

CDISC Public Webinar – Standards Updates and Additions

11 June 2015



Strength through Collaboration

Agenda

- Quarterly Technical Updates
 - Wayne Kubick, CDISC
- Traumatic Brain Injury TAUG (Public Review)
 - Amy Palmer, CDISC
 - Steve Kopko, CDISC
 - Dana Booth, CDISC
- CDISC Online Education & Event Updates
 - John Ezzell, CDISC

Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

Amy: What are new updates in the TBI TAUG?

OR

CDISC: When can we start registering for the US Interchange?



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Quarterly Update: The State of CDISC Standards

Wayne Kubick, CTO

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

A decorative graphic at the bottom of the slide consists of several overlapping, wavy lines in shades of blue and green. These lines transition into a horizontal bar with a diagonal hatched pattern in blue and green.

Strength *through Collaboration*

Keeping up with CDISC Standards

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



Search... [social media icons]

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 on the technical roadmap. The roadmap is formulated, and standards are being developed.

Because project availability of a check regularly

[Technical Plan Updates](#)

[What's New in Technical Updates](#)

[Monthly Technical Updates](#)

- [Technical Updates](#)
- [Technical Updates](#)
- [Technical Updates](#)
- [Technical Updates](#)
- [Technical Updates](#)

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.



New Projects: 2015 Technical Plan

Team	Project	Description	Reqs Date	State	Target Date
Foundational Content Standards					
PRG	Protocol Concepts	Protocol Concepts V1.0 spreadsheet release for review and collaboration with TransCelerate Common Protocol Template project (concept mapping to Template)		Draft	Q3
CDASH	CDASHIG v2	CDASH Model, new domains (PR, HO, SR, DD, MI, MO, RP, PC, PP, FA, QS) to correspond to newer SDTMIG v3.2 domains.	2014	Draft	Q4
SDTM	SDTM v1.5	<p>New variables, domain-specific variable class, disease milestones, new special purpose domains to support SEND, PGx, Devices, Human Clinical Trials.</p> <ul style="list-style-type: none"> • New Intervention domains: Procedure Agents (AG) and Meal (ML) • Physiology/Morphology domain(s), with changes to existing and draft domains and new domain(s). • Broadening TU and TR domains to handle non-tumor lesions and RS to handle more kinds of disease responses, including clinical classifications. • Proposal for "Non-Standard Variables" in parent domains rather than as supplemental qualifiers 	2013-2015	Draft	Q3
SDS	SDTMIG v3.3	<ul style="list-style-type: none"> • Proposal for Disease Milestones 	2013	Final	Q4

Progress Update – Foundational Standards

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)*
- **Pharmacogenomics SDTMIG v1**
- *SEND v3.1 Draft*
- ADaM Results Metadata Spec for Define-XML
- **ADaM Occurrence Data Structure v1**
- **ADaM v1.3 Validation Checks**
- *ADaM IG v1.1 Draft*
- ***ADaM Data Structure for Integration (ADSL)***
- *CDISC in RDF Reference Guide (PhUSE)*
- Periodic Terminology and QRS Packages
- Updated COP and Process Docs
- ***BRIDG R4***

Upcoming Major New Drafts for Comment:

- *SEND DART (Reproductive Toxicology)*
- *CTReg XML Schema*
- *SDTMIG Batch 3, SDTM v1.5*
- *Define-XML v2.1, IG*

Therapeutic Area	Coordinating Organization	Stage 3b Public Review	*Stage 3c **Projected Publication
Traumatic Brain Injury v1	CDISC Rhonda	Jun	Q315
Schizophrenia v1	CDISC Amy	Mar	Q215
Breast Cancer v1	John	Jun	Q315
Dyslipidemia v1	John	Apr	Q215
COPD v1	John	Aug	Q315
ADaM Supplement to Diabetes v1	Rachael	Jun	Q215
Virology v2	CDISC Laurie		Q315
Diabetic Kidney Disease v1	Rachael		Q116
Tuberculosis v2	CDISC Laurie		Q116
Rheumatoid Arthritis v1	Trisha		Q116
CV Imaging v1	CDISC Amy		Q216
Prostate Cancer v1	CDISC John		Q216

TAUGs released in 2014-2015:

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

Upcoming Provisionals:

- Dyslipidemia v1

Upcoming Drafts:

- *Traumatic Brain Injury*
- *Breast Cancer*
- *Diabetes ADaM Supplement*
- *Virology v2*
- *COPD*

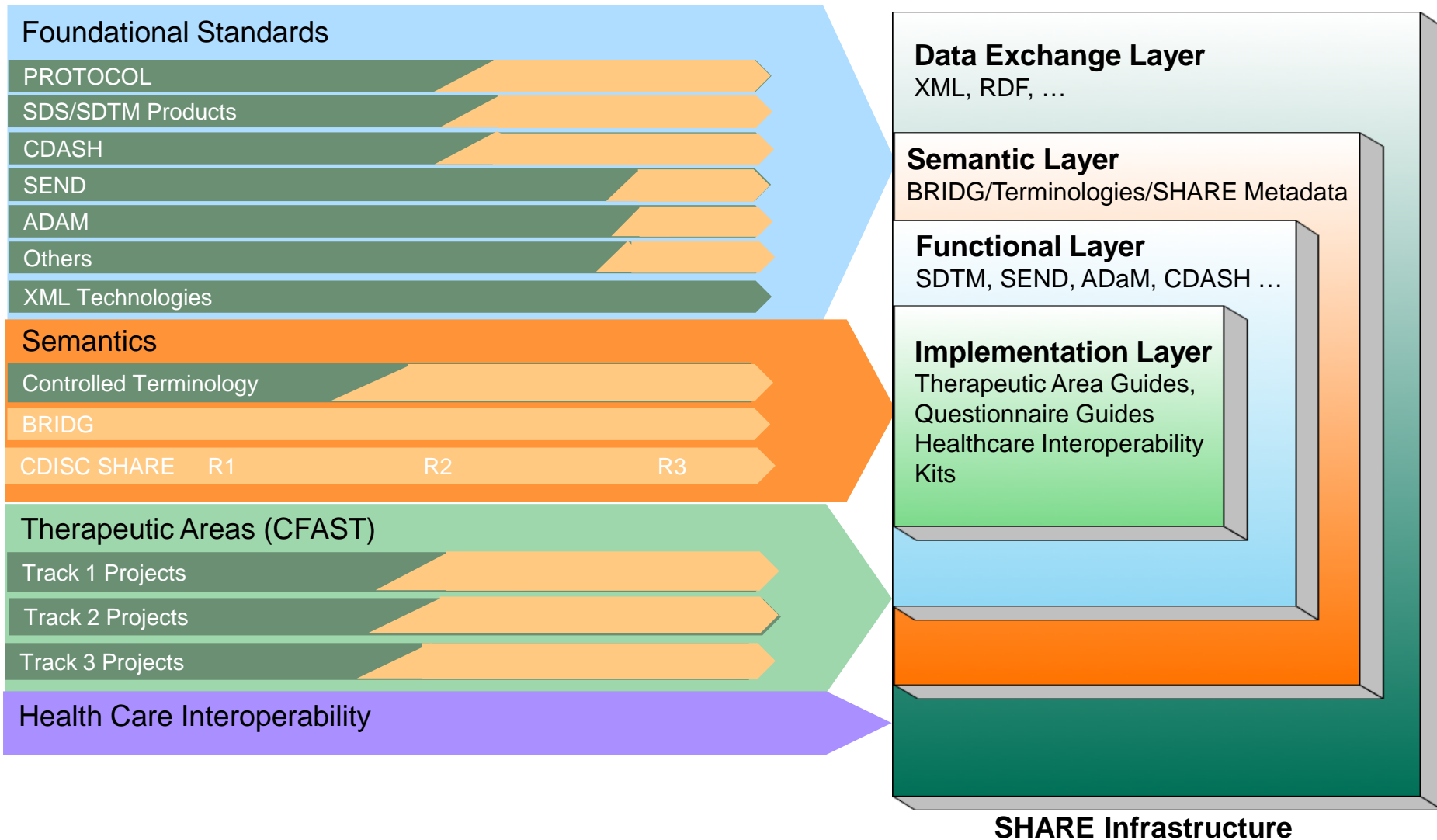
2015 CDISC Strategic Goals

- 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.
- Implement clinical research standards that are compatible with standards in the broader healthcare ecosystem and thus add value for clinical researchers, healthcare providers and patients.
- 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.

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

CDISC Technical Roadmap - 2015



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

CDISC SHARE



CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

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.

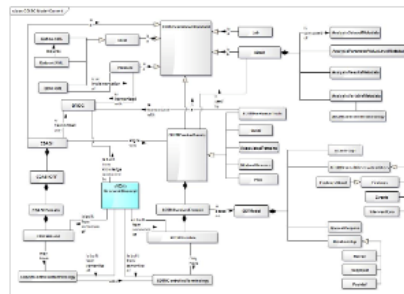
Volunteer for CDISC

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 \(pdf\)](#)

SHARE SHARE Home

Added by Max Kanevsky, last edited by Julie Chason on Apr 06, 2015 (view change)



Quick Links

[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](#)



Strength *through collaboration.*



CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

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

A decorative graphic consisting of several overlapping, wavy lines in shades of blue and green that flow from the left side of the slide towards the right. These lines terminate in a horizontal bar with a diagonal hatched pattern in blue and green.

Strength *through Collaboration*

TAUG-Traumatic Brain Injury v1.0

Public Review Webinar

June 11, 2015

Dana Booth, Steve Kopko and Amy Palmer, CDISC



Strength through Collaboration

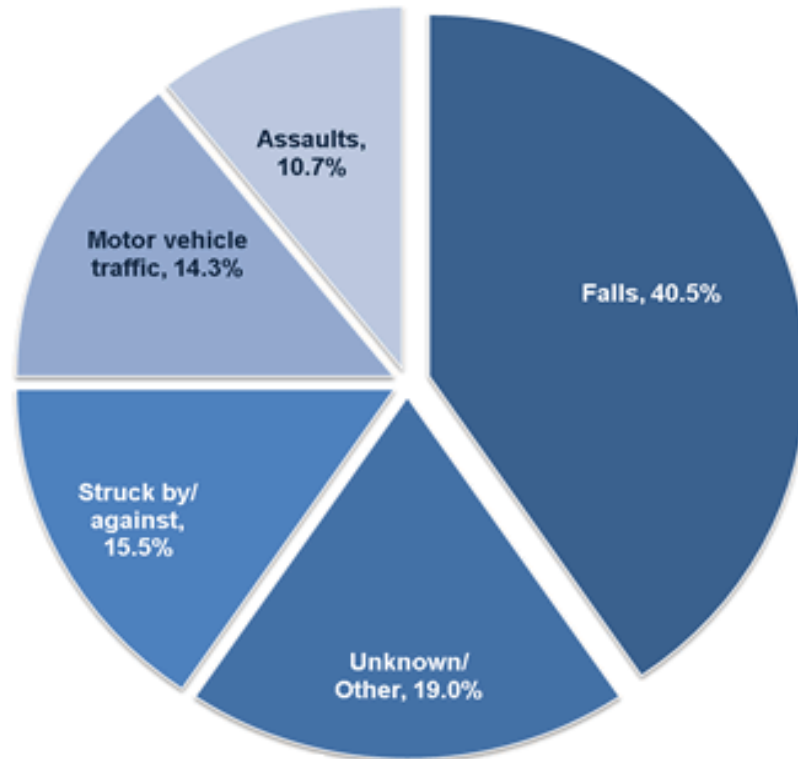
Introduction to Traumatic Brain Injury

- Traumatic Brain Injury (TBI) is a significant public health problem
 - defined as damage to the brain caused by an external mechanical force rather than degenerative or congenital causes
- Everyone is at risk for a TBI
- TBI is a major cause of death and disability worldwide
- TBI affects not only those directly injured, but also caregivers and family members, as well as society as a whole

Causes of Traumatic Brain Injury

- TBI is a very complex disease because different types of trauma can produce varying types of injuries and symptoms.
- In the United States, leading causes of TBI include
 - falls, motor vehicle collisions (MVC)
 - blunt trauma
 - blasts, particularly for active military personnel
 - unknown or other causes

Causes of Traumatic Brain Injury



Leading Causes of TBI, 2006-2010 [source: [CDC](http://www.cdc.gov/traumaticbraininjury/get_the_facts.html#causes)
http://www.cdc.gov/traumaticbraininjury/get_the_facts.html#causes]

Treatment and Prognosis

- Treatment required may be minimal or may include interventions such as medications or surgery.
- Outcomes can range from complete recovery to permanent disabilities and death.
- Long-term disabilities can involve physical, cognitive, social, and emotional functions.
- Since there is no known intervention to cure the consequences of TBI, public health needs to focus on prevention.

NINDS Common Data Elements

- US National Institute of Neurological Disorders and Stroke (NINDS) developed Common data elements (CDEs)
 - Initially developed in 2010 with a focus on acute TBI in adults.
- **NINDS CDEs Version 2 (2012) focused on four major study types:**
 - Epidemiological research
 - Studies on acute, hospitalized patients
 - Studies of the rehabilitation for moderate/severe TBI
 - Mild TBI/Concussion research
- **The NINDS CDEs can be found on the NINDS website at:**
http://www.commondataelements.ninds.nih.gov/tbi.aspx#tab=Data_Standards.




The screenshot shows the header of the NINDS Common Data Elements website. On the left is a stylized orange brain icon. To its right, the text reads "NINDS Common Data Elements" in large blue letters, with the tagline "Harmonizing Information. Streamlining Research." below it. A dark blue navigation bar contains three menu items: "CDEs", "Tools", and "Learn", each with a small downward-pointing triangle. Below the navigation bar, the breadcrumb "CDEs > Traumatic Brain Injury" is visible, followed by the page title "Traumatic Brain Injury" in a larger, bold font.



Therapeutic Area Data Standards
User Guide for Traumatic Brain Injury
Version 1.0 (Draft)

Prepared by
CEAST Traumatic Brain Injury Standards Team



- Version 1.0 of the Therapeutic Area User Guide for Traumatic Brain Injuries is focused on acute TBI in adults.
- Topics Included in the Therapeutic Area User Guide
 - Prior TBI exposure, treatment, therapies and procedures
 - Neurological assessments, Secondary insults and complications
 - Substance use
 - Protective devices
 - Outcome Measures - Questionnaires, Ratings, and Scales

Project Status and Next Steps

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping and Planning	Identification/Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

- Project Status

- Completed Stages 0, 1, 2 and 3a – Scoping and Identification/Modeling of Research Concepts; Development of Draft Standards and Internal Review
- Supplements & Terminology completed for 18 Questionnaires, Ratings, and Scales (8 additional were denied by copyright holder)
- Terminology and Supplements in progress for 11 additional Questionnaires, Ratings, and Scales

- Next Steps

- Stage 3b – Public Review

TBI Use Cases and Examples

- Prior TBI Exposure and Treatment
 - Items of interest include:
 - Number and type of prior TBIs over a lifetime
 - The cause of the injury
 - International Classification of Diseases, 9th Revision (ICD-9) code (future versions may include ICD-10)
 - Type and mechanism of TBI
 - Elapsed time between injury and presentation for treatment
 - Other hospitalizations or occurrence of serious trauma, broken bone, and treatment for alcohol/substance abuse

Prior TBI Exposure and Treatment Example

The example shows historical TBI episodes and the Qualifying events for one subject.

- Specific TBI events defined by protocol that are required for entry into a TBI clinical study are denoted “Qualifying Event” in MHSCAT.

Prior TBI Exposure and Treatment Example

Row 1: Shows that this subject had an initial head injury in August of 2008.

Row 2: Shows that this subject also had a spinal fracture on the same day on 8 August 2008 which resolved on 1 December 2008.

Row 3: Shows that this subject had a subsequent head injury 2 years later on 17 September 2010.

Row 4: Shows that this subject had a subdural hematoma on 14 February 2014 which qualified them for the current clinical trial.

Row 5: Shows that this subject had a skull fracture on 14 February 2014. The skull fracture is a qualifying event to the TBI diagnosis.

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHDECOD	MHCAT	MHSCAT	MHSTDTC	MHENDTC
1	ABC123	MH	001-001	1	HEAD INJURY	Head injury	TRAUMATIC BRAIN INJURY		2008-08-08	
2	ABC123	MH	001-001	2	SPINAL FRACTURE	Spinal fractures and dislocations	TRAUMATIC BRAIN INJURY		2008-08-08	2008-12-01
3	ABC123	MH	001-001	3	HEAD INJURY	Head injury	TRAUMATIC BRAIN INJURY		2010-09-17	
4	ABC123	MH	001-001	4	SUBDURAL HEMATOMA	Haematoma subdural	TRAUMATIC BRAIN INJURY	QUALIFYING EVENT	2014-02-14T05:35	
5	ABC123	MH	001-001	5	SKULL FRACTURE	Skull fracture	TRAUMATIC BRAIN INJURY	QUALIFYING EVENT	2014-02-14T05:35	

Prior TBI Exposure and Treatment Example – Supplemental Qualifiers

Rows 1-3: Show that the cause of the first TBI (QNAM=TBICAUSE) and spinal fracture (QNAM=INJCAUSE) was a motor vehicle traffic accident. The cause of the 2nd TBI was an accidental fall.

Rows 4-10: Show that the cause of the 3rd TBI, identified as the QUALIFYING EVENT in the MHCAT above, was an accidental fall. The Injury ICD9 External Cause Code is also provided. The TBI was classified as a closed TBI and the mechanism was a ground level fall. The subject presented early to the hospital (shortly after the injury). There was no suspicion of abuse, but the investigator did suspect that alcohol might be involved in the TBI-causing injury.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC123	MH	001-001	MHSEQ	1	TBICAUSE	Cause of TBI	Motor Vehicle Traffic Accident	CRF	
2	ABC123	MH	001-001	MHSEQ	2	INJCAUSE	Cause of Injury	Motor Vehicle Traffic Accident	CRF	
3	ABC123	MH	001-001	MHSEQ	3	TBICAUSE	Cause of TBI	Accidental Fall	CRF	
4	ABC123	MH	001-001	MHSEQ	4	TBICAUSE	Cause of TBI	Accidental Fall	CRF	
5	ABC123	MH	001-001	MHSEQ	4	ICD9ECD	Injury ICD9 External Cause Code	e880	CRF	
6	ABC123	MH	001-001	MHSEQ	4	TBITYP	TBI Type	Closed	CRF	
7	ABC123	MH	001-001	MHSEQ	4	MECHTBI	Mechanism of TBI	Ground Level Fall	CRF	
8	ABC123	MH	001-001	MHSEQ	4	INJPRCAT	Time to Presentation	Early	CRF	
9	ABC123	MH	001-001	MHSEQ	4	ABUSEINJ	Injury Due to Abuse	No Concern	CRF	
10	ABC123	MH	001-001	MHSEQ	4	ALCOINFL	Under the Influence of Alcohol	Suspected	CRF	

Prior TBI Exposure and Treatment Example – Findings About

Number of Prior Head Injuries and Concussions

The following example shows an alternate method to model proxy questions regarding the number of head injuries and concussions when the detailed medical history data were not available. In this study, the dates of the prior head injuries and concussions were not collected, rather the subject was asked about the total number of events in the prior six months and over the course of a lifetime.

Row	STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FACAT	FAORRES	FASTRESC	FASTRESN	FAEVLINT	FAEVINTX	FADTC
1	DEF456	FA	001-010	1	NUMEVNTS	Number of Events	Head Injury	TRAUMATIC BRAIN INJURY	2	2	2	-P6M		2014-07-17
2	DEF456	FA	001-010	2	NUMEVNTS	Number of Events	Concussion	TRAUMATIC BRAIN INJURY	3	3	3		LIFETIME	2014-07-17

Post Discharge Therapies and Treatments Example

In the example below, subjects in this study were followed for post-discharge therapies and procedures. Therapy types, frequencies and lengths are customized to the specific subject and may vary depending upon the subject's recovery. In order to standardize the verbatim therapy texts, coding from a medical dictionary was applied in PRDECOD. In general, PRSTDTC values should be populated; however, PRENDTC values may not be available and could be represented with a PRENRTPT value.

PR represents the various therapies the subject received both pre- and post-discharge. The ICD-9 code for the specified therapy is found in SUPPPR. The average length and frequency of each session are represented in the PRDOSE, PRDOSU, and PRFREQ fields.

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRDECOD	PRDOSE	PRDOSU	PRFREQ	PRSTDTC	PRENDTC	PRENRTPT	PRENTPT
1	ABC123	PR	001-001	1	OCCUPATIONAL THERAPY	Occupational Therapy	60	min	4 TIMES PER WEEK	2010-06-08		ONGOING	DISCHARGE
2	ABC123	PR	001-001	2	PHYSICAL THERAPY	Physical Therapy	90	min	BID	2010-08-06	2010-08-06		
3	ABC123	PR	001-001	3	BEHAVIORAL SUPPORT	Behavioral Support	120	min	EVERY 2 WEEKS	2010-12-12		ONGOING	DISCHARGE
4	ABC123	PR	001-001	4	ADAPTIVE PHYSICAL EDUCATION	Adaptive Physical Education	60	min	EVERY WEEK	2010-12-12		U	DISCHARGE
5	ABC123	PR	001-001	5	SPEECH THERAPY	Speech Therapy	30	min	2 TIMES PER WEEK	2011-08-29	2011-08-29		

Post Discharge Therapies and Treatments Example – Supplemental Qualifiers

A supplemental qualifier is used to show the ICD-9 Supplemental Classification Codes for the various therapies that the subject is receiving.

Row	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	ABC123	HO	001-001	PRSEQ	1	ICD9SCD	ICD9 Supplemental Classification Code	V57.21	CRF	
2	ABC123	HO	001-001	PRSEQ	2	ICD9SCD	ICD9 Supplemental Classification Code	V57.1	CRF	
3	ABC123	HO	001-001	PRSEQ	3	ICD9SCD	ICD9 Supplemental Classification Code	94.33	CRF	
4	ABC123	HO	001-001	PRSEQ	4	ICD9SCD	ICD9 Supplemental Classification Code	V57.1	CRF	
5	ABC123	HO	001-001	PRSEQ	5	ICD9SCD	ICD9 Supplemental Classification Code	V57.3	CRF	

Domains Represented in TAUG-TBI v1.0

IG	Class	Domain	Section
SDTMIG	Interventions	PR - Procedures	5.3
SDTMIG	Interventions	SU - Substance Use	5.1
SDTMIG	Events	HO - Healthcare Encounters	5.2
SDTMIG	Events	MH - Medical History	3.2 , 4.1.3 , 4.1.4 , 4.2 , 4.3 , 5.4
SDTMIG	Findings	CC - Clinical Classifications*	4.1.1
SDTMIG	Findings	MO - Morphology	4.1.2 , 4.3
SDTMIG	Findings	OE - Ophthalmology Physiology*	4.1.2
SDTMIG	Findings About	FA - Findings About Events or Interventions	3.2 , 4.1.3 , 4.1.4 , 4.2 , 4.3
SDTMIG-MD	Special Purpose	DI - Device Identification [†]	4.3 , 5.4
SDTMIG-MD	Findings	DU - Device-In-Use [†]	4.3

A list of domains used in the examples in this document, and the sections in which these examples appear, is given below:

* Domain is not final. The domain document is listed in the Supplemental Material for TAUG-TBI for review.

† Medical devices domains are used in examples only and not further discussed in this document. See SDTMIG-MD for further details.

Questionnaires, Ratings, and Scales

Brief summary of development steps

- Research copyright status, obtain references and, for copyrighted measures, contact copyright holder for permission to develop supplement (allow 2-3 months).
- Develop terminology – review and approval during QRS terminology team meeting
- Develop supplement and annotate measure – review and approval during QRS team meeting (supplements range from 5-10 pages each, on average)

Questionnaires, Ratings, and Scales - Questionnaire Supplement

The QRS supplement is a small document which discusses standards for the structure of data collected using the QRS measure of interest.

CDISC SDTM GOSE Questionnaire Supplement (Version 1.0)



Extended Glasgow Outcome Scale (GOSE)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

Prepared by
TBI Standards Team and CDISC Questionnaire Sub-team



Questionnaires, Ratings, and Scales - Questionnaire Supplement (cont.)

QRS supplements include a model dataset for the measure of interest.

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSORRES
1	STUDYX	QS	P0001	1	GOSE101	GOSE1-Obey Simple Commands or Say Words	GOSE	Yes
2	STUDYX	QS	P0001	2	GOSE102A	GOSE1-Daily Assistance at Home Essential	GOSE	Yes
3	STUDYX	QS	P0001	3	GOSE102B	GOSE1-Need Frequent Help at Home	GOSE	Yes (Lower SD)
4	STUDYX	QS	P0001	4	GOSE102C	GOSE1-Assistance at Home Before Injury	GOSE	No
5	STUDYX	QS	P0001	5	GOSE103A	GOSE1-Shop Without Assistance	GOSE	No (Upper SD)
6	STUDYX	QS	P0001	6	GOSE103B	GOSE1-Shop Without Assist Before Injury	GOSE	Yes
7	STUDYX	QS	P0001	7	GOSE104A	GOSE1-Travel Locally Without Assistance	GOSE	No (Upper SD)

Row	QSBLFL	QSSCAT	QSEVAL	QSEVALID	VISITNUM	QSDTC
1 (cont)		CONSCIOUSNESS	INTERVIEWER	GEC	2	2014-11-16
2 (cont)		INDEPENDENCE IN THE HOME	INTERVIEWER	GEC	2	2014-11-16
3 (cont)		INDEPENDENCE IN THE HOME	INTERVIEWER	GEC	2	2014-11-16
4 (cont)		INDEPENDENCE IN THE HOME	INTERVIEWER	GEC	2	2014-11-16
5 (cont)		INDEPENDENCE OUTSIDE THE HOME	INTERVIEWER	GEC	2	2014-11-16
6 (cont)		INDEPENDENCE OUTSIDE THE HOME	INTERVIEWER	GEC	2	2014-11-16
7 (cont)		INDEPENDENCE OUTSIDE THE HOME	INTERVIEWER	GEC	2	2014-11-16

Questionnaires, Ratings, and Scales - Annotated CRF

QRS supplements also include an annotated CRF for the measure of interest.

CONSCIOUSNESS	QSSCAT		QSORRES
1.	Is the head injured person able to obey simple commands, or say any words?	<input type="checkbox"/>	1 = No (VS) 2 = Yes
	QSTESTCD=GOSE101		
<p>Anyone who shows ability to obey even simple commands, or utter any word or communicate specifically in any other way is no longer considered to be in the vegetative state. Eye movements are not reliable evidence of meaningful responsiveness. Corroborate with nursing staff. Confirmation of VS requires full assessment as in the Royal College of Physician Guidelines.</p>			

INDEPENDENCE IN THE HOME	QSSCAT		
2a	Is the assistance of another person at home essential every day for some activities of daily living?	<input type="checkbox"/>	1 = No 2 = Yes
	QSTESTCD=GOSE102A		
<p>For a 'No' answer they should be able to look after themselves at home for 24 hours if necessary, though they need not actually look after themselves. Independence includes the ability to plan for and carry out the following activities: getting washed, putting on clean clothes without prompting, preparing food for themselves, dealing with callers, and handling minor domestic crises. The person should be able to carry out activities without needing prompting or reminding, and should be capable of being left alone overnight.</p>			
2b	Do they need frequent help or someone to be around at home most of the time?	<input type="checkbox"/>	1 = No (Upper SD) 2 = Yes (Lower SD)
	QSTESTCD=GOSE102B		
<p>For a 'No' answer they should be able to look after themselves at home for up to 8 hours during the day if necessary, though they need not actually look after themselves.</p>			
	QSTESTCD=GOSE102C		

Questionnaires, Ratings, and Scales – Measures with Completed Supplements

Full Name and Abbreviation
Alcohol Use Disorders Identification Test: Self-Report Version (AUDIT-SR)
Alcohol Use Disorders Identification Test - Consumption Questions (AUDIT-C)
Columbia Suicide Severity Rating Scale (C-SSRS) - Baseline Screening
Columbia Suicide Severity Rating Scale (C-SSRS) – Since Last Visit
Craig Handicap Assessment and Reporting Technique - Short Form Paper Version (CHART-SF PAPER VERSION)
Craig Handicap Assessment and Reporting Technique - Short Form Interview Version (CHART-SF INTERVIEW VERSION)
Disability Rating Scale
EuroQol Group EQ-5D™- 5L (EQ-5D-5L)
EuroQol Group EQ-5D™- 3L (EQ-5D-3L)
Generalized Anxiety Disorder -7 (GAD-7)
Glasgow Coma Scale
Glasgow Outcome Scale – Extended (GOS-E)
JFK Coma Recovery Scale – Revised (CRS-R)
Mayo-Portland Adaptability Inventory (MPAI)
Patient Health Questionnaire – 9 (PHQ-9)
RAND 36-item Health Survey (RAND-36)
Rivermead Postconcussive Symptom Questionnaire (RPQ)
Satisfaction With Life Scale (SWLS)

Questionnaires, Ratings, and Scales - Supplements In Progress

QRS supplements are being developed for the following measures and will be completed as time permits. Permission has been received for the copyrighted measures in this list; others are public domain.

Full Name and Abbreviation
Auditory Verbal Learning Test – Rey’s (AVLT – Rey’s)
Expanded Disability Rating Scale (E-DRS-PI) Postacute Interview – Caregiver Version
Expanded Disability Rating Scale (E-DRS-PI) Postacute Interview – Survivor Version
Galveston Orientation and Amnesia Test (GOAT)
Marshall CT Grade
Neurobehavioral Symptom Inventory (NSI)
Neurological Outcome Scale for Traumatic Brain Injury (NOS-TBI)
Posttraumatic Stress Disorder Checklist-Civilian Version (PCL-C)
Posttraumatic Stress Disorder Checklist-Military Version (PCL-M)
Posttraumatic Stress Disorder Checklist-Specific Version (PCL-S)
Trail Making Test (TMT)

Questionnaires, Ratings, and Scales - Permission Being Sought

The following QRS measures are copyrighted. Permission is being sought to develop QRS supplements for them. As permission is received and time permits, QRS supplements will be developed for them.

Full Name and Abbreviation
Controlled Oral Word Association Test
Maddocks Score
Modified Balance Error Scoring System (Modified BESS)
Post-Concussion Symptom Inventory (PCSI)
Posttraumatic Stress Disorder Checklist-5 (PCL-5)
Standardized Assessment of Concussion (SAC)
Sport Concussion Assessment Tool – 3rd Edition (SCAT3)
Traumatic Brain Injury—Quality of Life (TBI-QOL)

Questionnaires, Ratings, and Scales - No Permission Received

The following QRS measures are copyrighted and CDISC was unable to obtain permission to develop supplements for them at this time. If anyone has connections with any of the developers of these measures and is willing to assist CDISC in obtaining permission, please contact CDISC.

Full Name and Abbreviation
Brief Symptom Inventory 18 (BSI-18)
FIM®
SF-36
Quality of Life After Brain Injury (QOLIBRI) - short version
Wechsler Adult Intelligence Scale (WAIS-III/WAIS-IV) - Processing Speed
Wechsler Adult Intelligence Scale (WAIS-III/WAIS-IV) - Letter-Number Sequencing Subtest
Wechsler Adult Intelligence Scale (WAIS-III/WAIS-IV) - Digital Span
Wechsler Test of Adult Reading (WTAR)

Questionnaires, Ratings, and Scales

- QRS Supplements are not considered to be part of the TAUG.
- QRS Supplements are a work in progress.
- We will continue to develop QRS Supplements after the TAUG is published.
- Please visit cdisc.org/qrs for the latest supplements.

TBI – Public Review

- Public Review upcoming
 - Will be posted for comment on the CDISC website within the next several weeks
 - The Public Review period will be **60 days**
- Download the document using Adobe Reader (<http://get.adobe.com/reader/>)
- Submit comments using the CDISC public commenting tool located on the CDISC website located here:
 - <http://portal.cdisc.org/CT/default.aspx>
- Instructions on using the comment tracker tool
 - <http://portal.cdisc.org/CT/Documents/How%20to%20Use%20the%20CDISC%20Public%20Comment%20Tracker.docx>

Thank you to the TBI Standards Team

Name	Institution/Organization
Rhonda Facile	CDISC
Dana Booth	CDISC
Steven Broglio	University of Michigan
Thomas DeGraba	National Intrepid Center of Excellence (NICoE)
Sureyya Dikmen	University of Washington School of Medicine
Christine Fleeman	UCB
Joseph Giacino	Spaulding Rehabilitation Hospital
Bron Kisler	CDISC
Steve Kopko	CDISC
Geoff Manley	University of California, San Francisco
Kathleen Mellars	CDISC Fellow
Jon Neville	Critical Path Institute
Amy Palmer, Team Lead	CDISC
Joanne Odenkirchen	NINDS
Munim Saeed	Pharma Medica Research
Tasneem Shamalak	Theorem Clinical
Alex Valadka	Seton Brain and Spine Institute
Olga Vovk	FITBIR
Elizabeth Wilde	Baylor College of Medicine
Darcy Wold	CDISC
Diane Wold	CDISC
Ron Fitzmartin	FDA Liaison

TBI – Public Review Webinar



CDISC Education Events Announcements

Learn CDISC from CDISC!
Authoritative. Global. Vendor neutral.






Strength through Collaboration

Standards currently out for review

- ADaM Integration-IADSL v1 Draft
 - Visit <http://www.cdisc.org/standards/dataexchange> for more information.
 - Deadline for Comments: 10 July 2015

- Click [here](#) to submit your comments.



Upcoming North America Public Courses and Events

Location	Dates	Courses Offered	Online Registration Deadline	Early Registration Discounts	Host
Minneapolis, MN	23-26 June 2015	SDTM for Med. Devices, CDASH, CT	Offline Registration	<i>Expired</i>	
Durham, NC	27-31 July 2015	SDTM, ADaM	27 June 2015	<i>Expired</i>	
Gaithersburg, MD	1-4 Sep 2015	SDTM, CDASH, ADaM	1 Aug 2015	<i>Expired</i>	
Whippany, NJ	29 Sep – 2 Oct	SDTM, CDASH, ADaM	29 Aug 2015	<i>30 Jun 2015</i>	
Seattle, WA	6-9 Oct 2015	SDTM, ADaM, ODM/Define-XML Combo	6 Sep 2015	<i>Expired</i>	

Registration deadline indicates online deadline. Onsite registration is available before each event begins. Additional 2015 public training events can be found @ <http://cdisc.org/public-courses>.

Check CDISC website for up-to-date information on Public Courses




Upcoming Europe Public Courses and Events

Location	Dates	Courses Offered	Online Registration Deadline	Early Registration Discounts	Host
Eschborn (Frankfurt), Germany	28-31 Jul 2015	SDTM, CDASH, ADaM	28 June 2015	<i>Expired</i>	
Brussels, Belgium	7-10 Sep 2015	SDTM, CDASH, ADaM	7 August 2015	<i>Expired</i>	

Registration deadline indicates online deadline. Onsite registration is available before each event begins. Additional 2015 public training events can be found @ <http://cdisc.org/public-courses>.

Check CDISC website for up-to-date information on Public Courses

Upcoming Asia Public Courses and Events

Location	Dates	Courses Offered	Online Registration Deadline	Early Registration Discounts	Host
Japan Interchange, Tokyo 	22-26 Jun 2015	SDTM, CDASH, ODM, Dataset-XML, Define-XML, ADaM	8 June 2015	<i>Expired</i>	
Guangzhou, China	8-11 Sep 2015	SDTM, CDASH, ADaM	8 August 2015	<i>Expired</i>	Guangdong Provincial Hospital of Chinese Medicine 

Registration deadline indicates online deadline. Offline registration deadlines for each event available up until start date. Additional public training events can be found @ <http://cdisc.org/public-courses>.

Check CDISC website for up-to-date information on Public Courses

Public Classroom Training

www.cdisc.org/public-courses



Learn CDISC from CDISC!

CDISC Public Courses in USA

Hosted by Astellas in Chicago, IL from 24-27 Mar 2015

Hosted by BioCruc

Hosted by Med

Hosted by Duk

Hosted by Med

Hosted by Axio

International I

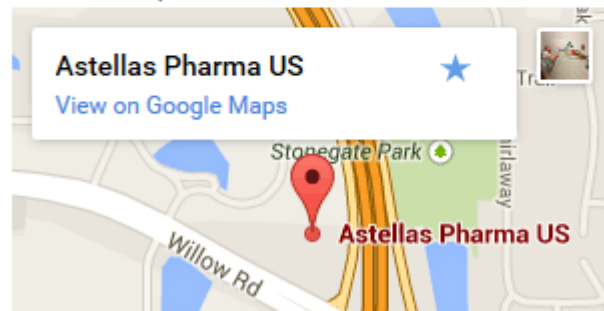
Public Courses in Chicago, IL

24-27 Mar 2015

Astellas Pharma Inc.

1 Astellas Way

Northbrook, IL 60062



CDISC Public Courses in Europe

Europe Interchange in Basel, Switzerland from 4-8 May 2015

Hosted by Accovion GmbH in Eschborn (Frankfurt), Germany from 28-31 July 2015

Hosted by Business & Decision Life Sciences in Brussels, Belgium from 7-10 Sep 2015

CDISC Public Courses in Asia

Hosted by CAC Europe in Tokyo, Japan from 9-11 Mar 2015

Hosted by

Course Information:

Name: 2-day SDTM Theory and Application

Date/Time: 24-25 Mar 2015; 09:00-17:00

Instructor: Gary Walker

Name: 1-day CDASH Implementation

Date/Time: 26 Mar 2015; 09:00-17:00

Instructor: Gary Walker

Name: 1-day ADaM Implementation

Date/Time: 27 Mar 2015; 09:00-17:00

Instructor: Mario Widel

[Online Registration](#)

[Offline Registration](#)

[Course Fees](#)

In-House Classroom Training

www.cdisc.org/private-courses

Benefits:

- Learn with your group using specific use cases and implementation questions
- On-location authorized instructor
- Cost-effective group training



Private (In-House) Courses

Learn CDISC from CDISC!

Private, in-house courses, delivered to your staff by an authorized instructor, are available to any organization, regardless of membership status. CDISC member organizations will receive discounted pricing.

To request information about private courses, please complete the form found at the button below.

CLICK HERE!
To request CDISC
In-House Training

Someone from the Education team will contact you within a few days to discuss your training request.

If you have any questions regarding CDISC in-house training please e-mail us at training@cdisc.org.

 EDUCATION

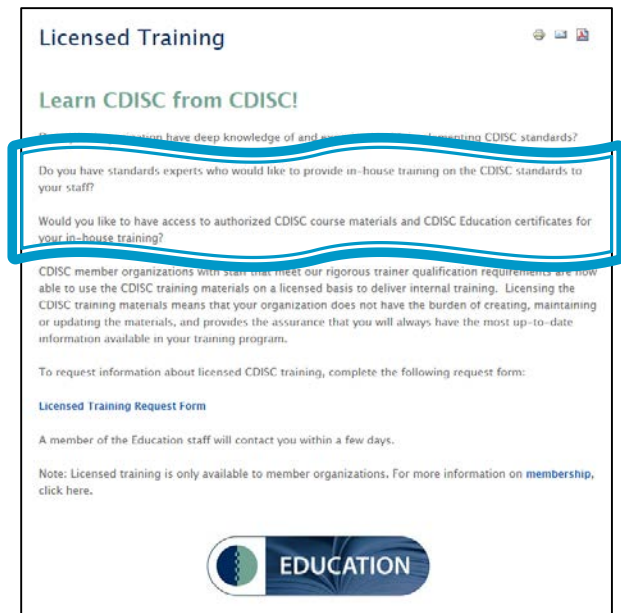
Licensed Training - *Exclusively for our Members*

<http://www.cdisc.org/licensed-training-subpage>

Benefits:

- Standard qualification and training process
- All materials developed by standards teams
- Your instructor delivers training
- Training when your staff needs it
- Official CDISC Education certificates

***You get the best
training, just when you
need it, and save time
and money!***



The screenshot shows a web form titled "Licensed Training" with a sub-header "Learn CDISC from CDISC!". The form contains several sections: a blue-bordered box with a question about in-house training, a paragraph explaining the benefits of licensing, a link to a request form, and a note about membership. At the bottom right is the "EDUCATION" logo.

Licensed Training

Learn CDISC from CDISC!

Do you have standards experts who would like to provide in-house training on the CDISC standards to your staff?

Would you like to have access to authorized CDISC course materials and CDISC Education certificates for your in-house training?

CDISC member organizations with staff that meet our rigorous trainer qualification requirements are now able to use the CDISC training materials on a licensed basis to deliver internal training. Licensing the CDISC training materials means that your organization does not have the burden of creating, maintaining or updating the materials, and provides the assurance that you will always have the most up-to-date information available in your training program.

To request information about licensed CDISC training, complete the following request form:

[Licensed Training Request Form](#)

A member of the Education staff will contact you within a few days.

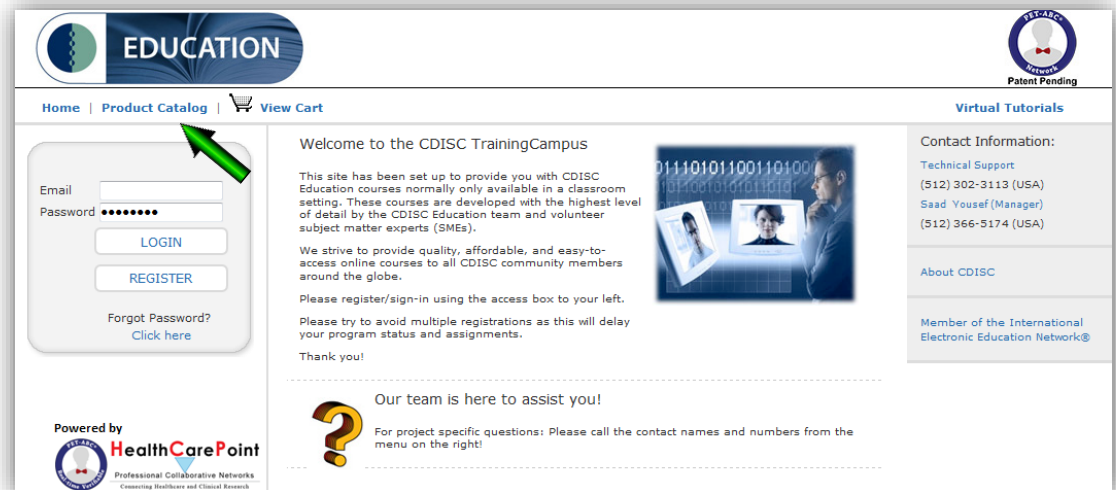
Note: Licensed training is only available to member organizations. For more information on [membership](#), click here.

EDUCATION

CDISC Online Training

Cdisc.trainingcampus.net

- Online training created with support from CDISC standards development teams
- New CDISC trainings developed in tandem with standards development
 - Goal: Instructional content published when it is most needed
- Online courses are not constrained by time
 - more content
 - greater depth
 - updated frequently



The screenshot shows the CDISC TrainingCampus website. At the top, there is a navigation bar with the 'EDUCATION' logo and links for 'Home', 'Product Catalog', and 'View Cart'. A green arrow points to the 'Product Catalog' link. Below the navigation bar is a login and registration section with fields for 'Email' and 'Password', and buttons for 'LOGIN', 'REGISTER', and 'Forgot Password? Click here'. To the right of the login section is a welcome message and a 'Virtual Tutorials' section with contact information for technical support. At the bottom left, there is a 'Powered by HealthCarePoint' logo. At the bottom right, there is a 'Our team is here to assist you!' section with a question mark icon and contact information.

Next Members Only Mini-Training

- **Agenda:**

- Best Practices of ADaM Validation Checks: Past, Present, and Future

- **Date:** 16 July 2015, 11:00-12:30 PM EST

- **Speakers:**

- Shelley Dunn, d-Wise
- Ed Lombardi, Agility Clinical

- Register [here](#).

Webinar details also at www.cdisc.org/webinars

Access to these mini-training webinars is an exclusive benefit of being a member. Visit www.cdisc.org/membership for more information.

Next Public Webinar

- **Agenda:**
 - TBD
- **Date:** 23 July 2015, 11:00-12:30 PM EST
- **Speakers:**
 - TBD
- Register [here](#).

Webinar details also at www.cdisc.org/webinars

Any more questions?

Thank you for attending this webinar.

**CDISC's vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research**



Strength *through collaboration.*

CDISC Members Drive Global Standards

Thank you for your support!



Learn CDISC from CDISC!
Authoritative. Global. Vendor neutral.