

# *Customizing SDTM DATA Can Be As Easy As Learning Your XYZ's*

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# ***SDTM Domains: Your Options***

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SDTM IG V3.1.1 Released  
2005-08-26

Three Intervention  
Domains (CM, EX, SU)

Three Events Domains (AE,  
DS, MH)

Seven Findings Domains  
(EG, IE, LB, PE, QS, SC, VS)

SDTM IG V3.4 Released  
2021-11-29

Seven Intervention  
Domains (AG, CM, EX, EC,  
ML, PR, SU)

Seven Event Domains (AE,  
BE, CE, DS, HO, MH, DV)

Twenty Seven Findings  
Domains (DA, DD, EG, IE,  
BS, CP, GF, IS, LB, MB, MS,  
MI, PC, PP, MO, CV, MK, NV,  
OE, RP, RE, UR, PE, FT, QS,  
RS, SC, SS, TU, TR, VS)

# *The FDA's Expectations when Creating Your Custom Domain*

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Sponsors should confirm that the data does not fit into an existing domain

If it is necessary to create a custom domain, make sure to follow the SDTMIG recommendations

Present your implementation approach in the CSDRG (Clinical Study Data Reviewers Guide)

Consider creating a custom dataset aligned with the Study Data Tabulation Model

Questions about your custom domain should be addressed in pre-submission meetings and documented in the Study Data Standardization Plan (SDSP)

# *The Study Data Tabulation Models Do's*

Must be based on 1 of the 3 SDTM General  
Observation Classes

You must confirm that none of the existing published  
domains will fit the need.

You must check the SDTM Draft Domains area of the  
CDISC wiki for proposed domains developed since the  
last published version of the SDTMIG

Page	Dataset	Description	Class	Version	Structure	Purpose	Keys*	Location
<a href="#">Product Accountability (DA)</a>	DA	Product Accountability	Findings	1.1	One record per product accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD, DADTC	da.xpt
<a href="#">Environmental and Social Factors (ER)</a>	ER	Environmental and Social Factors	Events	1.0	One record per event per subject	Tabulation	STUDYID, USUBJID, ERTERM	er.xpt
<a href="#">Gastrointestinal System Findings (GI)</a>	GI	Gastrointestinal System Findings	Findings	1.0	One record per finding or result per time point per visit per subject	Tabulation	STUDYID, USUBJID, VISITNUM, GITESTCD, GILOC, GILAT	gi.xpt
<a href="#">ECG QT Correction Model Data (QT)</a>	QT	ECG QT Correction Model Data	Findings	1.0	One record per finding or result per time point per visit per subject	Tabulation	STUDYID, USUBJID, QTTESTCD	qt.xpt
<a href="#">Whole-Body System (WB)</a>	WB	Whole-Body System	Findings	1.1	One record per observed whole-body system finding per subject	Tabulation	STUDYID, USUBJID, SEQ	sb.xpt

\* Note that the key variables shown in this table are examples only. A sponsor's actual key structure may be different.

# Naming Your Custom Domain

Make sure that the domain abbreviation is not already listed in the CDISC Controlled Terminology SDTM Domain Abbreviation Codelist: (<https://datascience.cancer.gov/resources/cancervocabulary/cdisc-terminology>)

Domain codes beginning with the letters X, Y, and Z have been reserved for the creation of custom domains. This is optional.

If you have an interest to have the domain code be a part of CDISC CT submit a request at <https://ncitform.nci.nih.gov/ncitform/?version=cdisc>

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C00734		Yes	SDTM Domain Abbreviation	DOMAIN	SDTM Domain Abbreviation	A unique, 2-character domain code used in the regulatory submission process. The domain abbreviation is used consistently throughout the submission, i.e. in the dataset name, as the value of the domain variable within the dataset, and as a prefix for most variable names in the dataset. (CDISC Glossary)
C49562	C00734		SDTM Domain Abbreviation	AE	Adverse Events; Adverse Experiences	An events domain used for data describing unintended signs (including an abnormal laboratory finding, for example), symptoms, or diseases temporally associated with the defined study period.
C117755	C00734		SDTM Domain Abbreviation	AG	Procedure Agents	An interventions domain that contains the agents administered to the subject as part of a procedure or assessment, as opposed to drugs, medications and therapies administered with therapeutic intent.
C147175	C00734		SDTM Domain Abbreviation	APREL SUB	Relationship between Associated Persons and Subjects	A dataset used to represent relationships between associated persons (individuals who are not study subjects, but about whom data is collected) and study subjects.
C111138	C00734		SDTM Domain Abbreviation	BE	Biospecimen Events	An events domain that documents actions taken that affect or may affect a specimen (e.g. specimen collection, freezing and thawing, aliquoting, transportation).
C111137	C00734		SDTM Domain Abbreviation	BS	Biospecimen Findings	A findings domain that contains data related to biospecimen characteristics.
C35441	C00734		SDTM Domain Abbreviation	CE	Clinical Events	An events domain that contains clinical events of interest that would not be classified as adverse events.
C49568	C00734		SDTM Domain Abbreviation	CM	Concomitant/Prior Medications	An interventions domain that contains concomitant and prior medications used by the subject, such as those given on an as needed basis or condition-appropriate medications.
C49569	C00734		SDTM Domain Abbreviation	CO	Comments	A special-purpose domain that contains comments that may be collected alongside other data.

## *More SDTM Do's*

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### Include

Include the topic variable from whichever observation class you have chosen (--TESTCD, --TERM, --TRT)

### Include

Include relevant qualifier variables

### Include

Include applicable timing variables

## *The Study Data Tabulation Models Don'ts*

Do not create a custom domain if the nature of the data is the same as another published domain

Do not create separate domains based on time

How collected data is used must not result in the creation of a custom domain

# More SDTM Don'ts

## Do not include

- Do not include irrelevant qualifier variables belonging to a different observation class you have chosen for your custom domain

## Do not reinvent

- Do not try to reinvent the wheel when creating variables labels for your domain. Use resources available

## Do not use

- Do not use AD, AX, AP, SQ, and SA as your custom domain codes

## 3.1.1 The Interventions Observation Class

Interventions—Topic and Qualifier Variables—One Record per Constant-dosing Interval or Intervention Episode

#	Variable Name	Variable Label	Type	Format	Role	Variable(s) Qualified	Usage Restrictions	Variable C-code	Definition	Notes	Examples
1	--TRT	Name of Treatment	Char		Topic			C82542	The reported name of the drug, procedure, or therapy.	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.	
2	--MODIFY	Modified Treatment Name	Char		Synonym Qualifier	--TRT		C170998	A value which represents an alteration to a collected value for coding purposes.	If the value for --TRT is modified for coding purposes, then the modified text is placed here.	
3	--DECOD	Standardized Treatment Name	Char		Synonym Qualifier	--TRT		C170991	Standardized or dictionary-derived text for the description of an event or intervention.	Equivalent to the generic drug name in WHODrug, or a term in SNOMED, ICD-9, or other published or sponsor-defined dictionaries.	
4	--MOOD	Mood	Char		Record Qualifier			C117051	The state that may be applied to a record to indicate its phase in a life cycle or business process (e.g., scheduled, performed).		"SCHEDULED", "PERFORMED"
5	--CAT	Category	Char		Grouping Qualifier			C25372	A grouping or classification of the topic of the finding, event, or intervention.		
6	--SCAT	Subcategory	Char		Grouping Qualifier				A further grouping or classification of the category for the topic of the finding, event, or intervention.	The category is in --CAT.	



# *Documenting your custom domain*



Present your implementation approach in the cSDRG (Clinical Study Data Reviewers Guide)



Questions about custom domains should be addressed in pre-submission meetings



Document your custom domain in the SDSP



Describe the dataset within the Define-XML document

# *Thank You for Listening*

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