SDTM Overview

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October 30, 2017

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Agenda

01 Introduction to SDTM s

SDTM - Benefits

FDA and PMDA require standards for their review

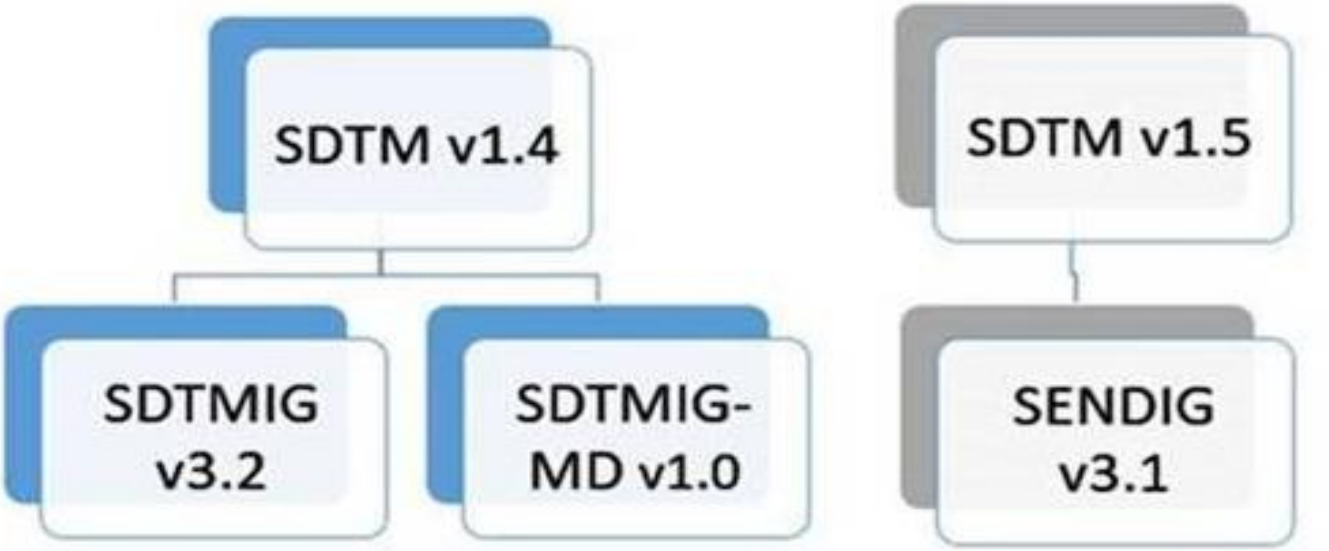
- Provides a standard for representation of data
- Eases data review – facilitating standard tools
- Provides guidance to handle atypical data
- Standardizes non clinical, medical devices, pharmacogenomics/ genetic study data

Sponsor Benefits

- Standard and streamlined process in collecting, organizing, managing, analyzing and reporting of data
- Flexibility to handle instream data changes protocol – CRF – data – Analysis
- Eases implementation of data aggregation and warehouse creation; facilitating data mining and re-usability
- Facilitates the process of data sharing
- Shorter timelines for data review
- Similar standards for submission across different HAs – cost and time benefits
- Trial design standards and library for trial components
- Accelerates and improves the submission process – efficient data submission

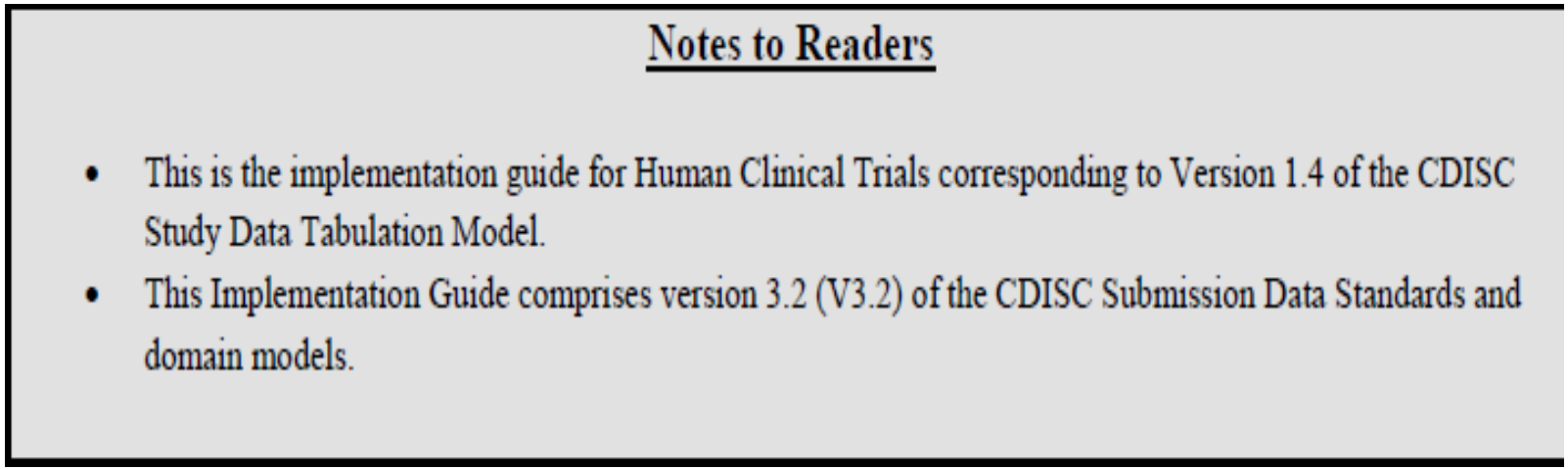
SDTM and SDTM IG

One SDTM version can be referenced by multiple IGs.



SDTM and SDTM IG

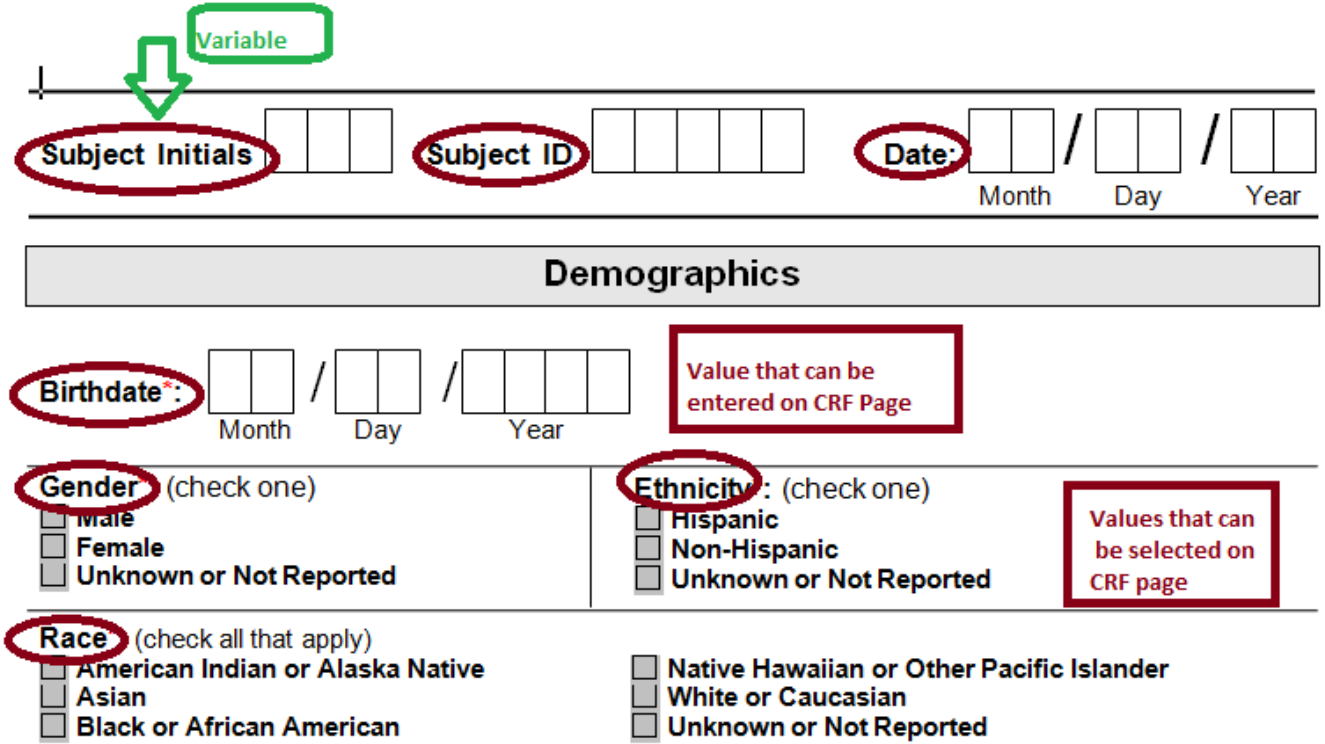
Each IG will reference the SDTM version it is associated with.



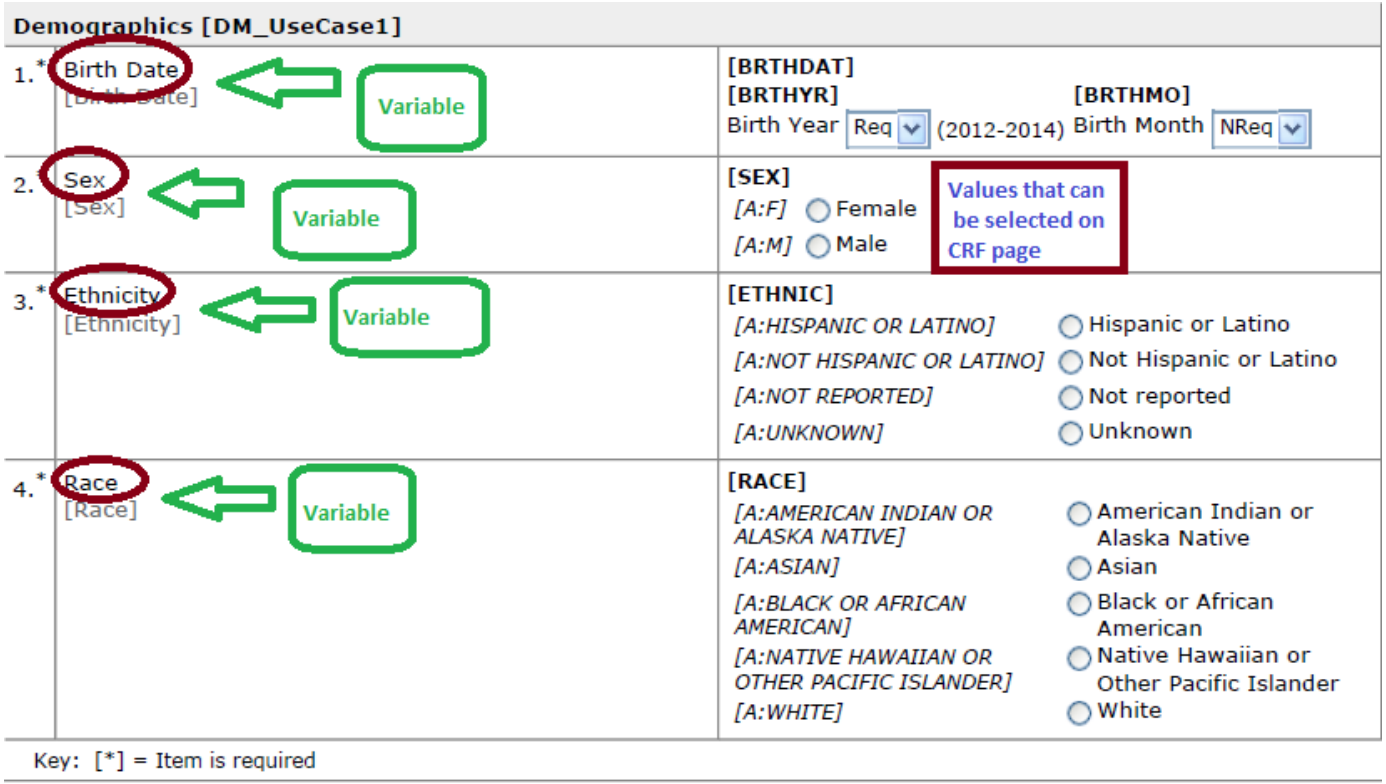
Notes to Readers

- This is the implementation guide for Human Clinical Trials corresponding to Version 1.4 of the CDISC Study Data Tabulation Model.
- This Implementation Guide comprises version 3.2 (V3.2) of the CDISC Submission Data Standards and domain models.

Example 1 : Demographic Page – non standard



Example 2 : Demographic Page – standard



Exercise using Example 1 & 2

1. What are Variables?
2. Comparison of Example 1 & 2

Understanding Key Terms in SDTMs

- The model is built around the concept of Observations.
- Observations are *discrete pieces of information* collected during a study.
- Observations normally correspond to rows in a dataset.
- Each observation can be described by a series of named variables.
- Each variable, normally *corresponds to a column in a dataset*, can be classified according to its Role.
- A domain is defined as a *collection of observations with a topic-specific commonality about a subject*.

Understanding Contents of SDTM

SUBJID	USUSBJID	BRTHDTC	SEX	RACE	ETHNIC
1001	XYZ12345-1001	2006-01-12	M	ASIAN	Non Hispanic
1002	XYZ12345-1002	1980-07-14	M	ASIAN	Non Hispanic
1003	XYZ12345-1003	1945-03-21	M	ASIAN	Non Hispanic
1004	XYZ12345-1004	2000-12-12	F	ASIAN	Non Hispanic

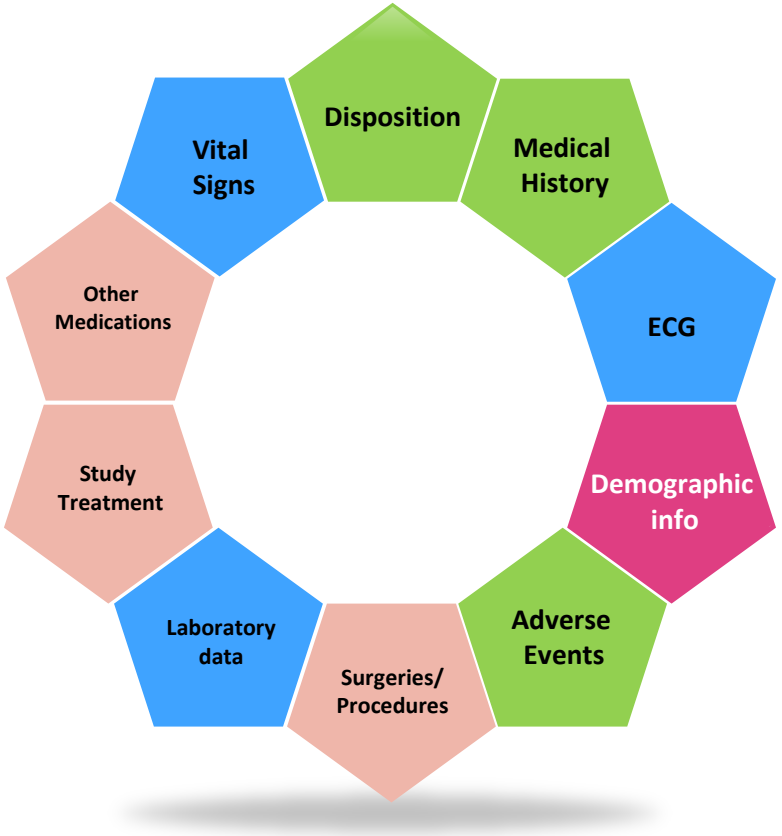
Variables

Values

Here we have 4 observations and 6 variables.

Data Captured During Clinical Trial

- We collect information for a patient on various Case Report forms as displayed in the adjoining figure
- In SDTM terminology we call this as Domains
- It is important to Classify this information as objective of each information is different



Classification of Data

Events	Interventions	Findings
When you want to know What happened to a patient in past, what is happening to a patient during trial or what are the different milestones patient is completing as defined in Protocol, CDISC classifies this Info as EVENTS	Which study treatment patient has taken, what was the frequency, route etc. In addition to the study medications what other medications are taken by patient. Did the patient undergo any procedure? Did the patient use any substance during trial?	Did the patient do any test? (e.g Laboratory test, ECG, Vital signs etc), what were the results of the test? Were any pharmacokinetic tests done? Did the subject fill any questionnaire data? If yes what were the answers to the questions

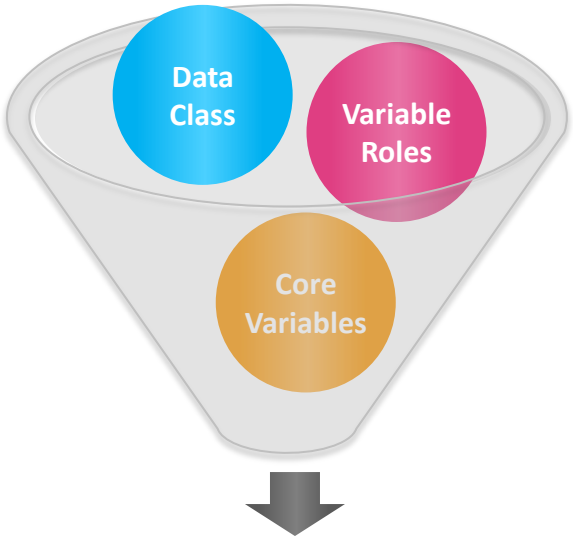
Some data can not be classified in the above categories that will go as “Special Purpose” domain

Data related to Trial design, Trial visit, Trial Element, Trial Summary can not be mapped into above classes and is mapped in Trial Design Domains

Relationship between different domains or additional information in a same domain can be mapped into RELREC or SUPPQUAL

SDTM Overview

Major components of SDTM which helps in structuring the data are:



SDTM Overview : Data Class

Describes the datasets or domains within the SDTM. These are Categorized into 6 classes

General Observations

Interventions	Events	Findings	Special Purpose	Trial Design	Relationship
Investigational drug, medicinal product, therapeutic or any other treatments administered to the subject which can cause a physiologic change in the subject	Planned protocol milestones, study evaluations and the incidents that occur during the or prior to the course of the clinical trial.	Planned and unplanned observations/evaluation during the course of the clinical trial.	Additional important information that does not fit the General observation class	The clinical trial design, objectives and the planned schedule as defined in the protocol are represented in this class	Related records (RELREC)
Intervention Domains: Exposure (EX) Exposure as collected (EC) Concomitant/Prior Medications (CM) Procedures (PR) Substance Use (SU)	Event domains: Adverse Events (AE) Medical History (MH) Clinical Events (CE) Disposition (DS) Protocol Deviations (PD)	Finding domains: ECG test Results (EG) Laboratory Test Results (LB) Pharmacokinetics Findings (PC) Questionnaires (QS) Physical Examination (PE) etc.	Special Purpose domains: Demographics (DM) Subject Visit (SV) Subject Elements (SE) Comments (CO)	Trial Design domains: Trial Arms (TA) Trial Inclusion/Exclusion (TI) Trial Elements (TE) Trial Visits (TV) Trial Summary (TS).	Supplemental Qualifiers (SUPP--)

SDTM Overview : Variable Roles

A Role determines the type of information conveyed by the variable about each distinct observation and how it can be used.

Variables have 5 main roles within SDTM

Identifier	Topic	Timing	Qualifier	Rule
Key Distinguishers aid in identifying the records	Specifies the focus of the observation	Timing of the observation	Additional important information that describes the results or traits of the observation	Algorithm or method to define start, end, branching or looping condition in Trial Domains
Study Identifier (STUDYID) Subject Identifier (USUBJID) Sequence Identifier (--SEQ)	Lab Test Name (LBTEST) Adverse Event Term (AETERM) Reported Drug Name (CMTRT)	Lab Lab Assessment Date (LBDTC) Adverse Event Start Date (AESTDTC) Exposure End Date (EXENDTC)	Lab Test Result (LBORRES) Adverse Event Severity (AESEV) Conmed Dose (CMDOSE)	TABRANCH, TATRANSITION in TA domain

SDTM Overview : Qualifier classification

The Qualifier variable is further classified in to 5 subclasses

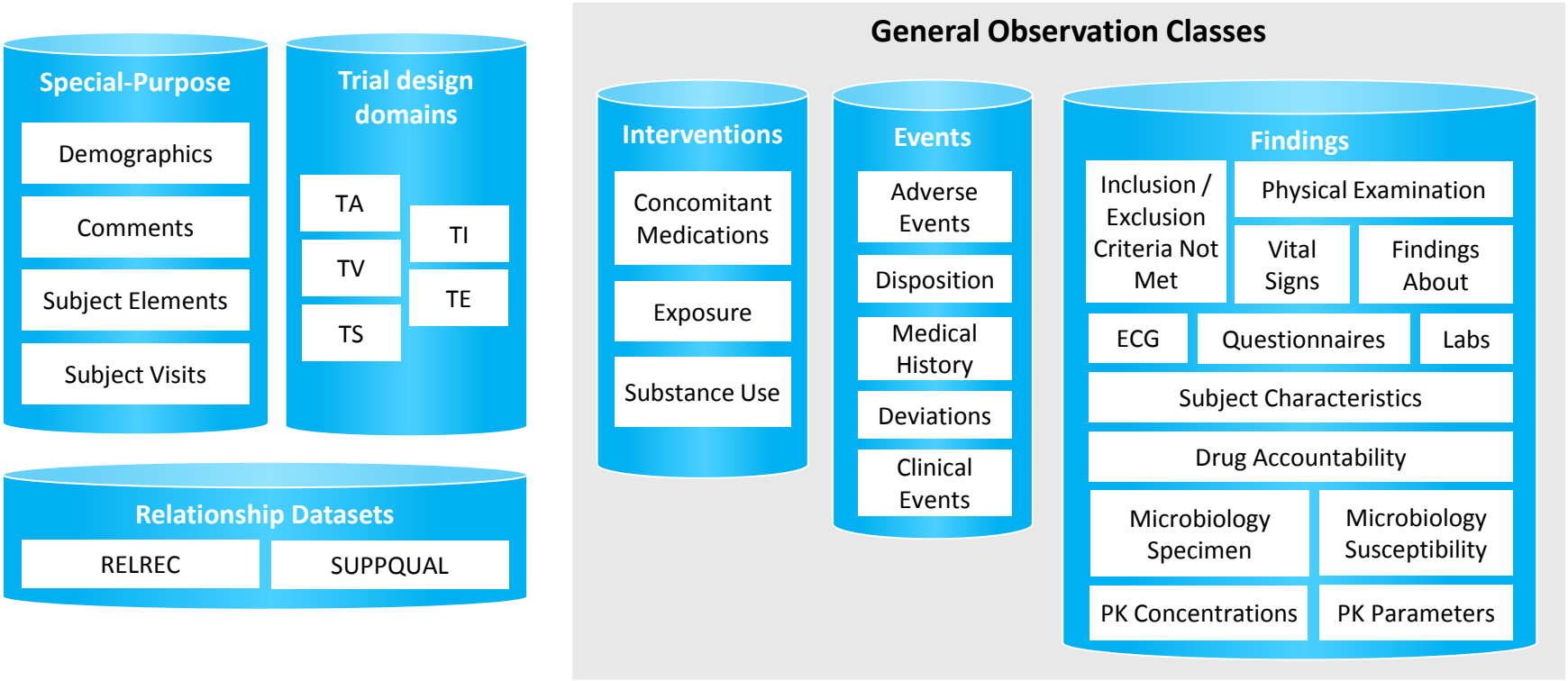
Grouping	Result	Variable	Synonym	Record
Used to group or categorize observations within a domain	Contains specific results in “Findings” domain, either original or standardized format.	Contain additional information to more clearly define values in another variable.	Contain an alternative name for another variable (usually the topic variable)	Contains additional information about the observation as a whole
Lab Category (LBCAT)/ (LBSCAT) etc.	LAB Results and Ranges (LBORRES), (LBSTRESN), (LBSTRESC) etc.	(e.g., units, normal range). E.g. CMDOSU, LBORRESU, LBSTRESU etc.	LBTEST, AEMODIFY etc.	(e.g., severity, subject position for vital signs) e.g. AEOUT, AEACN, CMSTAT etc.

SDTM Overview : Core Variable Classification

The Core variable is further classified in to 3 types

Required	Expected	Permissible
Basic to the identification of a data record	Establish the observation context	If collected or derived
Must always be included	Must always be included	Must be included if collected
Cannot be null for any record	Can be null for some records	Can be null or present

SNAPSOT of Standard Domain



List of SDTM Domain - IG 3.2

Special-Purpose Domains

• Comments (CO) • Demographics (DM)
• Subject Elements (SE) • Subject Visits (SV)

Interventions General Observation Class

• Concomitant Medications (CM) • Exposure as Collected (EC)
• Exposure (EX) • Substance Use (SU) • Procedures (PR)

Events General Observation Class

• Adverse Events (AE) • Clinical Events (CE)
• Disposition (DS) • Protocol Deviations (DV)
• Healthcare Encounters (HO) • Medical History (MH)

Trial Design Domains

• Trial Arms (TA) • Trial Disease Assessment (TD) • Trial Elements (TE) • Trial Visits (TV) • Trial Inclusion/Exclusion Criteria (TI) • Trial Summary (TS)

Findings General Observation Class

• Drug Accountability (DA) • Death Details (DD)
• ECG Test Results (EG) • Inclusion/Exclusion Criterion Not Met (IE)
• Immunogenicity Specimen Assessments (IS)
• Laboratory Test Results (LB)
• Microbiology Specimen (MB) • Microscopic Findings (MI)
• Morphology (MO) • Microbiology Susceptibility Test (MS)
• PK Concentrations (PC) • PK Parameters (PP)
• Physical Examination (PE) • Questionnaires (QS)
• Reproductive System Findings (RP)
• Disease Response (RS)
• Subject Characteristics (SC) • Subject Status (SS)
• Tumor Identification (TU) • Tumor Results (TR)
• Vital Signs (VS)

Findings About

• Findings About (FA) • Skin Response (SR)

RELATIONSHIP Datasets

• RELREC • Supplemental Qualifier (SUPPQUAL)

Before and After SDTM

BEFORE SDTM	AFTER SDTM
Non standard Domain names	Standard Domain names
Variable Domain structure	Standard Domain structure
Variable Domain variables	Standard Domain variables
Variability of Domain variable names	Standard Domain variable names
Variety of Data classification	Standardized Data classification
Variety of Data storage / formatting	Standardized Data storage / formatting
Variability of variable roles	Standardized variable roles
Variable Data structure for atypical data e.g. questionnaires, TA specific data	Harmonized Data structure for atypical data

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End of Session

30-OCT-2017