## **Custom Domains**

LPO Support Webinar 17 April 2019



## Upon Completion of this Webinar, You Should Be Able To:

- Explain what a custom domain is
- Decide whether or not you need to create a custom domain
- Construct a valid custom domain that follows CDASH and SDTM rules
- Decide when you need a custom codelist
- Describe a set of best practices for using custom domains and codelists in your implementation

# What is a Custom Domain?

And...when do you need to create one?

	L						
	\isits>	Screening	Month 1	Month 2	Month 6	Month 12	End of Study
Informed Consent		Х					
Demographics		Х					
Medical History		Х					
Meditation Practice		Х					
Vacations		Х					
Prior Medications		Х					
Physical Exam		Х	Х	Х	Х	Х	
Vital Signs		Х	Х	Х	Х	Х	
ECG		Х	Х	Х	Х	Х	
Concomitant Medications			Х	Х	Х	Х	
Adverse Events			Х	Х	Х	Х	
Randomization			Х				
Dispense Study Treatment			Х	Х	Х	Х	
Administer Study Treatment			Х	Х	Х	Х	
Quality of Life Assessment			Х	Х	Х	Х	
Dermatology Findings		Х	Х	Х	Х	Х	
End of Study Status							Х

## Custom **CDASH** Domains - What they are

- Entire topics of data you need to collect, for which there is no currently published CDISC CDASHIG domain
- https://www.cdisc.org/standards/foundational/cdash/cdash-20

8.1 CDASH Interventions Dom:	ains	8.3 CDASH Findings Domains		
0.1.5 SU - SUDS	nitant Medications cted and EX - Exposure SPECIAL-PURPOSE DOMAINS	tory Test Results		
8.2 CDASH Events 8.2.1 General CD 7.3 DM - D	ral CDASH Assumptions for Speci Comments Demographics	opic Findings acokinetics Sampling I Examination		
8.2.2 AE - Adverse Events		8.3.10 QRS - Questionnaires, Ratings and Scales		
8.2.3 CE - Clinical Events		8.3.11 SC - Subject Characteristics		
8.2.4 DS - Disposition		8.3.12 RP - Reproductive System Findings		
8.2.5 DV - Protocol Deviations		8.3.13 SR - Skin Response		
8.2.6 HO - Healthcare Encounte	ers	8.3.14 VS - Vital Signs		
8.2.7 MH - Medical History		8.3.15 FA - Findings About		

## **Recommendations for Custom Domains**

#### Make sure you need a Custom Domain

- Don't create one just because you think your efficacy data is "special"
  - E.g., Lab values are always LB domain even if one of them is the primary endpoint in your study
- FDA Technical Conformance Guide Section 4.1.1.3
  - Prior to creating a custom domain, sponsors should confirm that the data do not fit into an existing domain.

۱ Informed Consent	/isits>	Screening X	Month 1	Month 2	Month 6	Month 12	End of Study		
7. Meditation Practice	<ul> <li>7 CDASH SPECIAL-PURPOSE DOMAINS</li> <li>7.1 General CDASH Assumptions for Special-Purpose Domains</li> <li>7.2 CO - Comments</li> <li>7.3 DM - Demographics</li> </ul>								
Physical Exam		Х	Х	Х	Х	Х			
Vital Signs		Х	Х	Х	Х	Х			
ECG		Х	Х	Х	Х	Х			
Concomitant Medications			Х	Х	Х	Х			
Adverse Events			Х	Х	Х	Х			
Randomization			Х						
Dispense Study Treatment			Х	Х	Х	Х			
Administer Study Treatment			Х	Х	Х	Х			
Quality of Life AssessmentXXX									
Dermatology Findings X X X X X									
End of Study Status							Х		

Visits>	Screening	Month 1	Month 2	Month 6	Month 12	End of Study
Informed Consent	Х					
Demographics	Х					
Medical History	Х					
Meditation Practice	Х					
Vacations	Х					
Prior Medications	Х					
Physical Exam	Х	Х	Х	Х		
Vital Signs	Х	Х	Х	X	Х	
ECG 8.1	CDASH Inter	rventions Domains		ĸ	Х	
Concomitant Medications 8.1	1 Assumption	tions for Intervention:	s Domains	ĸ	Х	
Adverse Events 8.1	.Z CM - Pric	or and Concomitant M	ledications	ĸ	Х	
Randomization 8.1	.3 EC - Exp	osure as Collected an	d EX - Exposi	ure		
Dispense Study Treatment	.4 PR - Pro	cedures		ĸ	Х	
Administer Study Treatment 8.1	.5 SU - Sub	stance Use	ĸ	Х		
Quality of Life Assessment		Х	Х	X	Х	
Dermatology Findings	Х	Х	Х	Х		
End of Study Status					Х	

Visits>	Screening	Month 1	Month 2	Month 6	Month 12	End of Study
Informed Consent	Х					
Demographics	Х					
Medical History	Х					
Meditation Practice	Х					
Vacations	8.2	CDASH Events Domains				
Prior Medications	8.2.1	General CDASH Ass		Events Doma	ins	
Physical Exam	822	AE - Adverse Events	-		Х	
Vital Signs	8.2.3	CE - Clinical Events			Х	
ECG	8.2.4	DS - Disposition			Х	
Concomitant Medications	8.25	DV - Protocol Deviat	ions		Х	
Adverse Events	6.2%	HO - Healthcare End	ounters		Х	
Randomization	8.2.7	MH - Medical Histor	у			
Dispense Study Treatment		Х	Х	Х	Х	
Administer Study Treatment		Х	Х	Х	Х	
Quality of Life Assessment		Х	Х	Х	Х	
Dermatology Findings	Х	Х	Х	Х	Х	
End of Study Status						Х

Visits>	Screening	Month 1	Month 2	Month 6	Month 12	End of Study
Informed Consen Demographics Medical History Meditation Practice Vacations Prior Medications Physical Exam Vital Signs ECC Concomitant Medication Adverse Events Randomization Dispense Study Treatment Administer Study Treatment Quality of Life Assessment Dermatology Findings	8.3 8.3.1 8.3.2 8.3.3 8.3.4 8.3.5 8.3.6 8.3.7 8.3.8 8.3.7 8.3.8 8.3.7 8.3.8 8.3.7 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.1 8.3.2 8.3.3 8.3.1 8.3.2 8.3.3 8.3.1 8.3.2 8.3.3 8.3.1 8.3.2 8.3.3 8.3.2 8.3.3 8.3.4 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.3.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.5.5 8.	DA - Drug Accounta DD - Death Details EG - ECG Test Result IE - Inclusion/Exclus LB - Laboratory Tes MI - Microscopic Fin PC - Pharmacokine PE - Physical Exami QRS - Questionnain SC - Subject Charac RP - Reproductive S SR - Skin Response VS - Vital Signs	umptions for bility ts sion Criteria N t Results idings tics Sampling nation es, Ratings an teristics System Findin	lot Met d Scales	ains X X X X X X X X X X X X X X X X X X X	
End of Study Status						Х

Visits> Informed Consent Demographics Medical History	Screening X X X	Month 1	Month 2	Month 6	Month 12	End of Study
Meditation Practice Vacations Prior Medications Physical Exam Vital Signs ECG Concomitant Medications Adverse Events	X X X X	No existing, domain = Cus	•			
Randomization	_	Х				
Dispense Study Treatment		Х	Х	Х	Х	
Administer Study Treatment		Х	Х	Х	Х	
Quality of Life Assessment		Х	Х	Х	Х	
Dermatology Findings	Х	Х	Х	Х	Х	
End of Study Status						Х

## Custom **SDTM** Domains - What they are

- Entire topics of data you need to tabulate, for which there is no currently published CDISC SDTMIG domain
- https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-v3-3

	odels for Interventions Domains	1	6.3 Mo	odels for Findings Domains	6.3.11	Pharmacokinetics Do	omains
6.1.1	Procedure Agents		6.3.1	Drug Accountability	6.3.11.1	Pharmacokinetic	s Concentrations
6.1.2	Concomitant and Prior Medications			с ,	6.3.11.2	Pharmacokinetic	s Parameters
6.1.3	Exposure Domains		6.3.2	Death Details	6.3.11.3	Relating PP Reco	rds to PC Records
6.1.3.1	Exposure		6.3.3	ECG Test Results		Physical Examination	
6.1.3.2	Exposure as Collected		6.3.4	Inclusion/Exclusion Criteria Not Met	6.3.12	-	
6.1.3.3	Exposure/Exposure as Collected	Examples	6.3.5	Immunogenicity Specimen Assessments		- · ·	ngs, and Scales (QRS) Domains
6.1.4	Meal Data		6.3.6	Laboratory Test Results	6.3.13.1	Functional Tests	
6.1.5		ditation?	>	Microbiology Domains	6.3.13.2	<b>C</b>	
				Microbiology Specimen	6.3.13.3	Disease Response	e and Clin Classification
6.1.6	Substance Use Vaca	ations?		Microbiology Susceptibility	6.3.14	Subject Characteristi	ics
				Microbiology Specimen/Microbiology Susceptibility Ex	6.3.15	Subject Status	
6.2 1	Models for Ever	matolog	<mark>J</mark> Υ :	Microscopic Findings	6.3.16	Tumor/Lesion Doma	ins
			630	Morphology	6.3.16.1	Tumor/Lesion Ide	entification
6.2.1	Adverse Events					d an	sults
6.2.2	Clinical Events	Inese	topi	cs are not found in SDTMI	G, 0	ther	ion/Tumor Results Examples
6.2.3	Discouting	SDTM	-has	sed IG,or any TAUG			ion/ funition recourse countyres
	Disposition						
6.2.4	Protocol Deviations	So…th	iese	are custom domains.			Interventions
6.2.5	Healthcare Encounters	<b></b>					s About
			6.3.10.5	Ophthalmic Examinations	6.4.2	Naming Findings Abo	out Domains
6.2.6	Medical History		6.3.10.6	Reproductive System Findings	6.4.3	Variables Unique to F	Findings About
			6.3.10.7	Respiratory System Findings	6.4.4	Findings About	
			6.3.10.8		6.4.5	Skin Response	
	TIONAL CANCER INSTITUTE				4		

## These topics will need Custom Domains

Visits	Screening	Month 1	Month 2	Month 6	Month 12	End of Study
Informed Consent	Х					
Demographics	Х					
Medical History	Х					
Meditation Practice	Х					
Vacations	Х					
Prior Medications	Х					
Physical Exam	Х	Х	Х	Х	Х	
Vital Signs	Х	Х	Х	Х	Х	
ECG	Х	Х	Х	Х	Х	
Concomitant Medications		Х	Х	Х	Х	
Adverse Events		Х	Х	Х	Х	
Randomization		Х				
Dispense Study Treatment		Х	Х	Х	Х	
Administer Study Treatment		Х	Х	Х	Х	
Quality of Life Assessment		Х	Х	Х	Х	
Dermatology Findings	Х	Х	Х	Х	Х	
End or Study Status						Х

## How to Construct Custom Domains

Begin with the end in mind?

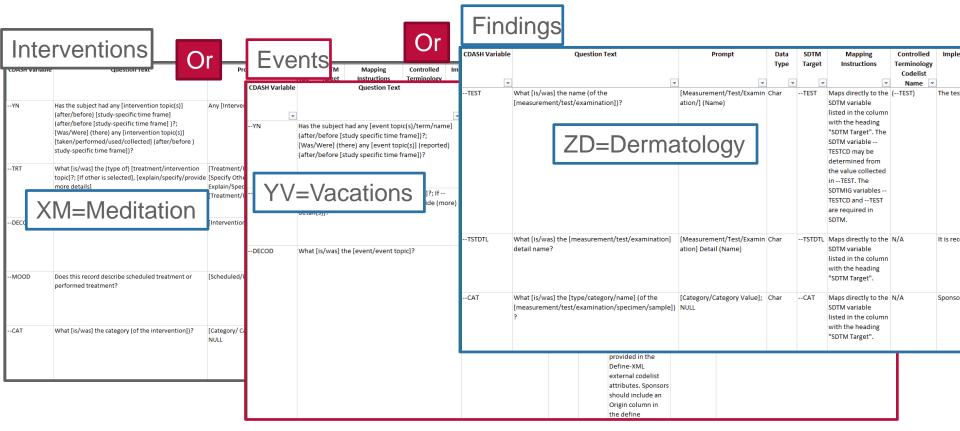
## **High Level Process**

- Identify all the topics in your study
  - Confirm the need for one or more custom domains
- Identify the right General Observation Class for each custom domain
  - See SDTMIG Sections 2 and 8
- Create a Custom Domain code for each Custom Domain
  - Create a unique (*within your implementation*) domain code for each custom topic
    - Cannot conflict with a standard domain code (CT DOMAIN list)
    - X, Y and Z will never conflict reserved for custom domains

Consider assigning one letter to each Observation Class X = Interventions, Y=Events, Z=Findings (<u>not</u> required to use this way)

## **Custom** Data Collection Domains

- Are based on the a standard General Observation Class from CDASH Model (the ROOT data collection metadata)
- CDASH Model is aligned with/ mapped to the analogous Observation Class in SDTM



https://www.cdisc.org/standards/foundational/cdash/cdash-model-10

## **Plus - CDASH Model Identifiers**

CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist	Implementation Notes
<b>v</b>	· · · · · · · · · · · · · · · · · · ·	<b>•</b>		<b>•</b>	<b>•</b>	Name 💌	
SITEID	Study Site Identifier	What [is/was] the site identifier?	Site Identifier	DM.SITEI D	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Paper: This is typically pr
INVID	Investigator Identifier	What [is/was] the investigator identifier?	Investigator Identifier	DM.INVI D	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	May be used in addition (
SUBJID	Subject Identifier for the Study	What [is/was] the subject identifier?	Subject Identifier	DM.SUBJ ID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	This CDASH variable is ty
FOCID	Focus of Study Specific Interest	[Protocol specific question]?	[Protocol Specific Prompt]	FOCID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	This SDTM variable has bi
SPID	Sponsor-Defined Identifier	What [is/was] the [test/procedure/observation] identifier?	[Line Number/ Number]	SPID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target". May be used to create RELREC to link this	N/A	Since SPID is a sponsor-d

## Plus - CDASH Model Timing Fields

CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM	Mapping	Controlled	Implementation Notes
				Target	Instructions	Terminology	
		_				Codelist	
•					<b>•</b>	Name 💌	<b></b>
EPOCH	Epoch	What [is/was] the trial [period/phase/sponsor-	Trial Period	EPOCH	Maps directly to the	(EPOCH)	If the same information is o
		defined phrase] (for this			SDTM variable		
		[event/intervention/finding])?			listed in the column		
					with the heading		
					"SDTM Target".		
DAT	Date of Collection	What [is/ was] the date the [event or intervention]	[Event/Intervention]	DTC	This field does not	N/A	This is a generic DATE field
		[is/was] collected?; What [is/ was] the (start) date (of	Collection Date; [Finding]		map directly to an		
		the [Finding])?	(Start) Date		SDTM variable. For		
					the SDTM dataset,		
					concatenate all		
					collected CDASH		
					DATE and TIME		
					components and		
					populate the SDTM		
					variableDTC in		

## Mapped to **Custom** Tabulation (Submission Data) Domains

- Are based on a standard General Observation Class from SDTM (the Model)
  - Use the same root variables as all SDTMIG domains
  - Use the same root variables as all other SDTM Custom Domains

Table 2.2.1 three trents         2.2.2 The Events Observation Class         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Torong All         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Table 2.2.1 fearts-rapic and Qualifier Variables-On Record per Moding           Main         Main         Table 2.2.1 fearts-rapic and Qualifier Variables         Table Variables           Main         Main         Main         Main         Main         Main         Main           Main         Main         Main         Main         Main         Main         Main<	2.2.1 T	2.1 The Interventions Observation Class				2.2.3 T	he Findings C	)bse	ervation Class	S	
Number         Variable         Variable Market	Table 2.2.1.	1 Interventions-T	2.2.2 T	he Events Obs	servation	Class	Table 2.2.3	.1 Findings—Topic and G	Qualifi	ier Variables–One Rec	cord per Finding
Head         Numer		Variable Label					Variable		-	1	
Init         Name         Name <th< th=""><th>Name</th><th></th><th></th><th></th><th></th><th></th><th>Name</th><th></th><th></th><th></th><th></th></th<>	Name						Name				
Image: Constraint of the second state state of the second state of the second state of the second state	TRT	Name of Treatmen		Variable Label	Type Role	Description			-	1	
Modified Training         Topic         Topic Start         Decim         Decim         Decim         Complete Training         Complete Tra			Name				TESTCD		Char	Topic	
PROD         Source defendence         Construction         Construction <td></td> <td></td> <td>TERM</td> <td>Reported Term</td> <td>Char Topic</td> <td>Topic variab</td> <td></td> <td></td> <td></td> <td></td> <td>format. The short value can be up to 8 characters. Examples: "PLAT", "SYSBP", "RRMIN", "EYEEXAM".</td>			TERM	Reported Term	Char Topic	Topic variab					format. The short value can be up to 8 characters. Examples: "PLAT", "SYSBP", "RRMIN", "EYEEXAM".
LECCU         Sundardad Testers Name         -MODEY         Modified Reported Test (Testers Name         -MODEY         Modified Test (Testers Name        MODEY         Modified Testers Name	MODIFY		T LINIT	Reported renn	chai Topic	Topic variab		Exam			
Teatment Name         Construint         Cons	DECOD		MODIFY	Modified Reported Term	Char Synonym	If the value f	TICT	Name of Manuscreen	Char	Cup opum Qualifier of	
HOOD         Mode         High Level Term         Char Weikabe         MedDALs         MedDALs           CAL         Gaugery	DECOD					:		Test, or Exam		TESTCD	
LAD         Callage of Callage of PRCS         Callage of Callage of PRCS         Callage of Callage of	MOOD	Mood	LLT	Lowest Level Term	Char Variable	MedDRA Lo	MODIFY	Modified Ierm	Char		If the value ofORRES is modified for coding purposes, then the modified text is placed here.
Subclisticity         Subclisticity	CAT	Category			Qualifier o		TETET	Management Task as	Char		Further description of TECTED and TECT Examples #The examples of calls with a fabric in a subset MITECT
PHSRLING       PLUD       Cover rest       PLUD       P							I-ISIDIL		Char		
CCCUR         Occurrence tender         Constraint         Const	PRESP	Pre-specified	LLTCD	Lowest Level Term Code			-CAT		Char		
STATI       Completion Status      BECOD       Debtorary-Derived Term       Char       Operating Outsider       Char       Grouping Qualifier       Used to define a further categorization of -CAT values. Example: "MRCD IFFERENTIAL".         -STATI       Completion Status      DECOD       Debtorary-Derived Term       Char       Record Qualifier       Peatro of Subject       Char       Record Qualifier       Peatro of Subject       Processing Completions of the subject Charge Record Qualifier       Peatro of Subject       Processing Completions of the subject Charge Record Qualifier       Peatro of the subject Charge Record Qualifier       Unit for -ORRES and -ORREF.       Peatro of the subject Charge Record Qualifier       Peatro of the subject Charge Record Qualifier       Peatro of the Record Qualifier       Peatro of the	OCCUR	Occurrence Indicat						Category	Cridi	Grouping Qualinel	
-SIAT       Completion Status       -RECOD       Octoballing/Control field       Datable of the subject during a measurement or examination. Examples: "SUPNE", "STANDING", "STITNG".         -READN       Record Qualifier       Postion of the subject during a measurement or examination. Examples: "SUPNE", "STANDING", "STITNG".         -READN       Record Qualifier of -DOSE       Processor       Processor       Record Qualifier of -DOSE       Record Qualifier of -DOSE       Processor       Processor       Record Qualifier of -DOSE       Record Qualifier of -DOSE       Processor       <	CCCON	occurrence indicat	DECOD	Dictionary-Derived Term		Dictionany o	SCAT	Subcategory	Char	Grouping Qualifier	
-REARD       Reacon AU Deer -PTCD       Preferred Term Code       Num       Number Qualifier of -DECCO       For an and the standard hierarchy for dictionary-coded results.		Completion Status	DECOD	Dictionally-Derived Territ	Qualifier o		POS				Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".
Indication       Class       Cash       Cash <td></td> <td></td> <td>PTCD</td> <td>Preferred Term Code</td> <td></td> <td>MedDRA Pro</td> <td>BODSYS</td> <td></td> <td>Char</td> <td>Record Oualifier</td> <td>Body System or Oroan Class that is involved for a finding from the standard hierarchy for dictionary-coded results.</td>			PTCD	Preferred Term Code		MedDRA Pro	BODSYS		Char	Record Oualifier	Body System or Oroan Class that is involved for a finding from the standard hierarchy for dictionary-coded results.
-CARCD     Class G     Cas     Ca			1100	ricicited term code							
UNCL       Lase Currence	CLAS	Class			DECOD		ORRES	Result or Finding in	Char	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: "120", "<1", "POS".
Operation         Qualifier of -ORES and -ORREF         Unit for -ORRES and -ORREF.         Dumbles in the standard of momentance of the subscription of the subscripting the subscription of the su	CLASCD	Class Co	T.	High Level Term	Char Variable	MedDRA Hi		Original Units			
-OOSTXT       Dose Dramonal Parage Lower       High Level Term Code       Num       Variable Qualifier of -URLS.       Lower end of normal range or reference range for results stored in -ORRES.         -OOSTM       Dose Units      HLGT       High Level Group Term       Char       Variable Qualifier of -HLT       -ORRES         -ODSFRM       Dose Form      HLGT       High Level Group Term       Char       MedDRA He Qualifier of -HLT       -ORREF       Char Variable Qualifier of -HLT       Upper end of normal range or reference range for results stored in -ORRES.         -DOSFRM       Dose Form      HLGT       High Level Group Term       MedDRA He Qualifier of -HLT       -ORREF       Reference Result Units       -ORRES       applicable. Examples: value for Infrangs, copied or derived from -ORRES in a standard format or in standard units.         -DOSFRM       Dosing Frequency per Interval      CAT       Category       Char       MedDRA He Qualifier of -HLGT       -STRESC       Result or Finding in Standard format in -STRESC should store all results on findings, copied or derived from -ORRES in a standard format or in standard units.         -DOSFRM       Interded Dose      SCAT       Subcategory       Char       Grouping Qualifier of Qualifier of Qualifier       -STRESN       Num Result Qualifier       -STRESN       Standard format copie in numeric fewts for an -STRESC, -STRESN, -STRESC, -STRESN, -STRESC, -STRESN, -STRESC, -STRESN, -STRESC, -STRESN, -STRESC, -S			r				OPRESU	Original Units	Char		Unit forORRES andORREF. Examples: "in", "LB", "kg/L".
OUSE			TCD	High Level Term Code			r IRLO	Normal Range Lower	Char	Variable Qualifier of	Lower end of normal range or reference range for results stored inORRES.
HLGT       High Level Group Term       Char       Variable Qualifier of TERSN       Normal Range Open       Char       Variable Qualifier of TERSN       MedDRA Hig Original Units       ORRES       Opper end of normal range or reference range for results stored inORRES.        DOSFRM       Dosing Frequency per Interval      HLGTC       High Level Group Term Qualifier of HLGTC       Num       Variable Qualifier of HLGTC       MedDRA Hig Original Units      ORREF       Reference Result in Original Units      ORREF       Reference value for the result value for all findings, in character format, if results are numeric, they should also be stored in numeric format in -STRESC should store all results or inflanging, in character format, if results are numeric, they should also be stored in numeric format in -STRESC should store all results or inflanging, in character format, if results are numeric, they should also be stored in numeric format in -STRESC, should store all results or inflanging, in character format, in results are numeric, they should also be stored in numeric format in -STRESC should store all results or inflanging, in character format, in results are numeric, they should also be stored in numeric format in -STRESC, should store all numeric test results or finding in standard format, copied in numeric format in -STRESC, and "Stresc", and "NEGATIVE" in -ORREF        DOSIGN       Intended Dose Regimen      SCAT       Subcategory       Char       Grouping Qualifier o	DOSU	Dose Units									
-DOSFRM       Dose Form			LILCT	Llich Lougl Croup Torm		MedDDATE	IRHI		Char		Upper end of normal range or reference range for results stored inORRES.
Image: Construction     Image: Construct	DOSEDM	Doce Form	HLGT	High Level Gloup Terri							
Image: Construct of the co	DOSERIN	Dose Form					ORREF		Char		
DOSFRQ     Dosing Frequency per Interval     Code     Qualifier of HLGT     -STRESC     Result or Finding in Standard format     Char Point     Result or Finding in Standard format     Contains the result value for opied or derived fromORRES in a standard format or in standard format or in standard format or in -HLGT       -DOSTOT     Total Daily Dose -DOSRGM     -CAT     Category     Char Grouping Qualifier     Used to defi Qualifier     Used to defi Qualifier     -STRESC     Numeric Result/Finding in Standard Units     Contains the result value for presented in standard format; copied on derived fromORRES in a standard format; copied on derived in TRESC       -DOSRGM     Intended Dose Regimen     -SCAT     Subcategory     Char Grouping Qualifier     Used to defi Qualifier     -STRESN     Numeric Result/Finding in standard Units     Num     Result Qualifier     Used for continuous on numeric results or findings.       -ROUTE     Route of Administration			HLGTCD	High Level Group Term		MedDRA Hi	CTDF07	2	<b>C1</b>		
Per line/val	DOSFRQ						STRESC		Char	Result Qualifier	
-DOSTOT       Total Daly Dose       -CAI       Category       Char Grouping Qualifier       Used to define Qualifier		per Interval						Standard Format			
-DOSRGM       Intended Dose Regimen       -SCAT       Subcategory       Char Qualifier       Used to defind Qualifier       -STRESN       Numeric Result/Finding In Standard Units       Num       Result Qualifier       Used for continuous or numeric results or findings.        ROUTE       Route of Administration	DOSTOT	Total Daily Doco	CAT	Category		Used to defi					
Regimen     -SCAI     Subcategory     Char Grouping     Output of Grouping     Output of Grouping     In Standard Units     should store all numeric test results or findings.       -ROUTE     Route of Administration     -PRESP     Pre-Specified     Char Variable Qualifier of Qualifier of Variable Qualifier of Administration     Variable Qualifier of Qualifier of Or STRESC, -STRESN, -STRESC, -STRESN, -STRESC, and -STRESN, -STRESN, and -STRESN, -STRESC, and -STRESN, -STRESN, and -STRESN, -STRESC, and -STRESN, -STRESN, and -STRESN, and -STRESN, -STRESN, and -					-		STRESN	Numeric Result/Finding	Num	Result Qualifier	
-ROUTE     Route of Administration     -PRESP     Pre-Specified     Char     Variable upuifier of Spontaneou     Variable Char     Variable Variable -STRESC and -STRESC and     Standard Units     Standardized units used for -STRESC, -STRESN, -STREFC, and -STREFN, Example: *moi/L*.       -LOT     Lot Number -LOC     -OCCUR     Occurrence Indicator     Char     Variable yontaneou -TERM     -STRESC and -STRESN and -STREFC and -STREFN     -STRESN and -STREFN       -LAT     Laterality     -STAT     Completion Status     Char     Record     Used to indi Qualifier     -STRLEN     Normal Range Lower Limit-Standard Units     Normal Range Lower     Lower end of normal range or reference range for standardized results (e.g., -STRESN, -	Doardh		SCAI	Subcategory		Used to defi	J J I I I I I			and a second second	
Index			PRESP	Pre-Specified	~	Lised to indi	STRESU	Standard Units	Char	Variable Qualifier of	
Administration	ROUTE		FREDF	i re-specified						STRESC and	
-LOC     Location of Dose Administration     -OCCUR     Occurrece Indicator     Char     Record Qualifier     Used to recd     -STREFN       -LAT     Laterality     -STAT     Completion Status     Char     Qualifier     Vised to recd     -STNRLO       Unit     Laterality     -STAT     Completion Status     Char     Record     Used to recd     -STNRLO     Normal Range Lower     Variable Qualifier of     Lower end of normal range or reference range for standardized results (e.g., -STRESO, -STRESO, -STRESO, restreson) represented in	LOT										
Administration         Administration         Qualifier         Qualifier         FNRLO         Administration         -STRESC and         Lower end of normal range or reference range for standardized results (e.g., -STRESC, -STRESN) represented in standardized units (-STRESC).			OCCUR	Occurrence Indicator		Used to reco					
-LAT Laterality -STAT Completion Status Char Record Qualifier of NOT DOD V Used to Indi Qualifier of NOT DOD V Used to Indi On NOT DOD V Used to India On	LOC				Qualifier						
	LAT		STAT	Completion Status			STNRLO		Num		
								Limit-Standard Units			standardized units (STRESU).
			REASND	Reason Not Done	Char Record	Reason not	CTNID!."			STRESN	
NIH NATIONA Qualifier Qualifier -STNRHI Normal Range Upper Num Variable Qualifier of Upper end of normal range or reference range for standardized results (e.g., -STRESC, -STRESN) represented in standardized units (-STRESU).	NIH	NATIONA	DODEVC	De du Custana de Os		Derturn			Num		
-BODSYS Body System or Organ Char Record Body system Limit-Standard Units -STRESC and standardized units (-STRESU).			ROD212						1		Stalitaruizeu ulits (~517C50).

## Identifiers - SDTM Table 2.2.4

#### Plus

Variable	Variable Label	Туре	Description		
Name					
STUDYID	Study Identifier	Char	Unique identifier for		
Domain	Domain Abbreviation	Char	2-character abbre	pmain most relevant to the observation. The domain abbreviation is also	used as a prefix for variables to ensure
			uniqueness w		
USUBJID	Unique Subject Identifier	Char	ldentifier uz		e product.
APID	Associated Persons	Char	Ident Some	identifiers are required to be in	PID identifies a pool, POOLDEF records
	Identifier				odel Fundamentals to Associated Persons).
POOLID	Pool Identifier	Char	anv o	domain: STUDYID, DOMAIN,	
SPDEVID	Sponsor Device Identifier	Char	SA.	USUBJID andSEQ	
NHOID	Non-Host Organism Identifier	Char	Sponsor organism as		based on the identity of the non-host
FETUSID	Fetus Identifier	Char	Identifier used		es a fetus within a subject. Not to be used
			with human clinica		-
FOCID	Focus of	Char	Identification of a foc	pecific interest on or within a subject or specimen as called out in the pro	
	Study-Specific		examination was perform	as a drug application site (e.g., "Injection site 1", "Biopsy site 1", "Treated	
	Interest		(right eye) or "Upper left qua	of the back"). The value in this variable should have inherent semantic me	-
SEQ	Sequence Number	Num		ueness of records within a dataset for a subject (or within a parameter, in t cimals) and does not have to start at 1.	the case of the Trial Summary domain). May
GRPID	Group ID	Char	Optional group identifier, used to	link together a block of related records within a subject in a domain. Also	used to link together a block of related
			records in the Trial Summary Infor	rmation (Section 3.3).	
REFID	Reference ID	Char	Optional internal or external ident	tifier such as lab specimen ID, or UUID for an ECG waveform or a medical i	mage.
RECID	Invariant Record	Char	-	e within a domain for a study and that remains invariant through subsequ	
	Identifier			When a record is deleted, this value must not be reused to identify anoth	er record in either the current or future
			versions of the domain.		
SPID	Sponsor-Defined	Char	Sponsor-defined identifier. Examp	ble: pre-printed line identifier on a Concornitant Medications page.	
	Identifier				
LNKID	Link ID	Char		rds across domains. This may be a one-to-one or a one-to-many relations	hip. For example, a single turnor may have
				ents performed at each study visit.	
LNKGRP	Link Group ID	Char		rds across domains. This will usually be a many-to-one relationship. For e	cample, multiple turnor
			measurements/assessments will	contribute to a single response to therapy determination record.	

### Timing Variables - SDTM Table 2.2.5



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## **Recommendations for Custom Domains**

#### Begin with the end in mind

Conformant SDTM data is the target objective

- Use CDASH Model to Create Custom Domains
- Why? Because the CDASH Model is aligned to SDTM (Model)
  - Same General Observation Classes (Interventions/Events/Findings)
  - CDASH root variables are mapped to SDTM root variables

Create your custom domains using the **CDASH** Model to **collect** the data  You will be able to standardize the programming to convert collected data to SDTM

 You will be able to add your custom domains to your GLIB for everyone to use -improve consistency across LPOs

## Constructing a Custom Data Collection Domain

Use root metadata from:

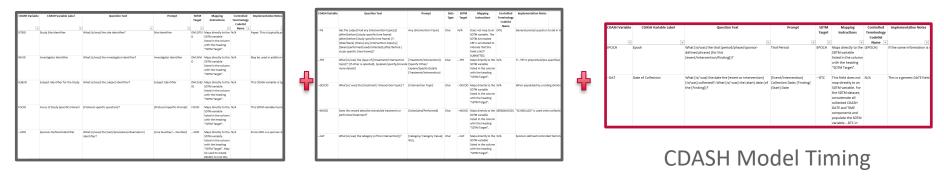


**CDASH Model Identifiers** 

ONE of the three General Observation Class tables in the CDASH Model

## Custom Interventions Data Collection Domain

If your custom topic is "Meditation" use root metadata from:

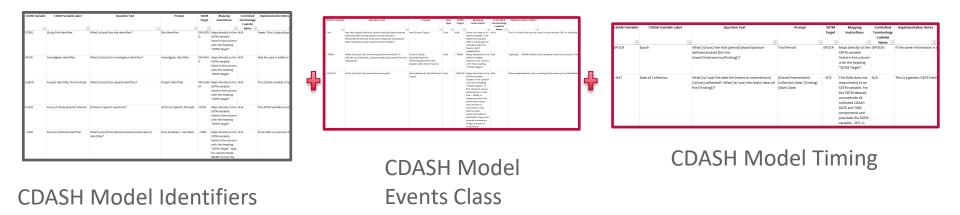


**CDASH Model Identifiers** 

CDASH Model Interventions Class

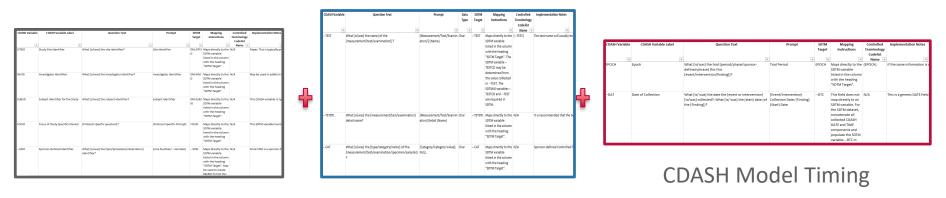
## Custom Events Data Collection Domain

If your custom topic is "Vacations" use root metadata from:



## Custom Findings Data Collection Domain

If you custom topic is "Dermatology Findings" use root metadata from:

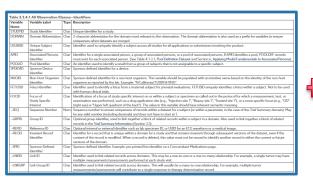


CDASH Model Identifiers

CDASH Model Findings Class

## Constructing a Custom Tabulation (Submission Data) Domain

Use root variables from:



SDTM Table 2.2.4 Identifiers



ONE of the three General Observation Class tables in SDTM

Table 2.2.5.1	1 All Observation Classes—T	imina	Variable	4
Variable	Variable Label			Description
Name	Variable Caber	inte	Format	Vesception
VISITNUM	Visit Number	Num		Clinical encounter number. Numeric version of VISIT, used for sorting.
VISIT	Visit Name	Char		Protocol-defined description of a clinical encounter.
VISITDY	Planned Study Day of Visit	Num		Planned study day of VISIT. Should be an integer.
TAFTORD	Planned Order of Element	Num		Number that gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).
114,10100	Within Arm			reaction and Buch are hearing a part of our ensurement and hear periods of the second
EPOCH	Epoch	Char		Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is not
				collected (see Section 3.1.2, Trial Arms).
RPHASE	Repro Phase	Char		Reproductive Phase with which the Reproductive Stage of the Reproductive Path is associated. Defined in Trial Paths domain. The
				RPHASE variable is Required when any Reproductive Phase Day variable is used. Not to be used with human clinical trials.
RPPLDY	Planned Repro Phase Day of	Num		The planned day within the Reproductive Phase on which the observation was scheduled to occur. Expressed as an integer. Not to
	Observation			be used with human clinical trials.
RPPLSTDY	Planned Repro Phase Day of	Num		The planned day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human
	Obs Start			clinical trials.
RPPLENDY	Planned Repro Phase Day of	Num		The planned day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human
	Obs End			clinical trials.
DTC	Date/Time of Collection	Char		Collection date and time of an observation.
			8601	
-STDTC	Start Date/Time of	Char	ISO	Start date/time of an observation.
	Observation		8601	
-ENDTC	End Date/Time of	Char		End date/time of the observation.
	Observation		8601	
-DY	Study Day of	Num		Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
	Visit/Collection/Exam			
-STDY	Study Day of Start of	Num		Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
	Observation			
ENDY	Study Day of End of	Num		Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
-NOMDY	Observation Nominal Study Day for	Num		
-NOMDY	Nominal Study Day for Tabulations	Num		The nominal study day used by data-collection and reporting systems for grouping records for observations that may be scheduled to occur on different days into a single study day (e.g., output on a tabulation report). Not to be used with human clinical trials.
NOMLBL	Label for Nominal Study Day	Char		to occur on dimenent days into a single study day (e.g., output on a tabuation report). Not to be used with human clinical trials. A label for a given value ofNOMDY, within a domain, as presented in the study report. Not to be used with human clinical trials.
RPDY	Actual Repro Phase Day of	Num		Haber for a given value ofreCMD1, within a domain, as presented in the study report. Not to be used with numan carical than. The actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with
-10101	Observation	Num		I ne actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with human clinical trials.
RPSTDY	Actual Repro Phase Day of	Num		The actual day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human
-RESIDI	Obs Start	Regin		clinical trials.
RPENDY	Actual Repro Phase Day of	Num		The actual day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human
10 0 001	Obs End			chical trials.
DUR	Duration	Char	ISO	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.
			8601	
TPT	Planned Time Point Name	Char		Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented
				as an elapsed time relative to a fixed reference point, such as time of last dose. SeeTPTNUM andTPTREF,
TPTNUM	Planned Time Point Number	Num		Numeric version of planned time point used in sorting.
FLTM	Planned Elapsed Time from	Char	150	Planned Elapsed time relative to a planned fixed reference (TPTREF) such as "Previous Dose" or "Previous Meal". This variable is
	Time Point Ref		8601	useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval.
TPTREF	Time Point Reference	Char		Description of the fixed reference point referred to byELTM,TPTNUM,TPT,STINT, andENINT. Examples: "PREVIOUS DOSE",
				"PREVIOUS MEAL".
RFTDTC	Date/Time of Reference Time	Char	150	Date/time for a fixed reference time point defined byTPTREF.
	Point		8601	
STRF	Start Relative to Reference	Char		Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-defined
	Period			reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by
				RFSTDTC and RFENDTC in Demographics.
ENRF	End Relative to Reference	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined
	Period			reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by
				RFSTDTC and RFENDTC in Demographics.
EVLINT	Evaluation Interval	Char	150	Duration of interval associated with an observation such as a findingTESTCD. Usually used withDTC to describe an interval of
	1		8601	this duration that ended at the time represented inDTC. Example: "-P2M" to represent a period of the past 2 months as the
				evaluation interval for a question from a questionnaire.

SDTM Table 2.2.5 Timing

Prefix the custom domain variables with a 2 character custom domain code

If you have started with the CDASH Model, you are already most of the way there.

## Custom Interventions Class Domain

If your custom topic is "Meditation" use root variables from:



#### SDTM Table 2.2.4 Identifiers

				One Record per Constant-Dosing Interval or Intervention Episode
Variable Name	Variable Label	Туре	Role	Description
				Topic Variable
TRT	Name of Treatment	Char	Topic	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.
MODEY	Modified Treatment	1	Synonym Qualifier of	Qualifier Variables If the value forTRT is modified for coding purposes, then the modified text is placed here.
	Name	Char	TRT	
-DECOD	Standardized Treatment Name	Char	Synonym Qualifier of TRT	Standardized or dictionary-derived name of the topic variable,TRT, or the modified topic variable (MODEY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
-M000	Mood		Record Qualifier	Made or condition of the record (e.g., "SCHEDULED", "PERFORMED").
CAL	Category		Grouping Qualifier	Used to define a category of topic variable values.
SCAT	Subcategory		Grouping Qualifier	Used to define a further categorization ofCAT values.
PRESP	Pre-specified	Char	Variable Qualifier of TRT	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.
-OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.
-STAT	Completion Status	Char	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
REASND	Reason Not Done	Char	Record Qualifier	Reason not done. Used in conjunction withSTAT when value is "NOT DONE".
INDC	Indication	Char	Record Qualifier	Denotes the indication for the intervention (e.g., why the therapy was taken or administered).
-CLAS	Class	Char	Variable Qualifier of TRT	Class for a medication or treatment, often obtained from a coding dictionary.
-CLASCD	Class Code	Char	Variable Qualifier of TRT	Used to represent code forCLAS.
-DOSE	Dose	Num		Amount ofTRT given. Not populated whenDOSTXT is populated.
DOSTXT	Dose Description	Char	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated whenDOSE is populated.
-DOSU	Dose Units	Char	Variable Qualifier of DOSE,DOSTXT or DOSTOT	Units forDOSE,DOSTOT, orDOSTXT: Examples: 'ng', 'mg', 'mg/kg'.
	Dose Form		Variable Qualifier of DOSE,DOSTXT or DOSTOT	Dose form for the treatment. Examples: "TABLET, "CAPSULE".
-DOSFRQ	Dosing Frequency per Interval		Variable Qualifier of DOSE,DOSTXT or DOSTOT	Usually expressed as the number of doses given per a specific interval. Examples: "Q2P", "QD", "FRP".
-DOSTOT	Total Daily Dose		Record Qualifier	Total daily dose ofTRT using the units inDOSU. Used when dosing is collected as Total Daily Dose.
-DOSRGM	Regimen	Char	Variable Qualifier of DOSE,DOSTXT or DOSTOT	Text description of the (intended) schedule or regimen for the intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".
ROUTE	Route of Administration	Char	Variable Qualifier of TRT	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".
	Lot Number	Char	Record Qualifier	Lot number for the intervention described in -TRT.
-LOC	Location of Dose	Char	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: ARM for an injection.
-I AT	Administration			Qualifier for anatomical location further detailing laterality of intervention administration. Damples: "RIGHT: "LEFT".

#### SDTM Table 2.2.1 Interventions Observation Class

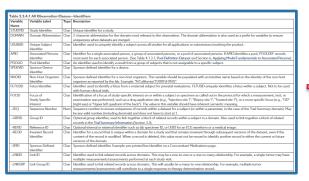
Prefix the custom domain variables with a 2 character custom domain code

Table 2.2.5.1 All Observation Classes—Timing Variables							
Variable	Variable Label	Type	Format	Description			
Name							
VISITNUM	Visit Number	Num		Clinical encounter number. Numeric version of VISIT, used for sorting.			
VISIT	Visit Name	Char		Protocol-defined description of a clinical encounter.			
VISITDY	Planned Study Day of Visit	Num		Planned study day of VISIT. Should be an integer.			
TAETORD	Planned Order of Element	Num		Number that gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).			
	Within Arm						
EPOCH	Epoch	Char		Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is not			
				collected (see Section 3.1.2, Trial Arms).			
RPHASE	Repro Phase	Char		Reproductive Phase with which the Reproductive Stage of the Reproductive Path is associated. Defined in Trial Paths domain. The			
				RPHASE variable is Required when any Reproductive Phase Day variable is used. Not to be used with human clinical trials.			
RPPLDY	Planned Repro Phase Day of	Num		The planned day within the Reproductive Phase on which the observation was scheduled to occur. Expressed as an integer. Not to			
	Observation			be used with human clinical trials.			
RPPLSTDY	Planned Repro Phase Day of	Num		The planned day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human			
	Obs Start			clinical trials.			
RPPLENDY	Planned Repro Phase Day of	Num		The planned day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human			
	Obs End			clinical trials.			
DTC	Date/Time of Collection	Char		Collection date and time of an observation.			
			8601				
-STDIC	Start Date/Time of	Char	БО	Start date/time of an observation.			
	Observation		8601				
ENDTC	End Date/Time of	Char	150	End date/time of the observation.			
	Observation		8601				
DY	Study Day of	Num		Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.			
	Visit/Collection/Exam						
-STDY	Study Day of Start of	Num		Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.			
	Observation						
ENDY	Study Day of End of	Num		Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.			
	Observation						
-NOMDY	Nominal Study Day for	Num		The nominal study day used by data-collection and reporting systems for grouping records for observations that may be scheduled			
	Tabulations			to occur on different days into a single study day (e.g., output on a tabulation report). Not to be used with human clinical trials.			
NOMLBL	Label for Nominal Study Day	Char		A label for a given value ofNOMDY, within a domain, as presented in the study report. Not to be used with human clinical trials.			
-RPDY	Actual Repro Phase Day of	Num		The actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with			
	Observation			human clinical trials.			
RPSTDY	Actual Repro Phase Day of	Num		The actual day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human			
	Obs Start			clinical trials.			
RPENDY	Actual Repro Phase Day of	Num		The actual day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human			
	Obs End			dinical trials.			
-DUR	Duration	Char	БО	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.			
		_	8601				
-TPT	Planned Time Point Name	Char		Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented			
				as an elapsed time relative to a fixed reference point, such as time of last dose. SeeTPTNUM andTPTREF.			
TPTNUM	Planned Time Point Number	Num		Numeric version of planned time point used in sorting.			
ELTM	Planned Elapsed Time from	Char		Planned Elapsed time relative to a planned fixed reference (TPTREF) such as "Previous Dose" or "Previous Meal". This variable is			
	Time Point Ref		8601	useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval.			
TPTREF	Time Point Reference	Char		Description of the fixed reference point referred to byELTM,TPTNUM,TPT,STINT, andENINT. Examples: "PREVIOUS DOSE",			
		-		"PREVIOUS MEAL".			
-RFTDTC	Date/Time of Reference Time	Char	60	Date/time for a fixed reference time point defined byTPTREF.			
	Point	-	8601				
STRF	Start Relative to Reference	Char		Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-defined			
	Period			reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by			
		L		RFSTDTC and RFENDTC in Demographics.			
ENRF	End Relative to Reference	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined			
	Period			reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by			
		-		RFSTDTC and RFENDTC in Demographics.			
EVLINT	Evaluation Interval	Char	ISO	Duration of interval associated with an observation such as a findingTESTCD. Usually used withDTC to describe an interval of			
	1		8601	this duration that ended at the time represented inDTC. Example: "-PZM" to represent a period of the past 2 months as the			
		-		evaluation interval for a question from a questionnaire.			

SDTM Table 2.2.5 Timing

## Custom Events Class Domain

If your custom topic is "Vacations" use root variables from:



#### SDTM Table 2.2.4 Identifiers

Variable	Variable Label	Type	Role	Description
reame	1	-		Topic Variable
TERM	Reported Term	Char	Topic	Topic variable for an event observation, which is the verbatim or pre-specified name of the event.
				Qualifier Variables
-MODIFY	Modified Reported Term	Char	Synonym Qualifier of TERM	If the value forTERM is modified for coding purposes, then the modified text is placed here.
-ur	Lowest Level Term	Char	Variable Qualifier of -TERM	MedDRALowest Level Term.
-LLTCD	Lowest Level Term Code	Num	Variable Qualifier of	MedDRA Lowest Level Term code.
DECOD	Dictionary-Derived Term	Char	Synorrym Qualifier of TERM	Dictionary or sponsor-delined derived text description of the topic variable,TERM, or the modified topic variable (MCDIFY), if applicable, Equivalent to the Preferred Term (PT in MedDRA).
PTCD	Preferred Term Code	Num	Variable Qualifier of DECOD	MedDRA Preferred Term code.
-HLT	High Level Term	Char	Variable Qualifier of TERM	MedDRA High Level Term from the primary path.
HLTCD	High Level Term Code	Num	Variable Qualifier of HLT	MedDRA High Level Term code from the primary path.
-HLGT	High Level Group Term	Char	Variable Qualifier of TERM	MedDRA High Level Group Term from the primary path.
HLGTCD	High Level Group Term Code	Num	Variable Qualifier of -HLGT	MedDRA High Level Group Term code from the primary path.
CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values.
-SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization ofCAT values.
PRESP	Pre-Specified	Char	Variable Qualifier of TERM	Used to indicate whether the event described byTERM was pre-specified on a CRF. Value is Y for pre-specified events, null for spontaneously reported events.
-OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to record whether a pre-specified event occurred when information about the occurrence of a specific event is solicited.
-STAT	Completion Status	Char	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified event was not answered. Should be null or have a value of NOT DONE.
-REASND	Reason Not Done	Char	Qualifier	Reason not done. Used in conjunction withSTAT when its value is "NOT DONE".
-BODSYS	Body System or Organ Class	Char	Record Qualifier	Body system or system organ class assigned for analysis from a standard hierarchy (e.g., MedDRA) associated with an event. Example: "GASTROINTESTINAL DISORDERS".

#### SDTM Table 2.2.2 Events Observation Class

Prefix the custom domain variables with a 2 character custom domain code

Variable	Variable Label	Tree	Format	Description
Name			- ormat	
VISITNUM	Visit Number	Num		Clinical encounter number. Numeric version of VISIT, used for sorting.
VISIT	Visit Name	Char		Protocol-defined description of a clinical encounter.
VISITDY	Planned Study Day of Visit	Num		Planned study day of VISIT. Should be an integer.
TAETORD	Planned Order of Element Within Arm	Num		Number that gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).
EPOCH	Epoch	Char		Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is collected (see Section 3.1.2, Trial Arms).
RPHASE	Repro Phase	Char		Reproductive Phase with which the Reproductive Stage of the Reproductive Path is associated. Defined in Trial Paths domain. Th RPI/ASE variable is Required when any Reproductive Phase Day variable is used. Not to be used with human clinical trials.
RPPLDY	Planned Repro Phase Day of Observation	Num		The planned day within the Reproductive Phase on which the observation was scheduled to occur. Expressed as an integer. Not t be used with human clinical trials.
RPPLSTDY	Planned Repro Phase Day of Obs Start	Num		The planned day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with hurr clinical trials.
RPPLENDY	Planned Repro Phase Day of Obs End	Num		The planned day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with huma clinical trials.
-DTC	Date/Time of Collection	Char	ISO 8601	Collection date and time of an observation.
STDTC	Start Date/Time of Observation	Char	ISO 8601	Start date/time of an observation.
ENDTC	End Date/Time of Observation	Char	ISO 8601	End date/time of the observation.
DY	Study Day of Visit/Collection/Exam	Num		Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
STDY	Study Day of Start of Observation	Num		Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
ENDY	Study Day of End of Observation	Num		Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
-NOMDY	Nominal Study Day for Tabulations	Num		The nominal study day used by data-collection and reporting systems for grouping records for observations that may be schedule to occur on different days into a single study day (e.g., output on a tabulation report). Not to be used with human clinical trials.
NOMLBL	Label for Nominal Study Day	Char		A label for a given value ofNOMDY, within a domain, as presented in the study report. Not to be used with human clinical trials.
-RPDY	Actual Repro Phase Day of Observation	Num		Preserved a given water or "receiver, we are a constraint, as preserved in the accuracy report. Not to be used with namer cancer cases." The actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with human chickled trials.
-RPSTDY	Actual Repro Phase Day of Obs Start	Num		numan concert trans. The actual day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human clinical trans.
RPENDY	Actual Repro Phase Day of Ohs End	Num		The actual day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human clinical trials.
DUR	Duration	Char	ISO 8601	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.
TPT	Planned Time Point Name	Char	0001	Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. See -IPTNUM and -IPTRF.
TPTNUM	Planned Time Point Number	Num		Numeric version of planned time point used in sorting.
ELTM	Planned Elapsed Time from	Char	ISO	Planned Elapsed time relative to a planned fixed reference (TPTREF) such as "Previous Dose" or "Previous Meal". This variable is
	Time Point Ref		8601	useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval.
TPTREF	Time Point Reference	Char		Description of the fixed reference point referred to byELTM,TPTNUM,TPT,STINT, andENINT. Examples: "PREVIOUS DO: "PREVIOUS MEAL".
RFTDTC	Date/Time of Reference Time Point		ISO 8601	Date/time for a fixed reference time point defined byTPTREF.
STRF	Start Relative to Reference Period	Char		Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-definec reference period is a continuous period time defined by a discrete starting point and a discrete ending point represented by RSTDTC and RENDTC in Demographics.
ENRF	End Relative to Reference Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined references period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RENDTC in Demographics.
EVLINT	Evaluation Interval	Char	ISO 8601	Duration of Interval associated with an observation such as a finding –TESTCD. Usually used with –DTC to describe an interval of this duration that ended at the time represented in –DTC. Example: "PZM" to represent a period of the past 2 months as the evaluation interval for a question from a outstornaria.
	F 1 1 1 1 1 1 1 1 1 1	0		sensitives intervention and the sensitive intervention of the sensitive sensitive in the sensitive sensitive in the sensitive sens

SDTM Table 2.2.5 Timing

## Custom Findings Class Domain

If your custom topic is "Dermatology Findings" use root variables from:



#### SDTM Table 2.2.4 Identifiers

				ord per Finding
Variable	Variable Label	Туре	Role	Description
				Topic Variable
TESTCD	Short Name of Measurement, Test, or Exam	Char	Topic	Short character value forTEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: "PLAT", "SYS8P", "RMIN", "EYECAM",
		-		Qualifier Variables
TEST	Name of Measurement, Test, or Exam	Char	Synonym Qualifier of TESTCD	Long name ForTESTCD. Examples: Platelets, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
-MODIFY	Modified Term	Char	Synonym Qualifier of ORRES	If the value ofORRES is modified for coding purposes, then the modified text is placed here.
TSTDTL	Measurement, Test, or Examination Detail	Char	Variable Qualifier of TESTCD andTEST	Further description ofTESTCD andTEST. Example: "The percentage of cells with +1 intensity of staining" when MITEST "Thyroid Transcription Factor 1".
CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY", "HAMD 17", "\$F36 V2.0 ACUTE", "EGFR MUTATION ANALYSIS".
SCAT	Subcategory		Grouping Qualifier	Used to define a further categorization ofCAT values. Example: "WBC DIFFERENTIAL".
POS	Position of Subject During Observation	Char	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".
-BODSYS	Body System or Organ Class	Char	Record Qualifier	Body System or Organ Class that is involved for a finding from the standard hierarchy for dictionary-coded results. Example: MedDRA SOC.
-ORRES	Result or Finding in Original Units	Char	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: "120", "<1", "POS".
ORRESU	Original Units	Char	Variable Qualifier of ORRES andORREF	Unit forORRES andORREF. Examples: "In", "LB", "kg/L".
ORNRLO	Normal Range Lower Limit-Original Units	Char	Variable Qualifier of ORRES	Lower end of normal range or reference range for results stored inORRES.
ORNRHI	Normal Range Upper Limit-Original Units	Char	Variable Qualifier of ORRES	Upper end of normal range or reference range for results stored inORRES.
ORREF	Reference Result in Original Units	Char	Variable Qualifier of ORRES	Reference value for the result or finding as originally received or collectedORREF uses the same units asORRES, if applicable. Examples: value from predicted normal value in spirometry tests.
STRESC	Result or Finding in Standard Format	Char	Result Qualifier	Contains the result value for all findings, copied or derived from - CORES in a standard format or in standard units. - STRES: chools to all results of findings in character format, if results are nameric, they should also be stored in numeric format in - STRES N. For example, if values tasks have results "NONE", "NEC", and "NECATIVE" in - CORES and these results findings in the standard to result and the standard format in - STRES C. and "NECATIVE" in - CORES and NECESTRESS and the standard format in - STRESS are NECATIVE.
-STRESN	Numeric Result/Finding In Standard Units	Num	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format fromSTRESCSTRESP should store all numeric test results or findings.
STRESU	Standard Units	Char	Variable Qualifier of STRESC and STRESN and STREFC and STREFN	Standardteed units used for -STRESC, -STRESN, -STREFC, and -STREFN. Example: "moUL".
STNRLO	Normal Range Lower Limit-Standard Units	Num	Variable Qualifier of STRESC and STRESN	Lower end of normal range or reference range for standardized results (e.g., -STRESC, -STRESN) represented in standardized units (-STRESU).
STNRH	Normal Range Upper Limit-Standard Units	Num	Variable Qualifier of STRESC and	Upper end of normal range or reference range for standardized results (e.g., -STRESC, -STRESN) represented in standardized units (-STRESU).

#### SDTM Table **2.2.3** Findings Observation Class

Prefix the custom domain variables with a 2 character custom domain code

Table 2.2.5.1 All Observation Classes—Timing Variables							
Variable	Variable Label	Type	Format	Description			
Name VISITNUM	Visit Number						
VISITNUM	Visit Number Visit Name	Num		Clinical encounter number. Numeric version of VISIT, used for sorting. Protocol-defined description of a clinical encounter.			
VISIT	Planned Study Day of Visit	Num		Protocol-denned description or a canical encounter. Planned study day of VISIT, Should be an integer.			
TAFTORD	Planned Order of Element	Num		Number that gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).			
11210105	Within Arm			Transfer one greating particulation on the content mean and and part becautions, mananaly,			
EPOCH	Epoch	Char		Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is not collected (see Section 3.1.2, Trial Arms).			
RPHASE	Repro Phase	Char		Reproductive Phase with which the Reproductive Stage of the Reproductive Path is associated. Defined in Trial Paths domain. The RPIASE variable is Required when any Reproductive Phase Day variable is used. Not to be used with human clinical trials.			
RPPLDY	Planned Repro Phase Day of Observation	Num		The planned day within the Reproductive Phase on which the observation was scheduled to occur. Expressed as an integer. Not to be used with human clinical trials.			
RPPLSTDY	Planned Repro Phase Day of Obs Start	Num		The planned day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human clinical trials.			
RPPLENDY	Planned Repro Phase Day of Obs End	Num		The planned day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human clinical trials.			
DIC	Date/Time of Collection	Char	ISO 8601	Collection date and time of an observation.			
STDTC	Start Date/Time of Observation	Char	ISO 8601	Start date/time of an observation.			
ENDTC	End Date/Time of Observation	Char	ISO 8601	End date/time of the observation.			
-DY	Study Day of Visit/Collection/Exam	Num		Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.			
-STDY	Study Day of Start of Observation	Num		Actual study day of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.			
ENDY	Study Day of End of Observation	Num		Actual study day of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.			
-NOMDY	Nominal Study Day for	Num		The nominal study day used by data-collection and reporting systems for grouping records for observations that may be scheduled			
	Tabulations			to occur on different days into a single study day (e.g., output on a tabulation report). Not to be used with human clinical trials.			
NOMLBL	Label for Nominal Study Day	Char		A label for a given value ofNOMDY, within a domain, as presented in the study report. Not to be used with human clinical trials.			
RPDY	Actual Repro Phase Day of Observation	Num		The actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with human clinical trials.			
RPSTDY	Actual Repro Phase Day of Obs Start	Num		The actual day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with human clinical trials.			
RPENIDY	Actual Repro Phase Day of Obs End	Num		The actual day within the Reproductive Phase of the end of the observation. Expressed as an integer. Not to be used with human clinical trials.			
DUR	Duration	Char	ISO 8601	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.			
-TPT	Planned Time Point Name	Char		Text description of time when a measurement or observation should be taken as defined in the protocol. This may be represented as an elapsed time relative to a fixed reference point, such as time of last dose. SeeTPTNUM andTPTREF.			
TPTNUM	Planned Time Point Number	Num		Numeric version of planned time point used in sorting.			
ELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601	Planned Elapsed time relative to a planned fixed reference (TPTREF) such as "Previous Dose" or "Previous Meal". This variable is useful where there are repetitive measures. Not a clock time or a date/time variable, but an interval.			
TPTREF	Time Point Reference	Char		Description of the fixed reference point referred to byELTM,TPTNUM,TPT,STINT, andENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".			
RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined byTPTREF.			
STRF	Start Relative to Reference	Char		Identifies the start of the observation as being before, during, or after the sponsor-defined reference period. The sponsor-defined			
	Period			reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RFENDTC in Demographics.			
ENRF	End Relative to Reference	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined			
	Period			reference period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by RFSTDTC and RFENDTC in Demographics.			
EVLINT	Evaluation Interval	Char	ISO 8601	Duration of interval associated with an observation such as a finding -TESTCD. Usually used with -DTC to describe an interval of this duration that ended at the time represented in -DTC. Example: "+P2M" to represent a period of the past 2 months as the evaluation interval for a questionnaire.			
10 AN (70)	E 1 11 1 1 1 1 1 1 1	63		Each strategy between the second strategy of the second seco			

SDTM Table 2.2.5 Timing

## CDASH Example: Meditation

- This topic (meditation) is not found in SDTMIG (or CDASHIG)
- It most closely aligns with Interventions Class
  - Subject experiences it and experience can cause physiological change
  - Can be described using start and end date/time, or collected duration
  - Can be described using an amount with a unit (e.g., 2 hours)
  - A frequency and/or regimen can be described

Meditation CRF
Describe type of meditation you practice For how many years have you been practicing meditation?
For how long do you Meditate each session?
How frequently do you meditate?

## **Example: Create Meditation Custom Domain Specifications**



CDASH	XM-Meditation		SDTM	XM-Meditation					
CDASH Variable	Question Text/ Prompt	Mapping Instructions	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT		IMPLEMENTATION NOTES	CORE
STUDYID	1001	Direct	STUDYID	Study Identifier	Char		Identifier		REQ
			DOMAIN	Domain Abbreviation	Char	XM	Identifier	Default to XM	REQ
			USUBJID	Unique Subject Identifier	Char		Identifier	follow implementation rules	REQ
			XMSEQ	Sequence Number	Num		Identifier	follow implementation rules	REQ
XMTRT	vhat is the type of meditation practiced?	Direct	XMTRT	Name of Meditation Regimen	Char		Торіс		REQ
XMDOSE	What is the length of each medidation ession?	Direct	XMDOSE	Meditation Session Length	Num	(XMDECOD)	Record Qualifier		PERM
XMDOSU	lisplay LINIT values	Direct	XMDOSU	Meditation Session Length Unit	Char	(UNIT)	Variable Qualifier		PERM
XMDOSFRQ	vitac is the frequency of medidation ractice?	Direct	XMDOSFRQ	Frequency of Meditation Sessions	Char	(FREQ)	Variable Qualifier		PERM
	For how many years have you been practicing meditation	To populate XMDUR, Concatenate XMCDUR with XMCDURU and format as ISO 8601 Period	XMDUR	Duration of Meditation Practice	Char	ISO 8601	Timing		PERM
XMCDURU	display UNIT value: YEAR	To populate XMDUR, Concatenate XMCDUR with XMCDURU and format as ISO 8601 Period							

Many CDASH variables are a 1:1 match with SDTM Add in the SDTM submission-only variables Apply standard programming to transform other collected values to SDTM

## CDASH Example: Meditation

- Apply CDASH Metadata
  - Find the appropriate fields for each question
  - Apply root Question Text or Prompt
  - Apply the root variable for database setup



CDASH Model Identifiers

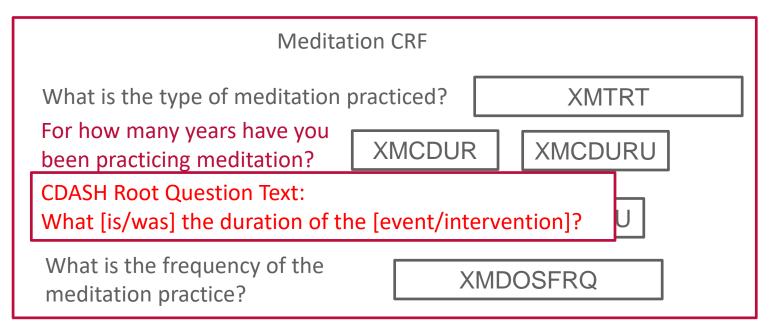
CDASH Model Interventions Class

Prefix the custom domain variables with a 2 character custom domain code

CDASH Model Timing

## CDASH Example: Meditation

CDASH has been applied as much as possible:



Creating custom domains may reveal deficiencies in CDASH metadata which should be reported to the CDASH team.

<u>At least make sure your question MEANS the SAME thing.</u>

## Example: Meditation CDASH Metadata

CDASH	XM-Meditation	
CDASH Variable	Question Text/ Prompt	Mapping Instructions
STUDYID	STUDY	Direct
-		
XMTRT	What is the type of meditation practiced?	Direct
XMDOSE	What is the length of each medidation session?	Direct
XMDOSU	display UNIT values	Direct
XMDOSFRQ	What is the frequency of medidation practice?	Direct
XMCDUR	For how many years have you been practicing meditation	To populate XMDUR, Concatenate XMCDUR with XMCDURU and format as ISO 8601 Period
XMCDURU	display UNIT value: YEAR	To populate XMDUR, Concatenate XMCDUR with XMCDURU and format as ISO 8601 Period

## SDTM Example: Meditation (Topic and Qualifiers)

Custom	
Domain	
Code	

Char Variable Qualifier of

Laterality

Variable Name	Variable Label	Туре	Role	Description					
				Topic V					
TRT	Name of Treatment	Char	Торіс	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.					
				Qualifier					
MODIFY	Nodified Treatment Name		Synonym Qualifier c TRT	If the value forTRT is modified for coding purposes, then the modified text is placed here.					
DECOD	Standardized Treatment Name	Char	Synonym Qualifier of TRT	Standardized or dictionary-derived name of the topic variable,TRT, or the modified topic variable (MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.					
MOOD	Mood	Char	SDTM X	M-N editation					
CAT	Category	Char	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED	ROLE	IMPLEMENTATION NOTES	CORE
SCAT	Subcategory	Char	-			TERMS,			
PRESP	Pre-specified	Char				CODELIST OR FORMAT			
OCCUR	Occurrence Indicator	Char	STUDYID St	udy Identifier	Char		Identifier		REQ
STAT	Completion Status	Char	DOMAIN D	omain Abbreviation	Char	XM	Identifier	Default to XM	REQ
		$\mathbf{\Gamma}$		nique Subject Identifier	Char		Identifier	follow implementation rules	REQ
REASND	Reason Not Done	Char		equence Number	Num		Identifier	follow implementation rules	REQ
INDC	Indication	Char	XMTRT N	ame of Meditation Regimen	Char		Topic		REQ
CLAS	Class	Char							
CLASCD	Class Code	Char	XMDOSE N	leditation Session Length	Num	(XMDECOD)	Record Qualifier		PERM
			XMDOSU N	leditation Session Length Unit	Char	(UNIT)	Variable Qualifier		PERM
DOSE	Dose	Num							
DOSTXT	Dose Description	Char	XMDOSFRQ F	requency of Meditation Sessions	Char	(FREQ)	Variable Qualifier		PERM
DOSU	Dose Units	Char							
			XMDUR D	uration of Meditation Practice	Char	ISO 8601	Timing		PERM
DOSFRM	Dose Form	Char	-						
DOSERIT	Dose Form	Chai							
1			DOSTOT						
DOSFRQ	Dosing Frequency	Char	Variable Qualifier of	Usually expressed as the numb	er of doses given per a	specific interval.	Examples: "O2H". "(	DD", "PRN".	
	per Interval		DOSE,DOSTXT or	,	<u>5</u> pur		.p		
			DOSTOT						
DOSTOT	Total Daily Dose	Num	Record Qualifier	Total daily dose ofTRT using the units inDOSU. Used when dosing is collected as Total Daily Dose.					
DOSRGM	Intended Dose	Char	Variable Qualifier of	Text description of the (intende	ed) schedule or regime	n for the Intervent	ion. Example: "TW	D WEEKS ON, TWO WEEKS OFF".	
	Regimen		DOSE,DOSTXT or DOSTOT						
ROUTE	Route of Administration	Char	Variable Qualifier of TRT	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".					
				Lot number for the intervention described inTRT.					
LOT		Char	Record Oualifier	Lot number for the intervention	n described inTRT				
LOT LOC	Lot Number Location of Dose		Record Qualifier Record Qualifier	Lot number for the intervention Anatomical location of an inter		ection site. Examp	le: ARM for an inied	tion.	

Qualifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT",

#### SDTM Example: Meditation (Identifiers)

Variable	Variable Label	Туре	Description	otion					
Name	Studie Libert (Con	CL	I I - the other free and a						
TUDYID	Study Identifier	Char	Unique identifier for a study.						
DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the uniqueness when datasets are m		e observation. The	domain ab	breviation is al	so used as a prefix for variable	es to ensure
JSUBJID	Unique Subject	Chat		2	- f II It tt			- the see dust	
120R1D	Identifier	Cha	identifier used to uniquely identifi	used to uniquely identify a subject across all studies for all applications or submissions involving the product.					
APID	Associated Persons	Char	Nentifier for a single associated	or a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records					
	Identifier		must exist for each associated p	for each associated person. (See Table 4.1.3.1, Pool Definition Dataset and Section 6, Applying Model Fundamentals to Associated Persons).					
POOLID	Pool Identifier	Char	An Mentifier used to identify a re	ier used to identify a result from a group of subjects that is not assignable to a specific subject.					
SPDEVID	Sponsor Device	Char	Sponsor-defined identifier for a d	levice.					
NHOID	Non-Host Organism Identifier	Char	Sponsor defined identifier for a roorganism as reported by the lab.	-		pulated with	n an intuitive n	ame based on the identity of	the non-host
ETUSID	Fetus Identifier	Char	Identifier used to ide sommer with human dinical VARIABLE	XM-Meditation				<u> </u>	
			with human clinical VARIABLE	VARIABLE LABEL	TYPE	CONTROLLED	ROLE	IMPLEMENTATION NOTES	CORE
OCID	Focus of	Char	Identification of a fo	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS,		IMPLEMENTATION NOTES	CORE
OCID	Focus of Study-Specific	Char		VARIABLE LABEL	ТҮРЕ	TERMS, CODELIST OR		IMPLEMENTATION NOTES	CORE
OCID		Char	Identification of a fo	VARIABLE LABEL	TYPE	TERMS,		IMPLEMENTATION NOTES	CORE
	Study-Specific		Identification of a fo examination waspe (right eye) or "Uppe Sequence number t			TERMS, CODELIST OR	Identifier	IMPLEMENTATION NOTES	
-SEQ	Study-Specific Interest		Identification of a fo examination waspe (right eye) or "Uppe" studyid Sequence number t	Study Identifier Domain Abbreviation	Char	TERMS, CODELIST OR	Identifier Identifier	Default to XM	REQ
-SEQ	Study-Specific Interest		Identification of a fo examination was pe (right eye) or "Uppa Sequence number t be any valid numbe	Study Identifier Domain Abbreviation	Char	TERMS, CODELIST OR FORMAT	Identifier	Default to XM follow implementation rules	REQ
-SEQ	Study-Specific Interest Sequence Number	Num	Identification of a fo examination waspe (right eye) or "Uppe" studyid Sequence number t	Study Identifier Domain Abbreviation	Char Char Char	TERMS, CODELIST OR FORMAT	Identifier Identifier Identifier	Default to XM	REQ. REQ. REQ.
-SEQ -GRPID	Study-Specific Interest Sequence Number	Num	Identification of a fo examination was pe (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider XMSEQ	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen	Char Char Num Char	TERMS, CODELIST OR FORMAT	ldentifier Identifier Identifier Identifier Topic	Default to XM follow implementation rules	REQ. REQ. REQ. REQ.
	Study-Specific Interest Sequence Number Group ID	Num Char	Identification of a fo examination waspe (right eye) or "Uppt" Sequence number t be any valid numbe Optional group iden XMTRT records in the Trial S	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number	Char Char Char Num	TERMS, CODELIST OR FORMAT	Identifier Identifier Identifier Identifier	Default to XM follow implementation rules	REQ REQ REQ REQ REQ
-SEQ -GRPID -REFID	Study-Specific Interest Sequence Number Group ID Reference ID	Num Char Char	Identification of a fo examination waspe (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider records in the Trial S Optional internal or XMDOSE	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen	Char Char Num Char	TERMS, CODELIST OR FORMAT	ldentifier Identifier Identifier Identifier Topic	Default to XM follow implementation rules follow implementation rules	REQ REQ REQ REQ REQ
-SEQ -GRPID -REFID	Study-Specific Interest Sequence Number Group ID Reference ID Invariant Record	Num Char Char	Identification of a fo examination was be (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider XMSEQ records in the Trial S XMTRT Optional internal or content of the recor XMDOSU	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen Meditation Session Length Meditation Session Length Unit	Char Char Char Num Char Num Char	XM (XMDECOD) (UNIT)	Identifier Identifier Identifier Identifier Topic Record Qualifier Variable Qualifier	Default to XM follow implementation rules follow implementation rules	REQ. REQ. REQ. REQ. REQ. PERM
SEQ GRPID REFID RECID	Study-Specific Interest Sequence Number Group ID Reference ID Invariant Record	Num Char Char Char	Identification of a fo examination waspe (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider records in the Trial S Optional internal or Identifier for a recor content of the recor	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen Meditation Session Length	Char Char Char Num Char Num Char	XM (XMDECOD)	Identifier Identifier Identifier Identifier Topic Record Qualifier	Default to XM follow implementation rules follow implementation rules	REQ REQ REQ REQ REQ PERM PERM
SEQ GRPID REFID	Study-Specific Interest Sequence Number Group ID Reference ID Invariant Record Identifier	Num Char Char Char	Identification of a fo examination waspe (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider XMSEQ records in the Trial S Optional internal or Identifier for a recor content of the recor versions of the dom XMDOSEQ	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen Meditation Session Length Meditation Session Length Unit	Char Char Char Num Char Num Char	XM (XMDECOD) (UNIT)	Identifier Identifier Identifier Identifier Topic Record Qualifier Variable Qualifier	Default to XM follow implementation rules follow implementation rules	REQ REQ REQ REQ REQ PERM PERM
SEQ GRPID REFID RECID SPID	Study-Specific Interest Sequence Number Group ID Reference ID Invariant Record Identifier Sponsor-Defined	Num Char Char Char	Identification of a fo examination waspe (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider records in the Trial S Optional internal or MDOSE Identifier for a recor content of the recor versions of the dom Sponsor-defined ide	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen Meditation Session Length Meditation Session Length Unit Frequency of Meditation Sessions	Char Char Char Num Char Num Char Char	XM XM XM (XMDECOD) (UNIT) (FREQ)	Identifier Identifier Identifier Identifier Topic Record Qualifier Variable Qualifier Variable Qualifier	Default to XM follow implementation rules follow implementation rules	REQ REQ REQ REQ REQ PERM PERM PERM
-SEQ -GRPID -REFID -RECID	Study-Specific Interest Sequence Number Group ID Reference ID Invariant Record Identifier Sponsor-Defined Identifier	Num Char Char Char	Identification of a fo examination waspe (right eye) or "Uppe Sequence number t be any valid numbe Optional group ider XMSEQ Optional internal or Identifier for a recor content of the recor versions of the dom XMDOSE Sponsor-defined ide	Study Identifier Domain Abbreviation Unique Subject Identifier Sequence Number Name of Meditation Regimen Meditation Session Length Meditation Session Length Unit Frequency of Meditation Sessions Duration of Meditation Practice	Char Char Char Char Num Char Char Char Char Char	XM XM XM (XMDECOD) (UNIT) (FREQ)	Identifier Identifier Identifier Identifier Topic Record Qualifier Variable Qualifier Variable Qualifier	Default to XM follow implementation rules follow implementation rules	REQ REQ REQ REQ REQ PERM PERM PERM

### SDTM Example: Meditation (Timing)

T-14-2-2-5-1	1 All Observation Classes—T		Variable	_						ו	
Variable											
Name	Variable Label		Format	Description							
VISITNUM	Visit Number	Num				version of VISIT, used for sorting.					
VISIT	Visit Name	Char			ocol-defined description of a clinical encounter. ned study day of VISIT. Should be an integer.						
VISITDY	Planned Study Day of Visit	Num				-					
TAETORD	Planned Order of Element Within Arm	Num		Number that gives	er that gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).						
EPOCH	Epoch	Char			with the start date tion 3.1.2, Trial Arm	or start date and time of the observa ns).	ation, or the date/time of	collection if star	t date/time is not		
RPHASE	Repro Phase	Char				eproductive Stage of the Reproducti y Reproductive Phase Day variable is					
RPPLDY	Planned Repro Phase Day of Observation	Num		The planned day v be used with hum		tive Phase on which the observation	n was scheduled to occur.	Expressed as an	integer. Not to		
RPPLSTDY	Planned Repro Phase Day of Obs Start	Num		The planned day v clinical trials.	within the Reproduc	tive Phase of the start of the observ	ration. Expressed as an int	teger. Not to be u	used with human		
RPPLENDY	Planned Repro Phase Day of Obs End	Num			within the Reproduc	tive Phase of the end of the observa	ation. Expressed as an inte	eger. Not to be u	sed with human		
DTC	Date/Time of Collection	Char	ISO 8601	Collection date an	d time of an observ	vation.					
STDTC	Start Date/Time of Observation	Char	ISO 8601	Start date/time of	an observation.						
ENDTC	End Date/Time of Observation	Char	ISO 8601	End date/time of t	sDTM	XM-Meditation			-	<u> </u>	
DY	Study Day of Visit/Collection/Exam	Num		Actual study day of	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS,	ROLE	IMPLEMENTATION NOTES	CORE
STDY	Study Day of Start of Observation	Num		Actual study day of				CODELIST OR FORMAT			
ENDY	Study Day of End of Observation	Num		Actual study day of	STUDYID	Study Identifier	Char		Identifier		REQ
NOMDY	Nominal Study Day for Tabulations	Num		The nominal study		Domain Abbreviation	Char	XM	Identifier	Default to XM	REQ
NOMLBL	Label for Nominal Study Day	Char		to occur on differe	USUBJID	Unique Subject Identifier	Char		Identifier	follow implementation rules	REQ
RPDY	Actual Repro Phase Day of	Num		A label for a given The actual day wit	XMSEQ	Sequence Number	Num		Identifier	follow implementation rules	REQ
	Observation			human clinical tria	XMTRT	Name of Meditation Regimen	Char		Topic		REQ
RPSTDY	Actual Repro Phase Day of Obs Start	Num		The actual day wit clinical trials.	XMDOSE	Meditation Session Length	Num	(XMDECOD)	Record Qualifier		PERM
RPENDY	Actual Repro Phase Day of	Num		The actual day wit clinical trials.	XMDOSU	Meditation Session Length Unit	Char	(UNIT)	Variable Qualifier		PERM
DUR	Duration	Char	ISO 8601	Collected duration	XMDOSFRQ	Frequency of Meditation Sessions	Char	(FREQ)	Variable Qualifier		PERM
TPT	Planned Time Point Name	Char		Text description as an elapsed time	XMDUR	Duration of Meditation Practice	Char	ISO 8601	Timing		PERM
TPTNUM	Planned Time Point Number	Num		Numeric version o							
ELTM	Planned Elapsed Time from	Char	ISO	Planned Elapsed ti	ime relative to a pla	nned fixed reference (TPTREF) suc	has Previous Dose or P	revious Meal . I	his variable is		
	Time Point Ref		8601			sures. Not a clock time or a date/tin					
TPTREF	Time Point Reference	Char		Description of the "PREVIOUS MEAL"		nt referred to byELTM,TPTNUM,	,TPT,STINT, andENII	NT. Examples: "P	REVIOUS DOSE",		
RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fix	ed reference time p	point defined byTPTREF.					
STRF	Start Relative to Reference	Char		Identifies the start	t of the observation	as being before, during, or after the	sponsor-defined reference	ce period. The sp	onsor-defined		
	Period				s a continuous perio NDTC in Demograp	od of time defined by a discrete start	ting point and a discrete e	ending point repr	esented by		
ENRF	End Relative to Reference	Char					sponsor-defined reference	e period. The spo	nsor-defined		
ALC: YE W	Period			reference period is	the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined period is a continuous period of time defined by a discrete starting point and a discrete ending point represented by and RFENDTC in Demographics.						
EVLINT	Evaluation Interval	Char	ISO			n observation such as a findingTES	STCD. Usually used with -	-DTC to describe	an interval of		
			8601	this duration that		epresented inDTC. Example: "-P2N					
EVANITY.	E. L. C. L. L. IT. I	<b>C</b> 1		E L	nor a quesuori non	-		100 0/01/			

#### Example: Meditation SDTM Custom Domain Metadata

SDTM	XM-Meditation					
VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT		IMPLEMENTATION NOTES	CORE
STUDYID	Study Identifier	Char		Identifier		REQ
DOMAIN	Domain Abbreviation	Char	XM	Identifier	Default to XM	REQ
USUBJID	Unique Subject Identifier	Char		Identifier	follow implementation rules	REQ
XMSEQ	Sequence Number	Num		Identifier	follow implementation rules	REQ
XMTRT	Name of Meditation Regimen	Char		Торіс		REQ
XMDOSE	Meditation Session Length	Num	(XMDECOD)	Record Qualifier		PERM
XMDOSU	Meditation Session Length Unit	Char	(UNIT)	Variable Qualifier		PERM
XMDOSFRQ	Frequency of Meditation Sessions	Char	(FREQ)	Variable Qualifier		PERM
XMDUR	Duration of Meditation Practice	Char	ISO 8601	Timing		PERM

#### **Example:** Vacation

- Most closely aligned with Event Observation Class
  - Something that either happens or does not happen for each subject (similar to Medical History)
  - Can be described using start and end dates

Vacations	
Did the subject have a Vacation in the past 12 months?	YVOCCUR
What was the vacation start date?	YVSTDAT
What was the vacation end date?	YVENDAT
Was the vacation ongoing as of the Screening Visit?	YVONGO

CDASH	YV - Vacation		·	SDTM	YV-Vacation					
CDASH Variable	Question Text/ Prompt	Controlled Terminology	Mapping Instructions	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES	CORE
STUDYID	STUDY		Direct	STUDYID	Study Identifier	Char		Identifier		REQ
				DOMAIN	Domain Abbreviation	Char	YV	Identifier	Default to YV	REQ
				USUBJID	Unique Subject Identifier	Char		Identifier		REQ
				YVSEQ	Sequence Number	Num		Identifier		REQ
				YVTERM	Vacation Event	Char		Торіс	Default to VACATION	REQ
				YVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Default to Y	PERM
	Did the subject have a Vacation within the past 12 months?	(NY_2)	Map the collected value to YVOCCUR; pepulate YVTERM with "VACATION", populate YVEVLINT with "-P12M"	YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate YVSTDTC	YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC	YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
				YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
	Was the vacation ongoing as of the Screening Visit?	(NY_2)	If "Y", populate YVENRTPT with "ONGOING"; if "N" populate YVENRTPT with "BEFORE"; if "U" populate							
			YVENRTPT with "UNKNOWN"		End Relative to	-	()			
				YVENRTPT	Reference Time Point End Reference Time	Char	(STENRF)	Timing	Default to	PERM
				YVENTPT	Point	Char		Timing	SCREENING VISIT	PERM

Some CDASH variables will be a 1:1 match with SDTM

CDASH	YV - Vacation			SDTM	YV-Vacation					
CDASH Variable	Question Text/ Prompt	Controlled Terminology	Mapping Instructions	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES	CORE
STUDYID	STUDY		Direct	STUDYID	Study Identifier	Char		Identifier		REQ
				DOMAIN	Domain Abbreviation	Char	YV	Identifier	Default to YV	REQ
				USUBJID	Unique Subject Identifier	Char		Identifier		REQ
				YVSEQ	Sequence Number	Num		Identifier		REQ
				YVTERM	Vacation Event	Char		Торіс	Default to VACATION	REQ
				YVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Default to Y	PERM
	Did the subject have a Vacation within the past 12 months?	(NY_2)	Map the collected value to YVOCCUR; populate YVTERM with "VACATION", populate YVEVLINT with "-P12M"	YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate VVSTDTC	YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDIC	YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
				YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
YVONGO	Was the vacation ongoing as of the Screening Visit?	(NY_2)	If "Y", populate YVENRTPT with "ONGOING"; if "N" populate YVENRTPT with "BEFORE"; if "U" populate YVENRTPT with "UNKNOWN"		End Relative to					
				YVENRTPT	Reference Time Point	Char	(STENRF)	Timing		PERM
					End Reference Time				Default to	
				YVENTPT	Point	Char		Timing	SCREENING VISIT	PERM

Some CDASH values will have a standard mapping to the relevant SDTM variables

CDASH	YV - Vacation			SDTM	YV-Vacation					
CDASH Variable	Question Text/ Prompt	Controlled Terminology	Mapping Instructions	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES	CORE
STUDYID	STUDY		Direct	STUDYID	Study Identifier	Char		Identifier		REQ
				DOMAIN	Domain Abbreviation	Char	YV	Identifier	Default to YV	REQ
				USUBJID	Unique Subject Identifier	Char		Identifier		REQ
				YVSEQ	Sequence Number	Num		Identifier		REQ
			_	YVTERM	Vacation Event	Char		Торіс	Default to VACATION	REQ
				YVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Default to Y	PERM
	Did the subject have a Vacation within the past 12 months?	(NY_2)	Map the collected value to YVOCCUR; populate YVTERM with "VACATION", populate YVEVLINT with "-P12M"	YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDAT	What was the vacation start date?		Convert to ISC 8001 and populate YVSTDTC	YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC	YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
			<b>`</b>	YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
	Was the vacation ongoing as of the Screening Visit?	(NY_2)	If "Y", populate YVENRTPT with "ONGOING"; if "N" populate YVENRTPT with "BEFORE"; if "U" populate YVENRTPT with "UNKNOWN"							
				YVENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing		PERM
				TVENKIPI	End Reference Time	Cildi	(STEINNE)	Timing	Default to	PERIVI
				YVENTPT	Point	Char		Timing	SCREENING VISIT	PERM

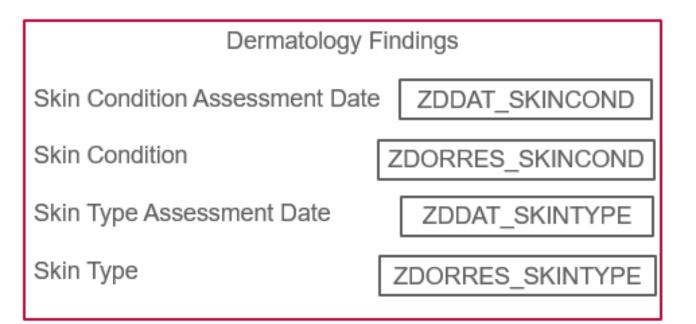
Apply programming rules for pre-specified Term ("Vacation") and Evaluation Intervals

CDASH	YV - Vacation			SDTM	YV-Vacation					
CDASH Variable	Question Text/ Prompt	Controlled Terminology	Mapping Instructions	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES	CORE
STUDYID	STUDY		Direct	STUDYID	Study Identifier	Char		Identifier		REQ
				DOMAIN	Domain Abbreviation	Char	(V	Identifier	Default to YV	REQ
				USUBJID YVSEQ	Unique Subject Identifier Sequence Number	Char Num		Identifier Identifier		REQ.
			•	TVSEQ	Sequence Number	Num		identifier	Default to	REQ
				YVTERM	Vacation Event	Char		Topic		REQ
				YVPRESP	Pre-specified	Char	NY)	Variable Qualifier		PERM
	Did the subject have a Vacation within the past 12 months?	(NY_2)	Map the collected value to YVOCCUR; populate YVTERM with "VACATION", populate YVEVLINT with "-P12M"	YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate YVSTDTC	YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC	YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
				YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
	Was the vacation ongoing as of the Screening Visit?	(NY_2)	If "Y", populate YVENRTPT with "ONGOING"; if "N" populate YVENRTPT with "BEFORE"; if "U" populate							
			YVENRTPT with "UNKNOWN"		End Relative to		(075105)	<b>_</b>		
				YVENRTPT	Reference Time Point End Reference Time	Char	(STENRF)	Timing	Default to	PERM
				YVENTPT	Point	Char		Timing	SCREENING VISIT	PERM
				TACALLY I		e. mi				I LINNI

#### Add SDTM-only submission variables

#### Example: Dermatology Assessments

- Most closely aligned with FindingsObservation Class
  - Results from Measurements, Tests or Observations
  - Test names should use controlled terminology (standard or custom)
  - Usually a Point in Time measurement, so not usually start/end dates



#### Example: Dermatology - Findings Observation Class

CDASH	ZD - Dermatology Findings			SDTM	ZD-Dermatology Findings					
CDASH Variable	Question Text/ Prompt	Controlled Terminology	Mapping Instructions	VARIABLE	VARIABLE LABEL	ТҮРЕ	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES	CORE
STUDYID	STUDY		Direct	STUDYID	Study Identifier	Char		Identifier		REQ
				DOMAIN	Domain Abbreviation	Char	ZD	Identifier	Default to ZD	REQ
-				USUBJID ZDSEQ	Unique Subject Identifier Sequence Number	Char Num		Identifier Identifier		REQ.
				ZDTESTCD	Dermatology Test Code	Char	(DERMCD)	Topic		REQ
-				ZDTEST	Dermatology Test	Char	(DERM)	Synonym	Qualifier	REQ
ZDORRES_SKINCOND	Skin Condition	(SKNCOND)	Map response to ZDORRES; Populate ZDTESTCD with "SKINCOND"; Populate ZDTEST with "Skin Condition"	ZDORRES	Dermatology Test Original Result	Char	*	Result Qu	alifier	EXP
ZDORRES_SKINTYPE	Skin Type	(SKNTYPE)	Map response to ZDORRES; Populate ZDTESTCD with "SKINTYPE"; Populate ZDTEST with "Skin Type"							
				ZDSTRESC	Dermatology Test Standardized Result - Character	Char	*	Result Qu	alifier	EXP
ZDDAT_SKINCOND	Skin Condition Assessment Date		Convert to ISO 8601 and populate ZDDTC where ZDTESTCD=SKINCOND	ZDDTC	Evaluation Interval	Char	ISO 8601	Timing		EXP
ZDDAT_SKINTYPE	Skin Type Assessment Date		Convert to ISO 8601 and populate ZDDTC where ZDTESTCD=SKINTYPE							

Data Collection is typically horizontal and de-normalized

Test names and result values are transposed into the vertical, normalized SDTM data structure as in all other Findings Class domains

## Do You Need Custom Codelists?



#### Use Controlled Terminology

- Even for Custom domain, use standard, published CDISC codelists as much as possible
  - Common codelists: NY, NRIND, LOC, POS, LAT, DIR
  - Extensible
  - Non-extensible
  - Subsets
- Only create custom codelists if CDISC does not have an appropriate one that you can use

#### **Example: Custom Codelists for Meditation**

Codelist							
Extensible	Codelist Name	Codelist Values	Synonyms				
Y	XMCAT	MEDITATION CATEGORIES					
	XMCAT	FOCUSED ATTENTION					
	XMCAT	OPEN MONITORING					
	XMCAT	EFFORTLESS PRESENCE					
	XMCAT	BUDDHIST					
	XMCAT	HINDU	Vedic, Yogic				
	XMCAT	CHINESE					
Y	XMDECOD	STANDARDIZED MEDITATION REGIMEN NAME					
	XMDECOD	ZEN MEDITATION	Seated meditation, Zazen meditation				
	XMDECOD	VIPASSANA MEDITATION	Insight, Clear Seeing Meditation, Vipassana Dhura				
	XMDECOD	MINDFULNESS MEDITATION	Anapanasati, MBSR, Palouse				
	XMDECOD	LOVING KINDNESS MEDITATION	Metta Meditation, Compassion Meditation				
	XMDECOD	MANTRA MEDITATION	OM Meditation, MANTRA YOGA				
	XMDECOD	TRANSCENDENTAL MEDITATION	TM				
	XMDECOD	YOGA MEDITATION	Third Eye, Chakra, Trataka, Kundalini, Kriya Yoga, Nada Yoga, Sound Meditation, Tantra, Pranayama				
	XMDECOD	SELF ENQUIRY MEDITATION	Atma Vichara,				
	XMDECOD	TAOIST MEDITATION	EMPTINESS MEDITATION, ZUOWANG, VISUALIZATION, INNER VISION, INTERNAL ALCHEMY, NEIGUAN, NE	EIDAN, CUN	NXIANG, Z	HUANQI, E	DAOIST
	XMDECOD	QIGONG MEDITATIOn	CHI KUNG, CHI GUNG, LIFE ENERGY CULTIVATION,				
	XMDECOD	CHRISTIAN	CONTEMPLATIVE PRAYER, CONTEMPLATIVE READING, SITTING WITH GOD,				
	XMDECOD	SUFI MEDITATION	SUFI WHIRLING, SUFI MANTRA, ZIKR, JIKR, DHIKR				
	XMDECOD	GUIDED MEDITATION	GUIDED IMAGERY, BINAUAL BEATS, RELAXATION				
				/			

#### Example: Custom Codelist/ Mapping Table for Dermatology

Dermatology Findings Test ( (DERMCD)	Code Dermatology Findings Test Name (DERM)	Skin Condition Response (SKNCOND)
SKINCOND	Skin Condition	Acanthosis Nigricans
SKINCOND	Skin Condition	Acne
SKINCOND	Skin Condition	Actinic Keratosis
SKINCOND	Skin Condition	Alopecia Areata
SKINCOND	Skin Condition	Atopic Dermatitis
SKINCOND	Skin Condition	Cellulitis
SKINCOND	Skin Condition	Cold Sores
SKINCOND	Skin Condition	Contact Dermatitis
SKINCOND	Skin Condition	Dandruff
SKINCOND	Skin Condition	Diaper Rash
SKINCOND	Skin Condition	Dermatofibrosarcoma Protuberans
SKINCOND	Skin Condition	Dry Skin
SKINCOND	Skin Condition	Dyshidrotic Eczema
SKINCOND	Skin Condition	Eczema
SKINCOND	Skin Condition	Genital Herpes
SKINCOND	Skin Condition	Genital Warts
SKINCOND	Skin Condition	Herpes Simplex
SKINCOND	Skin Condition	Hidradenitis Suppurativa
SKINCOND	Skin Condition	Hives
SKINCOND	Skin Condition	Hyperhidrosis
SKINCOND	Skin Condition	Imiquimod
SKINCOND	Skin Condition	Impetigo
SKINCOND	Skin Condition	Isotretinoin
SKINCOND	Skin Condition	Ichthyosis Vulgaris
SKINCOND	Skin Condition	Keloids
SKINCOND	Skin Condition	Keratosis Pelaris
SKINCOND	Skin Condition	Moles
DERM-Codetabl	e-Mapping-20190407 (+)	

# Custom Domain Summary

And some Best Practices



#### Summary of Custom Domains

- Confirm that a custom domain is needed
  - Check current SDTMIG, CDASHIG and TAUGs
  - A currently published domain can be "custom" if used with an older version of SDTMIG, but you should use that published domain if it fits your purpose
- Begin with the end in mind:
  - Use General Observation Classes from CDASH Model and map to SDTM
- Follow same rules that have been used for Standard Domains (in the SDTMIG)
  - SDTM CDISC Notes
  - SDTMIG Sections 2, 4 and 8
- Create a unique (*within your implementation*) domain code for each custom topic
  - Cannot conflict with a standard domain code (CT DOMAIN list)
  - X, Y and Z will never conflict reserved for custom domains
  - X = Interventions, Y=Events, Z=Findings (not required to use this way)

#### Summary of Custom Domains

- Use published terminology as much as possible (e.g. NY, NRIND, LOC, POS)
- Submit requests to NCI CDISC Harmonization Working Group (NCICDISCSUPPORT@NIH.GOV)
  - Confirmation that you need a custom domain for your topic
    - Is this truly a new topic? Or should you use an existing domain?
  - Domain Code (this is controlled terminology) you propose to use
  - Confirmation of the Observation Class you propose to use
- Maintain an implementation-wide set of custom domain specifications and custom controlled terminologies so everyone in your implementation can use the same ones for the same purpose
  - Make custom domains consistent and make them available

### Q&A NCICDISCSupport@nih.gov

