PP14

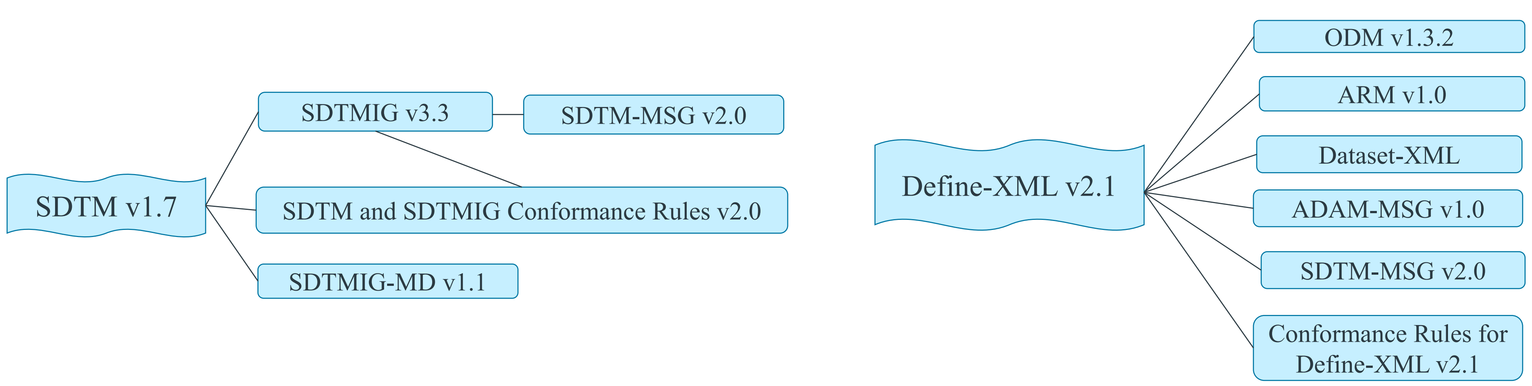
Your Guide to Successfully Upversioning CDISC Standards

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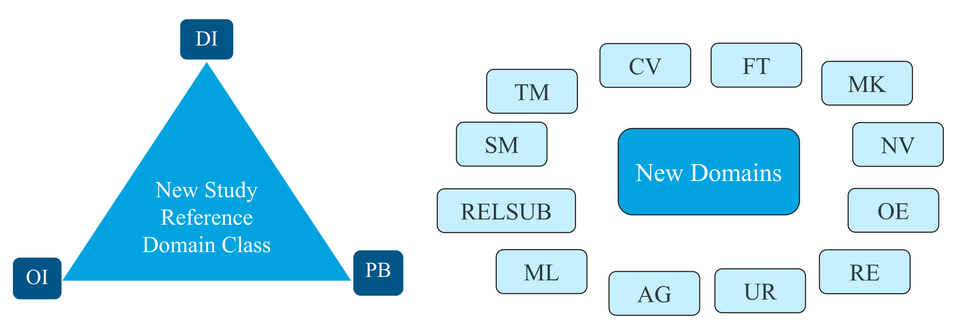
Abstract

As of this past year, new versions of the CDISC standards (i.e., SDTM v1.7, SDTM v2.0, SDTMIG v3.3, SDTMIG v3.4, and Define.xml 2.1) are either required or supported by the industry's regulatory agencies. This poster brings together best practices and resources for up versioning to these standards. Highlights include strategies for dealing with value level metadata for variables with multiple codelist references, a new domain class, new domains, and changes in submission of permissible variables.

Alignment of CDISC Standards



Changes in SDTMIG v3.3



Points To Consider While Upversioning

- Sponsor/Regulatory Agency agreement on versions of standards
- Alignment with company's processes
- Pooled analyses (ISS/ISE)
- Study Data Standardization Plan (SDSP)
- Statuses of the studies (startup/ongoing/legacy)
- Evaluate metadata updates as needed (new/modification/deprecation)
- Submission documents revisions (SDTM aCRF, SDRG, and define.xml)
- Time/cost/benefit analysis
- Traceability

Permissible Variables Example

Serious Adverse Event **If this event is serious, please answer to the following questions:**	AESER	Yes ☐ No ☐
Death	AESDTH	
Hospitalization (initial or prolonged)	AESHOSP	
Life Threatening	AESLIFE	

DOMAIN	USUBJID	AESEQ	AETERM	AESEV	AESER	AESDTH	AESHOSP	AESLIFE	AESTDTC
AE	101	1	HEADACHE	MODERATE	N				1/21/2023
AE	101	2	FEVER	MILD	N				1/22/2023
AE	101	3	BACK PAIN	MILD	N				1/24/2023

Subject Visits (SV)

- Advise to add SVREASOC, SVCNTMOD, SVEPCHGI as mentioned by FDA and SVPRESP and SVOCCUR.
- Use def:IsNonStandard = "Yes"
- Explain the conformance warnings/errors in SDRG

DOMAIN	USUBJID	VISITNUM	VISIT	SVPRESP	SVOCCUR	SVREASOC	SVCNTMOD	SVEPCHGI	SVSTDTC	SVENTDTC
SV	101	1	SCREEN	Y	Y		IN PERSON		2020-02-13	2020-02-18
SV	101	2	DAY 1	Y	Y		IN PERSON		2020-02-19	2020-02-19
SV	101	3	WEEK 1	Y	N	CLINIC CLOSED				
SV	101	4	WEEK 2	Y	Y		TELEPHONE	Y	2020-03-20	2020-03-20

def:Origin Type and Source

- Origin Type indicates how the data for the variable originated
- Source identifies the party responsible for the data's origin

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
LBORRES VAP		Result or Finding in Original Units	text	8		Origin specified at Value Level Metadata
	LBTESTCD = "HCT" (Hematocrit) and LBSPEC = "BLOOD" and LBNAM = "LOCAL LAB"	Hematocrit	float	4		Collected (Source: Vendor) From Central lab (LB.LBNAM NE "LOCAL LAB")
	LBTESTCD = "HCT" (Hematocrit) and LBSPEC = "BLOOD" and LBNAM = "LOCAL LAB"	Hematocrit	float	4		Collected (Source: Investigator) From Local lab (LB.LBNAM="LOCAL LAB"). Note that the CRF page reference is given only for illustration purposes. The sample acrf.pdf does not include the local lab CRF page. Annotated CRF [1]

def:HasNoData

Dataset and variable level use. Comment required when used.

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
NV (STDTMIG 3.3) [No Data]	Nervous System Findings	FINDINGS	One record per finding per visit per subject	Tabulation	STUDYID, USUBJID, NVTESTCD, VISITNUM	Per protocol, electroencephalograms are only performed after such an event were to occur. No subjects within the trial had an occurrence of an electroencephalogram event. Therefore, no data exists for the NV dataset and as such was not submitted.	

Variable	Where Condition	Label / Description	Type	Role	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
VSSTAT [No Data]		Completion Status	text	Record Qualifier	8	Not Done • "NOT DONE" = "Not Done"	Collected (Source: Investigator) Annotated CRF [8] [9] [10] [11] [12] [13] All vital signs were performed as expected, so VSSTAT was never populated. The variable is included as it was possible to populate it in this study.

def:IsNonStandard

Used for datasets, variables, and codelists.

Subcategory for Disposition Event [Non Standard]

Permitted Value (Code)	Display Value (Decode)
STUDY TREATMENT	Study Treatment
STUDY PARTICIPATION	Study Participation

References: SDTMIG v3.3, SDTM v1.7, SDTMIG for Medical Devices v1.1, SDTMIG-AP v1.0, SDTM Metadata Submission Guidelines v2.0, Conformance Rules v1.1 for SDTMIG v3.2 and v3.3, SDTM and SDTMIG , Conformance Rules v2.0, Knowledge Base Article - Subject Visits and COVID-19, Guidance for Ongoing Studies Disrupted by COVID-19, Knowledge Base Article - How Should I Represent Whether, Physical Exam Was Performed In SDTM, Define-XML v2.1, Conformance Rules for Define-XML v2.1, CDISC Controlled Terminology, CDISC Library.

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