

CDISC SME Meeting

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Meeting Plan

- **Review and discuss additional SDTM Implementation Guides**
- **Review and discuss Codetable Mapping Files**
- **Q&A**

SDTM Implementation Guides

- The SDTMIG is the primary document used to tabulate data from human clinical trials
- Additional SDTMIGs (MD, AP, PGx) are available, including
 - SDTMIG-AP for data about Associated Persons
 - SDTMIG-MD for data about medical devices
 - SDTMIG-PGx for data about biospecimens, biomarkers and genetic/genomic data
- Where to find these documents on www.cdisc.org
 - SDTMIG-AP <https://www.cdisc.org/standards/foundational/sdtmig>
 - SDTMIG-MD <https://www.cdisc.org/standards/foundational/sdtm-ig-md>
 - SDTMIG-PGx <https://www.cdisc.org/standards/foundational/pgx>

SDTMIG-AP (Associated Persons)

- Use for data collected about people who are not the study subject
 - Biological Family Medical History
 - Organ Donor Blood Type
 - Caregiver QOL Questionnaire
 - Sexual Partner Pregnancy History
- Uses same domains and data structures as subject data (SDTMIG)
 - Prefixes “AP” to domain code to indicate it is AP data
 - Uses APID (instead of USUBJID) to identify the person in the record
 - If the AP has a relationship with the study subject, the study subject’s USUBJID value will appear in a RSUBJID variable in the AP record
 - The relationship is described in the SREL variable

SDTMIG-AP use case: Family Medical History

History of:	Subject's Father's Family			Subject's Father		
	Yes	No	Unknown	Yes	No	Unknown
Heart Disease						
Stroke						
Cancer						
Depression						
Diabetes						
Sexually Transmitted Disease						
Alzheimer's Disease						
Obesity						
Blindness						
Deafness						
Allergies						
Asthma						
Congenital Abnormalities						
Learning Disabilities						
Psychomotor Retardation						
Subfertility/Infertility						
Miscarriages						
Stillbirths						
Infant deaths						

SDTMIG-AP use case: Family Medical History

History of:	Subject's Father's Family			Subject's Father		
	Yes	No	Unknown	Yes	No	Unknown
Heart Disease						
Stroke						
Cancer						
Depression						
Diabetes						
Sexually Transmitted Disease						
Alzheimer's Disease						

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHTERM	MHPRESP	MHOCCUR
1	A1999	APMH	A1999-123	1	A1999-031	FATHER, BIOLOGICAL	HEART DISEASE	Y	N
2	A1999	APMH	A1999-123	2	A1999-031	FATHER, BIOLOGICAL	STROKE	Y	N
3	A1999	APMH	A1999-123	3	A1999-031	FATHER, BIOLOGICAL	CANCER	Y	N
4	A1999	APMH	A1999-123	4	A1999-031	FATHER, BIOLOGICAL	DEPRESSION	Y	N
5	A1999	APMH	A1999-123	5	A1999-031	FATHER, BIOLOGICAL	DIABETES	Y	N
6	A1999	APMH	A1999-123	6	A1999-031	FATHER, BIOLOGICAL	SEXUALLY TRANSMITTED DISEASE	Y	U
7	A1999	APMH	A1999-123	7	A1999-031	FATHER, BIOLOGICAL	ALZHEIMER'S DISEASE	Y	N
8	A1999	APMH	A1999-123	8	A1999-031	FATHER, BIOLOGICAL	OBESITY	Y	N
9	A1999	APMH	A1999-123	9	A1999-031	FATHER, BIOLOGICAL	BLINDNESS	Y	N
10	A1999	APMH	A1999-123	10	A1999-031	FATHER, BIOLOGICAL	DEAFNESS	Y	N
11	A1999	APMH	A1999-123	11	A1999-031	FATHER, BIOLOGICAL	ALLERGIES	Y	N
12	A1999	APMH	A1999-123	12	A1999-031	FATHER, BIOLOGICAL	ASTHMA	Y	N
13	A1999	APMH	A1999-123	14	A1999-031	FATHER, BIOLOGICAL	CONGENITAL ABNORMALITIES	Y	N
14	A1999	APMH	A1999-123	15	A1999-031	FATHER, BIOLOGICAL	LEARNING DISABILITIES	Y	N
15	A1999	APMH	A1999-123	16	A1999-031	FATHER, BIOLOGICAL	PSYCHOMOTOR RETARDATION	Y	N
16	A1999	APMH	A1999-123	13	A1999-031	FATHER, BIOLOGICAL	SUBFERTILITY/INFERTILITY	Y	U
17	A1999	APMH	A1999-G02	1	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	HEART DISEASE	Y	N
18	A1999	APMH	A1999-G02	2	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	STROKE	Y	N
19	A1999	APMH	A1999-G02	3	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	CANCER	Y	N
20	A1999	APMH	A1999-G02	4	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	DEPRESSION	Y	U
21	A1999	APMH	A1999-G02	5	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	DIABETES	Y	Y
22	A1999	APMH	A1999-G02	6	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	SEXUALLY TRANSMITTED DISEASE	Y	U
23	A1999	APMH	A1999-G02	7	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	ALZHEIMER'S DISEASE	Y	U
24	A1999	APMH	A1999-G02	8	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	OBESITY	Y	N
25	A1999	APMH	A1999-G02	9	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	BLINDNESS	Y	N
26	A1999	APMH	A1999-G02	10	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	DEAFNESS	Y	N
27	A1999	APMH	A1999-G02	11	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	ALLERGIES	Y	N
28	A1999	APMH	A1999-G02	12	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	ASTHMA	Y	U
29	A1999	APMH	A1999-G02	17	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	CONGENITAL ABNORMALITIES	Y	N
30	A1999	APMH	A1999-G02	18	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	LEARNING DISABILITIES	Y	U
31	A1999	APMH	A1999-G02	19	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	PSYCHOMOTOR RETARDATION	Y	N
32	A1999	APMH	A1999-G02	13	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	SUBFERTILITY/INFERTILITY	Y	N
33	A1999	APMH	A1999-G02	14	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	MISCARRIAGES	Y	N
34	A1999	APMH	A1999-G02	15	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	STILLBIRTHS	Y	N
35	A1999	APMH	A1999-G02	16	A1999-031	RELATIVE OF FATHER, BIOLOGICAL	INFANT DEATHS	Y	N

SDTMIG-MD (Medical Devices)

- Seven (7) domains that have been defined to hold Device information
 - Device Identifiers (DI)
 - Device In Use (DU)
 - Device Exposure (DX)
 - Device Events (DE)
 - Device Tracking and Disposition (DT)
 - Device Subject Relationship (DR)
 - Device Properties (DO)

SDTMIG-MD - Use Case Device In Use (DU): MRI Settings

du.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DUSEQ	DUREFID	DUSPID	DULNKID	DUTESTCD	DUTEST	DUORRES	DUORRESU
1	STUDYX	DU	2324-P0001	ABC174	1	223-45	1	DUNV1	COILSTR	Coil Strength	1.5	T
2	STUDYX	DU	2324-P0001	ABC174	2	223-45	2	DUNV1	ANTPLANE	Anatomical Plane	CORONAL	
3	STUDYX	DU	2324-P0001	ABC174	3	223-45	3	DUNV1	STHICK	Slice Thickness	1	mm
4	STUDYX	DU	2324-P0001	ABC174	4	223-45	4	DUNV1	MATRIX	Matrix	256X256	
5	STUDYX	DU	2324-P0001	ABC174	5	223-45	5	DUNV1	SFTWRVER	Software Version	15.0	
6	STUDYX	DU	2324-P0001	ABC174	6	223-45	6	DUNV1	FLDVIEW	Field of View	24	cm
7	STUDYX	DU	2324-P0001	ABC174	7	223-45	7	DUNV1	RCBDWTH	Receiver Bandwidth	16	kHz
8	STUDYX	DU	2324-P0001	ABC174	8	445-77	1	DUNV2	COILSTR	Coil Strength	1.0	T
9	STUDYX	DU	2324-P0001	ABC174	9	445-77	2	DUNV2	ANTPLANE	Anatomical Plane	CORONAL	
10	STUDYX	DU	2324-P0001	ABC174	10	445-77	3	DUNV2	STHICK	Slice Thickness	2	mm
11	STUDYX	DU	2324-P0001	ABC174	11	445-77	4	DUNV2	MATRIX	Matrix	256X256	
12	STUDYX	DU	2324-P0001	ABC174	12	445-77	5	DUNV2	SFTWRVER	Software Version	15.1	
13	STUDYX	DU	2324-P0001	ABC174	13	445-77	6	DUNV2	FLDVIEW	Field of View	25	cm
14	STUDYX	DU	2324-P0001	ABC174	14	445-77	7	DUNV2	RCBDWTH	Receiver Bandwidth	16	kHz

Row	DUSTRESC	DUSTRESN	DUSTRESU	VISITNUM	VISIT	VISITDY	DUDTC	DUDY
1 (cont)	1.5	1.5	T	1	SCREENING	-7	2011-04-19	-7
2 (cont)	CORONAL			1	SCREENING	-7	2011-04-19	-7
3 (cont)	1	1	mm	1	SCREENING	-7	2011-04-19	-7
4 (cont)	256X256			1	SCREENING	-7	2011-04-19	-7
5 (cont)	15.0			1	SCREENING	-7	2011-04-19	-7
6 (cont)	24	24	cm	1	SCREENING	-7	2011-04-19	-7
7 (cont)	16	1	kHz	1	SCREENING	-7	2011-04-19	-7
8 (cont)	1.0	1.0	T	2	IMPLANTATION	1	2011-04-26	1
9 (cont)	CORONAL			2	IMPLANTATION	1	2011-04-26	1
10 (cont)	2	2	mm	2	IMPLANTATION	1	2011-04-26	1
11 (cont)	256X256			2	IMPLANTATION	1	2011-04-26	1
12 (cont)	15.1			2	IMPLANTATION	1	2011-04-26	1
13 (cont)	25	25	cm	2	IMPLANTATION	1	2011-04-26	1
14 (cont)	16	16	kHz	2	IMPLANTATION	1	2011-04-26	1

* Findings from the scan belong in the relevant body-system domain, e.g., Nervous System (NV) Findings domain for brain MRI results

SDTMIG-MD - Use Case Device Exposure (DX) : Sutures

Example 5

This is an example of a study investigating the safety and efficacy of a particular suture material in closing wounds. In this example, the same subject had two wounds. One was on the left forearm and was sutured using the material under study, while the other was on the right thigh and was sutured using a control.

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	DXSEQ	DXTRT	DXDOSE	DXDOSTXT	DXDOSU
1	P47-923	DX	923-021	STRONG2	1	Strong Suture No 2	15		cm
2	P47-923	DX	923-021	COMP465	1	GenSuture	12		cm

Row	DXLOC	DXLAT	DXSTDTC	DXENDTC	DXSTDY	DXENDY
1 (cont)	FOREARM	LEFT	2011-12-24T15:25	2001-12-30T09:38	1	7
2 (cont)	THIGH	RIGHT	2011-12-24T15:45	2001-12-30T09:32	1	7

SDTMIG-PGx (Pharmacogenomics/Pharmacogenetics)

- Six (6) domains for handling Pharmacogenetic / Pharmacogenomic data
 - Biospeciman Events (BE)
 - Biospecimen Findings (BS)
 - Pharmacogenomics/Genetics Findings (PF)
 - Pharmacogenomics/Genetics Methods and Supporting Information (PG)
 - PGx Biomarker (PB) - Study Level reference dataset

pb.xpt

Row	STUDYID	DOMAIN	PBSEQ	PBMRKRID	PBMRKR	PBGENRI	PBGENTYP	PBNSPCES	PBSTRN	PBDRUG	PBDIAG	PBSTMT
1	STDY-505357	PB	1	G48V	p.G48V	Protease	SECTOR	HIV	1a	Saquinavir		RESISTANCE
2	STDY-505357	PB	2	L10I+K20R+M36I+A71V+V82T	p.L10I	Protease	SECTOR	HIV	1a	Indinavir		RESISTANCE
3	STDY-505357	PB	3	L10I+K20R+M36I+A71V+V82T	p.K20R	Protease	SECTOR	HIV	1a	Indinavir		RESISTANCE
4	STDY-505357	PB	4	L10I+K20R+M36I+A71V+V82T	p.M36I	Protease	SECTOR	HIV	1a	Indinavir		RESISTANCE
5	STDY-505357	PB	5	L10I+K20R+M36I+A71V+V82T	p.A71V	Protease	SECTOR	HIV	1a	Indinavir		RESISTANCE
6	STDY-505357	PB	6	L10I+K20R+M36I+A71V+V82T	p.V82T	Protease	SECTOR	HIV	1a	Indinavir		RESISTANCE

- *Subject Biomarker (SB)*

SDTMIG-PGx use case: Specimen Tracking using BE

- *Biospecimen Events (BE)*

be.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	BESEQ	BEREFID	BETERM	BEDECOD	BEPARTY	BEPRTYID	BECAT	BELOC
1	ABC134	BE	43871	TS409871	1	1148.267	Collected	COLLECTED	SITE	01	COLLECTION	BRAIN
2	ABC134	BE	43871		2	1148.267	Flash Frozen	FLASH FROZEN	SITE	01	PREPARATION	
3	ABC134	BE	43871	309827	3	1148.267	Stored in Freezer	STORED	SITE	01	STORING	
4	ABC134	BE	43871		4	1148.267	Thaw	THAW	SITE	01	PREPARATION	
5	ABC134	BE	43871	LN43871	5	1148.267	Shipped	SHIPPED	ABC LAB		TRANSPORT	

Codetable Mapping Files

- Relationships / mapping across codelists
 - e.g., which tumor identification short names map to which tumor identification long names, and what codelist is used for responses
- Codetable mapping files (available at <https://www.cdisc.org/standards/terminology>):
 - Disposition: DS
 - Cardiovascular: CV
 - ECG Tests and Results: EG
 - Oncology (multiple domains: TU, TR, RS)
 - Race, Ethnicity: Demographics (DM)
 - Subject Characteristics: SC
 - Trial Summary: TS
 - Vital Signs: VS

Codetable Mapping Files

- Relationships / mapping across codelists

C-code (Concept Code)	Tumor or Lesion Identification Test Code (TUTESTCD) (codelist code = C96784)	Tumor or Lesion Identification Test Name (TUTEST) (codelist code = C96783)		C-code (Concept Code)	Tumor or Lesion Identification Test Results (TUIDRS) (codelist code = C123650)		C-code (Concept Code)	No Yes Response (NY) (codelist code = C66742)
C161485	CVLIND	Cardiovascular Lesion Indicator					C49487	N
C161485	CVLIND	Cardiovascular Lesion Indicator					C17998	U
C161485	CVLIND	Cardiovascular Lesion Indicator					C49488	Y
C123633	DRCRLTLC	Disease Recurrence Relative Location		C25321	DISTANT			
C123633	DRCRLTLC	Disease Recurrence Relative Location		C67263	LOCAL			
C123633	DRCRLTLC	Disease Recurrence Relative Location		C25388	LOCOREGIONAL			
C123633	DRCRLTLC	Disease Recurrence Relative Location		C25643	REGIONAL			
C161484	FIBLIND	Fibrotic Lesion Indicator					C49487	N
C161484	FIBLIND	Fibrotic Lesion Indicator					C17998	U
C161484	FIBLIND	Fibrotic Lesion Indicator					C49488	Y
C119567	GRLIDENT	Graft Lesion Identification		C94521	NON-TARGET			
C119567	GRLIDENT	Graft Lesion Identification		C94520	TARGET			
C94189	LESIDENT	Lesion Identification		C94521	NON-TARGET			
C94189	LESIDENT	Lesion Identification		C94520	TARGET			
C119568	LMLIDENT	Limb Lesion Identification		C94521	NON-TARGET			
C119568	LMLIDENT	Limb Lesion Identification		C94520	TARGET			
C161482	MEASIND	Measurable Tumor Indicator					C49487	N
C161482	MEASIND	Measurable Tumor Indicator					C17998	U
C161482	MEASIND	Measurable Tumor Indicator					C49488	Y
C154853	METIND	Metastatic Tumor Site Indicator					C49487	N
C154853	METIND	Metastatic Tumor Site Indicator					C17998	U
C154853	METIND	Metastatic Tumor Site Indicator					C49488	Y
C161483	NTIND	Non-Target Indicator					C49487	N
C161483	NTIND	Non-Target Indicator					C17998	U
C161483	NTIND	Non-Target Indicator					C49488	Y
C94525	TUMERGE	Tumor Merged		C94520	TARGET			
C94523	TUMIDENT	Tumor Identification		C14172	BENIGN			
C94523	TUMIDENT	Tumor Identification		C132466	BONE LESION			
C94523	TUMIDENT	Tumor Identification		C103416	MEASURED			
C94523	TUMIDENT	Tumor Identification		C94522	NEW			
C94523	TUMIDENT	Tumor Identification		C132467	NEW BONE LESION			

Codetable Mapping Files

- Review codetable mapping files
 - [Oncology mapping file](#)
 - [Vital Signs mapping file](#)
 - [Subject Characteristics mapping file](#)
 - [Disposition mapping file](#)



Q&A

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