PINNACLE 21 BY CERTARA

SUMMARY OF NEW STANDARDS

SDTM-IG 3.4, ADaM-IG 1.3, and Additional Documents

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- More than 15 years experience in the industry (including Pharma, CROs, and P21)
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AGENDA

- SDTM-IG 3.4 / SDTM 2.0
  - Overview of SDTM / Implementation Guide recent release combinations
  - New domains and variables
  - Changes to existing domains and variables
  - Changes to conformance rules
- ADaM-IG 1.3
  - Minor revisions
  - Associated documents
- Q & A

SDTM / IG RECENT RELEASES

SDTM / Implementation Guide combinations

- SDTM 2.0 / SDTM-IG 3.4
  - SDTM 2.0 is a major release – content has been reorganized and restructured, sections renamed and added, Usage Restrictions column added, etc.
- SDTM 1.8 / SEND-IG-Animal Rule 1.0
- SDTM 1.7 / SDTM-IG 3.3 and Medical Devices 1.1
- SDTM 1.6 / SEND-IG-DART 1.1
- SDTM 1.5 / SEND-IG 3.1 and SEND-IG 3.1.1
- SDTM 1.4 / SDTM-IG 3.2 and Medical Devices 1.0 and SDTM-IG-AP 1.0

SDTM-IG 3.4 / SDTM 2.0

What's New or Changed?

SDTM-IG 3.4 / SDTM 2.0 - DOMAINS ADDED

- 5 New Domains added in SDTM-IG 3.4
  - BE (Biospecimen Events) – copied from SDTMIG-PGx
  - BS (Biospecimen Findings) – copied from SDTMIG-PGx
  - RELSPEC (Related Specimens) – copied from SDTMIG-PGx
  - CP (Cell Phenotype Findings)
  - GF (Genomics Findings) – replaces old PF domain from SDTMIG-PGx
- 1 New Domain added in SDTM 2.0
  - RELSPEC (Related Specimens)
- 1 New Domain added in SDTM 1.8
  - AC (Challenge Agent Characterization)
    - Typically used for nonclinical Animal Rule studies, no obvious use cases for clinical trials at the moment

SDTM-IG 3.4 / SDTM 2.0 - DOMAINS REMOVED

- 1 Domain has been decommissioned in SDTM-IG 3.4
  - MO (Morphology)

SDTM-IG 3.4 / SDTM 2.0 - DOMAIN CHANGES

- 5 Domain Labels were changed in SDTM-IG 3.4
  - DA
    - SDTM-IG 3.3 label: Drug Accountability
    - SDTM-IG 3.4 label: Product Accountability
  - TS
    - SDTM-IG 3.3 label: Trial Summary Information
    - SDTM-IG 3.4 label: Trial Summary

SDTM-IG 3.4 / SDTM 2.0 - DOMAIN CHANGES

- Domain Structure was changed in SDTM-IG 3.4 for 5 domains
  - DA
    - SDTM-IG 3.3 structure: One record per drug accountability finding per subject
    - SDTM-IG 3.4 structure: One record per product accountability finding per subject
  - SC
    - SDTM-IG 3.3 structure: One record per characteristic per subject.
    - SDTM-IG 3.4 structure: One record per characteristic per visit per subject.
  - SS
    - SDTM-IG 3.3 structure: One record per finding per visit per subject
    - SDTM-IG 3.4 structure: One record per status per visit per subject
  - SV
    - SDTM-IG 3.3 structure: One record per subject per actual visit
    - SDTM-IG 3.4 structure: One record per actual or planned visit per subject
  - TI
    - SDTM-IG 3.3 structure: One record per I/E crierion
    - SDTM-IG 3.4 structure: One record per I/E criterion

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES ADDED

- 16 New variables added in SDTM, and listed in SDTM-IG 3.4 for certain domains

Variable Name	Variable Label	Type	CT/Format	Role	Core	Observation Class	Usage Restrictions	SDTM Version	Included in IG
--BDAGNT	Binding Agent	Char	(MICROORG)(ISBDAGT) - codelists only for IS	Variable Qualifier	Perm	Findings	CP, IS, and LB domains only	Introduced in v2.0	CP, IS, LB domains
--CLSIG	Clinically Significant, Collected	Char	(NY)	Record Qualifier	Perm	Findings		Introduced in v2.0	CP, EG, LB, VS domains
--CNDAGT	Test Condition Agent	Char		Record Qualifier	Perm	Findings	CP, IS, and LB domains only	Introduced in v2.0	CP, IS domains
--CNTMOD	Contact Mode	Char	(CNTMODE)	Record Qualifier	Perm	Interventions, Events, Findings, SV		Introduced in v2.0	SV domain
--COLSRT	Collected Summary Result Type	Char	(COLSTYP)	Record Qualifier	Perm	Findings		Introduced in v2.0	CP, LB domains
--EPCHGI	Epi/Pandemic Related Change Indicator	Char	(NY)	Record Qualifier	Perm	Interventions, Events, Findings, SV		Introduced in v2.0	SV domain
--LLOD	Lower Limit of Detection	Char		Variable Qualifier	Perm	Findings		Introduced in v2.0	LB domain
--PDUR	Planned Duration	Char	ISO 8601 duration	Timing	Perm	All Classes	Only in Findings class specimen-based domains: BS, CP, GF, IS, LB, MB, MS, MI, PC, PP	Introduced in v2.0	LB domain
--PTFL	Point in Time Flag	Char	(NY)	Timing	Perm	All Classes	Only in Findings class specimen-based domains: BS, CP, GF, IS, LB, MB, MS, MI, PC, PP	Introduced in v2.0	LB domain
--REASOC	Reason for Occur Value	Char		Record Qualifier	Perm	Interventions, Events, SV	Not in AE domain	Introduced in v2.0	EC, SV domains
--RESSCL	Result Scale	Char	(RSLSCLRS)	Record Qualifier	Perm	Findings		Introduced in v2.0	CP, LB domains
--RESTYP	Result Type	Char	(RESTYPRS)	Record Qualifier	Perm	Findings		Introduced in v2.0	CP, LB domains
--RLDEV	Relationship of Event to Device	Char	*	Record Qualifier	Perm	Events		Introduced in v2.0	AE domain
--TMTHSN	Test Method Sensitivity	Char	(TSTMTHSN)	Record Qualifier	Perm	Findings		Introduced in v2.0	LB domain
--TSTCND	Test Condition	Char	(TESTCOND)	Variable Qualifier	Perm	Findings	CP, IS, and LB domains only	Introduced in v2.0	CP, IS, LB domains
--TSTOPO	Test Operational Objective	Char	(TSTOPOBJ)	Variable Qualifier	Perm	Findings		Introduced in v2.0	IS, LB domains

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES ADDED

- 30 New DOMAIN-SPECIFIC variables added in SDTM (only for use in 1 domain)

Domain	Variable Name	Variable Label	Type	CT/Format	Role	Core	Usage Restrictions	SDTM Version
AE	AESINTV	Needs Intervention to Prevent Impairment	Char	(NY)	Record Qualifier	Perm	AE domain only	Introduced in SDTM v2.0
AE	AEUNANT	Unanticipated Adverse Device Effect	Char	(NY)	Record Qualifier	Perm	AE domain only	Introduced in SDTM v2.0
AE	AERLPRT	Rel of AE to Non-Dev-Rel Study Activity	Char	*	Record Qualifier	Perm	AE domain only	Introduced in SDTM v2.0
AE	AERLPRC	Rel of AE to Device-Related Procedure	Char	*	Record Qualifier	Perm	AE domain only	Introduced in SDTM v2.0
CP	CPSBMRKS	Sublineage Marker String	Char		Variable Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPCELSTA	Cell State	Char	(CELSTATE)	Variable Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPCSMRKS	Cell State Marker String	Char		Variable Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPABCLID	Antibody Clone Identifier	Char		Record Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPMRKSTR	Marker String	Char		Record Qualifier	Exp	CP domain only	Introduced in SDTM v2.0
CP	CPGATE	Gate	Char		Record Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPGATDEF	Gate Definition	Char		Record Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPSPTSTD	Sponsor Test Description	Char		Record Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
CP	CPTSTPNL	Test Panel	Char		Grouping Qualifier	Perm	CP domain only	Introduced in SDTM v2.0
DM	RFCSTDTC	Date/Time of First Challenge Agent Admin	Char	ISO 8601 datetime or interval	Record Qualifier	Perm		Introduced in SDTM v1.8
DM	RFCENDTC	Date/Time of Last Challenge Agent Admin	Char	ISO 8601 datetime or interval	Record Qualifier	Perm		Introduced in SDTM v1.8
GF	GFINHERT	Inheritability	Char	(INHERTGF)	Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFGENREF	Genome Reference	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFCHROM	Chromosome Identifier	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFSYM	Genomic Symbol	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFSYMTYP	Genomic Symbol Type	Char	(SYMTYPGF)	Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFGENLOC	Genetic Location	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFGENSR	Genetic Sub-Region	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFSEQID	Sequence Identifier \n	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFPVRID	Published Variant Identifier	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
GF	GFCOPYID	Copy Identifier	Char		Variable Qualifier	Perm	GF domain only	Introduced in SDTM v2.0
IS	ISMSCBCE	Molecule Secreted by Cells	Char		Variable Qualifier	Perm	IS domain only	Introduced in SDTM v2.0
RELSPEC	REFID	Specimen ID	Char		Identifier	Req		Introduced in SDTM v2.0
RELSPEC	SPEC	Specimen Type	Char	(SPECTYPE)(GENSMP)	Variable Qualifier	Perm		Introduced in SDTM v2.0
RELSPEC	PARENT	Specimen Parent	Char		Identifier	Exp		Introduced in SDTM v2.0
RELSPEC	LEVEL	Specimen Level	Num		Variable Qualifier	Req		Introduced in SDTM v2.0

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES ADDED

- 11 New variables added in SDTM, but NOT listed in SDTM-IG 3.4 for any domains

Variable Name	Variable Label	Type	CT/Format	Role	Observation Class	Usage Restrictions	SDTM Version
--REASPF	Reason Test Performed	Char		Record Qualifier	Findings		Introduced in SDTM v2.0
--CHDY	Day of Obs Rel to Challenge Agent	Num		Timing	All Classes		Introduced in SDTM v1.8
--CHSTDY	Start Day of Obs Rel to Challenge Agent	Num		Timing	All Classes	Not in Findings class domains	Introduced in SDTM v1.8
--CHENDY	End Day of Obs Rel to Challenge Agent	Num		Timing	All Classes		Introduced in SDTM v1.8
--FTDOSD	Factor for Toxic/Physiologic Dose Descr	Num		Variable Qualifier	Interventions		Introduced in SDTM v1.8
--TDOSD	Toxic/Physiologic Dose Descr	Char		Record Qualifier	Interventions		Introduced in SDTM v1.8
--XDY	Day of Obs Relative to Exposure	Num		Timing	All Classes		Introduced in SDTM v1.8
--XSTDY	Start Day of Obs Relative to Exposure	Num		Timing	All Classes	Not in Findings class domains	Introduced in SDTM v1.8
--XENDY	End Day of Obs Relative to Exposure	Num		Timing	All Classes		Introduced in SDTM v1.8
--RSTIND	Restraint Indicator	Char		Record Qualifier	Interventions, Findings	Not in human clinical trials	Introduced in SDTM v1.8
--RSTMOD	Restraint Mode	Char		Record Qualifier	Interventions, Findings	Not in human clinical trials	Introduced in SDTM v1.8

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES ADDED

- Existing variables now listed in SDTM-IG 3.4 (but weren't previously for that domain)

Variable Name	Variable Label	Type	CT/Format	Role	Core	Included in IG
--ACNDEV	Action Taken with Device	Char	(DEACNDEV)	Record Qualifier	Perm	AE domain
--ANMETH	Analysis Method	Char	(LBANMET) for LB or (PKANMET) for PP	Record Qualifier	Perm	LB and PP domains
--DRVFL	Derived Flag	Char	(NY)	Record Qualifier	Perm	IS domain
--ELTM	Planned Elapsed Time from Time Point Ref	Char	ISO 8601 duration	Timing	Perm	IS domain
--ENDTC	End Date/Time of Specimen Collection	Char	ISO 8601 datetime or interval	Timing	Perm	IS domain
--ENDY	Study Day of End of Element	Num		Timing	Perm	SE domain
--ENDY	Study Day of End of Specimen Collection	Num		Timing	Perm	IS domain
--EVINTX	Evaluation Interval Text	Char		Timing	Perm	QS domain
--LNKGRP	Link Group ID	Char		Identifier	Perm	DA domain
--LNKID	Link ID	Char		Identifier	Perm	DA domain
--METHOD	Method of Test or Examination	Char	(QRSMTHOD)	Record Qualifier	Perm	QS and RS domains
NHOID	Non-host Organism ID	Char		Identifier	Perm	IS domain
--NRIND	Reference Range Indicator	Char	(NRIND)	Variable Qualifier	Exp	IS domain
--OCCUR	Occurrence	Char	(NY)	Record Qualifier	Exp	SV domain
--ORNRHI	Reference Range Upper Limit in Orig Unit	Char		Variable Qualifier	Exp	IS domain
--ORNRLO	Reference Range Lower Limit in Orig Unit	Char		Variable Qualifier	Exp	IS domain
--PRESP	Pre-specified	Char	(NY)	Variable Qualifier	Exp	SV domain
--RFTDTC	Date/Time of Reference Time Point	Char	ISO 8601 datetime or interval	Timing	Perm	IS domain
--SPCCND	Specimen Condition	Char	(SPECCOND)	Record Qualifier	Perm	IS domain
--SPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Perm	IS domain
--SPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Perm	LB domain
SPDEVID	Sponsor Device Identifier	Char		Identifier	Perm	AE domain
--STDY	Study Day of Start of Element	Num		Timing	Perm	SE domain
--STNRC	Reference Range for Char Rslt-Std Units	Char		Variable Qualifier	Perm	IS domain
--STNRHI	Reference Range Upper Limit-Std Units	Num		Variable Qualifier	Exp	IS domain
--STNRLO	Reference Range Lower Limit-Std Units	Num		Variable Qualifier	Exp	IS domain
--TOX	Toxicity	Char	*	Variable Qualifier	Perm	VS domain
--TOXGR	Standard Toxicity Grade	Char	*	Record Qualifier	Perm	CE and VS domains
--TPT	Planned Time Point Name	Char		Timing	Perm	IS domain
--TPTNUM	Planned Time Point Number	Num		Timing	Perm	IS domain
--TPTREF	Time Point Reference	Char		Timing	Perm	IS and PP domains
--TSTDTL	Test Detail	Char		Variable Qualifier	Perm	IS domain
VISIT	Visit Name	Char		Timing	Perm	SC domain
VISITDY	Planned Study Day of Visit	Num		Timing	Perm	SC domain
VISITNUM	Visit Number	Num		Timing	Perm	SC domain

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES EXPANDED USE

- 2 Variables from SDTM 1.8 added to additional Observation Classes in SDTM 2.0
  - --METHOD (Method of Test or Examination)
    - Was previously just for Findings, now added to Interventions (only EX) as well…but only for nonclinical studies
  - SPDEVID (Sponsor Device Identifier)
    - Was previously just for: All Classes, Relationship – DR domain, Study Reference – DI domain
    - Now added to Special Purpose – CO domain, Relationship – RELREC and SUPPQUAL domains as well

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES REMOVED

- 15 Variables from SDTMIG 3.3 no longer listed in SDTMIG 3.4

Domain	Variable Name	Variable Label	Type	CT (old)	Role	Core (old)	Usage Restrictions (new)	IG Assumptions/Revision History
FT	FTEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Perm	Not in QS, FT, and clinical classifications use case of RS	"--EVAL and --EVALID must not be used to model QRS data in SDTM….If needed, supplemental qualifiers may be used to represent this data."
LB	LBSTREFC	Reference Result in Standard Format	Char		Variable Qualifier	Exp		"Revised Core value for LBSTREFC to Perm (from Exp)." and "LBORREF, LBSTREFC, and LBSTREFN were removed because there is no clear use case."
MS	MSENDTC	End Date/Time of Observation	Char	ISO 8601	Timing	Perm		*No explanation or mention in Revision History*
MS	MSENDY	Study Day of End of Observation	Num		Timing	Perm		*No explanation or mention in Revision History*
MS	MSENRF	End Relative to Reference Period	Char	(STENRF)	Timing	Perm		*No explanation or mention in Revision History*
MS	MSENRTPT	End Relative to Reference Time Point	Char	(STENRF)	Timing	Perm		*No explanation or mention in Revision History*
MS	MSENTPT	End Reference Time Point	Char		Timing	Perm		*No explanation or mention in Revision History*
MS	MSMODIFY	Modified Reported Name	Char		Synonym Qualifier	Perm		*No explanation or mention in Revision History*
MS	MSSPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Perm		*No explanation or mention in Revision History*
MS	MSSTRF	Start Relative to Reference Period	Char	(STENRF)	Timing	Perm		*No explanation or mention in Revision History*
MS	MSSTRTPT	Start Relative to Reference Time Point	Char	(STENRF)	Timing	Perm		*No explanation or mention in Revision History*
MS	MSSTTPT	Start Reference Time Point	Char		Timing	Perm		*No explanation or mention in Revision History*
QS	QSEVAL	Evaluator	Char	(EVAL)	Record Qualifier	Perm	Not in QS, FT, and clinical classifications use case of RS	
UR	URSPCUFL	Specimen Usability for the Test	Char	(NY)	Record Qualifier	Perm		*No explanation or mention in Revision History*
UR	URSPEC	Specimen Material Type	Char	(SPECTYPE)	Record Qualifier	Perm		*No explanation or mention in Revision History*

SDTM-IG 3.4 / SDTM 2.0 - VARIABLES REMOVED

- 1 Variable from SDTM 1.8 no longer listed in SDTMIG 2.0 for a specific Observation Class
  - APID (Associated Persons Identifier)
    - Removed from Observation Class = General Observations in SDTM 2.0
    - Still exists for Observation Classes: Associated Persons and Relationship

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- 10 Variable Labels changed in SDTM-IG 3.4 (compared against SDTM-IG 3.3)

Domain	Variable Name	New Label (in SDTM-IG v3.4)	Old Label (in SDTM-IG v3.3)	IG Assumptions/Revision History
DV	DVENDY	Study Day of End of Deviation Event	Study Day of End of Observation	"Revised label for DVENDY to 'Study Day of End of Deviation Event' (from Study Day of End of Observation) to be consistent with DVSTDY's label."
FT	FTMETHOD	Method of Test or Examination	Method of Test	*No explanation or mention in Revision History*
LB	LBTESTCD	Lab Test or Examination Short Name	Lab Test or Examination Short Name.	"Revised LBTESTCD variable label to Lab Test or Examination Short Name."
SM	DOMAIN	Domain Abbreviation	Domain	*No explanation or mention in Revision History*
SV	SVENDTC	End Date/Time of Observation	End Date/Time of Visit	*No explanation or mention in Revision History*
SV	SVENDY	Study Day of End of Observation	Study Day of End of Visit	*No explanation or mention in Revision History*
SV	SVSTDTC	Start Date/Time of Observation	Start Date/Time of Visit	*No explanation or mention in Revision History*
SV	SVSTDY	Study Day of Start of Observation	Study Day of Start of Visit	*No explanation or mention in Revision History*
TM	DOMAIN	Domain Abbreviation	Domain	*No explanation or mention in Revision History*
TS	TSVALNF	Parameter Value Null Flavor	Parameter Null Flavor	*No explanation or mention in Revision History*

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- 7 Variable Labels changed in SDTM 2.0 (compared against SDTM 1.8)

Observation Class	Domain	Variable Name	New Label (in SDTM v2.0)	Old Label (in SDTM v1.8)
Findings		--MODIFY	Modified Result Term	Modified Term
Findings		--SEV	Severity/Intensity	Severity
General Observations		--DUR	Collected Duration	Duration
Interventions		--LOC	Location of Administration	Location of Dose Administration
Interventions		--PRESP	Pre-Specified	Pre-specified
Special-Purpose	SM	DOMAIN	Domain Abbreviation	Domain
Trial Design	TM	DOMAIN	Domain Abbreviation	Domain

- Note: No mention of any of these changes in the “Changes from SDTM v1.8 to SDTM v2.0” section of SDTM 2.0

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- Previous values of 'ISO 8601' have been updated to be more specific in SDTM-IG 3.4 and SDTM 2.0. Values now include:
  - ISO 8601 datetime or interval
    - For 25 variables
  - ISO 8601 duration
    - For 11 variables
  - ISO 8601 duration or interval
    - Just for 1 variable: the –EVLINT variable

- Other minor changes
  - TSVALNF – old value of 'ISO 21090 NullFlavor enumeration' changed to 'ISO 21090 NullFlavor'

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- Variable Controlled Terms, Codelist, or Format changed in SDTM-IG 3.4, cont.

Domain	Variable Name	Variable Label	New CT/Format (in SDTM-IG v3.4)	Old CT/Format (in SDTM-IG v3.3)
CE	CESEV	Severity/Intensity	(SEVRS)	
CO	COEVAL	Evaluator	(EVAL)	
CO	RDOMAIN	Related Domain Abbreviation	(DOMAIN)	
DM	ARMNRS	Reason Arm and/or Actual Arm is Null	(ARMNULRS)	
DM	COUNTRY	Country		ISO 3166-1 Alpha-3
DS	DSDECOD	Standardized Disposition Term	(NCOMPLT)(PROTMLST)(OTHEVENT)	(NCOMPLT), (PROTMLST)
DS	DSSCAT	Subcategory for Disposition Event	(DSSCAT)	
EC	ECPSTRGU	Pharmaceutical Strength Units	(UNIT)	
EG	EGSTRESC	Character Result/Finding in Std Format	(EGSTRESC)(HESTRESC)(NORMABNM)	(EGSTRESC)(HESTRESC)
FA	FATEST	Findings About Test Name	(FATEST)	
FA	FATESTCD	Findings About Test Short Name	(FATESTCD)	
FT	FTMETHOD	Method of Test or Examination	(QRSMTHOD)	(METHOD)
HO	HODECOD	Dictionary-Derived Term	(HODECOD)	
LB	LBLOINC	LOINC Code	LOINC	
MB	MBTSTDTL	Measurement, Test or Examination Detail	(MBFTSDTL)	
MS	MSNRIND	Normal/Reference Range Indicator	(NRIND)	
OI	OIPARM	Non-host Organism ID Element Name	(OIPRM)	
OI	OIPARMCD	Non-host Organism ID Element Short Name	(OIPRMCD)	
PR	PRDECOD	Standardized Procedure Name	(PROCEDUR)	
SU	SUDOSFRM	Dose Form	(FRM)	
TS	TSVCDREF	Name of the Reference Terminology	(DICTNAM)	

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- Variable Role values changed in SDTM 2.0

Observation Class	Domain	Variable Name	Variable Label	New Role (in SDTM v2.0)	Old Role (in SDTM v1.8)	Changed in IG
Events		--PRTYID	Identification of Accountable Party	Variable Qualifier	Record Qualifier	Hasn't yet been corrected in SDTM-IG
Findings		--LOINC	LOINC Code	Record Qualifier	Synonym Qualifier	Hasn't yet been corrected in SDTM-IG
Findings		--RESLOC	Result Location of Finding	Record Qualifier	Result Qualifier	SEND Only variable
Interventions		--DOSFRQ	Dosing Frequency per Interval	Record Qualifier	Variable Qualifier	Also corrected in IG for: AG, CM, EC, EX, PR domains
Interventions		--DOSRGM	Intended Dose Regimen	Record Qualifier	Variable Qualifier	Also corrected in IG for: CM, EC, EX, PR domains
Interventions		--ROUTE	Route of Administration	Record Qualifier	Variable Qualifier	Hasn't yet been corrected in SDTM-IG
Special-Purpose	SV	SVUPDES	Description of Unplanned Visit	Record Qualifier	Synonym Qualifier	Also corrected in IG for: SV domain
Special-Purpose	SV	VISIT	Visit Name	Synonym Qualifier	Timing	SDTM-IG v3.3 already had correct Role 'Synonym Qualifier'
Trial Design	TM	TMDEF	Disease Milestone Definition	Variable Qualifier	Rule	Also corrected in IG for: TM domain
	EG	--BEATNO	ECG Beat Number	Identifier	Variable Qualifier	Also corrected in IG for: EG domain

- Role values corrected in SDTM-IG 3.4

Domain	Variable Name	Variable Label	New Role (in SDTM-IG v3.4)	Old Role (in SDTM-IG v3.3)	Changed in IG
IS	--CAT	Category for Immunogenicity Test	Grouping Qualifier	Synonym Qualifier	Previous incorrect label in SDTM-IG v3.3 corrected to now match SDTM label

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- 7 Variable Core values changed in SDTM-IG 3.4

Domain	Variable Name	Variable Label	New Core (in SDTM-IG v3.4)	Old Core (in SDTM-IG v3.3)	IG Assumptions/Revision History
DS	DSDY	Study Day of Collection	Perm	Exp	"DSDY's Core value was updated to Perm (from Exp) to be consistent with DSDTC's Core which is Perm."
DS	DSSTDY	Study Day of Start of Disposition Event	Exp	Perm	"DSSTDY's Core value updated to Exp (from Perm) to be consistent with DSSTDTC's Core which is Exp."
FA	FADTC	Date/Time of Collection	Exp	Perm	to "Exp" for consistency with other Findings domains."
MI	MIBLFL	Baseline Flag	Perm	Exp	"Corrected Core values for the following variables: DSDY, DSSTDY, LBSTREFC, MILOBXFL, and MIBLFL."
MI	MILOBXFL	Last Observation Before Exposure Flag	Exp	Perm	"Corrected Core values for the following variables: DSDY, DSSTDY, LBSTREFC, MILOBXFL, and MIBLFL."
QS	QSLOBXFL	Last Observation Before Exposure Flag	Exp	Perm	*No explanation or mention in Revision History*
TV	VISIT	Visit Name	Req	Perm	"Made VISIT required and revised VISIT CDISC Notes."

- Note: DSDY, MIBLFL, and MILOBXFL Core values were actually corrected in the SDTM-IG 3.3 Errata

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- Variable Order changed in SDTM-IG 3.4

Domain	Variable Name	Variable Label	Order	IG Assumptions/Revision History
EG	EGBEATNO	ECG Beat Number	Was previously after EGPOS and before EGORRES, now it is after EGSPID and before EGTESTCD	"Because the role of the domain-specific variable --BEATNO was changed to Identifier, it was moved from Section 3.1.3, The Findings Observation Class, to Section 3.1.4, Identifiers for All Classes."
MS	MSTSTDTL	Measurement, Test or Examination Detail	Was previously after MSTEST and before MSAGENT, now it is after MSCONCU and before MSCAT	*No explanation or mention in Revision History*

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE CHANGES

- Changes were made to Assumptions in the IG, for “the following qualifiers would not generally be used” assumption for 8 domains
  - CO
    - VISIT, VISITNUM, and VISITDY are no longer listed
  - EC
    - --VAMT and –VAMTU are no longer listed
  - IS
    - It now states: “Any Identifier variables, Timing variables, or Findings general observation class qualifiers may be added to the IS domain.”
  - MB
    - --LOINC is no longer listed
  - FT
    - --POS and –LOC are now listed, but weren’t previously
  - SC
    - --METHOD is no longer listed
  - SS
    - --STAT is no longer listed
  - VS
    - --TOX and –TOXGR are no longer listed

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE DIFFERENCES (MISTAKES?)

- 1 Variable CT/Format Differences between SDTM-IG 3.4 and SDTM 2.0
  - DM.COUNTRY
    - SDTM 2.0:

#	Variable Name	Variable Label	Type	Format	Role	Variable(s) Qualified	Usage Restrictions	Variable C-code	Definition	Notes	Examples
36	COUNTRY	Country	Char	ISO 3166-1 Alpha-3	Record Qualifier		Not in nonclinical trials	C170990	The country in which the investigational site is located.		

    - SDTM-IG 3.4:

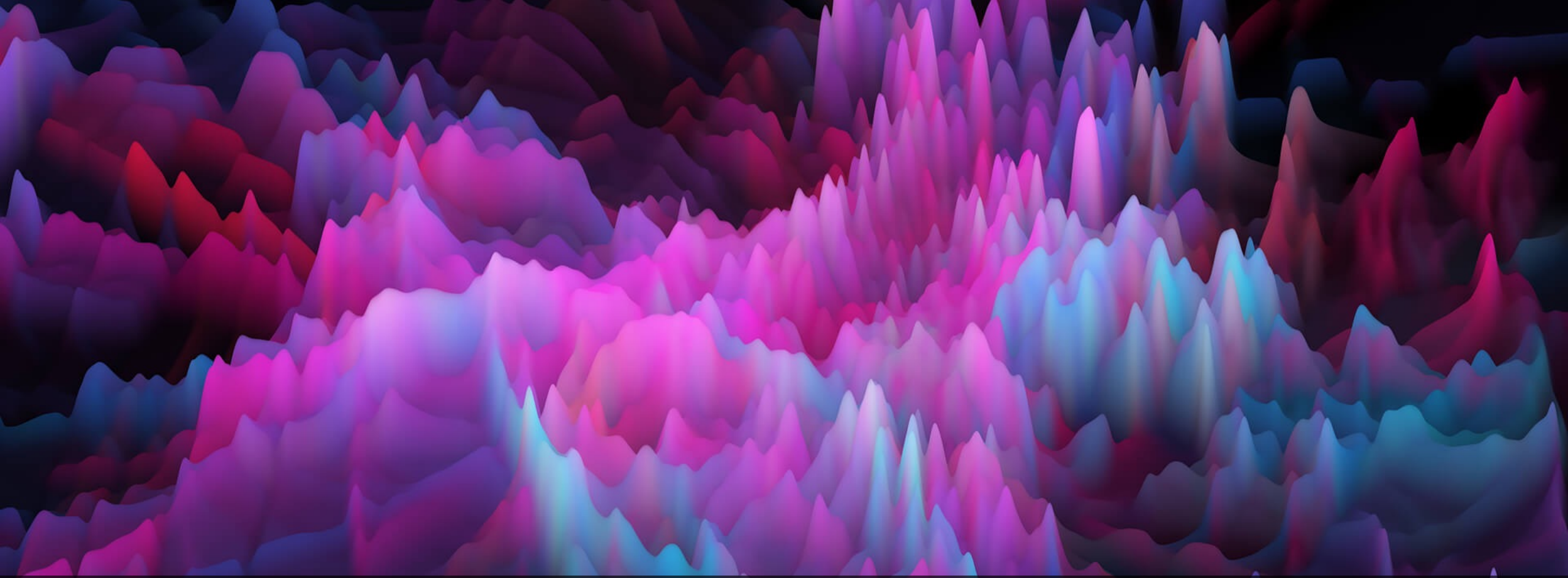
Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format[1]	Role	CDISC Notes	Core
COUNTRY	Country	Char		Record Qualifier	Country of the investigational site in which the subject participated in the trial. Generally represented using ISO 3166-1 Alpha-3. Note that regulatory agency specific requirements (e.g., US FDA) may require other terminologies; in such cases, follow regulatory requirements.	Req

- Note: SDTM-IG 3.4 Revision History states: “We removed the ISO 3166-1 Alpha-3 format from the Controlled Terms column as we became aware of the varied national requirements for this terminology.”

SDTM-IG 3.4 / SDTM 2.0 - VARIABLE DIFFERENCES (MISTAKES?)

- 20 Variable Role Differences between SDTM-IG 3.4 and SDTM 2.0

Observation Class	Domain	Variable Name	Variable Label	Type	CT/Format	Core	Role (in SDTM-IG v3.4)	Role (in SDTM v2.0)	Usage Restrictions
Events	BE	BEPRTYID	Identification of Accountable Party	Char		Perm	Record Qualifier	Variable Qualifier	Not in nonclinical trials
Findings	MS	MSAGENT	Agent Name	Char		Exp	Variable Qualifier	Record Qualifier	MS Domain only
Findings	CP	CPBDAGNT	Binding Agent	Char		Perm	Record Qualifier	Variable Qualifier	CP, IS, and LB domains only
Findings	CP	CPCNDAGT	Test Condition Agent	Char		Perm	RecordQualifier	Record Qualifier	CP, IS, and LB domains only
Findings	LB	LBCOLSRT	Collected Summary Result Type	Char	(COLSTYP)	Perm	Record Qualifier	Variable Qualifier	
Findings	CP	CPCOLSRT	Collected Summary Result Type	Char	(COLSTYP)	Perm	Record Qualifier	Variable Qualifier	
Findings	VS	VSLAT	Laterality	Char	(LAT)	Perm	Result Qualifier	Variable Qualifier	
Findings	MS	MSLOINC	LOINC Code	Char		Perm	Synonym Qualifier	Record Qualifier	
Findings	LB	LBLOINC	LOINC Code	Char	LOINC	Perm	Synonym Qualifier	Record Qualifier	
Findings	CP	CPLOINC	LOINC Code	Char	LOINC	Perm	Synonym Qualifier	Record Qualifier	
Findings	MB	MBLOINC	LOINC Code	Char		Perm	Synonym Qualifier	Record Qualifier	
Findings	MI	MITSTDTL	Microscopic Examination Detail	Char	(MIFTSDTL)	Perm	Record Qualifier	Variable Qualifier	
Interventions	SU	SUDOSFRQ	Use Frequency Per Interval	Char	(FREQ)	Perm	Variable Qualifier	Record Qualifier	
Interventions	EC	ECROUTE	Route of Administration	Char	(ROUTE)	Perm	Variable Qualifier	Record Qualifier	
Interventions	AG	AGROUTE	Route of Administration	Char	(ROUTE)	Perm	Variable Qualifier	Record Qualifier	
Interventions	EX	EXROUTE	Route of Administration	Char	(ROUTE)	Perm	Variable Qualifier	Record Qualifier	
Interventions	SU	SUROUTE	Route of Administration	Char	(ROUTE)	Perm	Variable Qualifier	Record Qualifier	
Interventions	PR	PRROUTE	Route of Administration	Char	(ROUTE)	Perm	Variable Qualifier	Record Qualifier	
Interventions	CM	CMROUTE	Route of Administration	Char	(ROUTE)	Perm	Variable Qualifier	Record Qualifier	
Special-Purpose	CO	COEVALID	Evaluator Identifier	Char	(MEDEVAL)	Perm	Record Qualifier	Variable Qualifier	



SDTM / SDTMIG CONFORMANCE RULES 2.0

What's New or Changed?

SDTM CONFORMANCE RULES 2.0 - RULES REMOVED

- 3 Conformance Rules from 1.1 (SDTM-IG 3.2 and 3.3 rules) removed

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Release Notes
CG0292	3.2	1	TDM	TS	GEN	TSPARMCD equals one of the values in the list of Trial Summary Codes in Appendix C1 and TSVALNF is null	TSVAL ^= null	Rule retired - redundant with rules CG0259 and CG0260
CG0292	3.3	1	TDM	TS	GEN	TSPARMCD equals one of the values in the list of Trial Summary Codes in Appendix C1 and TSVALNF is null	TSVAL ^= null	Rule retired - redundant with rules CG0259 and CG0260
CG0543	3.2	1	SPC, INT	SE, PR	--SEQ		--SEQ is in consistent chronological order	Rule Retired and replaced with CG0662 Rule applies to SE and PR in 3.2, SE, SM, and PR in 3.3. While PR has this condition in the CDISC Notes in both 3.2 and 3.3, this is considered an error.
CG0544	3.3	1	SPC, INT	SM, SE, PR	--SEQ		--SEQ is in consistent chronological order	Rule Retired and replaced with CG0620: Rule applies to SE and PR in 3.2, SE, SM, and PR in 3.3. While PR has this condition in the CDISC Notes in both 3.2 and 3.3, this is considered an error.

SDTM CONFORMANCE RULES 2.0 - RULES ADDED

- 4 Conformance Rules added to 2.0 for older versions of SDTM-IG (3.2 and 3.3)

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Release Notes
CG0620	3.3	1	SPC	SM, SE	--SEQ		--SEQ is in a consistent chronological order	New Rule. This rule replaces CG0544. This rule is not applicable to PR domain.
CG0620	3.4	1	SPC	SM, SE	--SEQ		--SEQ is in a consistent chronological order	New Rule. This rule replaces CG0544. This rule is not applicable to PR domain.
CG0650	3.2	1	AP	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 4 and <= 6	Added rule for 3.2
CG0650	3.3	1	AP	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 4 and <= 6	Added rule for 3.3
CG0650	3.4	1	AP	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 4 and <= 6	New Rule
CG0651	3.3	1	ALL	ALL	GEN	Variable Core Status = Permissible and data is planned to be collected	Variable present in dataset	New Rule
CG0651	3.4	1	ALL	ALL	GEN	Variable Core Status = Permissible and data is planned to be collected	Variable present in dataset	New Rule
CG0662	3.2	1	SPC	SE	--SEQ		--SEQ is in consistent chronological order	Rule replaces CG0543 v1 for SDTMIG v3.2. Rule CG0620 does the same for SDTMIG v3.3. While PR has this condition in the CDISC Notes in both 3.2 and 3.3, this is considered an error.

SDTM CONFORMANCE RULES 2.0 - RULES ADDED

- 59 New Conformance Rules added to 2.0 for SDTM-IG 3.4 (Not including existing conformance rules assigned to SDTM-IG 3.4)
  - 36 new conformance rules are already covered by existing P21 rules
    - Note that a minor tweak or assigning the rule to a new domain may be needed
  - 5 new conformance rules will result in new P21 rules
  - 17 new conformance rules may not be able to be implemented
    - Due to vague/unclear Condition or Rule, or just unable to be programmatically checked
  - 1 new conformance rule appears to be an identical duplicate with another rule

SDTM CONFORMANCE RULES 2.0 - RULES ADDED

- 36 new conformance rules are already covered by existing P21 rules
  - Rules CG0621 – CG0644 (24 rules) all check that nonclinical-only variables are not included in SDTM data
    - Covered by existing P21 rule SD1074 (Variable which can be used only in SEND)

- The rest:

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Corresponding P21 rule
CG0091	3.4	1	ALL	ALL	--TPT	--TPTNUM present in dataset	--TPT present in dataset	SD1244 (Missing --TPT variable, when --TPTNUM variable is present)
CG0619	3.4	1	FND	ALL	--SPCUFL		--SPCUFL = 'N' or null	CT2001 (Variable value not found in non-extensible codelist)
CG0649	3.4	1	TDM	TS	TSVALNF	TSVAL not populated with values or synonyms of values in the ISO 21090 null flavor codelist (or other terms that can be represented as null flavors), unless the term is included in published terminology.	TSVALNF = null	SD2018 (Both TSVAL and TSVALNF variables are populated) and SD1297 (TSVAL is populated with a value from the ISO 21090 null flavor codelist)
CG0650	3.4	1	AP	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 4 and <= 6	SD1095 (Invalid dataset name for split domain)
CG0653	3.4	1	SPC	SV	SVPRESP		SVPRESP in ("Y", null)	CT2001 (Variable value not found in non-extensible codelist)
CG0654	3.4	1	SPC	SV	SVPRESP	SVOCCUR ^= null	SVPRESP = "Y"	SD0041 (Value for --OCCUR is populated for unsolicited Intervention or Event)
CG0655	3.4	1	SPC	SV	VISITNUM	SVPRESP = 'Y'	VISITNUM in TV.VISITNUM	SD1017 (VISITNUM value does not match TV domain data) and SD1018 (VISITNUM/VISIT/VISITDY values do not match TV domain data)
CG0657	3.4	1	SPC	SV	VISIT	SVPRESP = 'Y'	VISIT in TV.VISIT	SD1018 (VISITNUM/VISIT/VISITDY values do not match TV domain data)
CG0658	3.4	1	SPC	SV	VISITDY	SVPRESP = null	VISITDY = null	SD1019 (VISITDY is populated for unplanned visit),
CG0664	3.4	1	ALL	ALL	GEN		Variables are ordered with Identifiers first, followed by the Topic, Qualifier, and Timing variables. Within each role, variables are ordered as shown in SDTM tables in sections 3.1.1, 3.1.2, 3.1.3, 3.1.3.1, 3.1.4, and 3.1.5	SD1079 (Variable is in wrong order within domain)
CG0665	3.4	2	SPC	DM	AGEU	AGE ^= null	AGEU ^= null	SD0093 (Missing value for AGEU, when AGE is provided) and SD2202 (Missing value for AGEU, when AGE or AGETXT is populated)
CG0666	3.4	2	SPC	DM	AGE	AGEU ^= null	AGE ^= null	SD1003 (Missing value for AGE, when AGEU is provided)

SDTM CONFORMANCE RULES 2.0 - RULES ADDED

- 5 new conformance rules will result in new P21 rules

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule
CG0646	3.4	1	SPC	SJ			SJ dataset not present
CG0647	3.4	1	TDM	TJ			TJ dataset not present
CG0648	3.4	1	TDM	TP			TP dataset not present
CG0656	3.4	1	SPC	SV	VISITNUM	SVPRESP = null	VISITNUM not in TV.VISITNUM
CG0663	3.4	1	AP	NOT(APRELSUB, POOLDEF)	DOMAIN	AP Core Domain	Value length = 4 characters beginning with 'AP' and ending with 2 character SDTM domain

SDTM CONFORMANCE RULES 2.0 - RULES ADDED

- 17 new conformance rules may not be able to be implemented

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Concerns
CG0601	3.4	1	FND	FA	--OBJ	Events parent record exists and DECOD = null	--OBJ = --TERM	How can it programmically be determined if parent record exists?
CG0602	3.4	1	FND	FA	--OBJ	Interventions parent record exists and DECOD = null	--OBJ = --TRT	How can it programmically be determined if parent record exists?
CG0603	3.4	1	FND	FA	--OBJ	Parent record exists and DECOD ^= null	--OBJ = --DECOD	How can it programmically be determined if parent record exists?
CG0604	3.4	1	FND	FA	--OBJ	Parent record does not exist, and NO name of event or intervention is coded	--OBJ = verbatim value	How can it programmically be determined if parent record does not exist?
CG0605	3.4	1	FND	FA	--OBJ	Parent record does not exist, and name of event or intervention is coded	--OBJ = coded value	How can it programmically be determined if parent record does not exist?
CG0607	3.4	1	FND	MB	MBTEST	Test targets an organism, group of organisms, or antigen	MBTEST = name of the organism or antigen	How can it programmically be determined what a test targets?
CG0608	3.4	1	FND	MB	MBTSTDTL	Test targets an organism, group of organisms, or antigen	MBTSTDTL='DETECTION'	How can it programmically be determined what a test targets?
CG0609	3.4	1	FND	MB	MBTESTCD	Test for non-targeted identification of an organism	MBTESTCD='MCORGIDN'	How can it programmically be determined what a test targets?
CG0610	3.4	1	FND	MB	MBTEST	Test for culture characteristics	MBTEST = name of the organism or group of organisms	How can it programmically be determined what a test targets?
CG0614	3.4	1	FND	MB	MBTEST	Test targets an organism, group of organisms, or antigen	MBTEST = name of the organism or antigen	How can it programmically be determined what a test targets?
CG0615	3.4	1	FND	MB	MBTSTDTL	Test targets an organism, group of organisms, or antigen	MBTSTDTL = 'DETECTION'	How can it programmically be determined what a test targets?
CG0616	3.4	1	FND	MB	MBTESTCD	Test for non-targeted identification of an organism	MBTESTCD = 'MCORGIDN'	How can it programmically be determined what a test targets?
CG0617	3.4	1	FND	MB	MBTEST	Test for culture characteristics	MBTEST = name of the organism or group of organisms	How can it programmically be determined what a test targets?
CG0620	3.4	1	SPC	SM, SE	--SEQ		--SEQ is in a consistent chronological order	what is a 'consistent' chronological order?
CG0651	3.4	1	ALL	ALL	GEN	Variable Core Status = Permissible and data is planned to be collected	Variable present in dataset	How can it programmically be determined if data is planned to be collected?
CG0659	3.4	1	FND	QS, FT, RS	--EVAL	Domain in ('QS', 'FT') or (Domain = 'RS' and it's the Clinical Classification Use Case)	--EVAL not present in dataset	For RS...how to differentiate Clinical Classifications? What if some records are Clinical Classifications, and some are not? Can the variable can be present in that case?
CG0660	3.4	1	FND	QS, FT, RS	--EVALID	Domain in ('QS', 'FT') or (Domain = 'RS' and it's the Clinical Classification Use Case)	--EVALID not present in dataset	For RS...how to differentiate Clinical Classifications? What if some records are Clinical Classifications, and some are not? Can the variable can be present in that case?

SDTM CONFORMANCE RULES 2.0 - RULES ADDED - ISSUES

- Some issues with the new conformance rules

Rule ID	SDTMIG Version	Rule Version	Class	Domain	Variable	Condition	Rule	Issues
CG0637	3.4	1	ALL		--RPDY		--NOMLBL not present in dataset	Variable = --RPDY, but Rule references --NOMLBL. Will just assume it is a mistake and --RPDY should be checked
CG0641	3.4	1	SPC	DM	AGETXT		AGETXT not present in dataset	AGETXT has no Usage Restrictions in SDTM v2.0, therefore it is unclear what this rule is based on
CG0661	3.4	1	ALL	ALL	--TPT	--TPTNUM present in dataset	--TPT present in dataset	Looks like an identical duplicate of CG0091

- Also, there are rules (CG0646-CG0648) to check that nonclinical domains (SJ, TJ, and TP) aren't used for clinical studies…however the domain TT appears to have been missed

SDTM CONFORMANCE RULES 2.0 - RULE CHANGES

- 25 Conformance Rules have Rule Version changed in 2.0
  - 4 of those Conformance Rules have rule version changed in 2.0, but no actual changes were made to the rule

Rule ID	SDTMIG Version	Rule Version v2.0	Class v2.0	Domain v2.0	Variable v2.0	Condition v2.0	Rule v2.0	Rule Version v1.1	Class v1.1	Domain v1.1	Variable v1.1	Condition v1.1	Rule v1.1
CG0006	3.3	2	ALL	ALL	--DY	Date portion of --DTC is complete and date portion of RFSTDTC is a complete date AND --DY is ^= null	--DY calculated as per the study day algorithm as a non-zero integer value	1	ALL	ALL	--DY	Date portion of --DTC is complete and date portion of RFSTDTC is a complete date AND --DY is ^= null	--DY calculated as per the study day algorithm as a non-zero integer value
CG0095	3.3	2	ALL	ALL	--LAT	--LOC not present in dataset	--LAT not present in dataset	1	ALL	ALL	--LAT	--LOC not present in dataset	--LAT not present in dataset
CG0208	3.2	3	SPC	SE	SESTDTC		SESTDTC ^= null	2	SPC	SE	SESTDTC		SESTDTC ^= null
CG0208	3.3	3	SPC	SE	SESTDTC		SESTDTC ^= null	2	SPC	SE	SESTDTC		SESTDTC ^= null
CG0334	3.2	2	ALL	SUPP----	RDOMAIN	Dataset name begins with 'SUPP'	Value of RDOMAIN equals characters 5 and 6 of the dataset name	1	ALL	SUPP----	RDOMAIN	Dataset name begins with 'SUPP'	Value of RDOMAIN equals characters 5 and 6 of the dataset name
CG0334	3.3	2	ALL	SUPP----	RDOMAIN	Dataset name begins with 'SUPP'	Value of RDOMAIN equals characters 5 and 6 of the dataset name	1	ALL	SUPP----	RDOMAIN	Dataset name begins with 'SUPP'	Value of RDOMAIN equals characters 5 and 6 of the dataset name

SDTM CONFORMANCE RULES 2.0 - RULE CHANGES

- 4 Conformance Rules have Class changed in 2.0

Rule ID	SDTMIG Version	Rule Version v2.0	Class v2.0	Domain v2.0	Variable v2.0	Condition v2.0	Rule v2.0	Rule Version v1.1	Class v1.1	Domain v1.1	Variable v1.1	Condition v1.1	Rule v1.1
CG0017	3.2	2	NOT (AP)	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 2 and <= 4	1	ALL	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 2 and <= 4
CG0017	3.3	2	NOT (AP)	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 2 and <= 4	1	ALL	ALL	GEN	Non-Supplemental Qualifier datasets	Split dataset names length > 2 and <= 4
CG0082	3.2	2	EVT	ALL	--BDSYCD	--BODSYS ^= null	--BDSYCD ^= null	1	EVT, FND	ALL	--BDSYCD	--BDSYCD ^= null	--BODSYS ^= null
CG0082	3.3	2	EVT	ALL	--BDSYCD	--BODSYS ^= null	--BDSYCD ^= null	1	EVT, FND	ALL	--BDSYCD	--BDSYCD ^= null	--BODSYS ^= null
CG0083	3.2	2	EVT	ALL	--BDSYCD		--BDSYCD and --BODSYS have a one-to-one relationship	1	EVT, FND	ALL	--BDSYCD		--BDSYCD and '--BODSYS have a one-to-one relationship
CG0083	3.3	2	EVT	ALL	--BDSYCD		--BDSYCD and --BODSYS have a one-to-one relationship	1	EVT, FND	ALL	--BDSYCD		--BDSYCD and '--BODSYS have a one-to-one relationship
CG0563	3.3	1	FND	RS	RSDRFVL	Record is derived in a data collection tool.	RSDRVFL = 'Y'	1	RND	RS	RSDRFVL	Record is derived in a data collection tool.	RSDRVFL = 'Y'

SDTM CONFORMANCE RULES 2.0 - RULE CHANGES

- 1 Conformance Rule has Domain changed in 2.0

Rule ID	SDTMIG Version	Rule Version v2.0	Class v2.0	Domain v2.0	Variable v2.0	Condition v2.0	Rule v2.0	Rule Version v1.1	Class v1.1	Domain v1.1	Variable v1.1	Condition v1.1	Rule v1.1
CG0084	3.2	2	EVT, FND	ALL	--TOX	--TOXGR not present in dataset	--TOX not present in dataset	1	EVT, FND	AE, LB	--TOX	--TOXGR not present in dataset	--TOX not present in dataset
CG0084	3.3	2	EVT, FND	ALL	--TOX	--TOXGR not present in dataset	--TOX not present in dataset	1	EVT, FND	AE, LB	--TOX	--TOXGR not present in dataset	--TOX not present in dataset

SDTM CONFORMANCE RULES 2.0 - RULE CHANGES

- 3 Conformance Rules have Variable changed in 2.0

Rule ID	SDTMIG Version	Rule Version v2.0	Class v2.0	Domain v2.0	Variable v2.0	Condition v2.0	Rule v2.0	Rule Version v1.1	Class v1.1	Domain v1.1	Variable v1.1	Condition v1.1	Rule v1.1
CG0032	3.2	2	ALL	ALL	VISITDY	VISITNUM is in TV.VISITNUM	VISITDY = TV.VISITDY	1	ALL	ALL	VISIT	VISITNUM is in TV.VISITNUM	VISITDY = TV.VISITDY
CG0032	3.3	2	ALL	ALL	VISITDY	VISITNUM is in TV.VISITNUM	VISITDY = TV.VISITDY	1	ALL	ALL	VISIT	VISITNUM is in TV.VISITNUM	VISITDY = TV.VISITDY
CG0033	3.2	2	ALL	ALL	VISITNUM	VISITNUM ^= null and is planned	VISITNUM in TV.VISITNUM	1	ALL	ALL	VISIT	VISITNUM ^= null and is planned	VISITNUM in TV.VISITNUM
CG0033	3.3	2	ALL	ALL	VISITNUM	VISITNUM ^= null and is planned	VISITNUM in TV.VISITNUM	1	ALL	ALL	VISIT	VISITNUM ^= null and is planned	VISITNUM in TV.VISITNUM
CG0034	3.2	2	ALL	ALL	VISITNUM	VISITNUM ^= null	VISITNUM in SV.VISITNUM	1	ALL	ALL	VISIT	VISITNUM ^= null	VISITNUM in SV.VISITNUM
CG0034	3.3	2	ALL	ALL	VISITNUM	VISITNUM ^= null	VISITNUM in SV.VISITNUM	1	ALL	ALL	VISIT	VISITNUM ^= null	VISITNUM in SV.VISITNUM

SDTM CONFORMANCE RULES 2.0 - RULE CHANGES

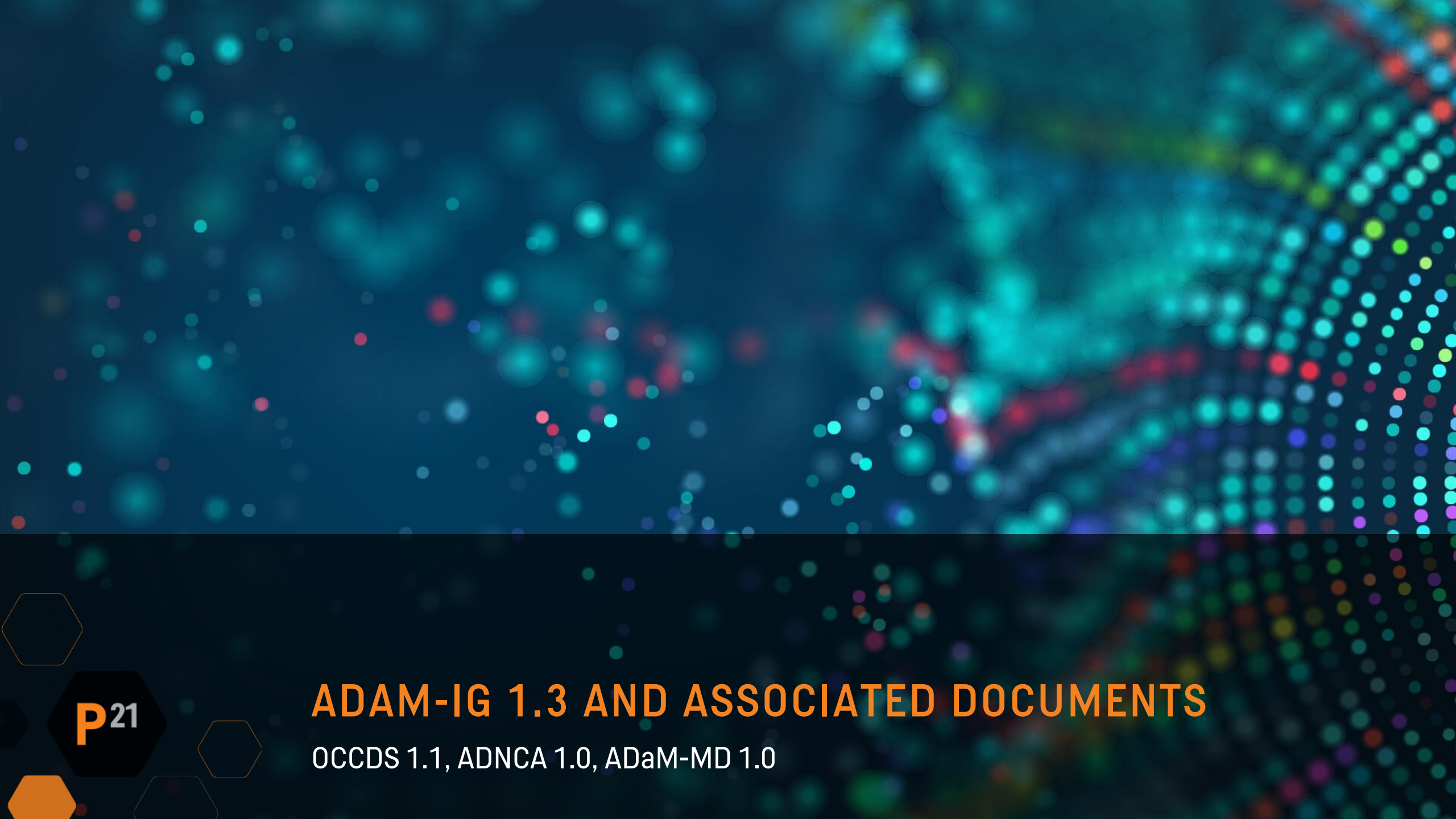
- 2 Conformance Rules have Condition and Rule changed in 2.0

Rule ID	SDTMIG Version	Rule Version v2.0	Class v2.0	Domain v2.0	Variable v2.0	Condition v2.0	Rule v2.0	Rule Version v1.1	Class v1.1	Domain v1.1	Variable v1.1	Condition v1.1	Rule v1.1
CG0082	3.2	2	EVT	ALL	--BDSYCD	--BODSYS ^= null	--BDSYCD ^= null	1	EVT, FND	ALL	--BDSYCD	--BDSYCD ^= null	--BODSYS ^= null
CG0082	3.3	2	EVT	ALL	--BDSYCD	--BODSYS ^= null	--BDSYCD ^= null	1	EVT, FND	ALL	--BDSYCD	--BDSYCD ^= null	--BODSYS ^= null
CG0148	3.2	2	SPC	DM	RFXSTDTC	EX records present for subject	RFXSTDTC = earliest EX.EXSTDTC	1	SPC	DM	RFXSTDTC	EX dataset present in study	RFXSTDTC = earliest EX.EXSTDTC for that subject
CG0148	3.3	2	SPC	DM	RFXSTDTC	EX records present for subject	RFXSTDTC = earliest EX.EXSTDTC	1	SPC	DM	RFXSTDTC	EX dataset present in study	RFXSTDTC = earliest EX.EXSTDTC for that subject

TREVOR MANKUS

PRODUCT LEADER

- CDISC member since 2009
- CDISC ADaM conformance sub-team lead
- Involved with pharma and CROs since 2007


P21
ADAM-IG 1.3 AND ASSOCIATED DOCUMENTS
OCCDS 1.1, ADNCA 1.0, ADaM-MD 1.0

NEW DOCUMENTS

- ADaM-IG 1.3 Release Package
  - 29-Nov-2021
    - ADaM 1.3
    - OCCDS 1.1
    - ADaM NCA 1.0
    - ADaM Medical Devices 1.0

NEW DOCUMENT CONSIDERATIONS

- Also included:
  - Considerations when using ADaM 2.1 (PDF)
    - Describes subsequent developments since publication date of Dec. 2009

- Additional classes of ADaM datasets
  - Device Level Analysis Dataset (ADDL)
  - Medical Device Occurrence Data Structure (MDOCCDS)
  - Medical Device Basic Data Structure (MDBDS)

- SubClasses of ADaM datasets
  - ADVERSE EVENT (for OCCDS)
  - TIME-TO-EVENT (for BDS)
  - NON-COMPARTMENTAL ANALYSIS (for BDS)
  - MEDICAL DEVICE TIME-TO-EVENT (for BDS)

DOCUMENT APPLICABILITY

Document	ADaMIG v1.0	ADaMIG v1.1	ADaMIG v1.2	ADaMIG v1.3
Analysis Data Model (ADaM) v2.1, December 2009	Foundational document for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Structure for Occurrence Data (OCCDS) Implementation Guide v1.1, November 2021	Not written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Occurrence Data Structure (OCCDS) v1.0, February 2016	Not written for ADaMIG v1.0	Written for ADaMIG v1.1	Applicable	Applicable
ADaM Data Structure for Adverse Event Analysis v1.0, May 2012	Written for ADaMIG v1.0	Superseded by OCCDS v1.0	Superseded by OCCDS v1.0	Superseded by OCCDS v1.0
ADaM Implementation Guide for Non-compartmental Analysis Input Data (ADNCA), v1.0, November 2021	Not written for ADaMIG v2.0	Applicable	Applicable	Applicable
ADaM Implementation Guide for Medical Devices (ADaMIG-MD), v1.0, November 2021	Applicable	Applicable	Applicable	Applicable
ADaM Conformance Rules v4.0, November 2021	Applicable	Applicable	Applicable	Applicable
The ADaM Basic Data Structure for Time-to-Event Analyses v1.0, May 2012	Written for ADaMIG v1.0	Applicable	Applicable	Applicable
ADaM Examples in Commonly Used Statistical Analysis Methods v1.0, December 2011	Written for ADaMIG v1.0	Applicable	Applicable	Applicable
Define-XML v2.0, March 2013	Applicable	Applicable	Applicable	Applicable
Analysis Results Metadata Specification for Define-XML Version 2 v1.0, January 2015	Applicable	Applicable	Applicable	Applicable

Table 1.3.1.1 Other CDISC Documents and Their Applicability to ADaM-IG Versions

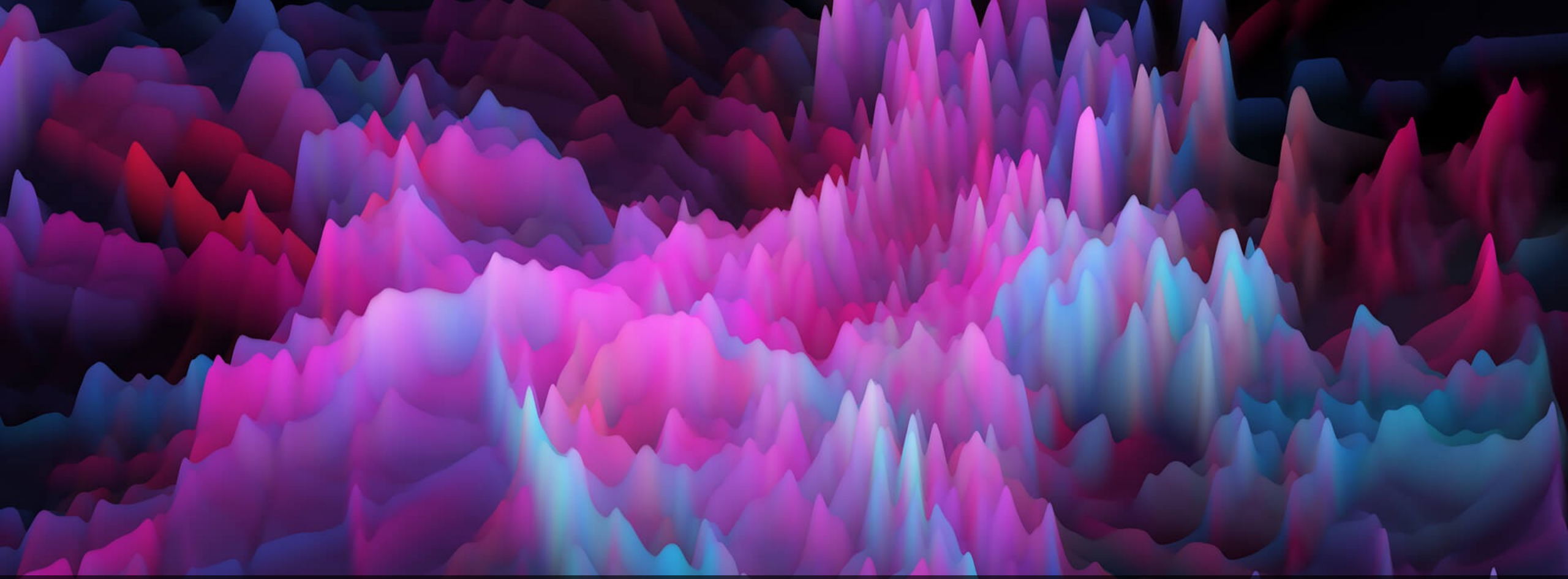
ADAM-IG 1.3

- A minor update
  - 3 clarifications
  - 5 modifications
  - 4 corrections

- 0 new variables
- 0 modified metadata attributes
- But… new data structures!

ADAM-IG 1.3

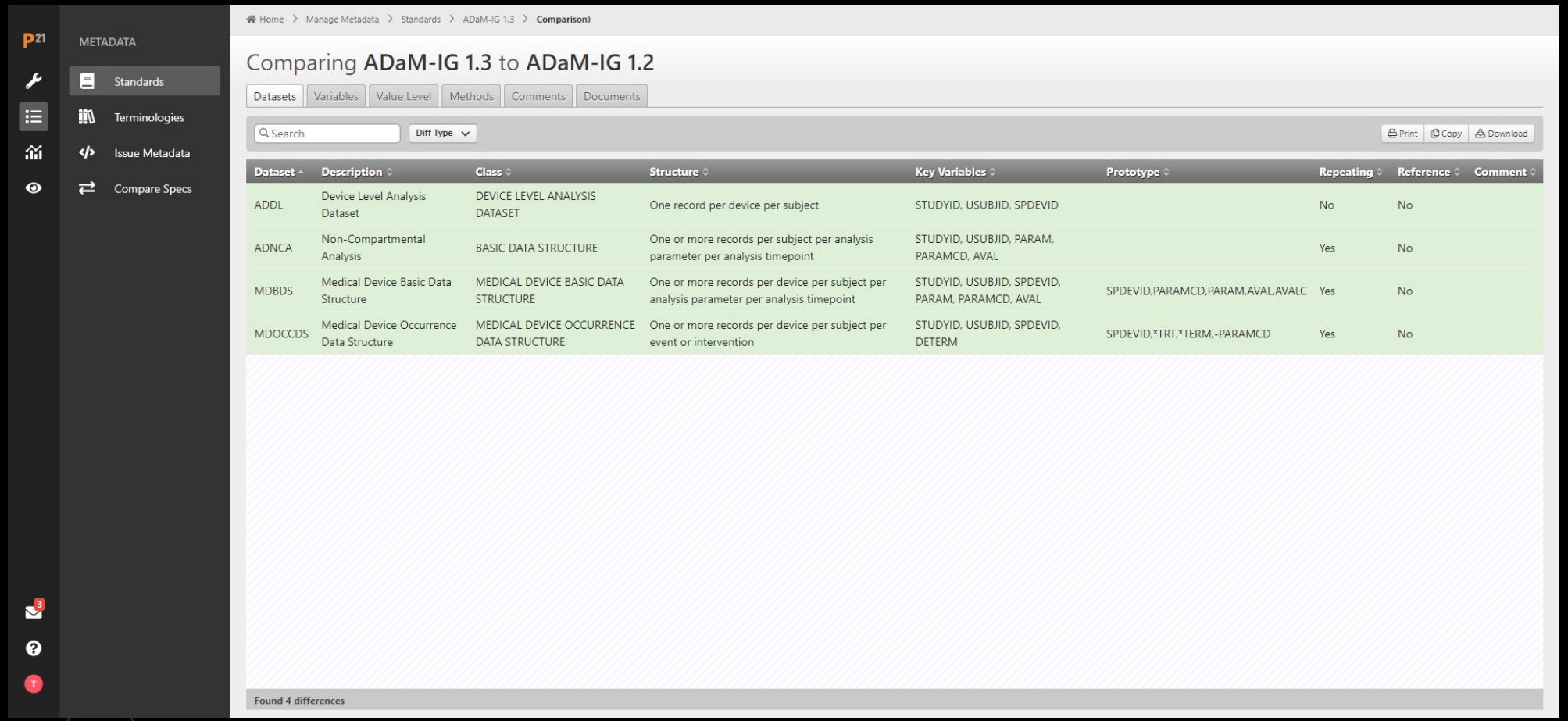
- New data structures
  - ADNCA 1.0
    - ADNCA - Non-Compartmental Analysis
  - ADaM-IG-MD 1.0
    - ADDL - Device Level Analysis Dataset
    - MDBDS - Medical Device Basic Data Structure
    - MDOCCDS - Medical Device Occurrence Data Structure



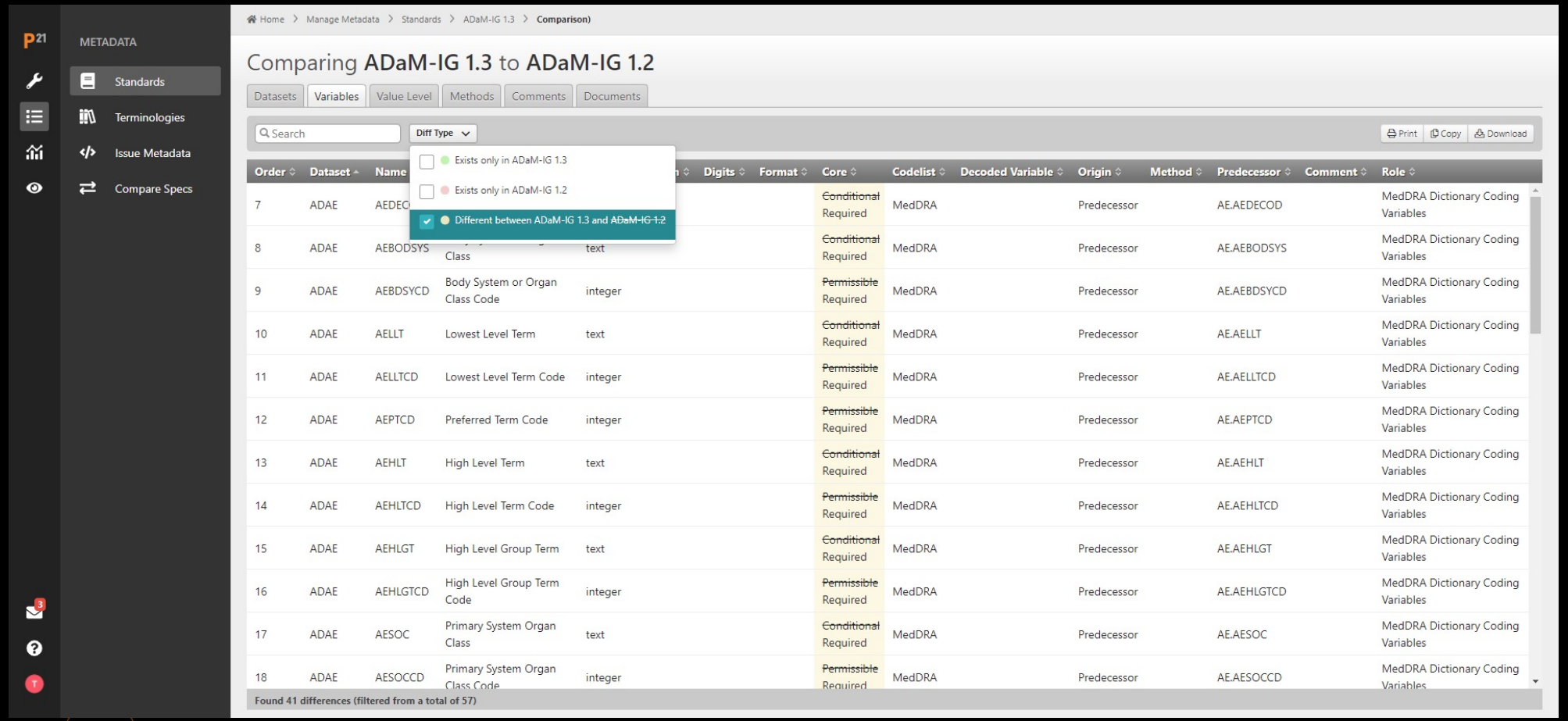
COMPARING ADAM-IG VERSIONS

Enterprise can help with that

COMPARING STANDARDS



COMPARING STANDARDS



Order	Dataset	Name	Label	Type	Digits	Format	Core	Codelist	Decoded Variable	Origin	Method	Predecessor	Comment	Role
7	ADAE	AEDEC					~~Conditional~~ Required	MedDRA		Predecessor		AE.AEDECOD		MedDRA Dictionary Coding Variables
8	ADAE	AEBODSYS	Class	text			~~Conditional~~ Required	MedDRA		Predecessor		AE.AEBODSYS		MedDRA Dictionary Coding Variables
9	ADAE	AEBDSYCD	Body System or Organ Class Code	integer			~~Permissible~~ Required	MedDRA		Predecessor		AE.AEBDSYCD		MedDRA Dictionary Coding Variables
10	ADAE	AELLT	Lowest Level Term	text			~~Conditional~~ Required	MedDRA		Predecessor		AE.AELLT		MedDRA Dictionary Coding Variables
11	ADAE	AELLTCD	Lowest Level Term Code	integer			~~Permissible~~ Required	MedDRA		Predecessor		AE.AELLTCD		MedDRA Dictionary Coding Variables
12	ADAE	AEPTCD	Preferred Term Code	integer			~~Permissible~~ Required	MedDRA		Predecessor		AE.AEPTCD		MedDRA Dictionary Coding Variables
13	ADAE	AEHLT	High Level Term	text			~~Conditional~~ Required	MedDRA		Predecessor		AE.AEHLT		MedDRA Dictionary Coding Variables
14	ADAE	AEHLTCD	High Level Term Code	integer			~~Permissible~~ Required	MedDRA		Predecessor		AE.AEHLTCD		MedDRA Dictionary Coding Variables
15	ADAE	AEHLGT	High Level Group Term	text			~~Conditional~~ Required	MedDRA		Predecessor		AE.AEHLGT		MedDRA Dictionary Coding Variables
16	ADAE	AEHLGTCD	High Level Group Term Code	integer			~~Permissible~~ Required	MedDRA		Predecessor		AE.AEHLGTCD		MedDRA Dictionary Coding Variables
17	ADAE	AESOC	Primary System Organ Class	text			~~Conditional~~ Required	MedDRA		Predecessor		AE.AESOC		MedDRA Dictionary Coding Variables
18	ADAE	AESOCCD	Primary System Organ Class Code	integer			~~Permissible~~ Required	MedDRA		Predecessor		AE.AESOCCD		MedDRA Dictionary Coding Variables

OCCDS 1.1

What's New or Changed?

OCCDS 1.1

- Revised metadata
  - "Core" refinements
- New naming convention
  - "U" = unmodified
    - Example: AEBODSYS + MHBODSYS can be combined into UBODSYS
- New variables

OCCDS 1.1 - DETAILS

- MedDRA Dictionary Coding Variables
  - Core is now "Req" for SubClass of ADVERSE EVENT
- WHO Drug Dictionary Coding Variables
  - Core is now "Not Used" for SubClass of ADVERSE EVENT
- Timing Variables (--STDTC, --ENDTC, etc.)
  - Core is now "Req" for SubClass of ADVERSE EVENT

OCCDS 1.1 - DETAILS

- New variables added
  - ADECODy – Analysis Dictionary-Derived Term y
  - ONTRxxFL – On Treatment Period xx Flag
  - ONTRTwFL – On Treatment Record w Flag
  - TREMxxFL – Treatment Emergent Period xx Flag
  - TRTEMwFL – Treatment Emergent Analysis w Flag

ADNCA 1.0

ADaM-IG for Non-compartmental Analysis (NCA) input data

NCA - WHAT IS IT?

- Pharmacokinetics (PK) is the study of the effect of the body on a drug
- Different mathematical methods are used to calculate PK parameters
- NCA is one class of these methods
  - Commonly used to analyze drug concentration data
  - Why? The input data for non-compartmental parameter calculation is subject to submission to regulatory bodies

NCA - WHAT IS IT?

- ADNCA 1.0 describes what a BDS dataset should look like for this purpose

- ADSL and BDS variables commonly used in NCA include:

- STUDYID
- USUBJID and SUBJID
- SITEID
- AGE or AAGE, and AGEU
- SEX
- RACE
- TRTP and TRTPN
- TRTA and TRTAN
- DOSEP*, DOSEA*, and DOSEU*
- APERIOD and APERIODC
- AVISIT* and AVISITN
- ADT, ATM, and ADTM
- ASTDT, ASTTM, and ASTDTM
- AENDT, AENTM, and AENDTM
- ATPT and ATPTN
- PARAM, PARAMCD, and PARAMN
- AVAL
- DTYP

NCA - CHANGES TO CORE

- DOSEA, DOSEU, and AVISIT have a stronger value for Core
  - In BDS:
    - DOSEA and DOSEU = Perm
    - AVISIT = Cond
  - In NCA:
    - DOSEA, DOSEU, and AVISIT = Req

NCA - NEW VARIABLES

- Described in Table 4.2.1: New Standard Non-compartmental Analysis Variables
  - Exclusion flags, cohorts, treatment intervals, timing variables (e.g., first date of dose for analyte), time from analyte dosing, dose duration, volumes, weights, etc.

ADAM-MD 1.0

ADaM-IG for Medical Devices

MEDICAL DEVICES - WHAT IS IT?

- IG for statistical analysis needs of data for trials where medical devices are used

- New classes that are like existing classes
  - ADDL (ADSL)
  - MDBDS and MDTTE (BDS)
  - MDOCCDS (OCCDS)

MEDICAL DEVICES – MORE INFO

- Medical devices…
  - are given a unique identifier (SPDEVID)
  - can be analyzed by device alone or with regard to subject
- ADDL is the same as ADSL, but for device information
- ADSL is conditionally required for medical device studies
  - Required only when subject information is collected and needs to be reported


QUESTIONS?

THANK YOU ;)

KEEP IN TOUCH!

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