

HAVE YOU MET DEFINE.XML 2.0?

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Have You Met Define.xml 2.0?

- ▶ Introduction and background
- ▶ Examine the various sections of a study's define.xml
- ▶ Get acquainted with our new friend define.xml
 - Quick introductions – Study Information/Header
 - Initial conversation – Tabulation Datasets List
 - Getting to know study define – Variable and Value Level Metadata
 - Learning the lingo – Controlled Terminology
 - Revisiting old stories – Computational Algorithms Summary
 - Meet friends and family of define – External Linked Files
- ▶ Explore information that each section should reveal to reviewer

What is define.xml?

► Metadata for SDTM or ADaM datasets

- What type of datasets
- Which datasets
- Variables
- Controlled Terminology
- Source or derivation

► Purpose

- Documentation
- Communicate to reviewer

► What define.xml is not

- Programming specification
- Last minute creation

What Does define.xml Look Like?

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet type="text/xsl" href="define2-0-0.xsl"?>
<ODM
  xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:def="http://www.cdisc.org/ns/def/v2.0"
  ODMVersion="1.3.2"
  FileType="Snapshot"
  FileOID="ABC-XYZ.SDTM-IG.3.2"
  CreationDateTime="2018-12-28T02:55:55">
  <Study OID="ABC-XYZ.SDTM-IG.3.2">
    <GlobalVariables>
      <StudyName>ABC-XYZ</StudyName>
      <StudyDescription>Phase II, Randomized Study Placebo
Controlled Study of Drug A in Bad Disease</StudyDescription>
      <ProtocolName>ABC-XYZ</ProtocolName>
    </GlobalVariables>
    <MetaDataVersion OID="MDV.ABC-XYZ.SDTM-IG.3.2" Name="Study
ABC-XYZ Data Definitions"
```

Define.xml Using Stylesheet

Study ABC-XYZ, Data Defini... x

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SDTM-IG 3.2

Annotated Case Report For
Study Data Reviewer's Guide

- Tabulation Datasets
- Value Level Metadata
- Controlled Terminology
- Computational Algorithms
- Comments

Date of document generation: 2018-12-28T02:55:55

Stylesheet version: 2013-04-24

Tabulation Datasets for Study ABC-XYZ (SDTM-IG 3.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	ex.xpt	
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	ds.xpt	
VS	Vital Signs	FINDINGS	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM	vs.xpt	

Go to the [top](#) of the define.xml

Demographics (DM) [Location: [dm.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	10		Assigned	
DOMAIN	Domain Abbreviation		text	2	["DM" = "Demographics", "DS" = "Disposition", "EX" = "Exposure", "VS" = "Vital Signs"] < SDTM Domain Abbreviation >	Assigned	

Same Define.xml Using Newer Stylesheet

ABC-XYZ, SDTM-IG3.2

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X Find: ageu Previous Next Options 1 match

ABC-XYZ Date/Time of Define-XML document generation: 2018-12-28T02:55:55
Define-XML version: 2.0.0
Stylesheet version: 2018-11-21

Annotated Case Report Form

- Supplemental Documents
 - Study Data Reviewer's Gui
- Datasets
 - DM (Demographics)
 - EX (Exposure)
 - DS (Disposition)
 - VS (Vital Signs)
- Controlled Terminology
 - CodeLists
 - External Dictionaries
- Methods

Expand all VLM

Collapse all VLM

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID		dm.xpt
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC		ex.xpt
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC		ds.xpt
VS	Vital Signs	FINDINGS	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM		vs.xpt

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Study Information/Header Section

Study ABC-XYZ, Data Definition

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SDTM-IG 3.2

- + Annotated Case Report Form
- + Study Data Reviewer's Guide
- + Tabulation Datasets
 - Demographics (DM)
 - Exposure (EX)
 - Disposition (DS)
 - Vital Signs (VS)
- + Value Level Metadata
 - VS [VSORRES]
- + Controlled Terminology
 - + Controlled Terms

Date of document generation: 2018-12-07T22:33:20
Stylesheet version: 2013-04-24

Tabulation Datasets for Study ABC-XYZ (SDTM-IG 3.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	
EX	Exposure	INTERVENTIONS	One record per constant dosing interval per subject	Tabulation	STUDYID, USUBJID, EXTRT, EXSTDTC	ex.xpt	
DS	Disposition	EVENTS	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	ds.xpt	

Tabulation Datasets List

► List and description of all datasets described by the define.xml

- Class
- Structure/Keys

Tabulation Datasets for Study ABC-XYZ (SDTM-IG 3.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	
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VS	Vital Signs	FINDINGS	One record per vital sign measurement per time point per visit per subject	Tabulation	STUDYID, USUBJID, VSTESTCD, VISITNUM	vs.xpt	

Variable Level Metadata – Dataset Sections

Vital Signs (VS) [Location: [vs.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	10		Assigned	
DOMAIN	Domain Abbreviation		text	2	["DM" = "Demographics", "DS" = "Disposition", "EX" = "Exposure", "VS" = "Vital Signs"] < SDTM Domain Abbreviation >	Assigned	
USUBJID	Unique Subject Identifier	2	text	19		Assigned	
VSSEQ	Sequence Number		integer	8		Derived	Sequential integer within USUBJID assigned after sorting by dataset keys.
VSTESTCD	Vital Signs Test Short Name	3	text	8	["HEIGHT" = "Height", "WEIGHT" = "Weight", "BMI" = "Body Mass Index"] < Vital Signs Test Code >	Assigned	
VSTEST	Vital Signs Test Name		text	40	["Height", "Weight", "Body Mass Index"] < Vital Signs Test Name >	CRF Pages 3 Z	
VSORRES	Result or Finding in Original Units		text	200			

Value Level Metadata

Vital Signs (VS) [Location: [vs.xpt](#)]

Variable	Label	Key	Type	Length	Controlled Terms or Format	Origin	Derivation/Comment
STUDYID	Study Identifier	1	text	10		Assigned	
DOMAIN	Domain Abbreviation		text	2	["DM" = "Demographics", "DS" = "Disposition", "EX" = "Exposure", "VS" = "Vital Signs"] < SDTM Domain Abbreviation >	Assigned	
USUBJID	Unique Subject Identifier	2	text	19		Assigned	
VSSEQ	Sequence Number		integer	8		Derived	Sequential integer within USUBJID assigned after sorting by dataset keys.
VSTESTCD	Vital Signs Test Short Name	3	text	8	["HEIGHT" = "Height", "WEIGHT" = "Weight", "BMI" = "Body Mass Index"] < Vital Signs Test Code >	Assigned	
VSTEST	Vital Signs Test Name		text	40	["Height", "Weight", "Body Mass Index"] < Vital Signs Test Name >	CRF Pages 3 Z	
VSORRES	Result or Finding in Original Units		text	200			

Value Level Metadata

- Used when derivations/source differs on records depending on another value
 - Where clause – example: xxTESTCD

Value Level Metadata

Value Level Metadata - VS [VSORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
VSORRES	VSTESTCD EQ HEIGHT (Height)	float	6		CRF Page 3	
VSORRES	VSTESTCD EQ WEIGHT (Weight)	float	6		CRF Pages 3 7	
VSORRES	VSTESTCD EQ BSA	float	6		Derived	Set to VS.VSSTRESN when (VS.VSTESTCD=WEIGHT / [VS.VSSTRESN when VS.VSTESTCD=HEIGHT]^2)/100

Controlled Terminology

► Types of lists

- Value
- Value to decode

► Terminology types

- CDISC
- User defined
- Extended values

► Codelist content

- As applicable to study
- As applicable to domain

Controlled Terms

Age Unit [CL.AGEU, C66781]

Permitted Value (Code)

YEARS [C29848]

SDTM Domain Abbreviation [CL.DOMAIN, C66734]

Permitted Value (Code)	Display Value (Decode)
------------------------	------------------------

DM [C49572]	Demographics
-------------	--------------

DS [C49576]	Disposition
-------------	-------------

EX [C49587]	Exposure
-------------	----------

VS [C49622]	Vital Signs
-------------	-------------

Epoch [CL.EPOCH, C99079]

Permitted Value (Code)

SCREENING [C48262]

BLINDED TREATMENT PERIOD 1 [*]

BLINDED TREATMENT PERIOD 2 [*]

* Extended Value

Computational Algorithms

- Consolidated summary of Derivation/Comment values
 - Check for consistencies and differences

Computational Algorithms

Method	Type	Description
Algorithm to derive MT.DM.RFSTDTC	Computation	Date/time of first study drug administration. Missing for screen failures.
Algorithm to derive MT.DS.EPOCH	Computation	SCREENING if RFICDTC<=DSSTDTC<RFXSTDTC. BLINDED TREATMENT if RFXSTDTC<=DSSTDTC<=RFXENDTC.
Algorithm to derive MT.EX.EXSEQ	Computation	Sequential integer within USUBJID assigned after sorting by dataset keys.
Algorithm to derive MT.EX.EPOCH	Computation	SCREENING if RFICDTC<=EXSTDTC<RFXSTDTC. BLINDED TREATMENT if RFXSTDTC<=EXSTDTC<=RFXENDTC.

Comments

CommentOID	Description
COM.COM.DM.AGEU	Set to YEARS when AGE is nonmissing.

External Linked Files

► acrf.pdf

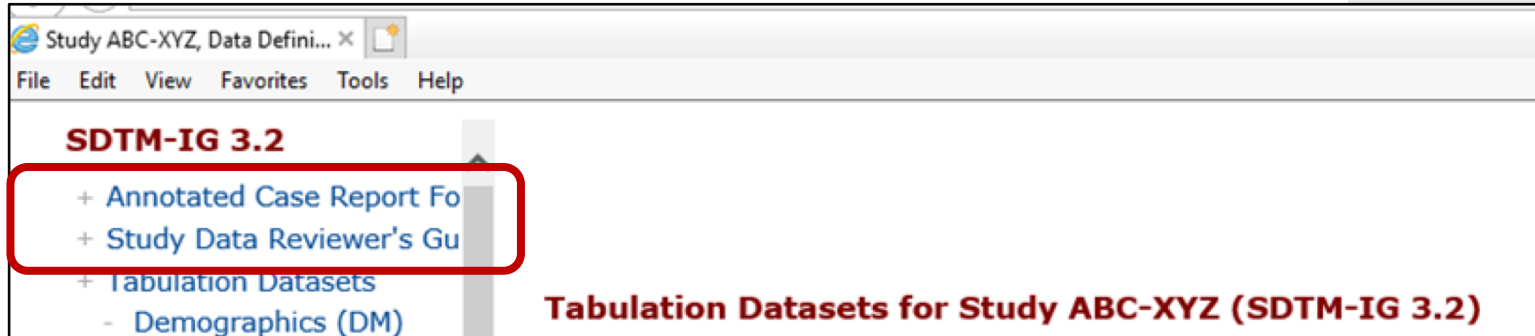
- Annotated Case Report Form (referenced by SDTM define.xml)

► csdrg.pdf

- Clinical Study Data Reviewer's Guide (referenced by SDTM define.xml)

► adrg.pdf

- Analysis Data Reviewer's Guide (referenced by ADaM define.xml)



Summary

► Achievements

- General familiarity with define.xml
- Understanding of information define.xml shares with reviewer
- Start of a friendly relationship with define.xml

► Up next: define.xml 2.1



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