Variable Naming Conventions and Non-standard Variables

LPO Webinar

28 March 2019

NIH NATIONAL CANCER INSTITUTE

Upon completion of this webinar, you should be able to:

- Discuss the purpose of using CDASH variables to support creation of SDTM
- Use CDASH-only variables to support data collection needs
- Use variable naming patterns to support ETL programming
- Create CDASH-conformant non-standard variables

CDASH and SDTM Models

Alignment of Observation Classes and Root Variables

CDASH is Harmonized with SDTM (*and* is user-friendly for the site)

- CDASH was designed to
  - Efficiently get to SDTM by collecting data in a harmonized way
    - CDASH uses the same Observation Classes as SDTM (aligned at the Model level)
    - CDASH uses the same Domains as SDTM (aligned at the Implementation Guide level)
    - CDASH uses the exact same variables as SDTM when the data can be collected exactly as needed for SDTM
    - CDASH specifies Question Text/Prompts that align to SDTM variable concept “definitions”
    - CDASH uses the exact same terminology as SDTM
    - CDASH standardizes data collection variables for SDTM concepts that are not “data collection friendly”
  - Make data collection more user friendly (**SDTM is not designed for data collection**)
    - Terminology displayed to the site can use synonyms
    - Dates and times are entered in separate fields, using unambiguous, user-friendly formats

Interventions Model

2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—Topic and C

Variable Name	Variable Label	Type
--TRT	Name of Treatment	Char
--MODIFY	Modified Treatment Name	Char
--DECOD	Standardized Treatment Name	Char
--MC		Char
--CA		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
--DOSTOT	Total Daily Dose	Num
--DOSRGM	Intended Dose Regimen	Char
--ROUTE	Route of Administration	Char
--LOT	Lot Number	Char
--LOC	Location of Dose Administration	Char
--LAT	Laterality	Char

SDTM

CDASH Model

Interventions

CDASH Variable	CDASH Variable Label	DRAFT CDASH Definition	Question Text	Prompt
--YN	Any [Intervention]	An indication whether or not any data was collected for the intervention topic.	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]
--TRT	Name of Treatment	The topic for the intervention observation, usually the reported name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.	What [is/was] the (type of) [treatment/intervention topic]?; [If other is selected], [explain/specify/provide more details]	[Treatment/Intervention]; [Specify Other/ [Treatment/Intervention]
--DECOD	Dictionary or Standardized	The dictionary or sponsor-defined standardized text description of the topic variable, --TRT, or	What [is/ was] the [treatment/ intervention topic] ?	[Intervention Topic]
--MOOD	Mood	The mode or condition of the record that specifies whether the intervention (activity) is intended to happen or has happened.	Does this record describe scheduled treatment or performed treatment?	[Scheduled/Performed]
--CAT	Category	A grouping of topic-variable values based on user-defined characteristics.	What [is/was] the category (of the intervention])?	[Category/ Category Value]; NULL
--SCAT	Subcategory	A sub-division of the --CAT values based on user-defined characteristics.	What [is/was] the subcategory (of the [intervention])?	[Subcategory/ Subcategory Value]; NULL
--PRESP	Pre-Specified Intervention	An indication that a specific intervention or a group of interventions is pre-specified on a CRF.	N/A	N/A
--OCCUR	Occurrence	An indication that the pre-specified intervention	Was [--TRT/ intervention] [taken/performed/administered/consumed]	[--TRT/ Intervention] [Had/Taken/Performe

Events Model

2.2.2 The Events Observation Class

Table 2.2.2.1 Events—Topic and Qu

Variable Name	Variable Label
--TERM	Reported Term
--MODIFY	Modified Reported Term
--LLT	Lowest Level Term
	Term Code
--DECOD	Dictionary-Derived Term
--PTCD	Preferred Term Code
--HLT	High Level Term
--HLTCD	High Level Term Code
--HLGT	High Level Group Term
--HLGTCD	High Level Group Term Code
--CAT	Category
--SCAT	Subcategory
--PRESP	Pre-Specified
--OCCUR	Occurrence Indicator
--STAT	Completion Status
--REASND	Reason Not Done
--BODSYS	Body System or Organ Class

SDTM

Events

CDASH Variable	CDASH Variable Label	DRAFT CDASH Definition	Question Text	Prompt	Data Type	SDTM Targe
--YN	Any [Event]	An indication whether or not any data was collected for the event topic.	Has the subject had any [event topic(s)/term/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
--TERM	Reported Term	The topic variable for an event observation, which is the reported or pre-specified name of the event.	What [is/was] the [event topic/term/name]?; If --DECOD (is selected), [explain/specify/provide (more) detail(s)]?	[Event Topic]; [Specify/Specify Other/Explain/Provide Details ([for Event Topic])	Char	--TERI
--DECOD	Dictionary-Derived/Standardized Term	The dictionary or sponsor-defined standardized text description of the topic variable, --TERM, or the modified topic variable (-- MODIFY), if applicable.	What [is/was] the [event/event topic]?	(Standardized) [Event/Event Topic]	Char	--DEC
--CAT	Category	A grouping of topic-variable values based on user-defined characteristics.	What [is/was] the category (of the [--TERM/event topic])?	[Category/Category Value]; NULL	Char	--CAT
--SCAT	Subcategory	A sub-division of the --CAT values based on user-defined characteristics.	What [is/was] the subcategory (of the [--TERM/event topic])?	[Subcategory/Subcategory Value]; NULL	Char	--SCA
--PRESP	Pre-Specified	An indication that a specific event, or group of events, is pre-specified on a CRF.	N/A	N/A	Char	--PRE
--OCCUR	Occurrence	An indication whether the pre-specified event or the group of events occurred when the occurrence of the specific event or group of events is solicited.	[Did/Does] the subject have [--TERM] (after/before [study-specific time frame])?; Is the [pre-specified medical occurring]?	[--TERM]	Char	--OCC
--STAT	Completion Status	The variable used to indicate that data are not available by having the site recording the value as "Not Done".	Was the [event topic] not [answered/ done/ assessed/evaluated] ?; Indicate if ([event topic] was) not [answered/assessed/done/evaluated].	Not Done	Char	--STA
--CSTAT	Collected Completion Status	The variable used to indicate that data are not available by having the site recording a sponsor-defined value (e.g., Not Collected/Not Evaluated/Not Assessed/Not Available/Not Answered).	Was the [event topic] not [answered/ done/ assessed/evaluated] ?; Indicate if ([event topic] was) not [answered/assessed/done/evaluated].	Not Collected	Char	--STA
--REASND	Reason Not Done	An explanation of why the assessment/evaluation/question was not answered/collected/done, etc.	What [is/was] the reason that the ([data/information/ sponsor-defined phrase]) was not [answered/collected/ done/ evaluated/ assessed]?	Reason Not [Answered/ Collected/ Done/ Evaluated/ Assessed/Available]	Char	--REA
--LOC	Location	A description of the anatomical location relevant for the event.	What [is/was] the anatomical location (of the [--TERM/event topic])?	Anatomical Location	Char	--LOC
--LAT	Laterality	Qualifier for anatomical location further detailing	What [is/was] the side (of the anatomical location of	Side	Char	--LAT

CDASH Model

findings Model

2.2.3 The Findings Observation Class

Table 2.2.3.1 Findings—Topic and

Variable Name	Variable Label
--TESTCD	Short Name of Measurement, Test, or Exam
--TEST	Name of Measurement, Test, or Exam
--MODIFY	Modified Term
--	est, or Examination Detail
--CAT	Category
--SCAT	Subcategory
--POS	Position of Subject During Observation
--BODSYS	Body System or Organ Class
--ORRES	Result or Finding in Original Units
--ORRESU	Original Units
--ORNRLO	Normal Range Lower Limit-Original Units
--ORNRHI	Normal Range Upper Limit-Original Units
--ORREF	Reference Result in Original Units
--STRESC	Result or Finding in Standard Format
--STRESN	Numeric Result/Finding in Standard Units
--STRESU	Standard Units
--STNRLO	Normal Range Lower Limit-Standard Units
--STNRHI	Normal Range Upper Limit-Standard Units

SDTM

Findings

CDASH Variable	CDASH Variable Label	DRAFT CDASH Definition	Question Text	Prompt
--OBJ	Object of the Observation	Describes the event or intervention whose property is being measured in --TESTCD/--TEST.	N/A	N/A
--YN	Any [Finding]	An indication whether or not any data was collected for the finding topic.	Has the subject had any [Findings topic(s)] (after/before [study specific time frame]) ?; [Was/Were] (there) any [Findings topic(s)] (reported) (after/before [study specific time frame])?; Were all eligibility criteria met?	Any [Finding Topic]
--PERF	[Observation] Performed	An indication whether or not a planned measurement, test, observation or specimen was performed/collected.	[Were any/Was the] [--TEST/topic] ([measurement(s)/test(s)/examination(s)/specimen(s)/sample(s)]) [performed/collected]?	([--TEST/ topic] ([Measurement (s)/Test(s)/Examination(s)/Specimen(s)/Sample([Performed/Collected]?
--TESTCD	Short Name of Measurement, Test or Examination	Short character value code for the test being performed.	N/A	N/A
--TEST	Name of Measurement, Test or Examination	Descriptive name for the test being performed. Examples: Platelet, Systolic Blood Pressure, ye	What [is/was] the name (of the [measurement/test/examination])?	[Measurement/Test/Examination/] (Name)
--TSTDTL	Measurement, Test or Examination Detail	A further description of --TESTCD and --TEST.	What [is/was] the [measurement/test/examination] detail name?	[Measurement/Test/Examination] Detail (Name)
--CAT	Category	A grouping of topic-variable values based on user-defined characteristics.	What [is/was] the [type/category/name] (of the [measurement/test/examination/specimen/sample])?	[Category/Category Value]; NULL

CDASH Model

CDASH and SDTM Implementation Guides

Alignment of Domains and Domain Variables

2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—Topic

Variable Name	Variable Label
--TRT	Name of Treatment
--MODIFY	Modified Treatment Name
--CAT	Category
--SCAT	Subcategory
--PRESP	Pre-specified
--OCCUR	Occurrence Indicator
--STAT	Status
--DOSE	Dose
--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

SDTM

-- has been replaced with a 2-character Domain code to make this topic-specific for exposure to study treatments

Example Interventions

6.1.3.1 Exposure

EX – Description/Overview

An interventions domain tha
defined as a test material wi

EX – Specification

ex.xpt, Exposure — Interver

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbrev
USUBJID	Unique Subject
EXGRPID	Group ID
EXREFID	Reference ID
EXSPID	Sponsor-Define Identifier
EXLNKID	Link ID
EXLNKGRP	Link Group ID
EXTRT	Name of Treatn
EXCAT	Category of Tre
EXSCAT	Subcategory of Treatment
EXDOSE	Dose
EXDOSTXT	Dose Descriptio
EXD	
EXD	
EXD	
EXD	
EXR	
EXL	
EXLOC	Location of Dose Administration
EXLAT	Laterality

SDTMIG

CDASH EC domain makes --TRT "entry" friendly - e.g., Treatment Name can be **collected** using a masked name, "Treatment B"

Exposure as Collected (EC)

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt
Interventions	EC	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]
Interventions	EC	N/A	N/A	2	SITEID				Site (Identifier)
Interventions	EC	N/A	N/A	3	SUBJID				Subject
Interventions	EC	N/A	N/A	4	EPOCH				Trial Period
Interventions	EC				ECYN				Any Study Treatr
Interventions	EC		N/A	6	ECCAT	Category of Treatment	A grouping of topic-variable values based on user defined characteristics.	What is the category of the study treatment?	[Study Treatmen Category]; NULL
Interventions	EC			7	ECSCAT	Subcategory of Treatment	A sub-division of the ECCAT values based on user defined characteristics.	What is the subcategory of the study treatment?	[Study Treatmen Subcategory]; NU
					ECTRT	Treatment Name	Name of the intervention or treatment known to the subject and/or administrator.	What was the study treatment name?	(Study) Treatmer Name

CDASHIG

Exposure as Collected can be put into SDTM EC domain, and then translated/derived into SDTM EX.

Qualifier	Lot number of the intervention product.	Perm
Record Qualifier	Specifies location of administration. Examples: "ARM", "LIP".	Perm
Variable Qualifier	Qualifier for anatomical location further detailing laterality of the intervention administration. Examples: "LEFT", "RIGHT".	Perm

Example Interventions domains

2.2.1 The Interventions Observation Class

Table 2.2.1.1 Interventions—Topic and

Variable Name	Variable Label	Type
--TRT	Name of Treatment	Char
--MODIFY	Modified Treatment Name	Char
[illegible]	[illegible]	Char
--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
--DOSTOT	Total Daily Dose	Num
--DOSRGM	Intended Dose Regimen	Char
--ROUTE	Route of Administration	Char
--LOT	Lot Number	Char
--LOC	Location of Dose Administration	Char
--LAT	Laterality	Char

SDTM

6.1.5 Procedures

PR – Description/Overview

An interventions domain that contains interventional activity intended to have diagnostic, preventive, therapeutic, or palliative effects

PR – Specification

pr.xpt, Procedures — Interv

Variable Name	Variable Label
STUDYID	Study Identifier
DOMAIN	Domain Abbrev
USUBJID	Unique Subject
PRGRPID	Group ID
PRSPID	Sponsor-Define Identifier
PRLNKID	Link ID
PRLNKGRP	Link Group ID
PRTRT	Reported Nam Procedure
PRDECOD	Standardized P Name
PRCAT	Category
PRSCAT	Subcategory
PRPRESP	Pre-specified
PROCCUR	Occurrence
PRINDC	Indication
PRDOSE	Dose
PRDOSTXT	Dose Descripti
PRDOSU	Dose Units
PRDOSFRM	Dose Form
PRDOSFRQ	Dosing Freque Interval
PRDOSRGM	Intended Dose
PRROUTE	Route of Administration

SDTMIG

Procedure (PR)

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt	Data Type	CDASHIG Core
Interventions	PR	N/A	N/A	1	STUDYID	Study Identifier	A unique identifier for a study.	What is the study identifier?	[Protocol/Study]	Char	HR
Interventions	PR	N/A	N/A	2	SITEID	Study Site Identifier	A unique identifier for a site within a study.	What is the site identifier?	Site (Identifier)	Char	HR
Interventions	PR	N/A	N/A	3	SUBJID	Subject Identifier for the Study	A unique subject identifier within a site and a study.	What is the subject identifier?	Subject	Char	HR
Interventions	PR	N/A	N/A	4	PRYN	Any Procedures Performed	An indication whether or not the subject had any procedures performed.	Were any surgical, therapeutic or diagnostic procedures performed?	Any Procedures	Char	O
Interventions	PR	N/A	N/A	5	PRCAT	Category of Procedure	A grouping of topic-variable values based on user defined characteristics.	What was the category of the procedure?	[Procedure Category]; NULL	Char	O
Interventions	PR	N/A	N/A	6	PR	Subcategory of Procedure	A sub-division of the PRCAT values based on user defined characteristics.	What was the subcategory of the procedure?	[Procedure Subcategory]; NULL	Char	O
Int							A sponsor-defined identifier which can e used for pre-printed or auto- rated numbers on the CRF.	What is the procedure identifier?	[Line Number/PR Number]	Char	O
Int							atim surgical, therapeutic or ostic procedures' name.	What was the procedure name?	Procedure Name	Char	HR
Int						ed	The dictionary or sponsor-defined standardized text description of PRTRT, or the modified topic variable (PRMODIFY), if applicable.	N/A	N/A	Char	O

CDASHIG

CDASH has metadata for asking questions (Question Text or Prompt) that are **aligned with the meaning of the SDTM variable**.

			Qualifier		
PRROUTE	Route of Administration	Char	(ROUTE)	Variable	Route dministration for PRTRT. Perm

Rule for Using SDTM variables for Data Collection

- If the value you are collecting is EXACTLY the same as the value that will populate the SDTM variable, you can use the SDTM variable for data collection
- What does “exactly the same” mean?
  - Same value
  - Same data type
  - Same format
  - Same spelling
  - Cannot be transformed in any way (except CASE) before populating the SDTM variable
- If any transformations have to be made, you should **not** use the SDTM variable, including:
  - Decoding (collecting using a numeric value that will be translated later to a text value)
  - Combining two separate values to make a new value (dates, times)
  - Splitting values (e.g., CM: allowing them to record free text combinations of medication name, dose, unit, frequency in a single field)

CDASH-Only Variables

Making SDTM Variables "Collection-Friendly"

CDASH Only Variables

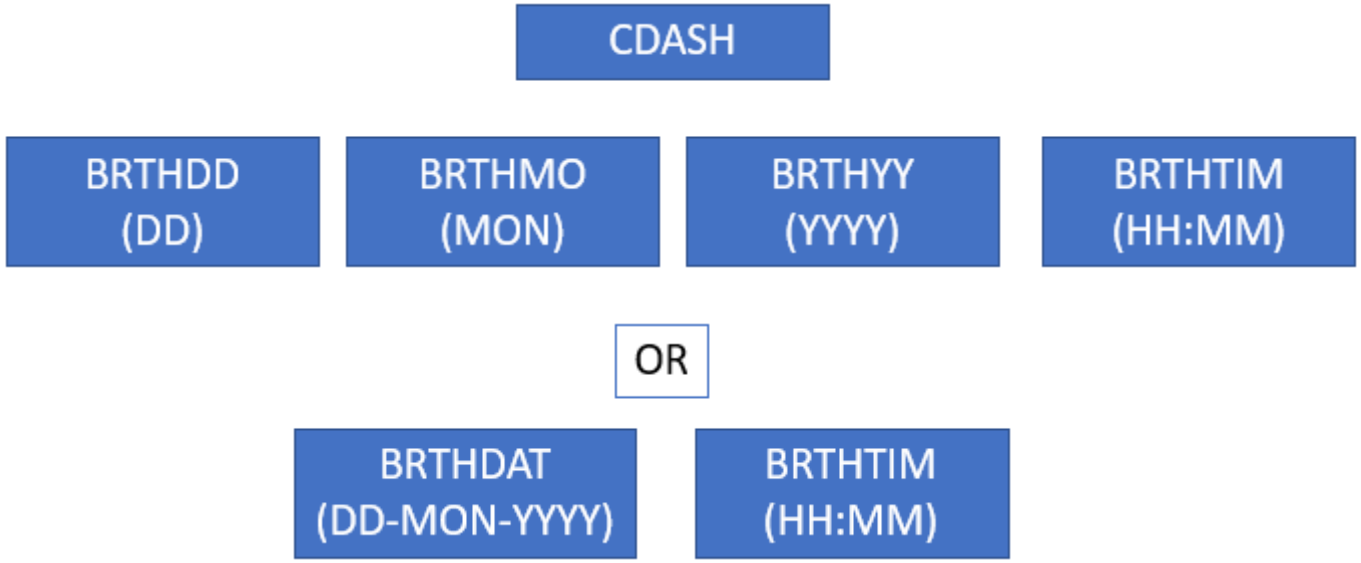
- SDTM Programmers should be able to expect that any value coming to them in a valid SDTMIG variable should not have to be modified in any way (except, perhaps, case)
- Some concepts in SDTM are NOT collection-friendly, so the SDTM variable should NOT be used to collect those concepts

  SDTM was designed for data review - NOT for data collection

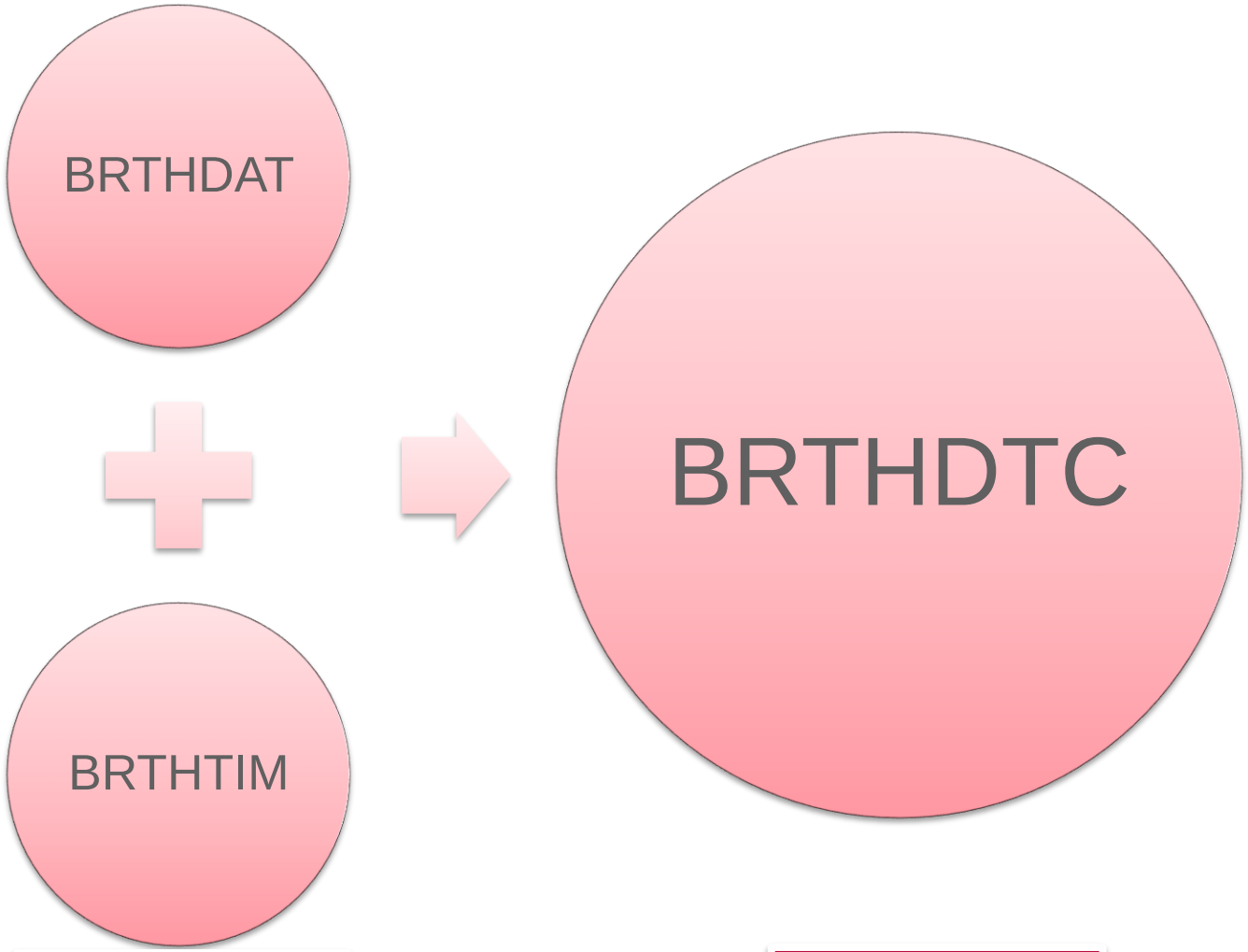
- Programming to handle transformation from collected value to SDTM value has to be written: e.g.
  - Dates and times
  - Collected durations
  - Collected doses
  - Collection using different code lists
  - Normalized Findings variables
- CDASH provides a set of STANDARDIZED variables to handle these necessary transformations to SDTM with standard programming

CDASH vs. SDTM - Dates and Times

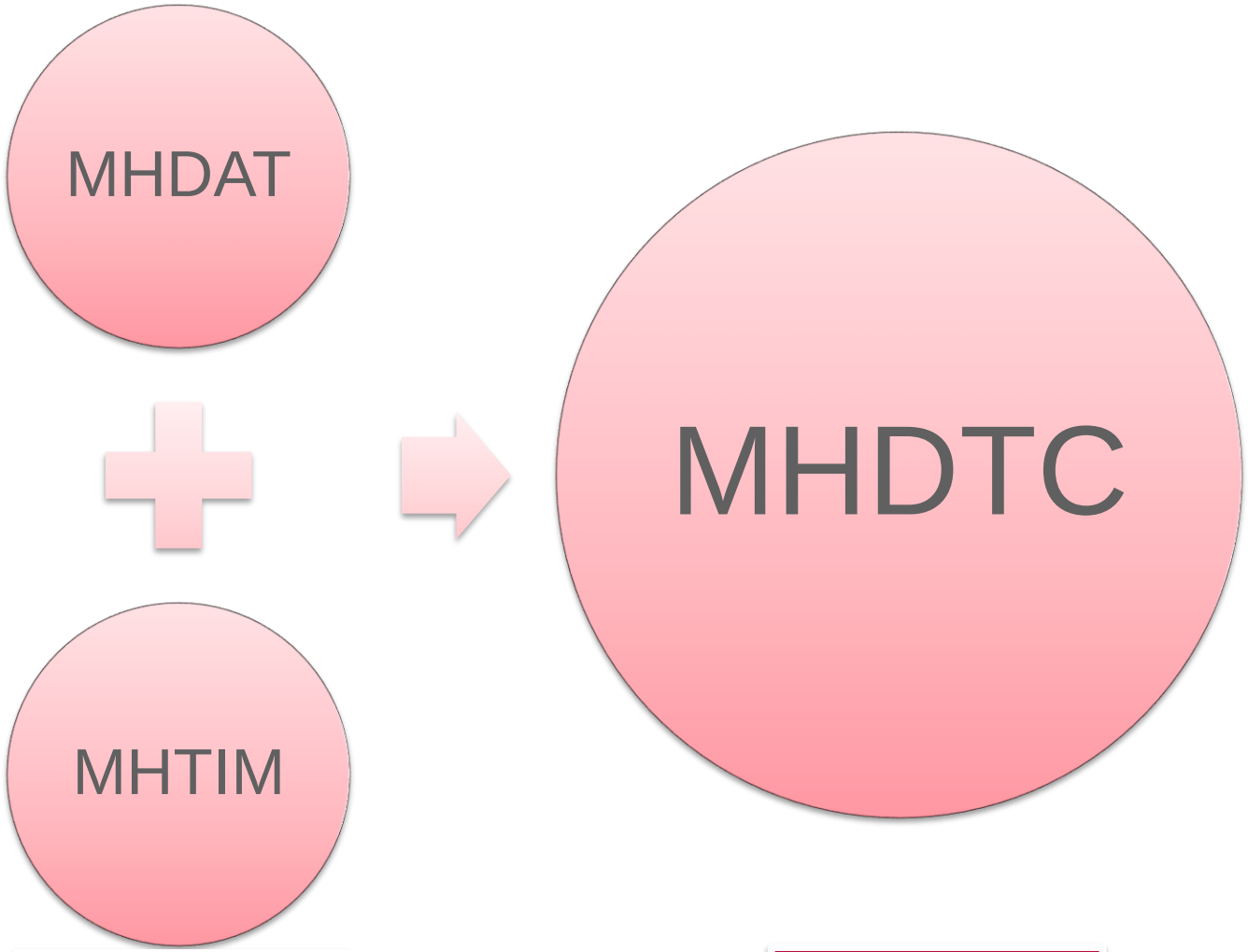
- CDASH Dates and Times
  - Two (or more) separate fields
  - Allow collection of partial dates
  - User friendly, unambiguous format
- SDTM Dates and Times
  - One field using ISO 8601 format
  - Designed for review of dates/times
  - Standard format supported by common software



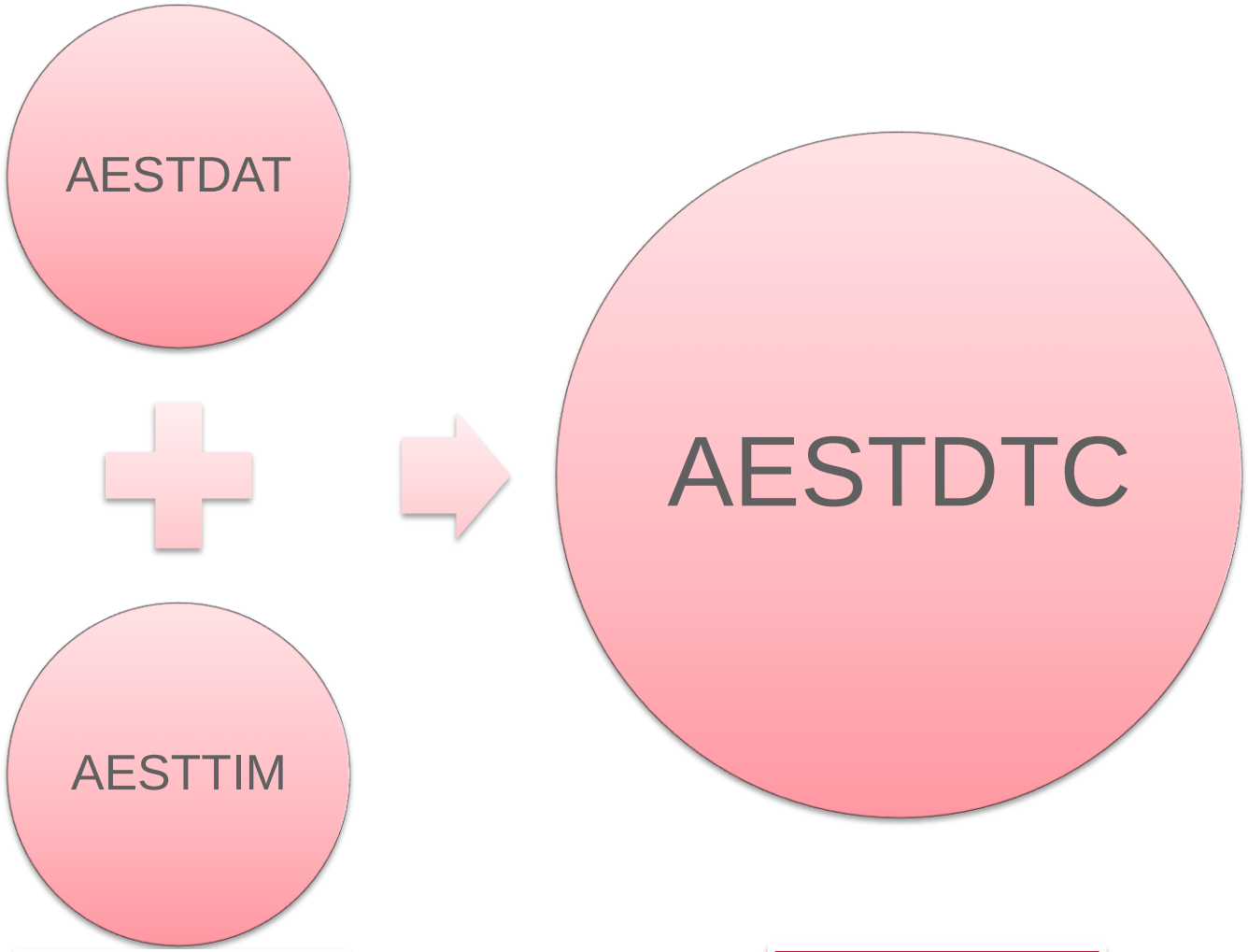
Collected Dates and Times to Date/Time Tabulation



Collected Dates and Times to Date/Time Tabulation



Collected Dates and Times to Date/Time Tabulation



CDASH vs. SDTM - Collected Durations

- CDASH Collected Duration
  - Separate fields for duration value and duration unit to support edit checks

Tobacco Usage	☐ Current ☐ Former ☑ Never	If Current or Former: Duration _____ ☐Years☐ Months
Alcohol Usage	☑ Current ☐ Former ☐ Never	If Current or Former: Duration __22____ ☑Years☐ Months

- SDTM Collection Duration
  - Single field for collected duration/unit
  - Uses ISO 8601 Period format

SUTRT	SUOCCUR	SUDUR
TOBACCO	N	
ALCOHOL	Y	P22Y

CDASH vs. SDTM - Prior and Ongoing

- CDASH Prior and Ongoing
  - **User friendly** way to collect whether an event or intervention started prior to a particular timepoint, or whether it was ongoing at a particular timepoint
  - Flexible: Uses “Yes/No” or “Prior” or “Ongoing” to answer the question

- SDTM Relative Timing Variables
  - **Reviewer friendly** - standardized with specific terminology (e.g., BEFORE, DURING, AFTER)
  - Start or End may reference a timepoint in the study, OR
  - Start or End may reference analysis concepts for the study (i.e., study reference period)

Study Reference Period is defined the same way for all subjects. Actual dates for start and end of study reference period for each subject are in DM.

RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. See Assumption 9 for additional detail on when RFSTDTC may be null.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.	Exp

Will it end Before, During or After the study reference period?

RFSTDTC

Study Reference Period

RFENDTC

Has the subject had any medical conditions or events? NOT SUBMITTED MHYN	o Yes o No
Medical History Category *Defaulted* MHCAT	**Sponsor Defined**
What is the medical condition or event identifier? MHSPID	
What is the medical condition or event? *Defaulted* MHTERM	**CIRRHOSIS**
Was the medical condition or event pre-specified? *Defaulted* MHPRESP	**Y**
Does the subject have cirrhosis? MHOCCUR	o Yes o No
Start Date MHSTDTC MHSTDAT	__/___/____
Ongoing MHONGO	o Yes o No
End Date MHENDTC MHENDAT	__/___/____

Uses Y/N

Has it ended? If not, WHEN will it end?

If they collect "Yes":

MHENRF = "DURING/AFTER"

If they collect "No":

MHENRF = "BEFORE"

MHENRF uses STENRF terminology and rules from SDTMIG 4.4.7

Is it Ongoing *as of* this date

03 May 2018

Has the subject had any medical conditions or events? NOT SUBMITTED MHYN	o Yes o No
Medical History Category *Defaulted* MHCAT	**Sponsor Defined**
What is the medical condition or event identifier? MHSPID	
What is the medical condition or event? *Defaulted* MHTERM	**CIRRHOSIS**
Was the medical condition or event pre-specified? *Defaulted* MHPRESP	**Y**
Does the subject have cirrhosis? MHOCCUR	o Yes o No
Start Date MHSTDTC MHSTDAT	__/___/____
Ongoing MHONGO	o Yes o No
End Date MHENDTC MHENDAT	__/___/____

Uses Y/N

If they collect "Yes", and want to **compare it to the actual date** they asked the question:

MHENRTPT = "ONGOING"
MHENTPT = "2018-05-03"

If they collect "No":

MHENRTPT = "BEFORE"
MHENTPT = "2018-05-03"

MHENRTPT uses STENRF terminology and rules from SDTMIG 4.4.7, AND must reference a date or timepoint (in MHENTPT)

Is it Ongoing *as of* this timepoint

	Screening Visit
Has the subject had any medical conditions or events? NOT SUBMITTED MHYN	o Yes o No
Medical History Category *Defaulted* MHCAT	**Sponsor Defined**
What is the medical condition or event identifier? MHSPID	
What is the medical condition or event? *Defaulted* MHTERM	**CIRRHOSIS**
Was the medical condition or event pre-specified? *Defaulted* MHPRESP	**Y**
Does the subject have cirrhosis? MHOCCUR	o Yes o No
Start Date MHSTDTC MHSTDAT	__/___/____
Ongoing MHENRTPT MHENTPT MHONGO	o Yes o No
End Date MHENDTC MHENDAT	__/___/____

Uses Y/N

If they collect "Yes" and want to **compare it to a timepoint description** (e.g., Visit name)

MHENRTPT = "ONGOING"
MHENTPT = "SCREENING VISIT"

If they collect "No":

MHENRTPT = "BEFORE"
MHENTPT = "SCREENING VISIT"

MHENRTPT uses STENRF terminology and rules from SDTMIG 4.4.7, AND must reference a date or timepoint (in MHENTPT)

Relative Timing Terminology

MHENRF	End Relative to Reference Period	Char	(STENRF)
MHENRTPT	End Relative to Reference Time Point	Char	(STENRF)

STENRF (Relation to Reference Period)

NCI Code: C66728, Codelist extensible: No

C66728	STENRF			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C38008	AFTER		The time period following a point or another period of time. (NCI)	Post
C25629	BEFORE		Earlier in time or order. (NCI)	Prior
C25456	COINCIDENT		Occurring or operating at the same time.	Concurrent
C25490	DURING		At some point in a given period of time. (NCI)	During
C49640	DURING/AFTER		Within a certain period of time or after a certain point or period in time. (NCI)	During or After
C53279	ONGOING	Continuous	Remain in force or carry on without letup; keep or maintain in unaltered condition; exist in time or space without stop or interruption. (NCI)	Continue
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

SDTM uses STENRF terminology and rules from SDTMIG 4.4.7

SDTMIG 4.4.7 Rules

MHENRF	End Relative to Reference Period	Char	(STENRF)
MHENRTPT	End Relative to Reference Time Point	Char	(STENRF)

STENRF (Relation to Reference Period)

NCI Code: C66728, Codelist extensible: No

C66728	STENRF			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C38008	AFTER		The time period following a point or another period of time. (NCI)	Post
C25629	BEFORE		Earlier in time or order. (NCI)	Prior
C25456	COINCIDENT		Not used for --STRF or --ENRF	Concurrent
C25490	DURING		At some point in a given period of time. (NCI)	During
C49640	DURING/AFTER		Within a certain period of time or after a certain point or period in time. (NCI)	During or After
C53279	ONGOING		Not used for --STRF or --ENRF	Continue
C17998	UNKNOWN	U;UNK;Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

Allowable values for --STRF are "BEFORE", "DURING", "DURING/AFTER", "AFTER", and "U" (for unknown). Although "COINCIDENT" and "ONGOING" are in the STENRF codelist, they describe timing relative to a point in time rather than an interval of time, so are not appropriate for use with --STRF variables. It would be unusual for an event or intervention to be recorded as starting "AFTER" the Study Reference Period, but could be possible, depending on how the Study Reference Period is defined in a particular study.

Allowable values for --ENRF are "BEFORE", "DURING", "DURING/AFTER", "AFTER" and "U" (for unknown). If --ENRF is used, then --ENRF = "AFTER" means that the event did not end before or during the Study Reference Period. Although "COINCIDENT" and "ONGOING" are in the STENRF codelist, they describe timing relative to a point in time rather than an interval of time, so are not appropriate for use with --ENRF variables.

CDASH vs. SDTM - Collected Dosing Information

- CDASH allows flexibility
  - Collecting doses as both numeric and non-numeric values in the same field,
    - More user friendly than having one field for numeric values and another one for non-numeric
    - --DSTXT functions as a “catch-all” collection field
    - Post collection programming splits numeric values out to --DOSE and non-numeric values to --DOSTXT in SDTM
    - Depending on what is actually collected, you may have to split out other concepts (unit, formulation, route)

Were any concomitant medications taken?	☒ Yes ☐ No
Medication	Aspirin
Dose CMDSTXT	One or two 82 mg pills each day

CDASH vs. SDTM - Collected Dosing Information

Were any concomitant medications taken?	☐ Yes ☐ No
Medication	
Dose CMDSTXT	82 100-200
Dose Unit	[UNIT]
Dose Frequency	[FREQ]
Formulation	[FRM]
Route of Administration	[ROUTE]
Start Date	
End Date	
Ongoing	☐ Yes ☐ No

Even if you are collecting more information, and providing a clear structure for units, frequency, etc., it's still a good idea to use only a single field for DOSE.

If you limit it to numeric (only) values, you can use CMDOSE.

If you do not limit it to numeric values, consider using the CDASH CMDSTXT variable.

Data Collection vs. SDTM Tabulations

- CDASH / EDC

- A different set of questions, measurements and tests may be necessary for each study
- New tests are being developed all the time, and they each need a unique name
- In general, EDC systems require a unique variable name for each question, test or measurement being collected in the EDC screen
- These attributes of data collection make it necessary for EDC to handle denormalized, horizontal data

- SDTM Review Datasets

- SDTM has been “normalized” to make it more predictable for reviewers and to make it easier for software systems to consume the data
- SDTM Findings Observation Class is a vertical structure, meaning it has the same set of variables no matter which tests or measurements are being done for a particular study.

Vertical vs. Horizontal

- These words refer to the structure of the resulting dataset.

CDASHIG

SYSBP	DIABP	PULSE	TEMP	WEIGHT	HEIGHT
154	44	72	34.7	90.5	157
152	48		36.2		
95	44				

Horizontal

Horizontal: The more tests you have, the WIDER the dataset will be.

SDTMIG

VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU
SYSBP	Systolic Blood Pressure	Sitting	154	mmHg
SYSBP	Systolic Blood Pre	Sitting	152	mmHg
DIABP	Dia B Pre		4	mmHg
DIABP	Dia B Pre		8	mmHg
PULSE	Puls		2	beats/min
TEMP	Temp		.7	C
TEMP	Temp		.2	C
WEIGHT	W		.5	kg
HEIGHT	Height	Standing	157	cm
SYSBP	Systolic Blood Pressure	Sitting	95	mmHg
DIABP	Diastolic Blood Pressure	Sitting	44	mmHg

Vertical

Vertical: The more tests you have, the LONGER the dataset will be (more rows).

Normalized vs. De-normalized

- These words refer to the contents of the resulting dataset.

De-normalized: Unpredictable set of (tests) variables

SYSBP	DIABP	PULSE	TEMP	WEIGHT	HEIGHT
154	44	72	34.7	90.5	157
152	48		36.2		

SYSBP	DIABP	PULSE	TEMP	WEIGHT	HEIGHT	RESP
154	44	72	34.7	90.5	157	14
152	48		36.2			11
95	44					12

SYSBP	DIABP	PULSE	TEMP	WEIGHT
154	44	72	34.7	90.5
152	48		36.2	
95	44			

Normalized: Predictable set of variables

VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU
SYSBP	Systolic Blood Pressure	Sitting	154	mmHg
SYSBP	Systolic Blood Pressure	Sitting	152	mmHg
DIABP	Diastolic Blood Pressure	Sitting	44	mmHg
DIABP	Diastolic Blood Pressure	Sitting	48	mmHg
PULSE	Pulse Rate	Sitting	72	beats/min
TEMP	Temperature		34.7	C
TEMP	Temperature		36.2	C
WEIGHT	Weight	Standing	90.5	kg
HEIGHT	Height	Standing	157	cm
SYSBP	Systolic Blood Pressure	Sitting	95	mmHg
DIABP	Diastolic Blood Pressure	Sitting	44	mmHg

CDASH vs. SDTM - De-normalized vs. Normalized

Date VSDTC VSDAT	__/___/____
Time VISTIM VISTIM	__:__
Temperature VSORRES WHERE VSTESTCD = "TEMP" TEMP_VSORRES	___.__
Temperature Unit VSORRESU WHERE VSTESTCD = "TEMP" TEMP_VSORRESU	o C o F
Respiratory Rate VSORRES WHERE VSTESTCD = "RESP" RESP_VSORRES	___
Respiratory Rate Unit VSORRESU WHERE VSTESTCD = "RESP" RESP_VSORRESU	breaths/min
Systolic Blood Pressure VSORRES WHERE VSTESTCD = "SYSBP" SYSBP_VSORRES	___
Systolic Blood Pressure Unit VSORRESU WHERE VSTESTCD = "SYSBP" SYSBP_VSORRESU	mmHg
Diastolic Blood Pressure VSORRES WHERE VSTESTCD = "DIABP" DIABP_VSORRES	___
Diastolic Blood Pressure Unit VSORRESU WHERE VSTESTCD = "DIABP" DIABP_VSORRESU	mmHg

EDC: One variable per question or test

ABC	VS	ABC-001-001	1	SYSBP	Systolic Blood Pressure	Sitting	154	mmHg
ABC	VS	ABC-001-001	2	SYSBP	Systolic Blood Pressure	Sitting	152	mmHg
ABC	VS	ABC-001-001	3	DIABP	Diastolic Blood Pressure	Sitting	44	mmHg
ABC	VS	ABC-001-001	4	DIABP	Diastolic Blood Pressure	Sitting	48	mmHg
ABC	VS	ABC-001-001	5	PULSE	Pulse Rate	Sitting	72	beats/min
ABC	VS	ABC-001-001	6	TEMP	Temperature		34.7	C
ABC	VS	ABC-001-001	7	TEMP	Temperature		36.2	C
ABC	VS	ABC-001-001	8	WEIGHT	Weight	Standing	90.5	kg
ABC	VS	ABC-001-001	9	HEIGHT	Height	Standing	157	cm
ABC	VS	ABC-001-001	10	SYSBP	Systolic Blood Pressure	Sitting	95	mmHg
ABC	VS	ABC-001-001	11	DIABP	Diastolic Blood Pressure	Sitting	44	mmHg
ABC	VS	ABC-001-001	12	TEMP	Temperature		97.16	F

SDTM: One record per result

2.2.3 The Findings Observation Class

Table 2.2.3.1 Findings—Topic and

Variable Name	Variable Label
--TESTCD	Short Name of Measurement, Test, or Exam
--TEST	Name of Measurement Test, or Exam
--MODIFY	Modified Term
--TSTDTL	Measurement, Test, or Examination Detail
--CAT	Category
--POS	Position of Subject During Observation
--BODSYS	Body System or Organ Class
--ORRES	Result or Finding in Original Units
--ORRESU	Original Units
--STRESC	Result/Finding Standard Units
--STRESU	Standard Units
--STNRLO	Normal Range Lower Limit-Standard Units
--STNRHI	Normal Range Upper Limit-Standard Units

SDTM

6.3.17 Vital Signs

VS – Description/Overview

A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight.

VS – Specification

vs.xpt, Vital Signs — Findings, Version 3.3. One record per vital sign measurement per time point per visit per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req
USU		Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name	Req
VSTEST	Vital Signs Test Name	Ch				
VSCAT	Category for Vital Signs	Ch				
VSSCAT	Subcategory for Vital Signs	Ch				
VSPOS	Vital Signs Position of Subject	Ch				
VSORRES	Re...					
VSORRESU	Or...					
VSSTRESC	Ch... Re... Fo...					
VSSTRESN	Nu... Re... St...					
VSSTRESU	St...					
VSSTAT	Completion Status	Ch				
VSREASND	Reason Not Performed	Ch				

SDTMIG

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt
Findings	VS	Denormalized	Horizontal-Example	1	TEMP_VSORRES	Temperature	Result of the vital signs measurement as originally received or collected.	What was the result of the temperature measurement?	Temperature
Findings	VS		Horizontal-Example	2	TEMP_VSORRESU	Temperature Unit	The unit of the result as originally received or collected.	What was the unit of the temperature measurement?	Temperature Unit
Findings	VS			3	TEMP_VSCLSIG	Temperature Clinical Significance	An indication whether the temperature result was clinically significant.	Was the temperature result clinically significant?	Temperature Clinically Significant
					RESP_VSORRES	Respiratory Rate	Result of the vital signs measurement as originally received or collected.	What was the result of the respiratory rate measurement?	Respiratory Rate
					RESP_VSORRESU	Respiratory Rate Unit	The unit of the result as originally received or collected.	What was the unit of the respiratory rate measurement?	Respiratory Rate Unit
				6	RESP_VSCLSIG	Respiratory Rate Clinical	An indication whether the respiratory rate result was clinically significant.	Was the respiratory rate result clinically significant?	Respiratory Rate Clinically Significant

CDASHIG

SDTM/IG results are normalized / vertical: Variable Name/Label always the same

CDASH allows the use of Controlled Terminology from --TESTCD code lists to create test-specific, denormalized/horizontal **variable** names/labels.

Example findings d

2.2.3 The Findings Observation Class

Table 2.2.3.1 Findings—Topic and

Variable Name	Variable Label
--TESTCD	Short Name of Measurement, Test, or Exam
--TEST	Name of Measurement, Test, or Exam
--MODIFY	Modified Term
--TSTD	Measurement, Test, or Examination Detail
--CAT	Category
--ORNH	Range Upper Original Units
--ORRE	ference Result in Original Units
--STRES	Result or Finding in Standard Format
--STRESN	Numeric Result/Finding in Standard Units
--STRESU	Standard Units
--STNRLO	Normal Range Lower Limit-Standard Units
--STNRHI	Normal Range Upper Limit-Standard Units

6.3.17 Vital Signs

VS – Description/Overview

A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight.

VS – Specification

vs.xpt, Vital Signs — Findings, Version 3.3. One record per vital sign measurement per time point per visit per subject, Tabulation.

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Req
USU		Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
VSSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
VSGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
VSSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined in the sponsor's operational database.	Perm
VSTESTCD	Vital Signs Test Short Name	Char	(VSTESTCD)	Topic	Short name of the measurement, test, or examination described in VSTEST. It can be used as a column name	Req
VSTEST	Vital Signs Test Name	Ch				
VSCAT	Category for Vital Signs	Ch				
VSSCAT	Subcategory for Vital Signs	Ch				
VSPOS	Vital Signs Position of Subject	Ch				
VSORRES	Result or Finding in Original Units	Ch				
VSORRESU	Original Units	Ch				
VSSTRESC	Character Result/Finding in Std Format	Ch				
VSSTRESN	Numeric Result/Finding in Standard Units	Nu				
VSSTRESU	Standard Units	Ch				
VSSTAT	Completion Status	Ch				
VSREASND	Reason Not Performed	Ch				

SDTMIG

SDTM

SDTM/IG tests are normalized / vertical: Variable Name / Label always the same

Observation Class	Domain	Data Collection Scenario	Implementation Options	Order Number	CDASHIG Variable	CDASHIG Variable Label	DRAFT CDASHIG Definition	Question Text	Prompt
Findings	VS	Denormalized	Horizontal-Example	1	TEMP_VSORRES	Temperatu	Result of the vital signs measurement as originally eived or collected.	What was the result of the temperature measurement?	Temperature
Findings	VS	Denormalized	Horizontal-Example	2	TEMP_VSORRESU	Temperatu	f the result as eived or collected.	What was the unit of the temperature measurement?	Temperature Unit
Findings	VS	Denormalized	Horizont Example			he nically		Was the temperature result clinically significant?	Temperature Clinically Significant
Findings	VS	Denormalized	Horizont Example			iginally cted.		What was the result of the respiratory rate measurement?	Respiratory Rate
Findings	VS	Denormalized	Horizontal-Example	5	RESP_VSORRESU	Respirator Unit	of the result as ally received or collected.	What was the unit of the respiratory rate measurement?	Respiratory Rate Unit
Findings	VS	Denormalized	Horizontal-Example	6	RESP_VSCLSIG	Respirator te Clinical	An indication whether the respiratory rate result was clinically significant.	Was the respiratory rate result clinically significant?	Respiratory Rate Clinically Significant

CDASHIG

CDASH allows the use of Controlled Terminology from --TEST code lists to create test-specific Question Text or Prompts

Example findings domain

Pattern-based Variable Names

Balancing Data Collection Needs with Programming Needs

Why use pattern-based variable names?

- Data collection needs:
  - May want to “mix” domains on a single CRF
  - Need to collect the specific tests / measurements that are needed for the study

- SDTM programming needs:
  - Predictability of incoming data increases efficiency:
    - Values that are in an SDTM variable - you should be able to assume that you don’t have to transform these (possibly change case)
    - Values that are in a standard CDASH variable - you should be able to write standard transformation programs - such as combining --DAT and --TIM values and re-formatting as ISO 8601
  - Mitigate unpredictability and write reusable programming as much as possible

What is pattern-based variable naming?

- Create a pattern that can be used for all variables
  - CDASHIG example:
  - Example pattern is [--TESTCD_ targetVariable]

- This pattern is okay, but it has limitations
  - Primarily works with Findings class data
  - Have to extract the domain code from the variable (not all variables include a domain code prefix) or from the Form OID or other source

[VSTESTCD]_VSORRES	Vital Signs Result
[VSTESTCD]_VSORRESU	Vital Signs Unit
[VSTESTCD]_VSCLSIG	Vital Signs Clinical Significanc

CDASHIG Variable	CDASHIG Variable Label
TEMP_VSORRES	Temperature
TEMP_VSORRESU	Temperature Unit
TEMP_VSCLSIG	Temperature Clinical Significance
RESP_VSORRES	Respiratory Rate
RESP_VSORRESU	Respiratory Rate Unit
RESP_VSCLSIG	Respiratory Rate Clinical Significance

Pattern-based Variable Names

- Patterns can be useful for **all** variable names
  - Not just for Findings class variables
- Pattern-based variables allow us to handle data collection needs
  - e.g., mix domains on a single CRF
  - collect study-specific tests/measurements
- Pattern-based variables address SDTM programming needs
  - Creates predictability of incoming data
  - Allows use of more standardized conversion programming

- Is there a pattern that will work for ALL variables?
  - Let’s find out…

Recommended Pattern Based Variable Naming Convention

[domainCode_ targetVariable(_optionalPrespecifiedTopicValue)]

- Start each variable name with the 2-character domain code
- Next, add in the target variable name
- Finally, as an OPTION, add in the value for the Topic Variable in that record in the case where the value is “pre-specified” for the record.

Pattern based programming:

- Scan the characters up to the first underscore, find or create that domain
- Scan the characters up to the end (or second underscore), find or create that variable and populate the target variable with the value that was collected
- If there is a second underscore, find or populate the Topic Variable for the record with this value

Use Case: Mixing questions from multiple domains on a single CRF

[domainCode_ targetVariable(_optionalPrespecifiedTopicValue)]

- DM_SEX
- DM_AGE
- DM_AGEU
- VS_VSORRES_HEIGHT
- VS_VSORRESU_HEIGHT
- VS_VSORRES_WEIGHT
- VS_VSORRESU_WEIGHT

Use Case: Unpredictability of tests from study to study, or visit to visit

[domainCode_ targetVariable(_optionalPrespecifiedTopicValue)]

- Example for tests that may be different from study to study (or from visit to visit):
  - VS_VSORRES_HEIGHT
  - VS_VSORRESU_HEIGHT
  - VS_VSORRES_TEMP
  - VS_VSORRESU_TEMP
  - VS_VSORRES_SYSBP
  - VS_VSORRES_DIABP
  - VS_VSORRES_RESP
  - VS_VSORRES_PULSE

Recommended Pattern Based Variable Names

[domainCode_ targetVariable(_optionalPrespecifiedTopicValue)]

- LIMITATION of this pattern
  - If the **topicValue** has multiple words (e.g., Informed Consent) this would require a different approach to variable naming and programming
    - Common use cases could be handled with a standard mapping table, e.g., Informed Consent could be abbreviated to ICF in the variable name (and other abbreviations and mappings could be created study by study as needed)
    - DS_DSSTDAT_ICF
    - MH_MHOCCUR_T2DM

topicValue Abbreviation in Variable	topicValue in SDTM Domain
ICF	Informed Consent
T2DM	Type 2 Diabetes Mellitus

Non-Standard Variables

Strive for consistency

What is a “Non-Standard” Variable?

- A concept that is not part of the Model (SDTM)
  - i.e., the concept does not have a variable defined already
- A concept that has been defined and published in CDASH, but not in SDTM
  - May also be in the SDTMIG Appendix C2
- A concept that is defined for use in a different SDTM Observation Class
  - E.g., Using a Findings class-only variable in an Events class dataset

Resources for Creating Non-Standard Variables

- First, look at variables that are already available:
  - CDASH Model and CDASH IG
    - Look in the other Observation Classes for an appropriate variable
  - Look at some commonly used NSVs in SDTMIG Appendix C2
  - Look in the CDISC Therapeutic Area User Guides
- Second:
  - Look at the Variable Naming Fragments (SDTMIG Appendix D)
  - Construct new variable names from these fragments as much as possible
  - Create and document additional fragments that you need
- Third:
  - Look at other published sources, including controlled terminology

Good Practices for Creating Non-Standard Variables

- Create a list of “allowed” variables for all SDTMIG domains (i.e., which variables are allowed to be brought into a domain from the SDTM)
  - Avoid a common mistake of putting standard variables into SUPP--
- Keep an organization-wide list of all NSVs (perhaps with references to which programs/indications/therapies/studies use them)
  - Re-use NSVs consistently within your own studies
- Use NSVs that have been published in CDISC documentation (e.g., TAUGs, IG examples)
- Review new SDTM and CDASH publications for new variables that might replace your NSVs

Summary

Begin with the end in mind

Summary

- Begin with the end in mind:
  - Use SDTM Variables when the value you can collect is exactly the same as the value that will populate the SDTM variable
  - Use standardized CDASH variables when you have to transform a collected value for SDTM
  - Use a standard variable naming pattern to support standard transformation programming
  - Manage your non-standard variables in a way that supports consistency and standard transformations to SDTM
- Upfront planning will save you many hours… weeks… months when you are preparing an FDA submission

Q&A

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