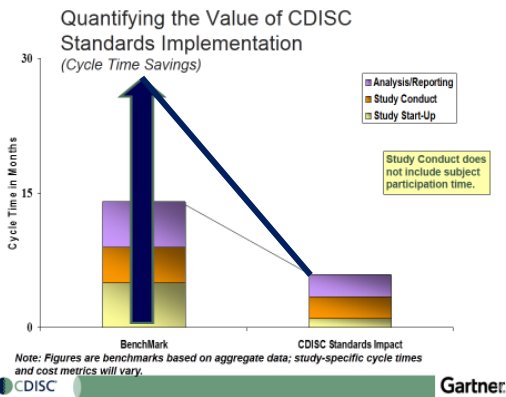
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## Members by Country – 31 March 2015



## The Value of Using Standards from the Start



### 2007 CDISC Business Case

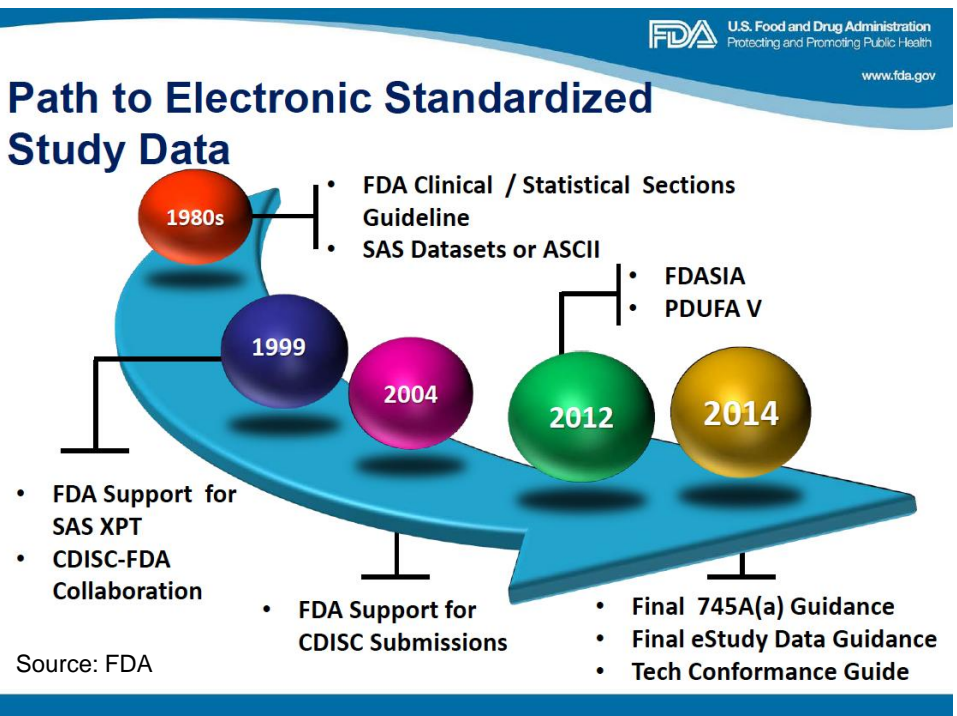
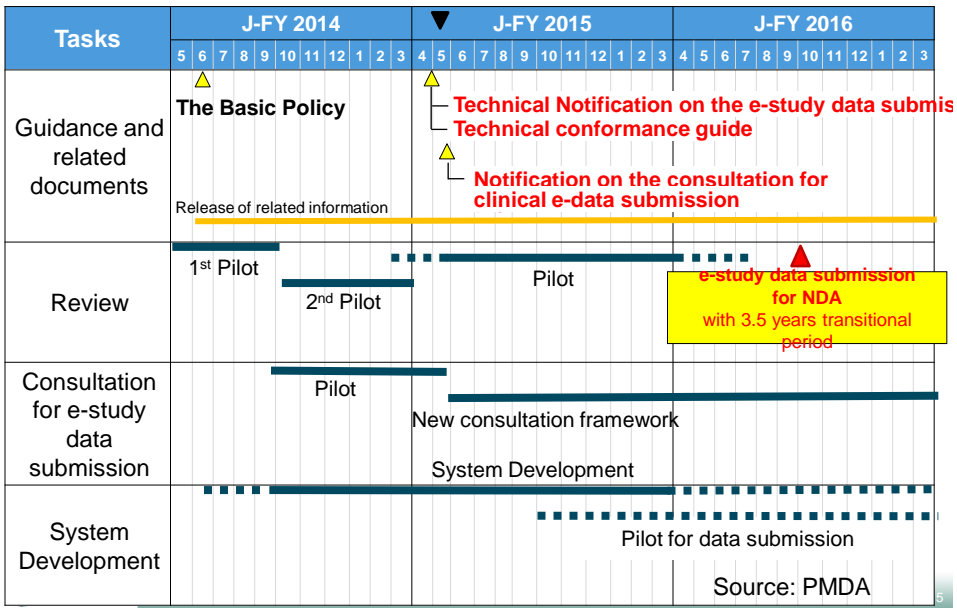
### 2014 Business Case

#### Current Landscape

**2014**

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

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



## 2015 Guiding Themes for Standards Development

- Transparency
  - Share all, requirements and plans in advance; invite feedback
  - Make it easier for global participants to get more involved
- Agility - Scrum for standards development
  - Expand use of collaboration tools to improve team interactions
  - Smaller teams, scrum sprints, through JIRA
  - Get content into SHARE early – as soon as its stable
  - Rollout SHARE Collaborative Curation Initiative – to rapidly fill gaps in content
  - Engage a second class of Fellows
- Focus and Execution
  - Do what's necessary so industry and regulatory authorities get what they need when they need it to better realize the benefits of CDISC standards



## Keeping up with CDISC Standards

NEWSLETTER SIGNUP MAKE A GIFT CDISC CERTIFICATION CDISC PORTAL BECOME A MEMBER HI, WAYNE LOG OUT

**CDISC** Strength Through Collaboration

Search...

ABOUT ABOUT STANDARDS COLLABORATIONS RESOURCES NEWS/PUBLICATIONS EDUCATION EVENTS MEMBERSHIP MEMBERS ONLY

### Technical Plan Updates

The CDISC Technical Plan deliverables for 2015 are posted sequentially as technical roadmaps are formulated, and standards are published.

Because project availability of content is checked regularly

[Technical Plan Update](#)

**Why** [Technical Update](#)

**Now / Guide** [Monthly Technical Plan Update](#)

**New for PL**

- [Technical Update](#)
- [Technical Update](#)
- [Technical Update](#)
- [Technical Update](#)
- [Technical Update](#)

**CDISC of CD**

### CDISC Technical Update - June 2015

**Semantics:**

- Terminology Package 23, with 210 new terms, will be posted for comment in late June.

**Therapeutic Areas:**

- The provisional CFAST TAUG for Chronic Hepatitis C was released on May 8.
- The provisional CFAST TAUGs for Schizophrenia and Dyslipidemia are being readied for publication in June.
- Next up is the CFAST TAUGs for Traumatic Brain Injury, expected to go to public comment in June.

**Foundational Standards:**

- The ADaM v1.3 validation checks were posted on May 16.
- The ADaM Structure for Occurrence Data (OCCDS), which extends the ADaM ADAE Data Structure to other occurrence data such as ConMeds, should be published in June.
- Next up from ADaM is the draft ADaM Data Structure for Integration (ADSL), due to be posted for comment in June.
- The CDISC PGx team is finalizing the provisional version of the SDTMIG for Pharmacogenomics/Genetics data for publication in early June.



## Progress Update – Foundational Standards

### Four Foundational Products Released in 2014-2015:

- Dataset-XML v1 Final
- SDTMIG 3.3 Batch 1 (7 draft domains)
- SDTMIG 3.3 Batch 2 (Milestones, 2 Domains)
- SDTM v1.5
- Pharmacogenomics SDTMIG v1
- SEND v3.1 Draft B
- SEND DART (Reproductive Toxicology)
- ADaM Results Metadata Spec for Define-XML
- ADaM IG v1.1 Draft
- ADaM Occurrence Data Structure v1
- ADaM v1.3 Validation Checks
- ADaM Data Structure for Integration (ADSL)
- CDISC in RDF (PhUSE)
- BRIDG R4
- Periodic Terminology and QRS Packages
- Updated COP and Process Docs

### Upcoming Major New Drafts for Comment:

- CTReg XML Schema
- SDTMIG Batch 3 and Conformance Rules
- Define-XML v2.1 and IG



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**CFAST Therapeutic-Area Data Standards:**

*It's about Patients, People!*



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Therapeutic Area	Coordinating Organization/PM	Notes
Traumatic Brain Injury v1	CDISC Amy Palmer	PR: July 21-Sep 21 (60 days)
Breast Cancer v1	CDISC John Owen	RC review for PR Aug 10
COPD v1	CDISC Sherwood Barbee	R: July 10-July 31
ADaM Supp to Diabetes v1	TCB Rachael Zirkle	PR: July 20-Aug 21
Virology v2	C-Path Laura Butte	PR: July 21-Aug 24
Diabetic Kidney Disease v1	TCB Rachael Zirkle	R start goal: mid-Sept
Tuberculosis v2	C-Path Laura Butte	R start goal: early-Sept
Rheumatoid Arthritis v1	TCB Trisha Simpson	Charter approved 7/9
CV Imaging v1	CDISC Amy Palmer	
Prostate Cancer v1	CDISC John Owen	
Major Depressive Disorder	CDISC Amy Palmer	
General Anxiety Disorder	CDISC Amy Palmer	
Bi-Polar Disease	CDISC Amy Palmer	

**TAUGs released in 2014-2015:**

- Multiple Sclerosis
- Diabetes
- Cardiovascular
- Influenza
- QT Studies
- **Chronic Hep-C**
- **Schizophrenia**
- **Dyslipidemia v1**

**Upcoming Provisionals:**

- *Virology v2*
- *Diabetes ADaM Supplement*
- *Traumatic Brain Injury*

**Upcoming Drafts:**

- *Breast Cancer*
- *COPD*

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

July 22, 2015

\*The Stage 3b concludes at the end of the 30-day review period and Stage 3c concludes when all tasks have been completed and the standard is publicly available.  
\*\* Specific projected publication dates to be added to the notes section at the conclusion of Stage 3b.

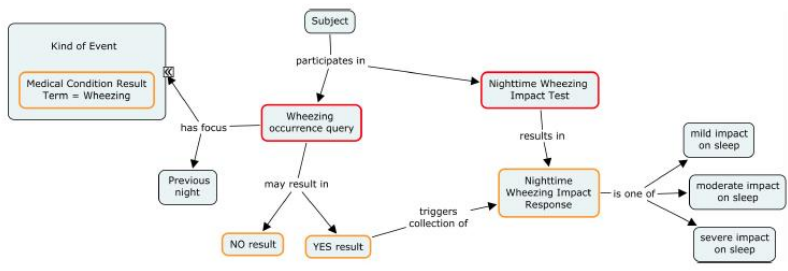
## Asthma User Guide Example

### 5 Symptom Assessment

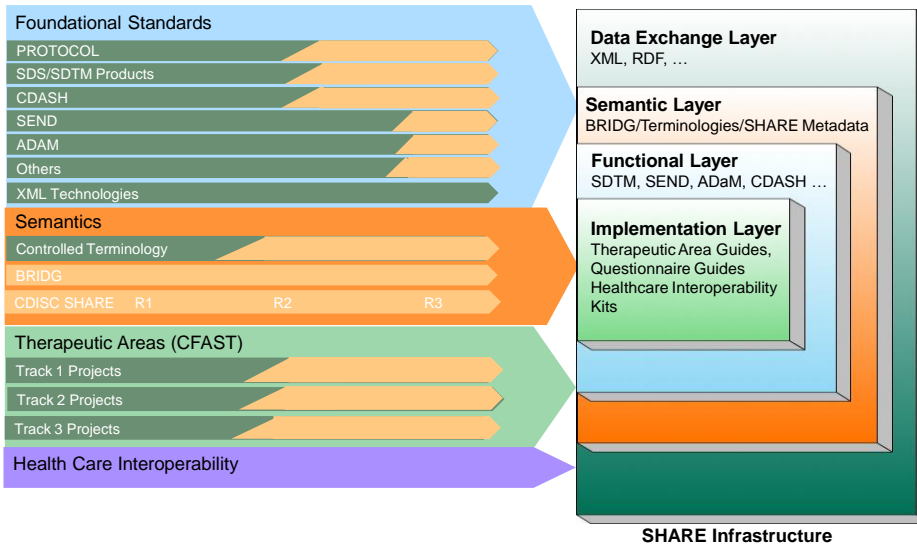
Asthma symptoms can present in various forms. The most common symptoms of asthma are wheezing, cough, breathlessness, chest tightness and night time awakenings. These symptoms are often assessed using validated instruments as described in the section on Patient Reported Outcomes. They may also be described using sponsor-defined Likert scales or visual analog scales.

Symptom	Closest MedDRA LLT	MedDRA Preferred Term
Wheezing	Wheezing	Wheezing
Cough	Cough	Cough
Breathlessness	Breathlessness	Dyspnoea
Chest tightness	Chest tightness	Chest discomfort
Nighttime awakening	Nocturnal awakening	Middle Insomnia

Data typically collected for asthma symptoms include the focal time period and the subject's rating of symptom severity or symptom impact. Occurrence is sometimes combined with severity or impact by including a value of "None" or "Absent" in the set of severity or impact responses.



# CDISC Technical Roadmap - 2015



The Roadmap depicts evolution from siloed standards to an integrated stack based on BRIDG and SHARE



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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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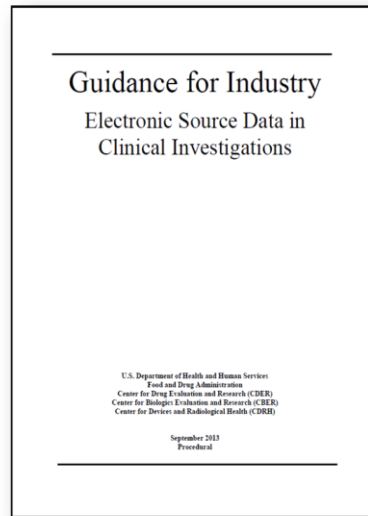


09 June 2010  
 EMA/INS/GCP/454280/2010  
 GCP Inspectors Working Group (GCP IWG)  
 Date for coming into effect 01 August 2010

**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/be850811feb48f381f0af41ca40ade2emisc/cdisc\\_2009\\_glossary.pdf](http://www.cdisc.org/stuff/contentmgr/files/0/be850811feb48f381f0af41ca40ade2emisc/cdisc_2009_glossary.pdf)
3. **CDISC e-source standard requirements**-CDISC (Clinical Data Interchange Standards Consortium) Version 1.0 20 November 2006.

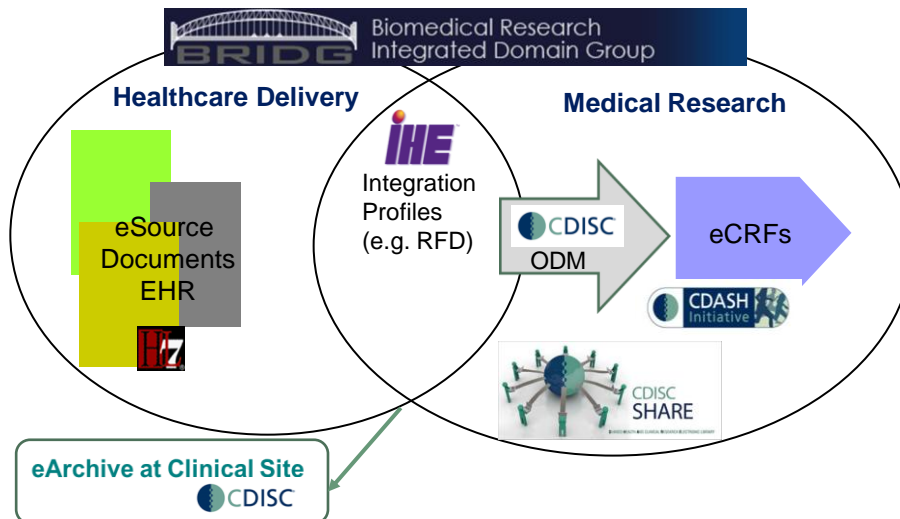


**eSource = data entered electronically first, i.e.EHRs, eDiaries....**



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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)



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



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-

cal 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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## 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.

**“Data are More Meaningful when SHARE’d”**



See the SHARE video on the CDISC website – [www.cdisc.org](http://www.cdisc.org).

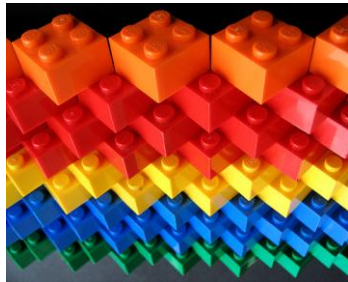
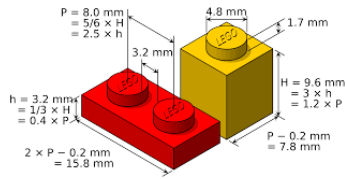
## SHARE Through the Eyes of a Child



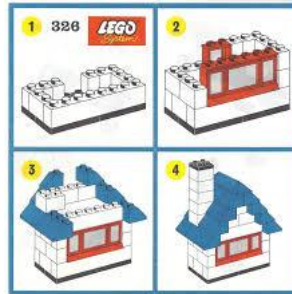
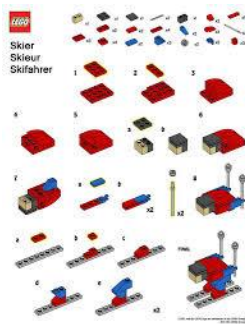
## A World Without Data Standards



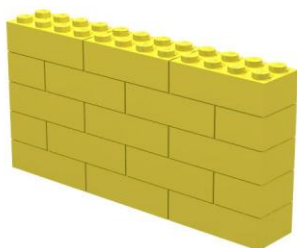
# Elements, Metadata, Terminology



# User Guides / Solution Kits



## Research Concepts



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### 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	

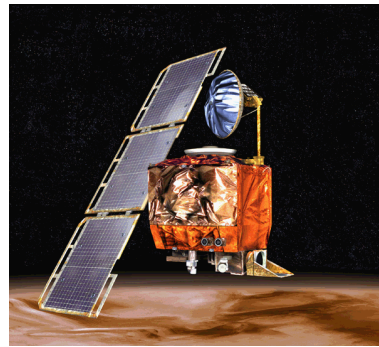
Event	Time	D	S	F
Start	19990923 05:01:00	196,200,000	5.5	640
Finish	19990923 05:17:23		4.4	

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	



© CDISC 2015

Source: Dave Christiansen

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## Research Concepts

Metadata set Components

STUDYID	DOMAIN	USUBJID	VSTESTCD	VSTEST	VSPPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
CDISCPIL	VS	01-701-1015	1	DIABP	Diastolic Blood Pressure	SUPINE	64	mmHg	64	mmHg
CDISCPIL	VS	01-701-1015	2	DIABP	Diastolic Blood Pressure	STANDING	83	mmHg	83	cm
CDISCPIL	VS	01-701-1015	3	DIABP	Diastolic Blood Pressure	STANDING	57	mmHg	57	mmHg
CDISCPIL	VS	01-701-1015	4	DIABP	Diastolic Blood Pressure	SITTING	68	mmHg	68	mmHg
CDISCPIL	VS	01-701-1015	5	DIABP	Diastolic Blood Pressure	STANDING	59	mmHg	59	mmHg
CDISCPIL	VS	01-701-1015		HEIGHT	Height	SITTING	59.0	mmHg	147.32	147.32
CDISCPIL	VS	01-701-1015		PULSE	Pulse Rate	SUPINE	57	BEATS/MIN	57	BEATS/MIN
CDISCPIL	VS	01-701-1015		PULSE	Pulse Rate	STANDING	WARNING: VSPPOS 'SITTING' is not valid VSPPOS value for Test Code 'HEIG'			
CDISCPIL	VS	01-701-1015		PULSE	Pulse Rate	STANDING	65	BEATS/MIN	65	BEATS/MIN
CDISCPIL	VS	01-701-1015		SYSBP	Systolic Blood Pressure	SUPINE	131	mmHg	131	mmHg
CDISCPIL	VS	01-701-1015		SYSBP	Systolic Blood Pressure	STANDING	129	mmHg	129	mmHg
CDISCPIL	VS	01-701-1015		SYSBP	Systolic Blood Pressure	STANDING	147	cm	147	mmHg
CDISCPIL	VS	01-701-1015		SYSBP	Systolic Blood Pressure	SUPINE	138	mmHg	138	mmHg
CDISCPIL	VS	01-701-1015		SYSBP	Diastolic Blood Pressure	STANDING	137	mmHg	137	mmHg
CDISCPIL	VS	01-701-1015		TEMP	Temperature		96.9	F	36.06	36.06
CDISCPIL	VS	01-701-1015		TEMP	Temperature	SITTING	97.0	F	36.11	36.11
CDISCPIL	VS	01-701-1015		TEMP	Temperature		97.2	F	36.22	36.22

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 interventions, 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.
What is the visit date?	Visit Date				format (DD-MON-YYYY).	collected are : 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 VISDAT field.
VISITNUM	Visit Number					Exp
VISIT	Visit Name					Perm
VISITDY	Planned Status					Perm
QSDTC	Date/Time of Finding	Char	ISO 8601	Timing	Date of questionnaire.	Exp
ADT	Analysis Date	Num		Timing	The date associated with AVAT and/or AVAT.C in standard format.	
AVISIT						TSIT, derived visit, Endpoint, etc.), or have to map to record, but it does not

CDASH: 15-APR-2015

SDTM: 2015-04-15

ADaM: Integer with Format



# SHARE and End-to-End Standards



PEF

Each Visit

VS CRF Questions

RS Domain Records

△ ADEFF BDS From Baseline



## CDISC SHARE



### What is SHARE?

CDISC SHARE, a cornerstone of the CDISC technical roadmap, is a global electronic repository for developing, integrating and accessing CDISC metadata standards in electronic format. SHARE is envisioned to help users find, understand and use rich metadata and controlled terminologies relevant to clinical studies more efficiently and consistently, and to improve integration and traceability of clinical data from protocol through analysis.

### 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

CDISC eSHARE Downloads Now Available for Platinum Members!

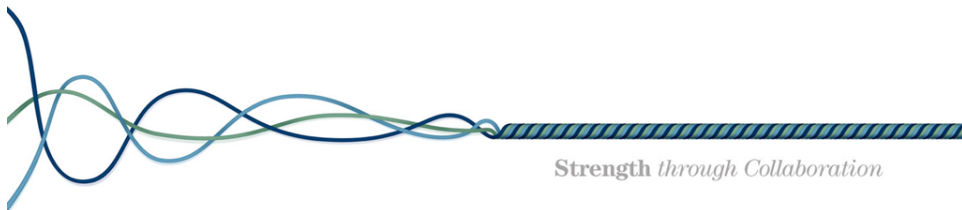
*If your organization is a Platinum member, please sign in with your organization's email address.*

### Volunteer for CDISC

#### SHARE Related Downloads / Links

- [eSHARE Content Catalog](#)
- [Subscribe to SHARE\\_News](#)
- [Volunteer for SHARE](#)
- [SHARE on CDISC Wiki](#)
- [CDISC SHARE Video](#)
- [SHARE Requirements \(pdf\)](#)
- [2013 International Interchange SHARE Presentation \(pdf\)](#)

## What is SHARE?



*Strength through Collaboration*

## 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*

## 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*

# 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

## What Can SHARE Do for *ME*?



## eSHARE Downloads Page

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



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## eSHARE Content: *For Review & Experimental*

TAUG				
Date Posted	Content	Version	Type	Download Files
<b>Asthma 1.0</b>				
2015-03-23	Asthma TA	1.0	For Review (Experimental)	<a href="#">Asthma TAUG Metadata Bundle</a>
2015-04-28	Asthma TA	1.0 (Draft)	For Review	<a href="#">Asthma TAUG Metadata</a>
2015-04-28	Alzheimer's TA	1.0 (Draft)	For Review	<a href="#">Alzheimer's TAUG Metadata</a>
2015-04-28	SDTM UG	1.0 (Draft)	For Review	<a href="#">Virology TAUG Metadata</a>
2015-05-05	Cardiovascular TA	1.0 (Draft)	For Review	<a href="#">Cardiovascular TAUG Metadata</a>



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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

## Early Evidence of Success



## 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.”

## 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."



## Calling All SHARE Users!

CDISC is currently working to develop the SHARE API functionality to enable automated access to the CDISC standards.

CDISC is currently seeking additional metrics around time and cost savings associated with use of SHARE, particularly as we begin to offer an increasing number of value-added products to SHARE.

If you should like to share the value you have found through use of SHARE, please contact [communications@cdisc.org](mailto:communications@cdisc.org).

## That's Exciting! Do I Have Access?



## CDISC Membership Benefits

### Gold Level

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

### eSHARE Access Starting Today



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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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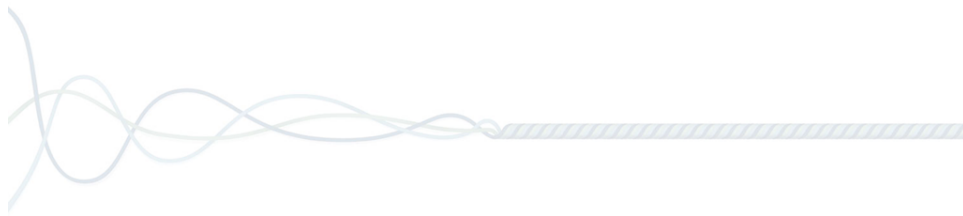
# How to Access eSHARE?

- 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

## eSHARE End-User License Agreement

The screenshot shows the CDISC website header with navigation links: CONTACT LIST SIGNUP, MAKE A GIFT, CDISC CERTIFICATION, CDISC PORTAL, BECOME A MEMBER, HI, JOEBENMANAGER, LOG OUT. The CDISC logo and tagline "Strength Through Collaboration" are prominent. A search bar and social media icons (Facebook, LinkedIn, Twitter, YouTube) are visible. The main navigation menu includes: ABOUT, STANDARDS, COLLABORATIONS, RESOURCES, NEWS/PUBLICATIONS, EDUCATION, EVENTS, MEMBERSHIP, MEMBERS ONLY. The page title is "CDISC eShare Agreement". A section titled "CDISC eSHARE Enterprise Subscription" contains the following text: "Your access and use of CDISC eSHARE is subject to the terms and conditions of this CDISC eSHARE Enterprise Subscription License (the "Agreement"). Accordingly, You automatically accept the terms and conditions of this Agreement (and are bound hereunder) when You (e.g., via Your employee, agent or representative) access or use CDISC eSHARE. If You do not want to accept use of CDISC eSHARE under the terms and conditions of this Agreement, then: (a) before using CDISC eSHARE, destroy all originals and copies of any access keys or codes in Your...". Below the text is a checkbox labeled "I agree to the Terms & Conditions" which is checked. At the bottom are "Continue" and "Cancel" buttons.

## I'd Like to be Involved!



## 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](http://Jira.cdisc.org)
    - SHARE project
  - Email me: [shume@cdisc.org](mailto:shume@cdisc.org)

## 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 Home

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

CDISC SHARE SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

**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!

Comment Title	Comment	Document Being Commented On	Document Section	Comment Category	Current State	Comment Author	Assigned To - Team R
NUNMLV instead of NUJMLV	page 9, RD.XFT, Row 2, RDTESTCD: NUNMLV instead of NUJMLV	XXX Comment Period Closed - SDTM IG 003 - RD Reproductive Details v3.1.4 Draft	6.3.14.2	Select or Blank	Closed	Lorenz Dolanski-Aghamanoukjan	
Request for Additional Example	Would it be possible to add an additional example of how to collect data in EX domain for combination drugs. For example, 1 tablet contains 3 drugs: Drug A (10mg), Drug B(50mg) Drug C(Dmg). Since this is a combination I am not sure what to put in EXCODE.	XXX Comment Period Closed - SDTM IG 001 - Ex and EC ExposureDomains v3.1.4 Draft		Suggestion	Select or Blank	David Ramage	
comments to EX and EC doc	<ol style="list-style-type: none"> <li>EXNODD has controlled terminology (NODD). The most recent CT does not contain CT for this, so want to make sure that this will be released in conjunction with the 3.1.4 release?</li> <li>Is it intentional that BRIDC mapping is missing for EXDIR and EXPORTOT?</li> <li>Same question as #1 for EXPORTOT (PORTOT), EXMETHOD (MTRADIR), etc.</li> <li>font size inconsistencies on page 20</li> <li>Page 24, second paragraph of Example 2, should say "ABC123-0201" instead of "ABC123-1001" in the paragraph.</li> </ol>	XXX Comment Period Closed - SDTM IG 001 - Ex and EC ExposureDomains v3.1.4 Draft		Select or Blank	Select or Blank	kris ilano	



## 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

2014 CDISC Winter IntraChange: Learn, Meet, Interact

Final IntraChange Agenda and Rooms

spaces | #tags | 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





**Strength *through* collaboration.**