



Bay Area CDISC User Network Meeting

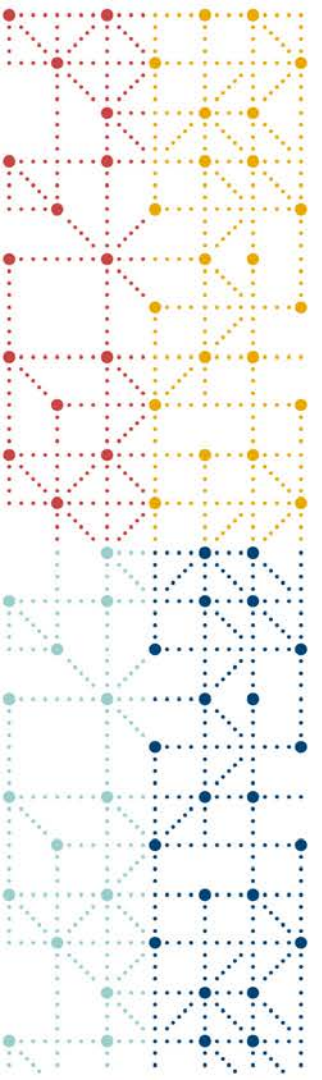
Presented by Sally Cassells
Sr Director, Data Exchange Standards and
Certification

25 April 2019



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- *The author(s) have no real or apparent conflicts of interest to report.*



Agenda

Define-XML v2.1

CDISC News

A decorative graphic on the left side of the slide, consisting of a grid of dots and lines. The dots are colored in red, yellow, and blue, and the lines are colored in red, yellow, and blue. The grid is composed of a 10x10 grid of dots, with lines connecting the dots in a grid pattern. The dots are arranged in a grid, with lines connecting the dots in a grid pattern. The dots are colored in red, yellow, and blue, and the lines are colored in red, yellow, and blue. The grid is composed of a 10x10 grid of dots, with lines connecting the dots in a grid pattern. The dots are arranged in a grid, with lines connecting the dots in a grid pattern. The dots are colored in red, yellow, and blue, and the lines are colored in red, yellow, and blue.

Define-XML v2.1

- Standards identification metadata
- Changes to Origin for SDTM
- Reimplementation of def:Class with def:SubClass

Define-XML v2.1 – Standards Identification

CDISC01_1

- Annotated CRF
- Supplemental Documents
- Standards
- Datasets
- Controlled Terminology
- Methods

Expand all VLM

Collapse all VLM

Study Name CDISC01_1

Study Description CDISC Test Study Modified to illustrate Define-XML 2.1 features

Protocol Name CDISC01-1

Metadata Name Study CDISC01_1, Data Definitions V-1

Metadata Description
Data Definitions for CDISC01-01 SDTM datasets. This metadata version contains only a subset of datasets compared to the prior version. The metadata provided is only intended to illustrate most Define-XML 2.1 new features and not meant to serve as a comprehensive example of all metadata expected to be defined to fully describe an SDTM dataset package. Notes: 1) Supplemental documents released in prior Define-XML versions were not updated to reflect changes to the metadata. 2) This example is prepared for a context other than submission; however, still using the approach of non-standard variables prepared as supplemental qualifiers datasets.

Date/Time of Define-XML document generation: 2019-02-10T22:13:15
Define-XML version: 2.1.0
Define-XML Context: Other
Stylesheet version: 2019-02-11

Standards for Study CDISC01_1

Standard	Type	Status	Documentation
SDTMIG 3.1.2	IG	Final	The CDISC01 study was modeled on a very old SDTMIG and no attempt was done yet to upversion it to a newer SDTMIG
SDTMIG 3.2	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTM IG 3.2
SDTMIG-MD 1.0	IG	Final	As an example, the CDISC01 study was adjusted to include a new Domain available in SDTMIG-MD 1.0. The XS Domain is expected to reference the device used with variable SPDEVID.
CDISC/NCI SDTM 2011-12-09	CT	Final	Assuming the CT was not upversioned for this study
CDISC/NCI SDTM 2015-12-18	CT	Final	The CT version applicable for the new Domain is the 2015-12-18 version

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
IS [SDTMIG 3.1.2]	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ		ts.xml
DI [SDTMIG-MD 1.0]	Device Identifiers	SPECIAL PURPOSE	One record per device identifier per device	Tabulation	STUDYID, SPDEVID, DIDPARMCD	The DI domain is included to illustrate the use of a separate complementary SDTMIG. In this example, the device ID is referenced from a Findings Domain (XS).	di.xml
DM [SDTMIG 3.1.2]	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBID	See Reviewer's Guide, Section 2.1 Demographics Reviewers Guide [section2.1]	dm.xml
EP [SDTMIG 3.1.2]	Events per	INTERVENTIONS	One record per treatment	Tabulation	STUDYID, HDISYID		ep.xml

- Identify content standard(s) used by data definitions
- Identify all CDISC CT versions referenced

Each dataset definition identifies the standard it follows

New XSL Stylesheet – developed through PhUSE CSS Working Group.

Now included in downloads of Define-XML V2.

Define-XML v2.1 – SDTM Origin Metadata

DM (Demographics) - [SDTMIG 3.1.2]					Location: dm.xml
Related Supplemental Qualifiers Dataset: SUPPDM (Supplemental Qualifiers for DM)					
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	7		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	2	Domain Abbreviation (DM) • "DM" = "Demographics"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	14		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
SUBJID	Subject Identifier for the Study	text	6		Collected (Source: Investigator) Annotated CRF [1] [2]
RFSTDTM	Subject Reference Start Date/Time	date		ISO 8601	Derived (Source: Sponsor) RFSTDTM = first date/time of study drug, for safety subject. Null for screen failures.
RFENDTM	Subject Reference End Date/Time	date		ISO 8601	Derived (Source: Sponsor) RFENDTM = termination date, for safety subjects. Null for screen failures.
SITEID	Study Site Identifier	text	3		Collected (Source: Investigator) Annotated CRF [1] [2]
BRTHDTM	Date/Time of Birth	date		ISO 8601	Collected (Source: Investigator) Page 6 [6] [2]
AGE	Age	integer	2		Derived (Source: Sponsor) Age at Screening Date (Screening Date - Birth date). For the complete algorithm see the referenced external document. Complex Algorithms [DM] [2]
AGEU	Age Units	text	5		Assigned (Source: Sponsor) Defaulted to YEARS
SEX	Sex	text	16	Sex • "F" = "Female" • "M" = "Male" • "U" = "Unknown" • "UNDIFFERENTIATED" = "Undifferentiated"	Collected (Source: Investigator) Annotated CRF [6] [2]

Identify source in addition to origin details (page#, derivation)

LB (Laboratory Tests Results) - [SDTMIG 3.1.2]

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / C
LBORRES VLM		Result or Finding in Original Units	text	8		Collected (Source: Sponsor) Annotated CRF [23 25 26 27] Collected (Source: Vendor) Origin specified at Value Level Metadata
	LBTESTCD IN ("BILI" (Bilirubin), "GLUC" (Glucose)) and LBSPEC = "BLOOD"	Result or Finding in Orig Units - Set 1	float	3		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD IN ("BUN" (Blood Urea Nitrogen), "HGB" (Hemoglobin), "LYM" (Lymphocytes)) and LBSPEC = "BLOOD"	Result or Finding in Orig Units - Set 2	float	4		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD IN ("GLUC" (Glucose), "OCCBLD" (Occult Blood)) and LBSPEC = "URINE"	Result or Finding in Orig Units Set 3	text	8		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "HCT" (Hematocrit) and LBSPEC = "BLOOD" and LBNAM = "LOCAL LAB"	Hematocrit	float	4		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "HCT" (Hematocrit) and LBSPEC = "BLOOD" and LBNAM = "LOCAL LAB"	Hematocrit	float	4		Collected (Source: Investigator) From Local lab (LB.LBNAM="LOCAL LAB"). Note that the CRF page reference is given only for illustration purposes. The sample acrf.pdf does not include the local lab CRF page. Annotated CRF [1 2]
	LBTESTCD = "PH" (pH) and LBSPEC = "URINE"	pH	float	3		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "VITB12" (Vitamin B12) and LBSPEC = "SERUM"	Vitamin B12	integer	3		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")

Supports multiple origins when it is not possible to identify where clause criteria for value level origin definitions

Define-XML v2.1 def:Class and def:SubClass

Datasets

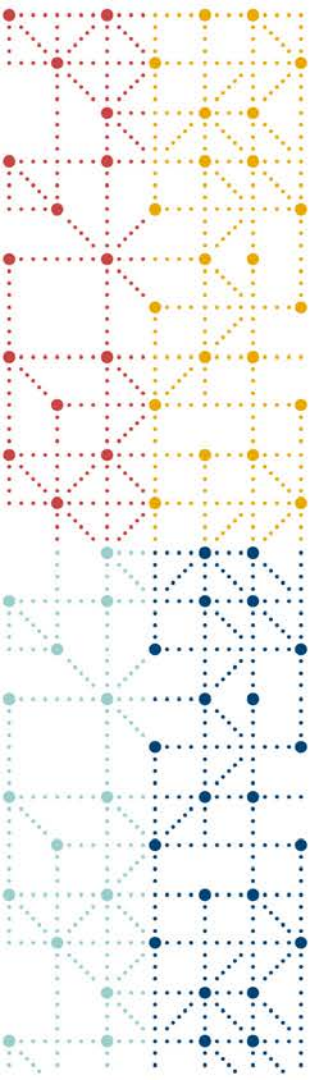
Dataset	Description	Class - SubClass	Structure	Purpose	Keys	Documentation	Location
ADSL [ADaMIG 1.1]	Subject-Level Analysis	SUBJECT LEVEL ANALYSIS DATASET	one record per subject	Analysis	STUDYID, USUBJID	Screen Failures are excluded since they are not needed for this study analysis. See referenced dataset creation program and ADRG adsl.sas Analysis Data Reviewer's Guide [6]	adsl.xpt
ADOSADAS [ADaMIG 1.1]	ADAS-Cog Analysis	BASIC DATA STRUCTURE	One record per subject per parameter per analysis visit per analysis date	Analysis	STUDYID, USUBJID, PARAMCD, AVISIT, ADT	See referenced dataset creation program and ADRG adosadas.sas Analysis Data Reviewer's Guide [Section2.1]	adosadas.xpt
ADAE [ADaMIG 1.1]	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE <ul style="list-style-type: none"> ADVERSE EVENT 	one record per subject per adverse event	Analysis	STUDYID, USUBJID, AETERM, ASTDT, AESEQ	See SAS program adae.sas 	adae.xpt

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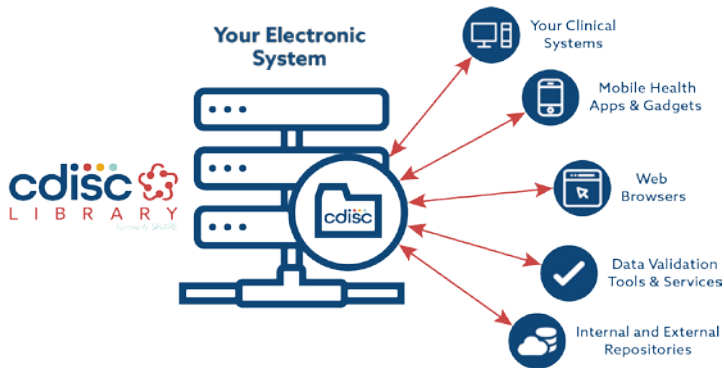
<!-- Dataset Definition (ADAE) -->
<ItemGroupDef OID="IG.ADAE"
  Name="ADAE"
  Repeating="Yes"
  IsReferenceData="No"
  SASDatasetName="ADAE"
  Purpose="Analysis"
  def:Structure="One record per subject per event"
  def:ArchiveLocationID="LF.ADAE">
  <Description>
    <TranslatedText xml:lang="en">Adverse Event Analysis Dataset</TranslatedText>
  </Description>
  <ItemRef ItemOID="IT.ADAE.STUDYID" OrderNumber="1" Mandatory="No" KeySequence="1" />
  <ItemRef ItemOID="IT.ADAE.USUBJID" OrderNumber="2" Mandatory="No" KeySequence="2" />
  ...
  <def:Class Name="OCCURRENCE DATA STRUCTURE">
    <def:SubClass Name="ADVERSE EVENT" />
  </def:Class>
  <def:leaf ID="LF.ADAE" xlink:href="adae.xpt">
    <def:title>adae.xpt</def:title>
  </def:leaf>
</ItemGroupDef>

```

- Re-implemented as an XML child element instead of an attribute.
- @Name attribute for def:Class follows CDISC Controlled Terminology
- Working with Controlled Terminology to develop SubClass codelist. (Request has been submitted.)



CDISC News



- New platform based on semantic technology s
- Linked metadata model better suited for ongoing development of CDISC standards content
- Expanded Restful API
- General release April 10 2019.

Form

Content:

DataCollection:
CDASH 1-0
CDASHIG 1-1-1
CDASHIG 2-0

DataTabulation:

SDTM 1-2
SDTM 1-3
SDTM 1-4
SDTM 1-5
SDTM 1-6
SDTM 1.7

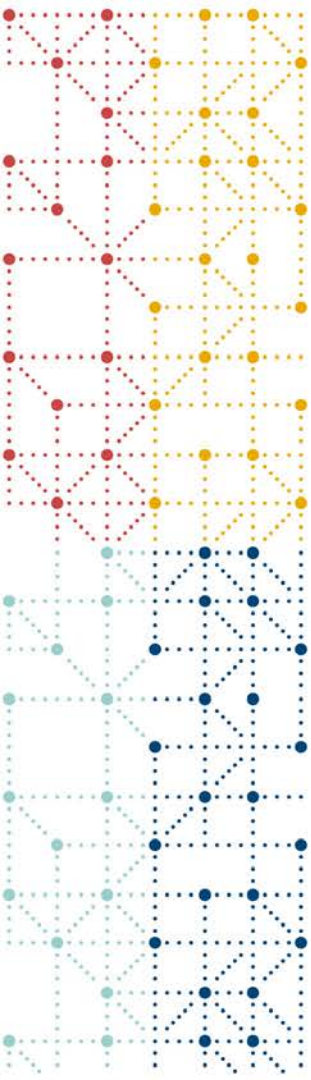
DataAnalysis:

ADaM-ADAE-1-0
ADaM-TTE-1-0
ADaM -OCCDS-1-0
ADaMIG-1-0
ADaMIG-1-1

SDTMIG 3-1-2
SDTMIG 3-1-3
SDTMIG 3-2
SDTMIG 3-3
SDTMIG AP 1-0
SDTMIG MD 1-1
SDTMIG PGx 1-0

Recent and Upcoming TAUGS

Therapeutic Area	Development	Public Review	Release Notes
Acute Kidney Injury Therapeutic Area User Guide v1.0	In Progress		In Development.
CDAD Therapeutic Area User Guide v1.0	Completed	Completed	Preparing for Publication.
Congestive Heart Failure Therapeutic Area User Guide v1.0	In Progress		In Development.
Crohn's Disease Therapeutic Area User Guide v1.0	In Progress		In Development.
Diabetes - Type 1 Therapeutic Area User Guide v1.0	In Progress		In Development.
Lung Cancer Therapeutic Area User Guide v1.0	Completed	Completed	Resolving Public Comments.
Nutrition Therapeutic Area User Guide v1.0	Completed	Completed	Resolving Public Comments.
Psoriasis Therapeutic Area User Guide v1.0	In Progress		In Development.
Traditional Chinese Medicine - Acupuncture	In Progress		In Development.
Traditional Chinese Medicine - Coronary Artery Disease/Angina Therapeutic Area User Guide v1.0	Completed	Completed	Preparing for Publication.



Thank You!

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