



# SDTM Basic and Implementation by Example

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## **吴崇胜**

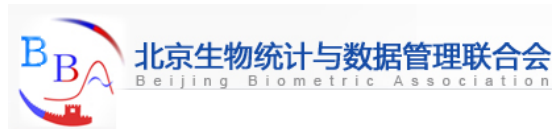
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- ▶ SDTM Basic
- ▶ General Observation Class
- ▶ SDTM Implementation by Example

# What's SDTM

## ► SDTM

- Study Data Tabulation Model (SDTM V1.4)
- SDTM Implementation Guide (SDTM IG V3.2)

### Study Data Tabulation Model

SDTM  
Implementation  
Guide

SEND

AP, MD...

# What's SDTM

## DM Example 1 – General Demographics

dm.xpt

Row	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICTTC	RFPENDTC
1	ABC123	DM	ABC12301001	001	2006-01-12	2006-03-10	2006-01-12	2006-03-10	2006-01-03	2006-04-01
2	ABC123	DM	ABC12301002	002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26
3	ABC123	DM	ABC12301003	003	2006-01-16	2006-03-19	2006-01-16	2006-03-19	2006-01-02	2006-03-19
4	ABC123	DM	ABC12301004	004					2006-01-07	2006-01-08
5	ABC123	DM	ABC12302001	001	2006-02-02	2006-03-31	2006-02-02	2006-03-31	2006-01-15	2006-04-12
6	ABC123	DM	ABC12302002	002	2006-02-03	2006-04-05	2006-02-03	2006-04-05	2006-01-10	2006-04-25

Row	SITEID	INVTNAM	BRTHDTC	AGE	AGEU	SEX	RACE	ETHNIC
1 (cont)	01	JOHNSON, M	1948-12-13	57	YEARS	M	WHITE	HISPANIC OR LATINO
2 (cont)	01	JOHNSON, M	1955-03-22	50	YEARS	M	WHITE	NOT HISPANIC OR LATINO
3 (cont)	01	JOHNSON, M	1938-01-19	68	YEARS	F	BLACK OR AFRICAN AMERICAN	NOT HISPANIC OR LATINO
4 (cont)	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO
5 (cont)	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO
6 (cont)	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO

Row	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY
1 (cont)	A	Drug A	A	Drug A	USA
2 (cont)	P	Placebo	P	Placebo	USA
3 (cont)	P	Placebo	P	Placebo	USA
4 (cont)	SCRNFAIL	Screen Failure	SCRNFAIL	Screen Failure	USA
5 (cont)	P	Placebo	P	Placebo	USA
6 (cont)	A	Drug A	A	Drug A	USA

- Reference:
  - <http://www.cdisc.org/sdtm>
  - [http://www.cdisc.org/system/files/members/standard/define\\_xml\\_2\\_0\\_releasepackage20140424.zip](http://www.cdisc.org/system/files/members/standard/define_xml_2_0_releasepackage20140424.zip)

# What's SDTM

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2	ABC123	DM	ABC12301002	002	2006-01-15	2006-02-28	2006-01-15	2006-02-28	2006-01-04	2006-03-26

## DM – Specification for the Demographics Domain Model

dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	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. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for	Exp
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be Y or null. Should be populated even when the death date is unknown.	Exp
SITEID	Study Site Identifier	Char		Record Qualifier	Unique identifier for a site within a study.	Req
INVID	Investigator Identifier	Char		Record Qualifier	An identifier to describe the Investigator for the study. May be used in addition to SITEID. Not needed if SITEID is equivalent to INVID.	Perm
INVNAM	Investigator Name	Char		Synonym Qualifier	Name of the investigator for a site.	Perm
BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier	Date/time of birth of the subject.	Perm
AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).	Exp
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.	Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race ( <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm</a> ) See Assumption below regarding RACE.	Exp
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity ( <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm</a> ).	Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-	Req

01-02 2006-03-19  
01-07 2006-01-08  
01-15 2006-04-12  
01-10 2006-04-25

ETHNIC
HISPANIC OR LATINO
NOT HISPANIC OR LATINO
NOT HISPANIC OR LATINO
NOT HISPANIC OR LATINO
NOT HISPANIC OR LATINO
DERS NOT HISPANIC OR LATINO





# What's SDTM

## DM Example 1 – General Demographics

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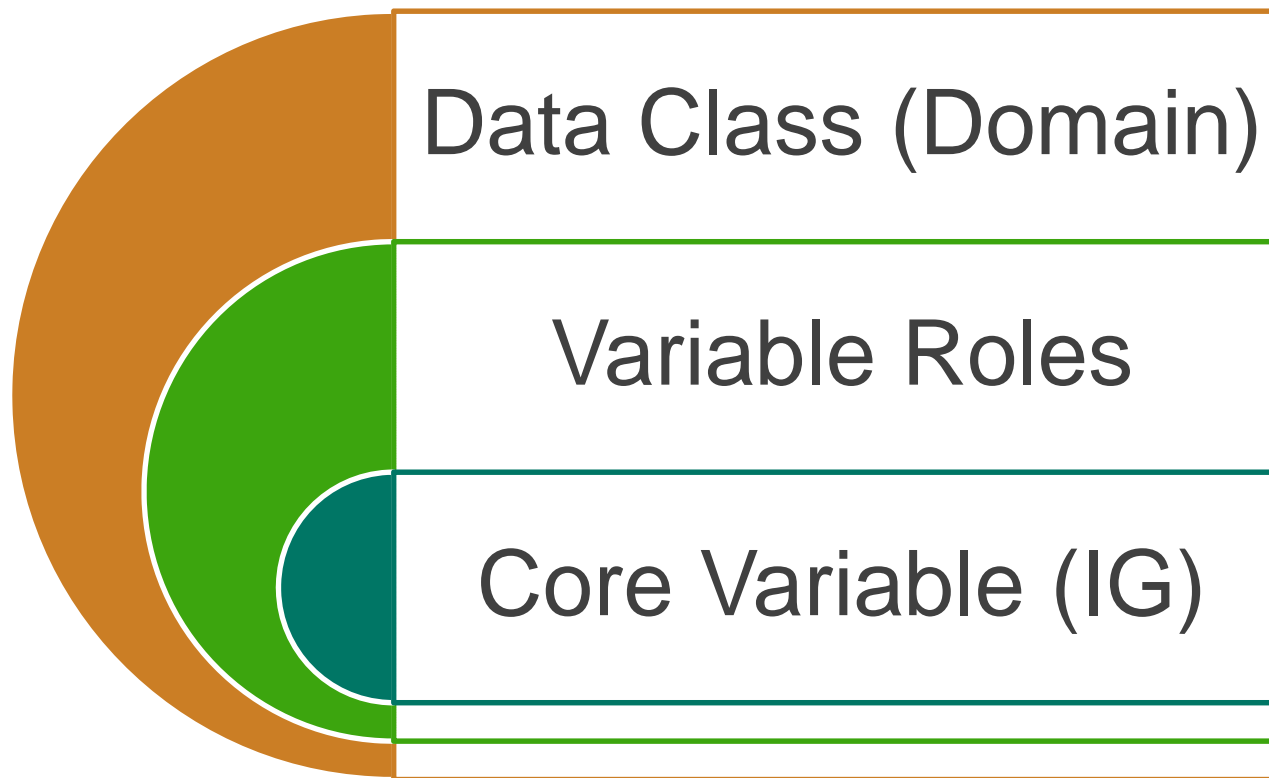
Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	Code	Codelist Cod	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.					
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.					
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify submissions involving the product.					
SUBJID	Subject Identifier	Char		Identifier	Compound identifier formed by concatenating the values of STUDYID, DOMAIN, and USUBJID.					
RFSTDTC	Study Death Flag	Char	(NY)	Record Qualifier						
SITEID	Study Site Identifier	Char		Record Qualifier						
INVID	Investigator Identifier	Char		Record Qualifier						
INVTNAM	Investigator Name	Char		Synonym Qualifier						
BRTHDTC	Date/Time of Birth	Char	ISO 8601	Record Qualifier						
AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).					Exp
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE.					Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.					Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race ( <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm</a> ). See Assumption below regarding RACE.					Exp
ETHNIC	Ethnicity	Char	(ETHNIC)	Record Qualifier	The ethnicity of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of ethnicity ( <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm</a> ).					Perm
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARMCD is limited to 20 characters and does not have special character restrictions. The maximum length of ARMCD is longer than for other "short" variables to accommodate the kind of values that are likely to be needed for crossover trials. For example, if ARMCD values for a seven-period crossover were constructed using two-					Req

# Basic Concept in SDTM

- ▶ The model is built around the *concept of observations*, which consist of *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, which normally *corresponds to a column in a dataset*, can be classified according to its Role.
- ▶ Observations are reported in a series of **domains**, usually corresponding to data that were collected together. A domain is defined as a *collection of observations with a topic-specific commonality about a subject*.

# SDTM Basic

- ▶ How Data is structured within SDTM





# SDTM Basic

## ► Data Class (Domain)

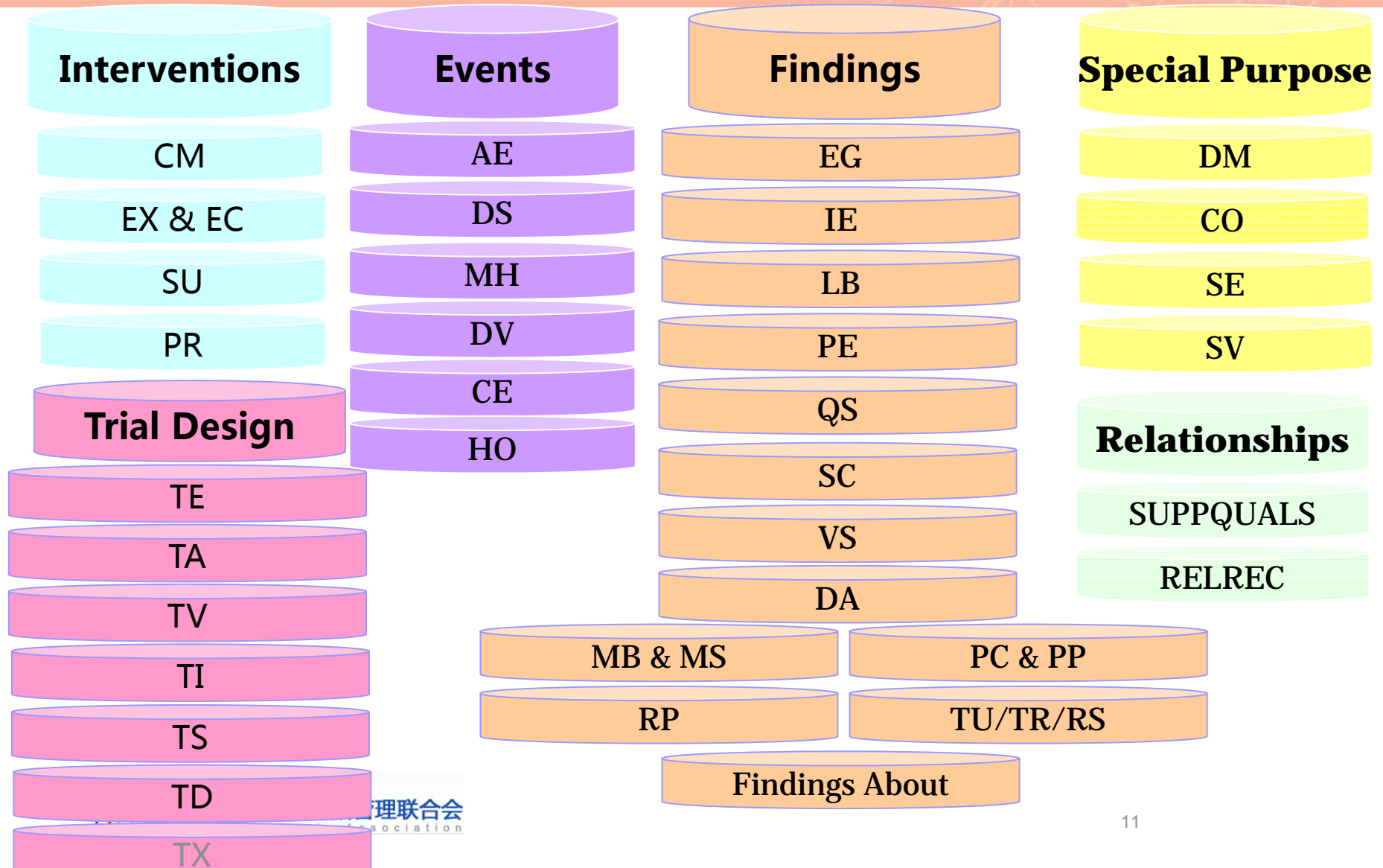
Domains are logical groupings of data, organized around a “Topic”

- Domains have a fixed set of allowed variables
- Variables have standard names and labels
- Variables have standard data types, formats and other attributes
- Data are represented using standard lists of values (Controlled Terminology)
- Many of the Questions (e.g., test names) are standardized

# SDTM Model Overview

- Special-Purpose Domains
  - DM: Demographics (2.2.6)
  - CO: Comments (2.2.7)
  - SE: Subject Elements (2.2.8)
  - SV: Subject Visits (2.2.9)
- General Observation Classes
  - Interventions (2.2.1)
  - Events (2.2.2)
  - Findings (2.2.3)
- Trial Design Domains
  - Seven Domains (Section 3)
  - Relationships (Section 4)
  - Associated Persons (Section 5)
- Within these structures there are fixed **variable names** and **order**
- Variables have defined attributes (e.g., data types, length)
- Some variables have required controlled terminology

# SDTMIG Domains – v3.2



# Variable Roles

## Identifier

Variables used to identify the object

Study Identifier  
(STUDYID)

Subject Identifier  
(USUBJID)

Sequence Identifier  
(--SEQ)

## Topic

Specifies the focus of the observation

Test short Name  
(LBTESTCD)

Adverse Event Term  
(AETERM)

Reported Drug Name  
(CMTRT)

## Qualifier

Values that describe the results or trails of the observation

Lab Test Result  
(LBORRES)

Adverse Event Severity  
(AESEV)

Commed Dose  
(CMDOSE)

## Timing

Timing of the observation

Lab Assessment Date  
(LBDTC)

Adverse Event Start  
(AESTDTC)

Conmed End Date  
(CMENDTC)



# SDTM Identifier Variables

**Table 2.2.4: All Observation Classes — Identifiers**

Variable Name	Variable Label	Type	Description
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain most relevant to the observation. The Domain abbreviation is also used as a prefix for variables to ensure uniqueness when datasets are merged.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
POOLID	Pool Identifier	Char	An identifier used to identify a result from a group of subjects that is not assignable to a specific subject.
SPDEVID	Sponsor Device Identifier	Char	Sponsor-defined identifier for a device
--SEQ	Sequence Number	Num	Sequence number to ensure uniqueness of records within a dataset for a subject (or within a parameter, in the case of the Trial Summary domain). May be any valid number (including decimals) and does not have to start at 1.
--GRPID	Group ID	Char	Optional group identifier, used to link together a block of related records within a subject in a domain. Also used to link together a block of related records in the Trial Summary dataset ( <a href="#">Section 3.4</a> ).
--REFID	Reference ID	Char	Optional internal or external identifier such as lab specimen ID, or UUID for an ECG waveform or a medical image.
--SPID	Sponsor-Defined Identifier	Char	Sponsor-defined identifier. Example: pre-printed line identifier on a Concomitant Medications page.
--LNKID	Link ID	Char	Identifier used to link related records across domains. This may be a one-to-one or a one-to-many relationship. For Example: A single tumor may have multiple measurements/assessments performed at each study visit.

# --SEQ is Surrogate Key

## ► Keys in SDTM

- **Natural keys** exist in the collected data.
- **Example** of natural keys:

**STUDYID**  
**USUBJID**  
**DOMAIN**  
**LBREFID**  
**LBTESTCD**  
**LBSPEC**  
**LBMETHOD**  
**LBDTC**

- **--SEQ** is a **surrogate** key, created so that a unique record in SDTM can be reliably identified using the **same four keys** in any general-observation-class dataset:

**STUDYID**  
**USUBJID**  
**DOMAIN**

**--SEQ** is the surrogate for these natural keys. --SEQ is usually **added after** the data are collected, tabulated and sorted.

# SDTM Timing Variable Table

Variable Name	Variable Label	Type	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 Trial Arms, <a href="#">Section 3.2.2</a> ).
EPOCH	Epoch	Char	Epoch associated with the start date/time of the observation, or the date/time of collection if start date/time is not collected. (See <a href="#">Section 3.2.2</a> ).
--DTC	Date/Time of Collection	Char	Collection date and time of an observation represented in ISO 8601 character format.
--STDTC	Start Date/Time of Observation	Char	Start date/time of an observation represented in ISO 8601 character format.

## SDTM Model: 2.2.5

# Core Variable

## Required

Basic to the  
identification of a  
data record

Must always be  
included

Can **not** be null  
for any record

## Expected

Establish the  
observation  
context

Must always be  
included

Can be null for  
some records

## Permissible

If collected or  
derived

Must always be  
included **if collected**

Can be null or  
not present



# Example: DM Domain in SDTM model

**Table 2.2.6: Subject Demographics Domain Variables**

Variable Name	Variable Label	Type	Description
<b>Identifier Variables</b>			
STUDYID	Study Identifier	Char	Unique identifier for a study.
DOMAIN	Domain Abbreviation	Char	Two-character abbreviation for the domain which must be DM.
USUBJID	Unique Subject Identifier	Char	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product.
<b>Topic Variables</b>			
SUBJID	Subject Identifier for the Study	Char	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
<b>Qualifier Variables</b>			
RFSTDTC	Subject Reference Start Date/Time	Char	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.
<b>Timing Variables</b>			
DMDTC	Date/Time of Collection	Char	Date/time of collection of the demographic information in ISO 8601 character format.
DMDY	Study Day of Collection	Num	Study day of collection measured as integer days. Algorithm for calculations must be relative to the sponsor-defined RFSTDTC in Demographics.

# Example: DM Domain in SDTM IG

## DM – Specification for the Demographics Domain Model

dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	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. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.	Exp
RFXSTDTC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).	Exp
AGE	Age	Num		Record Qualifier	Age expressed in AGEU. May be derived from RFSTDTC and BRTHDTC, but BRTHDTC may not be available in all cases (due to subject privacy concerns).	Exp
AGEU	Age Units	Char	(AGEU)	Variable Qualifier	Units associated with AGE.	Exp
SEX	Sex	Char	(SEX)	Record Qualifier	Sex of the subject.	Req
RACE	Race	Char	(RACE)	Record Qualifier	Race of the subject. Sponsors should refer to "Collection of Race and Ethnicity Data in Clinical Trials" (FDA, September 2005) for guidance regarding the collection of race ( <a href="http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm">http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm</a> ) See Assumption below regarding RACE.	Exp



# Example: DM Domain in SDTM IG

## DM – Specification for the Demographics Domain Model

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Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
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USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDT	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date time when subject was first exposed to study treatment. Required for	Exp

CDISC Codelist Specification			CDISC Codelist Values		
	Codelist_Name		Codelist	Controlled Terms	Comment
RFENDTC	Codelist_Label	Race	RACE	AMERICAN INDIAN OR ALASKA NATIVE	FDA code
	Upper_Case	Y	RACE	ASIAN	FDA code
RFXSTDT	Restriction_8char	N	RACE	BLACK OR AFRICAN AMERICAN	FDA code
RFXENDT	Extensible_NY	N	RACE	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	FDA code
AGE	Reference_Description	Organization Name: FDA Document Title: Draft Guidance for Industry Collection of Race and Ethnicity Data in Clinical Trials Date: January 2003 Chapter: III COLLECTING RACE AND ETHNICITY DATA IN CLINICAL TRIALS Codelist_Name: Race Page: 5	RACE	WHITE	FDA code
AGEU					
SEX					
RACE	Reference_URL	<a href="http://www.fda.gov/cder/guidance/5054dft.pdf">http://www.fda.gov/cder/guidance/5054dft.pdf</a>			

# Example: DM Domain Dataset

## DM Example 1 – General Demographics

dm.xpt

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4 (cont)	01	JOHNSON, M	1941-07-02			M	ASIAN	NOT HISPANIC OR LATINO
5 (cont)	02	GONZALEZ, E	1950-06-23	55	YEARS	F	AMERICAN INDIAN OR ALASKA NATIVE	NOT HISPANIC OR LATINO
6 (cont)	02	GONZALEZ, E	1956-05-05	49	YEARS	F	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDERS	NOT HISPANIC OR LATINO

Row	ARMCD	ARM	ACTARMCD	ACTARM	COUNTRY
1 (cont)	A	Drug A	A	Drug A	USA
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3 (cont)	P	Placebo	P	Placebo	USA
4 (cont)	SCRNFAIL	Screen Failure	SCRNFAIL	Screen Failure	USA
5 (cont)	P	Placebo	P	Placebo	USA
6 (cont)	A	Drug A	A	Drug A	USA



# TOC

- ▶ SDTM Basic
- ▶ General Observation Class
- ▶ SDTM Implementation by Example

# General Observation Class

## ► Intervention class:

- captures investigational, therapeutic and other treatments that are administered to the subject (with some actual or expected physiological effect) either as specified by the study protocol (e.g., “exposure”), coincident with the study assessment period (e.g., “concomitant medications”), or other substances self-administered by the subject (such as alcohol, tobacco, or caffeine).

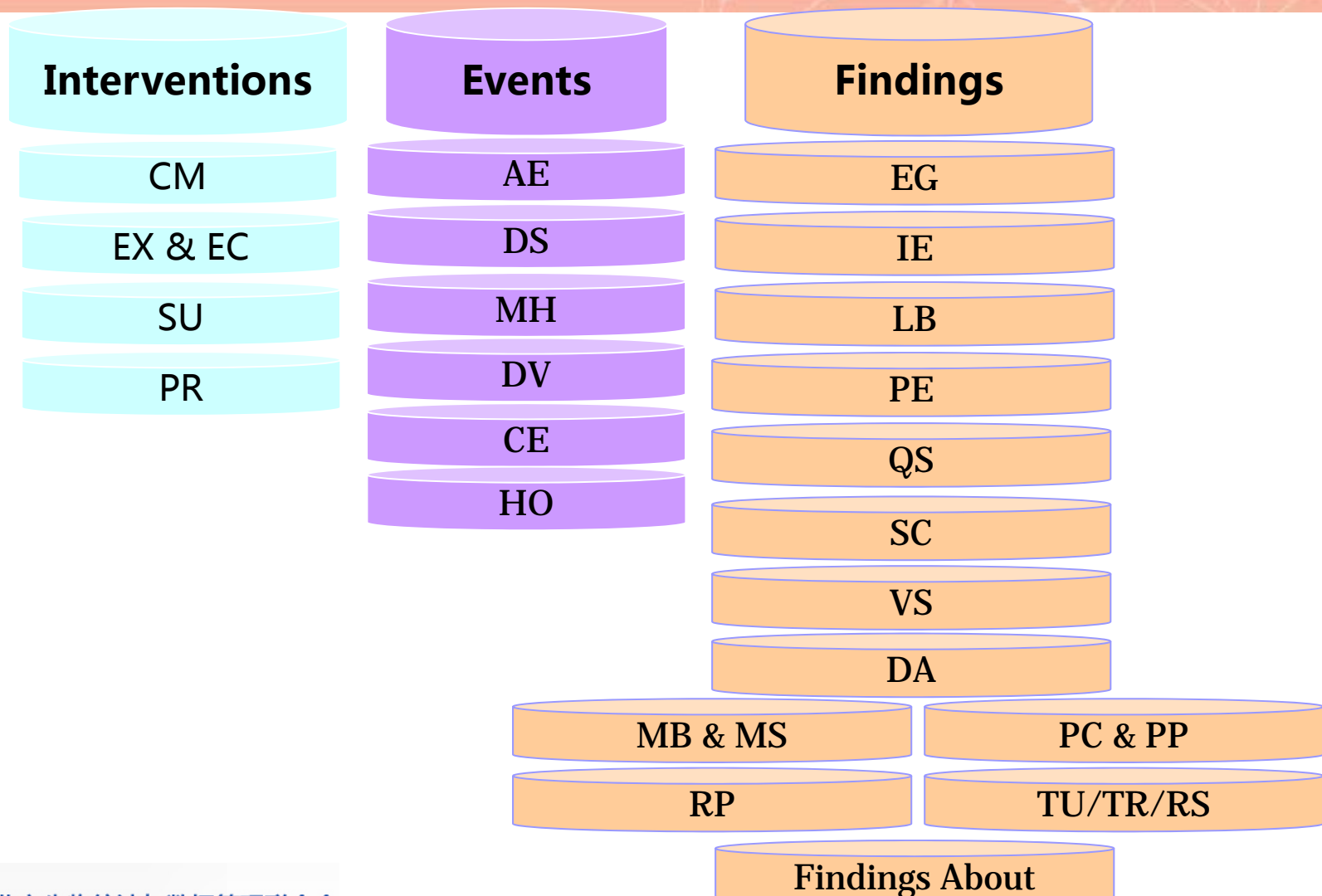
## ► Event class:

- captures planned protocol milestones such as randomization and study completion, and occurrences, conditions, or incidents independent of planned study evaluations occurring during the trial (e.g., adverse events) or prior to the trial (e.g., medical history).

## ► Finding class:

- captures the observations resulting from planned evaluations to address specific tests or questions.
- The Findings class also includes a sub-type “Findings About” which is used to record findings related to observations in the Interventions or Events class.

# General Observation Class



# Intervention Class

## 2.2.1 The Interventions Observations Class

Table 2.2.1: 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.



# Intervention Class

## 2.2.1 The Interventions Observations Class

Table 2.2.1: Interventions — Topic and Qualifier Variables, One Record per Constant-Dosing Interval or Intervention Episode

Variable Name	Variable Label	Type	Role	Description
Topic Variable				
--		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 Variable				
--SYN	Synonym	Char	Synonym	
--TRT	Standardized or controlled treatment, or the model	Char	TRT	Standardized or controlled treatment, or the model
--MOOD	Mood	Char	Mood	Condition of the record (e.g., SCHEDULED, D).
--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.

The “root” **Variable Name**. The double dash (--) will be replaced with a 2-character domain code when this variable is implemented in a domain.

A descriptive **Variable Label**, up to 40 characters, unique for each variable in the domain.

The **data Type** (e.g., whether the variable value is a character or a number).

The **Role** of the variable describes how the variable is used in the domain.

**Description** of the variable - very important to understand the purpose and use of this variable. May also include length restrictions, controlled terminology, examples.

# Event Class

## 2.2.2 The Events Observation Class

Table 2.2.2: 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.
Variable Name	Variable Label	Type	Role	Description
--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	MedDRA High Level Term code from the primary path.



# Finding Class

## 2.2.3 The Findings Observation Class

**Table 2.2.3: Findings — Topic and Qualifier Variables, One Record per Finding**

Variable Name	Variable Label	Type	Role	Description
<b>Topic Variable</b>				
--TESTCD	Short Name of Measurement, Test or Examination	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.
<b>Qualifier Variables</b>				
--TEST	Name of Measurement, Test or Examination	Char	Synonym Qualifier of --TESTCD	Long name For --TESTCD. Examples: Platelet, Systolic Blood Pressure, Summary (Min) RR Duration, Eye Examination.
--MODIFY	Modified Term	Char	Synonym Qualifier of	If the value of --ORRES is modified for coding purposes, then the modified text is placed here.
Variable Name	Variable Label	Type	Role	Description
--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 MITESTCD = TTF1.
--CAT	Category	Char	Grouping Qualifier	Used to define a category of topic-variable values. Examples: HEMATOLOGY, URINALYSIS, CHEMISTRY, HAMILTON DEPRESSION SCALE, SF36, MICRO ARRAY, EGFR MUTATION ANALYSIS
--SCAT	Subcategory	Char	Grouping Qualifier	Used to define a further categorization of --CAT values. Example: 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	Unit for --ORRES. Examples: IN, LB, kg/L.

# TOC

- ▶ SDTM Basic
- ▶ General Observation Class
- ▶ SDTM Implementation by Example

# SDTM Implementation by Example

- ▶ Demographics
- ▶ Vital Sign
- ▶ Advert Event
- ▶ Concomitant Medication



# Example: Demographics

**Demographics** DOMAIN = 'DM'

Date of BirthDayMonthYear

BRTHDTC

Sex

☐ Male ☐ Female

SEX

Race

☐ White

☐ Black or African American

☐ Asian

☐ American Indian or Alaska Native

☐ Native Hawaiian or Other Pacific Islander

☐ Other, specify: \_\_\_\_\_

RACE

When multiple selection, RACE=MULTIPLE, individual selected value goes SUPPDM

When only Other selection, RACE="OTHER", individual selected value goes SUPPDM

# Example: Demographics

## Source Data: Demographics

STUDY	FORM	SUBJID	BRTHDAT	SEX	RACE1	RACE2	RACE3	RACE4	RACE5	RACEOTH
Test001	DM	1001	8/18/1984	M	WHITE		ASIAN			EASTEN INDIAN
Test001	DM	1002	5/3/1994	F						AFRICAN AMERICAN

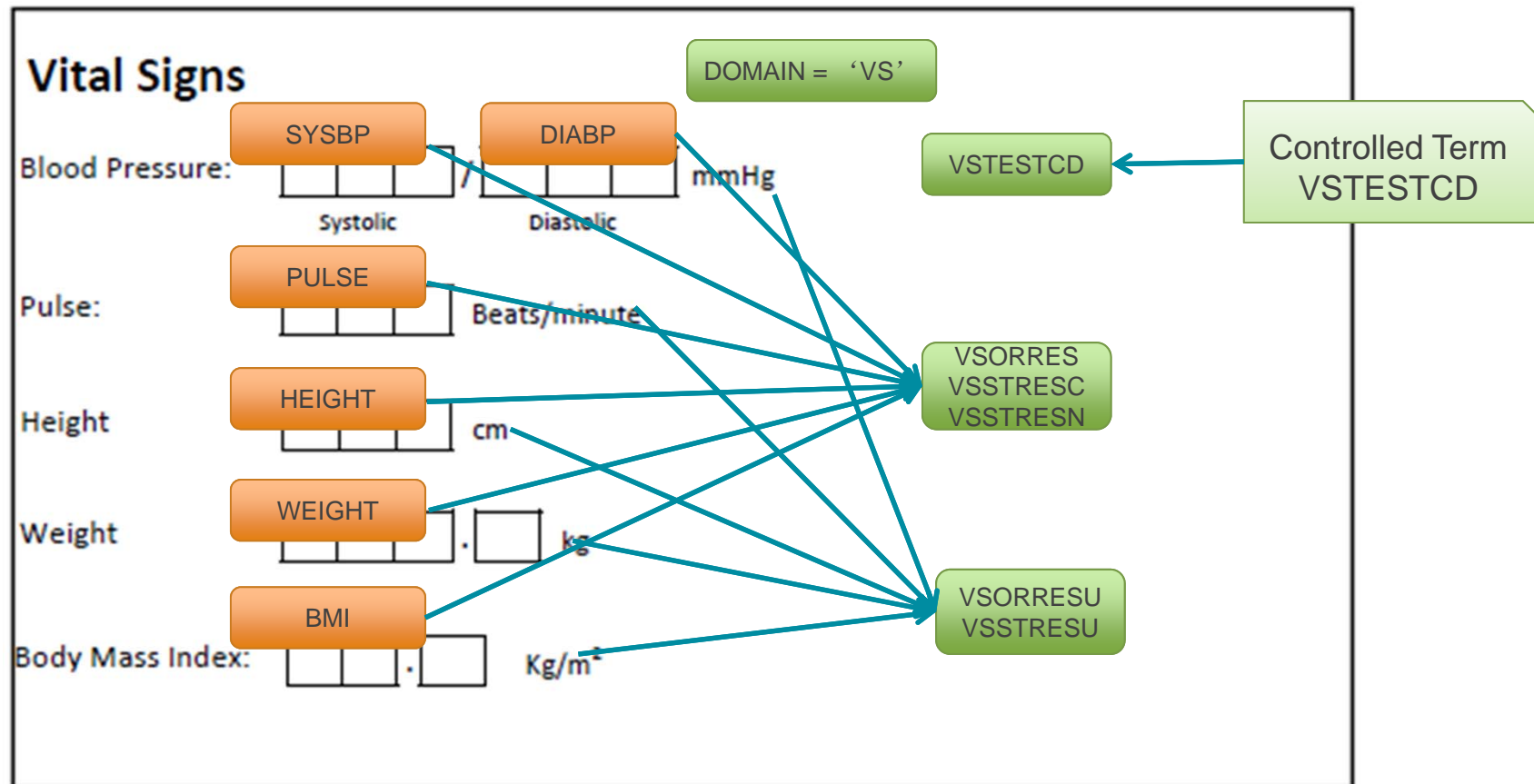
DM.XPT – Demographics one record per subject

STUDYID	DOMAIN	USUBJID	SUBJID	BRTHDTC	AGE	AGEU	SEX	RACE	COUNTRY
Test001	DM	001-001001	1001	8/18/1984	31	YEARS	M	MULTIPLE	USA
Test001	DM	001-001002	1002	5/3/1994	22	YEARS	F	OTHER	USA

## SUPPDM.XPT

STUDYID	DOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
Test001	DM	001-001001			RACE1	Race 1	WHITE	CRF Page 5	
Test001	DM	001-001001			RACE2	Race 2	ASIAN	CRF Page 5	
Test001	DM	001-001001			RACEOTH	Race other	EASTERN INDIA	CRF Page 5	
Test001	DM	001-001002			RACEOTH	Race other	AFRICAN AMERICAN	CRF Page 5	

# Example: Vital Signs



# Example: Vital Signs

Source Data: Vital Sign Horizontal Structure

STUDY	FORM	SUBJID	SYSBP	DIABP	PULSE	HEIGHT	WEIGHT	BMI
Test001	VS	1001	149	66	81	178	79	25

VS.XPT -- Vital Sign Vertical Structure

STUDYID	DOMAIN	USUBJID	VSTEST	VSTESTCD	VSORRES	VSSTRES	VSSTRESN	VSORRESU	VSSTRESU
Test001	VS	001-001001	Systolic Blood Pressure	SYSBP	149	149	149	mmHg	mmHg
Test001	VS	001-001001	Diastolic Blood Pressure	DIABP	66	66	66	mmHg	mmHg
Test001	VS	001-001001	Pulse Rate	PULSE	81	81	81	bpm	bpm
Test001	VS	001-001001	Height	HEIGHT	178	178	178	cm	cm
Test001	VS	001-001001	Weight	WEIGHT	79	79	79	kg	kg
Test001	VS	001-001001	Body Mass Index	BMI	25	25	25	kg/m2	kg/m2

# Example: Adverse Event

## Adverse Event

DOMAIN = AE

NOT  
SUBMITTED

Have there been any adverse events since signature of informed consent? <input type="radio"/> Yes, complete details <input type="radio"/> No					
Adverse Event (diagnosis if known or main sign/symptom)		Serious AE <input type="radio"/> No <input type="radio"/> Yes*, complete seriousness criteria below (tick all that apply)		AESER	
AETERM	AESDTH AESLIFE	AESHOSP AESDISAB	AESCONG AESMIE		
Start date		Toxicity grade/severity (tick only one)	Causality factor(s) other than study treatment (tick all that apply)	Action(s) taken with study treatment (tick all that apply)	Other action(s) taken (tick all that apply)
AESTDTC		AETOXGR / AESEV	AERELNST	AEACN	AEACNOTH
End date		Relationship with study treatment			
AEENDTC		AEREL			
					Outcome (tick only one)
					AEOUT

When multiple selection, AERELNST=MULTIPLE, individual selected value goes SUPPAE

When only Other selection, AERELNST="OTHER", individual selected value goes SUPPAE



# Example: Concomitant Medicine

## Concomitant Mediation

DOMAIN=CM

NOT  
SUBMITTED

When multiple selection, CMINDC=MULTIPLE,  
individual selected value goes SUPPCM

When only Other selection, CMINDC="OTHER",  
individual selected value goes SUPPCM

Has the subject received any concomitant medications? ☐ Yes, complete details ☐ No

Name of medication	Total Daily Dose	Unit (tick only one)	Frequency (tick only one)	Route (tick only one)	Reason for medication (indication)
<input type="text"/> <b>CMTRT</b> Start date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Day Month Year <input type="radio"/> Ongoing <b>CMENRTPT</b> End date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Day Month Year <b>CMENDTC</b>	<b>CMDOSTOT</b>	<input type="radio"/> MG <b>CMDOSU</b> <input type="radio"/> ML <input type="radio"/> TAB <input type="radio"/> IU <input type="radio"/> Other, specify: _____	<input type="radio"/> QD <b>CMDOSFRQ</b> <input type="radio"/> BID <input type="radio"/> QID <input type="radio"/> PRN <input type="radio"/> Other, specify: _____	<input type="radio"/> SC <b>CMROUTE</b> <input type="radio"/> IM <input type="radio"/> IV <input type="radio"/> TOPICAL <input type="radio"/> Other, specify: _____	Tick all that apply <input type="checkbox"/> Adverse event <input type="checkbox"/> Medical history <input type="checkbox"/> Disease related condition <input type="checkbox"/> Prophylaxis <input type="checkbox"/> Other

When only Other selection, CMXXXX="OTHER",  
individual selected value goes SUPPCM

Ask

