



2023

CHINA

INTERCHANGE

BEIJING | 25-26 AUGUST



Best Practice of Define-XML v2.1

Presented by Alice Liu



Meet the Speaker

Alice Liu

Title: Senior Manager, Clinical Programming

Organization: Jiangsu Hengrui Pharmaceuticals Co., Ltd

Alice Liu, has over 9 years SAS programming experience for phase I/II/III clinical trials in various therapeutic areas. Alice also has abundant experience in CDISC standard implementation, including developing annotated CRF, SDTM, ADaM and define-xml.



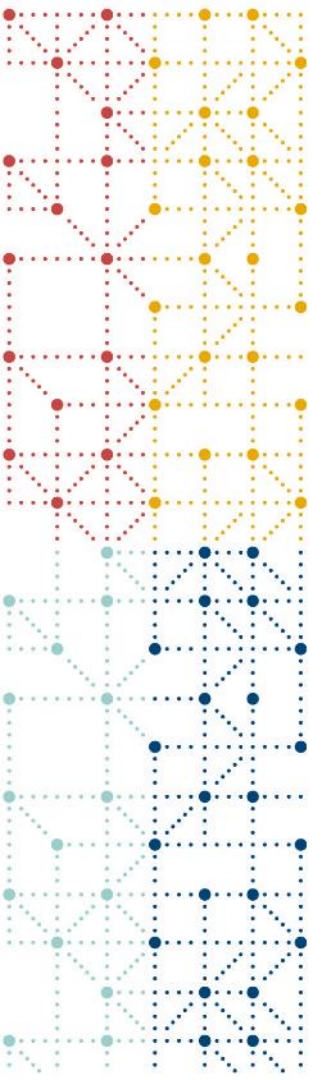
Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

1. Regulatory Requirements for Define-XML
2. Define-XML Introduction
3. Variable-level Metadata
4. Value-Level Metadata
5. Origin
6. Codelist



1. Regulatory Requirements for Define-XML

1. Regulatory Requirements for Define-XML

4.1.4.5 Data Definition Files for SDTM, SEND, and ADaM

The data definition file describes the metadata of the submitted electronic datasets, and is considered arguably the most important part of the electronic dataset submission for regulatory review. This data definition specification for submitted datasets defines the metadata structures that should be used to describe the datasets, variables, possible values of variables when appropriate, and controlled terminologies and codes. An insufficiently documented data definition file is a common deficiency that reviewers have noted. Consequently, the sponsor needs to provide complete detail in this file, especially for the specifications pertaining to derived variables. In addition, sponsors should also make certain that the code list and origin for each variable are clearly and easily accessible from the data definition file. The version of any external dictionary should be clearly stated both in the data definition file and in the full TS domain when it is submitted. The internal dataset label should also clearly describe the contents of the dataset. For example, the dataset label for an efficacy dataset might be 'Time to Relapse (Efficacy).'

Ref(FDA): Study data technical conformance guide, 2021.3



国家药品监督管理局

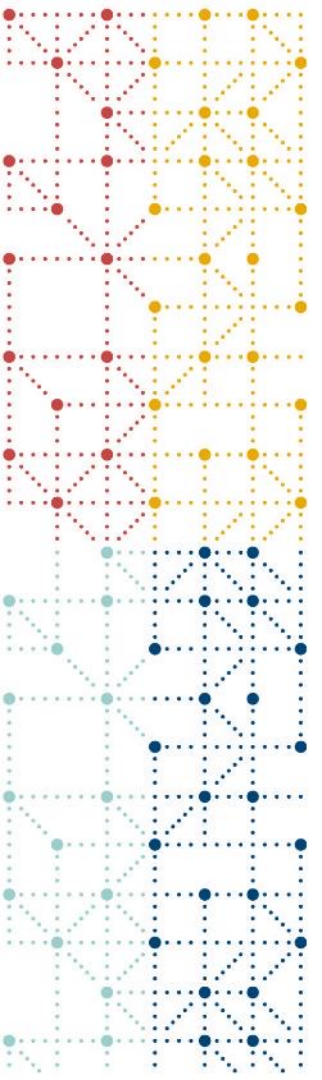
National Medical Products Administration

(三) 数据说明文件

递交的原始数据库和分析数据库必须有相应的数据说明文件。数据说明文件是一份用来描述递交数据的文件，至少应包含递交数据库中各数据集名称、标签、基本结构描述及每一数据集中各变量的名称、标签、类型、来源或衍生过程。

数据说明文件是监管机构审评时准确理解递交数据内容最重要的文件之一。申办方应确保每个变量的编码列表和来源都有清晰的定义，并且易于查找。如果使用外部词典，需要在数据说明文件中指明所用的词典及版本。需要通过数据说明文件建立起数据间良好的可追溯性（如：原始数据集与 CRF、分析数据集与原始数据集之间），以便于监管机构的审阅。申办方需要在数据说明文件中提供相关细节，尤其是和衍生变量相关的详细说明，必要时可使用关键程序代码辅助说明。

Ref(NMPA): 药物临床试验数据递交指导原则, 2020.7



2. Define-XML Introduction

2.1 What is Define-XML

Define-XML, a metadata standard used to describe any tabular dataset structure. The primary use case for Define-XML is to describe CDISC Study Data Tabulation Model (SDTM), Standard for Exchange of Nonclinical Data (SEND), and Analysis Data Model (ADaM) datasets for the purpose of submissions to regulatory authorities.

A Define-XML document includes the following key content components:

- XML header, the ODM root element, Study, and MetaDataVersion
 - Standards definitions
 - Information about linked PDF documents (e.g., annotated case report forms, Supplemental Data Definitions)
 - Dataset definitions
 - Variable definitions
 - Value definitions (including Where Clause definitions)
 - Controlled Terminology definitions
 - Computational Method definitions
 - Comment definitions
- External file Xlinks



2.2 Metadata

Data



Metadata

Artist: Vincent van Gogh
Title: Three Sunflowers
Objective Type: painting
Date: 1888
Medium: oil on canvas
Dimensions: Height: 73 cm;
Width: 58 cm

2.3 Metadata for Define-XML

Method

Dictionaries

Reference Name	External Dictionary	Dictionary Version
Adverse Event Dictionary	MEDDRA	8.0
Drug Dictionary	WHODRUG	200204
ISO3166	ISO3166	

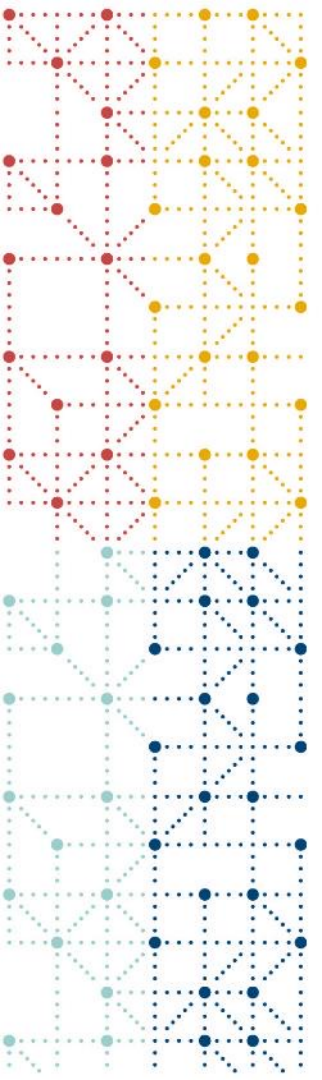


AEDECOD	Dictionary-Derived Term	text	18	Adverse Event Dictionary MEDDRA 8.0	Assigned
---------	-------------------------	------	----	--------------------------------------------------------	----------

CMDECOD	Standardized Medication Name	text	30	Drug Dictionary WHODRUG 200204	Assigned
---------	------------------------------	------	----	---------------------------------------------------	----------

COUNTRY	Country	text	3	ISO3166 ISO3166	Assigned
---------	---------	------	---	------------------------------------	----------

	Instructions))					
	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)	Analysis Value	integer	3		Derived (Source: Sponsor) Sum of ADAS scores for items 1, 2, 4, 5, 6, 7, 8, 11, 12, 13, and 14, see ADRG for details on adjusting for missing values. Analysis Data Reviewer's Guide [3 6]



3. Variable-level Metadata

3.1 Null Dataset and Variable

SDTM IG V3.3/3.2, section 3.2

In the event that no records are present in a dataset (e.g., a small PK study where no subjects took concomitant medications), the empty dataset should not be submitted and should not be described in the Define-XML document. The annotated CRF will show the data that would have been submitted had data been received; it need not be re-annotated to indicate that no records exist.

SDTM IG V3.4

Section 3. Submitting Data in a Standard Format		
3.2	Using the CDISC Domain Models in Regulatory Submissions – Dataset Metadata	<ul style="list-style-type: none">Removed the following paragraph as there are now guidelines in the MSG v2.0 and the Define-XML v2.1 standard: "In the event that no records are present in a dataset (e.g., a small PK study where no subjects took concomitant medications), the empty dataset should not be submitted and should not be described in the Define-XML document. The annotated CRF will show the data that would have been submitted had data been received; it need not be re-annotated to indicate that no records exist."

3.1 Null Dataset and Variable

def HasNoData	Conditional Required in the context of a regulatory submission when the dataset variable defined in the associated ItemDef has no data values (ODM@def:Context="Submission")	"Yes"	<ul style="list-style-type: none">Used to indicate that an ItemRef that represent a dataset's variable has no data. Note that <i>variables</i> refer to both standard and non-standard/ supplemental qualifiers variables (/ODM/Study/MetaDataVersion/ItemGroupDef/ItemRef or /ODM/Study/MetaDataVersion/def:ValueListDef/ItemRef).Business Rule: A comment must be included to explain why no data is present for dataset's variables that were planned for use in the study.
----------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Define specification v2.1

3.1 Basic Principles for Annotations

Sponsors may choose any available tool/application for creating annotations. Irrespective of the tool/application used, the CRF annotations should be searchable (i.e., text-based) to enhance the data package review process. Because the acrf.pdf supports the review process, annotations should reflect data intended to be submitted within the SDTM.

In the event that intended data were to be collected, but none actually were, the annotated CRF will represent the data that would have been submitted had they been collected. It is not necessary to re-annotate the acrf.pdf to indicate that no data were collected. The fact that no data were collected will be indicated in the Define-XML document using the "HasNoData" attribute for datasets and variables. Examples of this are included in the sample submission package; see the DM supplemental qualifier variables RACE4 and RACE5, and the NV, SUPPNV, and SUPPOE datasets. This can also be further described in the clinical study data reviewer's guide.

The purpose of the annotated CRF is to describe where each data item is represented in an SDTM dataset. The recommended dual bookmarking (see Section 3.2, [Bookmarking CRFs/eCRFs](#)) and table of contents will further provide the reviewer with an overview of the data collection design/structure for the study.

SDTM MSG V2.0

3.1 Null Dataset and Variable

Null dataset

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
LB [STDTMIG 3.3]	Laboratory Test Results	FINDINGS	One record per analyte per visit per subject	Tabulation	STUDYID, USUBJID, LBCAT, LBTESTCD, LBOTC, VISITNUM		lb.xpt
NV [STDTMIG 3.3] [No Data]	Nervous System Findings	FINDINGS	One record per finding per visit per subject	Tabulation	STUDYID, USUBJID, NVTESTCD, VISITNUM	Per protocol, electroencephalograms are only performed after such an event were to occur. No subjects within the trial had an occurrence of an electroencephalogram event. Therefore, no data exists for the NV dataset and as such was not submitted.	

Null variable

SUPPDM (Supplemental Qualifiers for DM, Demographics) - [STDTMIG 3.3]

Location: [suppdm.xpt](#)

Related Parent Dataset: DM (Demographics)							
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment	
QVAL VLM	Data Value	text	Result Qualifier	41			
QNAM = "RACE4" [No Data]	Race 4	text	Result Qualifier	41	Race <ul style="list-style-type: none"> "AMERICAN INDIAN OR ALASKA NATIVE" = "American Indian Or Alaska Native" "ASIAN" = "Asian" "BLACK OR AFRICAN AMERICAN" = "Black Or African American" "NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER" = "Native Hawaiian Or Other Pacific Islander" "WHITE" = "White" 	Collected (Source: Investigator) Annotated CRF [5] Since no subjects had more than 3 Races, RACE4 was not used.	

3.2 Variable Description

Derivations should be represented as human-readable descriptions or pseudocode as opposed to executable programming statements.

ADLBC (Analysis Dataset Lab Blood Chemistry) - [ADaMIG 1.1]

Location: [adlbc.xpt](#)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
PARAM		Parameter	text	100	PARAM ADLBC [18 Terms]	Derived (Source: Sponsor) For PARAMN<100: strip(LB.LBTEST) ' (' strip(LB.LBSTRESU) ')'. For PARAMN>100: strip(LB.LBTEST) ' (' strip(LB.LBSTRESU) ') ' change from previous visit, relative to normal range'.



ADLBC (Analysis Dataset Lab Blood Chemistry) - [ADaMIG 1.1]

Location: [adlbc.xpt](#)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
PARAM		Parameter	text	100	PARAM ADLBC [18 Terms]	Derived (Source: Sponsor) For PARAMN<100L same as LB.LBTEST concatenated with LB.LBSTRESU. For PARAMN>100: LB.LBTEST concatenated with LB.LBSTRESU concatenated with " change from previous visit, relative to normal range"

3.2 Variable Description



Variable derivation rule should not reference **raw data variables**.

Notice

- The regulatory review team do not see your raw data
- Do NOT copy-paste ALL the info from your mapping spec into the define.xml



AE (Adverse Events) - [SDTMIG 3.3]

Location: [ae.xpt](#) #

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
DOMAIN		Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation, subset used for Adverse Events • "AE" = "Adverse Events"	Assigned (Source: Sponsor)
USUBJID		Unique Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)
AESEQ		Sequence Number	integer	Identifier	3		Derived (Source: Sponsor) Unique sequence number within a subject, restarting at 1 for every subject, applied to sorted data.
AESPID		Sponsor-Defined Identifier	text	Identifier	50		Assigned (Source: Sponsor) AE.RECORDPOSITION
AELLT		Lowest Level Term	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor) AE.AELLT
AEDECOD		Dictionary-Derived Term	text	Synonym Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor) AE.AEDECOD
AEBODSYS		Body System or Organ Class	text	Record Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor) AE.AEBODSYS
AEBDSYCD		Body System or Organ Class Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor) AE.AEBDSYCD



AE (Adverse Events) - [SDTMIG 3.3]

Location: [ae.xpt](#) #

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
DOMAIN		Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation, subset used for Adverse Events • "AE" = "Adverse Events"	Assigned (Source: Sponsor)
USUBJID		Unique Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)
AESEQ		Sequence Number	integer	Identifier	3		Derived (Source: Sponsor) Unique sequence number within a subject, restarting at 1 for every subject, applied to sorted data.
AESPID		Sponsor-Defined Identifier	text	Identifier	50		Assigned (Source: Sponsor) Unique record identifier from the raw database. Provides traceability between raw, SDTM and AdM data.
AELLT		Lowest Level Term	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEDECOD		Dictionary-Derived Term	text	Synonym Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEBODSYS		Body System or Organ Class	text	Record Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEBDSYCD		Body System or Organ Class Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)



3.3 Variable – Name and Value

Any variable in an ADaM dataset whose name is the same as an SDTM variable must be a copy of the SDTM variable, and its label, meaning, and values must not be modified. ADaM adheres to a principle of harmonization known as "same name, same meaning, same values." However, to optimize file size, it is permissible that the length of the variables differ (e.g., trailing blanks may be removed).

Reference: ADAM-IG v1.3, section 3.1.1.1

ADSL (Subject-Level Analysis Dataset) - SUBJECT LEVEL ANALYSIS DATASET

Location: [adsl.xpt](#)

Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
NATIONTY	Ethnicity	text	\$11		Derived set to DM.NATIONTY, if not Han Chinese, then set to Others



3.4 Variable – Data Type

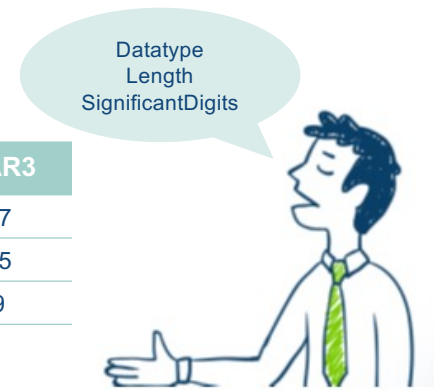
Define-XML Data Type	Submission Data Type	Length	Considerations
text	Char	Maximum allowable length	SAS v.5 Transport files restrict variable lengths to 200 characters.
integer	Num	The largest allowable integer width; note that for negative integers, the length will include the minus sign	Use for numeric or equivalent variables that have discrete whole values (non-fractional); can be positive, negative, or zero. ADaM numeric date variables are provided as integers.
float	Num	The largest allowable whole number width plus the maximum number of decimal digits	Use for numeric variables that may contain a fractional component. It represents the set of all the decimal numbers with arbitrary lengths.
datetime	Char	N/A	Use if values for SDTM or SEND variable represent Date Times (YYYY-MM-DDTHH:MM:SS).
date	Char	N/A	Use if values for SDTM or SEND variable represent complete (YYYY-MM-DD) dates.
time	Char	N/A	Use if values for SDTM or SEND variable represent complete (HH:MM:SS) times in ISO-8601 format.

3.5 Variable – Length

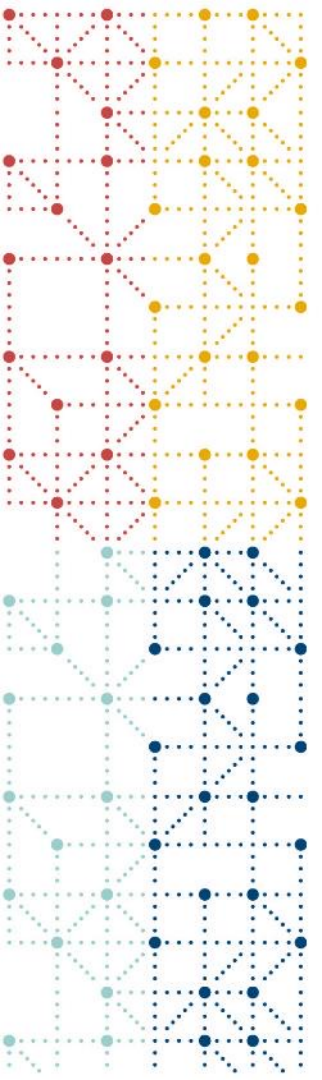
Define-XML Data Type	Submission Data Type	Length
text	Char	Maximum allowable length
integer	Num	The largest allowable integer width; note that for negative integers, the length will include the minus sign
float	Num	The largest allowable whole number width plus the maximum number of decimal digits
datetime	Char	N/A
date	Char	N/A
time	Char	N/A

Attribute	Usage	Allowable Values	Description
SignificantDigits	Conditional Required if DataType is "Float"	Integer	<ul style="list-style-type: none"> The number of digits following the decimal point in a floating point number Business Rule: When DataType is float, both Length and SignificantDigits must be provided.

VAR1	VAR2	VAR3
NORMAL	12	12.7
ABNORMAL	183	2.55
123	-1756	199



[Current pinnacle 21 bug for the length of float](#)



4. Value-Level Metadata

4.1 When to Use VLM?



Standard Use:

SDTM Finding domains to provide definitions for Variables (e.g., --ORRES, --ORRESU, --STRESC, --STRESU) that are specific to each test code (value of -TESTCD)

ADaM BDS data

Describes AVAL or AVALC in BDS data based on values of PARAMCD

SDTM SUPPQUAL dataset

Multiple Origins

Multiple Codelist Items (e.g. DSDECOD with CT of NCOMPLT/PROTMLST)

Additional Use:

Data Type
Precision
Comments
Computational Methods
Important Results

4.1 When to Use VLM?



LBORRES VLM		Result or Finding in Original Units	text	8	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 @]

Precision

Data type

Origin

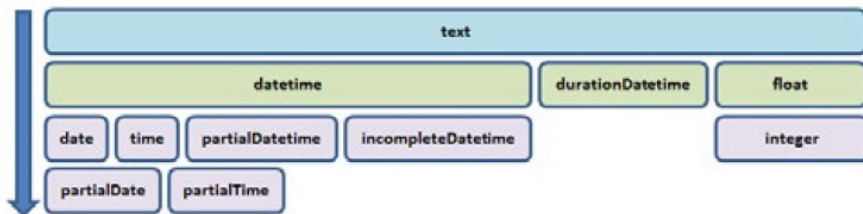
4.2 Value-Level Length



Value level length should \leq variable level length

RSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	198	Collected (Source: Investigator) Annotated CRF [19] [E]	
	RSTESTCD = "HAMD101" (HAMD1-Depressed Mood)	HAMD-17 Question 1	text		111	Hamilton Depression Rating Scale - 17 Item - Question 1 <ul style="list-style-type: none"> • "Absent." • "These feeling states indicated only on questioning." • "These feeling states spontaneously reported verbally." • "Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep." • "Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication." 	Collected (Source: Investigator) Annotated CRF [19] [E]
	RSTESTCD = "HAMD102" (HAMD1-Feelings of Guilt)	HAMD-17 Question 2	text		93	Hamilton Depression Rating Scale - 17 Item - Question 2 <ul style="list-style-type: none"> • "Absent." • "Self reproach, feels he/she has let people down." • "Ideas of guilt or rumination over past errors or sinful deeds." • "Present illness is a punishment. Delusions of guilt." • "Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations." 	Collected (Source: Investigator) Annotated CRF [19] [E]

4.3 Value-Level Data Type



VSORRES VLM		Result or Finding in Original Units	text	30		Collected (Source: Investigator) Annotated CRF [11] [?]
	VSTESTCD = "DIABP" (Diastolic Blood Pressure)	Diastolic Blood Pressure in Orig U	integer	2		Collected (Source: Investigator) Annotated CRF [11] [?]
	VSTESTCD = "FRMSIZE" (Body Frame Size)	Body Frame Size - Orig	text	6	Size • "SMALL" • "MEDIUM" • "LARGE"	Collected (Source: Investigator) Annotated CRF [11] [?]
	VSTESTCD = "HEIGHT" (Height)	Height in Orig U	float	5.1		Collected (Source: Investigator) Annotated CRF [11] [?]

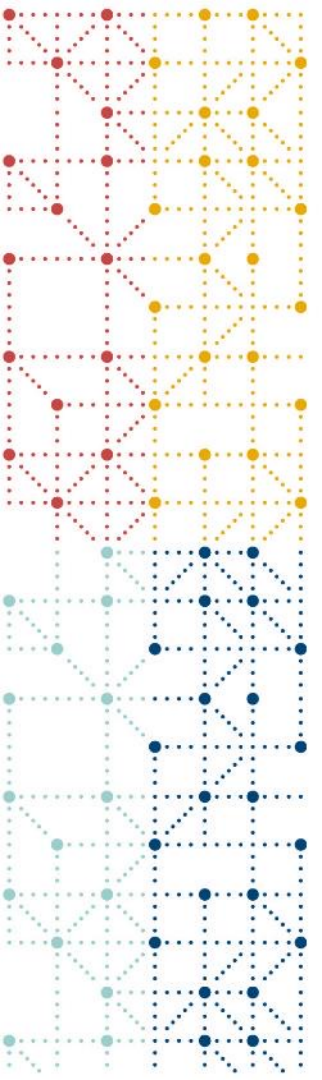
It is common, that Value-Level Metadata DataType is different from the variable-level DataType. It does not violate the compatibility rule as some of the DataType can "include" other DataType values.

4.4 Value-Level Origin

Variable Level ≠ Value Level

AVAL	VLM	Analysis Value	integer	3		
	PARAMCD IN ("ACITM01" (Word Recall Task), "ACITM02" (Naming Objects And Fingers (Refer To 5 C), "ACITM03" (Delayed Word Recall), "ACITM04" (Commands), "ACITM05" (Constructional Praxis), "ACITM06" (Ideational Praxis), "ACITM07" (Orientation), "ACITM08" (Word Recognition), "ACITM09" (Attention/Visual Search Task), "ACITM10" (Maze Solution), "ACITM11" (Spoken Language Ability), "ACITM12" (Comprehension Of Spoken Language), "ACITM13" (Word Finding Difficulty In Spontaneous Speech), "ACITM14" (Recall Of Test Instructions))	Analysis Value	integer	2		Predecessor: QS.QSSTRESN where QS.QSTESTCD=ADQSADAS.PARAMCD
	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)	Analysis Value	integer	3		Derived (Source: Sponsor) Sum of ADAS scores for items 1, 2, 4, 5, 6, 7, 8, 11, 12, 13, and 14, see ADRG for details on adjusting for missing values. Analysis Data Reviewer's Guide [3]

Variable level should be null!



5. Origin

5.1 Origin Definition

Origin is a metadata attribute defined for each dataset variable in the define document that refers to the source of a variable.

Type	Definition
Collected	A value that is actually observed and recorded by a person or obtained by an instrument. Note that a <u>collected entry translated to a synonymous controlled term still has a type Collected.</u>
Derived	A value that is calculated by an algorithm or reproducible rule, and which is dependent upon other data values, including data values available within the dataset or externally provided data values. MethodDef must be used to document the algorithm or rule used for a derived value.
Assigned	Data that is either: Determined by individual judgment as provided by an evaluator, or Coded terms supplied as part of a coding process, or Values set independently of any subject-related data value in order to complete a dataset.
Protocol	Data that is defined as part of the study protocol, investigator instructions, standard operating procedures or trial design preparation
Predecessor	An entry that is copied from a variable in another dataset. The Description child element identifies the dataset and variable that is copied.

5.1 Origin Definition

Type	Source				Notes
	Subject	Investigator	Vendor	Sponsor	
Collected	ePro	CRF	Lab data, ECG	X	This term should be used for clinical data that were actually observed or recorded by a person or received from an instrument; it should not be used for data that have been interpreted, calculated, or derived from other information.
Derived	X	X	Lab data, ECG	SDTM	Derivation examples include calculations performed during data collection (e.g., --DY). Other derivation examples: calculations within ePRO (e.g., questionnaire section scores) and calculations within EDC (e.g., BMI, BSA).
Assigned	X	X	Adjudicator	SDTM	Examples of this include third-party attributions by an adjudicator, coded terms that are supplied as part of a coding process, and values that are set independently of any subject-related data values in order to complete SDTM fields such as DOMAIN and --TESTCD
Protocol	X	X	X	SDTM	An example would be VSPOS (Vital Signs Position), which could be specified in the protocol and be provided by other means (e.g. CRF, eDT).
Predecessor	X	X	X	X	Use when a value is an exact copy of another value in an SDTM dataset.

5.2 Origin - Collected



Data collected on the CRF

CM (Concomitant and Prior Medications)

CONCOMITANT MEDICATIONS

[NOT SUBMITTED]

Were any medications taken? Yes No

Medication

CMTRT

Indication

Primary Study Condition Prophylaxis or Non-Therapeutic Use **CMINDC**

Dose

CMDOSE

Dose Unit

CMDOSU

CM (Concomitant Medications) - [STDTMIG 3.3]

Location: [cm.xpt](#)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
CMDOSU	Dose Units	text	Variable Qualifier	6	Unit, subset to be used for CMDOSU <ul style="list-style-type: none"> "mg" = "Milligram" "ng" = "Nanogram" "TABLET" = "Tablet" 	Collected (Source: Investigator) Annotated CRF [25]

5.2 Origin - Collected



Data received via external data transfer

LB (Laboratory Test Results) - [STDTMIG 3.3]

Location: [lb.xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
LBORRES VLM		Result or Finding in Original Units	text	Result Qualifier	6		Collected (Source: Vendor)
	LBTESTCD IN ("ALB" (Albumin Measurement), "BILI" (Total Billirubin Measurement), "CA" (Calcium Measurement), "CREAT" (Creatinine Measurement), "K" (Potassium Measurement), "PHOS" (Phosphate Measurement), "PROT" (Total Protein Measurement), "URATE" (Urate Measurement))	Lab Result or Finding in Original Units - Set 1	float		3		

5.3 Origin - Derived

Data are not directly collected on the CRF but are calculated by an algorithm or reproducible rule, which is dependent upon other data values.

VS (Vital Signs) - [STDTMIG 3.3]

Location: [vs.xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
VSSTRESC		Character Result/Finding in Std Format	text	Result Qualifier	200		Derived (Source: Sponsor) Data collected in conventional units (i.e. F, lbs, inches) is converted using standard conversion factors to standard units (C, kg, cm).
VSSTRESN		Numeric Result/Finding in Standard Units	float	Result Qualifier	8		Derived (Source: Sponsor) If --STRESC represents a numeric value then --STRESN is the numeric version of --STRESC, else null. "--" represents the domain code.
VSLOBXFL		Last Observation Before Exposure Flag	text	Record Qualifier	1	No Yes Response, subset for variables with only "Y" or null values • "Y" = "Yes"	Derived (Source: Sponsor) Set to "Y" for last record with non-null original result on or before the first dose date (RFSTSDTC). Null otherwise.
EPOCH		Epoch	text	Timing	9	Epoch • "SCREENING" = "Screening" • "TREATMENT" = "Treatment"	Derived (Source: Sponsor) EPOCH from SE where date >= SESTDTC and date < SEENDTC
VSDY		Study Day of Vital Signs	integer	Timing	8		Derived (Source: Sponsor) Study day relative to RFSTSDTC. Date - RFSTSDTC + 1 if on or after RFSTSDTC. Date - RFSTSDTC if date precedes RFSTSDTC.

5.4 Origin - Assigned

Coded terms supplied as part of a coding process

AE (Adverse Events) - [STDTMIG 3.3]

Location: [ae.xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
AELLTCD		Lowest Level Term Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEDECOD		Dictionary-Derived Term	text	Synonym Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEPTCD		Preferred Term Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEHLT		High Level Term	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEHLTCD		High Level Term Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEHLGT		High Level Group Term	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEHLGTC		High Level Group Term Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEBODSYS		Body System or Organ Class	text	Record Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)
AEBDSYCD		Body System or Organ Class Code	text	Variable Qualifier	1	Adverse Events Dictionary MedDRA 22.0	Assigned (Source: Sponsor)

5.4 Origin - Assigned

Values set independently of any subject-related data value in order to complete a dataset

ADADAS (ADAS-Cog Analysis) - [ADaMIG 1.1]

Location: [adadas.xpt](#)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
AVISIT		Analysis Visit	text	16	Analysis Visit (ADADAS) <ul style="list-style-type: none"> • "Baseline" • "Week 8" • "Week 16" • "Week 24" 	Derived (Source: Sponsor) Derived based on windowing algorithm described in SAP, Section 8.2
AVISITN		Analysis Visit (N)	integer	8	Analysis Visit (N) (ADADAS) <ul style="list-style-type: none"> • 0 = "Baseline" • 8 = "Week 8" • 16 = "Week 16" • 24 = "Week 24" 	Assigned (Source: Sponsor) Numeric code for AVISIT
PARAMCD		Parameter Code	text	8	PARAMCD_ADQSDAS [15 Terms]	Predecessor: QS.QSTESTCD
PARAMN		Parameter (N)	integer	8	PARAMN_ADQSDAS [15 Terms]	Assigned (Source: Sponsor) Assign a numeric code for each value of PARAMCD (see codelist PARAMN_ADADAS)

5.5 Origin - Protocol

Data that is defined as part of the study protocol, investigator instructions, standard operating procedures or trial design preparation.

EX (Exposure) - [STDTMIG 3.3]

Location: [ex.xpt](#)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation, subset used for Exposure <ul style="list-style-type: none">"EX" = "Exposure"	Assigned (Source: Sponsor)
EXDOSE	Dose	integer	Record Qualifier	8		Derived (Source: Sponsor) EXDOSE = ECDOSE * ECPSTRG expressed in mg.
EXDOSU	Dose Units	text	Variable Qualifier	2	Unit, subset to be used for EXDOSU <ul style="list-style-type: none">"mg" = "Milligram"	Protocol (Source: Sponsor)

5.6 Origin - Predecessor

An entry that is copied from a variable in another dataset. The description child element identified the dataset and variable that is copied.

EX (Exposure) - [STD TMIG 3.3]

Location: [ex.xpt](#)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier	text	Identifier	12		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	text	Identifier	2	SDTM Domain Abbreviation, subset used for Exposure • "EX" = "Exposure"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier	text	Identifier	8		Assigned (Source: Sponsor)
SPDEVID	Sponsor Device Identifier	text	Identifier	200		Predecessor: EC.SPDEVID
EXSEQ	Sequence Number	integer	Identifier	3		Derived (Source: Sponsor) Unique sequence number within a subject, restarting at 1 for every subject, applied to sorted data.
EXTRT	Name of Treatment	text	Topic	10	Study Treatment • "PLACEBO" = "Placebo" • "ZANOMALINE" = "Zanomaline"	Predecessor: ECTRT

ADCIBC (CIBIC+ Analysis) - [ADaMIG 1.1]

Location: [adcibc.xpt](#)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID		Study Identifier	text	12		Predecessor: ADSL.STUDYID
SITEID		Study Site Identifier	text	3		Predecessor: ADSL.SITEID
SITEGR1		Pooled Site Group 1	text	3		Predecessor: ADSL.SITEGR1

5.7 Origin for the Same Variable May Differ



In TA, the values are mapped from Protocol
Origin should be Protocol

TA (Trial Arms) - [STDTMIG 3.3]

Location: [ta.xpt](#)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
EPOCH	Epoch	text	Timing	9	Epoch <ul style="list-style-type: none"> "SCREENING" = "Screening" "TREATMENT" = "Treatment" 	Protocol (Source: Sponsor) EPOCH from SE where date >= SESTDTC and date < SEENDTC

In other datasets, the EPOCH values are derived based on the element start date and end date
Origin should be Derived

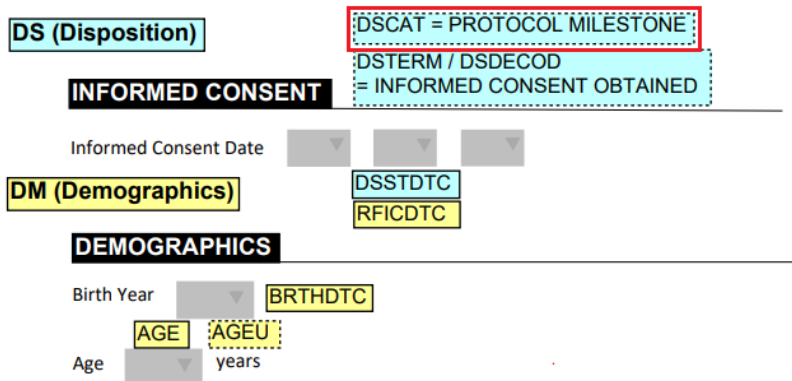
CM (Concomitant Medications) - [STDTMIG 3.3]

Location: [se.xpt](#)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
EPOCH	Epoch	text	Timing	9	Epoch <ul style="list-style-type: none"> "SCREENING" = "Screening" "TREATMENT" = "Treatment" 	Derived (Source: Sponsor) EPOCH from SE where date >= SESTDTC and date < SEENDTC

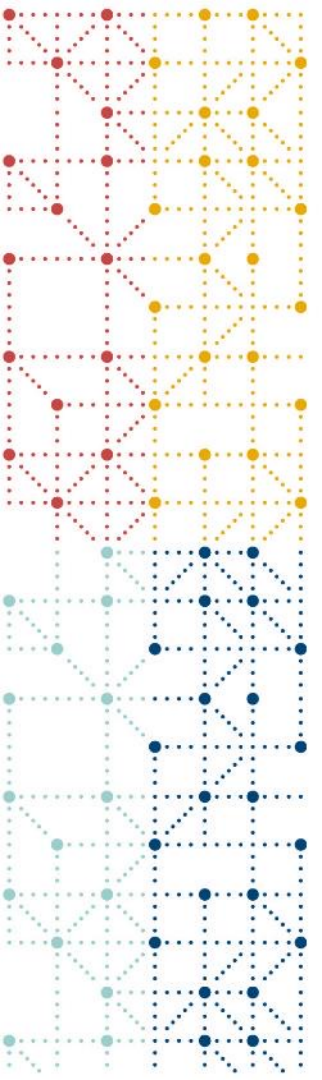
5.8 Collected or Assigned?

Common practice has been that if a variable is annotated on the CRF, it has to have an origin of "Collected". However, there are scenarios where additional annotations, for variables which are not considered "Collected", could help to clarify the data collection to a reviewer.



Location: [ds.xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
DSCAT		Category for Disposition Event	text	Grouping Qualifier	18	Category for Disposition Event <ul style="list-style-type: none"> "DISPOSITION EVENT" = "Disposition Event" "PROTOCOL MILESTONE" = "Protocol Milestone" 	Assigned (Source: Sponsor) Annotated CRF [5 27 28] Variable is Assigned but there are annotations to help understand the data and so references to the proper pages are included



6. Codelist

6. Codelist

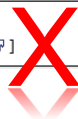


Controlled terminology should be displayed for variables that have CDISC controlled terminology per SDTM IG/ADaM IG.

EG (ECG Test Results) - FINDINGS

Location: [eg.xpt](#)

Related Supplemental Qualifiers Dataset: SUPPEG (Supplemental Qualifiers for EG)						
Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
EGORRES VLM		Result or Finding in Original Units	text	38		CRF Annotated Case Report Form [42]
	EGTESTCD = "EGHRMN" (ECG Mean Heart Rate)		text	3		CRF Annotated Case Report Form [42]
	EGTESTCD = "INTP" (Interpretation)		text	38		CRF Annotated Case Report Form [42]
	EGTESTCD = "PRAG" (PR Interval, Aggregate)		text	3		CRF Annotated Case Report Form [42]
	EGTESTCD = "QTAG" (QT Interval, Aggregate)		text	3		CRF Annotated Case Report Form [42]
	EGTESTCD = "QTCAG" (QTc Interval, Aggregate)		text	3		CRF Annotated Case Report Form [42]
EGORRESU		Original Units	text	9		CRF Annotated Case Report Form [42]



6. Codelist

For variables with CDISC codelist, should firstly check whether the value can map to a standard codelist, codelist only can be extended when no standard synonym.

Domain	Record	Count	Variables	Values	Pinnacle 21 II	Message	Category
TU		4	TULOC	LYMPH NODES	CT2002	TULOC value not found in 'Anatomical Location' extensible codelist	Terminology



Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C12745	C74456		Anatomical Location	LYMPH NODE	Lymphatic Gland

6. Codelist

The complete set of values relevant to the study must be provided regardless of whether they are referenced within the study data.

AE (Adverse Events)

ADVERSE EVENTS

Were any adverse events experienced?

Yes No [NOT SUBMITTED]

If yes please provide details below.

AE Identifier

AELNKID

What is the adverse event term?

AETERM

Start Date


/ / AESTDTC

Severity

Mild Moderate Severe AESEV

AE (Adverse Events) - [STDTMIG 3.3]

Location: [ae.xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
AESEV		Severity/Intensity	text	Record Qualifier	8	Severity/Intensity Scale for Adverse Events <ul style="list-style-type: none"> "MILD" = "Mild" "MODERATE" = "Moderate" 	Collected (Source: Investigator) Annotated CRF [22] [23] 

6. Codelist

When a domain or dataset specification includes a codelist for a variable, not every value in that codelist may have been part of planned data collection; only values that were part of planned data collection should be included in the define.xml document.

EC (Exposure as Collected) - INTERVENTIONS

Location: [ec.xpt](#)

Related Supplemental Qualifiers Dataset: SUPPEC (Supplemental Qualifiers for EC)					
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
ECDOSU	Dose Units	text	2	Unit [177 Terms]	CRF Annotated Case Report Form [52 72 95 111 132 148 167 183 205 221 240 256 277 293 313 329 351 367 386 402 425 441 485]



EC (Exposure as Collected) - INTERVENTIONS

Location: [ec.xpt](#)

Related Supplemental Qualifiers Dataset: SUPPEC (Supplemental Qualifiers for EC)					
Variable	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
ECDOSU	Dose Units	text	2	Unit , subset used for EX • "mg"	CRF Annotated Case Report Form [71 79]

6. Codelist

When a domain or dataset specification includes a codelist for a variable, not every value in that codelist may have been part of planned data collection; only values that were part of planned data collection should be included in the define.xml document.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format ¹	Role	CDISC Notes	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value
CMRESP	CM Pre-specified	Char	(NY)	Variable Qualifier	Used to indicate CRF.	No	Relation to Reference Period	STENRF
CMSTRPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the start defined by variable. Not all values of Variables.		Relation to Reference Period	AFTER
CMSTTPT	Start Reference Time Point	Char		Timing	Description or details of CMSTRPT. Example		Relation to Reference Period	BEFORE
CMENRPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Identifies the end defined by variable. Not all values of Variables.		Relation to Reference Period	BEFORE/DURING
CMENTPT	End Reference Time Point	Char		Timing	Description or details of CMENRPT. Example		Relation to Reference Period	COINCIDENT
							Relation to Reference Period	DURING
							Relation to Reference Period	DURING/AFTER
							Relation to Reference Period	ONGOING
							Relation to Reference Period	UNKNOWN

4.4.7 Use of Relative Timing Variables

--STRPT, --STTPT, --ENRPT, and --ENTPT

If the reference time point corresponds to the date of collection or assessment:

- Start values: An observation can start BEFORE that time point, can start COINCIDENT with that time point, or it can be UNKNOWN when it started.
- End values: An observation can end BEFORE that time point, can end COINCIDENT with that time point, or it can be known that it did not end but was ONGOING, or it can be UNKNOWN when it ended or if it was ongoing.
- AFTER is not a valid value in this case because it would represent an event after the date of collection.

4.5.7 Presence or Absence of Prespecified Interventions and Events

Interventions (e.g., concomitant medications) and events (e.g., medical history) can generally be collected in 2 different ways, by recording either verbatim free text or the responses to a prespecified list of treatments or terms. Because the method of solicitation for information on treatments and terms may affect the frequency at which they are reported, whether they were prespecified may be of interest to reviewers. The --PRESP variable is used to indicate whether a specific intervention (--TRT) or event (--TERM) was solicited. The --PRESP variable has controlled terminology of "Y" (for "Yes") or a null value.

6. Codelist

For cases where the Define-XML includes multiple sponsor-defined subsets of parent CDISC Controlled Terminology Codelist, the Name attribute of the subset Codelist element should **begin with the Name of parent Codelist**. The CodeList Name must be unique within the set of Codelist elements.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
C71113		Yes	Frequency	FREQ	Frequency
C64526	C71113		Frequency	1 TIME PER WEEK	One Time Per Week
C139179	C71113		Frequency	10 DAYS PER MONTH	10 Days Monthly
C176288	C71113		Frequency	2 TIMES PER CYCLE	
C64497	C71113		Frequency	2 TIMES PER WEEK	BIS; Twice per week
C98861	C71113		Frequency	2 TIMES PER YEAR	2 Times Per Year

CM (Concomitant Medications) - [STDTMIG 3.3]

Location: [cm.xpt](#)

Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
CMDOSFRQ	Dosing Frequency per Interval	text	Variable Qualifier	3	Frequency, subset used for CM [6 Terms]	Collected (Source: Investigator) Annotated CRF [25]

EC (Exposure as Collected) - [STDTMIG 3.3]

Location: [ec.xpt](#)

Related Supplemental Qualifiers Dataset: SUPPEC (Supplemental Qualifiers for EC)						
Variable	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
ECDOSFRQ	Dosing Frequency per Interval	text	Variable Qualifier	2	Frequency, subset used for EC and EX • "QD" = "Daily"	Assigned (Source: Sponsor)

6. Codelist

When variables have the same list of allowed values and same meaning across different domains, they are united into one codelist.

DM (Demographics) - [STDTMIG 3.3]

Location: [dm.xpt](#)

Related Supplemental Qualifiers Dataset: [SUPPDM](#) (Supplemental Qualifiers for DM)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
DTHFL		Subject Death Flag	text	Record Qualifier	1	No Yes Response, subset for variables with only "Y" or null values <ul style="list-style-type: none"> "Y" = "Yes" 	Derived (Source: Sponsor) If DTHDTC is populated then DTHFL="Y"

LB (Laboratory Test Results) - [STDTMIG 3.3]

Location: [lb.xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
LBLOBXFL		Last Observation Before Exposure Flag	text	Record Qualifier	1	No Yes Response, subset for variables with only "Y" or null values <ul style="list-style-type: none"> "Y" = "Yes" 	Derived (Source: Vendor) Set to "Y" for last record with non-null original result on or before the first dose date (RFXSTDTC). Null otherwise.

6. Codelist

Sponsor-specific controlled terminology is recommended. Codelist usually be provided for variables and value-level definitions which have a predefined and finite set of categorical allowable values, free-text fields should not use codelist.

XT=Extra Test Results


SV=Subject Visits

Unscheduled Single Test VISIT	
Unscheduled single test: <input type="radio"/> Not done	[NOT SUBMITTED]
No.:	XTSPID
Test item:	QVAL when SUPPXT.QNAM=XTORITEM
Reason for test: <input type="radio"/> AE <input type="radio"/> Others	QVAL when SUPPXT.QNAM=XTREAS
AE no.:	QVAL when SUPPXT.QNAM=XTAEID
Other reasons:	QVAL when SUPPXT.QNAM=XTREASOT
Test date: _____ (DD-MM-YYYY)	XTDTC SVSTDTC
Result:	XTORRES QVAL when SUPPXT.QNAM=XTCSRES
Clinical significance: <input type="radio"/> Normal <input type="radio"/> Abnormal without clinical significance <input type="radio"/> Abnormal with clinical significance	
Note:	QVAL when SUPPXT.QNAM=XTTXT

XT (Extra Test Results) - FINDINGS

Location: [xt.xpt](#)

Related Supplemental Qualifiers Dataset: [SUPPXT](#) (Supplemental Qualifiers for XT)

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
XTSTRESC		Character Result/Finding in Std Format	text	200	Character Result/Finding in Std Format [1499 Terms]	Derived Equal to XTORRES. 

6. Codelist

Sponsor-specific controlled terminology is recommended. Codelist usually be provided for variables and value-level definitions which have a predefined and finite set of categorical allowable values, free-text fields should not use codelist.

RS (Disease Response and Clin Classification)

RSCAT = HAMD 17

RSEVLINT = -P1W

RSORRES when RSTESTCD = HAMD101

- 1 DEPRESSED MOOD** (*sadness, hopelessness, helplessness, worthlessness*)
- 0 Absent.
 - 1 These feeling states indicated only on questioning.
 - 2 These feeling states spontaneously reported verbally.
 - 3 Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep.
 - 4 Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication.

- 10 ANXIETY PSYCHIC**
- 0 No difficulty.
 - 1 Subjective tension and irritability.
 - 2 Worrying about minor matters.
 - 3 Apprehensive attitude apparent in face or speech.
 - 4 Fears expressed without questioning.

RSORRES when RSTESTCD = HAMD110

RSORRES when RSTESTCD = HAMD102

- 2 FEELINGS OF GUILT**
- 0 Absent.
 - 1 Self reproach, feels he/she has let people down.
 - 2 Ideas of guilt or rumination over past errors or sinful deeds.
 - 3 Present illness is a punishment. Delusions of guilt.
 - 4 Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

- 11 ANXIETY SOMATIC** (physiological concomitants of anxiety) such as:
- gastro-intestinal – dry mouth, wind, indigestion, diarrhea, cramps, belching
 - cardio-vascular – palpitations, headaches
 - respiratory – hyperventilation, sighing
 - urinary frequency
 - sweating

RS (Disease Response and Clin Classification) - [STDTMIG 3.3]

Location: [rs_xpt](#)

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
RSORRES VLM		Result or Finding in Original Units	text	Result Qualifier	198		Collected (Source: Investigator) Annotated CRF [19]
	RSTESTCD = "HAMD101" (HAMD1-Depressed Mood)	HAMD-17 Question 1	text		111	Hamilton Depression Rating Scale - 17 Item - Question 1 <ul style="list-style-type: none"> • "Absent." • "These feeling states indicated only on questioning." • "These feeling states spontaneously reported verbally," • "Communicates feeling states non-verbally, i.e. through facial expression, posture, voice and tendency to weep." • "Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication." 	Collected (Source: Investigator) Annotated CRF [19]
	RSTESTCD = "HAMD102" (HAMD1-Feelings of Guilt)	HAMD-17 Question 2	text		93	Hamilton Depression Rating Scale - 17 Item - Question 2 <ul style="list-style-type: none"> • "Absent." • "Self reproach, feels he/she has let people down." • "Ideas of guilt or rumination over past errors or sinful deeds." • "Present illness is a punishment. Delusions of guilt." • "Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations." 	Collected (Source: Investigator) Annotated CRF [19]

6. Codelist

ADaM Codelist

If there is a codelist for the variable coming from the SDTM dataset, then applicable values from the same codelist must be carried forward into ADaM.

Example:

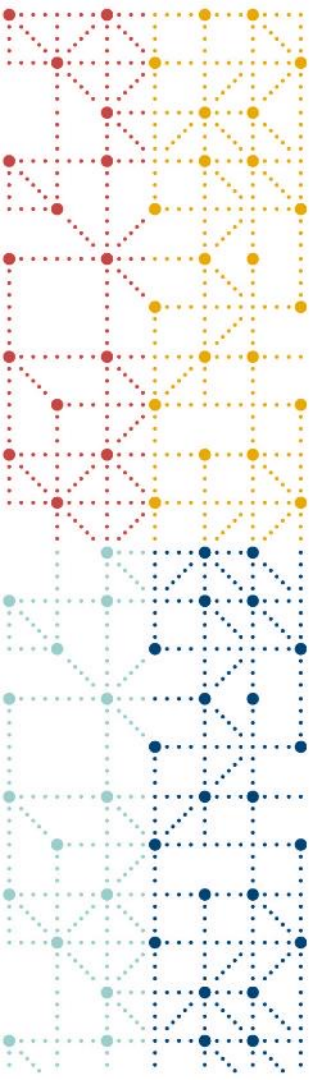
Variable	Label/Description	Type	Controlled Terms	Origin / Source / Method / Comment
AESEV	Severity/Intensity	text	AESEV	Predecessor: AE.AESEV

If the same variable exists in multiple ADaM datasets and has an associated codelist, then the associated codelist name should be differentiated if the list of allowed values is different from one dataset to another.

Ref: ADaM MSG v1.0

Reference

- PHUSE, [Define-XML+Version+2.0+Completion+Guidelines](#)
- CDISC, [CDISC Define-XML Specification Version 2.1](#)
- CDISC, [SDTM IG V3.4](#)
- CDISC, [SDTM MSG V2.0](#)
- CDISC, [ADAM MSG V1.0](#)
- FDA, [STUDY DATA TECHNICAL CONFORMANCE GUIDE v5.0](#)
- FDA, [FDA Validator Rules v1.6](#)



Thank You!

cdisc