

SDTMIG v3.3 / SDTM v1.7

Summary of changes to the standard since SDTMIG v3.2

Dataset Additions

- **12 New Datasets in SDTMIG v3.3**

Dataset	Description	Class	Structure
AG	Procedure Agents	INTERVENTIONS	One record per recorded intervention occurrence per subject
CV	Cardiovascular System Findings	FINDINGS	One record per finding or result per time point per visit per subject
FT	Functional Tests	FINDINGS	One record per Functional Test finding per time point per visit per subject
MK	Musculoskeletal System Findings	FINDINGS	One record per assessment per visit per subject
ML	Meal Data	INTERVENTIONS	One record per food product occurrence or constant intake interval per subject
NV	Nervous System Findings	FINDINGS	One record per finding per location per time point per visit per subject
OE	Ophthalmic Examinations	FINDINGS	One record per ophthalmic finding per method per location, per time point per visit per subject
OI	Non-host Organism Identifiers	STUDY REFERENCE	One record per taxon per non-host organism
RE	Respiratory System Findings	FINDINGS	One record per finding or result per time point per visit per subject
SM	Subject Disease Milestones	SPECIAL PURPOSE	One record per Disease Milestone per subject
TM	Trial Disease Milestones	TRIAL DESIGN	One record per Disease Milestone type
UR	Urinary System Findings	FINDINGS	One record per finding per location per per visit per subject

Dataset Changes

- Dataset Description changed from previous version
 - 6 Datasets

Dataset	old_Description	new_description
CM	Concomitant Medications	Concomitant/Prior Medications
RS	Disease Response	Disease Response and Clin Classification
SUPPQUAL	Supplemental Qualifiers	Supplemental Qualifiers for [domain name]
TR	Tumor Results	Tumor/Lesion Results
TS	Trial Summary	Trial Summary Information
TU	Tumor Identification	Tumor/Lesion Identification

Dataset Changes

- Dataset Structure changed from previous version
- 18 Datasets

Dataset	Description	old_structure	new_structure
CM	Concomitant Medications	One record per recorded medication occurrence or constant-dosing interval per subject	One record per recorded intervention occurrence or constant-dosing interval per subject
EG	ECG Test Results	One record per ECG observation per time point per visit per subject	One record per ECG observation per replicate per time point or one record per ECG observation per beat per visit per subject
EX	Exposure	One record per constant dosing interval per subject	One record per protocol-specified study treatment, constant-dosing interval, per subject
LB	Laboratory Test Results	One record per analyte per planned time point number per time point reference per visit per subject	One record per lab test per time point per visit per subject
PC	Pharmacokinetics Concentrations	One record per analyte per planned time point number per time point reference per visit per subject	One record per sample characteristic or time-point concentration per reference time point or per analyte per subject
RELREC	Related Records	One record per related record, group of records or datasets	One record per related record, group of records or dataset
RELSUB	Related Subjects	One record per relationship	One record per relationship per related subject per subject
RP	Reproductive System Findings	One record per Reproductive System Finding per time point per visit per subject	One record per finding or result per time point per visit per subject
RS	Disease Response	One record per response assessment per visit per subject per assessor	One record per response assessment or clinical classification assessment per time point per visit per subject per assessor per medical evaluator
SC	Subject Characteristics	One record per characteristic per subject	One record per characteristic per subject.
SE	Subject Elements	One record per actual element per subject	One record per actual Element per subject
SR	Skin Response	One record per test per visit per subject	One record per finding, per object, per time point, per visit per subject
SUPPQUAL	Supplemental Qualifiers	One record per IDVAR, IDVARVAL and QNAM value per subject	One record per IDVAR, IDVARVAL, and QNAM value per subject
SV	Subject Visits	One record per actual visit per subject	One record per subject per actual visit
TA	Trial Arms	One record per planned element per arm	One record per planned Element per Arm
TE	Trial Elements	One record per planned element	One record per planned Element
TI	Trial	One record per I/E criterion	One record per I/E criterion
TV	Trial Visits	One record per planned visit per arm	One record per planned Visit per Arm

Variable Additions

- 30 New variables in SDTM v1.7

Observation_Class	Domain	Variable	Label	Type	Role
All Classes		NHOID	Non-Host Organism Identifier	Char	Identifier
All Classes		FOCID	Focus of Study-Specific Interest	Char	Identifier
All Classes		__RECID	Invariant Record Identifier	Char	Identifier
All Classes		MIDS	Disease Milestone Instance Name	Char	Timing
All Classes		RELMIDS	Temporal Relation to Milestone Instance	Char	Timing
All Classes		MIDSDTC	Disease Milestone Instance Date/Time	datetime	Timing
Findings		__ORREF	Reference Result in Original Units	Char	Variable Qualifier of --ORRES
Findings		__STREFC	Reference Result in Standard Format	Char	Variable Qualifier of --STRESC
Findings		__STREFN	Numeric Reference Result in Std Units	Num	Variable Qualifier of --STRESN
Findings		__CHRON	Chronicity of Finding	Char	Variable Qualifier of --STRESC
Findings		__DISTR	Distribution Pattern of Finding	Char	Variable Qualifier of --STRESC
Findings		__LOBXFL	Last Observation Before Exposure Flag	Char	Record Qualifier
Findings		__REPNUM	Repetition Number	Num	Record Qualifier
Interventions		__RSDISC	Reason for Treatment Discontinuation	Char	Record Qualifier
Special-Purpose	CO	COEVALID	Evaluator Identifier	Char	Variable Qualifier of COEVAL
Special-Purpose	DM	ARMNRS	Reason Arm and/or Actual Arm is Null	Char	Record Qualifier
Special-Purpose	DM	ACTARMUD	Description of Unplanned Actual Arm	Char	Record Qualifier
Special-Purpose	SM	SMSEQ	Sequence Number	Num	Identifier
Special-Purpose	SM	MIDS	Disease Milestone Instance Name	Char	Topic
Special-Purpose	SM	MIDSTYPE	Disease Milestone Type	Char	Record Qualifier
Special-Purpose	SM	SMSTDTC	Start Date/Time of Milestone	datetime	Timing
Special-Purpose	SM	SMENDTC	End Date/Time of Milestone	datetime	Timing
Special-Purpose	SM	SMSTDY	Study Day of Start of Milestone	Num	Timing
Special-Purpose	SM	SMENDY	Study Day of End of Milestone	Num	Timing
Study Reference	OI	NHOID	Non-Host Organism Identifier	Char	Identifier
Study Reference	OI	OISEQ	Sequence Number	Num	Identifier
Study Reference	OI	OIPARMCD	Non-Host Organism ID Element Short Name	Char	Topic
Study Reference	OI	OIPARM	Non-Host Organism ID Element Name	Char	Synonym Qualifier of OIPARMCD
Study Reference	OI	OIVAL	Non-Host Organism ID Element Value	Char	Result Qualifier
Trial Design	TM	MIDSTYPE	Disease Milestone Type	Char	Topic
Trial Design	TM	TMDEF	Disease Milestone Definition	Char	Rule
Trial Design	TM	TMRPT	Disease Milestone Repetition Indicator	Char	Record Qualifier

Variable Additions

- New variables listed in SDTMIG v3.3

dataset	variable	label	data_type	core	codelist	role
CM	CMRSDISC	Reason the Intervention Was	Char	Permissible		Record Qualifier
CO	COEVALID	Evaluator Identifier	Char	Permissible	MEDEVAL	Record Qualifier
DM	ARMNRS	Reason Arm and/or Actual Arm is Null	Char	Expected		Record Qualifier
DM	ACTARMUD	Description of Unplanned Actual Arm	Char	Expected		Record Qualifier
EG	EGBEATNO	ECG Beat Number	Num	Permissible		Variable Qualifier
EG	EGLOBXFL	Last Observation Before Exposure Flag	Char	Expected	NY	Record Qualifier
EG	EGREPNUM	Repetition Number	Num	Permissible		Record Qualifier
IS	ISLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
LB	LBSTREFC	Reference Result in Standard Format	Char	Expected		Variable Qualifier
LB	LBLOBXFL	Last Observation Before Exposure Flag	Char	Expected	NY	Record Qualifier
MB	FOCID	Focus of Study-Specific Interest	Char	Permissible		Identifier
MB	MBLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
MH	MHEVDTYP	Medical History Event Date Type	Char	Permissible	MHEDTTYP	Variable Qualifier
MI	MILOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
MO	MOLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
MS	NHOID	Non-host Organism ID	Char	Permissible		Identifier
MS	MSAGENT	Agent Name	Char	Expected		Variable Qualifier
MS	MSCONC	Agent Concentration	Num	Permissible		Variable Qualifier
MS	MSCONCU	Agent Concentration Units	Char	Permissible	UNIT	Variable Qualifier
MS	MSLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
MS	MSREPNUM	Repetition Number	Num	Permissible		Record Qualifier
PE	PELOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
QS	QSLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
RP	RPLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
RS	RSLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
SR	SRLOBXFL	Last Observation Before Exposure Flag	Char	Permissible	NY	Record Qualifier
TR	TRLOBXFL	Last Observation Before Exposure Flag	Char	Expected	NY	Record Qualifier
TU	TULOBXFL	Last Observation Before Exposure Flag	Char	Expected	NY	Record Qualifier
VS	VSLOBXFL	Last Observation Before Exposure Flag	Char	Expected	NY	Record Qualifier

Variable Additions

- Model Permissible variables now listed in SDTMIG v3.3
- 130 variables

dataset	variable	label	data_type	core	codeinst	role	old_core
AE	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
AE	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
CE	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
CE	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
CE	CESTDY	Study Day of Start of Event	Num	Permissible		Timing	Model Permissible
CE	CEENDY	Study Day of End of Event	Num	Permissible		Timing	Model Permissible
CM	CMADJ	Reason for Dose Adjustment	Char	Permissible		Record Qualifier	Model Permissible
CM	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
CM	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
CO	CODY	Study Day of Comment	Num	Permissible		Timing	Model Permissible
DA	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
DA	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
DS	DSDY	Study Day of Collection	Num	Expected		Timing	Model Permissible
DV	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
DV	DVSTDY	Study Day of Start of Deviation Event	Num	Permissible		Timing	Model Permissible
DV	DVENDY	Study Day of End of Observation	Num	Permissible		Timing	Model Permissible
EC	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
EG	SPDEVID	Sponsor Device Identifier	Char	Permissible		Identifier	Model Permissible
EG	EVALID	Evaluator Identifier	Char	Permissible		MEDEVAL	Variable Qualifier
EG	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
EG	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
EX	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
HO	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
HO	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
IE	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
IE	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
IS	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
IS	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
LB	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
LB	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
LB	LBENDY	Study Day of End of Observation	Num	Permissible		Timing	Model Permissible
MB	MBLNKID	Link ID	Char	Permissible		Identifier	Model Permissible
MB	MBLNKGRP	Link Group ID	Char	Permissible		Identifier	Model Permissible
MB	MBTSTDTL	Measurement, Test or Examination Detail	Char	Permissible		Variable Qualifier	Model Permissible
MB	MBLAT	Laterality	Char	Permissible		LAT	Variable Qualifier
MB	MBDIR	Directionality	Char	Permissible		DIR	Variable Qualifier
MB	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
MB	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
MH	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
MH	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
MI	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
MI	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
MO	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
MO	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
MS	MSLNKID	Link ID	Char	Permissible		Identifier	Model Permissible
MS	MSSTDTL	Measurement, Test or Examination Detail	Char	Permissible		Variable Qualifier	Model Permissible
MS	MSNRIND	Normal/Reference Range Indicator	Char	Permissible		Variable Qualifier	Model Permissible
MS	MSXFN	External File Path	Char	Permissible		Record Qualifier	Model Permissible
MS	MSPCUFL	Specimen Usability for the Test	Char	Permissible	NY	Record Qualifier	Model Permissible
MS	MSLOC	Location Used for the Measurement	Char	Permissible	LOC	Record Qualifier	Model Permissible
MS	MSLAT	Laterality	Char	Permissible	LAT	Variable Qualifier	Model Permissible
MS	MSDIR	Directionality	Char	Permissible	DIR	Variable Qualifier	Model Permissible
MS	MSANMETH	Analysis Method	Char	Permissible		Record Qualifier	Model Permissible
MS	MSEVAL	Evaluator	Char	Permissible	EVAL	Record Qualifier	Model Permissible
MS	MSEVALD	Evaluator Identifier	Char	Permissible	MEDEVAL	Variable Qualifier	Model Permissible
MS	MSACPTFL	Accepted Record Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
MS	MSLLOQ	Lower Limit of Quantitation	Num	Permissible		Variable Qualifier	Model Permissible
MS	MSULOQ	Upper Limit of Quantitation	Num	Permissible		Variable Qualifier	Model Permissible
MS	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
MS	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
MS	MSENDTC	End Date/Time of Observation	datetime	Permissible		Timing	Model Permissible
MS	MSENDY	Study Day of End of Observation	Num	Permissible		Timing	Model Permissible
MS	MSDUR	Duration	datetime	Permissible		Timing	Model Permissible
MS	MSRFTDTC	Date/Time of Reference Time Point	datetime	Permissible		Timing	Model Permissible
MS	MSSTRF	Start Relative to Reference Period	Char	Permissible	STENRF	Timing	Model Permissible
MS	MSENRF	End Relative to Reference Period	Char	Permissible	STENRF	Timing	Model Permissible
MS	MSEVLINT	Evaluation Interval	datetime	Permissible		Timing	Model Permissible
MS	MSEVINTX	Evaluation Interval Text	Char	Permissible		Timing	Model Permissible
MS	MSSTRPT	Start Relative to Reference Time Point	Char	Permissible	STENRF	Timing	Model Permissible
MS	MSSTPT	Start Reference Time Point	Char	Permissible		Timing	Model Permissible
MS	MSENRTPT	End Relative to Reference Time Point	Char	Permissible	STENRF	Timing	Model Permissible
MS	MSENTPT	End Reference Time Point	Char	Permissible		Timing	Model Permissible
PC	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
PC	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
PC	PCENDY	Study Day of End of Observation	Num	Permissible		Timing	Model Permissible
PE	PELAT	Laterality	Char	Permissible	LAT	Variable Qualifier	Model Permissible
PE	PEBLFL	Baseline Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
PE	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
PE	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
PP	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
PP	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
PP	PPDY	Study Day of Parameter Calculations	Num	Permissible		Timing	Model Permissible
PR	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
PR	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
QS	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
QS	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
RP	RPLNKID	Link ID	Char	Permissible		Identifier	Model Permissible
RP	RPLNKGRP	Link Group ID	Char	Permissible		Identifier	Model Permissible
RP	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
RP	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
RP	RPDUR	Duration	datetime	Permissible		Timing	Model Permissible
RP	RPTPT	Planned Time Point Name	Char	Permissible		Timing	Model Permissible
RP	RPTPTNUM	Planned Time Point Number	Num	Permissible		Timing	Model Permissible
RP	RPELTM	Planned Elapsed Time from Time Point Ref	datetime	Permissible		Timing	Model Permissible
RP	RPTPTREF	Time Point Reference	Char	Permissible		Timing	Model Permissible
RP	RPFTDTC	Date/Time of Reference Time Point	datetime	Permissible		Timing	Model Permissible
RS	RSSCAT	Subcategory	Char	Permissible		Grouping Qualifier	Model Permissible
RS	RSORRESU	Original Units	Char	Permissible	UNIT	Variable Qualifier	Model Permissible
RS	RSSTRESN	Numeric Result/Finding in Standard Units	Num	Permissible		Result Qualifier	Model Permissible
RS	RSSTRESU	Standard Units	Char	Permissible	UNIT	Variable Qualifier	Model Permissible
RS	RSBLFL	Baseline Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
RS	RSORVFL	Derived Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
RS	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
RS	RSTPT	Planned Time Point Name	Char	Permissible		Timing	Model Permissible
RS	RSTPTNUM	Planned Time Point Number	Num	Permissible		Timing	Model Permissible
RS	RSELTM	Planned Elapsed Time from Time Point Ref	datetime	Permissible		Timing	Model Permissible
RS	RSTPTREF	Time Point Reference	Char	Permissible		Timing	Model Permissible
RS	RSRFTDTC	Date/Time of Reference Time Point	datetime	Permissible		Timing	Model Permissible
RS	RSEVLINT	Evaluation Interval	datetime	Permissible		Timing	Model Permissible
RS	RSEVINTX	Evaluation Interval Text	Char	Permissible		Timing	Model Permissible
RS	RSSTRPT	Start Relative to Reference Time Point	Char	Permissible	STENRF	Timing	Model Permissible
RS	RSSTPT	Start Reference Time Point	Char	Permissible		Timing	Model Permissible
RS	RSENRTPT	End Relative to Reference Time Point	Char	Permissible	STENRF	Timing	Model Permissible
RS	RSENTPT	End Reference Time Point	Char	Permissible		Timing	Model Permissible
SC	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
SC	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
SR	SRBLFL	Baseline Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
SR	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
SR	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
SS	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
SS	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
SU	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
SU	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible
TR	TRBLFL	Baseline Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
TR	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
TU	TULNKGRP	Link Group ID	Char	Permissible		Identifier	Model Permissible
TU	TUBLFL	Baseline Flag	Char	Permissible	NY	Record Qualifier	Model Permissible
TU	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
VS	TAETORD	Planned Order of Element within Arm	Num	Permissible		Timing	Model Permissible
VS	EPOCH	Epoch	Char	Permissible	EPOCH	Timing	Model Permissible

Variable Changes

- Variable Core changed from previous version

Dataset	Variable	Label	old_core	new_core
DM	ARMCD	Planned Arm Code	Required	Expected
DM	ARM	Description of Planned Arm	Required	Expected
DM	ACTARMCD	Actual Arm Code	Required	Expected
DM	ACTARM	Description of Actual Arm	Required	Expected
DS	DSDY	Study Day of Visit/Collection/Exam	Model Permissible	Expected
EG	EGBLFL	Baseline Flag	Expected	Permissible
LB	LGBLFL	Baseline Flag	Expected	Permissible
MB	MBGRPID	Group ID	Expected	Permissible
MB	MBRESCAT	Result Category	Expected	Permissible
MB	MBFAST	Fasting Status	Not Recommended	Permissible
MS	MSGRPID	Group ID	Required	Permissible
MS	MSMODIFY	Modified Term	Not Recommended	Permissible
MS	MSCAT	Category for Organism Findings	Required	Permissible
MS	MSORRESU	Original Units	Expected	Permissible
MS	MSSTRESN	Numeric Result/Finding in Standard Units	Expected	Permissible
MS	MSSTRESU	Standard Units	Expected	Permissible
MS	MSRESCAT	Result Category	Expected	Permissible
MS	MSSPEC	Specimen Material Type	Not Recommended	Permissible
MS	MSSPCCND	Specimen Condition	Not Recommended	Permissible
MS	MSMETHOD	Method of Test or Examination	Expected	Permissible
MS	MSFAST	Fasting Status	Not Recommended	Permissible
QS	QGBLFL	Baseline Flag	Expected	Permissible
RELSUB	RSUBJID	Related Subject or Pool Identifier	Expected	Required
RP	RPORRESU	Original Units	Expected	Permissible
RP	RPSTRESN	Numeric Result/Finding in Standard Units	Expected	Permissible
RP	RPSTRESU	Standard Units	Expected	Permissible
RP	VISITNUM	Visit Number	Permissible	Expected
RS	RSEVAL	Evaluator	Expected	Permissible
VS	VGBLFL	Baseline Flag	Expected	Permissible

Dataset Additions

- **New Datasets in SDTMIG v3.3 – Variables listed in Assumptions as ‘*Generally Not Used*’**
 - **Currently implemented by P21 as ‘*Not Recommended*’**
 - AG: AGINDC, AGDOSTOT, AGDOSRGM
 - CV: CVMODIFY, CVBODSYS, CVFAST, CVORNRL0, CVORNRHI, CVSTNRLO, CVSTNRHI, CVLOINC
 - FT: FTBODSYS, FTORNRL0, FTORNRHI, FTSTNRLO, FTSTNRHI, FTSTRNC, FTNRIND, FTXFN, FTLOINC, FTSPEC, FTSPCCND, FTFAST, FTTOX, FTTOXGR, FTSEV
 - MK: MKMODIFY, MKBODSYS, MKLOINC, MKTOX, MKTOXGR, MKFAST, MKORNRL0, MKORNRHI, MKSTNRLO, MKSTNRHI, MKORREF, MKSTREFC, MKSTREFN
 - ML: MLMOOD, MLLOT, MLLOC, MLLAT, MLDIR, MLPORTOT
 - NV: NVMODIFY, NVBODSYS, NVLOINC, NVTOX, NVTOXGR
 - OE: OEMODIFY, OENSPCES, OEPOS, OEBODSYS, OERREF, OESTREFC, OESTREFN, OECHRON, OEDISTR, OEANTREG, OELEAD, OEFAST, OETOX, OETOXGR, OELLOQ, OEULOQ
 - RE: REMODIFY, REBODSYS, REFAST
 - UR: URMODIFY, URBODSYS, URORNRL0, URORNRHI, URSTNRLO, URSTNRHI, URNRIND, URLOINC, URSPCCND, URFAS, URTOX, URTOXGR, URSEV, URLLOQ

Variable Changes

- Variable Label changed from previous version
 - SDTM v1.7

Dataset	Variable	old_label	new_label
INTERVENTIONS	TAETORD	Planned Order of Element within Arm	Planned Order of Element Within Arm
INTERVENTIONS	__OCCUR	Occurrence	Occurrence Indicator
EVENTS	TAETORD	Planned Order of Element within Arm	Planned Order of Element Within Arm
EVENTS	__OCCUR	Occurrence	Occurrence Indicator
EVENTS	__PRESP	Pre-specified	Pre-Specified
FINDINGS	TAETORD	Planned Order of Element within Arm	Planned Order of Element Within Arm
FINDINGS	__TEST	Name of Measurement, Test or Examination	Name of Measurement, Test, or Exam
FINDINGS	__TESTCD	Short Name of Measurement, Test or Exam	Short Name of Measurement, Test, or Exam
FINDINGS	__TSTDTL	Measurement, Test or Examination Detail	Measurement, Test, or Examination Detail
FINDINGSABOUT	TAETORD	Planned Order of Element within Arm	Planned Order of Element Within Arm
FINDINGSABOUT	__DY	Study Day of Collection	Study Day of Visit/Collection/Exam

Variable Changes

- Variable Label changed from previous version
- SDTMIG v3.3
- 86 variables

Dataset	Variable	old_label	new_label
CE	CECAT	Category for Clinical Event	Category for the Clinical Event
CE	CESCAT	Subcategory for Clinical Event	Subcategory for the Clinical Event
CE	CEPRES	Clinical Event Pre-Specified	Clinical Event Pre-specified
CE	CESTDY	Study Day of Start of Observation	Study Day of Start of Event
CE	CEENDY	Study Day of End of Observation	Study Day of End of Event
CM	CMPRESP	CM Pre-Specified	CM Pre-specified
CM	CMDUR	Duration of Medication	Duration
CO	CODY	Study Day of Visit/Collection/Exam	Study Day of Comment
DA	DACAT	Category of Assessment	Category
DA	DASCAT	Subcategory of Assessment	Subcategory
DA	DAORRES	Assessment Result in Original Units	Result or Finding in Original Units
DA	DASTRESC	Assessment Result in Std Format	Result or Finding in Standard Format
DA	DASTRESU	Assessment Standard Units	Standard Units
DA	DAREASND	Reason Not Performed	Reason Not Done
DA	DADTC	Date/Time of Accountability Assessment	Date/Time of Collection
DA	DADY	Study Day of Accountability Assessment	Study Day of Visit/Collection/Exam
DS	DSDY	Study Day of Visit/Collection/Exam	Study Day of Collection
DV	DVSTDY	Study Day of Start of Deviation	Study Day of Start of Deviation Event
DV	DVENDY	Study Day of End of Deviation	Study Day of End of Observation
EG	EGREASND	Reason ECG Not Performed	Reason ECG Not Done
EG	EGMETHOD	Method of ECG Test	Method of Test or Examination
HO	HOTERM	Reported Term for Healthcare Encounter	Healthcare Encounter Term
HO	HOSTDY	Study Day of Start of Observation	Study Day of Start of Encounter
IS	ISSTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
LB	LBTESTCD	Lab Test or Examination Short Name	Lab Test or Examination Short Name.
LB	LBENDY	Study Day of End of Specimen Collection	Study Day of End of Observation
MB	MBCAT	Category for Microbiology Finding	Category
MB	MBSCAT	Subcategory for Microbiology Finding	Subcategory
MB	MBSTRESC	Character Result/Finding in Std Format	Result or Finding in Standard Format
MB	MBREASND	Reason Microbiology Not Performed	Reason Not Done
MB	MBNAM	Vendor Name	Laboratory/Vendor Name
MB	MBSPEC	Specimen Type	Specimen Material Type
MB	MBDTC	Date/Time of Specimen Collection	Date/Time of Collection
MB	MBDY	Study Day of MB Specimen Collection	Study Day of Visit/Collection/Exam
MH	MHREASND	Reason Not Done	Reason Medical History Not Collected
MI	MISTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
MS	MSTESTCD	Microbiology Organism Finding Short Name	Short Name of Assessment
MS	MSTEST	Organism Test or Finding Name	Name of Assessment
MS	MSMODIFY	Modified Term	Modified Reported Name
MS	MSCAT	Category for Organism Findings	Category
MS	MSSCAT	Subcategory for Organism Findings	Subcategory
MS	MSSTRESC	Character Result/Finding in Std Format	Result or Finding in Standard Format
MS	MSREASND	Reason Test Not Done	Reason Not Done
MS	MSNAM	Vendor Name	Laboratory/Vendor Name
MS	MSDTC	Date/Time of Test	Date/Time of Collection
MS	MSDY	Study Day of Test	Study Day of Visit/Collection/Exam
PC	PCSTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
PE	PESTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
PP	PPSTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
PP	PPDY	Study Day of Visit/Collection/Exam	Study Day of Parameter Calculations
QS	QSSTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
RP	RPTESTCD	Repro System Findings Test Short Name	Short Name of Reproductive Test
RP	RPTEST	Reproductive System Findings Test Name	Name of Reproductive Test
RP	RPCAT	Category for Repro System Findings	Category for Reproductive Test
RP	RPSCAT	Subcategory for Repro System Findings	Subcategory for Reproductive Test
RP	RPSTRESC	Character Result/Finding in Std. Format	Character Result/Finding in Std Format
RP	RPREASND	Reason Not Performed	Reason Not Done
RP	RPDTC	Date/Time of Measurements	Date/Time of Collection
RP	RPDY	Study Day of Repro System Findings	Study Day of Visit/Collection/Exam
RS	RSLNKGRP	Link Group	Link Group ID
RS	RSTESTCD	Response Assessment Short Name	Assessment Short Name
RS	RSTEST	Response Assessment Name	Assessment Name
RS	RSCAT	Category for Response Assessment	Category for Assessment
RS	RSORRES	Response Assessment Original Result	Result or Finding in Original Units
RS	RSSTRESC	Response Assessment Result in Std Format	Character Result/Finding in Std Format
RS	RSREASND	Reason Response Assessment Not Performed	Reason Not Done
RS	RSDTC	Date/Time of Response Assessment	Date/Time of Assessment
RS	RSDY	Study Day of Response Assessment	Study Day of Assessment
SR	SRSTRESC	Result or Finding in Standard Format	Character Result/Finding in Std Format
SR	SRLC	Location used for Measurement	Location Used for Measurement
TI	IETESTCD	Inclusion/Exclusion Criterion Short Name	Incl/Excl Criterion Short Name
TR	TRTESTCD	Tumor Assessment Short Name	Tumor/Lesion Assessment Short Name
TR	TRTEST	Tumor Assessment Test Name	Tumor/Lesion Assessment Test Name
TR	TRREASND	Reason Tumor Measurement Not Performed	Reason Not Done
TR	TRNAM	Vendor Name	Laboratory/Vendor Name
TR	TRMETHOD	Method used to Identify the Tumor	Method Used to Identify the Tumor/Lesion
TR	TRDTC	Date/Time of Tumor Measurement	Date/Time of Tumor/Lesion Measurement
TR	TRDY	Study Day of Tumor Measurement	Study Day of Tumor/Lesion Measurement
TU	TUTESTCD	Tumor Identification Short Name	Tumor/Lesion ID Short Name
TU	TUTEST	Tumor Identification Test Name	Tumor/Lesion ID Test Name
TU	TUORRES	Tumor Identification Result	Tumor/Lesion ID Result
TU	TUSTRESC	Tumor Identification Result Std. Format	Tumor/Lesion ID Result Std. Format
TU	TUNAM	Vendor Name	Laboratory/Vendor Name
TU	TULOC	Location of the Tumor	Location of the Tumor/Lesion
TU	TUDTC	Date/Time of Tumor Identification	Date/Time of Tumor/Lesion Identification
TU	TUDY	Study Day of Tumor Identification	Study Day of Tumor/Lesion Identification

Variable Changes

- Variable Codelist changed from previous version
 - Codelist removed

Dataset	Variable	Label	old_codelist	new_codelist
MO	MOTESTCD	Test or Examination Short Name	MOTESTCD	
MO	MOTEST	Test or Examination Name	MOTEST	

Variable Changes

- Variable Codelist changed from previous version
- Codelist added

Dataset	Variable	Label	old_codelist	new_codelist
DD	DDTESTCD	Death Detail Assessment Short Name		DTHDXCD
DD	DDTEST	Death Detail Assessment Name		DTHDX
DS	DSDECOD	Standardized Disposition Term		MULTIPLE - NCOMPLT , PROTMLST
EG	EGSTRESC	Character Result/Finding in Std Format		MULTIPLE - EGSTRESC HESTRESC
IS	ISTESTCD	Immunogenicity Test/Exam Short Name		ISTESTCD
IS	ISTEST	Immunogenicity Test or Examination Name		ISTEST
IS	ISMETHOD	Method of Test or Examination		METHOD
LB	LBSTRESC	Character Result/Finding in Std Format		LBSTRESC
MB	MBTESTCD	Microbiology Test or Finding Short Name		MBTESTCD
MB	MBTEST	Microbiology Test or Finding Name		MBTEST
MI	MITSTDTL	Microscopic Examination Detail		MIFTSDTL
MS	MSTESTCD	Microbiology Organism Finding Short Name		MSTESTCD
MS	MSTEST	Organism Test or Finding Name		MSTEST
MS	MSSPCUFL	Specimen Usability for the Test		NY
RELREC	RDOMAIN	Related Domain Abbreviation		DOMAIN
RS	RSCAT	Category for Response Assessment		MULTIPLE - ONCRSCAT , CCCAT
SR	SRTESTCD	Skin Response Test or Exam Short Name		SRTESTCD
SR	SRTEST	Skin Response Test or Examination Name		SRTEST
SS	SSSTRESC	Character Result/Finding in Std Format		SSTATRS
SUPPQUAL	RDOMAIN	Related Domain Abbreviation		DOMAIN
TR	TRSTRESC	Character Result/Finding in Std Format		TRPROPRS

Variable Changes

- Variable Codelist changed from previous version
 - Codelist changed

Dataset	Variable	Label	old_codelist	new_codelist
EG	EGTESTCD	ECG Test or Examination Short Name	EGTESTCD	MULTIPLE - EGTESTCD HETESTCD
EG	EGTEST	ECG Test or Examination Name	EGTEST	MULTIPLE - EGTEST HETEST
MI	MITESTCD	Microscopic Examination Short Name	MITESTCD	MITSCD
MI	MITEST	Microscopic Examination Name	MITEST	MITS
PC	PCORRESU	Original Units	UNIT	PKUNIT
PC	PCSTRESU	Standard Units	UNIT	PKUNIT
PP	PPORRESU	Original Units	PKUNIT	MULTIPLE - PKUNIT , PKUWG , PKUWKG , PKUDMG ,
PP	PPSTRESU	Standard Units	PKUNIT	MULTIPLE - PKUNIT , PKUWG , PKUWKG , PKUDMG ,

Variable Changes

- Variable Codelist changed from previous version
 - Multiple codelists for a variable
 - Need to use VLM to handle these?

Datase	Variable	Label	old_codelist	new_codelist
DS	DSDECOD	Standardized Disposition Term		MULTIPLE - NCOMPLT , PROTMLST
EG	EGTESTCD	ECG Test or Examination Short Name	EGTESTCD	MULTIPLE - EGTESTCD HETESTCD
EG	EGTEST	ECG Test or Examination Name	EGTEST	MULTIPLE - EGTEST HETEST
EG	EGSTRESC	Character Result/Finding in Std Format		MULTIPLE - EGSTRESC HESTRESC
PP	PPORRESU	Original Units	PKUNIT	MULTIPLE - PKUNIT , PKUWG , PKUWKG , PKUDMG ,
PP	PPSTRESU	Standard Units	PKUNIT	MULTIPLE - PKUNIT , PKUWG , PKUWKG , PKUDMG ,
RS	RSCAT	Category for Response Assessment		MULTIPLE - ONCRSCAT , CCCAT

Variable Changes

- Variable Role changed from previous version
 - SDTM v.1.7

Dataset	Variable	Label	old_role	new_role
INTERVENTIONS	__PSTRG	Pharmaceutical Strength	Variable Qualifier	Record Qualifier
INTERVENTIONS	__VAMT	Treatment Vehicle Amount	Variable Qualifier	Record Qualifier
FINDINGS	__TOXGR	Toxicity Grade	Variable Qualifier	Record Qualifier

Variable Changes

- Variable Role changed from previous version
- SDTMIG v3.3

Dataset	Variable	Label	old_role	new_role
EC	ECPRESP	Pre-Specified	Record Qualifier	Variable Qualifier
EC	ECLAT	Laterality	Record Qualifier	Variable Qualifier
EC	ECPSTRG	Pharmaceutical Strength	Variable Qualifier	Record Qualifier
HO	HOPRESP	Pre-Specified Healthcare Encounter	Record Qualifier	Variable Qualifier
IS	ISCAT	Category for Immunogenicity Test	Grouping Qualifier	Synonym Qualifier
LB	LBTOXGR	Standard Toxicity Grade	Variable Qualifier	Record Qualifier
MB	MBLAT	Laterality	Record Qualifier	Variable Qualifier
MI	MIRESCAT	Result Category	Result Qualifier	Variable Qualifier
MI	MISPCOND	Specimen Condition	Variable Qualifier	Record Qualifier
MS	MSLAT	Laterality	Record Qualifier	Variable Qualifier
PE	PEBODSYS	Body System or Organ Class	Result Qualifier	Record Qualifier
PE	PELAT	Laterality	Record Qualifier	Variable Qualifier
PR	PRRESP	Pre-specified	Record Qualifier	Variable Qualifier
RELREC	IDVAR	Identifying Variable	Record Qualifier	Identifier
RELREC	IDVARVAL	Identifying Variable Value	Record Qualifier	Identifier
RELREC	RELTYPE	Relationship Type	Identifier	Record Qualifier
RELREC	RELID	Relationship Identifier	Identifier	Record Qualifier
RELSUB	STUDYID	Study Identifier		Identifier
RELSUB	RSUBJID	Related Subject or Pool Identifier		Identifier
RELSUB	SREL	Subject Relationship		Record Qualifier
RS	RSSTRESC	Response Assessment Result in Std Format	Record Qualifier	Result Qualifier
RS	RSSTAT	Completion Status	Result Qualifier	Record Qualifier
SR	SRLAT	Laterality	Result Qualifier	Variable Qualifier
SUPPQUAL	IDVAR	Identifying Variable	Record Qualifier	Identifier
SUPPQUAL	IDVARVAL	Identifying Variable Value	Record Qualifier	Identifier
SUPPQUAL	QORIG	Origin	Result Qualifier	Record Qualifier
SUPPQUAL	QEVAL	Evaluator	Result Qualifier	Record Qualifier
TR	TRSTRESC	Character Result/Finding in Std Format	Record Qualifier	Result Qualifier
TR	TRSTAT	Completion Status	Result Qualifier	Record Qualifier
TU	TUSTRESC	Tumor Identification Result Std. Format	Record Qualifier	Result Qualifier
TU	TULAT	Laterality	Record Qualifier	Variable Qualifier
TU	TUDIR	Directionality	Record Qualifier	Variable Qualifier
TU	TUPORTOT	Portion or Totality	Record Qualifier	Variable Qualifier

Issues

- Dataset Class changed from previous version
 - 4 Datasets
 - Notes:
 - ‘*RELATIONSHIPS*’ is incorrect per CDISC CT – should be ‘*RELATIONSHIP*’
 - ‘*FINDINGS*’ for SR appears incorrect...unclear why it would change from ‘*FINDINGS ABOUT*’

Dataset	Description	old_class	new_class
RELREC	Related Records	RELATIONSHIP	RELATIONSHIPS
RELSUB	Related Subjects	RELATIONSHIP	RELATIONSHIPS
SR	Skin Response	FINDINGS ABOUT	FINDINGS
SUPPQUAL	Supplemental Qualifiers	RELATIONSHIP	RELATIONSHIPS

Issues, cont.

- Variables modeled in SDTMIG v3.3 as Permissible for the domain, but are also listed in the Assumptions as Generally Not Used

Dataset	Variable	Label	old_core	new_core
FT	FTXFN	External File Path		Permissible
MB	MBFAST	Fasting Status	Not Recommended	Permissible
MS	MSMODIFY	Modified Term	Not Recommended	Permissible