What's New in SDTMIG v3.3 and SDTM v1.7

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DATA STANDARDS CONSULTING GROUP™

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Agenda

- SDTM and SDTM Versioning Overview
- Updates to the SDTM
  - New Tables
  - New Variables
- Changes to the SDTMIG
  - Format
  - New Domains
  - Changes to Demographics
  - Timing-Variable Clarification
  - Disease Milestones
  - Miscellaneous Updates
  - New Domain Details

SDTMIG v3.3 Public Review Batches

Why Batches

Given the volume of revised content and new concepts and domains, the SDS Team is dividing materials targeted for inclusion in SDTMIGs into manageable batches for public review. This was the process for SDTMIG v3.2.

Plan for SDTMIG v3.3

There were three batches:

Batch 1 – April 2014 (Completed)

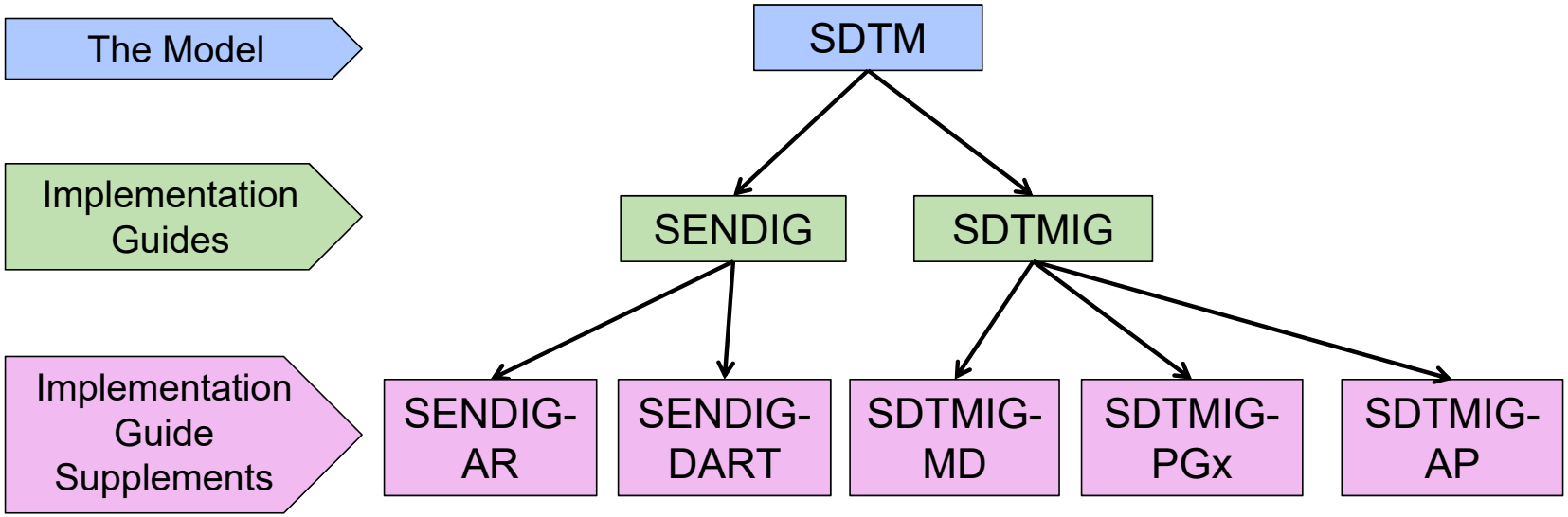
Batch 2 – November 2014 (Completed)

Batch 3 – August/September 2016

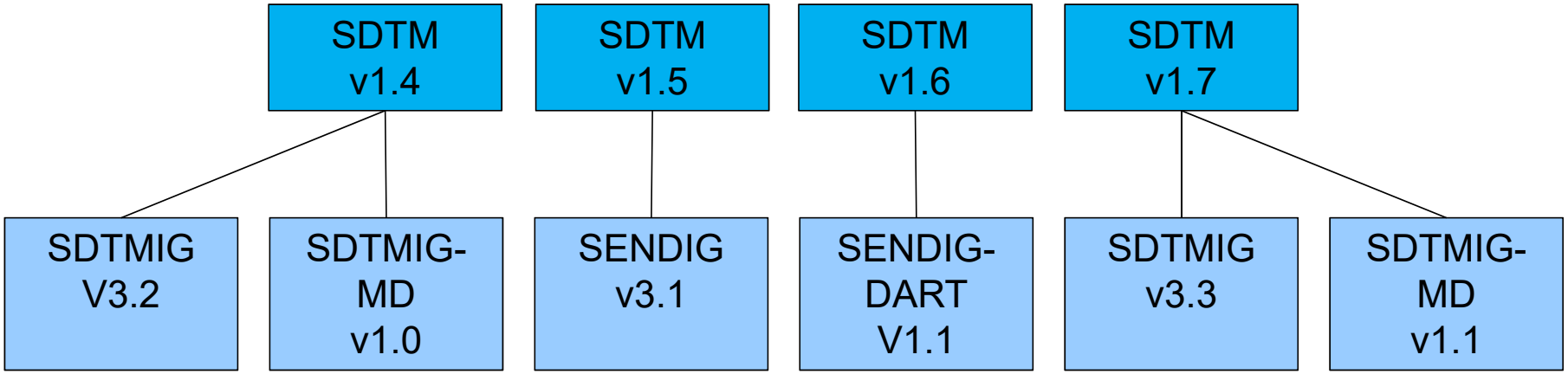
SDTM and IG Versioning Background

- The SDTM Governance Committee and the SDS Leadership Team made a decision that a version of the SDTM will be published with any new release of an SDTM-based implementation guide (IG)
- This will ensure alignment of new domains and concepts in each IG with the SDTM at the time of publication.

SDTM, and Implementation Guides



SDTM and SDTMIG Versions (1)



SDTM and SDTMIG Versions (2)

SDTM Version	Year	SDTMIG Version	Number of Domains*
1.0	2004	3.1	23
1.1	2005	3.1.1	30
1.2	2008	3.1.2	32
1.3	2012	3.1.3	32
1.4	2013	3.2	46
1.5	2016	NA**	
1.6	2017	NA***	
1.7	2018	3.3	56

* Includes all special-purpose and general-observation-class domains

** Created for the SENDIG v3.1

*** Created for the SENDIG-DART v1.1

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New SDTM Tables by Version

SDTM Version	New Tables
1.5	• **Table 2.2.10: Subject Disease Milestones** • **Table 2.2.11: Domain-Specific Variables for the General Observation Class** • **Table 3.5.2: Trial Disease Milestones**
1.6	• Table 2.2.11: Subject Repro Stages • Table 3.1.5: Trial Repro Stages • Table 3.1.6: Trial Repro Paths
1.7	• Table 4.1.5.1 Device-Subject Relationships Dataset New Datasets for Study Reference Section 5 added (Associated Persons modeling, moved to Section 6): • **Table 5.1.1.1 Device Identifiers Dataset** • **Table 5.1.2.1 Non-Host Organism Identifiers Dataset**

New SDTM Tables
Domain-Specific Variables, Table 2.2.12.1

Variable Name	Variable Label	
MHEVDTYP	Medical History Event Date Type	SYMPTOM ONSET, DIAGNOSIS
EXMETHOD	Method of Administration	
EGBEATNO	ECG Beat Number	Used in QT studies
ICIMPLBL	Implantation Site Label	SENDIG-DART
MSAGENT	Agent Name	Used with tests such as minimal inhibitory concentration
MSCONC	Agent Concentration	
MSCONCU	Agent Concentration Units	

New Variables SDTM v1.5

Table 2.2.1 Interventions	--USCHFL	Unscheduled Flag
Table 2.2.2 Events	--USCHFL	Unscheduled Flag
Table 2.2.3 Findings	--ORREF	Reference Result in Original Units
	--STREFC	Reference Result in Standard Format
	--STREFN	Numeric Reference Result in Std Units
	--IMPLBL	Implantation Site Label
	--CHRON	Chronicity of Finding
	--DISTR	Distribution Pattern of Finding
	--LOBXFL	Last Observation Before Exposure Flag
	--USCHFL	Unscheduled Flag
	--REPNUM	Repetition Number

Table 2.2.4 Identifiers	APID	Associated Persons Identifier
	FETUSID	Fetus Identifier
	FOCID	Focus of Study Specific Interest
	--RECID	Invariant Record Identifier
Table 2.2.5 Timing Variables	--NOMDY	Nominal Study Day for Tabulations
	--NOMLBL	Label for Nominal Study Day
	MIDS	Disease Milestone Instance Name
	RELMIDS	Temporal Relation to Milestone Instance
	MIDSDTC	Disease Milestone Instance Date/Time

New FOCID Variable

- An Identifier variable that has no domain prefix.
- Used to describe a focus of specific interest (e.g., body location) the same way across all domains.
  - Example: the right eye might be treated (data in EX) and then evaluated, with results in OE.
- The OE domain uses controlled terminology for FOCID:
  - OD (Oculus Dexter, Right Eye)
  - OS (Oculus Sinister, Left Eye)
  - OU (Oculus Uterque, Both Eyes).
- Implementations outside of OE will likely use protocol-defined terminology.
- The Findings variables --LOC (e.g., EYE) and --LAT (e.g., RIGHT), and to a lesser extent, --DIR, and --PORTOT may also be used.

New Variables SDTM v1.6

Table 2.2.3 Findings	--RESLOC	Result Location of Finding
Table 2.2.4 Identifiers	NHOID	Non-Host Organism Identifier
Table 2.2.5 Timing Variables	RPHASE	Repro Phase
	RPPLDY	Planned Repro Phase Day of Observation
	RPPLSTDY	Planned Repro Phase Day of Obs Start
	RPPLENDY	Planned Repro Phase Day of Obs End
	--RPDY	Actual Repro Phase Day of Observation
	--RPSTDY	Actual Repro Phase Day of Obs Start
	--RPENDY	Actual Repro Phase Day of Obs End
Table 2.2.6 Demographics	RPATHCD	Planned Repro Path Code

New Variables SDTM v1.7

Table 2.2.1.1* Interventions	--RSDISC	Reason for Treatment Discontinuation
Table 2.2.6.1* Demographics	ARMNRS	Reason Arm and/or Actual Arm is Null
	ACTARMUD	Description of Unplanned Actual Arm
Table 2.2.7.1* Comments	COEVALID	Evaluator Identifier
	CODY	Study Day of Comment
Table 2.2.12.1 Domain-Specific Variables for General Observation Class Domains	EXMETHOD	Method of Administration
	EGBEATNO	ECG Beat Number
	ICIMPLBL	Implantation Site Label
	MHEVDTYP	Medical History Event Date Type
	MSAGENT	Agent Name
	MSCONC	Agent Concentration
	MSCONCU	Agent Concentration Units

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SDTMIG v3.3 Format Changes

- The Publication Format
- Minor Format Changes
  - Enclosing all example values in double quotation marks (")
  - Linking codelists in specification tables to the specific codelist in the NCI-EVS website
  - Hyperlinking references to sections of the document
  - Referring to "Define-XML Document" instead of "define.xml" or "define.xml file“
  - Findings domains are grouped differently

New Domains in SDTMIG v3.3

Observation Class	Domain Name and Code
Interventions	Meal Data (ML)
	Procedure Agents (AG)
Findings	Cardiovascular Findings (CV)
	Musculoskeletal Findings
	Nervous System Findings (NV)
	Ophthalmic Examinations (OE)
	Respiratory System Findings (RE)
	Urinary System Findings
	Functional Tests (FT)
Special Purpose	Subject Milestones (SM)
Trial Design	Trial Milestones (TM)

Findings Domains with Expanded Scope

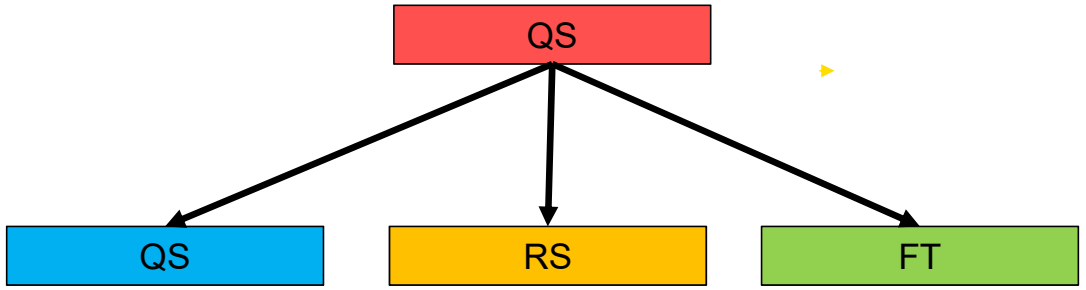
- **The Disease Response (RS)** domain was expanded to include data that would have been in submitted in the Clinical Classifications (CC) domain, and was renamed Disease Response and Clin Classification. The CC domain that was part of the Batch 2 Public Review was not implemented.
- **The tumor domains, TU and TR**, were expanded to include lesions. TU was renamed Tumor/Lesion Identification, and TR was renamed Tumor/Lesion Results.

Questionnaires, Ratings, and Scales (QRS)

- What represented in one domain (QS) in v3.2 has been divided into three domains.
- Many instruments previously were categorized as questionnaires when in fact they are not.
- Modeling and terminology development will remain consistent with that for questionnaires (QS).

SDTMIG v3.2

SDTMIG v3.3



Changes to Demographics - Screen Failures and Subjects Not Assigned

TCG Text states:

> *"Screen failures, when provided, should be included as a record in DM with the ARM, ARMCD, ACTARM, and ACTARMCD field left blank. For subjects who are randomized in treatment group but not treated, the planned arm variables (ARM and ARMCD) should be populated, but actual treatment arm variables (ACTARM and ACTARMCD) should be left blank."*

Variable Name	Variable Label	Description
ARMNRS	Reason Arm and/or Actual Arm is Null	The reason that Arm variables (ARM and ARMCD) and/or actual Arm variables (ACTARM and ACTARMCD) are null.
ACTARMUD	Description of Unplanned Actual Arm	A description of actual treatment for a subject who did not receive treatment described in one of the planned trial Arms.

Changes to Demographics - Population Flags

- Study population flags should not be included in SDTM data.
- The standard Supplemental Qualifiers included in previous versions of the SDTMIG (COMPLT, FULLSET, ITT, PPROT, and SAFETY) should not be used.
- The corresponding example in Section 8 was removed, as were the QNAMs from Appendix C2.

Added Guidance for Populating EPOCH

- Sponsors should not impute EPOCH values.
- The EPOCH value should be null if it's not possible to determine the EPOCH of an observation.
- Methods for assigning EPOCH values can be described in the Define-XML document.
- Since EPOCH is a study-design construct, it is not applicable observations prior to study start.
- EPOCH values may be determined as follows:

Most Findings	--DTC
Specimen Collection with End Dates	--ENDTC may be more appropriate
Events and Interventions	--STDTC

Relative Timing Variable Values Clarified

Version	Allowable Values for –STRF and --ENRF
Versions 3.1.2 and 3.1.3	BEFORE, DURING, DURING/AFTER, AFTER, and U
Version 3.2	BEFORE, DURING, DURING/AFTER, AFTER, COINCIDENT, ONGOING, and U
Version 3.3	BEFORE, DURING, DURING/AFTER, AFTER, and U

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New Section for Study References (Section 9)

A Study Reference section (Section 9) was added in v3.3. It includes the following datasets:

- Device Identifiers (DI)
  - Previously published in the SDTMIG-MD. It was originally classified as a special-purpose domain, but in SDTM v1.7.
- The Non-host Organism Identifiers (OI)
  - Represents the levels of taxonomic nomenclature of microbes
- Pharmacogenomic/Genetic Biomarker Identifiers (PB)
  - Introduced as part of the SDTMIG-PGx.
  - Establishes identifiers for pharmacogenomic/genetic biomarkers composed of groups of genetic variations.
  - It was originally classified as a special purpose domain.

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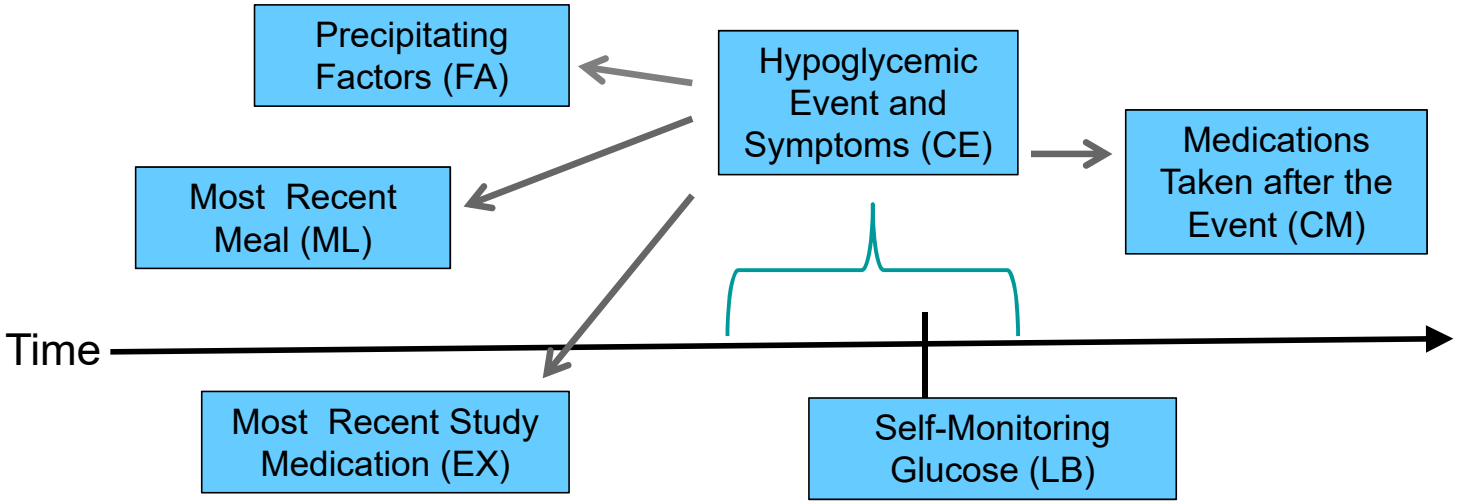
Disease Milestones Variables and Related Domains (1): Overview

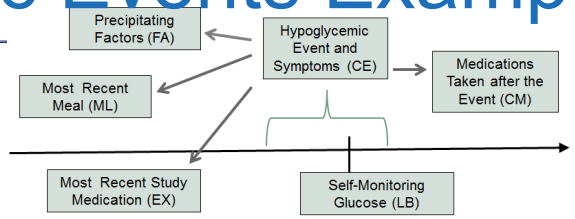
Additions to the SDTM and SDTMIG:

- New Timing Variables
  - SDTM Table 2.2.5.1
  - SDTMIG Section 4.1.11 (Disease Milestones and Disease Milestone Timing Variables)
- New Trial Milestones Dataset
  - SDTM Section 3.5
  - SDTMIG Section 7.33
- New Subject Milestones Dataset
  - SDTM Section 2.2.10
  - SDTMIG Section 5.4

Disease Milestones Variables and Related Domains (2): Hypoglycemic Events Example



Disease Milestones Variables and Related Domains (3): Hypoglycemic Events Example



ce.xpt

STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CECAT	CEPRESP	CEOCCUR	CESTDTC	MIDS	RELMIDS	MIDSDTC
ABC	CE	ABC-1001	1	HYPOGLYCEMIA	HYPOGLYCEMIA			2013-09-01T11:00	HYPO 1		2013-09-01T11:00
ABC	CE	ABC-1001	2	SWEATING	HYPOGLYCEMIA	Y	Y		HYPO 1	DURING	2013-09-01T11:00

a.xpt

STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FAORRES	MIDS	RELMIDS
ABC	FA	ABC-1001	2	POSSCAUS	Possible cause identified	HYPOGLYCEMIA	Y	HYPO 1	PRIOR TO EVENT
ABC	FA	ABC-1001	3	MEALCAUS	Missed or delayed meal a possible cause	HYPOGLYCEMIA	Y	HYPO 1	PRIOR TO EVENT
ABC	FA	ABC-1001	4	PACAUS	Physical activity a possible cause	HYPOGLYCEMIA	N	HYPO 1	PRIOR TO EVENT
ABC	FA	ABC-1001	5	ALCCAUS	Alcohol a possible cause	HYPOGLYCEMIA	N	HYPO 1	PRIOR TO EVENT

lb.xpt

STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBDTC	MIDS	RELMIDS
ABC	LB	ABC-1001	GLUCOMETER	1	GLUC	GLUCOSE	60	mg/dL	3.33	3.33	mmol/L	BLOOD	2013-09-01T11:00	HYPO 1	DURING

ml.xpt

STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MIDS	RELMIDS	MIDSDTC
ABC	ML	ABC-1001	1	EVENING MEAL	HYPO 1	LAST INTERVENTION PRIOR TO	2013-09-01T11:00

ex.xpt

STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXCAT	EXDOSE	EXDOSU	EXSTDTC	MIDS	RELMIDS	MIDSDTC
ABC	EX	ABC-1001	1	DRUG A	HIGHLIGHTED DOSE	10	mg	2013-09-01T07:00	HYPO 1	LAST INTERVENTION PRIOR TO	2013-09-01T11:00

cm.xpt

STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMSCAT	CMPRESP	CMOCCUR	MIDS	RELMIDS
ABC	CM	ABC-1001	1	HYPOGLYCEMIC TREATMENTS	HYPOGLYCEMIC TREATMENTS		Y	Y	HYPO 1	IMMEDIATLEY AFTER
ABC	CM	ABC-1001	4	GLUCOSE TABLETS	HYPOGLYCEMIC TREATMENTS	MEDICATION	Y	Y	HYPO 1	IMMEDIATLEY AFTER
ABC	CM	ABC-1001	5	GLUCAGON INJECTION	HYPOGLYCEMIC TREATMENTS	MEDICATION	Y	N	HYPO 1	IMMEDIATLEY AFTER
ABC	CM	ABC-1001	6	INTRAVENOUS GLUCOSE	HYPOGLYCEMIC TREATMENTS	MEDICATION	Y	N	HYPO 1	IMMEDIATLEY AFTER

28

ce.xpt

STUDYID	DOMAIN	USUBJID	CESEQ	CETERM	CECAT	CEPRESP	CEOCCUR	CESTDTC	MIDS	RELMIDS	MIDSDTC
ABC	CE	ABC-1001	1	HYPOGLYCEMIA	HYPOGLYCEMIA			2013-09-01T11:00	HYPO 1		2013-09-01T11:00
ABC	CE	ABC-1001	2	SWEATING	HYPOGLYCEMIA	Y	Y		HYPO 1	DURING	2013-09-01T11:00

a.xpt

STUDYID	DOMAIN	USUBJID	FASEQ	FATESTCD	FATEST	FAOBJ	FAORRES	MIDS	RELMIDS
ABC	FA	ABC-1001	2	POSSCAUS	Possible cause identified	HYPOGLYCEMIA	Y	HYPO 1	PRIOR TO EVENT
ABC	FA	ABC-1001	3	MEALCAUS	Missed or delayed meal a possible cause	HYPOGLYCEMIA	Y	HYPO 1	PRIOR TO EVENT
ABC	FA	ABC-1001	4	PACAUS	Physical activity a possible cause	HYPOGLYCEMIA	N	HYPO 1	PRIOR TO EVENT
ABC	FA	ABC-1001	5	ALCCAUS	Alcohol a possible cause	HYPOGLYCEMIA	N	HYPO 1	PRIOR TO EVENT

lb.xpt

STUDYID	DOMAIN	USUBJID	SPDEVID	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESN	LBSTRESU	LBSPEC	LBDTC	MIDS	RELMIDS
ABC	LB	ABC-1001	GLUCOMETER	1	GLUC	GLUCOSE	60	mg/dL	3.33	3.33	mmol/L	BLOOD	2013-09-01T11:00	HYPO 1	DURING

ml.xpt

STUDYID	DOMAIN	USUBJID	MLSEQ	MLTRT	MIDS	RELMIDS	MIDSDTC
ABC	ML	ABC-1001	1	EVENING MEAL	HYPO 1	LAST INTERVENTION PRIOR TO	2013-09-01T11:00

ex.xpt

STUDYID	DOMAIN	USUBJID	EXSEQ	EXTRT	EXCAT	EXDOSE	EXDOSU	EXSTDTC	MIDS	RELMIDS	MIDSDTC
ABC	EX	ABC-1001	1	DRUG A	HIGHLIGHTED DOSE	10	mg	2013-09-01T07:00	HYPO 1	LAST INTERVENTION PRIOR TO	2013-09-01T11:00

cm.xpt

STUDYID	DOMAIN	USUBJID	CMSEQ	CMTRT	CMCAT	CMSCAT	CMPRESP	CMOCCUR	MIDS	RELMIDS
ABC	CM	ABC-1001	1	HYPOGLYCEMIC TREATMENTS	HYPOGLYCEMIC TREATMENTS		Y	Y	HYPO 1	IMMEDIATLEY AFTER
ABC	CM	ABC-1001	4	GLUCOSE TABLETS	HYPOGLYCEMIC TREATMENTS	MEDICATION	Y	Y	HYPO 1	IMMEDIATLEY AFTER
ABC	CM	ABC-1001	5	GLUCAGON INJECTION	HYPOGLYCEMIC TREATMENTS	MEDICATION	Y	N	HYPO 1	IMMEDIATLEY AFTER
ABC	CM	ABC-1001	6	INTRAVENOUS GLUCOSE	HYPOGLYCEMIC TREATMENTS	MEDICATION	Y	N	HYPO 1	IMMEDIATLEY AFTER

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Disease Milestones Variables and Related Domains (4): TM and SM Examples

Trial Milestones (tm.xpt)

STUDYID	DOMAIN	MIDSTYPE	TMDEF	TMRPT
ABC	TM	HYPOGLYCEMIC EVENT	Hypoglycemic Event, the occurrence of a blood glucose concentration below the specified (by study) level of hypoglycemia	Y

Subject Milestones (sm.xpt)

STUDYID	DOMAIN	USUBJID	SMSEQ	MIDS	MIDSTYPE	SMSTDTC	SMENDTC	SMSTDY	SMENDY
ABC	SM	ABC-1001	2	HYPO 1	HYPOGLYCEMIC EVENT	2013-09-01T11:00	2013-09-01T11:00	25	25
ABC	SM	ABC-1001	3	HYPO 2	HYPOGLYCEMIC EVENT	2013-09-24T08:48	2013-09-24T08:48	50	50

Table in Section 2.5 Removed

2.5 The SDTM Standard Domain Models

The following standard domains, listed in alphabetical order by Domain Code, with their respective domain codes have been defined or referenced by the CDISC SDS Team in this document. Note that other domain models may be posted separately for comment after this publication.

Special-Purpose Domains (defined in *Section 5 – Models For Special-Purpose Domains*):

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

Interventions General Observation Class (defined in *Section 6.1 - Interventions*):

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

Events General Observation Class (defined in *Section 6.2 - Events*):

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

Findings General Observation Class (defined in *Section 6.3 - Findings*):

- 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 (defined in *Section 6.4 - FA Domain*)

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

Trial Design Domains (defined in *Section 7 - Trial Design Datasets*):

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

Relationship Datasets (defined in *Section 8 - Representing Relationships and Data*):

- Supplemental Qualifiers (SUPP-- datasets)
- Related Records (RELREC)

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Section 2.7 Updated
Variables not Allowed in SDTMIG

The following SDTM variables, defined for use in non-clinical studies (SEND), must ***NEVER*** be used in the submission of SDTM-based data for human clinical trials:	The following variables can be used for non-clinical studies (SEND) but must ***NEVER*** be used in the Demographics domain for human clinical trials, where all subjects are human.	The following variables have not been evaluated for use in human clinical trials and must therefore be used with extreme caution:
--USCHFL (Interventions, Events, Findings) --DTHREL (Findings) --EXCLFL (Findings) --REASEX (Findings) --IMPLBL (Findings) FETUSID (Identifiers) --DETECT (Timing Variables) --NOMDY (Timing Variables) --NOMLBL (Timing Variables)	SPECIES (Demographics) STRAIN (Demographics) SBSTRAIN (Demographics)	--METHOD (Interventions) --ANTREG (Findings) --CHRON (Findings) --DISTR (Findings) SETCD (Demographics)

Section 4.5.3.2 - Values Over 200 Characters

Text Strings >200 Char Conventions General Observation Class & Supplemental Qualifier Variables	Text Strings >200 Char Conventions CO.COVAL	Text Strings >200 Char Conventions TS.TSVAL	Text Strings >200 Char Conventions TI.IETEST and IE.IETEST
The first 200 characters of text should be stored in the variable and each additional 200 characters of text should be stored as a record in the SUPP-- dataset	The first 200 characters of text should be stored in COVAL and each additional 200 characters of text should be stored in COVAL1 to COVALn.	The first 200 characters of text should be stored in TSVAL and each additional 200 characters of text should be stored in TSVAL1 to TSVALn.	If the inclusion/exclusion criteria text is >200 characters, put meaningful text in IETEST and describe the full text in the study metadata.
When splitting a text string into several records, the text should be split between words to improve readability.	When splitting a text string into several records, the text should be split between words to improve readability.	When splitting a text string into several records, the text should be split between words to improve readability.	Not applicable.
The value for QLABEL should be the original domain variable label.	The variable labels for COVAL1 to COVALn should be "Comment".	The variable labels for TSVAL1 to TSVALn should be "Parameter Value".	Not applicable.

Section 4.1.5 Permissible Variables - Text Added

- Domain assumptions that say a Permissible variable is "generally not used" do not prohibit use of the variable.
- If a study includes a data item that would be represented in a Permissible variable, then that variable must be included in the SDTM dataset, even if null. Indicate no data were available for that variable in the Define-XML document.
- If a study did not include a data item that would be represented in a Permissible variable, then that variable should not be included in the SDTM dataset and should not be declared in the Define-XML document.

The End

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