Bay Area CDISC User Network Meeting
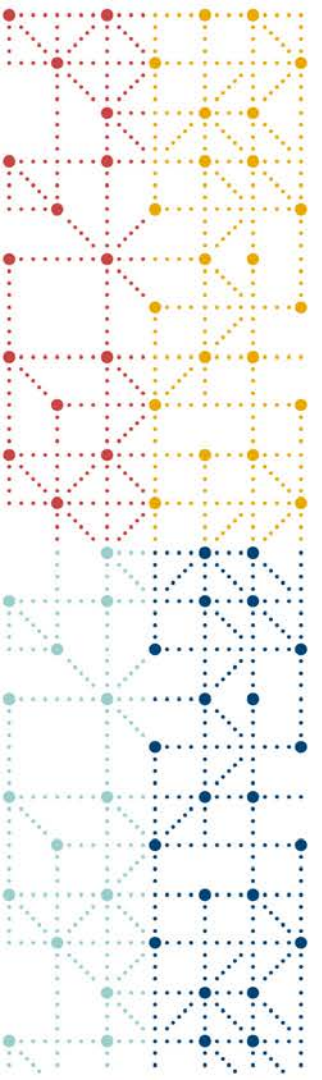
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Sr Director, Data Exchange Standards and Certification

25 April 2019

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

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Agenda

Define-XML v2.1

CDISC News

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

New XSL Stylesheet – developed through PhUSE CSS Working Group.

Now included in downloads of Define-XML V2.

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Define-XML v2.1 – SDTM Origin Metadata

DM (Demographics) - [SDTMIG 3.1.2]					Location: dm.xpt
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 [3 ⧉]
RFSTDTC	Subject Reference Start Date/Time	date		ISO 8601	Derived (Source: Sponsor) RFSTDTC = first date/time of study drug, for safety subject. Null for screen failures.
RFENDTC	Subject Reference End Date/Time	date		ISO 8601	Derived (Source: Sponsor) RFENDTC = termination date, for safety subjects. Null for screen failures.
SITEID	Study Site Identifier	text	3		Collected (Source: Investigator) Annotated CRF [3 ⧉]
BRTHDTC	Date/Time of Birth	date		ISO 8601	Collected (Source: Investigator) Page 6 [6 ⧉]
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 ⧉]
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 ⧉]

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 ⧉ 26 ⧉] 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 ⧉]
	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

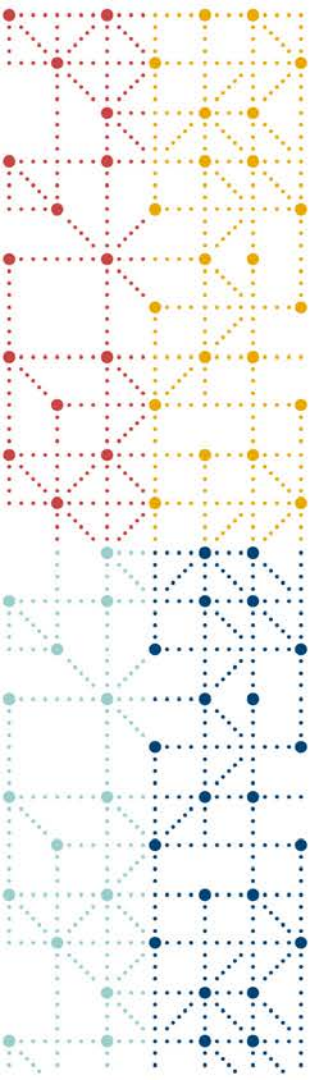cdisc

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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 ⧉
ADQSADAS [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 adqsadas.sas ⧉ Analysis Data Reviewer's Guide [Section2.1 ⧉]	adqsadas.xpt ⧉
ADAE [ADaMIG 1.1]	Adverse Events Analysis Dataset	OCCURRENCE DATA STRUCTURE • ADVERSE EVENT	one record per subject per adverse event	Analysis	STUDYID, USUBJID, AETERM, ASTDT, AESEQ	See SAS program adae.sas ⧉	adae.xpt ⧉

- 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.)

```xml
<!-- 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>
```
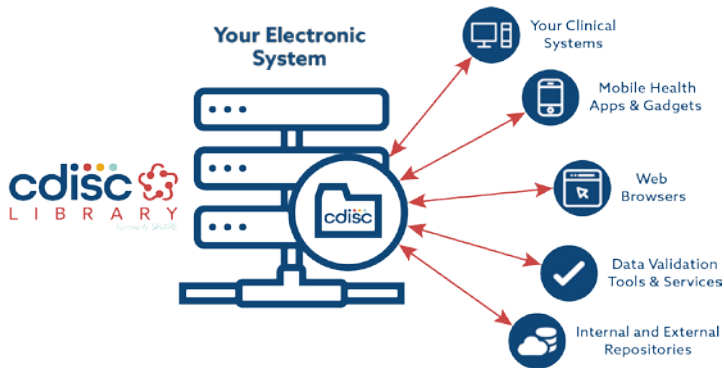
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CDISC News

CDISC LIBRARY
formerly SHARE

Your Electronic System

Your Clinical Systems
Mobile Health Apps & Gadgets
Web Browsers
Data Validation Tools & Services
Internal and External Repositories

- New platform based on semantic technology st
- Linked metadata model better suited for ongoir 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
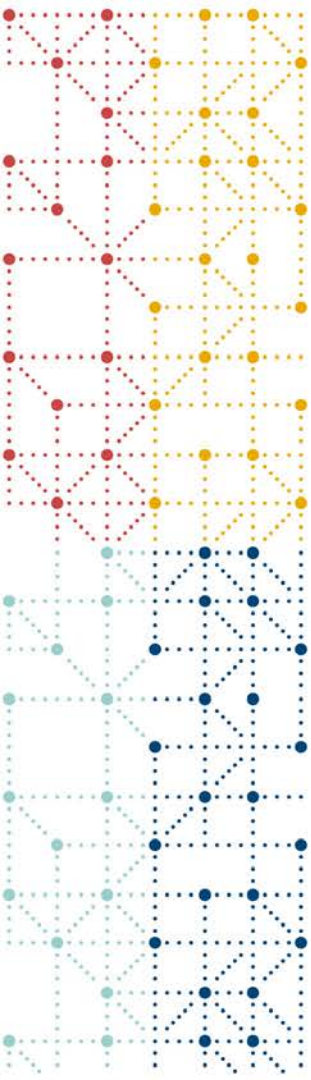SDTM 1-3
SDTM 1-4
SDTM 1-5
SDTM 1-6
SDTM 1.7

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 UpcomingTAUGS

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.

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Thank You!

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