CDISC Overview

LPO Webinar 7 March 2019



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

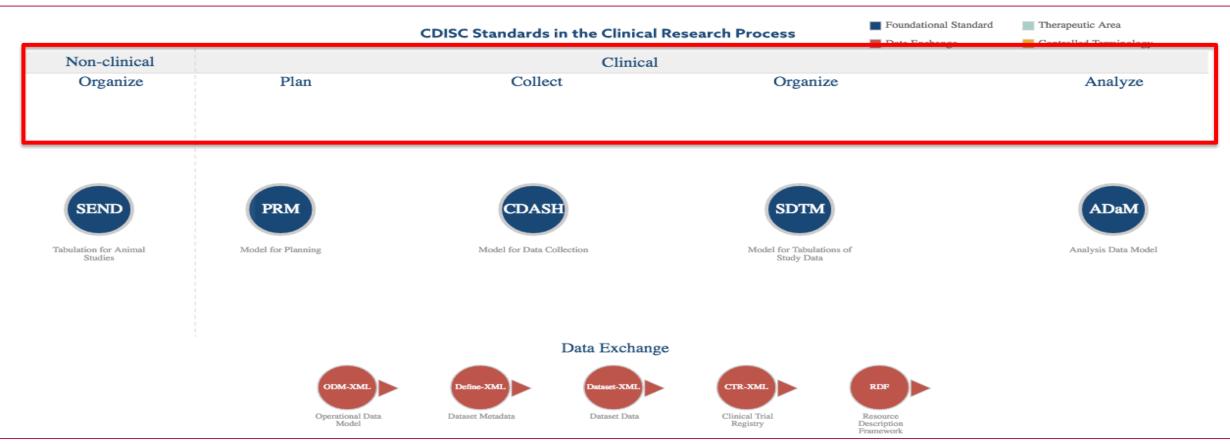
- Describe the CDISC organization and purpose
- Demonstrate finding and downloading the standards
 - Create an online account
 - Access the CDISC Library
- Explain the high level principles of CDASH, SDTM and Controlled Terminology (CT) standards
- Demonstrate the use of the CDISC standards in the NCI GLIB ALS

CDISC Organization

- Standards development began in 1997 by volunteers from industry and FDA
- Funded and incorporated as non-profit organization (2000)
- Robust standards development
 - 100s of volunteer SMEs
 - Standards development process controlled by SOP
 - Global, open, consensus-based
 - Input from 1000s of stakeholders during public review

CDISC Standards - Supports the Whole Clinical Research Process

www.cdisc.org/standards

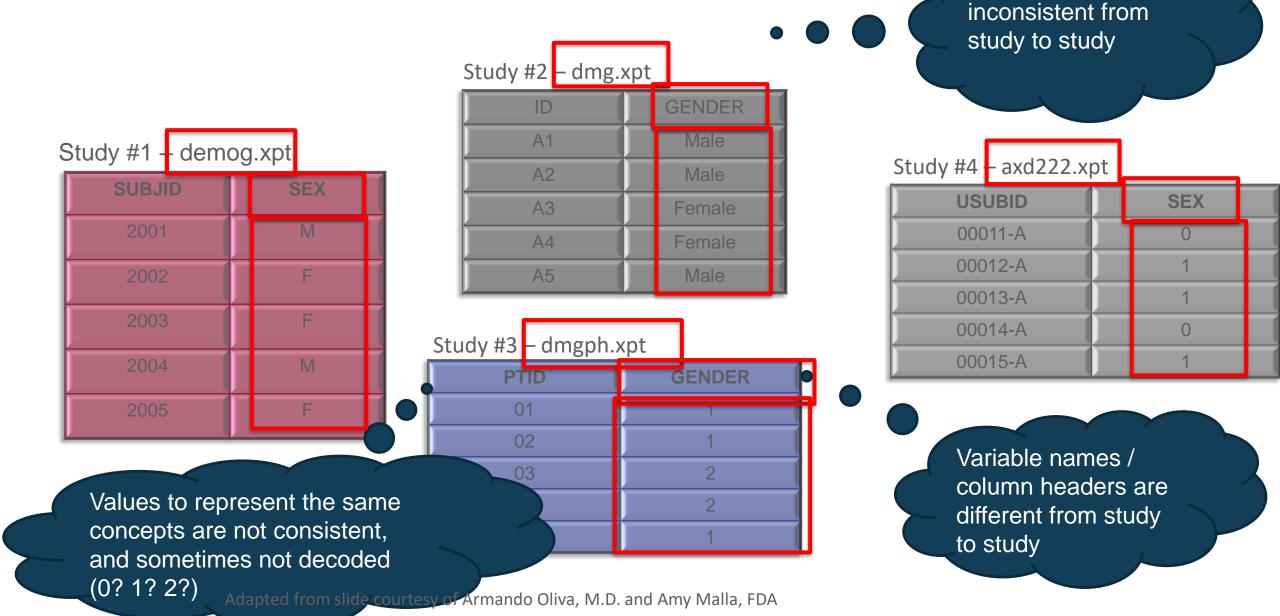


Accessing the Standards

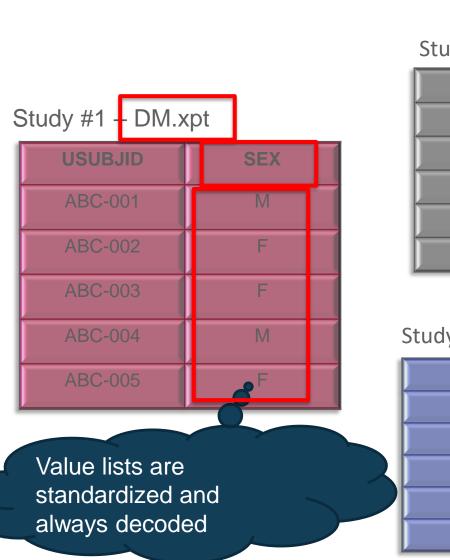
- Navigate to <u>www.cdisc.org</u>
- Create a user account
 - Use your NIH email (so you have access to Member areas)
- Log in
- Access standards from the public web pages
- Access additional files from the CDISC Library and Archives
- Access Controlled Terminology directly from NCI EVS

- Defined, consistently formatted data concepts and structures increases predictability, understanding and usability of data for all stakeholders, with reduced need for re-training
- Standardized data supports a more efficient process throughout the data lifecycle including reusability in programming (study databases, edit checks, derivations, tabulations, analysis),
- Standardized data supports analytics-based oversight, data aggregation, data mining
- Global standard "everyone" is using it facilitates more effective collaboration
- CDISC standards are useful beyond original use case (interventional, regulatory)

Without Standards- Unnecessary Variability



Dataset names are



Study #2 – DM.xp1	t
USUBJID	SEX
DEF-001	M
DEF-002	М
ABC-001	М
DEF-004	F
DEF-005	М

 Study #3 - DM.xpt

 USUBJID
 SEX

 GHI-001
 M

 GHI-002
 M

 GHI-003
 F

 GHI-004
 F

 GHI-005
 M

Adapted from slide courtesy of Armando Oliva, M.D. and Amy Malla, FDA

With Standards - Predictable Format/ Organization

Datasets are defined, with standardized names.

Study #4 – DM.xpt	
USUBJID	SEX
JKL-011	М
JKL-012	F
GHI-003	F
JKL-014	М
JKL-015	F

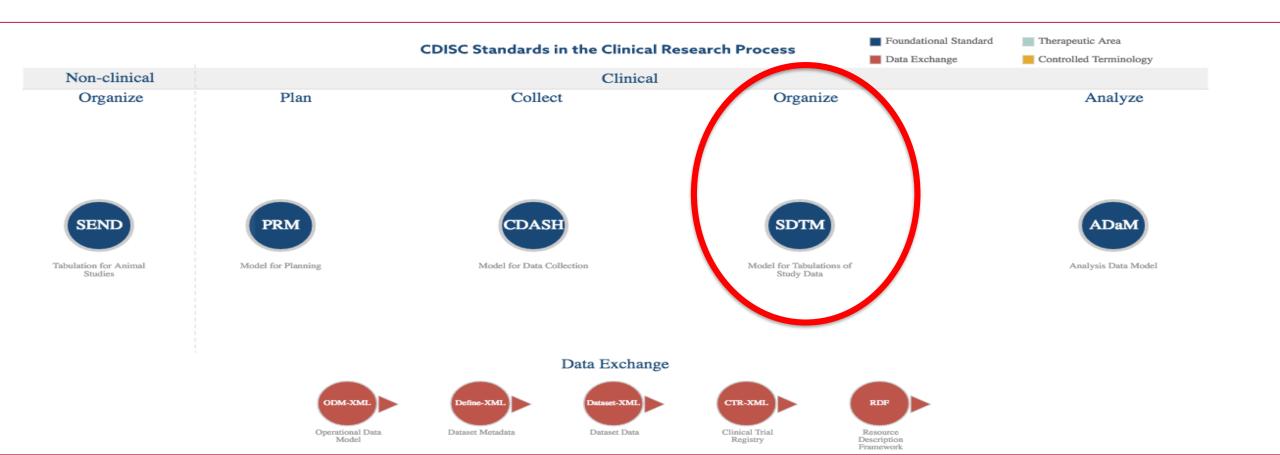
Variables are defined, with standardized names, formats, data types, etc.

- Required by FDA:
 - SEND, SDTM, ADaM, Define-XML and Controlled Terminology
 - All NDAs, BLAs and ANDAs with study start dates after 16 December 2016 https://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm
- Required by PMDA:
 - SDTM, ADaM, Define-XML and Controlled Terminology
 - Started pilot in October 2016 for NDAs

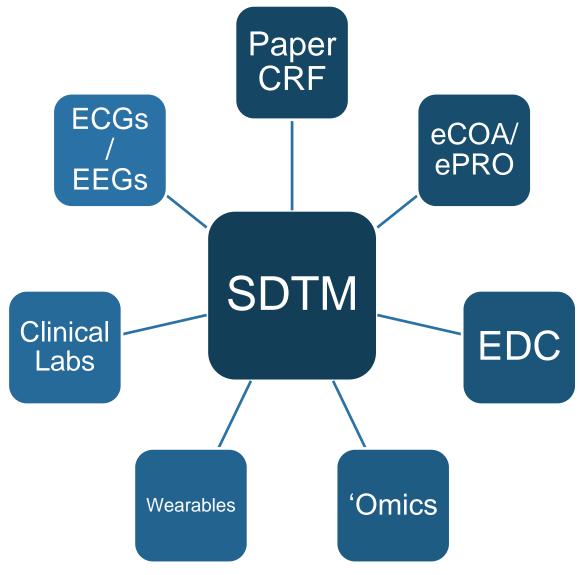
https://www.pmda.go.jp/english/review-services/reviews/advanced-efforts/0002.html

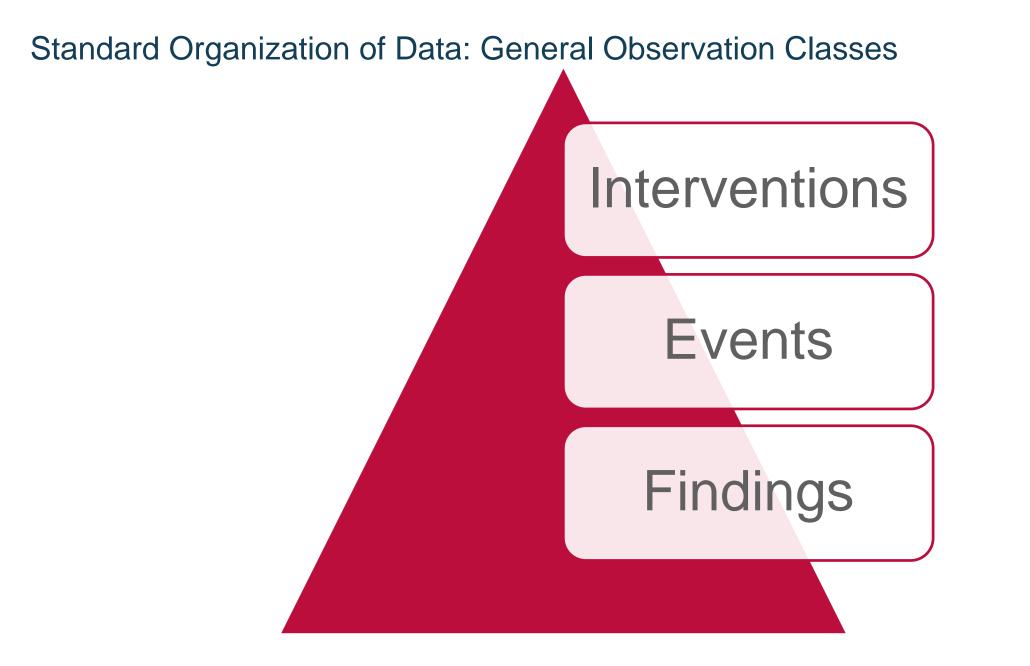
- Recommended and used by other global regulatory authorities
- Also used by researchers in other types of research (e.g., academic research, public health, observational trials)

CDISC Standards - SDTM for Predictable Data Organization to Support Review



SDTM Data Sources





Data about things the study participant takes into their body.

-- means this is Modellevel, generic, "**root**" variables

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	Туре	Role	Description
				Topic Variable
TRT	Name of Treatment	Char	Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.
				Qualifier Variables
MODIFY	Modified Treatment	Char	Synonym Qualifier of	If the value forTRT is modified for coding purposes, then the modified text is placed here.
	Name	Char	TRT	If the value forrights modified for couling 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 ofCAT values.
PRESP	Pre-specified	Char	Variable Qualifier of TRT	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.
OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.
STAT	Completion Status	Char	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
REASND	Reason Not Done	Char	Record Qualifier	Reason not done. Used in conjunction withSTAT when value is "NOT DONE".
INDC	Indication	Char	Record Qualifier	Denotes the indication for the intervention (e.g., why the therapy was taken or administered).
CLAS	Class	Char	Variable Qualifier of TRT	Class for a medication or treatment, often obtained from a coding dictionary.
CLASCD	Class Code	Char	Variable Qualifier of TRT	Used to represent code forCLAS.
DOSE	Dose	Num	Record Qualifier	Amount ofTRT given. Not populated whenDOSTXT is populated.
DOSTXT	Dose Description	Char	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated whenDOSE is populated.
DOSU	Dose Units	Char	Variable Qualifier of DOSE,DOSTXT or DOSTOT	Units forDOSE,DOSTOT, orDOSTXT. Examples: "ng", "mg", "mg/kg".
DOSFRM	Dose Form	Char	Variable Qualifier of DOSE,DOSTXT or DOSTOT	Dose form for the treatment. Examples: "TABLET", "CAPSULE".
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 ofTRT using the units inDOSU. 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 inTRT.
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",

Data about things that happen to the participant that aren't planned interventions or measurements/tests

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

Results from planned measurements and tests

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	Туре	Role	Description
				Topic Variable
TESTCD	Short Name of Measurement, Test, or Exam	Char	Торіс	Short character value forTEST used as a column name when converting a dataset from a vertical format to a horizontal format. The short value can be up to 8 characters. Examples: "PLAT", "SYSBP", "RRMIN", "EYEEXAM".
				Qualifier Variables
TEST	Name of Measurement, Test, or Exam	Char	Synonym Qualifier of TESTCD	Long name ForTESTCD. Examples: Platelets, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
MODIFY	Modified Term	Char	Synonym Qualifier of ORRES	If the value ofORRES is modified for coding purposes, then the modified text is placed here.
TSTDTL	Measurement, Test, or Examination Detail	Char	Variable Qualifier of TESTCD andTEST	Further description ofTESTCD andTEST. Example: "The percentage of cells with +1 intensity of staining" when MITEST = "Thyroid Transcription Factor 1".
CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY", "HAMD 17", "SF36 V2.0 ACUTE", "EGFR MUTATION ANALYSIS".
SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization ofCAT values. Example: "WBC DIFFERENTIAL".
POS	Position of Subject During Observation	Char	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".
BODSYS	Body System or Organ Class	Char	Record Qualifier	Body System or Organ Class that is involved for a finding from the standard hierarchy for dictionary-coded results. Example: MedDRA SOC.
ORRES	Result or Finding in Original Units	Char	Result Qualifier	Result of the measurement or finding as originally received or collected. Examples: "120", "<1", "POS".
ORRESU	Original Units	Char	Variable Qualifier of ORRES andORREF	Unit forORRES andORREF. Examples: "in", "LB", "kg/L".
ORNRLO	Normal Range Lower Limit-Original Units	Char	Variable Qualifier of ORRES	Lower end of normal range or reference range for results stored inORRES.
ORNRHI	Normal Range Upper Limit-Original Units	Char	Variable Qualifier of ORRES	Upper end of normal range or reference range for results stored inORRES.
ORREF	Reference Result in Original Units	Char	Variable Qualifier of ORRES	Reference value for the result or finding as originally received or collectedORREF uses the same units asORRES, if applicable. Examples: value from predicted normal value in spirometry tests.
STRESC	Result or Finding in Standard Format	Char	Result Qualifier	Contains the result value for all findings, copied or derived fromORRES 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 inSTRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" inORRES and these results effectively have the same meaning, they could be represented in standard format inSTRESC 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 fromSTRESCSTRESN 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 forSTRESC,STRESN,STREFC, andSTREFN. 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).

Organize all data by "Topic": Domains

• Root variables from one Class in the SDTM (Model) are used to form a topic-based Domain

2.2.1 The Interventions Observation Class

-Topic and Qualifier Variables-One Record per Constant-I

• Topic/Domain-specific 2 character codes are prefixed to the root variables (AE for Adverse Events, VS for Vital Signs)



	Variable Label		Туре	Role		Descriptio	n			
_								Topic Variable		
	Name of Treat	ment	Char	Topic		The topic	for the	e intervention observation	n, usually the verbatim name of the treatment, drug, medicine, or therapy given	
						during the	dosin	g interval for the observa Qualifier Variables	tion.	
FY	Modified Treat	ment	Char	Synonym Q	ualifier of	If the valu	e for		g purposes, then the modified text is placed here.	
D	Name Standardized		Char	TRT Synonym Q	until an of	Chandrash		distances destroid service	of the topic variable,TRT, or the modified topic variable (MODIFY), if applicable.	
"	Standardized Treatment Nar	ne	Char	-TRT	uarmer of	Equivalent	ted or to the	dictionary-derived name (e generic drug name in W	or the topic variable,	
_						dictionarie				
)	Mood Category		Char	Record Qual Grouping Q		Mode or o Used to d	onditi efine a	on of the record (e.g., "SC Lotegory of topic-variable	HEDULED", "PERFORMED"). e values.	
	Subcategory		Char	Grouping Q		Used to d	efine a	a further categorization of	CAT values.	
·	Pre-specified		Char	Variable Qua	difier of	Used whe	n a sp	ecific intervention is pre-s	specified on a CRF. Values should be "Y" or null.	
R	2.2.2 T	he	Ever	nts Obs	serva	tion C	las	s		
-	Table 2.2.2.	1 Eve	nts—To	pic and Qu	alifier V	ariables—C	ne R	ecord per Event		
D	Variable	Varia	ble Lab	el	Type F	Role	D	escription		
-							_		Topic Variable	
-		Repo	rted Ter	m	Char 1	lopic	Te		observation, which is the verbatim or pre-specified name of the event. salifier Variables	
	\mathbf{a}			orted Term		aynonym Qualifier of	lf		odified for coding purposes, then the modified text is placed here.	
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an -		-	stLevel	Term Code		/ariable Qualifier of	M	ledDRA Lowest Level Ten	m code.	
					-	-UUT				
Q	DECOD	Dictio	onary-D	erived Term	0	ynonym Qualifier of -TERM	D	ictionary or sponsor-defi pplicable. Equivalent to th	ned derived text description of the topic variable,TERM, or the modified topic variable re Preferred Term (PT in MedDRA).	(MODIFY), if
TC	PTCD	Prefe	rred Ter	m Code	Num V	/ariable	м	ledDRA Preferred Term o	ode.	
3M						Qualifier of -DECOD				
	HLT	High	Level Te	trm		/ariable Dualifier of	М	ledDRA High Level Term I	from the primary path.	
E						Juainer of TERM				
-	HILTCD	Hig	2.2	3 The	Findi	inas O	bse	ervation Class	5	
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	CAT CAT SCAT REASND	Hig Cor Cat	Varial Name TEST TE	Ale Varia Varia Shor Measa Dear Nam Nam Nam Nam Durir Dur	the Labe t Name o uurement e of Meaa e of Meaa E Dam Common s System at common s System at common at Common s System at Common at Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original Range -Original -Origina	First, or Surement, Test, or tail test, or tail bject vation or Organ ing in toupper Units Upper Units units ing in	Type Char Char Char Char Char Char Char Char	Rele Topic Topic Systemy Roualifier of Topic Variable Qualifier of Topic Qualifier Coccupy Qualifier Grouping Qualifier Grouping Qualifier Record Qualifier Record Qualifier Record Qualifier Record Qualifier Record Qualifier Anisola Qualifier Anisola Qualifier Anisola Qualifier Anisola Qualifier Anisola Qualifier Coccupy Qualifier Cocc	Description Taple Vortable Topic Vor	1, "YESIAM". (1) RE Duration, by: Examination, add Inter. Harring of ataling" when MITIST + HARDSS, "CLEMENTER", 14440 17, 44 MINORY, "JITTING". For dictionary coded results. 207, "47, "YOS". Inter same units an - CORES, # Inter same units an - CORES, # Inter same units an - CORES, # Inter same units an - CO
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	CAT CAT SCAT REASND	Hig Cor Cat	Varial Name -TEST -BOE -BOE -ORF -ORF -ORF -ORF -STRI	Je Variation Short Maap Earr Maap Earr Maap Posto Maap Short Maap Posto Maap String Bach String String String String	ble Labe IN Name o IN NAME O I	(, Test, or ; Test, or	Type Char Char Char Char Char Char Char Char	Refe Topic Topic Synowym Qualifier of 	Description Tech Voltable Tech	If: YTERXAM*. (1) RE Duration, by: Examination. (a) Bit Duration, by: Examination. (a) Bit Duration, by: Examination. (b) Bit Duration, by: Bit
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domain mo		uides.	See Sect	y domain based on one of the 3 general observation classes, except where restricted in the assumptions for the stan ione 2.2.6-2.11 for additional guidance relating to special-purpose domains.
Variable	Variable Label			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, Tital Arms).
EPOCH	Epoch	Char		Epoch associated with the start date or start date and time of the observation, or the date/time of collection if start date/time is collected (see Section 3.1.2, Tital 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 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 hur 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 hum clinical trials.
-DIC	Date/Time of Collection	Char	ISO 8601	Collection date and time of an observation.
-SIDIC	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 RESTDTC 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 schedu 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.
-NOMLEL	Label for Nominal Study Day	Char		A label for a given value ofNOMDY, within a domain, as presented in the study report. Not to be used with human clinical trials
-RPDY	Actual Repro Phase Day of Observation	Num		The actual day within the Reproductive Phase on which the observation occurred. Expressed as an integer. Not to be used with human clinical trials.
-RPSTDY	Actual Repro Phase Day of Obs Start	Num		The actual day within the Reproductive Phase of the start of the observation. Expressed as an integer. Not to be used with huma 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	Collected duration of an event, intervention, or finding. Used only if collected on the CRF and not derived.

Order of variables: (1) Identifiers, (2) Topic, (3) Qualifiers, (4) Timing

	2.2.1 T	he Interventi	ons Obs	ervation Clas	S				
	Table 2.2.1	1 Interventions—Topic	6.1.3.1 Ex	posure					
	Variable	Variable Label	EX – Descrip	tion/Overview					
	Name	Vallable Label	An interventi	and domain that contai	ne the	dataile of a subject		to protocol-specified study treatment. Study treatment may be any intervention that is prospeci	tion
		1 1				-			lively
	TRT	Name of Treatment	detined as a t	test material within a st	udy, ai	nd is typically but n	ot always si	upplied to the subject.	
			EX - Specific	ation					
			ay yet Eyes	sure Interventions W	larria	2.2 One record n	er protocol	-specified study treatment, constant-dosing interval, per subject, Tabulation.	
	MODIFY	Modified Treatment	Variable	Variable Label		Controlled Terms,	-	CDISC Notes	Core
	DECOD	Name Standardized	Name	Variable Label	туре	Codelist or	KOIC	CDISC Notes	Core
	DECOD	Treatment Name				Format ¹			
		in cathler in family	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
	NOOD	Mood	DOMAIN	Domain Abbreviation	Char	EX	Identifier	Two-character abbreviation for the domain.	Req
		Category	USUBJID	Unique Subject	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving	Req
		Subcategory		Identifier				the product.	
		Pre-specified	EXSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
		vrence Indicator	EXGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
has been replace	d with		EXREFID	Reference ID	Char		Identifier	Internal or external identifier (e.g., kit number, bottle label, vial identifier).	Perm
 has been replace 		d Status	EXSPID	Sponsor-Defined	Char		Identifier	Sponsor-defined reference number. Perhaps pre-printed on the CRF as an explicit line identifier or defined	Perm
2-character Doma	in cod		EXLNKID	Identifier Link ID	Char		Identifier	in the sponsor's operational database. Example: Line number on a CRF Page. Identifier used to link related records across domains.	Dorm
				Link Group ID	Char		Identifier	Identifier used to link related records across domains.	Perm Perm
to make this topic-	specifi	ic X		Name of Treatment	Char	*	Topic	Name of the protocol-specified study treatment given during the dosing period for the observation.	Req
-	-		EXCAI	Category of Treatment	Char	*	Grouping	Used to define a category of EXTRT values.	Perm
for exposure to a	studv			- · ·			Qualifier	, , , , , , , , , , , , , , , , , , ,	
			EXSCAT	Subcategory of	Char	*	Grouping	A further categorization of EXCAT values.	Perm
treatments				Treatment			Qualifier		
10	H	Description Se Units	EXDOSE	Dose	Num		Record Qualifier	Amount of EXTRT when numeric. Not populated when EXDOSTXT is populated.	Exp
S S		se onits	EXDOSTXT	Dose Description	Char		Record	Amount of EXTRT when non-numeric. Dosing amounts or a range of dosing information collected in text	Perm
							Qualifier	form. Example: 200-400. Not populated when EXDOSE is populated.	
0	RM	Dose Form	EXDOSU	Dose Units	Char	(UNIT)	Variable	Units for EXDOSE, EXDOSTOT, or EXDOSTXT representing protocol-specified values. Examples: "ng",	Exp
ti ti			EVDOCEDM	D	Charles	(EDM)	Qualifier	"mg", "mg/kg", "mg/m2".	
J ■ L			EXDOSFRM	Dose Form	Cnar	(FRM)	Variable Qualifier	Dose form for EXTRT. Examples: "TABLET", "LOTION".	Exp
xample iterventions	DOSFRQ	Dosing Frequency	EXDOSFRQ	Dosing Frequency per	Char	(FREQ)	Variable	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period.	Perm
ΣŠ		per Interval	EXEOSING	Interval	Chai	(FREQ)	Qualifier	Examples: "Q2H", "QD", "BID".	reim
	DOSTOT	Total Daily Dose	EXDOSRGM	Intended Dose Regimen	Char		Variable	Text description of the intended schedule or regimen for the Intervention. Example: "TWO WEEKS ON,	Perm
		Intended Dose					Qualifier	TWO WEEKS OFF".	
Exa Inte	b o o nor 1	Regimen	EXROUTE	Route of Administration	Char	(ROUTE)	Variable	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".	Perm
		_					Qualifier		
	ROUTE	Route of	EXLOT	Lot Number	Char		Record	Lot number of the intervention product.	Perm
		Administration	EXLOC	Location of Dece	Char	(100)	Qualifier	Constitute location of administration Examples: #ADM#_#LID#	Darra
	LOT	Lot Number	EXLOC	Location of Dose Administration	Char	(LOC)	Record Qualifier	Specifies location of administration. Examples: "ARM", "LIP".	Perm
	LOC	Location of Dose	EXLAT	Laterality	Char	(LAT)	Variable	Qualifier for anatomical location further detailing laterality of the intervention administration. Examples:	Perm
	LAT	Administration		Laterancy	Cildi	(Qualifier	"LEFT", "RIGHT".	1 cmi
	LAT	Laterality	EV(D)D	Dr	C 1	-010-	1 AL		

Variable	1 Interventions—Topi Variable Label	Туре							
Name	Variable Laber	Type		ription/Overview					
TRT	Name of Treatment	Char	An interventi		ns inte	rventional activity	intended to	have diagnostic, preventive, therapeutic, or palliative effects.	
		╝──╢			Varai			ed procedure per occurrence per subject, Tabulation.	
MODIFY	Modified Treatment	Char	Variable	Variable Label		Controlled Terms,	Role	CDISC Notes	Co
DECOD	Name Standardized	Char	Name			Codelist or Format ¹			
	Treatment Name		STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Re
			DOMAIN	Domain Abbreviation	Char	PR	Identifier	Two-character abbreviation for the domain.	Re
MOOD	Mood	Char	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions	Rec
CAT	Category	Char						involving the product.	
SCAT PRESP	Subcategory Pre-specified	Char Char	PRSEQ	Sequence Number	Num		Identifier	Sequence Number to ensure uniqueness of records within a dataset for a subject. Should be assigned to be in a consistent chronological order.	Req
			PRGRPID	Group ID	Char		Identifier	Used to link together a block of related records within a subject in a domain.	Per
OCCUR	Occurrence Indicator	Char	PRSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. Example: pre-printed line identifier on a CRF or record identifier defined in the sponsor's operational database.	
STAT	Completion Status	Char	PRLNKID	Link ID	Char		Identifier	Used to facilitate identification of relationships between records.	Per
			PRI NKGRP	Link Group ID	Char		Identifier	Used to facilitate identification of relationships between records.	Per
REASND INDC	Reason Not Done Indication	Char Char	PRTRT	Reported Name of Procedure	Char		Topic	Name of procedure performed, either pre-printed or collected on a CRF.	Req
CLAS	Class	Char	PRDECOD	Standardized Procedure Name	Char	*	Synonym Qualifier	Standardized or dictionary-derived name of PRTRT. The sponsor is expected to provide the dictionary name and version used to map the terms in the external codelist element in the Define-XML document.	Perr
CLASCD	Class Code	Char	PRCAT	Category	Char	*	Grouping	If an intervention term does not have a decode value in the dictionary, then PRDECOD will be null. Used to define a category of procedure values.	Per
DOSE	Dose	Num					Qualifier		
DOSTXT	Dose Description	Char	PRSCAT	Subcategory	Char	×	Grouping	Used to define a further categorization of PRCAT values.	Per
DOSU	Dose Units	Char	PRPRESP	Pre-specified	Char	(NY)	Qualifier Variable	Used when a specific procedure is pre-specified on a CRF. Values should be "Y" or null.	Per
DOSFRM	Dose Form	Char	PROCCUR	Occurrence	Char	(NY)	Qualifier Record	Used to record whether a pre-specified procedure occurred when information about the occurrence of a	ı Per
DODITAT	DOSCIONI	Cinta	PRINDC	Indication	Char		Qualifier Record	specific procedure is solicited. Denotes the indication for the procedure (e.g., why the procedure was performed).	Per
			FRINDC	Indication	Char		Qualifier	benotes the indication for the procedure (e.g., why the procedure was performed).	Fei
DOSFRQ	Dosing Frequency per Interval	Char	PRDOSE	Dose	Num		Record Qualifier	Amount of PRTRT administered. Not populated when PRDOSTXT is populated.	Per
			PRDOSTXT	Dose Description	Char		Record	Dosing information collected in text form. Examples: "<1", "200-400". Not populated when PRDOSE is	Per
DOSTOT	Total Daily Dose	Num					Qualifier	populated.	
DOSRGM	Intended Dose Regimen	Char	PRDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for PRDOSE, PRDOSTOT, or PRDOSTXT.	Pe
	_		PRDOSFRM	Dose Form	Char	(FRM)	Variable	Dose form for PRTRT.	Pe
ROUTE	Route of	Char					Qualifier		
	Administration		PRDOSFRQ	Dosing Frequency per	Char	(FREQ)	Variable	Usually expressed as the number of doses given per a specific interval.	Pe
LOT LOC	Lot Number Location of Dose	Char Char	PRDOSRGM	Interval Intended Dose Regimen	Char		Qualifier Variable	Text description of the intended schedule or regimen for the procedure.	Pe
	Administration			_			Qualifier		4
-LAT	Laterality	Char	PRROUTE	Route of Administration	Char	(KOUTE)	Variable	Route of administration for PRTRT.	P

Example Interventions domains

		0.2.17	dverse Events					
Variable Name	Variable Label	AE - Dese	cription/Overview					
Hame		An events d	omain that contains data	desci	ribing untoward n	nedical occu	urrences in a patient or subjects that are administered a pharmaceutical product and which may no	ot
TERM	Reported Term	necessarily	have a causal relationship	with	the treatment.			
MODIEV	Modified Reported Te	AE · Spec	rification					
MODIFY	Modified Reported Te			ersion	3.3. One record	per adverse	e event per subject, Tabulation.	
LLT	Lowest Level Term	Variable Name	Variable Label	Туре	Controlled Terms, Codelist	Role	CDISC Notes	Cor
		ATU 101/10			or Format ¹	1.1		
LLTCD	Lowest Level Term Co	STUDYID	Study Identifier	Char	45	Identifier	Unique identifier for a study.	Req
		DOMAIN	Domain Abbreviation	Char	AE	Identifier	Two-character abbreviation for the domain.	Req
DECOD		USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Req
DECOD	Dictionary-Delived Te	AESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
PTCD	Preferred Term Code	AEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
PICD	Preferred Territ Code	AEREFID	Reference ID	Char		Identifier	Internal or external identifier such as a serial number on an SAE reporting form.	Perm
		AESPID	Sponsor-Defined	Char		Identifier	Sponsor-defined identifier. It may be preprinted on the CRF as an explicit line identifier or defined in the	Perm
HLT	High Level Term		Identifier				sponsor's operational database. Example: Line number on an Adverse Events page.	
רובו		AETERM	Reported Term for the Adverse Event	Char		Topic	Verbatim name of the event.	Req
HLTCD	High Level Term Code	AEMODIFY	Modified Reported Term	Char		Synonym Qualifier	If AETERM is modified to facilitate coding, then AEMODIFY will contain the modified text.	Perm
		AELLT	Lowest Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the Lowest Level Term.	Exp
HLGT	High Level Group Terr	AELLTCD	Lowest Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Lowest Level Term.	Exp
		AEDECOD	Dictionary-Derived Term	Char	MedDRA	Synonym	Dictionary-derived text description of AETERM or AEMODIFY. Equivalent to the Preferred Term (PT in	Req
HLGTCD	High Level Group Terr Code					Qualifier	MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms utilizing the external codelist element in the Define-XML document.	
		AEPTCD	Preferred Term Code	Num	MedDRA	Variable	Dictionary-derived code for the Preferred Term.	Exp
CAT	Category				- Cubrot	Qualifier		24
SCAT	Subcategory	AEHLT	High Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Term for the primary System Organ Class.	Exp
PRESP	Pre-Specified	AEHLTCD	High Level Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Term for the primary System Organ Class.	Exp
		AEHLGT	High Level Group Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Group Term for the primary System Organ Class.	Exp
OCCUR	Occurrence Indicator	AEHLGTCD	High Level Group Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the High Level Group Term for the primary System Organ Class.	Exp
STAT	Completion Status	AECAT	Category for Adverse Event	Char	*	Grouping Qualifier	Used to define a category of related records. Example: "BLEEDING", "NEUROPSYCHIATRIC".	Perr
REASND	Reason Not Done	AESCAT	Subcategory for Adverse Event	Char	*	Grouping Qualifier	A further categorization of adverse event. Example: "NEUROLOGIC".	Perr
BODSYS	Body System or Orga	AEPRESP	Pre-Specified Adverse	Char	(NY)	Variable	A value of "Y" indicates that this adverse event was pre-specified on the CRF. Values are null for	Per
	Class		Event			Qualifier	spontaneously reported events (i.e., those collected as free-text verbatim terms).	

Example events domain

able 2.2.2.	1 Events-Ton	624M	edical History	,				
Variable	Variable Label	0.2.0	edical history					
Name		MH - Desc	cription/Overview					
		ine medical	history dataset includes	the su	ibiect's prior history	at the start	of the trial. Examples of subject medical history information could include general medical history	orv
TERM	Reported lern		al history, and primary di			at the start	or the that Examples of Subject medical history information could include general medical hist	~)
MODIFY	Modified Repo			agnos				
	Monified Repo	MH – Spec	cification					
		mh.xpt, Med	ical History – Events, V	ersior	3.3. One record pe	er medical h	istory event per subject, Tabulation.	
LLT	Lowest Level 7	Variable	Variable Label		Controlled Terms,	Role	CDISC Notes	
		Name		<i>C</i> 1	Codelist or Format ¹	1.1		4
LLTCD	Lowest level	STUDYID	Study Identifier	Char	No. 1	Identifier	Unique identifier for a study.	
		DOMAIN	Domain Abbreviation		MH	Identifier	Two-character abbreviation for the domain.	
		USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions	F
DECOD	Dictionary Der	MHSEQ	Sequence Number	Num		Identifier	involving the product.	F
		MINDEQ	sequence number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number,	ľ
DTCD		MHGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	T
PTCD	Preferred Tern	MHREFID	Reference ID	Char		Identifier	Internal or external medical history identifier.	
	N	MHSPID	Sponsor-Defined	Char		Identifier	Sponsor-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or	
HLT	High Level Ter		Identifier				defined in the sponsor's operational database. Example: Line number on a Medical History page.	
	High Level Ter	MHTERM	Reported Term for the	Char		Topic	Verbatim or preprinted CRF term for the medical condition or event.	+
			Medical History					
HLTCD	High Level Ter	MHMODIFY	Modified Reported Term	Char		Synonym	If MHTERM is modified to facilitate coding, then MHMODIFY will contain the modified text.	
	-					Qualifier		4
		MHDECOD	Dictionary-Derived Term	Char	*	Synonym	Dictionary-derived text description of MHTERM or MHMODIFY. Equivalent to the Preferred Term (PT in	
HLGT	High Level Gro					Qualifier	MedDRA). The sponsor is expected to provide the dictionary name and version used to map the terms	1
							utilizing the external codelist element in the Define-XML document.	4
		MHEVDTYP	Medical History Event	Char	(MHEDTTYP)	Variable	Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is	
HLGTCD	High Level Gro	MUCAT	Date Type	CL	*	Qualifier	defined. Examples: "DIAGNOSIS", "SYMPTOMS", "RELAPSE", "INFECTION".	+
	Code	MHCAT	Category for Medical	Char	^	Grouping	Used to define a category of related records. Examples: "CARDIAC" or "GENERAL".	4
CAT	<u></u>	MHSCAT	History Subcategory for Medical	Char	*	Qualifier	A further categorization of the condition or event.	4
CAT	Category	MHSCAI	History	Char		Grouping Qualifier	A further categorization of the condition of event.	
SCAT	Subcategory	MHPRESP	Medical History Event	Char	(NIV)	Variable	A value of "Y" indicates that this medical history event was pre-specified on the CRF. Values are null for	۲
-JUAI	Subcategory	PILITICE DI	Pre-Specified	Chai	((41)	Qualifier	spontaneously reported events (i.e., those collected as free-text verbatim terms).	
PRESP	Pre-Specified	MHOCCUR	Medical History	Char	(NY)	Record	Used when the occurrence of specific medical history conditions is solicited, to indicate whether or not	
TIL	r re-specified	1 moccon	Occurrence	Critar	((()))	Qualifier	("Y"/"N") a medical condition (MHTERM) had ever occurred. Values are null for spontaneously reported	
			occarrence			Quanter	events.	
-OCCUR	Occurrence In	MHSTAT	Completion Status	Char	(ND)	Record	The status indicates that the pre-specified question was not asked/answered.	Ē
						Qualifier		
-STAT	Completion St	MHREASND	Reason Medical History	Char		Record	Describes the reason why data for a pre-specified condition was not collected. Used in conjunction with	Γ
			Not Collected			Qualifier	MHSTAT when value is "NOT DONE".	
-REASND	Reason Not D	MHBODSYS	Body System or Organ	Char	*	Record	Dictionary-derived. Body system or organ class that is involved in an event or measurement from a	ĺ
			Class			Qualifier	standard hierarchy (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should	
-BODSYS	Body System						contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the	
	Class	1					primary SOC.	

Example events domain

	I Findings—Topic and		aboratory Te					
Variable Name	Variable Label	LB – Desc	ription/Overview	N				
Name		A findings do	omain that contains la	aborat	ory test data sucl	n as hemato	logy, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic	: data
TESTCD	Short Name of	which are sto	ored in separate dom	ains.				
	Measurement, Test, or	LB Spec	(f) +1					
	Exam	LD - Spec	ification					
		lb.xpt, Labo	ratory Test Results –		-	One record	l per lab test per time point per visit per subject, Tabulation.	
TEST	Name of Measurement	Variable	Variable Label	Туре	Controlled	Role	CDISC Notes	Core
MODIEV	Test, on Exam	Name			Terms, Codelist			
MODIFY	ModifiedTerm	STUDYID	Study Identifier	Char	or Format ¹	Identifier	Unique identifier for a study.	Reg
TSTDTL	Measurement, Test, or	DOMAIN	Domain Abbreviation	Char	LB	Identifier	Two-character abbreviation for the domain.	Req
SIDIL	Examination Detail	USUBJID	Unique Subject	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the	Req
CAT	Category		Identifier				product.	
C. II	category	LBSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
SCAT	Subcategory	LBGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Pern
	Position of Subject	LBREFID	Specimen ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Pern
	During Observation	LBSPID	Sponsor-Defined	Char		Identifier	Sponsor-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the	Pern
	Body System or Organ	LIDTECTOD	Identifier		(I DIFECTED)	T .	sponsor's operational database. Example: Line number on the Lab page.	
	Class	LBTESTCD	Lab Test or Examination Short	Char	(LBTESTCD)	Topic	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column name	Req
ORRES	Result or Finding in		Name.				when converting a dataset from a vertical to a horizontal format. The value in LBTESTCD cannot be longer than 8 characters, nor can it start with a number (e.g., "1TEST" is not valid). LBTESTCD cannot contain characters	
	Original Units		rianic.				other than letters, numbers, or underscores. Examples: "ALT", "LDH".	
ORRESU	Original Units	LBIEST	Lab lest or	Char	(LBTEST)	Synonym	Verbatim name of the test or examination used to obtain the measurement or finding. Note any test normally	Req
			Examination Name			Qualifier	performed by a clinical laboratory is considered a lab test. The value in LBTEST cannot be longer than 40	1
ORNRLO	Normal Range Lower						characters. Examples: "Alanine Aminotransferase", "Lactate Dehydrogenase".	
	Limit-Original Units	LBCAT	Category for Lab Test	Char	*	Grouping	Used to define a category of related records across subjects. Examples: "HEMATOLOGY", "URINALYSIS",	Exp
	Normal Range Upper	LDCCAT		<i>C</i> 1		Qualifier	"CHEMISTRY".	
	Limit-Original Units	LBSCAT	Subcategory for Lab Test	Char	*	Grouping	A further categorization of a test category such as "DIFFERENTIAL", "COAGULATION", "LIVER FUNCTION", "ELECTROLYTES".	Pern
	Reference Result in	LBORRES	Result or Finding in	Char		Qualifier Result	Result of the measurement or finding as originally received or collected.	Exp
	Original Units	LDUKKES	Original Units	Cildi		Qualifier	Result of the measurement of finding as originally received of collected.	Lxp
STRESC	Result or Finding in Standard Format	LBORRESU	Original Units	Char	(UNIT)	Variable	Original units in which the data were collected. The unit for LBORRES. Example: "g/L".	Exp
	Stanuaru Format		5			Qualifier		
		LBORNRLO	Reference Range	Char		Variable	Lower end of reference range for continuous measurement in original units. Should be populated only for	Ехр
STRESN	Numeric Result/Finding		Lower Limit in Orig			Qualifier	continuous results.	
JINCOL	in Standard Units	L D O D L D L D	Unit	<u></u>				-
STRESU	Standard Units	LBORNRHI	Reference Range	Char		Variable	Upper end of reference range for continuous measurement in original units. Should be populated only for	Exp
Diffeed	Standard Shits		Upper Limit in Orig Unit			Qualifier	continuous results.	
		LBSTRESC	Character	Char	(LBSTRESC)	Result	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard	Exp
			Result/Finding in Std	Ser Har	(Qualifier	units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also	1.40
			Format				be stored in numeric format in LBSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in	
	Normal Range Lower						LBORRES and these results effectively have the same meaning, they could be represented in standard format	
	Limit-Standard Units						in LBSTRESC as "NEGATIVE". For other examples, see general assumptions.	
1								
STNRHI	Normal Range Upper	LBSTRESN	Numeric Result/Finding in	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.	Exp

Example findings domain

	1 Findings—Topic and	0.3.17	vital signs					
Variable Name	Variable Label		ription/Overview			. h t. n. n. t. lin		:-b+
TESTCD	Short Name of Measurement, Test, or		ification	leasur	ements including	j but not iin	nited to blood pressure, temperature, respiration, body surface area, body mass index, height and wei	ignt.
	Exam	vs.xpt, Vital	Signs — Findings, Ve	rsion	3.3. One record j	oer vital sig	n measurement per time point per visit per subject, Tabulation.	
TEST	Name of Measurement Test, or Exam	Variable Name	Variable Label	Туре	Controlled Terms, Codelist or Format ¹	Role	CDISC Notes	Co
MODIFY	Modified Term	STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Red
		DOMAIN	Domain Abbreviation	Char	VS	Identifier	Two-character abbreviation for the domain.	Rec
TSTDTL	Measurement, Test, or Examination Detail	USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.	Rec
CAT	Category	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.	Perr
SCAT POS	Subcategory Position of Subject	VSSPID	Sponsor-Defined	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.	Perr
BODSYS	During Observation Body System or Organ	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 when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than a superior of a superior of a superior of the vertical to a horizontal format.	n Req
	Class						8 characters, nor can it start with a number (e.g., "1TEST" is not valid). VSTESTCD cannot contain characters other than letters, numbers, or underscores. Examples: "SYSBP", "DIABP", "BMI".	
ORRES	Result or Finding in Original Units	VSTEST	Vital Signs Test Name	Char	(VSTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. The value in VSTEST cannot be longer than 40 characters. Examples: "Systolic Blood Pressure", "Diastolic Blood Pressure", "Body	Req
ORRESU	Original Units					-	Mass Index".	
ORNRLO	Normal Range Lower	VSCAT	Category for Vital Signs	Char	*	Grouping Qualifier	Used to define a category of related records.	Perr
ORNRHI	Limit-Original Units Normal Range Upper	VSSCAT	Subcategory for Vital Signs	Char	*	Grouping Qualifier	A further categorization of a measurement or examination.	Perr
ORREF	Limit-Original Units Reference Result in	VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perr
STRESC	Original Units Result or Finding in	VSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
	Standard Format	VSORRESU	Original Units		(VSRESU)	Variable Qualifier	Original units in which the data were collected. The unit for VSORRES. Examples: "in", "LB", "beats/min".	Exp
		VSSTRESC	Character	Char		Result	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard	Exp
STRESN	Numeric Result/Finding in Standard Units		Result/Finding in Std Format			Qualifier	units. VSSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in VSSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in VSORRES, and these results effectively have the same meaning, they could be represented in standard format	
STRESU	Standard Units						in VSSTRESC as "NEGATIVE".	
		VSSTRESN	Numeric Result/Finding in	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESN should store all numeric test results or findings.	Exp
STNRLO	Normal Range Lower	VSSTRESU	Standard Units Standard Units	Char	(VSRESU)	Variable	Standardized unit used for VSSTRESC and VSSTRESN.	Exp
STINKLU	Limit-Standard Units	VSSTAT	Completion Status	Char	(ND)	Qualifier Record	Used to indicate that a vital sign measurement was not done. Should be null if a result exists in VSORRES.	Pe
STNRHI	Normal Range Upper Limit-Standard Units	VSREASND	Reason Not Performed	Char		Qualifier Record Qualifier	Describes why a measurement or test was not performed. Examples: "BROKEN EQUIPMENT" or "SUBJECT REFUSED". Used in conjunction with VSSTAT when value is "NOT DONE".	Pe

Example findings domain

SDTM Implementation Guide: Stai

SDTMIG v3.3

cdisc Study Data Tabulation N Implementation Guide: Hum Trials

Version 3.3 (Final)

Prepared by the

CDISC Submission Data Standards Team

IN MODELS BASED ON THE GENERAL OBSERVATION CLASSES	6.3.10.6 Reproductive System Findings
odels for Interventions Domains	6.3.10.7 Respiratory System Findings
Procedure Agents	6.3.10.8 Urinary System Findings
Concomitant and Prior Medications	6.3.11 Pharmacokinetics Domains
Exposure Domains	6.3.11.1 Pharmacokinetics Concentrations
Exposure	
Exposure as Collected	6.3.11.2 Pharmacokinetics Parameters
Exposure/Exposure as Collected Examples	6.3.11.3 Relating PP Records to PC Records
Meal Data	6.3.12 Physical Examination
Procedures	6.3.13 Questionnaires, Ratings, and Scales (QRS) Domains
Substance Use	6.3.13.1 Functional Tests
odels for Events Domains	6.3.13.2 Questionnaires
Adverse Events	6.3.13.3 Disease Response and Clin Classification
Clinical Events	6.3.14 Subject Characteristics
Disposition	6.3.15 Subject Status
Protocol Deviations	6.3.16 Tumor/Lesion Domains
Healthcare Encounters	
Medical History	6.3.16.1 Tumor/Lesion Identification
odels for Findings Domains	6.3.16.2 Tumor/Lesion Results
Drug Accountability	6.3.16.3 Tumor Identification/Tumor Results Examples
Death Details	6.3.17 Vital Signs
ECG Test Results	6.4 Findings About Events or Interventions
Inclusion/Exclusion Criteria Not Met	6.4.1 When to Use Findings About
Immunogenicity Specimen Assessments	6.4.2 Naming Findings About Domains
Laboratory Test Results	6.4.3 Variables Unique to Findings About
Microbiology Domains	6.4.4 Findings About
Microbiology Specimen	6.4.5 Skin Response
Missobiology Cussontibility	0.4.5 Skill Response

Microbiology Specimen 6.3.7.2 Microbiology Susceptibility

6 DOMAIN MODELS BASED ON THE GENER Models for Interventions Domains

Models for Events Domains

Models for Findings Domains

6.1

6.1.1

6.1.2

6.1.3

6.1.3.1

6.1.3.2

6.1.3.3

6.1.4

6.1.5

6.1.6 6.2

6.2

6.2.2

6.2.3

6.2.4

6.2.5

6.2.6

6.3.1

6.3.2

6.3.3

6.3.4

6.3.5

6.3.6

6.3.7

6.3.7.1

6.3

- 6.3.7.3 Microbiology Specimen/Microbiology Susceptibility Examples
- 6.3.8 Microscopic Findings
- 6.3.9 Morphology
- 6.3.10 Morphology/Physiology Domains
- 6.3.10.1 Generic Morphology/Physiology Specification
- 6.3.10.2 Cardiovascular System Findings
- 6.3.10.3 Musculoskeletal System Findings
- 6.3.10.4 Nervous System Findings
- 6.3.10.5 Ophthalmic Examinations

Custom Domains

- Based on the same General Observation Classes from SDTM (the Model)
 - Uses the same root variables
 - Uses published terminology
- Follows same rules that have been used for Standard Domains (in the SDTMIG)
 - SDTM CDISC Notes
 - SDTMIG Sections 2, 4 and 8
- You have to confirm that it is needed (no published domain for a topic)
- You have to create a unique (within your implementation) domain code for the 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)

Variable Name	Variable Label	Туре	Role	Description						
				Topic Variable						
TRT	Name of Treatment	Char	Topic	The topic for the intervention observation, u during the dosing interval for the observation		e verbatim name of the treatment	, drug, medicine, or therap	y given		
			1	Qualifier Variables						
MODIFY	Modified Treatment Name	Char	Synonym Qualifier of	If the value forTRT is modified for coding p	urposes,	then the modified text is placed h	nere.			
DECOD	Standardized	Char	XM Med	litation						
	Treatment Name					CONTROLLED TERMS,				
			VARIABLE	VARIABLE LABEL	TYPE	CODELIST OR FORMAT	ROLE	IMPLEMEN	TATION NOTES	CORE
MOOD CAT	Mood Category	Char Char		ly Identifier	Char		Identifier			REQ
SCAT	Subcategory	Char		,		VA A		Defeultte	() (-
PRESP	Pre-specified	Char		nain Abbreviation	Char	XIVI	Identifier	Default to X	(M)	REQ
				que Subject Identifier	Char		Identifier			REQ
OCCUR	Occurrence Indicator	Char	XMSEQ Seq	uence Number	Num		Identifier			REQ
STAT	Completion Status	Char	XMTRT Nam	ne of Meditation Regimen	Char		Topic			REQ
5074	completion status	Char	XMCAT Cate	glory of Meditation Regimen	Char	(XMCAT)	Grouping Qualifier	r		PERM
REASND	Reason Not Done	Char	XMDOSE Leng	OSE Length of Meditation Session Num Record Qualifier					PERM	
INDC	Indication	Char		Unit for Length of Meditation Session Char (UNIT) Variable Qualifier Minutes, H				ours	PERM	
CLAS	Class	Char		uency of Meditation Sessions		(FREQ)	Variable Qualifier		0010	PERM
CLASCD	Class Code	Char		t Date of Meditation Sessions		ISO 8601	Timing			PERM
							Thing			FLIM
DOSE	Dose Dose	Num	Record Qualifier	Amount ofTRT given. Not populated when						
DOSTXT DOSU	Dose Description Dose Units	Char	Record Qualifier Variable Qualifier of	Dosing information collected in text form. Ex Units forDOSE,DOSTOT, orDOSTXT. E			ed whenDOSE is populat	ted.		
	Dose offics	Chai	DOSE,DOSTXT of DOSTOT		varripies	. ng , mg , mg ∧g .				
DOSFRM	Dose Form	Char	Variable Qualifier of	Dose form for the treatment. Examples: "TA	BLET", "C	APSULE".				
			DOSE,DOSTXT or DOSTOT							
DOSFRQ	Dosing Frequency	Char	Variable Qualifier of	Usually expressed as the number of doses g	iven per a	a specific interval. Examples: "Q2H	I", "QD", "PRN".			
-	per Interval		DOSE,DOSTXT or DOSTOT							
DOSTOT	Total Daily Dose		Record Qualifier		tal daily dose ofTRT using the units inDOSU. 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 o	or regime	n for the Intervention. Example: "	TWO WEEKS ON, TWO WE	EKS OFF".		
ROUTE	Route of Administration	Char	Variable Qualifier of TRT	Route of administration for the intervention.	oute of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".					
LOT	Lot Number	Char	Record Qualifier	Lot number for the intervention described in						
LOC	Location of Dose Administration	Char	Record Qualifier	Anatomical location of an intervention, such	as an inj	ection site. Example: ARM for an i	njection.			25
LAT	Laterality	Char	Variable Qualifier of	Qualifier for anatomical location further deta	alifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT",					

Variable Name	Variable Label	Тур	e Role	Description						
Name				Topic Varia	able					
TERM	Reported Term	Cha	r Topic	Topic variable for an event observation	on, which is the ve	batim or pre-specified name of th	e event.			
MODIFY	Modified Reported Ter	YV	Vacation	1						
	ribulica reported rei	VARI/	ABLE	VARIABLE LABEL	TYPE	CONTROLLED TERMS,	ROLE	IMP	LEMENTATION	1
LLT	Lowest Level Term					CODELIST OR FORMAT			NOTES	
LL1	Lowest Level Term	STUD	YID Study Id	entifier	Char		Identifier			RE
		DOM	AIN Domain	Abbreviation	Char	YV	Identifier	Default to	YV	RE
LLTCD	Lowest Level Term Co	USUB	JID Unique	Subject Identifier	Char		Identifier			RE
		YVSE	2 Sequent	e Number	Num		Identifier			RE
DECOD	Dictionary-Derived Ter	YVTE	RM Vacation	i Event	Char		Topic			RE
								Default to	Y when a value has	
PTCD	Preferred Term Code	YVPR	ESP Pre-spec	cified	Char	(YN)	Variable Qualifier	been pre-s	pecified in YVTERM	PE
		YVOC	CUR Occurre	nce of Vacation	Char	(YN)	Record Qualifier			EX
HLT	High Level Term	rel Term YVSTDTC Start Date of Vacation Char ISO 8601 Timing			EX					
	-	YVEN	DTC End Date	e of Vacation	Char	ISO 8601	Timing			EX
HLTCD	High Level Term Code	YVEV	LINT Evaluati	on Interval	Char	ISO 8601	Timing			PE
			Qualifier of							_
HLGT	High Level Group Term	Cha	HLT r Variable	MedDRA High Level Group Term fror	n the primary path					
TILO I	rightever bloup fem		Qualifier of	Headlowing reversion preminior	in the philling path	•				
HLGTCD	Llich Laural Crown Tarm	Nha	TERM N Variable	MadDDA Lliab Lavel Crown Tarm and	le frans the asimon	th				
HLGTCD	High Level Group Term Code	Nun	Qualifier of	MedDRA High Level Group Term cod	le from the primary	pain.				
			HLGT							
CAT	Category	Cha	r Grouping Qualifier	Used to define a category of topic-va	ariable values.					
SCAT	Subcategory	Cha	r Grouping	Used to define a further categorization	on ofCAT values.					
88548			Qualifier							
PRESP	Pre-Specified	Cha	r Variable Qualifier of	Used to indicate whether the event of spontaneously reported events.	described byTER	1 was pre-specified on a CRF. Valu	e is Y for pre-specified eve	ents, null for		
			TERM							
OCCUR	Occurrence Indicator	Cha	r Record Qualifier	Used to record whether a pre-specifi	ed event occurred	when information about the occu	rrence of a specific event i	s solicited.		
STAT	Completion Status	Cha		Used to indicate when a question ab	out the occurrence	e of a pre-specified event was not a	answered. Should be null (or have a value		
			Qualifier	of NOT DONE.						
REASND	Reason Not Done	Cha		Reason not done. Used in conjunction	on withSTAT whe	n its value is "NOT DONE".			00	
Image: Problem in the system of Organ Qualifier 2 BODSYS Body System or Organ Char Record Body system or system organ class assigned for analysis from a standard hierarchy (e.g., MedDRA) associated with an event. 2						26				
	Class		Qualifier	Example: "GASTROINTESTINAL DISC		, (,			

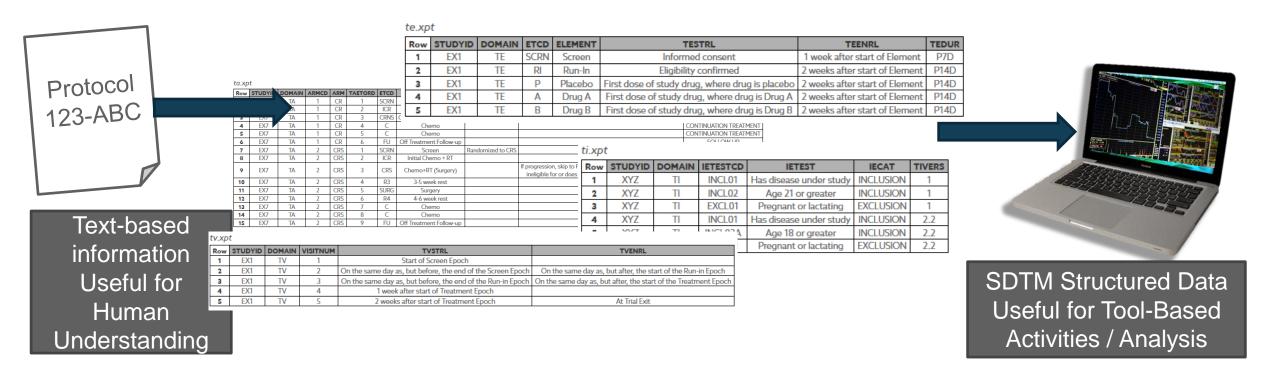
Example: Events Custom domain

Variable Name	Variable Label	Туре	Role		Description				
	·				Topic Variable				
TESTCD	bilore Harrie of	Char	Topic		Short character value forTEST used as a column	name when convert	ing a dataset from a vert	ical format to a horizontal	
		ZD		Dermatolog	y Findings				
	Exam	V/R	IABLE		VARIABLE LABEL	TYPE	CONTROLLED	ROLE	IMPLEMENTATION
TEST	Name of Measurement, Test, or Fram					TERMS, CODELIST OR FORMAT	r	NOTES	
MODIFY	Modified Term	STUD	DYID	Study Identi	fier	Char		Identifier	
TSTDTL	Measurement, Test, or	DOM	IAIN	Domain Abb		Char	ZD	Identifier	Default to ZD
CAT	Examination Detail	USU	BJID	Unique Subj	ect Identifier	Char		Identifier	
CAI	Category	ZDSE	Q	Sequence N	umber	Num		Identifier	
SCAT	Subcategory	ZDTE	STCD	Dermatolog	y Test Code	Char	(ZDTESTCD)	Topic	
POS	Position of Subject During Observation	ZDTE	ST	Dermatolog	y Test	Char	(ZDTEST)	Synonym Qualifier	
BODSYS	Body System or Organ	ZDO	RRES	Dermatolog	y Test Original Result	Char		Result Qualifier	
00050	Class				y Test Original Result Unit	Char	(UNIT)	Variable Qualifier	
ORRES	Result or Finding in Original Units	ZDST	RESC	Dermatolog	y Test Standardized Result - Character	Char		Result Qualifier	
ORRESU	Original Units	ZDST	RESN	Dermatolog	y Test Standardized Result - Numeric	Num		Result Qualifier	
ORNRLO	Normal Range Lower	ZDST	RESU	Dermatolog	y Test Standardized Result Unit	Char	(UNIT)	Variable Qualifier	
	Limit-Original Units	ZDDT	C	Evaluation I	nterval	Char	ISO 8601	Timing	
ORNRHI	Normal Range Upper Limit-Original Units	Char	ORRE		Upper end of normal range or reference range for n	results stored inO			
ORREF	Reference Result in Original Units	Char	Variable	e Qualifier of S	Reference value for the result or finding as original applicable. Examples: value from predicted normal				
STRESC	Result or Finding in Standard Format	Char	Result (Qualifier	Contains the result value for all findings, copied or STRESC should store all results or findings in cha numeric format inSTRESN. For example, if variou these results effectively have the same meaning, t	derived fromORR racter format; if resu is tests have results	ES in a standard format of Its are numeric, they sho "NONE", "NEG", and "NE	ould also be stored in GATIVE" inORRES and	
STRESN	Numeric Result/Finding	Num	Result (Qualifier	Used for continuous or numeric results or findings				-
CTDECU	in Standard Units	Char	Mariahla	- Overlifing of	should store all numeric test results or findings.	-			
STRESU	Standard Units	Char	ar Variable Qualifier of Standardized units used forSTRESC,STRESN, STRESC and STRESN and STREFC and STREFN			STREFC, andSTR	EFN. Example: "mol/L".		
STNRLO	Normal Range Lower Limit-Standard Units	Num		e Qualifier of SC and	Lower end of normal range or reference range for s standardized units (STRESU).	standardized results	(e.g.,STRESC,STRES	iN) represented in	27
STNRHI	Normal Range Upper Limit-Standard Units	Num	Variable	e Qualifier of SC and	Upper end of normal range or reference range for s standardized units (STRESU).	standardized results	(e.g.,STRESC,STRES	SN) represented in	

Example: Findings Custom domain

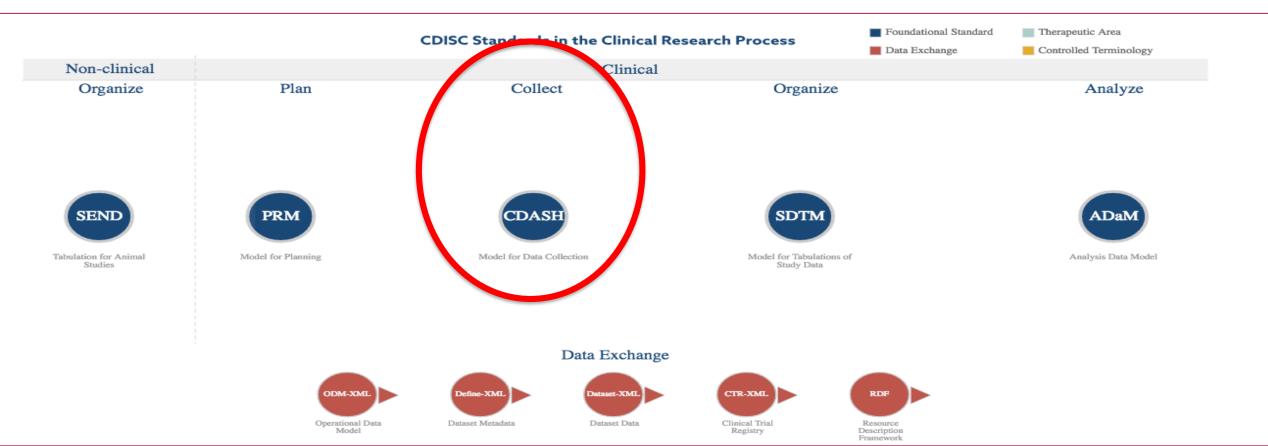
Trial Design

- Structured datasets to hold protocol-level information
- Reference SDTMIG Section 7



CDISC Standards - CDASH for Data Collection (Source and EDC)

Clinical Data Acquisition Standards Harmonization: CDASH HARMONIZES data collection with SDTM





Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials

Version 2.0

Prepared by the CDISC CDASH Team



https://www.cdisc.org/standards/foundational/cdash/cdash-20

*Note: you must be logged into the CDISC website to access

CDASH Principles (or How CDASH Supports Getting to SDTM)

	Study STUDYID		Site SITEID		Subject SUBJID	
		DEMOG	GRAPHIC	S		
 CDASH specifies a minimum set of fields: Logical set to have a valid record Target what is required for regulatory requirements including SDTM 	Birth Date	IX CE	HDAT	BRT	HDTC	CDASH specifies a standard variable name, with recommendations for implementation that support transformation to SDTM data
	☐ Hawaiian or Other Pa☐ Native American or A					
	□ White □ Other, (please specify	y)		RACE	OTH	

CDASH Principles (or How CDASH Supports Getting to SDTM)

CDASH specifies standard wording for the data collection questions, with flexibility to handle protocolspecific requirements

	Study			Site			Subject	_			
	STUDYID			SITEID			SUBJID]			
			DE	MOGRAPHI			_				
				CDASH specifies using							
	Birth Date standardized value li BRTHDAT BRTHDTC SDTM requirements										
Day Month Year Sex Male SEX											
□ F Race	emale	CDI	ISC Su	E bmission Value	-	CDISC Synonym(s)			s)		
		EX				Sex					
	Black or					Female					
	🔲 Hawaiian M						Male				
	Native Ar UNDIFFERENTIATED White					U; Ui	ıknown				
	Dther, (pied	ลงะ งุมะบบ	//		_				ļ		

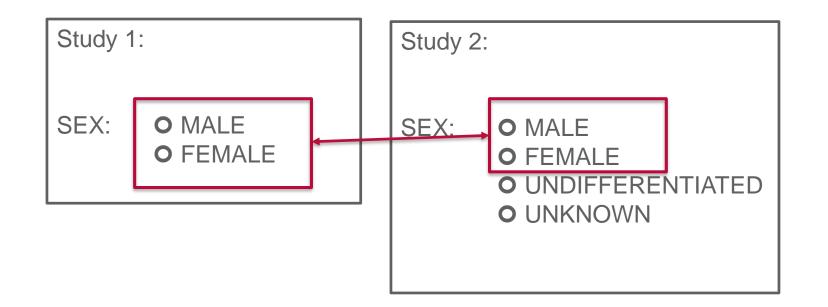
CDASH- Demographics Example Metadata*

*There are **18** columns of metadata in the CDASHIG - these 3 are used as examples

CDASHIG Variable	Prompt	Controlled Terminology Codelist Name
STUDYID	[Protocol/Study]	N/A
SITEID	Site (Identifier)	N/A
SUBJID	Subject	N/A
BRTHDAT	Birth Date	N/A
SEX	Sex	(SEX)
ETHNIC	Ethnicity	(ETHNIC)
RACE	Race	(RACE)

CDASH Supports Standardization *and* Study Specific Requirements

- CDASH is flexible enough to support the needs of different studies
- EDC can be specified *per study* (and per protocol version)
 - BUT, CDASH will ensure consistency from study to study for the same concepts



Controlled Terminology Principles

Cot	Codelist Co	Codelist Extensib (Yes/No	Codelist Name		CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66731		No	Sex	SEX			CDISC SDTM Sex of Individual Terminology
						from female; the physical difference between male and female; the distinguishing	
						peculiarity of male or female. (NCI)	
C16576	C66731		Sex	F	Female	A person who belongs to the sex that normally produces ova. The term is used to	Female
						indicate biological sex distinctions, or cultural gender role distinctions, or both. (NCI)	
C20197	C66731		Sex	M	Male	A person who belongs to the sex that normally produces sperm. The term is used to	Male
						indicate biological sex distinctions, cultural gender role distinctions, or both. (NCI)	
C17998	C66731		Sex	U	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C45908	C66731		Sex	UNDIFFERENTIATED		A person (one of unisexual specimens) who is born with genitalia and/or secondary	Intersex
						sexual characteristics of indeterminate sex, or which combine features of both sexes.	
						(NCI)	

- Thousands of standardized, <u>defined</u> terms
- A <u>single</u> way to represent each concept (CDISC Submission Value)
- Synonyms that promote usability
- Unique codes for each term and each codelist to support implementation
- Extensibility defined
- Process to request new terms and new codelists
- Connected to the NCI Thesaurus many terminologies published and linked
- Published in multiple file formats (xls, CSV, ODM, HTML, PDF...)
- Additional "tools" to support implementation (e.g., files with mappings to related terminologies like UCUM and LOINC)

CDISC Standards in the NCI GLIB ALS

]	FormOID J	FieldOID	▼ VariableOID ▼	DataDictionaryNam	PreText 💌	SASLabel
	DM	FieldOID/Var	iableOID =		FORM_OID	
	DM	CDASH (or S			PreText = CDASH	Study Identifier
	DM	variable			Question Text	Study Site Identifier
For	mOID =	SUBJID	SUBJID		(Prompt is also	
2 cł	naracter	SODJID	SUDJID		acceptable)	Subject Identifier for the Study
Dor	nain	BRTHDAT	BRTHDAT		,	sASLabel =
Coc		BRTHYY	DRIN	DictionaryNa		Y SDTM (or
	DM	BRTHMO		C Codelist N	ame s the subject's month of	,
					What is the subject's day of	CDASH)
	DM	BRTHDD	BRTHDD		birth? What is the subject's time of	Variable Label
	DM	BRTHTIM	BRTHTIM		birth?	Time of Birth
	DM	AGE	AGE	A0511	What is the subject's age?	Age
	DM	AGEU	AGEU	AGEU	What is the age unit used?	Age Units
	DM	DMDAT	DMDAT		What is the date of collection?	Date of Demographics Collection
	DM	SEX	SEX	SEX	What is the sex of the subject?	Sex
				N	Do you consider yourself Hispanic/Latino or not	
	DM		ataDictionaryName	JT CodedData		g 👻
	DM		EX EX	F	Female Male	,
		S	EX	U	Unknown	
		S	EX	UNDIFFERE	ENTIATED Intersex	
	DM	RACE	RACE	RACE	acceptable.)	Race
					Which of the following racial	
					designations best describes you? (More than one choice is	
	DM	CRACE	CRACE	RACEC	acceptable.)	Collected Race
	DM	RACEOTH	RACEOTH		What was the other race?	Race Other

Q&A Shannon.Labout@nih.gov

