SDTM Special Purpose Domain

Anagha Bhatkhande
Varsha Mahajan

October 31, 2017

Confidentiality Statement

This document contains information which is commercially confidential to Tata Consultancy Services Ltd. ("TCS") and is provided for the sole purpose of permitting the recipient to evaluate the proposal submitted within the document. In consideration of the receipt of this document, the recipient agrees to maintain the information it contains in confidence and not to reproduce or otherwise disclose the contents of this document to any person outside the recipient's evaluation team or nominated advisors. The document may not be used, reproduced or disclosed to others, except as specifically permitted by TCS in writing. The recipient of this document, by its retention and use, agrees to take reasonable endeavours to protect the document and the information it contains from loss or theft.

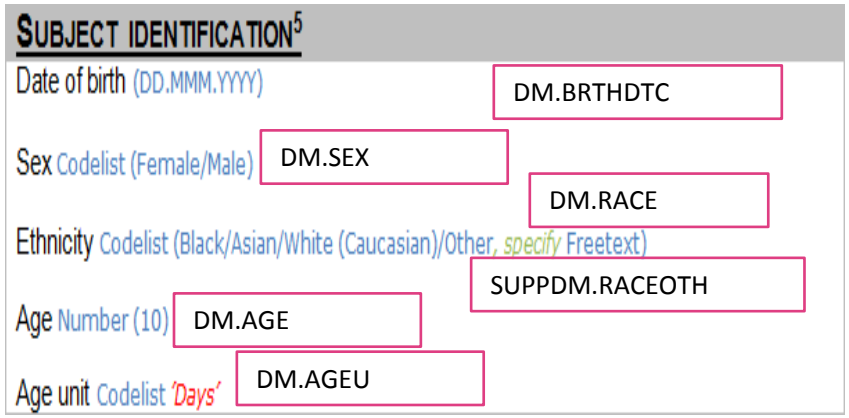
Agenda

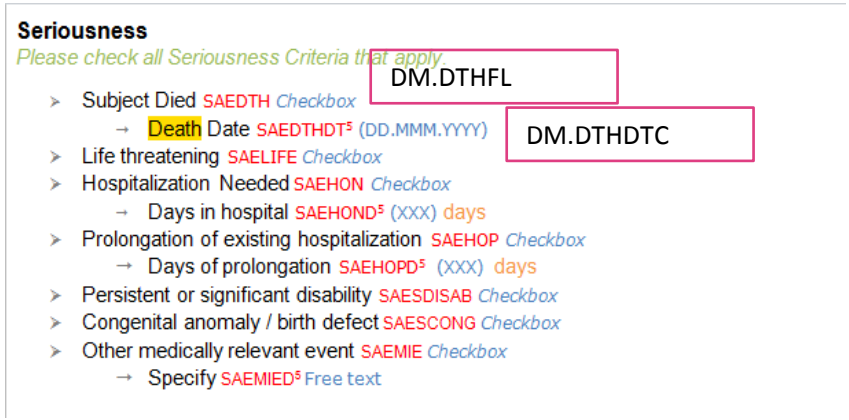
01 Overview of Special Purpose Domain – DM SDTM

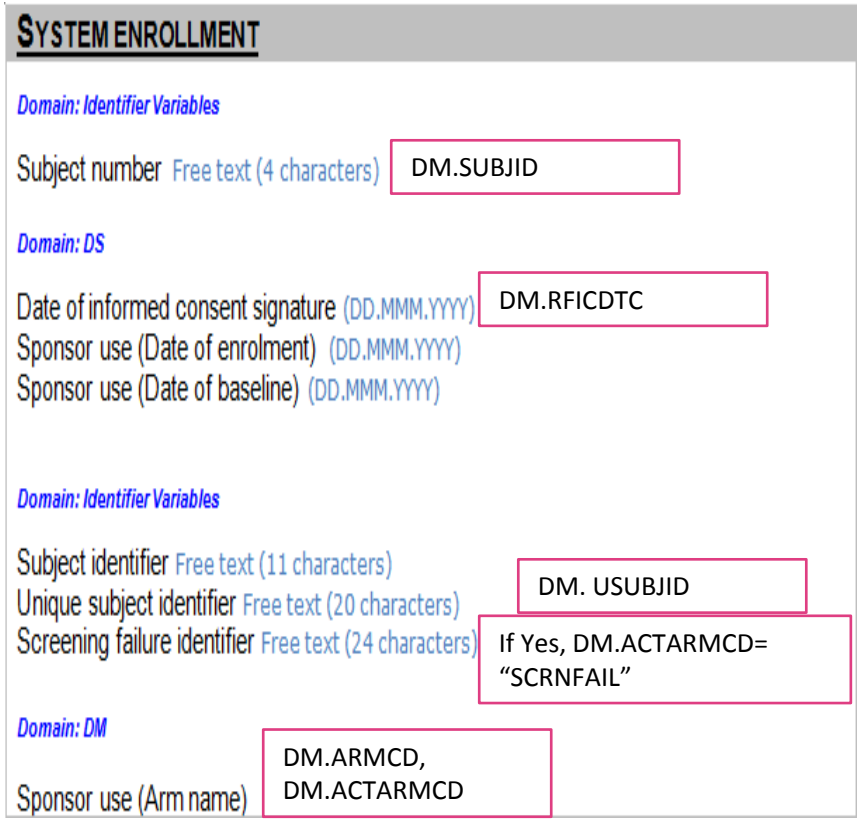
02 Understand Controlled Terminology

03 SDTM DM METADATA

Annotated CRF Example







SDTM DM

- **One record per subject**
- Parent domain for all other observations for human clinical subjects
- Set of essential standard variables that describe each subject in a study.
- Subjects occasionally change sites during the course of a clinical trial.
- USUBJID, SUBJID and SITEID should be used to handle the above problem, **only one DM record** should be submitted for the subject.
- The values of ARM and ARMCD in DM must match entries in the Trial Arms (TA) dataset, except for subjects who were not fully assigned to an Arm.
- For screen failures, ARMCD = “SCRNFAIL" and ARM = “Screen Failure”.
  Screen Failure record may be reported in the Disposition dataset indicating occurrence of screen failure vent

DM SDTM METADATA

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, 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

Every subject in a study must have a subject identifier (SUBJID)

DM SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID						Req
DOMAIN	Abbreviation					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

Why do I need this when I have subjid?

Similar subject number can be used in different studies, for Pooling data from different studies we need the reference of each study

DM SDTM METADATA

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	Su... En...			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

These variables are applicable for interventional studies

DM SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RFICDTC			ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDT			ISO 8601		, as defined in the last known date of follow-up, date	Exp
DTHDTC	of Death	Char			Should represent the	Exp
DTHFL	Subject Death Flag	Char			ted even when the	Exp
SITEID	Study Site Identifier	Char				Req
INVID	Investigator Identifier	Char			sed in addition to	Perm
INVNAM	Investigator Name	Char				Perm
BRTHDTC	Date/Time of Birth	Char				Perm
AGE	Age	Num			RTHDTC, but acy concerns).	Exp
AGEU	Age Units	Char				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 (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm) 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 (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm).	Perm

Can I map the Subject Died in DTHFL and death date collected on "Seriousness page" in DTHDTC?

Seriousness

Please check all Seriousness Criteria that apply.

- Subject Died SAEDTH *Checkbox*
  - → Death Date SAEDTHDT[5] (DD.MMM.YYYY)
- Life threatening SAELIFE *Checkbox*
- Hospitalization Needed SAEHON *Checkbox*
  - → Days in hospital SAEHOND[5] (XXX) days
- Prolongation of existing hospitalization SAEHOP *Checkbox*
  - → Days of prolongation SAEHOPD[5] (XXX) days
- Persistent or significant disability SAESDISAB *Checkbox*
- Congenital anomaly / birth defect SAESCONG *Checkbox*
- Other medically relevant event SAEMIE *Checkbox*
  - → Specify SAEMIED[5] Free text

DM SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last known date of contact. Examples include completion date, withdrawal date, last follow-up, date recorded for lost to follow up, or death date.	Exp
DTHDTC				Record Qualifier	Date/time of death for any subject who died, in ISO 8601 format. Should represent the date/time that is captured in the clinical-trial database.	Exp
DTHFL				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 (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm) 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 (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm).	Perm

Subject may change Site during trial, DM shold have a single record even in such casestrial.

DM SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 ch the date of informed consent in the Dispositic documented. Would be null only in studies nc
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or protocol, in ISO 8601 character format. Should corres contact. Examples include completion date, withdrawal recorded for lost to follow up, or death date.
DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/ date/t
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indica death
SITEID	Study Site Identifier	Char		Record Qualifier	Uniqu
INVID	Investigator Identifier	Char		Record Qualifier	An id SITE
INVNAM	Investigator Name	Char		Synonym	Name
BRTHDTC					
AGE					
AGEU					
SEX					
RACE					
ETHNIC					

Mapping Ethnicity in RACE variable of DM SDTM, the controlled Terminology used is RACEC ,it is an extensible codelist, so you can Store "OTHER" as value of RACE variable; Specified Free Text for OTHER will go in SUPPDM

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C128689		Yes	Race As Collected	RACEC	Race As Collected	A terminology codelist relevant to the race of an individual as collected on the case report form.	CDISC SDTM Collected Race Terminology
C42331	C128689		Race As Collected	AFRICAN		A person having origins in any of the original peoples of sub-Saharan Africa.	African
C128837	C128689		Race As Collected	AFRICAN AMERICAN		A person having origins in the original peoples of sub-Saharan Africa and the United States.	African American
C41226	C128689		Race As Collected	AFRICAN CARIBBEAN		A person having origins in the original peoples of sub-Saharan Africa and the Caribbean.	African Caribbean
C18237	C128689		Race As Collected	ALASKA NATIVE		The native people of Alaska.	Alaska Native
C43877	C128689		Race As Collected	AMERICAN INDIAN		The native people of North America.	American Indian
C41259	C128689		Race As Collected	AMERICAN INDIAN OR ALASKA NATIVE		A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. (FDA)	American Indian or Alaska Native
C43876	C128689		Race As Collected	ARAB		A person having origins in any of the original peoples of the Arabian peninsula and surrounding territories in the Middle East and northern Africa.	Arab
C41260	C128689		Race As Collected	ASIAN		A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (FDA)	Asian
C16310	C128689		Race As Collected	ASIAN AMERICAN		A person having origins in the original peoples of Asia and the United States.	Asian American

SUBJECT IDENTIFICATION[5]

Date of birth (DD.MMM.YYYY)

Sex Codelist (Female/Male)

Ethnicity Codelist (Black/Asian/White (Caucasian)/Other, *specify* Freetext)

Age Number (10)

Age unit Codelist *'Days'*

DM SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
RFICDTC	Date/Time of Informed Consent	Char	ISO 8601	Record Qualifier	Date/time of informed consent in ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be null only in studies not collecting the date of informed consent.	Exp
RFPENDTC	Date/Time of End of Participation	Char	ISO 8601	Record Qualifier	Date/time when subject ended participation or follow-up in a trial, as defined in the protocol, in ISO 8601 character format. Should correspond to the last [illegible] contact. Examples include completion date, withdrawal [illegible] recorded for lost to follow up, or death date.	Exp
DTHDTC	Date/Time of Death	Char	ISO 8601	Record Qualifier	Date/time of death for any subject who died. [illegible] date/time that is captured in the clinical-trial	[illegible]
DTHFL	Subject Death Flag	Char	(NY)	Record Qualifier	Indicates the subject died. Should be Y or [illegible] death date is unknown.	[illegible]
SITEID	Study Site Identifier	Char		Record Qualifier	Unique identifier for a site within a stu	
INVID	Investigator Identifier	Char		Record Qualifier	An identifier to describe the Investigator [illegible] SITEID. Not needed if SITEID is equiva	[illegible]
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 fr [illegible] FSTDTC an [illegible] TC, but BRTHDTC may not be available in all ca [illegible] e to subject privacy concerns).	Exp
AGEU	Age Units	Char	(AGEU)			
SEX	Sex	Char	(SEX)			
RACE	Race	Char	(RACE)			
ETHNIC	Ethnicity	Char	(ETHNIC)			

Codelist/Controlled Terminology for AGE Unit is not extensible. You need to use values available from CDISC Submission Value column only for Display

AGEU (Age Unit)

NCI Code: C66781, Codelist extensible: No

C66781	AGEU			
NCI Code	**CDISC Submission Value**	**CDISC Synonym**	**CDISC Definition**	**NCI Preferred Term**
C25301	DAYS		A unit of measurement of time equal to 24 hours.	Day
C25529	HOURS	Hours;h;hr	A unit of measurement of time equal to 60 minutes.	Hour
C29846	MONTHS	Month	One of the 12 divisions of a year as determined by a calendar. It corresponds to the unit of time of approximately to one cycle of the moon's phases, about 30 days or 4 weeks. (NCI)	Month
C29844	WEEKS	Week	Any period of seven consecutive days. (NCI)	Week
C29848	YEARS	Year	The period of time that it takes for Earth to make a complete revolution around the sun, approximately 365 days; a specific one year period. (NCI)	Year

DM SDTM METADATA

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
ACTARMCD	Actual Arm Code	Char	*	Record Qualifier	Code of actual Arm. When an Arm is not planned (not in Trial Arms), ACTARMCD will be UNPLAN. Randomized subjects who were not treated will be given a value of NOT… subjec… ACTA… restric… variab… trials.	Req
ACTARM	Description of Actua…	Char	*	Synonym Qualifier	Descr… will b… given… and "… Arms	
COUNTRY	Country	Char	(COUNTRY) ISO 3166	Record Qualifier	Count…	
DMDTC	Date/Time of Collection	Char	ISO 8601	Timing	Date/t…	
DMDY	Study Day of Collection	Num		Timing	Study…	
ARMCD	Planned Arm Code	Char	*	Record Qualifier	ARM… The m… accom… examp… charac… ARM…	
ARM	Description of Planned Arm	Char	*	Synonym Qualifier	Name of the Arm to which the subject was assigned.	Req

SYSTEM ENROLLMENT

Domain: Identifier Variables

Subject number Free text (4 characters)

Domain: DS

Date of informed consent signature (DD.MMM.YYYY)
Sponsor use (Date of enrolment) (DD.MMM.YYYY)
Sponsor use (Date of baseline) (DD.MMM.YYYY)

Domain: Identifier Variables

Subject identifier Free text (11 characters)
Unique subject identifier Free text (20 characters)
Screening failure identifier Free text (24 characters)

Domain: DM

Sponsor use (Arm name)

End of Session

Overview of Special Purpose Domain – DM SDTM

31-OCT-2017

Understand Controlled Terminology

Anagha Bhatkhande
Varsha Mahajan

October 31, 2017

Controlled Terminiology

- Set of CDISC-developed or CDISC-adopted standard expressions (values)
- Used with data items within CDISC-defined datasets
- CDISC partners with NCI EVS to develop and support controlled terminology for all CDISC foundational standards (SDTM, CDASH, ADaM, SEND) and all CFAST Therapeutic Area standards.

https://evs.nci.nih.gov/ftp1/CDISC/SDTM/SDTM%20Terminology.pdf

SDTM Controlled Terminology

About NCI EVS

- Since 1997, National Cancer Institute Enterprise Vocabulary Services (EVS) has provided terminology content, tools, and services to accurately code, analyze and share cancer and biomedical research, clinical and public health information.
- EVS creates, compiles, and cross-maps biomedical terminology needed by NCI and its community.

End of Session

Understand Controlled Terminology

31-OCT-2017

SDTM DM METADATA

Anagha Bhatkhande
Varsha Mahajan

October 31, 2017

METADATA Attributes as per Define.xml

- ***The Variable Name*** (Up to 8 characters)
- A descriptive ***Variable Label***, (up to 40 characters), unique for each variable
- The ***data Type*** (character or numeric)
- The set of ***controlled terminology*** for the value or the presentation format of the variable (Controlled Terms, Codelist or Format)
- The ***Origin*** of each variable (For Traceability)
- The ***Role*** of the variable (Roles represent the categories of variables such as Identifier, Topic, Timing, or the five types of Qualifiers)
- ***Comments*** or other relevant information about the variable

DM SDTM METADATA

Variable Name	Variable Label	Data Type	Length	Controlled Terminology/Codelist/ Format	Origin	Role	Comments
SUBJID	Subject Identifier for the study	Char	50		CRF	Topic	
USUBJID	Unique subject identifier	Char	50		Derived	Identifier	Concatenation of STUDYID-SITEID-SUBJID
DOMAIN	Domain Abbreviation	Char	2	DM	Assigned	Identifier	
BRTHDTC	Date/Time of Birth	Char	25	ISO 8601	CRF	Record Qualifier	
AGE	Age	Num	8		CRF	Record Qualifier	
AGEU	Age Unit	Char	6	AGEU	CRF	Variable Qualifier	
SEX	Sex	Char	2	SEX	CRF	Record Qualifier	
RACE	Race	Char	200	RACE	CRF	Record Qualifier	
DTHDTC	Date/Time of Death	Char	25	ISO 8601	CRF	Record Qualifier	
DTHFL	Subject Death Flag	Char	1	NY	CRF	Record Qualifier	
RFICDTC	Date/ Time of Informed consent	Char	25	ISO 8601	CRF	Record Qualifier	
ARM	Description of Planned Arm	Char	200		CRF	Synonym Qualifier	
ARMCD	Planned Arm Code	Char	20		CRF	Record Qualifier	
ACTARM	Description of Actual Arm	Char	200		CRF	Synonym Qualifier	
ACTARMCD	Actual Arm code	Char	20		CRF	Record Qualifier	

DM DATA SNAPSHOT

STUDYID	SUBJID	USUBJID	SITEID	BRTHDTC	AGE	AGEU	SEX	RACE	DTHFL	DTHDTC	RFICDTC	ARM	ARMCD	ACTARM	ACTARMCD
XXXX	001	XXX-001-002	1	1980-01-12	36	Years	M	ASIAN	N	.	2016-01-01	XYZ	A-1	XYZ	A-1
XXXX	002	XXX-001-002	1	2000-10-06	16	Years	F	BLACK OR AFRICAN AMERICAN	N	.	2016-01-01	XYZ	A-1	XYZ	A-1
XXXX	003	XXX-002-003	2	1990-07-25	26	Years	M	WHITE	Y	2017-10-12	2016-01-01	XYZ	A-1	XYZ	A-1
XXXX	004	XXX-002-004	2	1999-03-13	17	Years	F	Other	N		2016-01-01	XYZ	A-1	XYZ	A-1

SUPPDM DATA SNAPSHOT

STUDYID	USUBJID	RDOMAIN	QNAM	QLABEL	QVAL	QORIG
XXXX	XXX-002-004	DM	RACEOTH	Race, Other Specifys	BRAZILIAN	CRF

End of Session

SDTM DM METADATA

31-OCT-2017

TATA CONSULTANCY SERVICES
Experience certainty.

Thank You

IT Services
Business Solutions
Consulting