

What's new in draft SDTM IG 3.1.4

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Agenda

- ✓ CDISC SDTM IG 3.1.4 draft batch 1
 - EX/EC Exposure domains
 - IS/SR Immunogenicity domains
 - RD Reproductive details
- ✓ CDISC SDTM IG 3.1.4 draft batch 2
 - New domains: CV, DD, MI, MO, PR, SS, TD
 - SDS Proposal: Alternate handling of Supplemental Qualifiers
- ✓ CDISC SDTM IG 3.1.4 draft batch 3
 - AP Associated Persons
 - HO Healthcare Encounters
 - Study Data Tabulation Model v1.4
- ✓ Outlook

SDTM IG 3.1.4 draft batch 1 - EX/EC Exposure domains

✓ Clarification of:

- EX domain definition
- EXDOSU
- EXDOSE
- EXVAMT

✓ Added and/or updated variables:

- | | |
|-------------------|-------------|
| • --OCCUR | • --FAST |
| • --REASND | • --PSTRG/U |
| • --DOSE | • --DOSTKN |
| • --MOOD (--MODE) | • --MTHOBS |
| • --METHOD | • --PTTMFL |

SDTM IG 3.1.4 draft batch 1 - EC Exposure as Collected

- ✓ Study treatment as collected
- ✓ EC if not collected in protocol specified units
 - EC not needed if duplicate of EX
 - Exposure data only represented in EX only or EC & EX or DA & EX
- ✓ Summarization of records from EC to EX sponsor defined

SDTM IG 3.1.4 draft batch 1 - EX Exposure

- ✓ EX: derived dataset where EXDOSU reflects the protocol specified unit
- ✓ EX required for all studies
 - During blinded phase EX is not expected
- ✓ EXOCCUR = „N“ for doses not taken
- ✓ EXDOSE = 0 for placebo
- ✓ EXMOOD used to include planned and actual treatments

SDTM IG 3.1.4 draft batch 1 – EX/EC Exposure domains

Exposure CRF:

Subject: ABC1001

Bottle	Number of Tablets Taken Daily	Reason for Variation	Start Date	End Date
A	2		2011-01-14	2011-01-28

Subject: ABC2001

Bottle	Number of Tablets Taken Daily	Reason for Variation	Start Date	End Date
A	2		2011-01-14	2011-01-23
A	0	Patient mistake	2011-01-24	2011-01-24
A	2		2011-01-25	2011-01-28

ec.xpt

Row	STUDYID	DOMAIN	USUBJID	ECSEQ	ECLNKID	ECTRT	ECOCUR	ECREASND	ECDOSE	ECDOSU	ECDOSFRQ
1	ABC	EC	ABC1001	1	A-20110114	BOTTLE A			2	TABLET	QD
2	ABC	EC	ABC2001	1	A-20110114	BOTTLE A			2	TABLET	QD
3	ABC	EC	ABC2001	2	A-20110124	BOTTLE A	N	PATIENT MISTAKE			
4	ABC	EC	ABC2001	3	A-20110125	BOTTLE A			2	TABLET	QD

Row	EPOCH	ECSTDTC	ECENDTC
1 (cont)	TREATMENT	2011-01-14	2011-01-28
2 (cont)	TREATMENT	2011-01-14	2011-01-23
3 (cont)	TREATMENT	2011-01-24	2011-01-24
4 (cont)	TREATMENT	2011-01-25	2011-01-28

SDTM IG 3.1.4 draft batch 1 – EX/EC Exposure domains

Exposure CRF:

Subject: ABC1001

Bottle	Number of Tablets Taken Daily	Reason for Variation	Start Date	End Date
A	2		2011-01-14	2011-01-28

Subject: ABC2001

Bottle	Number of Tablets Taken Daily	Reason for Variation	Start Date	End Date
A	2		2011-01-14	2011-01-23
A	0	Patient mistake	2011-01-24	2011-01-24
A	2		2011-01-25	2011-01-28

- ABC1001 received Drug X (two 500-mg tablets once daily)
- ABC2001 received Drug Z (two 250-mg tablets once daily)

ex.xpt

Row	STUDYID	DOMAIN	USUBJID	EXSEQ	EXLNKID	EXTRT	EXOCUR	EXREASND	EXDOSE	EXDOSU	EXDOSFRM
1	ABC	EX	ABC1001	1	A-20110114	DRUG X			1000	mg	TABLET, EXTENDED RELEASE
2	ABC	EX	ABC2001	1	A-20110114	DRUG Z			500	mg	TABLET
3	ABC	EX	ABC2001	2	A-20110124	DRUG Z	N	PATIENT MISTAKE	500	mg	TABLET
4	ABC	EX	ABC2001	3	A-20110125	DRUG Z			500	mg	TABLET

Row	EXDOSFRQ	EXROUTE	EPOCH	EXSTDTC	EXENDTC
1 (cont)	QD	ORAL	TREATMENT	2011-01-14	2011-01-28
2 (cont)	QD	ORAL	TREATMENT	2011-01-14	2011-01-23
3 (cont)	QD	ORAL	TREATMENT	2011-01-24	2011-01-24
4 (cont)	QD	ORAL	TREATMENT	2011-01-25	2011-01-28

SDTM IG 3.1.4 draft batch 1 - IS/SR Immunogenicity

- ✓ Immunogenicity Specimen Assessments (IS): for assessments that determine immune response

Row	STUDYID	DOMAIN	USUBJID	ISSEQ	ISTESTCD	ISTEST	ISCAT	ISORRES	ISORRESU
1	ABC-123	IS	123457	1	HCAB	Hepatitis C Virus Antibody	Serology	3115.016	gpELISA unit/mL
2	ABC-123	IS	123457	3	HCAB	Hepatitis C Virus Antibody	Serology	1772.78	gpELISA unit/mL
3	ABC-123	IS	123457	2	IGDNA	Hepatitis C DNA	Serology	POSITIVE	

Row	ISSTRESC	ISSTRESN	ISSTRESU	ISSPEC	ISMETHOD	ISBLFL	ISLLOQ
1	3115.016	3115.016	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY	Y	100
2	1772.78	1772.78	gpELISA unit/mL	SERUM	ENZYME IMMUNOASSAY		100
3	POSITIVE			LIVER	POLYMERASE CHAIN REACTION		

Row	VISITNUM	VISIT	TAETORD	EPOCH	ISDY	ISDTC
1	1	VISIT 1	1	PRE-VACCINATION	1	2008-10-10
2	2	VISIT 2	2	POST-VACCINATION	43	2008-11-21
3	4	VISIT 4	2	POST-VACCINATION	343	2009-09-17

SDTM IG 3.1.4 draft batch 1 - IS/SR Immunogenicity

- ✓ Skin Response (SR): findings about domain for dermal responses to antigen
 - SROBJ represents test material

Row	STUDYID	DOMAIN	USUBJID	SRSEQ	SRTESTCD	SRTEST	SROBJ
1	SPI-001	SR	SPI-001-11035	1	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL
2	SPI-001	SR	SPI-001-11035	2	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL
3	SPI-001	SR	SPI-001-11035	3	WHEALDIA	Wheal Diameter	Histamine Control 10 mg/mL

Row	SRORRES	SRORRESU	SRSTRESC	SRSTRESN	SRSTRESN	SRLOC	VISITNUM	VISIT
1	5	mm	5	5	mm	BACK QUADRANT1	1	VISIT 1
2	4	mm	4	4	mm	BACK QUADRANT2	1	VISIT 1
3	5	mm	5	5	mm	BACK QUADRANT3	1	VISIT 1

SDTM IG 3.1.4 draft batch 1 - RD Reproduction details

- ✓ Reproduction Details (RD): captures all reproduction details
 - Related medication should be mapped to CM
 - Reproduction details should not be placed in SC any more

Row	STUDYID	DOMAIN	USUBJID	RDSEQ	RDTESTCD	RDTEST	RDCAT	RDORRES	RDORRESU	RDSTRESC	RDSTRESN
1	STUDYX	RD	2324-P0001	1	NUMSPAB	Number of Elective/Spontaneous Abortions		1		1	1
2	STUDYX	RD	2324-P0001	2	NUJMLIV	Number of Live Births		2		2	2
3	STUDYX	RD	2324-P0001	3	NUMPREG	Number of Pregnancies		3		3	3
4	STUDYX	RD	2324-P0001	4	PREGNT	Pregnant During the Study		N		N	

Row	RDSTRESU	RDDUR	RDBLFL	VISITNUM	VISIT	VISITDY	RDDTC	RDDY
1 (cont)			Y	1	SCREENING	1	2008-03-09	-10
2 (cont)			Y	1	SCREENING	1	2008-03-09	-10
3 (cont)			Y	1	SCREENING	1	2008-03-09	-10
4 (cont)			Y	1	SCREENING	1	2008-03-09	-10

SDTM IG 3.1.4 draft batch 2 - PR Procedures Domain

- ✓ Procedures (PR): intervention domain that reflects therapeutic and diagnostic procedures, e.g.
 - Endoscopic examinations
 - Diagnostic tests (e.g. CT scan, MRI)
 - Surgical procedures
 - Etc.
- ✓ Not used when only findings are collected

Row	STUDYID	DOMAIN	USUBJID	PRSEQ	PRTRT	PRSTDTC
1	XYZ	PR	XYZ789-002	1	Wisdom Teeth Extraction	2010-06-08
2	XYZ	PR	XYZ789-002	2	Reset Broken Arm	2010-08-06
3	XYZ	PR	XYZ789-002	3	Prostate Examination	2010-12-12
4	XYZ	PR	XYZ789-002	4	Endoscopy	2010-12-12
5	XYZ	PR	XYZ789-002	5	Heart Transplant	2011-08-29

SDTM IG 3.1.4 draft batch 2 - CV Cardiovascular Domain

Row	STUDYID	DOMAIN	USUBJID	CVSEQ	CVTESTCD	CVTEST	CVCAT	CVPOS	CVORRES	CVORRESU	CVSTRESC	CVSTRESN
1	XYZ	CV	XYZ-US-701-002	1	STENOSIS	Stenosis	NATIVE ARTERY	SUPINE	70	%	70	70
2	XYZ	CV	XYZ-US-701-002	2	STENOSIS	Stenosis	NATIVE ARTERY	SUPINE	<50	%	<50	
3	XYZ	CV	XYZ-US-701-002	3	STENOSIS	Stenosis	NATIVE ARTERY	SUPINE	>50	%	>50	
4	XYZ	CV	XYZ-US-701-002	4	STENOSIS	Stenosis	GRAFT		50	%	50	50

Row	CVSTRESU	CVMETHOD	CVLOC	CVLOCN	CVDIR	VISITNUM	VISIT	CVDTC	CVDY
1 (cont)	%	MRI	LEFT MAIN CORONARY ARTERY			1	Visit 1	2011-04-15T11:58	1
2 (cont)	%		CORONARY ARTERY, ANTERIOR DESCENDING	LEFT	PROXIMAL	1	Visit 1	2011-04-15T11:58	1
3 (cont)	%	MRI	MID/DISTAL LEFT ANTERIOR DESCENDING CORONARY ARTERY			1	Visit 1	2011-04-15T11:58	1
4 (cont)	%	MRI	LEFT POSTERIOR DESCENDING ARTERY			1	Visit 1	2011-04-15T11:58	1

Might be implemented in SDTM IG 3.1.5

SDTM IG 3.1.4 draft batch 2 - MI Microscopic Findings

- ✓ One record per microscopic finding
 - Biomarkers assessed by histologic or histopathologic examination or classified as 'PATH', 'CYTO' in LOINC
- ✓ MITSTDTL is used when biomarker tests are represented. It represents test parameter details descriptive of slide stain results.
 - MITESTCD reflects the biomarker and MITSTDTL further qualifies the record. The MITSTDTL stain results are used across different biomarkers.

SDTM IG 3.1.4 draft batch 2 - MI Microscopic Findings

Row	STUDYID	DOMAIN	USUBJID	MISEQ	MITESTCD	MITEST	MITSTDTL	MIORRES	MIORRESU	MISTRESC	MISTRESN	MISTRESU	MILOC	MISPEC
1	ABC	MI	ABC-1001	1	TTF1	Thyroid Transcription Factor 1	Cells with 0 intensity of staining	25	%	25	25	%	LUNG	TISSUE
2	ABC	MI	ABC-1001	2	TTF1	Thyroid Transcription Factor 1	The percentage of cells with +1 intensity of staining	40	%	40	40	%	LUNG	TISSUE
3	ABC	MI	ABC-1001	3	TTF1	Thyroid Transcription Factor 1	The percentage of cells with 2+ intensity of staining	35	%	35	35	%	LUNG	TISSUE
4	ABC	MI	ABC-1001	4	TTF1	Thyroid Transcription Factor 1	The percentage of cells with 3+ intensity of staining	0	%	0	0	%	LUNG	TISSUE
5	ABC	MI	ABC-1001	5	TTF1	Thyroid Transcription Factor 1	H-Score of staining	110		110	110		LUNG	TISSUE

Row	MIDRVFL	MIMETHOD	VISIT
1 (cont)		IHC	SCREENING
2 (cont)		IHC	SCREENING
3 (cont)		IHC	SCREENING
4 (cont)		IHC	SCREENING
5 (cont)	Y	IHC	SCREENING

✓ PR, LB and MI can be linked via RELREC, if procedures or additional laboratory tests were captured

SDTM IG 3.1.4 draft batch 2 - MO Morphology Domain

- ✓ In biology, morphology is a branch of bioscience dealing with the study of the form and structure of organisms and their specific structural features. ^[1]
- ✓ Macroscopic results (e.g. size, shape, color, and abnormalities of body parts or specimens)
- ✓ Not a replacement of Oncology domains!
- ✓ MOLNKID used to create a link to Procedures (PR)

[1] [http://en.wikipedia.org/wiki/Morphology_\(biology\)](http://en.wikipedia.org/wiki/Morphology_(biology))

SDTM IG 3.1.4 draft batch 2 - MO Morphology Domain

ROW	STUDYID	DOMAIN	USUBJID	MOSEQ	MOTESTCD	MOTEST	MOORRES	MOORRESU	MOSTRESC	MOSTRESN	MOSTRESU	MOLOC
1	STUDY01	MO	2324-P0001	1	WIDTH	Width	5	mm	5	5	mm	KIDNEY
2	STUDY01	MO	2324-P0001	2	WIDTH	Width	5	mm	5	5	mm	KIDNEY
3	STUDY01	MO	2324-P0001	3	LENGTH	Length	11	mm	11	11	mm	KIDNEY
4	STUDY01	MO	2324-P0001	4	LENGTH	Length	11	mm	11	11	mm	KIDNEY
5	STUDY01	MO	2324-P0001	5	DEPTH	Depth	2	mm	2	2	mm	KIDNEY
6	STUDY01	MO	2324-P0001	6	DEPTH	Depth	2	mm	2	2	mm	KIDNEY
7	STUDY01	MO	2324-P0001	7	VOLUME	Volume	25	mL	25	25	mL	LIVER
8	STUDY01	MO	2324-P0001	8	VOLUME	Volume	50	mL	50	50	mL	KIDNEY
9	STUDY01	MO	2324-P0001	9	VOLUME	Volume	50	mL	50	50	mL	KIDNEY
10	STUDY01	MO	2324-P0001	10	VOLUME	Volume	100	mL	100	100	mL	KIDNEY
11	STUDY01	MO	2324-P0001	11	MASS	Mass	25	g	25	25	g	HEART, LEFT VENTRICLE

ROW	MOLAT	MOMETHOD	VISITNUM	VISIT	MODTC
1 (cont)	LEFT	CT SCAN	1	Baseline	2010-06-19
2 (cont)	RIGHT	CT SCAN	1	Baseline	2010-06-19
3 (cont)	LEFT	CT SCAN	1	Baseline	2010-06-19
4 (cont)	RIGHT	CT SCAN	1	Baseline	2010-06-19
5 (cont)	LEFT	CT SCAN	1	Baseline	2010-06-19
6 (cont)	RIGHT	CT SCAN	1	Baseline	2010-06-19
7 (cont)		CT SCAN	1	Baseline	2010-06-19
8 (cont)	LEFT	CT SCAN	1	Baseline	2010-06-19
9 (cont)	RIGHT	CT SCAN	1	Baseline	2010-06-19
10 (cont)	BILATERAL	CT SCAN	1	Baseline	2010-06-19
11 (cont)		CT SCAN	1	Baseline	2010-06-19

SDTM IG 3.1.4 draft batch 2 - DD Death Details Domain

- ✓ Death Details (DD): additional information on death of subject
 - Should not replace records in DS or values in AEOUT / AESDTH
 - Intended to contain data obtained from autopsy, autopsy itself goes to PR
 - Not required to be implemented

Row	STUDYID	DOMAIN	USUBJID	DDSEQ	DDTESTCD	DDTEST	DDORRES	DSSTRESC	DDTTC
1	ABC123	DD	ABC12301001	1	PRCDTH	Primary Cause of Death	SUDDEN CARDIAC DEATH	SUDDEN CARDIAC DEATH	2011-01-12
2	ABC123	DD	ABC12301001	2	LOCPTH	Location of Death	HOME	HOME	2011-01-12
3	ABC123	DD	ABC12301002	1	PRCDTH	Primary Cause of Death	UNKNOWN	UNKNOWN	2011-03-15
4	ABC123	DD	ABC12301002	2	LOCPTH	Location of Death	UNKNOWN	UNKNOWN	2011-03-15
5	ABC123	DD	ABC12301023	1	PRCDTH	Primary Cause of Death	CARDIAC ARRHYTHMIA	CARDIAC ARRHYTHMIA	2011-09-09
6	ABC123	DD	ABC12301023	2	SECDTH	Secondary Cause of Death	CHF	CONGESTIVE HEART FAILURE	2011-09-09
7	ABC123	DD	ABC12301023	3	LOCPTH	Location of Death	MEMORIAL HOSPITAL	HOSPITAL	2011-09-09

SDTM IG 3.1.4 draft batch 2 - SS Subject Status Domain

- ✓ Subject Status (SS): contains status at a point in time or status evaluated periodically
 - Not a replacement of SC or any other domain

Row	STUDYID	DOMAIN	USUBJID	SSSEQ	SSTESTCD	SSTEST	SSORRES	SSSTRESC	VISITNUM	VISIT	SSDTC
1	XYZ	SS	XYZ-333-009	1	SURVSTAT	Survival Status	ALIVE	ALIVE	10	MONTH 1	2010-04-15
2	XYZ	SS	XYZ-333-009	2	SURVSTAT	Survival Status	ALIVE	ALIVE	20	MONTH 2	2010-05-12
3	XYZ	SS	XYZ-333-009	3	SURVSTAT	Survival Status	ALIVE	ALIVE	30	MONTH 3	2010-06-15
4	XYZ	SS	XYZ-428-021	1	SURVSTAT	Survival Status	ALIVE	ALIVE	10	MONTH 1	2010-08-03
5	XYZ	SS	XYZ-428-021	2	SURVSTAT	Survival Status	DEAD	DEAD	20	MONTH 2	2010-09-06

SDTM IG 3.1.4 draft batch 2 - TD Trial Disease Ass.

- ✓ Trial Disease Assessments (TD): reflects the protocol-specified disease assessment schedule
 - FDA has standard programs (panels) based on TD to evaluate 'assessment time bias' for efficacy assessments
 - For trials where all subjects traverse a set pattern of disease assessments
 - Should not be created for trials with a non-regular or event driven disease assessment
- ✓ TDANCVAR identifies ADSL "anchor" date variable
- ✓ TDSTOFF used if pattern of disease assessment does not start on date collected on CRF

SDTM IG 3.1.4 draft batch 2 - TD Trial Disease Ass.



Row	STUDYID	DOMAIN	TDORDER	TDANCVAR	TDSTOFF	TDTGTPRD	TDMINPRD	TDMAXPRD	TDNUMRPT
1	ABC123	TD	1	ANCH1DT	P0D	P8W	P53D	P9W	6
2	ABC123	TD	2	ANCH1DT	P48W	P12D	P14D	P17D	1
3	ABC123	TD	3	ANCH2DT	P0D	P12W	P11W	P13W	4
4	ABC123	TD	4	ANCH3DT	P0D	P24W	P20W	P28W	17

SDTM IG 3.1.4 draft batch 2 – SDS Proposal: Alternate Handling of Supplemental Qualifiers

- ✓ Proposal used as basis for discussion
 - Not a draft document
- ✓ Non standard variables (NSVs) are now placed directly in parent domain
 - Only variables that were placed in SUPP before
 - Metadata for NSVs should be provided
 - CTs should be assigned in variable metadata
 - Variable length should be shortened

Might be implemented in SDTM IG 3.1.5

SDTM IG 3.1.4 draft batch 3 - HO Healthcare Encounters

- ✓ Healthcare Encounters (HO): events domain for hospitalization, home stays, rehabilitation facility stays or visits, emergency stays
- ✓ If only occurrence captured HOOCCUR can be used
- ✓ Open discussions:
 - Name of healthcare facility/provider in --NAM?
 - Reason for healthcare in --INDC or new reason variable?
 - How to implement discharge information?

Row	STUDYID	DOMAIN	USUBJID	HOSEQ	HOTERM	HOSTDTC	HOENDTC	HODUR
1	ABC	HO	ABC123101	1	HOSPITALIZATION	2011-06-08	2011-06-13	
2	ABC	HO	ABC123101	2	NURSING HOME			P6D
3	ABC	HO	ABC123102	1	GENERAL WARD	2011-08-06	2011-08-08	
4	ABC	HO	ABC123102	2	INTENSIVE CARE	2011-08-08	2011-08-15	
5	ABC	HO	ABC123102	3	REHABILITATION FACILITY	2011-08-15	2011-08-20	

SDTM IG 3.1.4 draft batch 3 - AP Associated Persons

- ✓ AP domains parallel general observation class domains + DM + CO
 - AP domains use SDTM variables + specific AP variables
 - Treatment vars from DM are not used
- ✓ Use cases:
 - Family history
 - Donor information
 - Caretakers
 - Sexual partners
 - Etc.
- ✓ AP domains/datasets are named AP--, e.g. APMH
 - Domain variable contains 4 digits
 - Supplemental Qualifiers are named SQAP--
 - USUBJID replaced by APID
 - Variables are not renamed, e.g. MHTERM remains MHTERM

SDTM IG 3.1.4 draft batch 3 - AP Associated Persons

✓ APIDs should be assigned if not collected

- APIDs might identify a single person or a pool of persons

Variable Name	Variable Label	Type	Controlled Terms, Codelist, or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	
DOMAIN	Domain Abbreviation	Char		Identifier	Four-character abbreviation for the domain. AP--.	
APID	Associated Persons Identifier	Char		Identifier <i>Except in APDM where it is the Topic variable</i>	Identifier for a single associated person, a group of associated persons, or a pool of associated persons. If APID identifies a pool, POOLDEF records must exist for each associated person.	Req
--SEQ	Sequence Number	Num		Identifier	Sequence number to ensure uniqueness of records within a domain for associated persons. Unique within APID within the domain.	Req
RSUBJID	Related Subject	Char		Record Qualifier	Identifier for a related study subject or pool of study subjects. The subject(s) may be human or animal. RSUBJID will be populated with the USUBJID of the related subject or the POOLID of the related pool. RSUBJID will be null for data about associated persons who are related to the study but not to any of the study subjects.	Exp
RDEVID	Related Device	Char		Record Qualifier	Identifier for a related device. RDEVID will be populated with the SPDEVID of the related device	Perm
SREL	Subject, Device, or Study Relationship	Char	*	Record Qualifier	If RSUBJID is populated, describes the relationship of the associated person(s) identified in APID to the subject or pool identified in RSUBJID. If RDEVID is populated, describes the relationship of the associated person(s) identified in APID to the device identified in RDEVID. If RSUBJID and RDEVID are null, SREL describes the relationship of the associated person(s) identified in APID to the study identified in STUDYID.	Req

SDTM IG 3.1.4 draft batch 3 - AP Associated Persons

Family Pompe Disease History

Have any of the following biological relatives been diagnosed with Pompe Disease?

Mother: ☐ Yes ☐ No
 Father: ☐ Yes ☐ No
 Sibling(s): ☐ Yes ☐ No If yes, how many? ____
 Cousin(s): ☐ Yes ☐ No If yes, how many? ____

apmh.xpt

Row	STUDYID	DOMAIN	APID	MHSEQ	RSUBJID	SREL	MHTERM	MHPRESP	MHOCCUR
1	2011-02-02	APMH	2011-02-02-N120	1	2011-02-02-031	MOTHER, BIOLOGICAL	POMPE DISEASE	Y	N
2	2011-02-02	APMH	2011-02-02-N121	1	2011-02-02-031	FATHER, BIOLOGICAL	POMPE DISEASE	Y	Y
3	2011-02-02	APMH	2011-02-02-NS122	1	2011-02-02-031	SIBLING, FULL	POMPE DISEASE	Y	N
4	2011-02-02	APMH	2011-02-02-NS123	1	2011-02-02-031	COUSIN, BIOLOGICAL	POMPE DISEASE	Y	Y

sqapmh.xpt

Row	STUDYID	RDOMAIN	APID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QEVAL
1	2011-02-02	APMH	2011-02-02-NS123	MHSEQ	1	NUMDX	Number Diagnosed	2	CRF	

SDTM IG 3.1.4 draft batch 3 – Study Data Tabulation Model v1.4

✓ Sections added:

- Section 3.5 – The Trial Disease Assessments
- Section 5 – Applying Model Fundamentals to AP (following sections were renumbered)

✓ New tables added:

- Table 3.5.1 - The Trial Disease Assessments
- Table 5.1.1 – AP Data – Identifier variables
- Table 5.2.1 – APRELSUB Table

✓ New variables added to (some variables are still under discussion):

- Table 2.2.1 – Interventions
- Table 2.2.2 – Events
- Table 2.2.3 – Findings
 - --TSTDTL and --ANMETH still under discussion
- Table 2.2.4 – Identifiers
- Table 2.2.4 – Timing variables
- Section 7 includes detailed list of new variables and deleted variables

Outlook

- ✓ SDTM IG 3.1.4 will be finalized by Summer 2013
 - Will also contain Virology and PGx User Guide
- ✓ Work on SDTM IG 3.1.5 starting Summer 2013
 - General Administration
 - Spreadsheet maintenance
 - Liaising between SDS and TA teams
 - Lab findings
 - Biomarker Results
 - Pharmacogenomics domains
 - Virology Terminology
 - Findings NEC
 - NV (Nervous System Findings)
 - RE (Respiratory System Findings)
 - CV (Cardiovascular System Findings)
 - UR (Urinary System Findings)

Outlook

- ✓ Work on SDTM IG 3.1.5 starting Summer 2013
 - Events, Interventions & FA
 - CM (Concomitant Medications) Enhancements
 - FA (Findings About) model clarification
 - Special Purpose
 - SUPPQUAL - Evaluation of current model vs. added horizontal variables in observation classes
 - Oncology
 - Discuss additional requirements to satisfy FDA analysis “panels” - SDTM 1.4 / SDTM-IG 3.1.4
 - Questionnaires
 - Standard Questionnaire Implementation
 - Modelling Questionnaire Results
 - Representing Questionnaire Metadata

Questions?



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