Custom Domains

LPO Support Webinar

17 April 2019

NIH NATIONAL CANCER INSTITUTE

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?

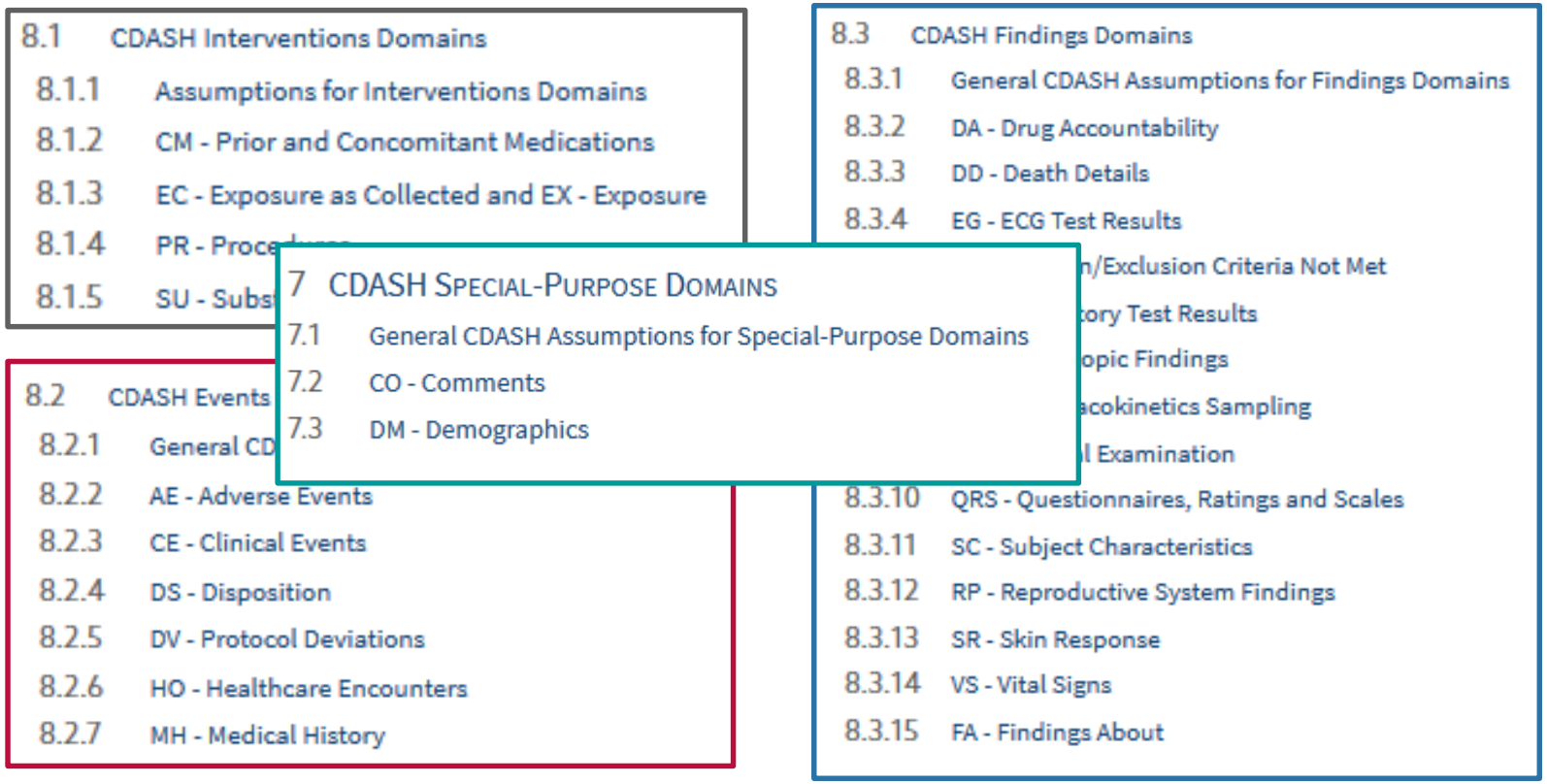
And…when do you need to create one?

Do I need Custom Domains for this Study?

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

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



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.*

Do I need Custom Domains for this Study?

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

7 CDASH Special-Purpose Domains

7.1 General CDASH Assumptions for Special-Purpose Domains

7.2 CO - Comments

7.3 DM - Demographics

Do I need Custom Domains for this Study?

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

8.1 CDASH Interventions Domains

8.1.1 Assumptions for Interventions Domains

8.1.2 CM - Prior and Concomitant Medications

8.1.3 EC - Exposure as Collected and EX - Exposure

8.1.4 PR - Procedures

8.1.5 SU - Substance Use

Do I need Custom Domains for this Study?

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

8.2 CDASH Events Domains

- 8.2.1 General CDASH Assumptions for Events Domains
- 8.2.2 AE - Adverse Events
- 8.2.3 CE - Clinical Events
- 8.2.4 DS - Disposition
- 8.2.5 DV - Protocol Deviations
- 8.2.6 HO - Healthcare Encounters
- 8.2.7 MH - Medical History

Do I need Custom Domains for this Study?

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

8.3 CDASH Findings Domains

- 8.3.1 General CDASH Assumptions for Findings Domains
- 8.3.2 DA - Drug Accountability
- 8.3.3 DD - Death Details
- 8.3.4 EG - ECG Test Results
- 8.3.5 IE - Inclusion/Exclusion Criteria Not Met
- 8.3.6 LB - Laboratory Test Results
- 8.3.7 MI - Microscopic Findings
- 8.3.8 PC - Pharmacokinetics Sampling
- 8.3.9 PE - Physical Examination
- 8.3.10 QRS - Questionnaires, Ratings and Scales
- 8.3.11 SC - Subject Characteristics
- 8.3.12 RP - Reproductive System Findings
- 8.3.13 SR - Skin Response
- 8.3.14 VS - Vital Signs
- 8.3.15 FA - Findings About

Do I need Custom Domains for this Study?

Visits>	Screening	Month 1	Month 2	Month 6	Month 12	End of Study
Informed Consent	X					
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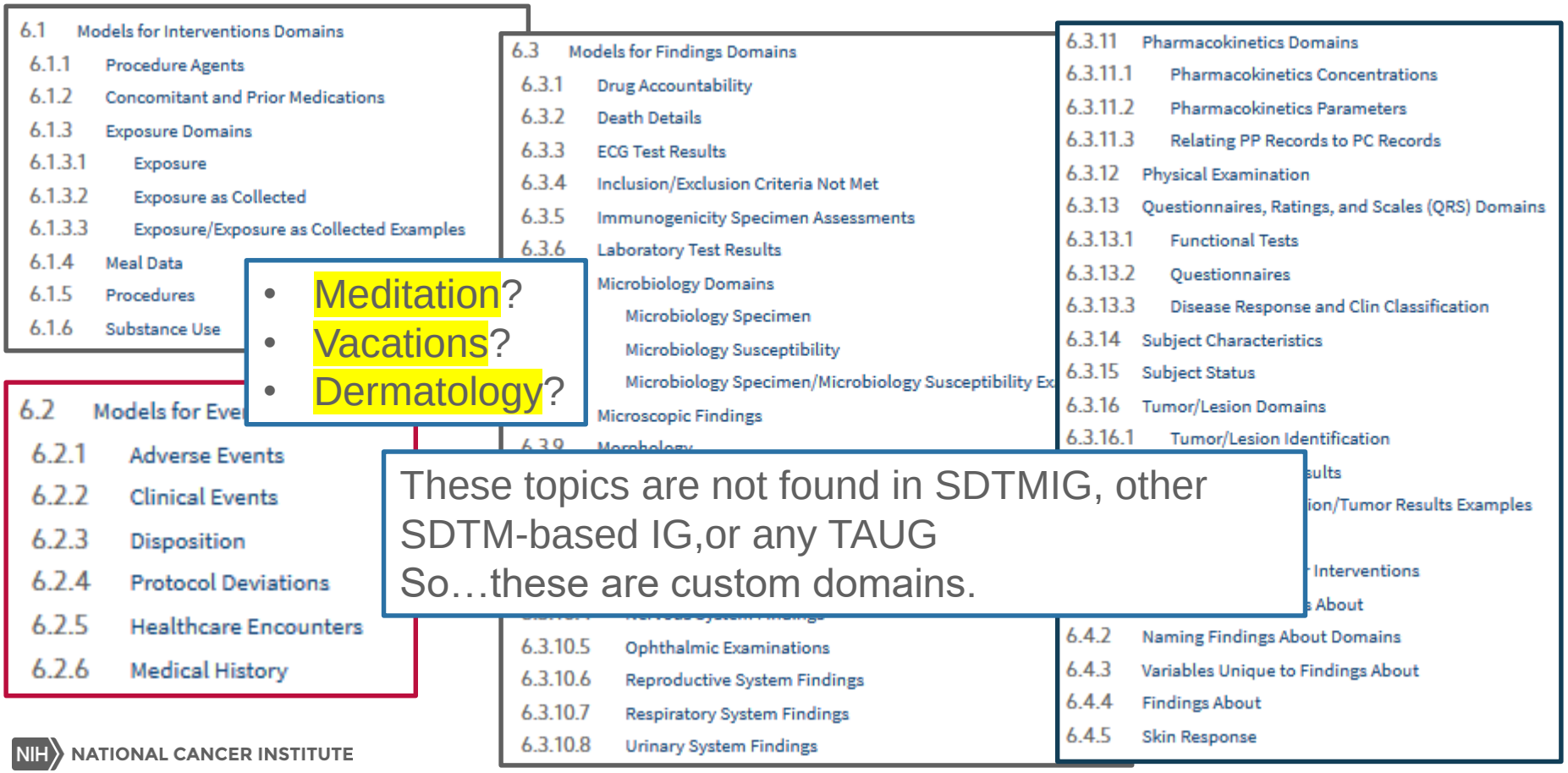
Concomitant Medications						
Adverse Events						
Randomization		X				
Dispense Study Treatment		X	X	X	X	
Administer Study Treatment		X	X	X	X	
Quality of Life Assessment		X	X	X	X	
Dermatology Findings	X	X	X	X	X	
End of Study Status						X

No existing, published, standard domain = Custom Domain needed

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



These topics will need Custom Domains

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

How to Construct Custom Domains

Begin with the end in mind?

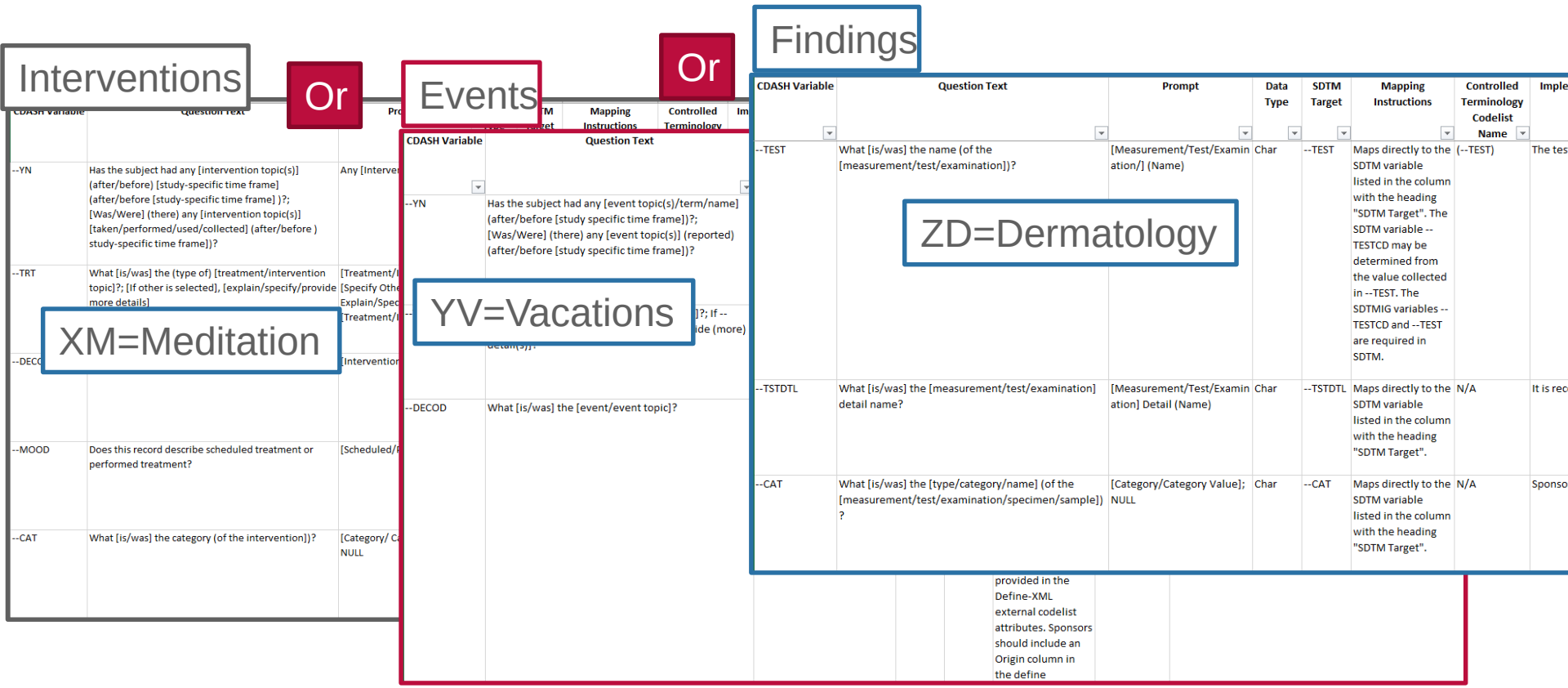
High Level Process

- 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
(**not** 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

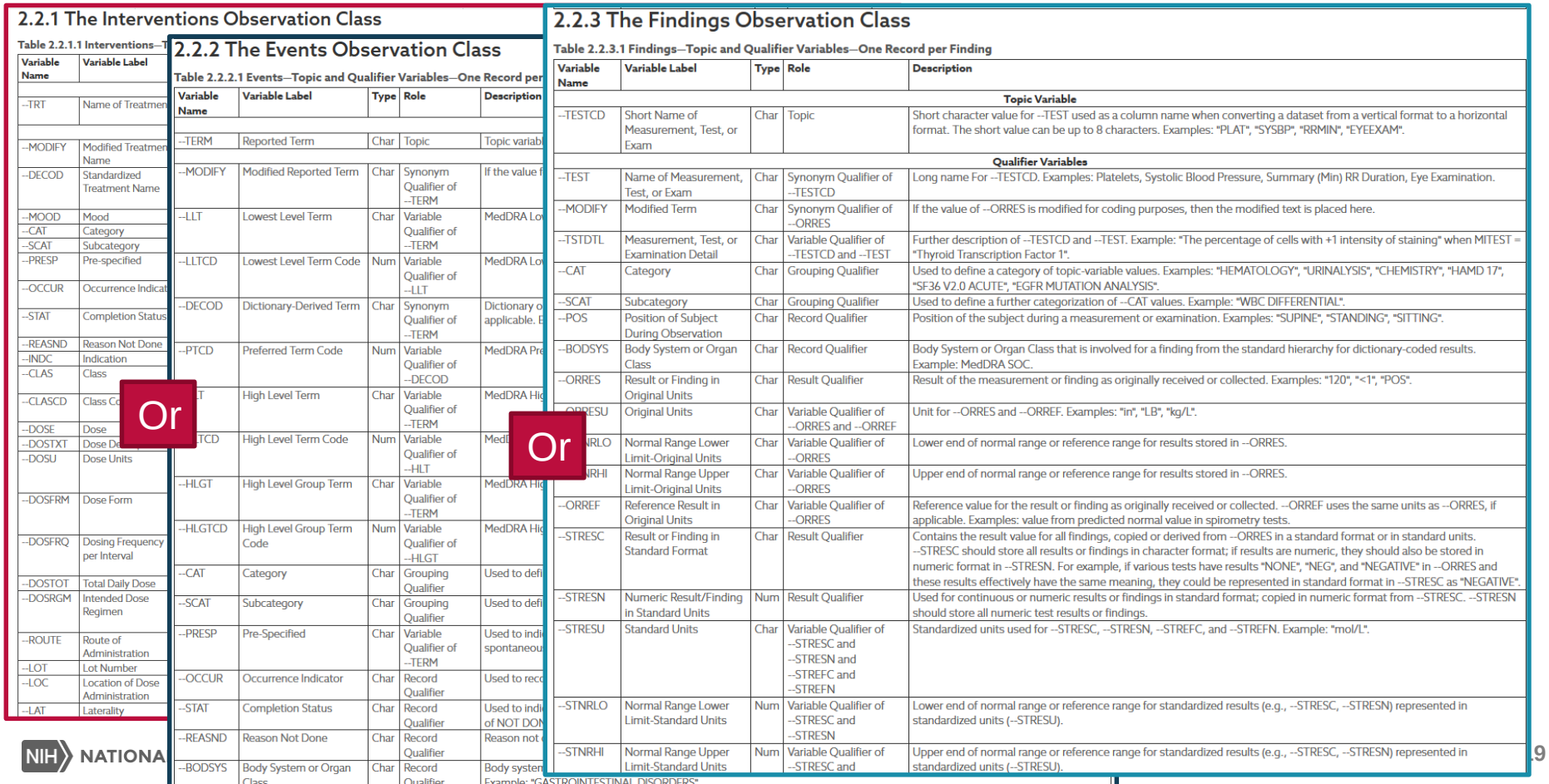
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
SITEID	Study Site Identifier	What [is/was] the site identifier?	Site Identifier	DM.SITEID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Paper: This is typically pr
INVID	Investigator Identifier	What [is/was] the investigator identifier?	Investigator Identifier	DM.INVID	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.SUBJID	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 b
--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 Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
EPOCH	Epoch	What [is/was] the trial [period/phase/sponsor-defined phrase] (for this [event/intervention/finding])?	Trial Period	EPOCH	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	(EPOCH)	If the same information is c
--DAT	Date of Collection	What [is/ was] the date the [event or intervention] [is/was] collected?; What [is/ was] the (start) date (of the [Finding])?	[Event/Intervention] Collection Date; [Finding] (Start) Date	--DTC	This field does not map directly to an SDTM variable. For the SDTM dataset, concatenate all collected CDASH DATE and TIME components and populate the SDTM variable --DTC in	N/A	This is a generic DATE field

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



2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—T

Variable Name	Variable Label
--TRT	Name of Treatmen
--MODIFY	Modified Treatmen Name
--DECOD	Standardized Treatment Name
--MOOD	Mood
--CAT	Category
--SCAT	Subcategory
--PRESP	Pre-specified
--OCCUR	Occurrence Indicat
--STAT	Completion Status
--REASND	Reason Not Done
--INDC	Indication
--CLAS	Class
--CLASCD	Class Co
--DOSE	Dose
--DOSTXT	Dose De
--DOSU	Dose Units
--DOSFRM	Dose Form
--DOSFRQ	Dosing Frequency per Interval
--DOSTOT	Total Daily Dose
--DOSRGM	Intended Dose Regimen
--ROUTE	Route of Administration
--LOT	Lot Number
--LOC	Location of Dose Administration
--LAT	Laterality

Or

2.2.2 The Events Observation Class

Table 2.2.2.1 Events—Topic and Qualifier Variables—One Record per

Variable Name	Variable Label	Type	Role	Description
--TERM	Reported Term	Char	Topic	Topic variabl
--MODIFY	Modified Reported Term	Char	Synonym Qualifier of --TERM	If the value f
--LLT	Lowest Level Term	Char	Variable Qualifier of --TERM	MedDRA Lo
--LLTCD	Lowest Level Term Code	Num	Variable Qualifier of --LLT	MedDRA Lo
--DECOD	Dictionary-Derived Term	Char	Synonym Qualifier of --TERM	Dictionary o applicable. E
--PTCD	Preferred Term Code	Num	Variable Qualifier of --DECOD	MedDRA Pr
T	High Level Term	Char	Variable Qualifier of --TERM	MedDRA Hig
TCD	High Level Term Code	Num	Variable Qualifier of --HLT	Med
--HLGT	High Level Group Term	Char	Variable Qualifier of --TERM	MedDRA Hig
--HLGTCD	High Level Group Term Code	Num	Variable Qualifier of --HLGT	MedDRA Hig
--CAT	Category	Char	Grouping Qualifier	Used to defi
--SCAT	Subcategory	Char	Grouping Qualifier	Used to defi
--PRESP	Pre-Specified	Char	Variable Qualifier of --TERM	Used to indi spontaneou
--OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to rec
--STAT	Completion Status	Char	Record Qualifier	Used to indi of NOT DON
--REASND	Reason Not Done	Char	Record Qualifier	Reason not
--BODSYS	Body System or Organ Class	Char	Record Qualifier	Body syste Example: "GASTROINTESTINAL DISORDERS".

Or

2.2.3 The Findings Observation Class

Table 2.2.3.1 Findings—Topic and Qualifier Variables—One Record per Finding

Variable Name	Variable Label	Type	Role	Description
			Topic Variable	
--TESTCD	Short Name of Measurement, Test, or Exam	Char	Topic	Short character value for --TEST 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", "SYSBP", "RRMIN", "EYEEXAM".
			Qualifier Variables	
--TEST	Name of Measurement, Test, or Exam	Char	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelets, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
--MODIFY	Modified Term	Char	Synonym Qualifier of --ORRES	If the value of --ORRES is modified for coding purposes, then the modified text is placed here.
--TSTDTL	Measurement, Test, or Examination Detail	Char	Variable Qualifier of --TESTCD and --TEST	Further description of --TESTCD and --TEST. 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", "SF36 V2.0 ACUTE", "EGFR MUTATION ANALYSIS".
--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT 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 and --ORREF	Unit for --ORRES and --ORREF. Examples: "in", "LB", "kg/L".
NRLO	Normal Range Lower Limit-Original Units	Char	Variable Qualifier of --ORRES	Lower end of normal range or reference range for results stored in --ORRES.
NRHI	Normal Range Upper Limit-Original Units	Char	Variable Qualifier of --ORRES	Upper end of normal range or reference range for results stored in --ORRES.
--ORREF	Reference Result in Original Units	Char	Variable Qualifier of --ORRES	Reference value for the result or finding as originally received or collected. --ORREF uses the same units as --ORRES, 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 --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
--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 from --STRESC. --STRESN should store all numeric test results or findings.
--STRESU	Standard Units	Char	Variable Qualifier of --STRESC and --STRESN and --STREFC and --STREFN	Standardized units used for --STRESC, --STRESN, --STREFC, and --STREFN. Example: "mol/L".
--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).
--STNRHI	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).

Identifiers - SDTM Table 2.2.4

Plus

Table 2.2.4.1 All Observation Classes—Identifiers

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a
DOMAIN	Domain Abbreviation	Char	2-character abbre omain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness wh
USUBJID	Unique Subject Identifier	Char	Identifier u e product.
APID	Associated Persons Identifier	Char	Ident PID identifies a pool, POOLDEF records m odel Fundamentals to Associated Persons).
POOLID	Pool Identifier	Char	
SPDEVID	Sponsor Device Identifier	Char	Sp
NHOID	Non-Host Organism Identifier	Char	Sponsor- e based on the identity of the non-host organism as
FETUSID	Fetus Identifier	Char	Identifier used s a fetus within a subject. Not to be used with human clinica
FOCID	Focus of Study-Specific Interest	Char	Identification of a foc pecific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was perfor as a drug application site (e.g., "Injection site 1", "Biopsy site 1", "Treated site 1"), or a more specific focus (e.g., "OD" (right eye) or "Upper left qu of the back"). The value in this variable should have inherent semantic meaning.
--SEQ	Sequence Number	Num	Sequence number to ensure u ueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
--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 Information (Section 3.3).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--RECID	Invariant Record Identifier	Char	Identifier for a record that is unique within a domain for a study and that remains invariant through subsequent versions of the dataset, even if the content of the record is modified. When a record is deleted, this value must not be reused to identify another record in either the current or future versions of the domain.
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.
--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For example, a single tumor may have multiple measurements/assessments performed at each study visit.
--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

Some identifiers are required to be in any domain: STUDYID, DOMAIN, USUBJID and --SEQ

Timing Variables - SDTM Table 2.2.5

Plus

Table 2.2.5.1 All Observation Classes—Timing Variables

Variable Name	Variable Label	Type	Format	Description
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		Gives the planned order of the Element within the Arm (see Section 3.1.2, Trial Arms).
EPOCH	Epoch	Char		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
RPHASE	Repro Phase	Ch		. The
RPPLDY	Planned Repro Phase Day of Observation			lot to
RPPLSTDY	Planned Repro Phase D Obs Start			human
RPPLENDY	Planned Repro P Obs End			human
--DTC	Date/Time of Colle			
--STDTC	Start Date/Time of Observation			
--ENDTC	End Date/Time of Observation			
--DY	Study Day of Visit/Collection/Exam	Num		
--STDY	Study Day of Start of Observation	Num		ay of start of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
--ENDY	Study Day of End of Observation	Num		Ac ay of end of observation expressed in integer days relative to the sponsor-defined RFSTDTC in Demographics.
--NOMDY	Nominal Study Day for Tabulations	Num		The nom udy day used by data-collection and reporting systems for grouping records for observations that may be scheduled to occur on ferent 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 of --NOMDY, 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.
--RPENDY	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. See --TPTNUM and --TPTREF.
--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 by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
--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-defined 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 Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined 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 question from a questionnaire.
--EVINTX	Evaluation Interval Text	Char		Evaluation interval associated with an observation, where the interval is not able to be represented in ISO 8601 format. Examples:

Should have at least one appropriate timing variable in every domain, to describe when the intervention or event started / ended / happened, or when the test or measurement was done

Recommendations for Custom Domains

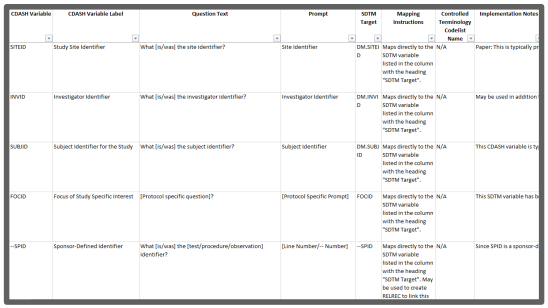
- **Begin with the end in mind**
  - ➢ Conformant SDTM data is the target objective
- Use **CDASH** Model to Create Custom Domains
- Why? Because the CDASH Model is aligned to SDTM (Model)
  - Same General Observation Classes (Interventions/Events/Findings)
  - CDASH root variables are mapped to SDTM root variables

Create your custom domains using the **CDASH** Model to **collect** the data

1. You will be able to standardize the programming to convert collected data to SDTM
2. 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 Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
SITEID	Study Site Identifier	What [is/was] the site identifier?	Site Identifier	DM.SITEID	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.INVID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	May be used in addition t
SUBJID	Subject Identifier for the Study	What [is/was] the subject identifier?	Subject Identifier	DM.SUBJID	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 ha
--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

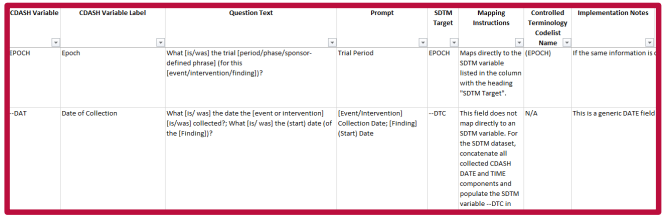
CDASH Model Identifiers

+

Interventions
or Events
or Findings

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

+



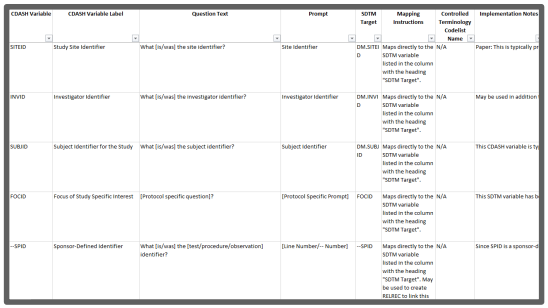
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
EPOCH	Epoch	What [is/was] the trial [period/phase/sponsor-defined phrase] (for this [event/intervention/finding])?	Trial Period	EPOCH	Maps directly to the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

CDASH Model Timing

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

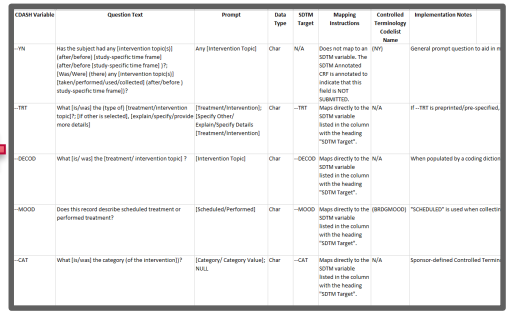
Custom **Interventions** Data Collection Domain

If your custom topic is “Meditation” use root metadata from:



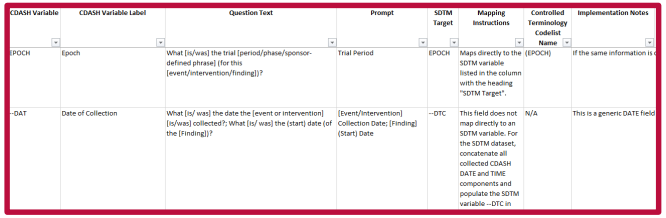
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
SITEID	Study Site Identifier	What [is/was] the site identifier?	Site Identifier	DM.SITEID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Paper: This is typically pr
INVID	Investigator Identifier	What [is/was] the investigator identifier?	Investigator Identifier	DM.INVID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	May be used in addition t
SUBJID	Subject Identifier for the Study	What [is/was] the subject identifier?	Subject Identifier	DM.SUBJID	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 h
--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

CDASH Model Identifiers



CDASH Variable	Question Text	Prompt	Data Type	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
--YN	Has the subject had any [intervention topic(s)] (after/before) [study-specific time frame] (after/before [study-specific time frame])?; (Was/Were) (there) any [intervention topic(s)] (taken/performed/used/collected) (after/before) study-specific time frame)?	Any [Intervention Topic]	Char	N/A	Does not map to an SDTM variable. The SDTM Annotated CRF is annotated to indicate that this field is NOT SUBMITTED.	(NY)	General prompt question to aid in m
--TRT	What [is/was] the [type of] [treatment/intervention topic]?; [If other is selected], [explain/specify/provide more details]	[Treatment/Intervention]; [Specify Other/ Explain/Specify Details [Treatment/Intervention]	Char	--TRT	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	If --TRT is preprinted/pre-specified,
--DECOD	What [is/ was] the [treatment/ intervention topic] ?	[Intervention Topic]	Char	--DECOD	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	When populated by a coding diction
--MOOD	Does this record describe scheduled treatment or performed treatment?	[Scheduled/Performed]	Char	--MOOD	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	(BRIDGMOOD)	"SCHEDULED" is used when collectio
--CAT	What [is/was] the category [of the intervention]]?	[Category/ Category Value]; NULL	Char	--CAT	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Sponsor-defined Controlled Termin

CDASH Model Interventions Class



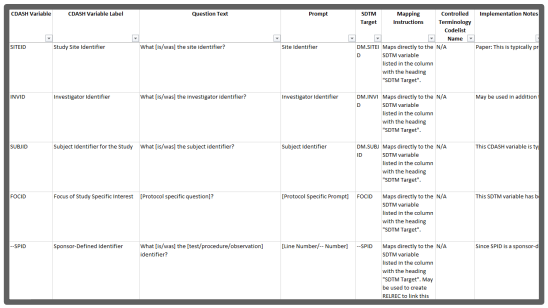
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
EPOCH	Epoch	What [is/was] the trial [period/phase/sponsor-defined phrase] (for this [event/intervention/finding])?	Trial Period	EPOCH	Maps directly to the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

CDASH Model Timing

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

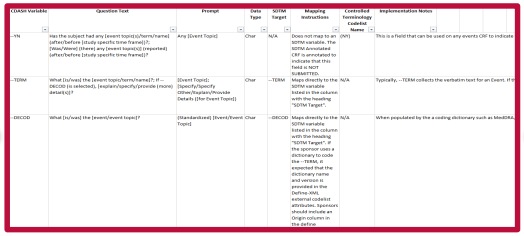
Custom **Events** Data Collection Domain

If your custom topic is “Vacations” use root metadata from:



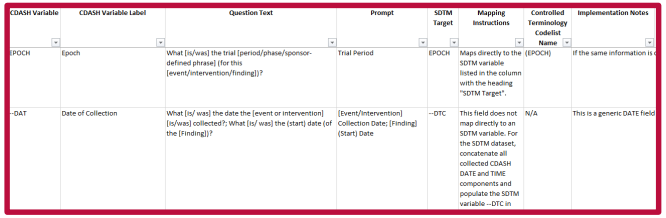
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
SITEID	Study Site Identifier	What [is/was] the site identifier?	Site Identifier	DM.SITEID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Paper: This is typically pr
INVID	Investigator Identifier	What [is/was] the investigator identifier?	Investigator Identifier	DM.INVID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	May be used in addition t
SUBJID	Subject Identifier for the Study	What [is/was] the subject identifier?	Subject Identifier	DM.SUBJID	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 h
--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

CDASH Model Identifiers



CDASH Variable	Question Text	Prompt	Data Type	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
--YN	Has the subject had any [event topic(s)/harm/name] (after/before [study-specific time frame])?; [Was/Were] (there) any [event topic(s)] (reported) (after/before [study-specific time frame])?	Any [Event Topic]	Char	N/A	Does not map to an SDTM variable. The CRF is annotated to indicate that this field is NOT SUBMITTED.	(NY)	This is a field that can be used on any events CRF to indicate
--TERM	What [is/was] the [event topic/harm/name]?; If --DECOD is selected), [explain/specify/provide (more detail)(s)]?	[Event Topic]; [Specify/Specify Other/Explain/Provide Details (Do-Event Topic)]	Char	--TERM	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Typically, --TERM collects the verbatim text for an Event. If th
--DECOD	What [is/was] the [event/event topic]?	[Standardized] [Event/Event Topic]	Char	--DECOD	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target". If the sponsor uses a dictionary to code the --TERM, at minimum, the dictionary name and version is provided in the Define-XML external codelist attributes. Sponsors should include an Origin column in the define	N/A	When populated by the a coding dictionary such as MedDRA,

CDASH Model Events Class



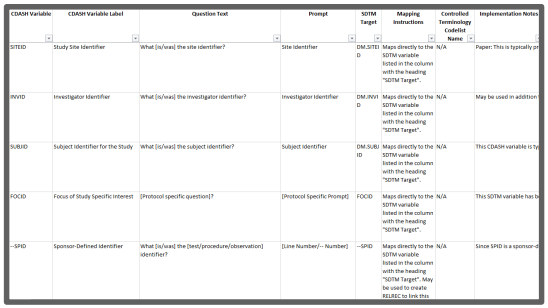
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
EPOCH	Epoch	What [is/was] the trial [period/phase/sponsor-defined phrase] (for this [event/intervention/finding])?	Trial Period	EPOCH	Maps directly to the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

CDASH Model Timing

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

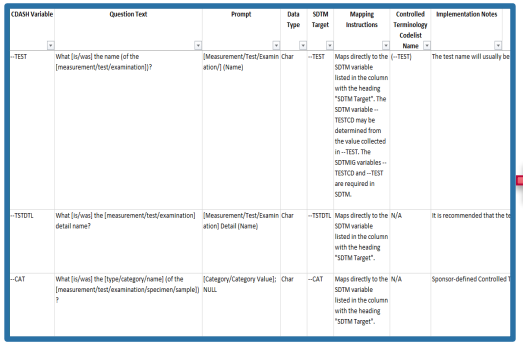
Custom **Findings** Data Collection Domain

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



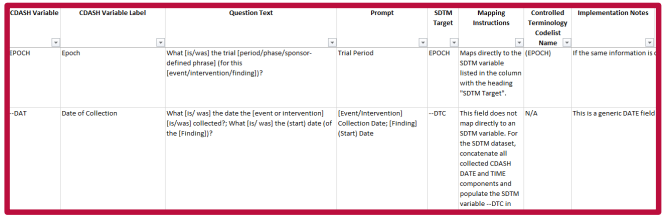
CDASH Variable	CDASH Variable Label	Question Text	Prompt	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
SITEID	Study Site Identifier	What [is/was] the site identifier?	Site Identifier	DM.SITEID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Paper: This is typically pr
INVID	Investigator Identifier	What [is/was] the investigator identifier?	Investigator Identifier	DM.INVID	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	May be used in addition t
SUBJID	Subject Identifier for the Study	What [is/was] the subject identifier?	Subject Identifier	DM.SUBJID	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 ha
--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

CDASH Model Identifiers



CDASH Variable	Question Text	Prompt	Data Type	SDTM Target	Mapping Instructions	Controlled Terminology Codelist Name	Implementation Notes
--TEST	What [is/was] the name [of the [measurement/test/examination]]?	[Measurement/Test/Examination] (Name)	Char	--TEST	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target". The SDTM variable --TESTCD may be determined from the value collected in --TEST. The SDTMIG variables --TESTCD and --TEST are required in SDTM.	(--TEST)	The test name will usually be
--TSTDTL	What [is/was] the [measurement/test/examination] detail name?	[Measurement/Test/Examination] Detail (Name)	Char	--TSTDTL	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	It is recommended that the te
--CAT	What [is/was] the [type/category/name] [of the [measurement/test/examination/specimen/sample]] ?	[Category/Category Value]; NULL	Char	--CAT	Maps directly to the SDTM variable listed in the column with the heading "SDTM Target".	N/A	Sponsor-defined Controlled T

CDASH Model Findings Class



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

CDASH Model Timing

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

Constructing a Custom Tabulation (Submission Data) Domain

Use root variables from:

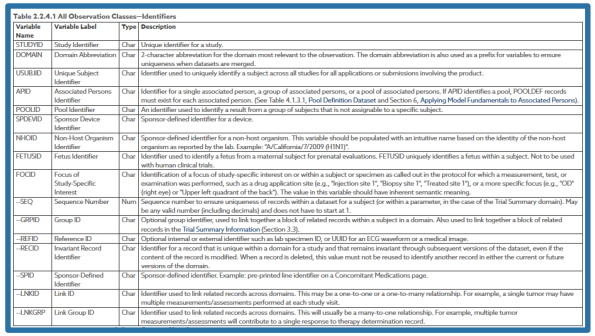


Table 2.2.4.1 All Observation Classes—Identifiers

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist 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 identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device.
NHOID	Non-Host Organism Identifier	Char	Sponsor-defined identifier for a non-host organism. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by the lab. Example: "A/California/7/2009 (H1N1)".
FETUSID	Fetus Identifier	Char	Identifier used to identify a fetus from a maternal subject for prenatal evaluations. FETUSID uniquely identifies a fetus within a subject. Not to be used with human clinical trials.
FOCID	Focus of Study-Specific Interest	Char	Identification of a focus of study-specific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was performed, such as a drug application site (e.g., "Injection site 1", "Biopsy site 1", "Treated site 1"), or a more specific focus (e.g., "OD" (right eye) or "Upper left quadrant of the back"). The value in this variable should have inherent semantic meaning.
--SEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
--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 Information (Section 3.3).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--RECID	Invariant Record Identifier	Char	Identifier for a record that is unique within a domain for a study and that remains invariant through subsequent versions of the dataset, even if the content of the record is modified. When a record is deleted, this value must not be reused to identify another record in either the current or future versions of the domain.
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.
--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For example, a single tumor may have multiple measurements/assessments performed at each study visit.
--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

SDTM Table 2.2.4 Identifiers

+

Interventions 2.2.1
or Events 2.2.2
or Findings 2.2.3

ONE of the three General Observation Class tables in SDTM

+

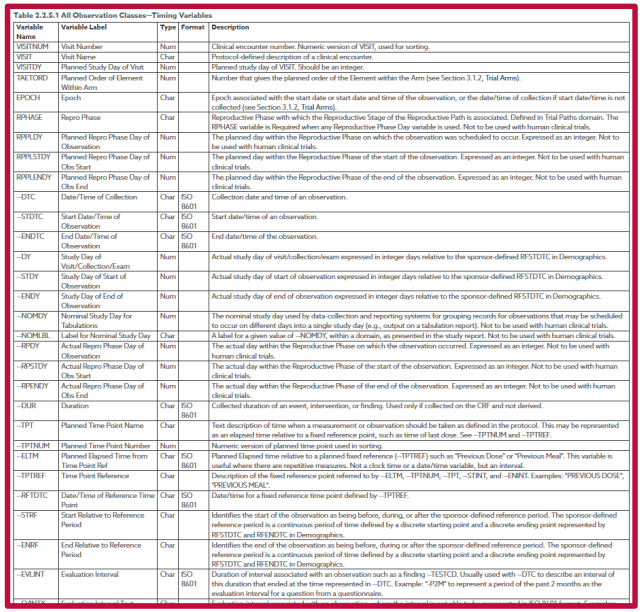


Table 2.2.5.1 All Observation Classes—Timing Variables

Variable Name	Variable Label	Type	Format	Description
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 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 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.
--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 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		A label for a given value of --NOMDY, 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.
--RPENDY	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. See --TPTNUM and --TPTREF.
--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 by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
--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-defined 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 Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined 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 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:

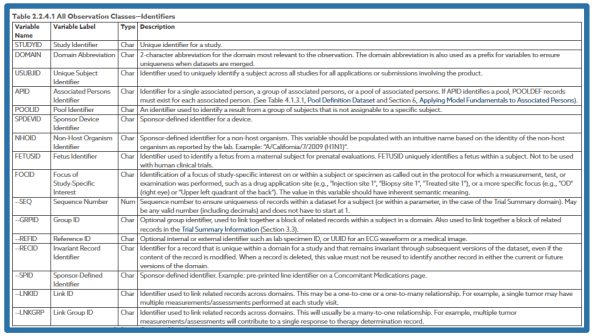


Table 2.2.4.1 All Observation Classes—Identifiers

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist 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 identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device.
NHOID	Non-Host Organism Identifier	Char	Sponsor-defined identifier for a non-host organism. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by the lab. Example: "A/California/7/2009 (H1N1)".
FETUSID	Fetus Identifier	Char	Identifier used to identify a fetus from a maternal subject for prenatal evaluations. FETUSID uniquely identifies a fetus within a subject. Not to be used with human clinical trials.
FOCID	Focus of Study-Specific Interest	Char	Identification of a focus of study-specific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was performed, such as a drug application site (e.g., "Injection site 1", "Biopsy site 1", "Treated site 1"), or a more specific focus (e.g., "OD" (right eye) or "Upper left quadrant of the back"). The value in this variable should have inherent semantic meaning.
--SEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
--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 Information (Section 3.3).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--RECID	Invariant Record Identifier	Char	Identifier for a record that is unique within a domain for a study and that remains invariant through subsequent versions of the dataset, even if the content of the record is modified. When a record is deleted, this value must not be reused to identify another record in either the current or future versions of the domain.
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.
--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For example, a single tumor may have multiple measurements/assessments performed at each study visit.
--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

SDTM Table 2.2.4
Identifiers

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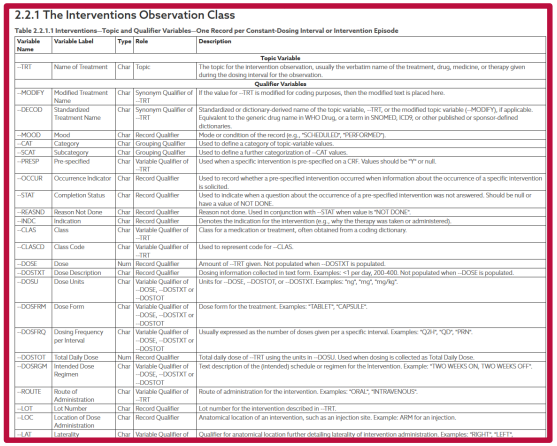

2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—Topic and Qualifier Variables—One Record per Constant-Dosing Interval or Intervention Episode

Variable Name	Variable Label	Type	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.
			Qualifier Variables	
--MODIFY	Modified Treatment Name	Char	Synonym Qualifier of --TRT	If the value for --TRT 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	Record Qualifier	Mode or condition of the record (e.g., "SCHEDULED", "PERFORMED").
--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 of --CAT 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 with --STAT 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 for --CLAS.
--DOSE	Dose	Num	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
--DOSTXT	Dose Description	Char	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
--DOSU	Dose Units	Char	Variable Qualifier of --DOSE, --DOSTOT or --DOSTXT	Units for --DOSE, --DOSTOT, or --DOSTXT. Examples: "ng", "mg", "mg/kg".
--DOSFRM	Dose Form	Char	Variable Qualifier of --DOSE, --DOSTOT or --DOSTXT	Dose form for the treatment. Examples: "TABLET", "CAPSULE".
--DOSFRQ	Dosing Frequency per Interval	Char	Variable Qualifier of --DOSE, --DOSTOT or --DOSTXT	Usually expressed as the number of doses given per a specific interval. Examples: "Q2H", "QD", "PRN".
--DOSTOT	Total Daily Dose	Num	Record Qualifier	Total daily dose of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
--DOSRGM	Intended Dose Regimen	Char	Variable Qualifier of --DOSE, --DOSTOT 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	Lot Number	Char	Record Qualifier	Lot number for the intervention described in --TRT.
--LOC	Location of Dose Administration	Char	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: ARM for an injection.
--LAT	Laterality	Char	Variable Qualifier of	Qualifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT".

SDTM Table **2.2.1**
Interventions Observation Class

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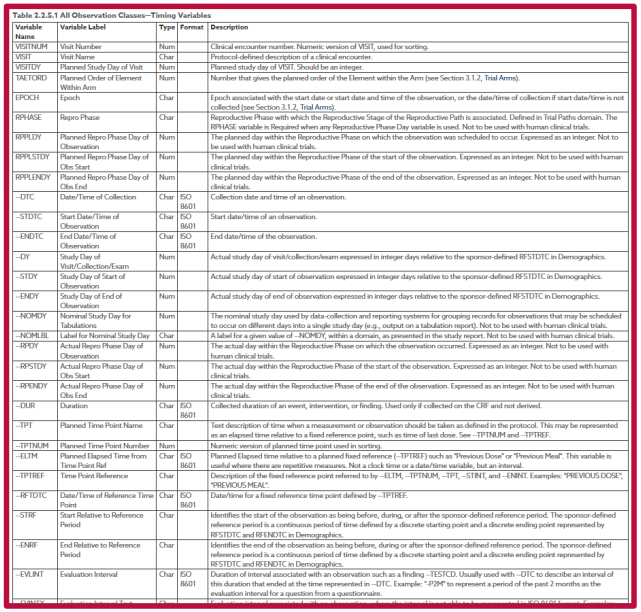


Table 2.2.5.1 All Observation Classes—Timing Variables

Variable Name	Variable Label	Type	Format	Description
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 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 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.
--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 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		A label for a given value of --NOMDY, 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.
--RPENDY	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. See --TPTNUM and --TPTREF.
--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 by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
--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-defined 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 Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined 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 question from a questionnaire.

SDTM Table 2.2.5
Timing

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

Custom **Events** Class Domain

If your custom topic is “Vacations” use root variables from:

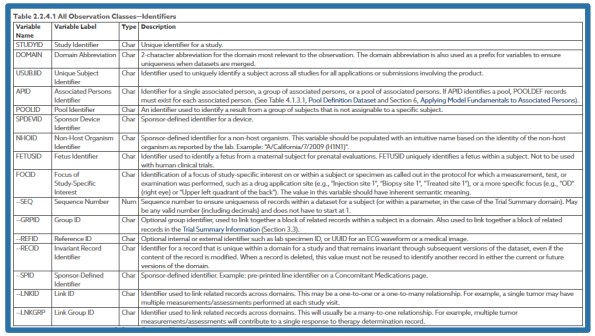
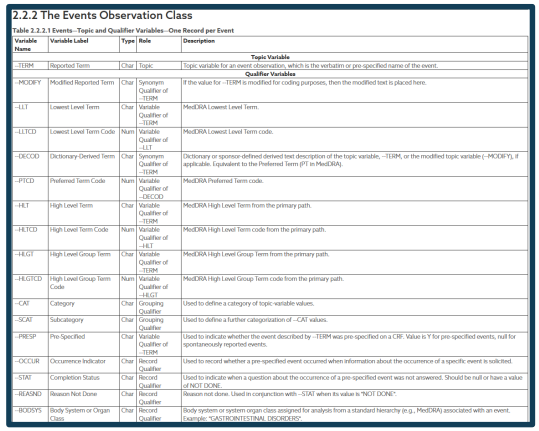


Table 2.2.4.1 All Observation Classes—Identifiers

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist 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 identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device.
NHOID	Non-Host Organism Identifier	Char	Sponsor-defined identifier for a non-host organism. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by the lab. Example: "A/California/7/2009 (H1N1)".
FETUSID	Fetus Identifier	Char	Identifier used to identify a fetus from a maternal subject for prenatal evaluations. FETUSID uniquely identifies a fetus within a subject. Not to be used with human clinical trials.
FOCID	Focus of Study-Specific Interest	Char	Identification of a focus of study-specific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was performed, such as a drug application site (e.g., "Injection site 1", "Biopsy site 1", "Treated site 1"), or a more specific focus (e.g., "OD" (right eye) or "Upper left quadrant of the back"). The value in this variable should have inherent semantic meaning.
--SEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
--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 Information (Section 3.3).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--RECID	Invariant Record Identifier	Char	Identifier for a record that is unique within a domain for a study and that remains invariant through subsequent versions of the dataset, even if the content of the record is modified. When a record is deleted, this value must not be reused to identify another record in either the current or future versions of the domain.
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.
--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For example, a single tumor may have multiple measurements/assessments performed at each study visit.
--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

SDTM Table 2.2.4
Identifiers



2.2.2 The Events Observation Class

Table 2.2.2.1 Events—Topic and Qualifier Variables—One Record per Event

Variable Name	Variable Label	Type	Role	Description
				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 for --TERM is modified for coding purposes, then the modified text is placed here.
--LLT	Lowest Level Term	Char	Variable Qualifier of --TERM	MedDRA Lowest Level Term.
--LLTCD	Lowest Level Term Code	Num	Variable Qualifier of --LLT	MedDRA Lowest Level Term code.
--DECOD	Dictionary-Derived Term	Char	Synonym Qualifier of --TERM	Dictionary or sponsor-defined derived text description of the topic variable, --TERM, or the modified topic variable (--MODIFY), 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 of --CAT values.
--PRESP	Pre-Specified	Char	Variable Qualifier of --TERM	Used to indicate whether the event described by --TERM 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	Record Qualifier	Reason not done. Used in conjunction with --STAT 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

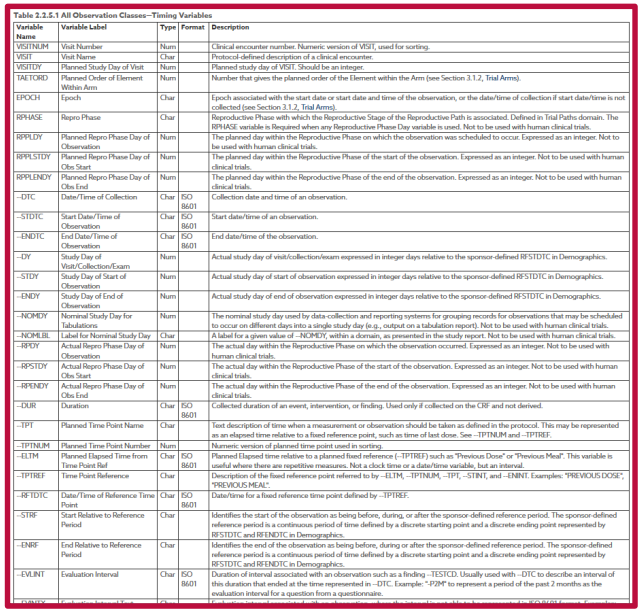


Table 2.2.5.1 All Observation Classes—Timing Variables

Variable Name	Variable Label	Type	Format	Description
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 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 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.
--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 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		A label for a given value of --NOMDY, 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.
--RPENDY	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. See --TPTNUM and --TPTREF.
--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 by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
--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-defined 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 Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined 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 question from a questionnaire.
--EVINT				

SDTM Table 2.2.5
Timing

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

Custom **Findings** Class Domain

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

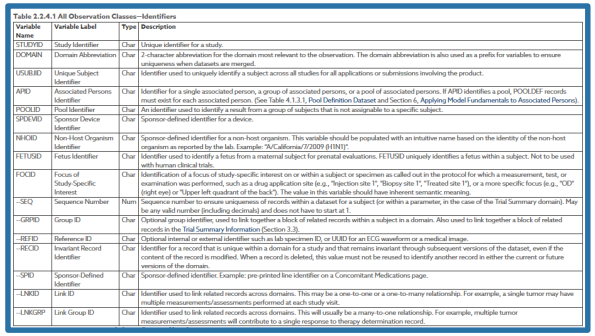
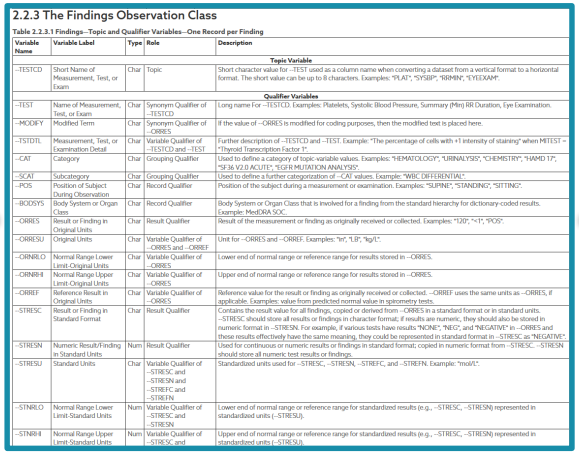


Table 2.2.4.1 All Observation Classes—Identifiers

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist 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 identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device.
NHOID	Non-Host Organism Identifier	Char	Sponsor-defined identifier for a non-host organism. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by the lab. Example: "A/California/7/2009 (H1N1)".
FETUSID	Fetus Identifier	Char	Identifier used to identify a fetus from a maternal subject for prenatal evaluations. FETUSID uniquely identifies a fetus within a subject. Not to be used with human clinical trials.
FOCID	Focus of Study-Specific Interest	Char	Identification of a focus of study-specific interest on or within a subject or specimen as called out in the protocol for which a measurement, test, or examination was performed, such as a drug application site (e.g., "Injection site 1", "Biopsy site 1", "Treated site 1"), or a more specific focus (e.g., "OD" (right eye) or "Upper left quadrant of the back"). The value in this variable should have inherent semantic meaning.
--SEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
--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 Information (Section 3.3).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--RECID	Invariant Record Identifier	Char	Identifier for a record that is unique within a domain for a study and that remains invariant through subsequent versions of the dataset, even if the content of the record is modified. When a record is deleted, this value must not be reused to identify another record in either the current or future versions of the domain.
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.
--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For example, a single tumor may have multiple measurements/assessments performed at each study visit.
--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

SDTM Table 2.2.4
Identifiers



2.2.3 The Findings Observation Class

Table 2.2.3.1 Findings—Topic and Qualifier Variables—One Record per Finding

Variable Name	Variable Label	Type	Role	Description
			Topic Variable	
--TESTCD	Short Name of Measurement, Test, or Exam	Char	Topic	Short character value for --TEST 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: "FLAT", "SYSBP", "RRMIN", "LYEXAM".
			Qualifier Variables	
--TEST	Name of Measurement, Test, or Exam	Char	Synonym Qualifier of --TESTCD	Long name for --TESTCD. Examples: Platelets, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
--MODIFY	Modified Term	Char	Synonym Qualifier of --ORRES	If the value of --ORRES is modified for coding purposes, then the modified text is placed here.
--TSTDTL	Measurement, Test, or Examination Detail	Char	Variable Qualifier of --TESTCD and --TEST	Further description of --TESTCD and --TEST. 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", "SF36 V2.0 ACUTE", "EGFR MUTATION ANALYSIS".
--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT 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 and --ORREF	Unit for --ORRES and --ORREF. 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 in --ORRES.
--ORNRHI	Normal Range Upper Limit-Original Units	Char	Variable Qualifier of --ORRES	Upper end of normal range or reference range for results stored in --ORRES.
--ORREF	Reference Result in Original Units	Char	Variable Qualifier of --ORRES	Reference value for the result or finding as originally received or collected. --ORREF uses the same units as --ORRES, 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 --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and those results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
--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 from --STRESC. --STRESN should store all numeric test results or findings.
--STRESU	Standard Units	Char	Variable Qualifier of --STRESC and --STRESN and --STREFC and --STREFN	Standardized units used for --STRESC, --STRESN, --STREFC, and --STREFN. Example: "mol/L".
--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).
--STNRHI	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

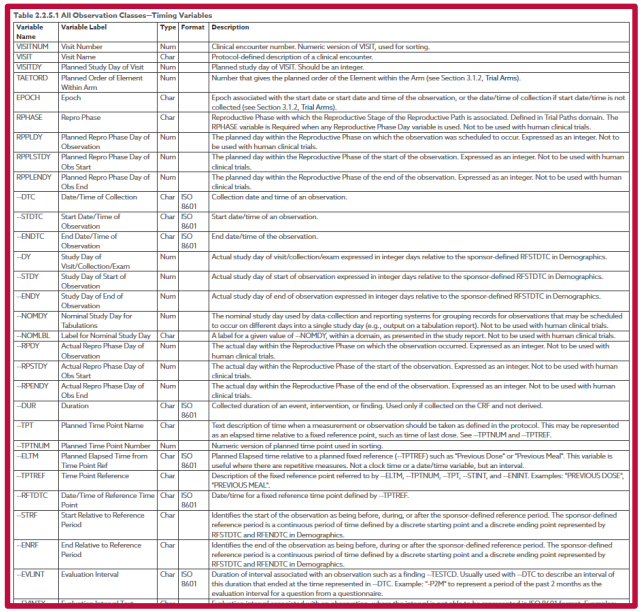


Table 2.2.5.1 All Observation Classes—Timing Variables

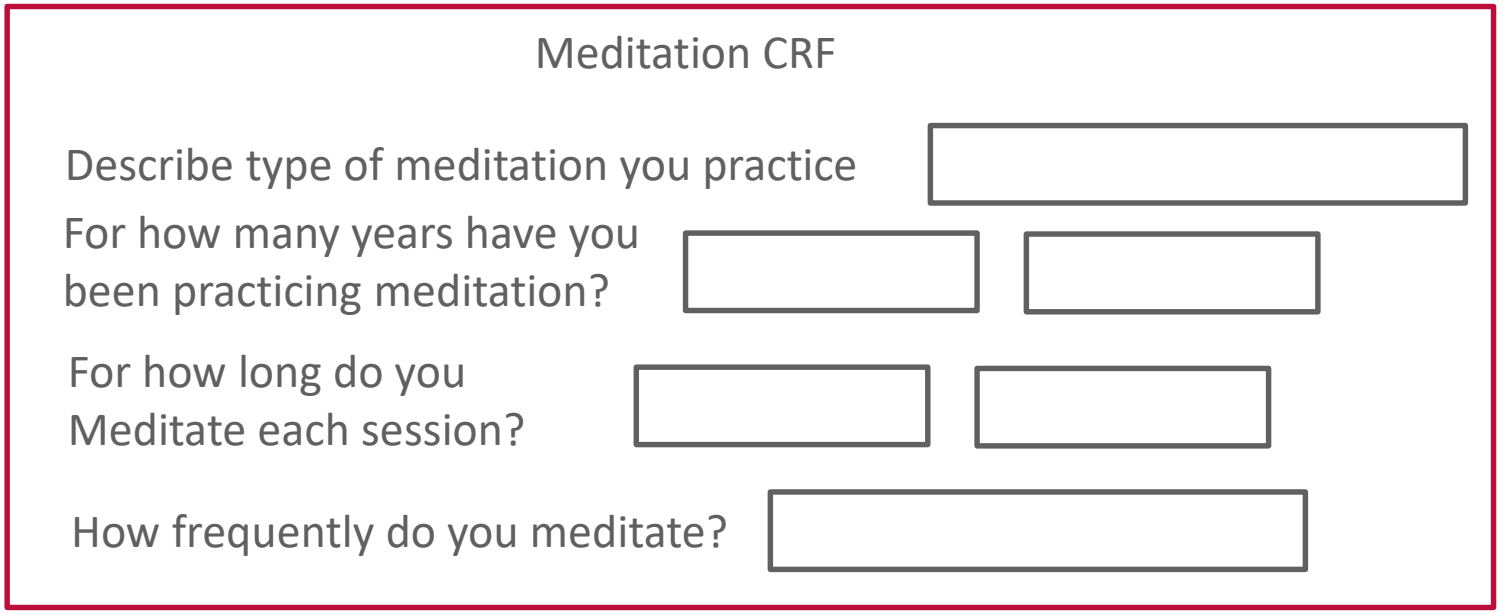
Variable Name	Variable Label	Type	Format	Description
VISITNUM	Visit Number	Num		Clinical encounter number. Numeric version of VISIT, used for sorting.
VISIT	Visit Name	Char		Protocol-defined description of a clinical encounter.
VISITDY	Planned Study Day of Visit	Num		Planned study day of VISIT. Should 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 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 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.
--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 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		A label for a given value of --NOMDY, 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.
--RPENDY	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. See --TPTNUM and --TPTREF.
--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 by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
--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-defined 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 Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined 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 question from a questionnaire.

SDTM Table 2.2.5
Timing

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

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



Example: Create Meditation Custom Domain Specifications

Start with CDASH Model

CDASH	XM-Meditation		SDTM	XM-Meditation					
CDASH Variable	**Question Text/ Prompt**	**Mapping Instructions**	**VARIABLE**	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**CORE**
STUDYID	~~STUDY~~	~~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	~~What is the type of meditation practiced?~~	~~Direct~~	**XMTRT**	Name of Meditation Regimen	Char		Topic		REQ
XMDOSE	~~What is the length of each meditation session?~~	~~Direct~~	**XMDOSE**	Meditation Session Length	Num	(XMDECOD)	Record Qualifier		PERM
XMDOSU	~~display UNIT values~~	~~Direct~~	**XMDOSU**	Meditation Session Length Unit	Char	(UNIT)	Variable Qualifier		PERM
XMDOSFRQ	~~What is the frequency of meditation practice?~~	~~Direct~~	**XMDOSFRQ**	Frequency of Meditation Sessions	Char	(FREQ)	Variable Qualifier		PERM
XMCDUR	**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							

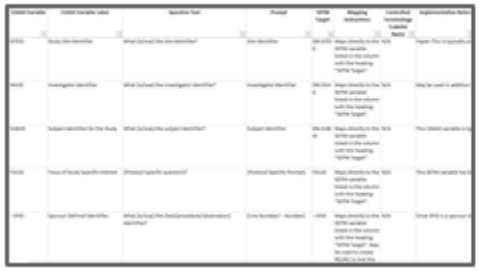
Many CDASH variables are a 1:1 match with SDTM

Add in the SDTM submission-only variables

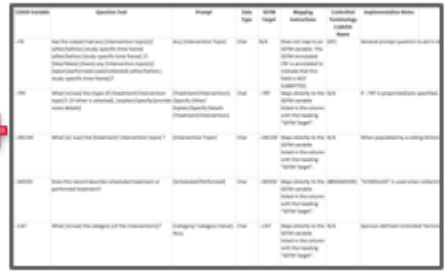
Apply standard programming to transform other collected values to SDTM

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



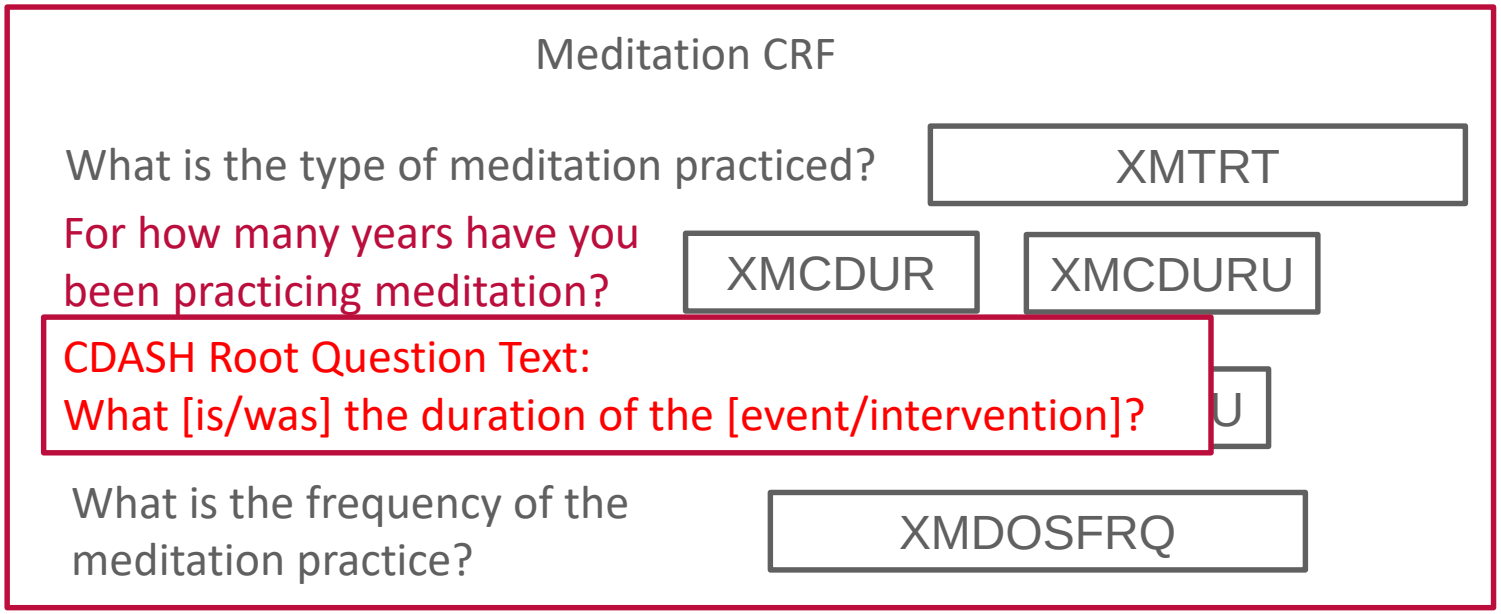
CDASH Model Interventions Class

CDASH Model Timing

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

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.

At least make sure your question MEANS the SAME thing.

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

2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—Topic and Qualifier Variables—One Record per Constant-Dosing Interval or Intervention Episode

Variable Name	Variable Label	Type	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.
				Qualifier Variables
--MODIFY	Modified Treatment Name	Char	Synonym Qualifier of --TRT	If the value for --TRT 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		
--CAT	Category	Char		
--SCAT	Subcategory	Char		
--PRESP	Pre-specified	Char		
--OCCUR	Occurrence Indicator	Char		
--STAT	Completion Status	Char		
--REASND	Reason Not Done	Char		
--INDC	Indication	Char		
--CLAS	Class	Char		
--CLASCD	Class Code	Char		
--DOSE	Dose	Num		
--DOSTXT	Dose Description	Char		
--DOSU	Dose Units	Char		
--DOSFRM	Dose Form	Char		
--DOSFRQ	Dosing Frequency per Interval	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Usually expressed as the number of doses given per a specific interval. Examples: "Q2H", "QD", "PRN".
--DOSTOT	Total Daily Dose	Num	Record Qualifier	Total daily dose of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
--DOSRGM	Intended Dose 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	Lot Number	Char	Record Qualifier	Lot number for the intervention described in --TRT.
--LOC	Location of Dose Administration	Char	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: ARM for an injection.
--LAT	Laterality	Char	Variable Qualifier of	Qualifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT",

SDTM XM-Meditation

VARIABLE	VARIABLE LABEL	TYPE	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	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		Topic		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

SDTM Example: Meditation (Identifiers)

Table 2.2.4.1 All Observation Classes—Identifiers

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	2-character abbreviation for the domain most relevant to the observation. The domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
APID	Associated Persons Identifier	Char	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist 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 identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device.
NHOID	Non-Host Organism Identifier	Char	Sponsor-defined identifier for a non-host organism. This variable should be populated with an intuitive name based on the identity of the non-host organism as reported by the lab. Example: "A/California/7/2009 (H1N1)".
FETUSID	Fetus Identifier	Char	Identifier used to ide… with human clinical …
FOCID	Focus of Study-Specific Interest	Char	Identification of a fo… examination was pe… (right eye) or "Upp…
--SEQ	Sequence Number	Num	Sequence number t… be any valid numbe…
--GRPID	Group ID	Char	Optional group iden… records in the Trial S…
--REFID	Reference ID	Char	Optional internal or…
--RECID	Invariant Record Identifier	Char	Identifier for a recor… content of the recor… versions of the dom…
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined ide…
--LNKID	Link ID	Char	Identifier used to lin… multiple measurements/assessments performed at each study visit.
--LNKGRP	Link Group ID	Char	Identifier used to link related records across domains. This will usually be a many-to-one relationship. For example, multiple tumor measurements/assessments will contribute to a single response to therapy determination record.

SDTM XM-Meditation

VARIABLE	VARIABLE LABEL	TYPE	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	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		Topic		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

SDTM Example: Meditation (Timing)

Table 2.2.5.1 All Observation Classes—Timing Variables

Variable Name	Variable Label	Type	Format	Description
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 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 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.
--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 o
--STDY	Study Day of Start of Observation	Num		Actual study day o
--ENDY	Study Day of End of Observation	Num		Actual study day o
--NOMDY	Nominal Study Day for Tabulations	Num		The nominal study to occur on differe
--NOMLBL	Label for Nominal Study Day	Char		A label for a given
--RPDY	Actual Repro Phase Day of Observation	Num		The actual day wit human clinical tria
--RPSTDY	Actual Repro Phase Day of Obs Start	Num		The actual day wit clinical trials.
--RPENDY	Actual Repro Phase Day of	Num		The actual day wit clinical trials.
--DUR	Duration	Char	ISO 8601	ollected duration
--TPT	Planned Time Point Name	Char		Text description as an elapsed time
--TPTNUM	Planned Time Point Number	Num		Numeric version o
--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 by --ELTM, --TPTNUM, --TPT, --STINT, and --ENINT. Examples: "PREVIOUS DOSE", "PREVIOUS MEAL".
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601	Date/time for a fixed reference time point defined by --TPTREF.
--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-defined 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 Period	Char		Identifies the end of the observation as being before, during or after the sponsor-defined reference period. The sponsor-defined 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 question from a questionnaire.
--EVINTX	Evaluation Interval Text	Char		Evaluation interval associated with an observation, where the interval is not able to be represented in ISO 8601 format. Examples:

SDTM	XM-Meditation					
VARIABLE	VARIABLE LABEL	TYPE	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	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		Topic		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: Meditation SDTM Custom Domain Metadata

SDTM	XM-Meditation					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**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		Topic		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

Example: Vacation - Events Observation Class

CDASH	YV - Vacation		
CDASH Variable	**Question Text/ Prompt**	**Controlled Terminology**	**Mapping Instructions**
STUDYID	STUDY		Direct
YVOCCUR	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"
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate YVSTDTC
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC
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"

SDTM	YV-Vacation					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**CORE**
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		Topic	Default to VACATION	REQ
YVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Default to Y	PERM
YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
YVENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing		PERM
YVENTPT	End Reference Time Point	Char		Timing	Default to SCREENING VISIT	PERM

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

Example: Vacation - Events Observation Class

CDASH	YV - Vacation		
CDASH Variable	**Question Text/ Prompt**	**Controlled Terminology**	**Mapping Instructions**
STUDYID	STUDY		Direct
YVOCCUR	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"
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate YVSTDTC
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC
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"

SDTM	YV-Vacation					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**CORE**
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		Topic	Default to VACATION	REQ
YVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Default to Y	PERM
YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
YVENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing		PERM
YVENTPT	End Reference Time Point	Char		Timing	Default to SCREENING VISIT	PERM

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

Example: Vacation - Events Observation Class

CDASH	YV - Vacation		
CDASH Variable	**Question Text/ Prompt**	**Controlled Terminology**	**Mapping Instructions**
STUDYID	STUDY		Direct
YVOCCUR	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"
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate YVSTDTC
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC
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"

SDTM	YV-Vacation					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**CORE**
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		Topic	Default to VACATION	REQ
YVPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Default to Y	PERM
YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
YVENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing		PERM
YVENTPT	End Reference Time Point	Char		Timing	Default to SCREENING VISIT	PERM

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

Example: Vacation - Events Observation Class

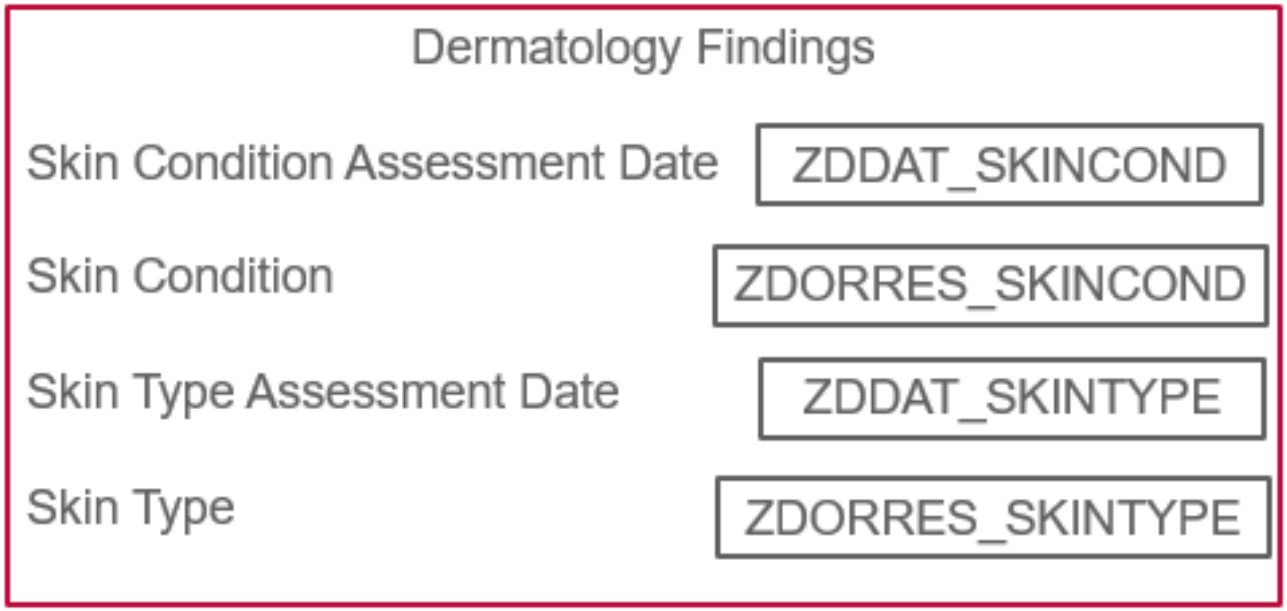
CDASH	YV - Vacation		
CDASH Variable	**Question Text/ Prompt**	**Controlled Terminology**	**Mapping Instructions**
STUDYID	STUDY		Direct
YVOCCUR	Did the subject have a Vacation within the past 12 months?	(NY_2)	Map the collected value to YVOCCUR; populate YVTERM with "VACATION", populate YVEVLINT with "-P12M"
YVSTDAT	What was the vacation start date?		Convert to ISO 8601 and populate YVSTDTC
YVENDAT	What was the vacation end date?		Convert to ISO 8601 and populate YVENDTC
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"

SDTM	YV-Vacation					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**CORE**
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		Topic	Default to VACATION	REQ
YVPRESP	Pre-specified	Char	NY)	Variable Qualifier	Default to Y	PERM
YVOCCUR	Occurrence of Vacation	Char	(NY)	Record Qualifier	Populate this with the collected value	EXP
YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PERM
YVENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing		PERM
YVENTPT	End Reference Time Point	Char		Timing	Default to SCREENING VISIT	PERM

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		
CDASH Variable	**Question Text/ Prompt**	**Controlled Terminology**	**Mapping Instructions**
STUDYID	STUDY		Direct
ZDORRES_SKINCOND	Skin Condition	(SKNCOND)	Map response to ZDORRES; Populate ZDTESTCD with "SKINCOND"; Populate ZDTEST with "Skin Condition"
ZDORRES_SKINTYPE	Skin Type	(SKNTYPE)	Map response to ZDORRES; Populate ZDTESTCD with "SKINTYPE"; Populate ZDTEST with "Skin Type"
ZDDAT_SKINCOND	Skin Condition Assessment Date		Convert to ISO 8601 and populate ZDDTC where ZDTESTCD=SKINCOND
ZDDAT_SKINTYPE	Skin Type Assessment Date		Convert to ISO 8601 and populate ZDDTC where ZDTESTCD=SKINTYPE

SDTM	ZD-Dermatology Findings					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**CORE**
STUDYID	Study Identifier	Char		Identifier		REQ
DOMAIN	Domain Abbreviation	Char	ZD	Identifier	Default to ZD	REQ
USUBJID	Unique Subject Identifier	Char		Identifier		REQ
ZDSEQ	Sequence Number	Num		Identifier		REQ
ZDTESTCD	Dermatology Test Code	Char	(DERMCD)	Topic		REQ
ZDTEST	Dermatology Test	Char	(DERM)	Synonym Qualifier		REQ
ZDORRES	Dermatology Test Original Result	Char	*	Result Qualifier		EXP
ZDSTRESC	Dermatology Test Standardized Result - Character	Char	*	Result Qualifier		EXP
ZDDTC	Evaluation Interval	Char	ISO 8601	Timing		EXP

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, NEIDAN, CUNXIANG, ZHUANQI, 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 Code (DERMCD)	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-Codetable-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