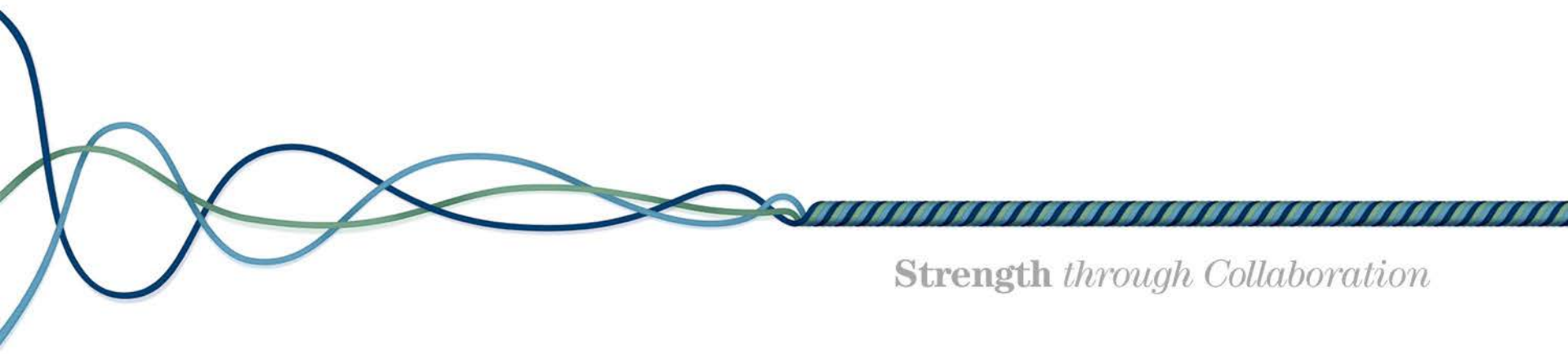
CDISC Public Webinar – Standards Updates and Additions

Jun 16 2016



Agenda

- CT Updates
  - Bernice Yost, CDISC
- CDASH V2 Public Review
  - Michael J Ward, Lilly
  - Trisha Simpson, UCB
  - Lorraine Spencer, Takeda
  - Kathleen Mellars
- CDISC Online Education & Event Updates
  - John Ezzell, CDISC

Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

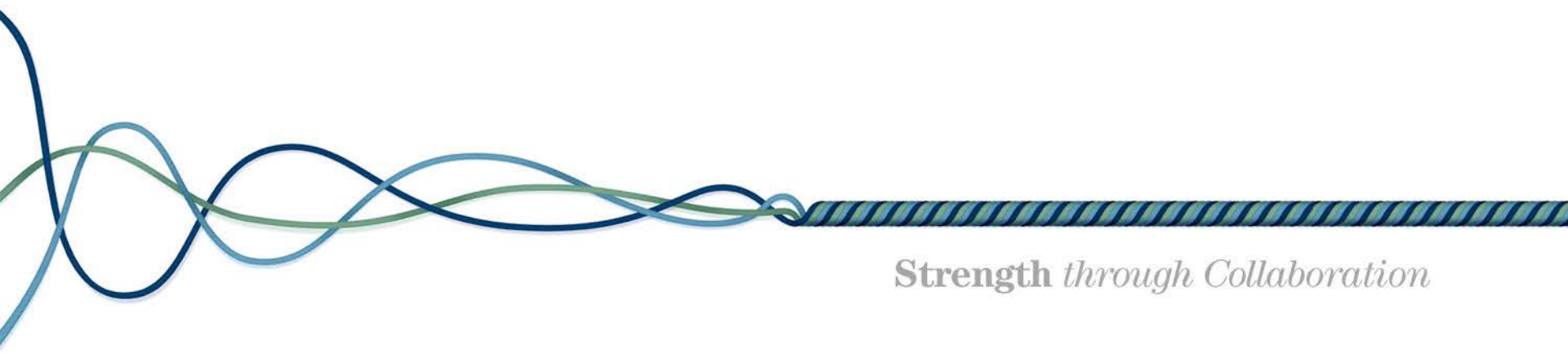
Mike: Where can I find the CDASH V2 document for review?

OR

CDASH V2: Are there new variables in this standard?

CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost



Controlled Terminology Agenda

- Package 26 Publication Release (24 Jun 2016)
  - What's new
  - What's changed

- Package 27 Public Review (17 Jun 2016 to 15 Jul 2016)
  - What's new
  - What's changed

Controlled Terminology Publication Schedule

Package Number	Team Cutoff (requests must be received at least two months before this date)	Public Review Start Date (1 wk from Team Cutoff)	Public Review Closed Date (4 wks)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
24	9/4/2015	9/11/2015	10/9/2015	11/6/2015	12/18/2015	Device	ECG	General	Lab
24						Oncology	PGx	PK	SEND
24						Unit	Virology		
25	12/4/2015	12/11/2015	1/15/2016	2/12/2016	3/25/2016	General	Lab	Oncology	PGx
25						PK	SEND	Spectype Speccond	Unit
25						Virology			
26	3/11/2016	3/18/2016	4/15/2016	5/13/2016	6/24/2016	CV	Device	General	Lab
26						Oncology	SEND	Spectype Speccond	Unit
26						Virology			
27	6/10/2016	6/17/2016	7/15/2016	8/19/2016	9/30/2016				
27									
27									
28	9/2/2016	9/9/2016	10/7/2016	11/4/2016	12/16/2016				
28									
28									
29	12/9/2016	12/16/2016	1/27/2017	2/17/2017	3/31/2017				
29									
29									
30	3/17/2017	3/24/2017	4/21/2017	5/19/2017	6/30/2017				
30									
30									
31	6/16/2017	6/23/2017	7/21/2017	8/18/2017	9/29/2017				

Controlled Terminology Package 26 Publication Release

Controlled Terminology Package 26 Publication Release

- Cardiovascular Terminology Team
  - New Term Added to Existing Codelist
    - Cardiovascular Test Code/Test Name

Controlled Terminology Package 26 Publication Release

- General Terminology Team:
  - Move Terms to a Different Codelist
    - Contact Setting codelist: all terms are being moved to a new codelist called Environmental Setting.
    - Directly Observed Therapy Location codelist: all terms are being moved to a new codelist called Environmental Setting.
      - Environmental Setting: Terminology relevant to the surroundings or environment.
  - Codelist Removed
    - Contact Setting
    - Directly Observed Therapy Location

Controlled Terminology Package 26 Publication Release

- General Terminology Team:
  - Submission Value Change
    - Method Codelist
      - Echocardiogram
        - » **Echocardiography**

          The correct method is Echocardiography. Echocardiogram is the result of an Echocardiography.

Controlled Terminology Package 26 Publication Release

- General Terminology Team:
  - New Codelist
    - Observational Study Model
      - The terminology relevant to the trial design for observational studies.
    - Observational Study Time Perspective
      - The terminology relevant to the temporal relationship between the observation period and time of subject enrollment in an observational study.
    - Observational Study Biospecimen Retention
      - The terminology relevant to whether biospecimens were retained and contain DNA within an observational study.
    - Observational Study Sampling Method
      - The terminology relevant to the method by which the study population is selected in an observational study.
    - Contact Role for Clinical Study
      - The terminology relevant to the role that the responsible individual or entity plays with respect to being a contact for the study.

Controlled Terminology Package 26 Publication Release

- General Terminology Team:
  - New Codelist continued:
    - Mode of Disease Transmission
      - The terminology relevant to the mechanism by which a disease is transmitted.
    - Tuberculosis Findings About Test Code/Test Name
      - Terminology relevant to the test codes/names that describe findings about a tuberculosis event or intervention.
    - Environmental Setting
      - Terminology relevant to the surroundings or environment.
    - Case Finding
      - Terminology relevant to how actively a search was performed for identifying individuals with a particular disease.
    - Musculoskeletal System Finding Test Code/Test Name
      - A terminology codelist to describe the test code for a physiological examination of the musculoskeletal system.

Controlled Terminology Package 26 Publication Release

- General Terminology Team:
  - New Term Added to Existing Codelist
    - Anatomical Location
    - Method
    - Trial Summary Parameter Test Code/Name
    - Trial Type
    - Relationship to Subject

Controlled Terminology Package 26 Publication Release

- Lab Terminology Team (*Laboratory/Microscopic Test Codelists*)
  - Move terms to a Different Codelist
    - Microscopic Findings Test Code/Test Name codelist to Microscopic Findings Test Details codelist
      - KNODELL FIBROSIS SCORE
      - BATTS-LUDWIG FIBROSIS SCORE
      - ISHAK FIBROSIS SCORE
      - METAVIR FIBROSIS SCORE
      - SCHEUER FIBROSIS SCORE

Controlled Terminology Package 26 Publication Release

- Lab Terminology Team (*Laboratory/Microscopic Test Codelists*)
  - Submission Value Change
    - Laboratory Test Code/Test Name Codelist
      - Lupus Anticoagulant Ratio
        - »**Dilute Russell's Viper Venom Time Ratio**

          The synonym Lupus Anticoagulant Ratio incorrectly replaced the previously existing submission value of Dilute Russell's Viper Venom Time Ratio. This is now being corrected.

Controlled Terminology Package 26 Publication Release

- Lab Terminology Team (*Laboratory/Microscopic Test Codelists*)
  - New Term Added to Existing Codelist
    - Laboratory Test Code/Test Name
    - Microscopic Findings Test Code/Test Name
    - Microscopic Findings Test Details

Controlled Terminology Package 26 Publication Release

- Lab Terminology Team (*Spectype/Speccond Codelists*)
  - New Term Added to Existing Codelist
    - Specimen Type

Controlled Terminology Package 26 Publication Release

- Lab Terminology Team (*Unit Codelist*)
  - New Term Added to Existing Codelist
    - Unit

Controlled Terminology Package 26 Publication Release

- Oncology Terminology Team
  - New Codelist
    - Disease Presentation Type
      - Terminology relevant to the symptoms and/or clinical manifestation of a disease.

Controlled Terminology Package 26 Publication Release

- Oncology Terminology Team
  - New Mapping Codetables
    - Category of Oncology Response Assessment codelist
      - RECIST 1.0
        - » Oncology Response Assessment Test Code/Test Name (ONCRTSCD/ONCRTS) and the Oncology Response Assessment Result (ONCRSR).
      - RECIST 1.1
        - » Oncology Response Assessment Test Code/Test Name (ONCRTSCD/ONCRTS) and the Oncology Response Assessment Result (ONCRSR).
    - Tumor Response Assessment Test Code/Test Name codelists (TUTESTCD/TUTEST) and the Tumor and Lesion Identification Test Results codelist (TUIDRS).

Controlled Terminology Package 26 Publication Release

- SEND Terminology Team
  - Submission Value Change
    - Non-Neoplastic Finding Type Codelist
      - OBSTRUCTIVE UROPATHY
      - **MURINE OBSTRUCTIVE UROPATHY**
        - » New C-code required – incorrectly assigned to Urinary System Disorder. The correct concept is Mouse Urological Syndrome.

Controlled Terminology Package 26 Publication Release

- SEND Terminology Team
  - Term Removed
    - Specimen Codelist
      - BRUNNER'S GLAND
      - DUCT, THYROGLOSSAL
      - EPICARDIUM
      - JOINT, STIFLE
      - LYMPH NODE, RETROSACRAL
        - » Not being used as a specimen but rather would be a location or anatomical region of the finding.

Controlled Terminology Package 26 Publication Release

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - Neoplasm Type
    - Specimen
    - Fetal Pathology Findings Result

Controlled Terminology Package 26 Publication Release

- Virology Terminology Team
  - Submission Value Change
    - SDTM Species Codelist
      - KOCURIA RHIZOPHILA
        - » **MICROCOCCUS LUTEUS**

          C86513 is the correct concept for Micrococcus Luteus. Kocuria Rhizophila is a new concept that will receive a new c-code.

    - Microorganism Codelist
      - KOCURIA RHIZOPHILA
        - » **MICROCOCCUS LUTEUS**

          C86513 is the correct concept for Micrococcus Luteus. Kocuria Rhizophila is a new concept that will receive a new c-code.

Controlled Terminology Package 26 Publication Release

- Virology Terminology Team
  - New Codelist
    - Culture Medium Type
      - Terminology relevant to the type of medium used to culture a specimen.
  - New Term Added to Existing Codelist
    - Microorganism
    - SDTM Species

Controlled Terminology Package 27 Public Review

Controlled Terminology Package 27 Public Review

- Cardiovascular Terminology Team:
  - Move Terms to a Different Codelist
    - Morphology Test Code/Test Name codelist: all cardiovascular terms are being moved to the Cardiovascular Test Code/Test Name codelist.
      - Mean Vessel Diameter
      - Minimum Vessel Lumen Diameter
      - Percent Diameter Stenosis
      - Etc.
  - Codelist Removed
    - Cardiac Valvular Regurgitation Severity
    - Cardiac Valvular Stenosis Severity
      - The ACC and ASE and FDA are working on the terminologies for valvular stenosis and valvular regurgitation.

Controlled Terminology Package 27 Public Review

- Cardiovascular Terminology Team:
  - Submission Value Change
    - Morphology Test Code/Test Name Codelist to Cardiovascular Test Code/Test Name Codelist
      - Test Name: Late Loss
        - **Late Lumen Loss**
      - Test Code: LATELOSS
        - **LLMLOSS**
      - Definition: The difference between the mean minimum lumen diameter (MLD) assessed immediately after an index procedure and the MLD assessed at follow-up angiography.
  - New Term Added to Existing Codelist
    - Cardiovascular Test Code/Test Name

Controlled Terminology Package 27 Public Review

- General Terminology Team:
  - Move Terms to a Different Codelist
    - Morphology Test Code/Test Name codelist: all terms are being moved to their corresponding physiology codelist
      - Ophthalmic Exam Test Code/Test Name
      - Nervous System Physiology Test Code/Test Name
      - Gastrointestinal Test Code/Test Name

Controlled Terminology Package 27 Public Review

- General Terminology Team:
  - Codelist Removed
    - Country
      - The information is already handled by ISO 3166 3-letter country codelist.
    - Morphology Test Code/Test Name
      - Morphology tests will go to the corresponding physiology codelist.
    - Findings About Test Code/Test Name
      - Each Therapeutic Area will have their own findings about codelist
    - Treatment Episode
    - Treatment Failure
    - Reason Treatment Not Administered
      - TB Therapeutic Area

Controlled Terminology Package 27 Public Review

- General Terminology Team
  - Codelist Name Change

• Size	Size Response
• Skin Classification	Fitzpatrick Skin Classification Response
• Marital Status	Marital Status Response
• Skin Type	Skin Type Response
• Diagnosis Group	Diagnosis Group Response
• Trial Phase	Trial Phase Response
• Control Type	Control Type Response
• Study Type	Study Type Response
• Route of Administration	Route of Administration Response
• Intervention Type	Intervention Type Response
• Trial Blinding Schema	Trial Blinding Schema Response
• Sex of Participants	Sex of Participants Response
• Intervention Model	Intervention Model Response
• Trial Type	Trial Type Response

Controlled Terminology Package 27 Public Review

- General Terminology Team
  - New Codelist
    - Gastrointestinal Test Code/Test Name
      - A terminology codelist based on the test codes for physiological findings related to the gastrointestinal system.

Controlled Terminology Package 27 Public Review

- General Terminology Team
  - New Term Added to Existing Codelist
    - ADaM Codelist: Derivation Type
    - Trial Type
    - Route
    - Anatomical Location
    - Musculoskeletal System Finding Test Code/Test Name
    - Method
    - Study Type

Controlled Terminology Package 27 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
  - Submission Value Change
    - Laboratory Test Code/Test Name
      - Test Name: Plasma Cells/Total Cells
        - » **Mature Plasma Cells/Total Cells**
      - Test Code: PLSCECE
        - » **PLSMCECE**

The intention of the term was to measure mature plasma cells/total cells. Therefore the submission value update is being done to decrease ambiguity in use of this term.

Controlled Terminology Package 27 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
  - New Term Added to Existing Codelist
    - Laboratory Test Code/Test Name

Controlled Terminology Package 27 Public Review

- Lab Terminology Team (*Spectype/Speccond Codelist*)
  - New Term Added to Existing Codelist
    - Specimen Condition

Controlled Terminology Package 27 Public Review

- Lab Terminology Team (*Unit Codelist*)
  - Term Removed
    - Unit Codelist
      - mL/g (C67411) - retire
      - L/kg (C73725)
        - » mathematical synonyms
        - » Concept C67411 will be retired and the mL/g will now be a synonym to L/kg (C73725).
  - New Term Added to Existing Codelist
    - Unit

Controlled Terminology Package 27 Public Review

- Oncology Terminology Team
  - Codelist Removed
    - Neoplasm Type
      - This codelist will be in use by SEND only. SDS oncology team will consider how tumors should best be represented in SDTM datasets along with proposal for alternate terminology.
  - Codelist Name Change
    - Tumor Identification Test Code/Test Name
      - **Tumor or Lesion Identification Test Code/Test Name**
    - Tumor and Lesion Identification Test Results
      - **Tumor or Lesion Identification Test Results**
        - » consistency with domain name update

Controlled Terminology Package 27 Public Review

- Oncology Terminology Team
  - Submission Value Change
    - Oncology Response Assessment Result Codelist
      - Non-CR/Non-PD
        - »**NON-CR/NON-PD**

          Only the casing of the submission value is changing for consistency with other terms in the codelist beginning with 'Non-'. Case change does not change the meaning of the term.

  - New Term Added to Existing Codelist
    - Oncology Response Assessment Result
    - Category of Oncology Response Assessment

Controlled Terminology Package 27 Public Review

- Oncology Terminology Team
  - Mapping Document
    - RECIST 1.1
      - Oncology Response Assessment Test Code/Test Name
      - Oncology Response Assessment Result

Controlled Terminology Package 27 Public Review

- PGx (Pharmacogenomics/Genetics) Terminology Team
  - New Term Added to Existing Codelist
    - Biospecimen Events Dictionary Derived Term
    - Biospecimen Characteristics Test Code/Test Name

Controlled Terminology Package 27 Public Review

- PK Terminology Team
  - Term Removed
    - PK Units of Measure Codelist
      - (mL/day)/g (C120772) - retire
      - (L/day)/kg (C73755)
        - » Mathematical synonyms
        - » Concept C120772 will be retired and the (mL/day)/g will now belong to the concept of C73755.

Controlled Terminology Package 27 Public Review

- PK Terminology Team
  - New Codelist
    - PK Units of Measure - Weight kg (PKUWKG)
      - Units of measure for pharmacokinetic data and parameters normalized by weight in kilograms.
    - PK Units of Measure - Weight g (PKUWG)
      - Units of measure for pharmacokinetic data and parameters normalized by weight in grams.
    - PK Units of Measure - Dose mg (PKUDMG)
      - Units of measure for pharmacokinetic data and parameters normalized by dose amount in milligrams.
    - PK Units of Measure - Dose ug (PKUDUG)
      - Units of measure for pharmacokinetic data and parameters normalized by dose amount in micrograms.

Controlled Terminology Package 27 Public Review

- SEND Terminology Team
  - Submission Value Change
    - Neoplasm Type Codelist
      - MIXED GLIOMA, BENIGN
        - » **GLIOMA, MIXED, BENIGN**
      - MIXED GLIOMA, MALIGNANT
        - » **GLIOMA, MIXED, MALIGNANT**
      - MIXED LYMPHOMA, MALIGNANT
        - » **LYMPHOMA, MIXED, MALIGNANT**
      - MIXED MULLERIAN TUMOR, MALIGNANT
        - » **MULLERIAN TUMOR, MIXED, MALIGNANT**
      - MIXED SERTOLI-LEYDIG CELL TUMOR, BENIGN
        - » **SERTOLI-LEYDIG CELL TUMOR, MIXED, BENIGN**
      - MIXED TUMOR, BENIGN
        - » **TUMOR, MIXED, BENIGN**
      - MIXED TUMOR, MALIGNANT
        - » **TUMOR, MIXED, MALIGNANT**

        MIXED is a modifier and as such should be in the middle of the CDISC submission value. This also follow INHAND preferred nomenclature.

Controlled Terminology Package 27 Public Review

- SEND Terminology Team
  - Term Removed
    - Specimen Codelist
      - GLAND, URETHRAL
        - » No one seems to be using this term currently as a specimen.
      - LYMPH NODE, PERITONEAL
        - » There isn't a named thing called a Peritoneal Lymph Node in anatomy lexicon. Team suggests that someone map this to LYMPH NODE and then use ANTREG to describe location as Peritoneum or use SUPPQUAL to describe general location.
      - LYMPH NODE, SUBLUMBAR
        - » There are inconsistent definitions for what this is within the literature and this does not commonly show up in anatomy textbooks. Either use the MULTIPLE convention or map to a specific lymph node in the CT.
      - LYMPH NODE, THORACIC
        - » Either use the MULTIPLE convention or map to a specific lymph node in the CT.
      - SPERMATIC CORD
        - » No one seems to be using this term currently as a specimen; please use more specific term like VAS DEFERENS.

Controlled Terminology Package 27 Public Review

- SEND Terminology Team
  - Term Removed continued:
    - Specimen Codelist
      - LYMPH NODE, SUPRAPHARYNGEAL (C77656) - retire
      - LYMPH NODE, RETROPHARYNGEAL (C77649)

        » Concept C77656 will be retired and the Suprapharyngeal Lymph Node will now be a synonym to Lymph Node, Retropharyngeal (C77649).

Controlled Terminology Package 27 Public Review

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - Non-Neoplastic Finding Type
    - Strain/SubStrain
    - Specimen
    - Category for Clinical Observation

Controlled Terminology Package 27 Public Review

- Virology Terminology Team
  - Move Terms to a Different Codelist
    - Viral Resistance Findings Test Code/Test Name codelist: all terms are being moved to the Microbiology Susceptibility Test Code/Test Name codelist
      - TB TAUG - The VR domain will be deprecated and all VR terminology will be moved to a new Microbiology Susceptibility codelist
  - Codelist Removed
    - Viral Resistance Findings Test Code/Test Name

Controlled Terminology Package 27 Public Review

- Virology Terminology Team
  - Submission Value Change
    - Microorganism Codelist
      - ARCANOBACTERIUM PYOGENES
        - »**TRUEPERELLA PYOGENES**
      - BACTEROIDES UREOLYTICUS
        - »**CAMPYLOBACTER UREOLYTICUS**

        Change in NCBI Taxonomy

Controlled Terminology Package 27 Public Review

- Virology Terminology Team
  - New Codelist
    - Microbiology Susceptibility Test Code/Test Name
  - New Term Added to Existing Codelist
    - Microorganism
    - Microbiology Test Code/Test Name
    - Culture Medium Type

Strength *through collaboration.*

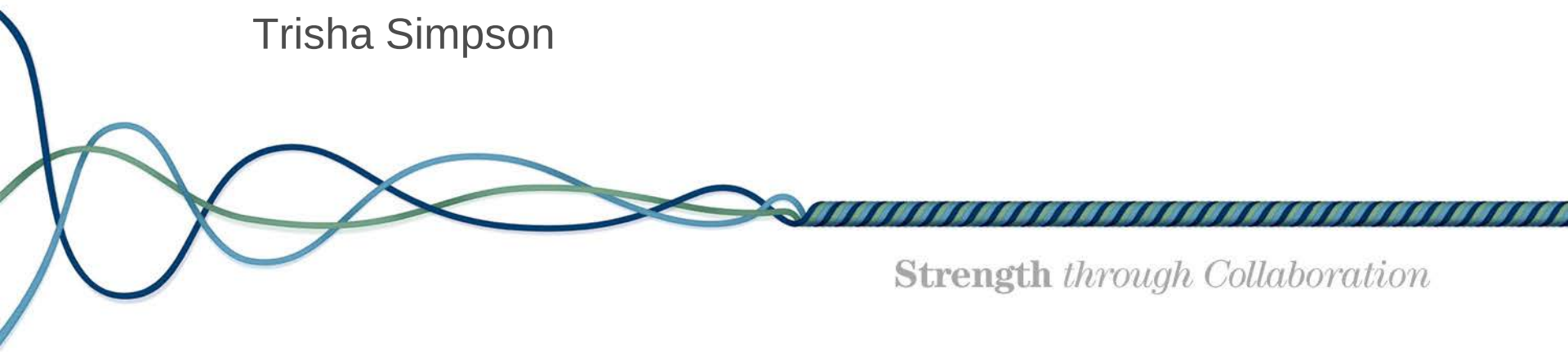
If you are interested in contributing to the CDISC Terminology Initiative, please contact us…

Bernice Yost, byost@cdisc.org

CDASH Model 1.0 and CDASHIG 2.0

An overview prior to Public Review

Mike Ward
Lorraine Spencer
Kathy Mellars
Trisha Simpson



Agenda

- CDASH Model:
  - What is it?
- CDASHIG 2.0
  - What's new and different?
- Public Review

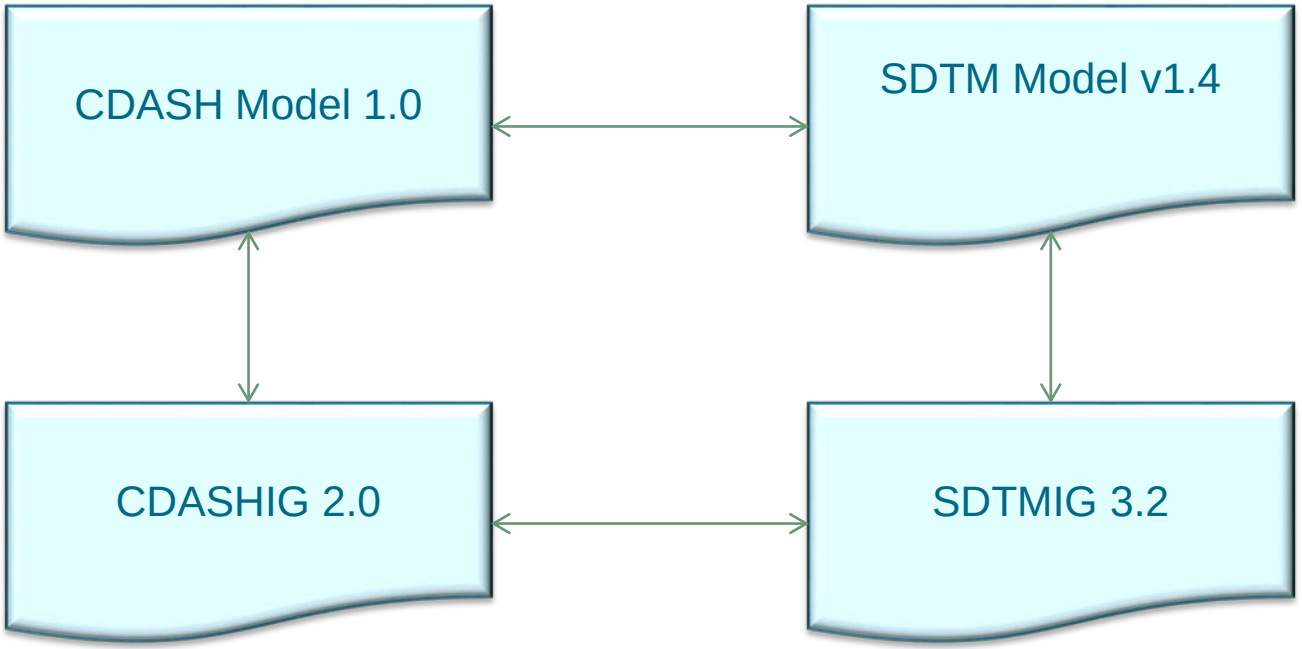
Principles of the CDASH Model

The CDASH Model

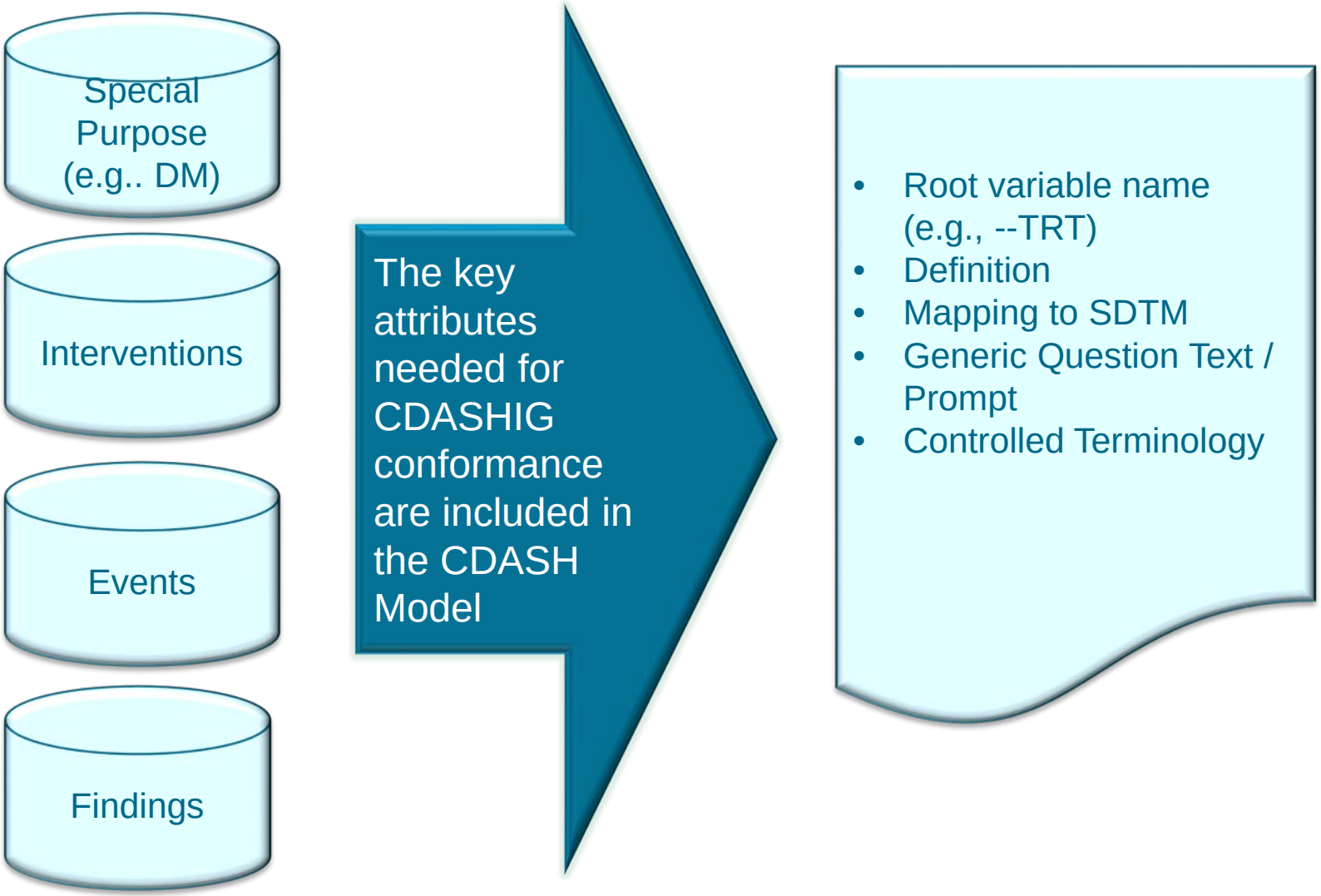
- defines the framework for creating standard variables that may be used for the collection of clinical trial data
- provides naming conventions for the CDASHIG variables
- includes metadata for the CDASHIG variables used in
  - Identifier Variables
  - Timing Variables
  - Special Purpose Domains (e.g., DM, CO)
  - SDTM General Observation Classes
  - Domain-specific variables

Relationships between SDTM and CDASH

- CDASH Model 1.0 aligns with SDTM Model 1.4
- CDASHIG 2.0 aligns with SDTMIG 3.2



CDASH Model Metadata builds in traceability to SDTM Model and CDASHIG conformance



Accessing the CDASH Model

The CDASH Model will not be a stand-alone .pdf document.

- Included as part of the CDASH Model / CDASHIG package on the CDASH Wiki: http://wiki.cdisc.org/display/CMIG/CDASH+Model+1.0

- Single spreadsheet with multiple tabs for each of the Classes
- Will be loaded to SHARE as a Metadata Element Set (MDES)

CDASH Model – Excerpt from Events

CDASH Variable	CDASH Variable Label	Maps to the SDTM Variable	Mapping Instructions	DRAFT CDASH Definition
--YN	Any [Event]	N/A	Does not map to an SDTM variable. The SDTM Annotated CRF is annotated to indicate that this field is NOT SUBMITTED.	An indication whether or not any data was collected for the event topic.
--TERM	Reported Term	--TERM	Maps directly to the SDTM variable listed in the column with the heading "Maps to the SDTM Variable".	The topic variable for an event observation, which is the reported or pre-specified name of the event.
--PRIOR	Prior to Study/Timepoint	--STRTPT; --STRF	This does not map directly to an SDTM variable. May be used to populate a value into an SDTM relative timing variable such as --STRF or --STRTPT. When populating --STRF, or --STRTPT, if the value of the CDASH field --PRIOR is 'Y' a value from the CDISC CT (STENRF) may be used. When --PRIOR refers to the Study Reference Period (defined in DM.RFSTDTC to DM.RFENDTC) the SDTM variable --STRF should be populated. When --PRIOR is compared to any other	An indication whether the event occurred prior to study start or a given timepoint.
--ONGO	Ongoing	--ENRTPT; --ENRF	This does not map directly to an SDTM variable. May be used to populate a value into an SDTM relative timing variable such as --ENRF or --ENRTPT. When populating --ENRF, or --ENRTPT, if the value of the CDASH field --ONGO is 'Y' a value from the CDISC CT (STENRF) may be used. When --ONGO refers to the Study Reference Period (defined in DM.RFSTDTC to DM.RFENDTC)	An indication whether the event is ongoing as of a given timepoint when no End Date is provided.

CDASH Model – Excerpt from Events

CDASH Variable	Question Text	Prompt	Data Type	Terminology Codelist Name	Implementation Notes and Examples for CDASH and SDTM mapping
--YN	Has the subject had any [event topic(s)] (after/before [study specific time frame])?; Or [Was/Were] (there) any [event topic(s)] (reported) (after/before [study specific time frame])?	Any [Event Topic]	Char	(NY)	This is a field that can be used in any CRF to indicate whether or not there is data to record. Used primarily as a data cleaning field. This provides …the CRF were deliberately left blank. If …be submitted in the SDTM …able should not be used and the …used instead (e.g., --OCCUR).
--TERM	What [is/was] the [event topic] term?; Or If other is selected [explain/specify/provide more detail]?	[Event Topic]; Or [Specify Other/Explain/Specify Details ([for Event Topic])	Char	N/A	…tim text for an Event. If the term is preprinted/prespecified, the value can be populated into the --TERM variable as a hidden field e.g., if Headache is preprinted on an AE CRF, 'Headache' should be stored in AETERM. The CDASH field --TERM can also be used to collect any free text values linked to the sponsor …CDASH field --DECOD. For example, -- …the associated free text event
--PRIOR	Did the [--TERM/event topic] occur [prior to the study/specific timepoint or period] ?	Prior to [Study/Study Specific Time Point or Period]	Char	(NY	…question text/prompt about …timepoint. Select the …CRF. This may also included in the CRF title or instructions. Used in conjunction with either a reference timepoint (--STTPT, --STRTPT) or in conjunction with the Study Reference Period (described as RFSTDTC to RFENDTC). May also be used as a …on 3.7 for more information.
--ONGO	[Is/Was] the [--TERM/event topic] ongoing ([after the end of the study/specific timepoint or period])?	Ongoing ([after the end of the Study/Specific Timepoint or Period])	Char	(NY)	…CDASH field --ONGO allows specific question text/prompt about events ending prior to the given timepoint. Select the appropriate text when designing the CRF. This may also included in the CRF title or instructions. Used in conjunction with either a reference timepoint (--ENTPT, --ENRTPT) or in conjunction with the Study Reference Period (described as RFSTDTC to RFENDTC). May also be used as a tick/checkbox. See the CDASH IG Section 3.7 for more information.

Standard Question Texts and Prompts with Parameters for Implementation

[Brackets] indicate parameters.

(Parenthesis) indicate optional text that may be included.

CDASHIG 2.0 – What's new?

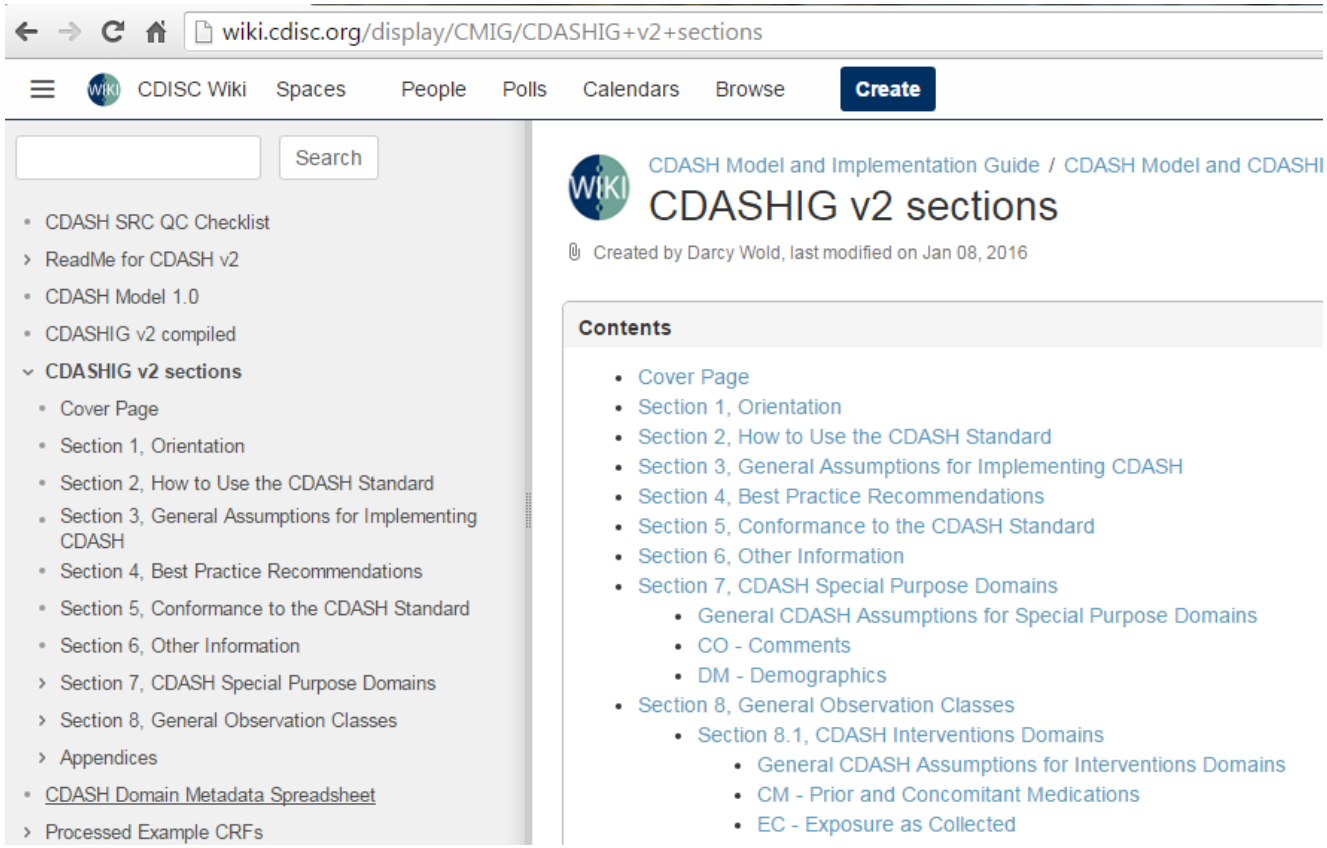
- Almost everything!
  - CDASH Standard v1.1 and CDASH User Guide v.1.0 were consolidated to create CDASHIG v2.0
  - Migrated source document from Microsoft Word to the CDISC Wiki
  - Changed the structure of the domain metadata from embedded Word tables to an Excel spreadsheet
  - Updated existing domains and added the following domains: CE, DD, EC, HO, MI, PC, PR, RP, and SR

CDASHIG 2.0 – What's new?

- Document Structure aligns with SDTMIG
  - Domains are organized by Class
- Common Identifier Variables were added to each of the Domains
- Updated attributes for every CDASHIG variable
- Changed the structure of Question Text and Prompt to allow for more flexible implementation (e.g., verb tense, sponsor defined time periods, parameterized topic variables)
- Added CRF Examples for each domain, unless otherwise specified

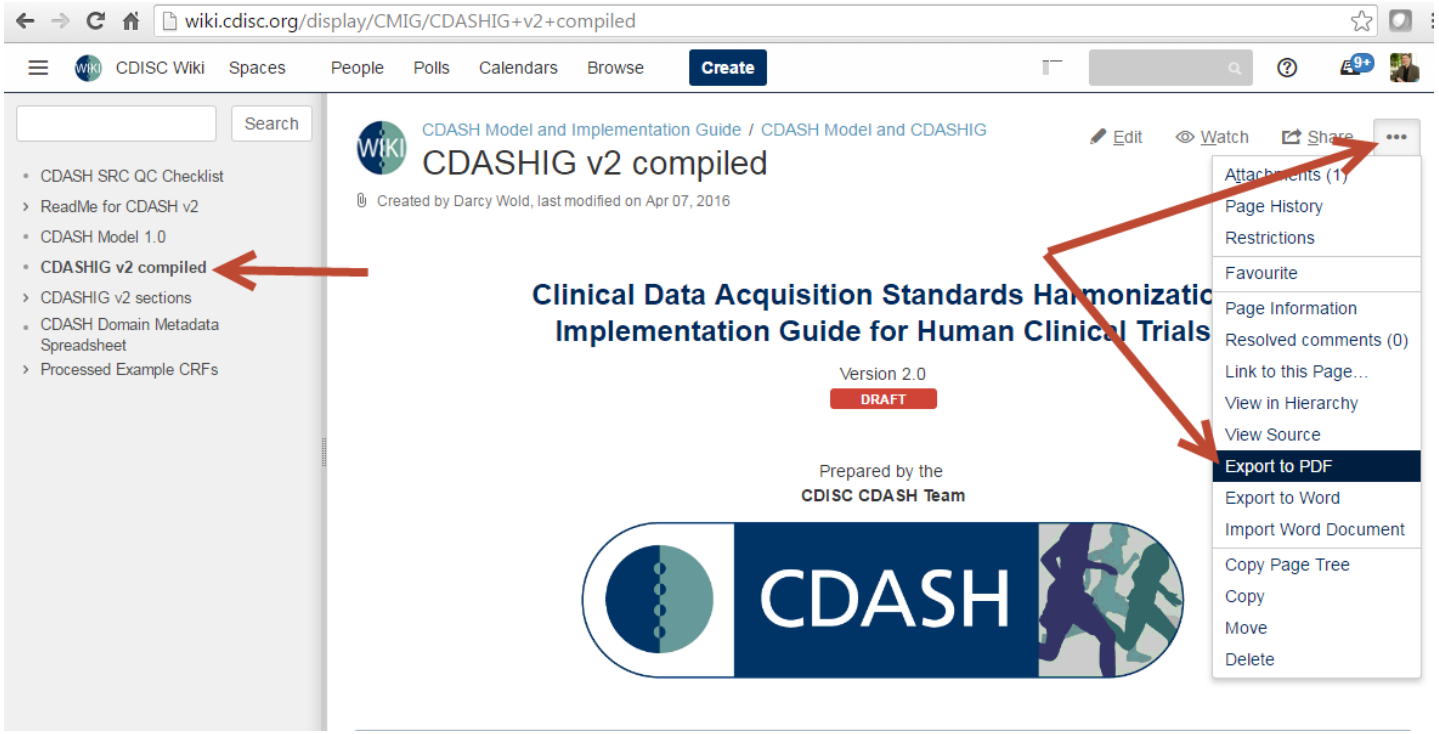
CDASHIG 2.0 on the Wiki

- http://wiki.cdisc.org/display/CMIG/CDASH+Model+and+CDASHIG



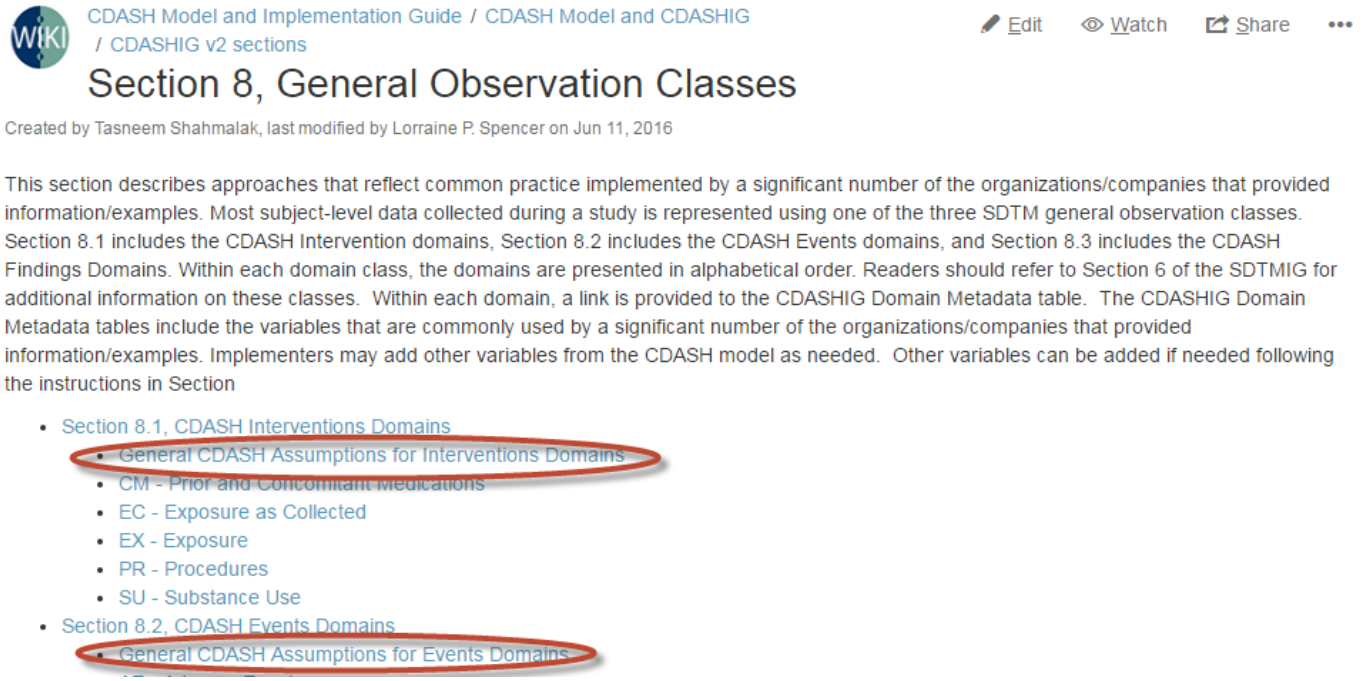
CDASHIG 2.0 on the Wiki

- The CDASHIG can be exported
- Select CDASHIG v2 compiled and export to desired format



CDASHIG 2.0 on the Wiki

- "General Assumptions" are written at the highest applicable level
  - General Assumptions per Class
  - General Assumptions per Domain



CDASH Model and Implementation Guide / CDASH Model and CDASHIG / CDASHIG v2 sections

Edit Watch Share •••

Section 8, General Observation Classes

Created by Tasneem Shahmalak, last modified by Lorraine P. Spencer on Jun 11, 2016

This section describes approaches that reflect common practice implemented by a significant number of the organizations/companies that provided information/examples. Most subject-level data collected during a study is represented using one of the three SDTM general observation classes. Section 8.1 includes the CDASH Intervention domains, Section 8.2 includes the CDASH Events domains, and Section 8.3 includes the CDASH Findings Domains. Within each domain class, the domains are presented in alphabetical order. Readers should refer to Section 6 of the SDTMIG for additional information on these classes. Within each domain, a link is provided to the CDASHIG Domain Metadata table. The CDASHIG Domain Metadata tables include the variables that are commonly used by a significant number of the organizations/companies that provided information/examples. Implementers may add other variables from the CDASH model as needed. Other variables can be added if needed following the instructions in Section

- Section 8.1, CDASH Interventions Domains
  - General CDASH Assumptions for Interventions Domains
  - CM - Prior and Concomitant Medications
  - EC - Exposure as Collected
  - EX - Exposure
  - PR - Procedures
  - SU - Substance Use
- Section 8.2, CDASH Events Domains
  - General CDASH Assumptions for Events Domains

CDASHIG 2.0 Domains

- Each CDASHIG Domain, unless otherwise specified, has:
  - Description / Overview

Description/Overview for the CDASHIG PR - Procedures Domain

The Procedures domain should be used to collect details describing a subject's therapeutic and diagnostic procedures conducted before, during and/or after the study. Measurements obtained from procedures are to be represented in the appropriate Findings domain(s).

  - Specifications defined in the CDASHIG Domain Metadata Spreadsheet
  - Domain Level Assumptions

Assumptions for the Procedures CDASHIG Domain Model

1. Information on procedures is generally collected in one of two different ways, either by recording free text or using a pre-specified list of terms.
2. Since the solicitation of information on specific therapeutic and diagnostic procedures may affect the frequency at which they are reported, the fact that a specific procedure was solicited may be of interest to reviewers. PROCCUR is used to indicate whether a pre-specified procedure occurred. A value of Y indicates that the procedure occurred and N indicates that it did not. If a procedure was not pre-specified, the value of PROCCUR should not be collected.

  - Annotated Example CRFs

CDASHIG 2.0 Example CRFs

- CRFs are only examples and are not meant to imply that any particular layout is preferable over another.
- CRFs are annotated to show mapping.
  - SDTM variables are in **RED**. If CDASH variable differs from SDTM, the CDASH variable is in **GREY**. Data collected, but not submitted in SDTM, are denoted as **[NOT SUBMITTED]**.
- Sponsors are responsible for understanding and implementing CDISC Controlled Terminology where applicable.
- Annotated CRFs are best understood in conjunction with their respective metadata tables. Consult the metadata tables for mapping details.

CDASHIG 2.0 Example CRF

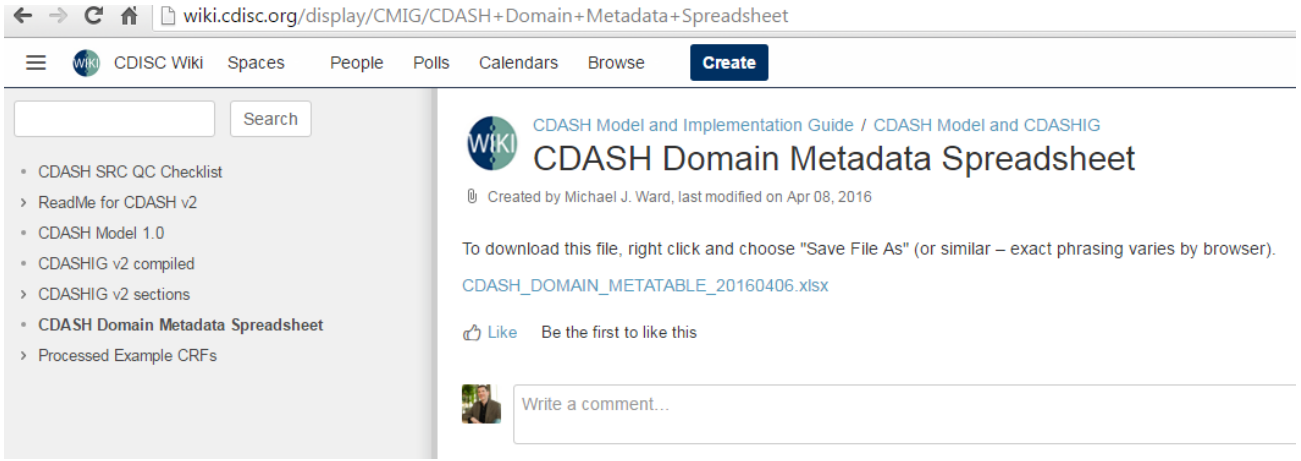
This CRF is only an example and is not meant to imply that any particular layout is preferable over another.
CRF annotated to show mapping. SDTM variables are in RED. If CDASH variable differs from SDTM, the CDASH variable is in GREY. Data collected, but not submitted in SDTM, are denoted as NOT SUBMITTED.

What is the disposition category? *Defaulted* DSCAT	**DISPOSITION EVENT**
To which period of the trial does this disposition event refer? *Defaulted* EPOCH	**BLINDED TREATMENT**
What was the subject's status? DSTERM DSDECOD	O COMPLETED O ADVERSE EVENT Specify: _____ DSTERM
What was the completion/discontinuation date? DSSTDTC DSSTDAT	_ _ / _ _ _ / _ _ _ _
What was the completion/discontinuation time? DSSTDTC DSSTTIM	_ _ : _ _
Was treatment unblinded by the site? [NOT SUBMITTED] DSUNBLND	O Yes O No
What is the next period the subject will continue to? [NOT SUBMITTED] DSCONT	O OPEN LABEL TREATMENT O FOLLOW-UP

Sponsors are responsible for understanding and implementing CDISC Controlled Terminology where applicable. Annotated CRFs are best understood in conjunction with their respective metadata tables. Consult the metadata tables for mapping details.

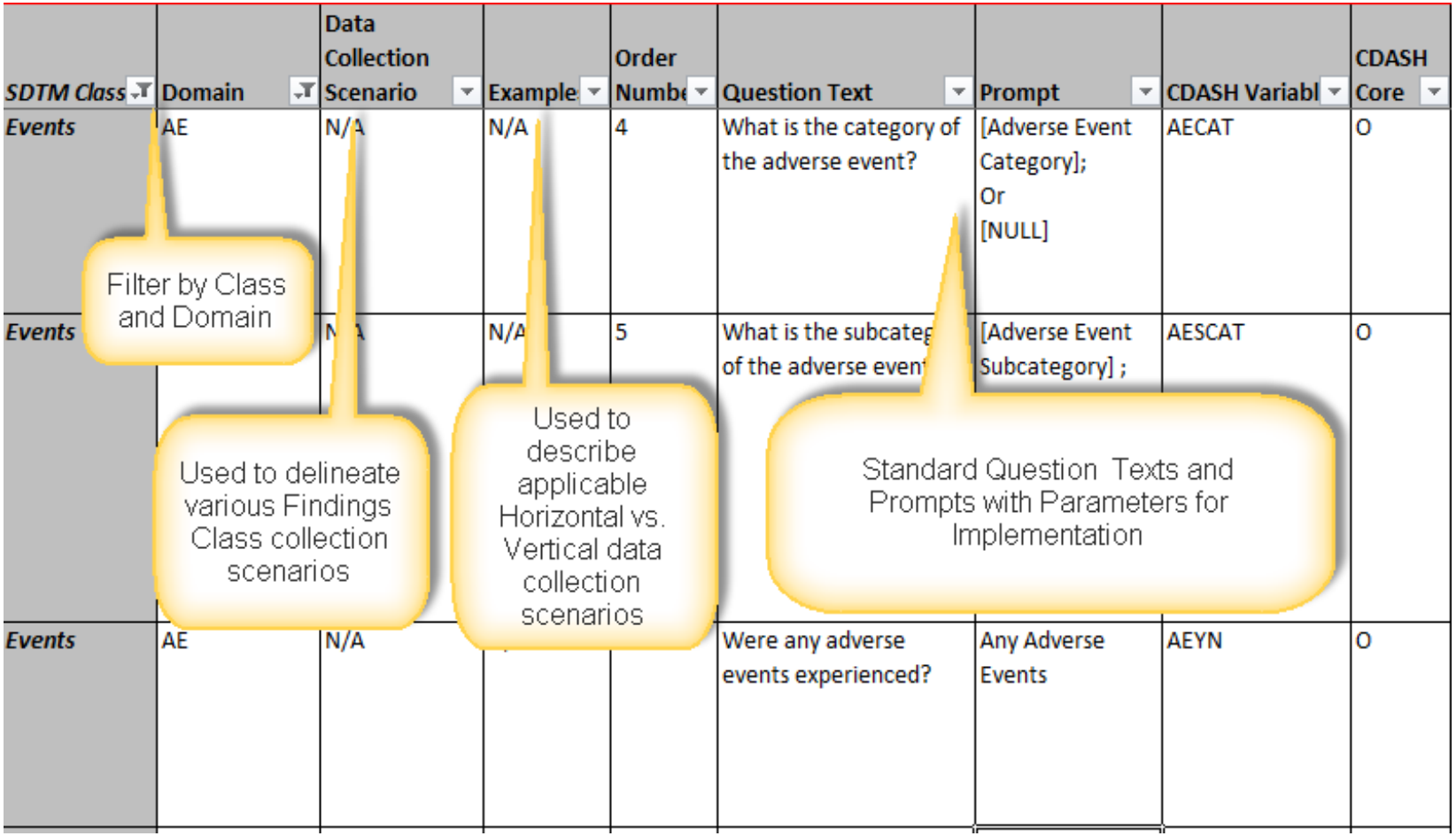
CDASHIG 2.0 Domain Metadata Tables

- The Domain Metadata Tables can be downloaded from the Wiki:
  - http://wiki.cdisc.org/display/CMIG/CDASH+Domain+Metadata+Spreadsheet



- It is a single tab worksheet that can be filtered by Class and/or Domain.

Excerpt from Domain Metadata Table



SDTM Class	Domain	Data Collection Scenario	Example	Order Numbe	Question Text	Prompt	CDASH Variabl	CDASH Core
Events	AE	N/A	N/A	4	What is the category of the adverse event?	[Adverse Event Category]; Or [NULL]	AECAT	O
Events			N/A	5	What is the subcateg of the adverse event	[Adverse Event Subcategory] ;	AESCAT	O
Events	AE	N/A			Were any adverse events experienced?	Any Adverse Events	AEYN	O

CDASH IG Domain Metadata Table

'Data Collection Scenarios' include, but are not limited to:

- Denormalized vs Normalized
- Central Processing
- Local Readings
- Central Reading

'Examples' are provided to demonstrate how to implement a denormalized structure for some example domains.

Excerpt from Domain Metadata Table

Case Report Form Completion Instructio	Implementation Notes and Examples for CDASH and SDTM mapping	DRAFT CDASH Definition	Maps to the SDTMIG Variable	SDTM Core	Mapping Instructions	Controlled Terminology Codelist Name	Subset Controlled Terminology / CDASH Codelist
Record the adverse event category, if not pre-printed on the CRF.	Sponsor-defined Controlled Terminology. This would most commonly be a heading on the CRF or screen, not a question to which the site would provide an answer.	A grouping of topic-variable values based on user defined characteristics.	AECAT	Perm	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable".	N/A	N/A
Record the adverse event subcategory, if not pre-printed on the CRF.	Sponsor-defined Controlled Terminology. This would most commonly be a heading on the CRF or screen, not a question to which the site would provide an answer. AESCAT can only be used if there is an AECAT and it must be a subcategorization of AECAT.	A sub-division of topic-variable values based on user defined characteristics.	AESCAT	Perm	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable".	N/A	N/A
Indicate if the subject experienced any adverse events. If yes, include the appropriate details where indicated on the CRF.	The intent/purpose of collecting this field is to help with data cleaning and monitoring. It provides verification that all other fields on the CRF were deliberately left blank.	An indication whether or not any AEs were experienced during the study.	N/A	N/A	Does not map to an SDTMIG variable. The SDTM Annotated CRF is annotated to indicate that this field is NOT SUBMITTED.	(NY)	N/A

Public Review

- Look for an announcement within the next few days
- Refer to detailed instructions on the CDASH Wiki
  - http://wiki.cdisc.org/display/CMIG/ReadMe+for+CDASH+v2

Highlights for Reviewing the Model

- Download the CDASH Model spreadsheet from http://wiki.cdisc.org/display/CMIG/CDASH+Model+1.0
- Go to the CDASH project in JIRA at: http://jira.cdisc.org/projects/CDASH/
- Click on the "Create" button in the top menu to bring up the Create Issue form
- Select CDASH as the **Project**.

Highlights for Reviewing the Model

- From the **Components** pull down list select CDASH Model as the document being reviewed.
- In the **Summary** field, indicate the worksheet tab (e.g. ‘Findings’) and worksheet cell reference (e.g., 'C16').
  - **Line Number** and **Section** # may be left blank.
  - Document your findings in the **Description** field.
- Click the "Create" button in the bottom right corner of the form to submit the comment.

Highlights for Reviewing the CDASHIG

- **To add comments to JIRA from within the Wiki:**
  - Select the text to which you wish to attach the comment.
    - Access the individual sections of the CDASHIG.
    - After a moment, a small contextual menu should appear.
  - Within the contextual menu, click on the icon that looks like an X (as shown to right). This will trigger an abbreviated Create Issue form.
  - Choose "CDASH" from the first drop-down menu.
  - Fill out the form and click the "Create" button in the bottom left corner of the form to submit your comment as an issue.
  - If you review a document without creating a Jira issue, please “Like” us at the bottom of the page to track who has reviewed!

Highlights for Reviewing the CDASHIG Metadata Tables

- Download the CDASH Metadata Table spreadsheet from http://wiki.cdisc.org/display/CMIG/CDASH+Domain+Metadata+Spreadsheet
- Go to the CDASH project in JIRA at: http://jira.cdisc.org/projects/CDASH/
- Click on the "Create" button in the top menu to bring up the Create Issue form
- Select CDASH as the **Project**.

Highlights for Reviewing the CDASHIG Metadata Tables

- From the **Components** pull down list select CDASH Domain Metadata as the document being reviewed.
- In the **Summary** field, indicate the worksheet cell reference (e.g., 'C16').
  - **Line Number** and **Section** # may be left blank.
  - Document your findings in the **Description** field.
- Click the "Create" button in the bottom right corner of the form to submit the comment.

Thank you!

CDASH Model and CDASHIG Team

Use Case: Using the CDASH Model to Create a new CDASHIG Domain

CDASH Variable	CDASH Variable Label	Question Text	Prompt
PRYN	Any [Intervention]	Has the subject had any [intervention topic(s)] (after/before) [study specific time frame] (after/before [study specific time frame])?; Or [Was/Were] there any [intervention topic(s)] [taken/performed/used/collected] (after/before) study specific time frame])?	Any [Intervention Topic]
PRONGO	Ongoing	[Is/Was] the [PRTRT/ Intervention] still ongoing [after the end of the study specific timepoint or period] ?	Ongoing [after the end of the Study Specific Timepoint or Period]
PRPRIOR	Prior to [Study/Timepoint]	Was the [PRTRT/Intervention] [taken/performed/used/administered/consumed] prior to the [study /study specific time point or period]?; Or Did the [PRTRT/Intervention] [start/occur] prior to the [study/study specific time point or period]?	[Taken /Performed /Used/Administered/Consumed/Started/Occurred] Prior to the [Study/Study Specific Time Point or Period]?
PRTRT	Name of Treatment	What [is/was] the [treatment/intervention topic]?; Or [If other is selected], [explain/specify/provide more details]	[Treatment/Intervention]; Or [Specify Other/ Explain/Specify Details [Treatment/Intervention]
PRCAT	Category	What [is/was]the category (of the intervention])?	[Category/ Category Value]; Or NULL
PRSCAT	Subcategory	What [is/was] the subcategory (of the [intervention])?	[Subcategory/ Subcategory Value]; Or NULL

Use Case: Using the CDASH Model to Create a new CDASHIG Domain

- Performed a Find and Replace from “--” to “PR”
- Assessed of all the Intervention Class CDASH Model variables
  - Deleted those that did not apply to Procedures
  - Evaluated Question Text and Prompts, replacing italicized parameters with Procedure specific language
  - Evaluated the remaining metadata to ensure it applied to Procedures
- Entire process to draft a new domain using the model took less than 2 hours

Use Case: Using the CDASH Model to Create a new CDASHIG Domain

Excerpt from final PR domain for CDASHIG 2.0

Question Text	Prompt	CDASH Variabl	CDASH Core	DRAFT CDASH Definition	Maps to the SDTMIG Variable	SDTM Core	Mapping Instructions
What is the study identifier?	[Protocol/Study]	STUDYID	HR	A unique identifier for a study.	STUDYID	Req	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable".
What is the site identifier?	Site Identifier	SITEID	HR	A unique identifier for a site within a study.	DM.SITEID	Req	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable".
What is the subject identifier?	Subject	SUBJID	HR	An identifier assigned to each trial subject to protect the subject's identity, and used instead of the subject's name when the Investigator reports trial data.	DM.SUBJID	Req	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable".
Were any surgical, therapeutic or diagnostic procedures performed?	Any Procedures	PRYN	O	An indication whether or not the subject had any procedures performed.	N/A	N/A	Does not map to an SDTMIG variable. The SDTM Annotated CRF is annotated to indicate that this field is NOT SUBMITTED.
What was the category of the procedure?	[Procedure Category]; or [NULL]	PRCAT	O	A grouping of topic-variable values based on user defined characteristics.	PRCAT	Perm	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable".
What is the procedure identifier?	[Line Number/PR Number]	PRSPID	O	A sponsor-defined identifier which can be used for pre-printed numbers on the CRF.	PRSPID	Perm	Maps directly to the SDTMIG variable listed in the column with the heading "Maps to the SDTMIG Variable". May be used to create RELREC to

Q&A

CDISC Online Education & Event Updates

John Ezzell, CDISC

Strength *through Collaboration*

CDISC Online Training Production Update

- Just Released
  - COPD TA Training
- In Final Stages of Production:
  - PGx Module 2
  - Breast Cancer TA Training

Online Courses in Development
TA Alzheimer's
TA QT Studies
TA Breast Cancer
TA Pain
TA Rheumatoid Arthritis
CT Module 1-3
Define XML
SDTM V3.2
ADaM Modules 3-8

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered	Host
Durham, NC	20-24 June	SDTM, ADaM Primer, ADaM T&A, Define-XML	Duke Clinical Research Institute, Duke University Medical Center
Whippany, NJ	18-22 July	SDTM, CDASH, ADaM Primer, ADaM T&A	Bayer HealthCare
Minneapolis, MN	22-26 Aug	SDTM-MD, CDASH, ADaM Primer, ADaM T&A	MedNet Solutions
Seattle, WA	22-26 Aug	SDTM, ADaM Primer, ADaM T&A, Define-XML	Axio Partners in Research
Bethesda, MD (International Interchange)	26-30 Sep	See online.	CDISC

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered	Early registration discount:	Host
Brussels, Belgium	5-9 Sep	SDTM, CDASH, ADaM Primer, ADaM T&A	6 Jun	Business & Decision Life Sciences
Copenhagen, Denmark	Oct 2016	SDTM, SEND, ADaM Primer, ADAM T&A, Defne-XML	3 Jul	SCUBED
Basel, Switzerland	7-11 Nov	SDTM, ADaM Primer, ADaM T&A, Define-XML	7 Aug	ACTELION

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Register by:	Early Registration Discounts	Host
Osaka, Japan	12-16 Sep	See web.	12 Aug	12 June	CAC EXICARE Corporation
Beijing, China	18-21 Oct	TBA	TBA	TBA	TBA
Shanghai, China	24-27 Oct	TBA	TBA	TBA	TBA
Tokyo, Japan	5-9 Dec	TBA	TBA	TBA	TBA

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

Upcoming Webinars

Presenter	Topic	Webinar Date
Rachael Zirkle, Lilly Matthew Vitale, Lilly Soonbum Kwon, Lilly	Diabetic Kidney Disease TA Public Review	Jun 20, 2016
Dr. Paul Harris, Vanderbilt University Sam Hume, CDISC	Applied Use of CDISC Standards – A Case Study Using REDCap Mini-Training	July 11, 2016

Webinar details and registration 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

CDISC Members Drive Global Standards

Thank you for your support!

Learn CDISC from CDISC!

Authoritative. Global. Vendor neutral.