CDISC Overview

LPO Webinar

7 March 2019

NIH NATIONAL CANCER INSTITUTE

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

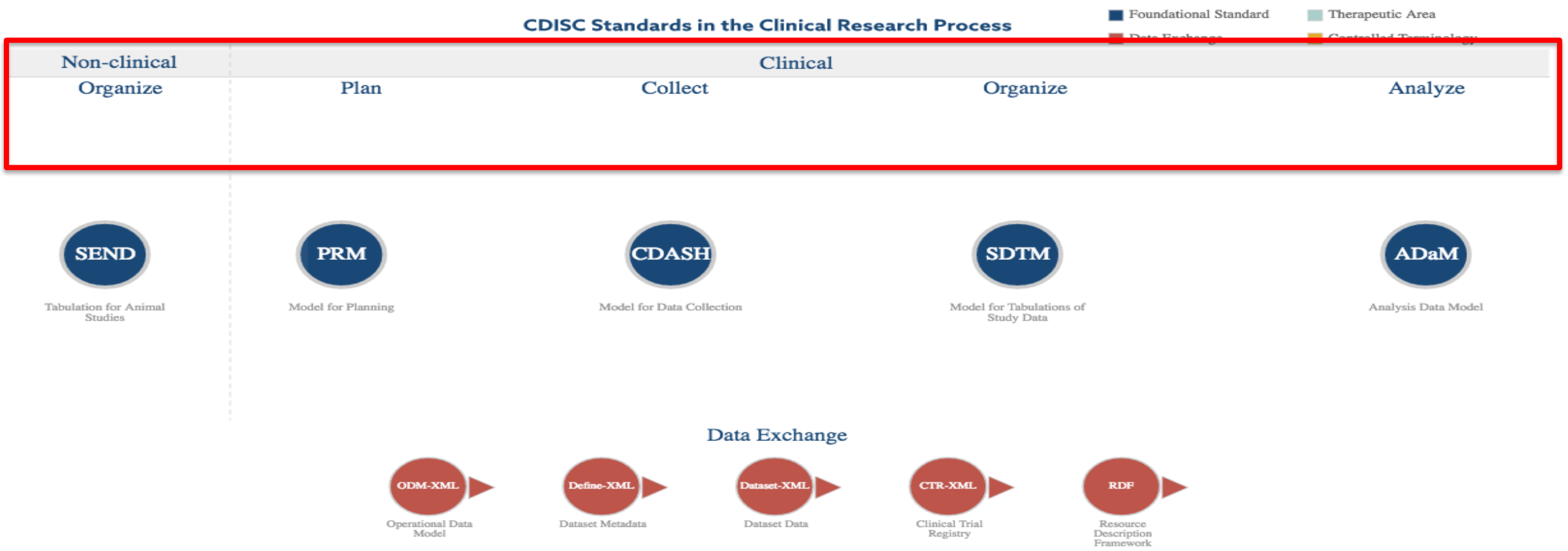
- Describe the CDISC organization and purpose
- Demonstrate finding and downloading the standards
  - Create an online account
  - Access the CDISC Library
- Explain the high level principles of CDASH, SDTM and Controlled Terminology (CT) standards
- Demonstrate the use of the CDISC standards in the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

CDISC Standards - Why

- 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 inconsistent from study to study

Study #1 – demog.xpt

SUBJID	SEX
2001	M
2002	F
2003	F
2004	M
2005	F

Study #2 – dmg.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #3 – dmgph.xpt

PTID	GENDER
01	1
02	1
03	2
	2
	1

Study #4 – axd222.xpt

USUBID	SEX
00011-A	0
00012-A	1
00013-A	1
00014-A	0
00015-A	1

Variable names / column headers are different from study to study

Values to represent the same concepts are not consistent, and sometimes not decoded (0? 1? 2?)

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 #1 – DM.xpt

USUBJID	SEX
ABC-001	M
ABC-002	F
ABC-003	F
ABC-004	M
ABC-005	F

Study #2 – DM.xpt

USUBJID	SEX
DEF-001	M
DEF-002	M
ABC-001	M
DEF-004	F
DEF-005	M

Study #3 – DM.xpt

USUBJID	SEX
GHI-001	M
GHI-002	M
GHI-003	F
GHI-004	F
GHI-005	M

Study #4 – DM.xpt

USUBJID	SEX
JKL-011	M
JKL-012	F
GHI-003	F
JKL-014	M
JKL-015	F

Value lists are standardized and always decoded

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

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

CDISC Standards - Why

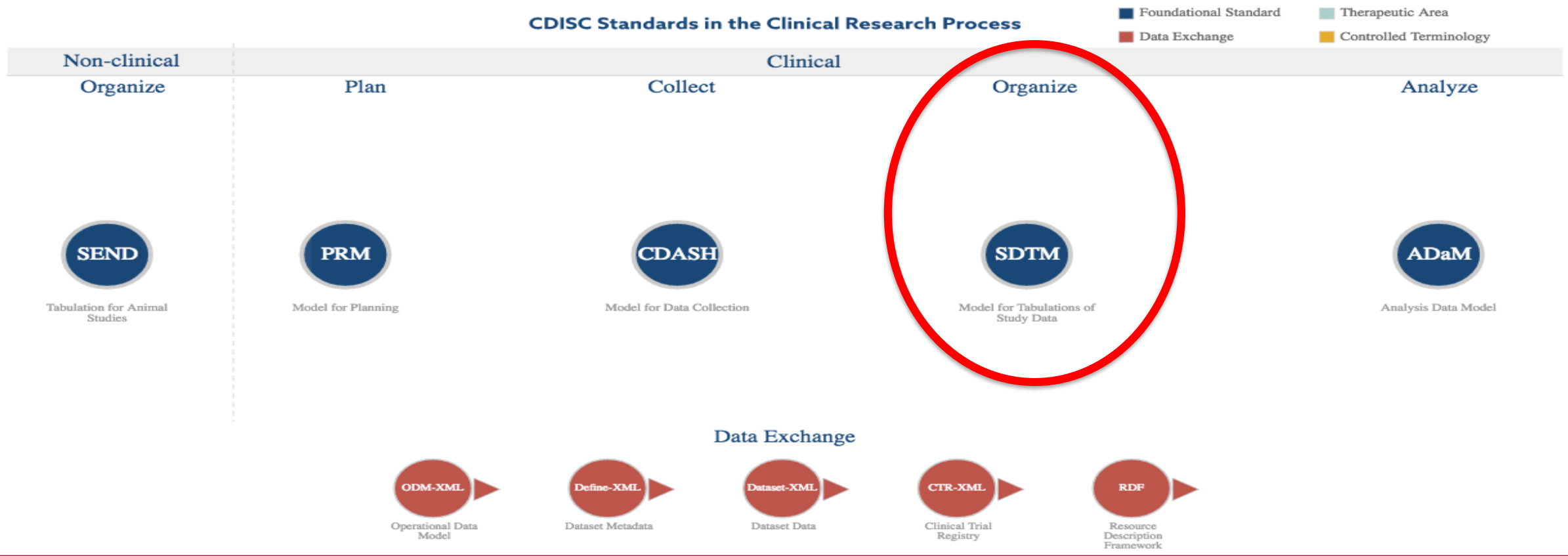
- Required by FDA:
  - SEND, SDTM, ADaM, Define-XML and Controlled Terminology
  - All NDAs, BLAs and ANDAs with study start dates after 16 December 2016

    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

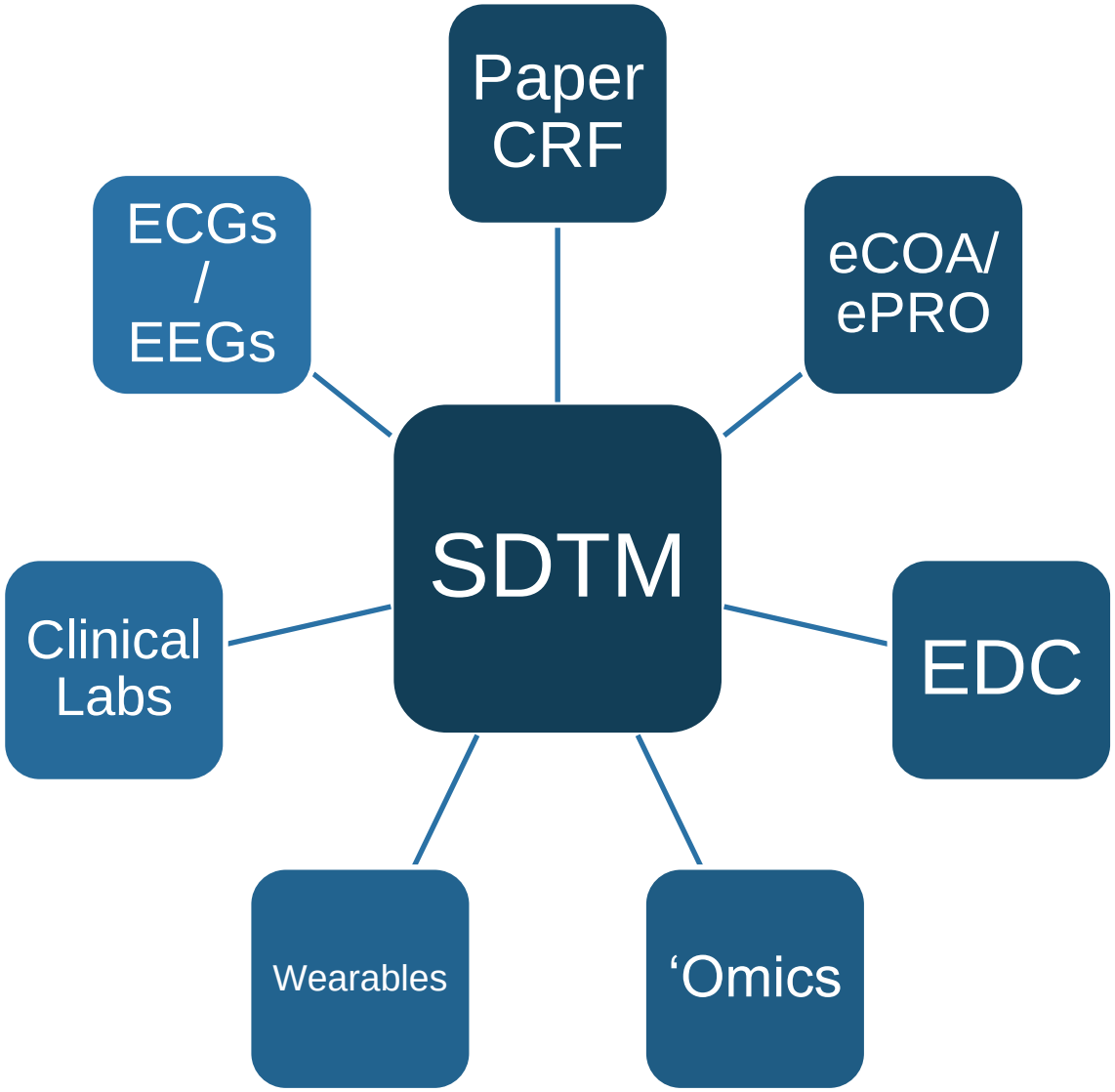
https://www.pmda.go.jp/english/review-services/reviews/advanced-efforts/0002.html

- 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)

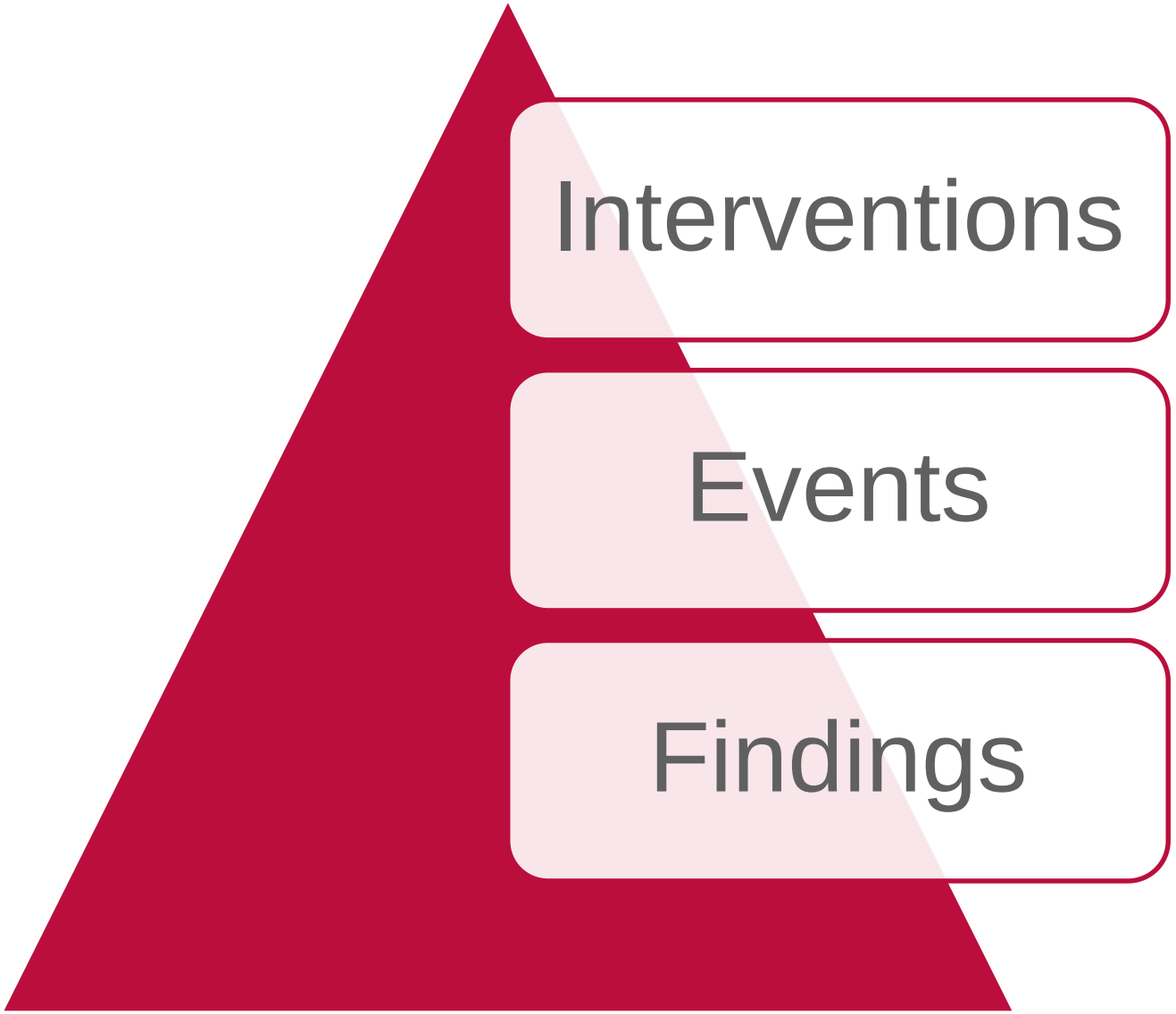
CDISC Standards - SDTM for Predictable Data Organization to Support Review



SDTM Data Sources



Standard Organization of Data: General Observation Classes



Data about things the study participant takes into their body.

-- means this is Model-level, generic, “**root**” variables

Interventions Model

2.2.1 The Interventions Observation Class

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

Variable Name	Variable Label	Type	Role	Description
Topic Variable				
--TRT	Name of Treatment	Char	Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.
Qualifier Variables				
--MODIFY	Modified Treatment Name	Char	Synonym Qualifier of --TRT	If the value for --TRT is modified for coding purposes, then the modified text is placed here.
--DECOD	Standardized Treatment Name	Char	Synonym Qualifier of --TRT	Standardized or dictionary-derived name of the topic variable, --TRT, or the modified topic variable (--MODIFY), if applicable. Equivalent to the generic drug name in WHO Drug, or a term in SNOMED, ICD9, or other published or sponsor-defined dictionaries.
--MOOD	Mood	Char	Record Qualifier	Mode or condition of the record (e.g., "SCHEDULED", "PERFORMED").
--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values.
--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values.
--PRESP	Pre-specified	Char	Variable Qualifier of --TRT	Used when a specific intervention is pre-specified on a CRF. Values should be "Y" or null.
--OCCUR	Occurrence Indicator	Char	Record Qualifier	Used to record whether a pre-specified intervention occurred when information about the occurrence of a specific intervention is solicited.
--STAT	Completion Status	Char	Record Qualifier	Used to indicate when a question about the occurrence of a pre-specified intervention was not answered. Should be null or have a value of NOT DONE.
--REASND	Reason Not Done	Char	Record Qualifier	Reason not done. Used in conjunction with --STAT when value is "NOT DONE".
--INDC	Indication	Char	Record Qualifier	Denotes the indication for the intervention (e.g., why the therapy was taken or administered).
--CLAS	Class	Char	Variable Qualifier of --TRT	Class for a medication or treatment, often obtained from a coding dictionary.
--CLASCD	Class Code	Char	Variable Qualifier of --TRT	Used to represent code for --CLAS.
--DOSE	Dose	Num	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
--DOSTXT	Dose Description	Char	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
--DOSU	Dose Units	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Units for --DOSE, --DOSTOT, or --DOSTXT. 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 of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
--DOSRGM	Intended Dose Regimen	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Text description of the (intended) schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".
--ROUTE	Route of Administration	Char	Variable Qualifier of --TRT	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".
--LOT	Lot Number	Char	Record Qualifier	Lot number for the intervention described in --TRT.
--LOC	Location of Dose Administration	Char	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: ARM for an injection.
--LAT	Laterality	Char	Variable Qualifier of	Qualifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT",

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

Events Model

2.2.2 The Events Observation Class

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

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

Results from planned measurements and tests

findings Model

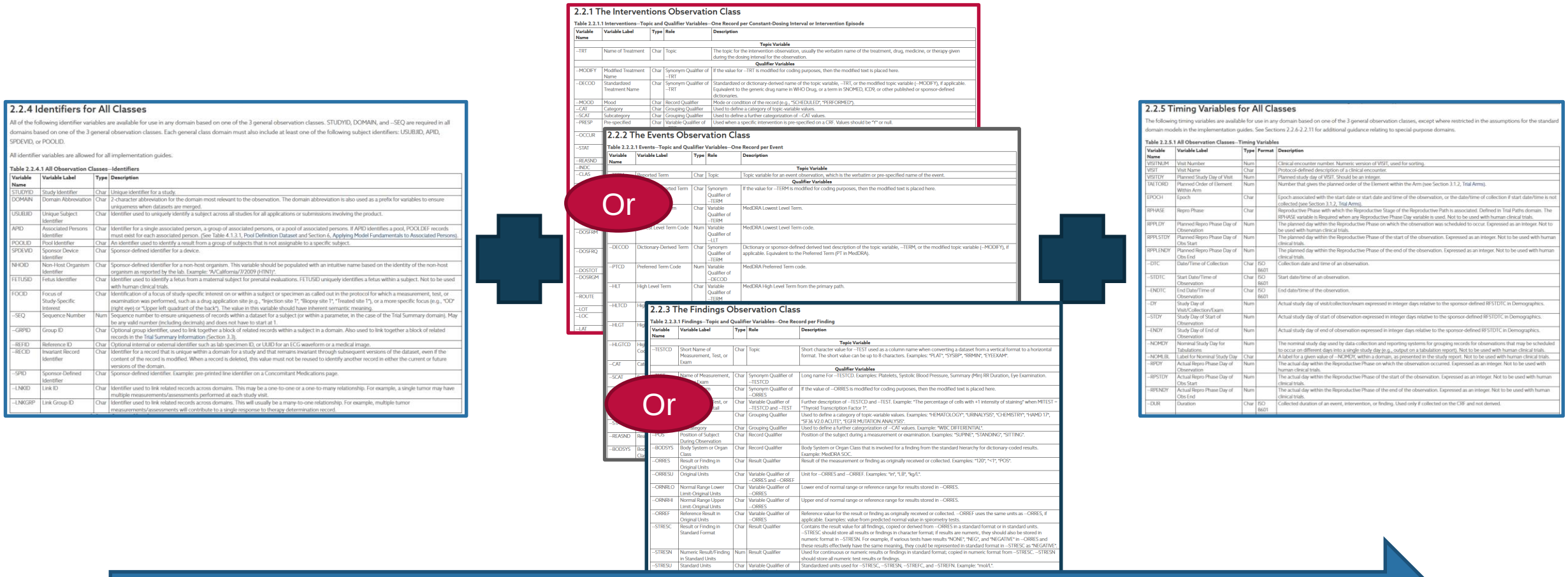
2.2.3 The Findings Observation Class

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

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

Organize all data by “Topic”: Domains

- Root variables from one Class in the SDTM (Model) are used to form a topic-based Domain
- Topic/Domain-specific 2 character codes are prefixed to the root variables (AE for Adverse Events, VS for Vital Signs)



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

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
--DECOD	Standardized Treatment Name
--MOOD	Mood
--	Category
--	Subcategory
--	Pre-specified
--	rence Indicator
--	Status
--	Description
--	se Units
--	RM 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

-- 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 that contains the details of a subject's exposure to protocol-specified study treatment. Study treatment may be any intervention that is prospectively defined as a test material within a study, and is typically but not always supplied to the subject.

EX – Specification

ex.xpt, Exposure — Interventions, Version 3.3. One record per protocol-specified study treatment, constant-dosing interval, 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	EX	Identifier	Two-character abbreviation for the domain.	Req
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
EXSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
EXGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
EXREFID	Reference ID	Char		Identifier	Internal or external identifier (e.g., kit number, bottle label, vial identifier).	Perm
EXSPID	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. Example: Line number on a CRF Page.	Perm
EXLNKID	Link ID	Char		Identifier	Identifier used to link related records across domains.	Perm
EXLNKGRP	Link Group ID	Char		Identifier	Identifier used to link related, grouped records across domains.	Perm
EXTRT	Name of Treatment	Char	*	Topic	Name of the protocol-specified study treatment given during the dosing period for the observation.	Req
EXCAT	Category of Treatment	Char	*	Grouping Qualifier	Used to define a category of EXTRT values.	Perm
EXSCAT	Subcategory of Treatment	Char	*	Grouping Qualifier	A further categorization of EXCAT values.	Perm
EXDOSE	Dose	Num		Record Qualifier	Amount of EXTRT when numeric. Not populated when EXDOSTXT is populated.	Exp
EXDOSTXT	Dose Description	Char		Record Qualifier	Amount of EXTRT when non-numeric. Dosing amounts or a range of dosing information collected in text form. Example: 200-400. Not populated when EXDOSE is populated.	Perm
EXDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for EXDOSE, EXDOSTOT, or EXDOSTXT representing protocol-specified values. Examples: "ng", "mg", "mg/kg", "mg/m2".	Exp
EXDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for EXTRT. Examples: "TABLET", "LOTION".	Exp
EXDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of repeated administrations of EXDOSE within a specific time period. Examples: "Q2H", "QD", "BID".	Perm
EXDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".	Perm
EXROUTE	Route of Administration	Char	(ROUTE)	Variable Qualifier	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".	Perm
EXLOT	Lot Number	Char		Record Qualifier	Lot number of the intervention product.	Perm
EXLOC	Location of Dose Administration	Char	(LOC)	Record Qualifier	Specifies location of administration. Examples: "ARM", "LIP".	Perm
EXLAT	Laterality	Char	(LAT)	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
--DECOD	Standardized Treatment Name	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

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 — Interventions, Version 3.3. One record per recorded procedure per occurrence 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	PR	Identifier	Two-character abbreviation for the domain.	Req
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
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.	Perm
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.	Perm
PRLNKID	Link ID	Char		Identifier	Used to facilitate identification of relationships between records.	Perm
PRLNKGRP	Link Group ID	Char		Identifier	Used to facilitate identification of relationships between records.	Perm
PRTRT	Reported Name of Procedure	Char		Topic	Name of procedure performed, either pre-printed or collected on a CRF.	Req
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. If an intervention term does not have a decode value in the dictionary, then PRDECOD will be null.	Perm
PRCAT	Category	Char	*	Grouping Qualifier	Used to define a category of procedure values.	Perm
PRSCAT	Subcategory	Char	*	Grouping Qualifier	Used to define a further categorization of PRCAT values.	Perm
PRPRESP	Pre-specified	Char	(NY)	Variable Qualifier	Used when a specific procedure is pre-specified on a CRF. Values should be "Y" or null.	Perm
PROCCUR	Occurrence	Char	(NY)	Record Qualifier	Used to record whether a pre-specified procedure occurred when information about the occurrence of a specific procedure is solicited.	Perm
PRINDC	Indication	Char		Record Qualifier	Denotes the indication for the procedure (e.g., why the procedure was performed).	Perm
PRDOSE	Dose	Num		Record Qualifier	Amount of PRTRT administered. Not populated when PRDOSTXT is populated.	Perm
PRDOSTXT	Dose Description	Char		Record Qualifier	Dosing information collected in text form. Examples: "<1", "200-400". Not populated when PRDOSE is populated.	Perm
PRDOSU	Dose Units	Char	(UNIT)	Variable Qualifier	Units for PRDOSE, PRDOSTOT, or PRDOSTXT.	Perm
PRDOSFRM	Dose Form	Char	(FRM)	Variable Qualifier	Dose form for PRTRT.	Perm
PRDOSFRQ	Dosing Frequency per Interval	Char	(FREQ)	Variable Qualifier	Usually expressed as the number of doses given per a specific interval.	Perm
PRDOSRGM	Intended Dose Regimen	Char		Variable Qualifier	Text description of the intended schedule or regimen for the procedure.	Perm
PRROUTE	Route of Administration	Char	(ROUTE)	Variable	Route of administration for PRTRT.	Perm

Example events domain

2.2.2 The Events Observation Class

Table 2.2.2.1 Events—Topic and

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

6.2.1 Adverse Events

AE – Description/Overview

An events domain that contains data describing untoward medical occurrences in a patient or subjects that are administered a pharmaceutical product and which may not necessarily have a causal relationship with the treatment.

AE – Specification

ae.xpt, Adverse Events — Events, Version 3.3. One record per adverse event 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	AE	Identifier	Two-character abbreviation for the domain.	Req
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
AESEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
AEGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
AEREFID	Reference ID	Char		Identifier	Internal or external identifier such as a serial number on an SAE reporting form.	Perm
AESPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined identifier. It may be preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on an Adverse Events page.	Perm
AETERM	Reported Term for the Adverse Event	Char		Topic	Verbatim name of the event.	Req
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
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 Qualifier	Dictionary-derived text description of AETERM or AEMODIFY. Equivalent to the Preferred Term (PT in 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.	Req
AEPTCD	Preferred Term Code	Num	MedDRA	Variable Qualifier	Dictionary-derived code for the Preferred Term.	Exp
AEHLT	High Level Term	Char	MedDRA	Variable Qualifier	Dictionary-derived text description of the High Level Term for the primary System Organ Class.	Exp
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
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
AECAT	Category for Adverse Event	Char	*	Grouping Qualifier	Used to define a category of related records. Example: "BLEEDING", "NEUROPSYCHIATRIC".	Perm
AESCAT	Subcategory for Adverse Event	Char	*	Grouping Qualifier	A further categorization of adverse event. Example: "NEUROLOGIC".	Perm
AEPRESP	Pre-Specified Adverse Event	Char	(NY)	Variable Qualifier	A value of "Y" indicates that this adverse event was pre-specified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms).	Perm

Example events domain

2.2.2 The Events Observation Class

Table 2.2.2.1 Events—Top

Variable Name	Variable Label
--TERM	Reported Term
--MODIFY	Modified Repo
--LLT	Lowest Level T
--LLTCD	Lowest Level T
--DECOD	Dictionary-De
--PTCD	Preferred Ter
--HLT	High Level Ter
--HLTCD	High Level Ter
--HLGT	High Level Gro
--HLGTCD	High Level Gro Code
--CAT	Category
--SCAT	Subcategory
--PRESP	Pre-Specified
--OCCUR	Occurrence In
--STAT	Completion St
--REASND	Reason Not D
--BODSYS	Body System Class

6.2.6 Medical History

MH – Description/Overview

The medical history dataset includes the subject's prior history at the start of the trial. Examples of subject medical history information could include general medical history, gynecological history, and primary diagnosis.

MH – Specification

mh.xpt, Medical History — Events, Version 3.3. One record per medical history event 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	MH	Identifier	Two-character abbreviation for the domain.	Req
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
MHSEQ	Sequence Number	Num		Identifier	Sequence Number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
MHGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
MHREFID	Reference ID	Char		Identifier	Internal or external medical history identifier.	Perm
MHSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on a Medical History page.	Perm
MHTERM	Reported Term for the Medical History	Char		Topic	Verbatim or preprinted CRF term for the medical condition or event.	Req
MHMODIFY	Modified Reported Term	Char		Synonym Qualifier	If MHTERM is modified to facilitate coding, then MHMODIFY will contain the modified text.	Perm
MHDECOD	Dictionary-Derived Term	Char	*	Synonym Qualifier	Dictionary-derived text description of MHTERM or MHMODIFY. Equivalent to the Preferred Term (PT in 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.	Perm
MHEVDTYP	Medical History Event Date Type	Char	(MHEDTTYP)	Variable Qualifier	Specifies the aspect of the medical condition or event by which MHSTDTC and/or the MHENDTC is defined. Examples: "DIAGNOSIS", "SYMPTOMS", "RELAPSE", "INFECTION".	Perm
MHCAT	Category for Medical History	Char	*	Grouping Qualifier	Used to define a category of related records. Examples: "CARDIAC" or "GENERAL".	Perm
MHSCAT	Subcategory for Medical History	Char	*	Grouping Qualifier	A further categorization of the condition or event.	Perm
MHPRESP	Medical History Event Pre-Specified	Char	(NY)	Variable Qualifier	A value of "Y" indicates that this medical history event was pre-specified on the CRF. Values are null for spontaneously reported events (i.e., those collected as free-text verbatim terms).	Perm
MHOCCUR	Medical History Occurrence	Char	(NY)	Record Qualifier	Used when the occurrence of specific medical history conditions is solicited, to indicate whether or not ("Y"/"N") a medical condition (MHTERM) had ever occurred. Values are null for spontaneously reported events.	Perm
MHSTAT	Completion Status	Char	(ND)	Record Qualifier	The status indicates that the pre-specified question was not asked/answered.	Perm
MHREASND	Reason Medical History Not Collected	Char		Record Qualifier	Describes the reason why data for a pre-specified condition was not collected. Used in conjunction with MHSTAT when value is "NOT DONE".	Perm
MHBODSYS	Body System or Organ Class	Char	*	Record Qualifier	Dictionary-derived. Body system or organ class that is involved in an event or measurement from a standard hierarchy (e.g., MedDRA). When using a multi-axial dictionary such as MedDRA, this should contain the SOC used for the sponsor's analyses and summary tables which may not necessarily be the primary SOC.	Perm

Example findings domain

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
--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

6.3.6 Laboratory Test Results

LB – Description/Overview

A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

LB – Specification

lb.xpt, Laboratory Test Results — Findings, Version 3.3. One record per lab test 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	LB	Identifier	Two-character abbreviation for the domain.	Req
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
LBSEQ	Sequence Number	Num		Identifier	Sequence number given to ensure uniqueness of subject records within a domain. May be any valid number.	Req
LBGRPID	Group ID	Char		Identifier	Used to tie together a block of related records in a single domain for a subject.	Perm
LBREFID	Specimen ID	Char		Identifier	Internal or external specimen identifier. Example: Specimen ID.	Perm
LBSPID	Sponsor-Defined Identifier	Char		Identifier	Sponsor-defined reference number. Perhaps preprinted on the CRF as an explicit line identifier or defined in the sponsor's operational database. Example: Line number on the Lab page.	Perm
LBTESTCD	Lab Test or Examination Short Name.	Char	(LBTESTCD)	Topic	Short name of the measurement, test, or examination described in LBTEST. It can be used as a column 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 other than letters, numbers, or underscores. Examples: "ALT", "LDH".	Req
LBTEST	Lab Test or Examination Name	Char	(LBTEST)	Synonym Qualifier	Verbatim name of the test or examination used to obtain the measurement or finding. Note any test normally performed by a clinical laboratory is considered a lab test. The value in LBTEST cannot be longer than 40 characters. Examples: "Alanine Aminotransferase", "Lactate Dehydrogenase".	Req
LBCAT	Category for Lab Test	Char	*	Grouping Qualifier	Used to define a category of related records across subjects. Examples: "HEMATOLOGY", "URINALYSIS", "CHEMISTRY".	Exp
LBSCAT	Subcategory for Lab Test	Char	*	Grouping Qualifier	A further categorization of a test category such as "DIFFERENTIAL", "COAGULATION", "LIVER FUNCTION", "ELECTROLYTES".	Perm
LBORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the measurement or finding as originally received or collected.	Exp
LBORRESU	Original Units	Char	(UNIT)	Variable Qualifier	Original units in which the data were collected. The unit for LBORRES. Example: "g/L".	Exp
LBORNRLO	Reference Range Lower Limit in Orig Unit	Char		Variable Qualifier	Lower end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Exp
LBORNRHI	Reference Range Upper Limit in Orig Unit	Char		Variable Qualifier	Upper end of reference range for continuous measurement in original units. Should be populated only for continuous results.	Exp
LBSTRESC	Character Result/Finding in Std Format	Char	(LBSTRESC)	Result Qualifier	Contains the result value for all findings, copied or derived from LBORRES in a standard format or standard units. LBSTRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in LBSTRESN. For example, if a test has results "NONE", "NEG", and "NEGATIVE" in LBORRES and these results effectively have the same meaning, they could be represented in standard format in LBSTRESC as "NEGATIVE". For other examples, see general assumptions.	Exp
LBSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from LBSTRESC. LBSTRESN should store all numeric test results or findings.	Exp

Example findings domain

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
--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

6.3.17 Vital Signs

VS – Description/Overview

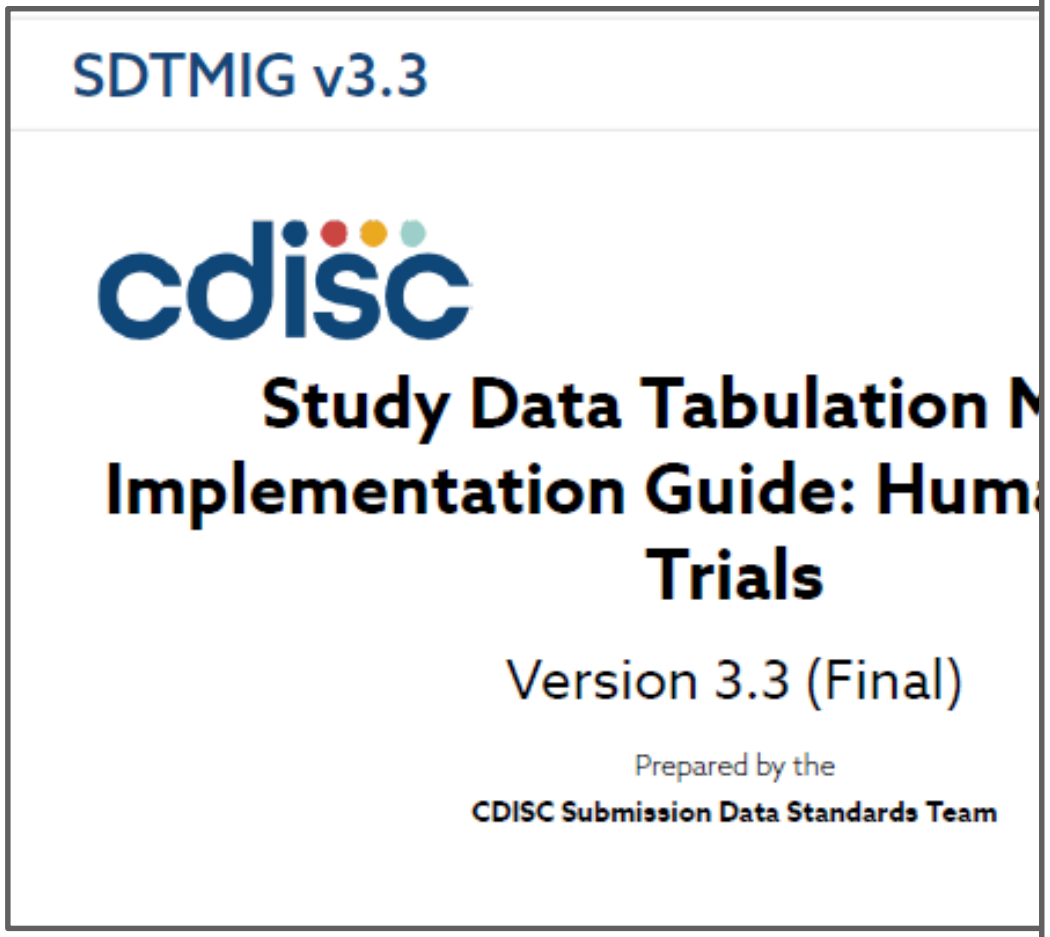
A findings domain that contains measurements including but not limited to blood pressure, temperature, respiration, body surface area, body mass index, height and weight.

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
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
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 when converting a dataset from a vertical to a horizontal format. The value in VSTESTCD cannot be longer than 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".	Req
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 Mass Index".	Req
VSCAT	Category for Vital Signs	Char	*	Grouping Qualifier	Used to define a category of related records.	Perm
VSSCAT	Subcategory for Vital Signs	Char	*	Grouping Qualifier	A further categorization of a measurement or examination.	Perm
VSPOS	Vital Signs Position of Subject	Char	(POSITION)	Record Qualifier	Position of the subject during a measurement or examination. Examples: "SUPINE", "STANDING", "SITTING".	Perm
VSORRES	Result or Finding in Original Units	Char		Result Qualifier	Result of the vital signs measurement as originally received or collected.	Exp
VSORRESU	Original Units	Char	(VSRESU)	Variable Qualifier	Original units in which the data were collected. The unit for VSORRES. Examples: "in", "LB", "beats/min".	Exp
VSSTRESC	Character Result/Finding in Std Format	Char		Result Qualifier	Contains the result value for all findings, copied or derived from VSORRES in a standard format or standard 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 in VSSTRESC as "NEGATIVE".	Exp
VSSTRESN	Numeric Result/Finding in Standard Units	Num		Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from VSSTRESC. VSSTRESN should store all numeric test results or findings.	Exp
VSSTRESU	Standard Units	Char	(VSRESU)	Variable Qualifier	Standardized unit used for VSSTRESC and VSSTRESN.	Exp
VSSTAT	Completion Status	Char	(ND)	Record Qualifier	Used to indicate that a vital sign measurement was not done. Should be null if a result exists in VSORRES.	Perm
VSREASND	Reason Not Performed	Char		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".	Perm

SDTM Implementation Guide: Star



6 Domain Models Based on the General Observation Classes
6.1 Models for Interventions Domains
6.1.1 Procedure Agents
6.1.2 Concomitant and Prior Medications
6.1.3 Exposure Domains
6.1.3.1 Exposure
6.1.3.2 Exposure as Collected
6.1.3.3 Exposure/Exposure as Collected Examples
6.1.4 Meal Data
6.1.5 Procedures
6.1.6 Substance Use
6.2 Models for Events Domains
6.2.1 Adverse Events
6.2.2 Clinical Events
6.2.3 Disposition
6.2.4 Protocol Deviations
6.2.5 Healthcare Encounters
6.2.6 Medical History
6.3 Models for Findings Domains
6.3.1 Drug Accountability
6.3.2 Death Details
6.3.3 ECG Test Results
6.3.4 Inclusion/Exclusion Criteria Not Met
6.3.5 Immunogenicity Specimen Assessments
6.3.6 Laboratory Test Results
6.3.7 Microbiology Domains
6.3.7.1 Microbiology Specimen
6.3.7.2 Microbiology Susceptibility
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
6.3.10.6 Reproductive System Findings
6.3.10.7 Respiratory System Findings
6.3.10.8 Urinary System Findings
6.3.11 Pharmacokinetics Domains
6.3.11.1 Pharmacokinetics Concentrations
6.3.11.2 Pharmacokinetics Parameters
6.3.11.3 Relating PP Records to PC Records
6.3.12 Physical Examination
6.3.13 Questionnaires, Ratings, and Scales (QRS) Domains
6.3.13.1 Functional Tests
6.3.13.2 Questionnaires
6.3.13.3 Disease Response and Clin Classification
6.3.14 Subject Characteristics
6.3.15 Subject Status
6.3.16 Tumor/Lesion Domains
6.3.16.1 Tumor/Lesion Identification
6.3.16.2 Tumor/Lesion Results
6.3.16.3 Tumor Identification/Tumor Results Examples
6.3.17 Vital Signs
6.4 Findings About Events or Interventions
6.4.1 When to Use Findings About
6.4.2 Naming Findings About Domains
6.4.3 Variables Unique to Findings About
6.4.4 Findings About
6.4.5 Skin Response

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)

Example: Interventions
Custom domain

2.2.1 The Interventions Observation Class

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

Variable Name	Variable Label	Type	Role	Description
Topic Variable				
--TRT	Name of Treatment	Char	Topic	The topic for the intervention observation, usually the verbatim name of the treatment, drug, medicine, or therapy given during the dosing interval for the observation.
Qualifier Variables				
--MODIFY	Modified Treatment Name	Char	Synonym Qualifier of --TRT	If the value for --TRT is modified for coding purposes, then the modified text is placed here.
--DECOD	Standardized Treatment Name	Char		
--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	Record Qualifier	Amount of --TRT given. Not populated when --DOSTXT is populated.
--DOSTXT	Dose Description	Char	Record Qualifier	Dosing information collected in text form. Examples: <1 per day, 200-400. Not populated when --DOSE is populated.
--DOSU	Dose Units	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Units for --DOSE, --DOSTOT, or --DOSTXT. 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 of --TRT using the units in --DOSU. Used when dosing is collected as Total Daily Dose.
--DOSRGM	Intended Dose Regimen	Char	Variable Qualifier of --DOSE, --DOSTXT or --DOSTOT	Text description of the (intended) schedule or regimen for the Intervention. Example: "TWO WEEKS ON, TWO WEEKS OFF".
--ROUTE	Route of Administration	Char	Variable Qualifier of --TRT	Route of administration for the intervention. Examples: "ORAL", "INTRAVENOUS".
--LOT	Lot Number	Char	Record Qualifier	Lot number for the intervention described in --TRT.
--LOC	Location of Dose Administration	Char	Record Qualifier	Anatomical location of an intervention, such as an injection site. Example: ARM for an injection.
--LAT	Laterality	Char	Variable Qualifier of	Qualifier for anatomical location further detailing laterality of intervention administration. Examples: "RIGHT", "LEFT",

XM Meditation

VARIABLE	VARIABLE LABEL	TYPE	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES	CORE
STUDYID	Study Identifier	Char		Identifier		REQ
DOMAIN	Domain Abbreviation	Char	XM	Identifier	Default to XM	REQ
USUBJID	Unique Subject Identifier	Char		Identifier		REQ
XMSEQ	Sequence Number	Num		Identifier		REQ
XMTRT	Name of Meditation Regimen	Char		Topic		REQ
XMCAT	Categlory of Meditation Regimen	Char	(XMCAT)	Grouping Qualifier		PERM
XMDOSE	Length of Meditation Session	Num		Record Qualifier		PERM
XMDOSU	Unit for Length of Meditation Session	Char	(UNIT)	Variable Qualifier	Minutes, Hours	PERM
XMFREQ	Frequency of Meditation Sessions	Char	(FREQ)	Variable Qualifier		PERM
XMSTDTC	Start Date of Meditation Sessions	Char	ISO 8601	Timing		PERM

Example: Events Custom domain

2.2.2 The Events Observation Class

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

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

YV	Vacation					
VARIABLE	**VARIABLE LABEL**	**TYPE**	**CONTROLLED TERMS, CODELIST OR FORMAT**	**ROLE**	**IMPLEMENTATION NOTES**	**C**
STUDYID	Study Identifier	Char		Identifier		REC
DOMAIN	Domain Abbreviation	Char	YV	Identifier	Default to YV	REC
USUBJID	Unique Subject Identifier	Char		Identifier		REC
YVSEQ	Sequence Number	Num		Identifier		REC
YVTERM	Vacation Event	Char		Topic		REC
YVPRESP	Pre-specified	Char	(YN)	Variable Qualifier	Default to Y when a value has been pre-specified in YVTERM	PER
YVOCCUR	Occurrence of Vacation	Char	(YN)	Record Qualifier		EXP
YVSTDTC	Start Date of Vacation	Char	ISO 8601	Timing		EXP
YVENDTC	End Date of Vacation	Char	ISO 8601	Timing		EXP
YVEVLINT	Evaluation Interval	Char	ISO 8601	Timing		PER

Example: Findings
Custom domain

2.2.3 The Findings Observation Class

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

Variable Name	Variable Label	Type	Role	Description
			Topic Variable	
--TESTCD	Short Name of Measurement, Test, or Exam	Char	Topic	Short character value for --TEST used as a column name when converting a dataset from a vertical format to a horizontal
--TEST	Name of Measurement, Test, or Exam			
--MODIFY	Modified Term			
--TSTDTL	Measurement, Test, 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	Char	Variable Qualifier of --ORRES	Upper end of normal range or reference range for results stored in --ORRES.
--ORREF	Reference Result in Original Units	Char	Variable Qualifier of --ORRES	Reference value for the result or finding as originally received or collected. --ORREF uses the same units as --ORRES, if applicable. Examples: value from predicted normal value in spirometry tests.
--STRESC	Result or Finding in Standard Format	Char	Result Qualifier	Contains the result value for all findings, copied or derived from --ORRES in a standard format or in standard units. --STRESC should store all results or findings in character format; if results are numeric, they should also be stored in numeric format in --STRESN. For example, if various tests have results "NONE", "NEG", and "NEGATIVE" in --ORRES and these results effectively have the same meaning, they could be represented in standard format in --STRESC as "NEGATIVE".
--STRESN	Numeric Result/Finding in Standard Units	Num	Result Qualifier	Used for continuous or numeric results or findings in standard format; copied in numeric format from --STRESC. --STRESN should store all numeric test results or findings.
--STRESU	Standard Units	Char	Variable Qualifier of --STRESC and --STRESN and --STREFC and --STREFN	Standardized units used for --STRESC, --STRESN, --STREFC, and --STREFN. Example: "mol/L".
--STNRLO	Normal Range Lower Limit-Standard Units	Num	Variable Qualifier of --STRESC and --STRESN	Lower end of normal range or reference range for standardized results (e.g., --STRESC, --STRESN) represented in standardized units (--STRESU).
--STNRHI	Normal Range Upper Limit-Standard Units	Num	Variable Qualifier of --STRESC and	Upper end of normal range or reference range for standardized results (e.g., --STRESC, --STRESN) represented in standardized units (--STRESU).

ZD Dermatology Findings

VARIABLE	VARIABLE LABEL	TYPE	CONTROLLED TERMS, CODELIST OR FORMAT	ROLE	IMPLEMENTATION NOTES
STUDYID	Study Identifier	Char		Identifier	
DOMAIN	Domain Abbreviation	Char	ZD	Identifier	Default to ZD
USUBJID	Unique Subject Identifier	Char		Identifier	
ZDSEQ	Sequence Number	Num		Identifier	
ZDTESTCD	Dermatology Test Code	Char	(ZDTESTCD)	Topic	
ZDTEST	Dermatology Test	Char	(ZDTEST)	Synonym Qualifier	
ZDORRES	Dermatology Test Original Result	Char		Result Qualifier	
ZDORRESU	Dermatology Test Original Result Unit	Char	(UNIT)	Variable Qualifier	
ZDSTRESC	Dermatology Test Standardized Result - Character	Char		Result Qualifier	
ZDSTRESN	Dermatology Test Standardized Result - Numeric	Num		Result Qualifier	
ZDSTRESU	Dermatology Test Standardized Result Unit	Char	(UNIT)	Variable Qualifier	
ZDDTC	Evaluation Interval	Char	ISO 8601	Timing	

Trial Design

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

Protocol 123-ABC

Text-based information Useful for Human Understanding

te.xpt

Row	STUDYID	DOMAIN	ETCD	ELEMENT	TESTRL	TEENRL	TEDUR
1	EX1	TE	SCRN	Screen	Informed consent	1 week after start of Element	P7D
2	EX1	TE	RI	Run-In	Eligibility confirmed	2 weeks after start of Element	P14D
3	EX1	TE	P	Placebo	First dose of study drug, where drug is placebo	2 weeks after start of Element	P14D
4	EX1	TE	A	Drug A	First dose of study drug, where drug is Drug A	2 weeks after start of Element	P14D
5	EX1	TE	B	Drug B	First dose of study drug, where drug is Drug B	2 weeks after start of Element	P14D

ta.xpt

Row	STUDYI	DOMAIN	ARMCD	ARM	TAETORD	ETCD			
		TA	1	CR	1	SCRN			
		TA	1	CR	2	ICR			
		TA	1	CR	3	CRNS	C		
4	EX7	TA	1	CR	4	C	Chemo		CONTINUATION TREATMENT
5	EX7	TA	1	CR	5	C	Chemo		CONTINUATION TREATMENT
6	EX7	TA	1	CR	6	FU	Off Treatment Follow-up		
7	EX7	TA	2	CRS	1	SCRN	Screen	Randomized to CRS	
8	EX7	TA	2	CRS	2	ICR	Initial Chemo + RT		
9	EX7	TA	2	CRS	3	CRS	Chemo+RT (Surgery)		If progression, skip to F ineligible for or does
10	EX7	TA	2	CRS	4	R3	3-5 week rest		
11	EX7	TA	2	CRS	5	SURG	Surgery		
12	EX7	TA	2	CRS	6	R4	4-6 week rest		
13	EX7	TA	2	CRS	7	C	Chemo		
14	EX7	TA	2	CRS	8	C	Chemo		
15	EX7	TA	2	CRS	9	FU	Off Treatment Follow-up		

ti.xpt

Row	STUDYID	DOMAIN	IETESTCD	IETEST	IECAT	TIVERS
1	XYZ	TI	INCL01	Has disease under study	INCLUSION	1
2	XYZ	TI	INCL02	Age 21 or greater	INCLUSION	1
3	XYZ	TI	EXCL01	Pregnant or lactating	EXCLUSION	1
4	XYZ	TI	INCL01	Has disease under study	INCLUSION	2.2
				Age 18 or greater	INCLUSION	2.2
				Pregnant or lactating	EXCLUSION	2.2

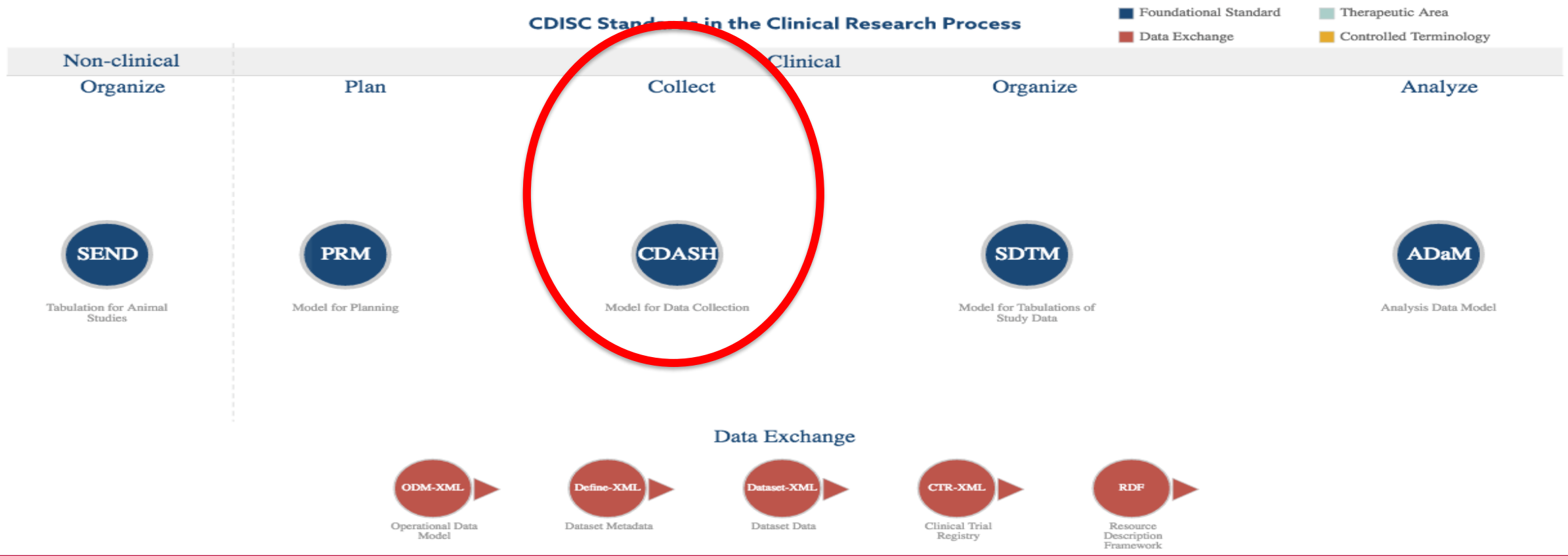
tv.xpt

Row	STUDYID	DOMAIN	VISITNUM	TVSTRL	TVENRL
1	EX1	TV	1	Start of Screen Epoch	
2	EX1	TV	2	On the same day as, but before, the end of the Screen Epoch	On the same day as, but after, the start of the Run-in Epoch
3	EX1	TV	3	On the same day as, but before, the end of the Run-in Epoch	On the same day as, but after, the start of the Treatment Epoch
4	EX1	TV	4	1 week after start of Treatment Epoch	
5	EX1	TV	5	2 weeks after start of Treatment Epoch	At Trial Exit

SDTM Structured Data Useful for Tool-Based Activities / Analysis

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

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



CDASH

Clinical Data Acquisition Standards Harmonization
Implementation Guide for Human Clinical Trials

Version 2.0

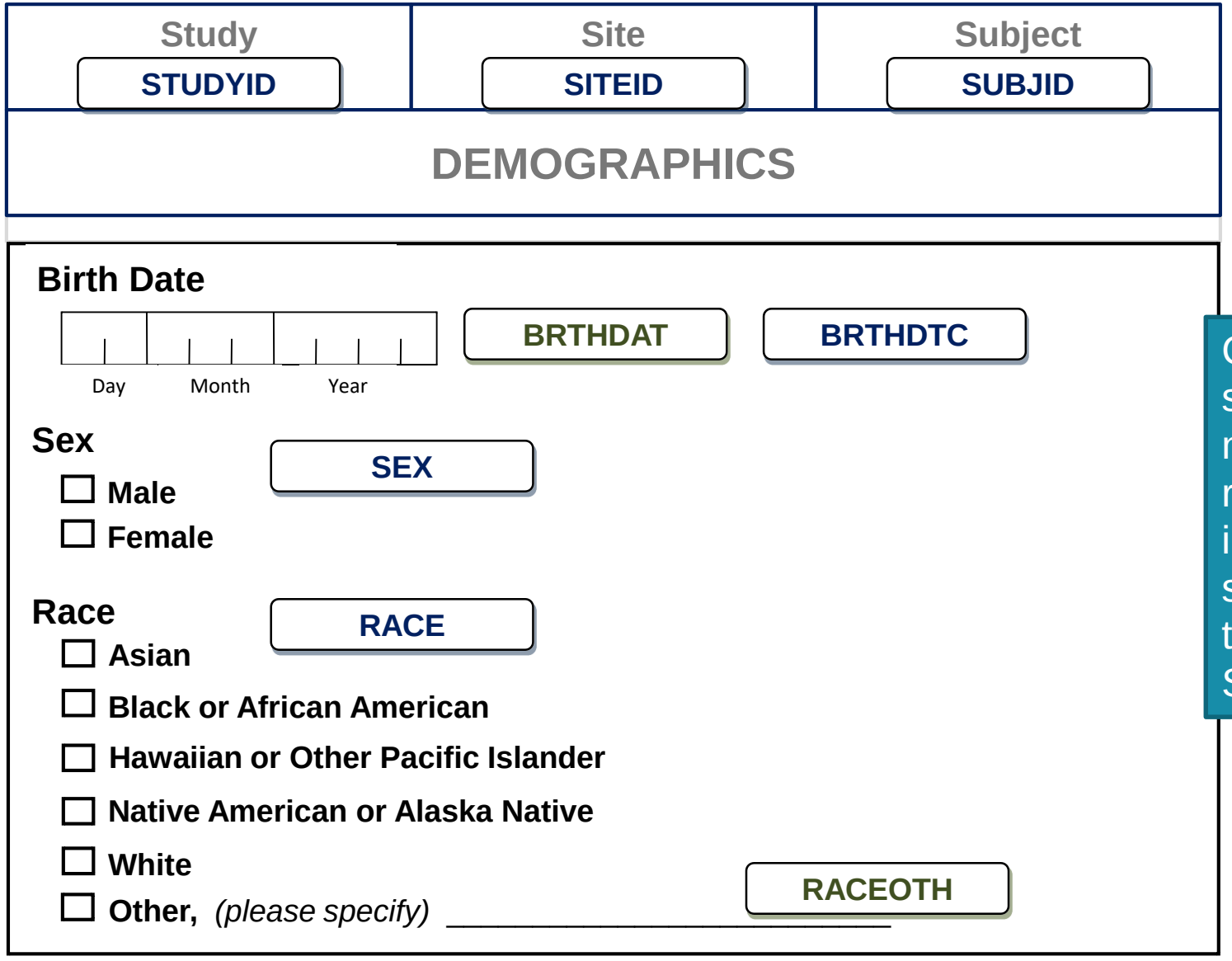
Prepared by the
CDISC CDASH Team

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)*

CDASH specifies a minimum set of fields:
- Logical set to have a valid record
- Target what is required for regulatory requirements including SDTM



CDASH specifies a standard variable name, with recommendations for implementation that support transformation to SDTM data

CDASH Principles (*or How CDASH Supports Getting to SDTM)*

CDASH specifies standard wording for the data collection questions, with flexibility to handle protocol-specific requirements

Study	Site	Subject
STUDYID	SITEID	SUBJID

DEMOGRAPHICS

Birth Date

Day Month Year

BRTHDAT BRTHDTC

Sex

- ☐ Male
- ☐ Female

SEX

Race

- ☐ Asian
- ☐ Black or
- ☐ Hawaiian
- ☐ Native Ar
- ☐ White
- ☐ Other, *(please specify)* _____

CDASH specifies using standardized value lists that are harmonized with SDTM requirements

E	F
CDISC Submission Value	CDISC Synonym(s)
SEX	Sex
F	Female
M	Male
U	U; Unknown
UNDIFFERENTIATED	

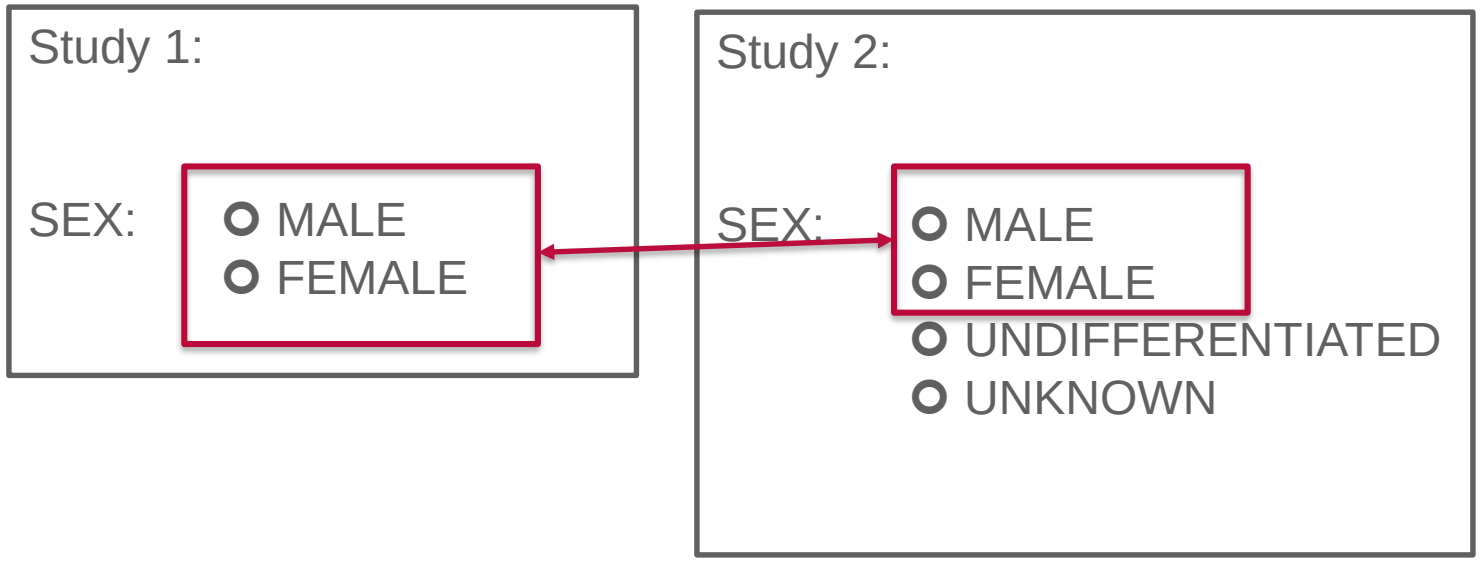
CDASH- Demographics Example Metadata*

*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

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C66731		No	Sex	SEX	Sex	The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. (NCI)	CDISC SDTM Sex of Individual Terminology
C16576	C66731		Sex	F	Female	A person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. (NCI)	Female
C20197	C66731		Sex	M	Male	A person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. (NCI)	Male
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 sexual characteristics of indeterminate sex, or which combine features of both sexes. (NCI)	Intersex

- Thousands of standardized, **defined** terms
- A **single** 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 = 2 character Domain Code

FieldOID/VariableOID = CDASH (or SDTM) variable

PreText = CDASH Question Text (Prompt is also acceptable)

DataDictionaryName = CDISC Codelist Name

SASLabel = SDTM (or CDASH) Variable Label

FormOID	FieldOID	VariableOID	DataDictionaryNam	PreText	SASLabel
DM				FORM_OID	
DM					Study Identifier
DM					Study Site Identifier
	SUBJID	SUBJID			Subject Identifier for the Study
	BRTHDAT	BRTHDAT			
	BRTHYY	BRTH		s the subject's year of	Y
DM	BRTHMO	BRTH		s the subject's month of birth?	M
DM	BRTHDD	BRTHDD		What is the subject's day of birth?	D
DM	BRTHTIM	BRTHTIM		What is the subject's time of birth?	Time of Birth
DM	AGE	AGE		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
DM	ETHNIC			Do you consider yourself Hispanic/Latino or not	
DM	CETHNIC				
DM	RACE	RACE	RACE	acceptable.)	Race
DM	CRACE	CRACE	RACEC	Which of the following racial designations best describes you? (More than one choice is acceptable.)	Collected Race
DM	RACEOTH	RACEOTH		What was the other race?	Race Other

DataDictionaryName	CodedData	UserDataString
SEX	F	Female
SEX	M	Male
SEX	U	Unknown
SEX	UNDIFFERENTIATED	Intersex

Q&A

Shannon.Labout@nih.gov