

Simplifying SAS® Clinical Standards Toolkit – Where’s the Easy Button?

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This poster represents CDISC SDTM 3.1.2. Other CDISC models in SAS Clinical Standards Toolkit 1.5 include ADaM 2.1, CRT-DDS 1.0, ODM 1.3.0, ODM 1.3.1, SDTM 3.1.1, SDTM 3.1.3, and SEND 3.0

Framework

Framework Macros
SAS macros specific to managing framework and standard metadata. Used to initiate new standards and contains **cross-standard** validation macros.

Name
cdt_createds.sas
cdt_createdfromtemplate.sas
cdt_createemptytables.sas
cdt_createstudyfromstandard.sas
cdt_createstandardfromstandard.sas
cdt_deleteproperties.sas
cdt_getregisterstandards.sas
cdt_getstandardmetadata.sas
cdt_getstandardreferences.sas
cdt_getstandardtypes.sas
cdt_getstatics.sas
cdt_insertstandardreferences.sas
cdt_registerstandard.sas
cdt_getproperties.sas
cdt_getstandardproperties.sas
cdt_getstandardversiondefault.sas
cdt_unregisterstandard.sas
cdt_unregisterproperties.sas
cdtcheck_column.sas
cdtcheck_columncompare.sas
cdtcheck_columnexists.sas

Framework Metadata
Contains metadata specific to the management of **cross-standard** metadata.

Name of Standard	Version of Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard
1	CDISC-ADAM	ADAM	2.1	CDISC ADAM V2.1	l_cdtRoot/standards/cdisc-adam-2.1				
2	CDISC-CRTDDS	CRT	1.0	CDISC CRT DDS V1.0	l_cdtRoot/standards/cdisc-crtdds-1.0				
3	CDISC-ODM	ODM	1.3.0	CDISC ODM V1.3.0	l_cdtRoot/standards/cdisc-odm-1.3.0				
4	CDISC-ODM	ODM	1.3.1	CDISC ODM V1.3.1	l_cdtRoot/standards/cdisc-odm-1.3.1				
5	CDISC-SDTM	SDTM	3.1.1	CDISC SDTM V3.1.1	l_cdtRoot/standards/cdisc-sdtm-3.1.1				
6	CDISC-SDTM	SDTM	3.1.2	CDISC SDTM V3.1.2 (includes Amendment 1 updates)	l_cdtRoot/standards/cdisc-sdtm-3.1.2				
7	CDISC-SEND	SEND	3.0	CDISC SEND V3.0	l_cdtRoot/standards/cdisc-send-3.0				
8	CDISC-TERMINOLOGY	CT	1.2	CDISC Terminology	l_cdtRoot/standards/cdisc-terminology-1.2				
9	CDISC-FRAMEWORK	CST		CDISC Framework	l_cdtRoot/standards/cdisc-framework-1.0				

Standard Metadata
contains information about the standard. This includes table, column and validation metadata. The “gold” standard used to verify **cross-study** metadata within a standard. Tables include reference_tables, reference_columns, validation_master, etc.

SASReference	Table Name	Table Label	Observation Class within Standard	(Relative) path to .xml file	File for .xml file
1	REFDATA	Adverse Events	Events	AdverseEvents	AdverseEvents SAS transport file
2	REFDATA	Clinical Events	Events	ClinicalEvents	ClinicalEvents SAS transport file
3	REFDATA	Concomitant Medications	Events	ConcomitantMedications	ConcomitantMedications SAS transport file
4	REFDATA	Comments	Events	Comments	Comments SAS transport file
5	REFDATA	Drug Accountability	Events	DrugAccountability	DrugAccountability SAS transport file
6	REFDATA	Findings	Events	Findings	Findings SAS transport file

SASReference	Table Name	Column Name	Column Description	Column Code	Column Type	Column Length	Display Format	SAS Data Type	SAS Format/Label	Column Properties
1	REFDATA	AE	STUDYID	Study Identifier	1	C		text		Ref
2	REFDATA	AE	DOMAIN	Domain Abbreviation	2	C		text		Ref
3	REFDATA	AE	SEQUENCE	Sequence Number	3	C		text		Ref
4	REFDATA	AE	EVENT	Event	4	C		text		Ref
5	REFDATA	AE	REASON	Reason for Event	5	C		text		Ref
6	REFDATA	AE	OUTCOME	Outcome	6	C		text		Ref

Validation check identifier	Standard	Source of check	Record identifier used by check	Severity of check	Category of check	SAS macro module name	Check should use source metadata	Domain/data sets to which check applies
1	SDTM001	CDISC-SDTM	WebSDM	Warning	Metadata	cdtcheck_metadata	Y	JALL
2	SDTM002	CDISC-SDTM	SAS	Error	Metadata	cdtcheck_metadata	N	DM-DS-EX
3	SDTM003	CDISC-SDTM	SAS	Warning	Metadata	cdtcheck_metadata	Y	JALL
4	SDTM004	CDISC-SDTM	SAS	Note	Metadata	cdtcheck_metadata	Y	JALL
5	SDTM005	CDISC-SDTM	SAS	Warning	Metadata	cdtcheck_metadata	Y	JALL
6	SDTM006	CDISC-SDTM	SAS	Warning	Metadata	cdtcheck_metadata	Y	JALL

Standard Macros
Contains macros designed to handle **standard** specific implementation across one or more studies.

sdm_validate.sas
sdmcheckutil_recordlookup.sas
sdmutil_buildcheckdomainlist.sas
sdmutil_createformatsfromcrtds.sas
sdmutil_createsasdatafromcpt.sas
sdmutil_createsrcmetadatasfromcrtds.sas
sdmutil_createsrcmetadatasfromsaslib.sas
sdmutil_jso601.sas

Framework Standard
SASReferences
Dictionaries Study

Customer supplied
SAS Formats

MedDRA

NCI Controlled
Terminology

Controlled Terminology/Dictionaries

SASReferences
The “glue” that holds all of this together. The SASReferences data set supplies information and metadata. This information can be user supplied or derived from standard metadata.

Name of Standard	Version of Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard	CDISC Standard
1	CDISC-ADAM	ADAM	2.1	CDISC ADAM V2.1	l_cdtRoot/standards/cdisc-adam-2.1				
2	CDISC-CRTDDS	CRT	1.0	CDISC CRT DDS V1.0	l_cdtRoot/standards/cdisc-crtdds-1.0				
3	CDISC-ODM	ODM	1.3.0	CDISC ODM V1.3.0	l_cdtRoot/standards/cdisc-odm-1.3.0				
4	CDISC-ODM	ODM	1.3.1	CDISC ODM V1.3.1	l_cdtRoot/standards/cdisc-odm-1.3.1				
5	CDISC-SDTM	SDTM	3.1.1	CDISC SDTM V3.1.1	l_cdtRoot/standards/cdisc-sdtm-3.1.1				
6	CDISC-SDTM	SDTM	3.1.2	CDISC SDTM V3.1.2 (includes Amendment 1 updates)	l_cdtRoot/standards/cdisc-sdtm-3.1.2				
7	CDISC-SEND	SEND	3.0	CDISC SEND V3.0	l_cdtRoot/standards/cdisc-send-3.0				
8	CDISC-TERMINOLOGY	CT	1.2	CDISC Terminology	l_cdtRoot/standards/cdisc-terminology-1.2				
9	CDISC-FRAMEWORK	CST		CDISC Framework	l_cdtRoot/standards/cdisc-framework-1.0				

Study Metadata
Source_tables.sas7bdat
Source_columns.sas7bdat
Validation_control.sas7bdat

SASReference	Table Name	Table Label	Observation Class within Standard	(Relative) path to .xml file	File for .xml file
1	REFDATA	Adverse Events	Events	AdverseEvents	AdverseEvents SAS transport file
2	REFDATA	Clinical Events	Events	ClinicalEvents	ClinicalEvents SAS transport file
3	REFDATA	Concomitant Medications	Events	ConcomitantMedications	ConcomitantMedications SAS transport file
4	REFDATA	Comments	Events	Comments	Comments SAS transport file
5	REFDATA	Drug Accountability	Events	DrugAccountability	DrugAccountability SAS transport file
6	REFDATA	Findings	Events	Findings	Findings SAS transport file

SASReference	Table Name	Column Name	Column Description	Column Code	Column Type	Column Length	Display Format	SAS Data Type	SAS Format/Label	Column Properties
1	REFDATA	AE	STUDYID	Study Identifier	1	C		text		Ref
2	REFDATA	AE	DOMAIN	Domain Abbreviation	2	C		text		Ref
3	REFDATA	AE	SEQUENCE	Sequence Number	3	C		text		Ref
4	REFDATA	AE	EVENT	Event	4	C		text		Ref
5	REFDATA	AE	REASON	Reason for Event	5	C		text		Ref
6	REFDATA	AE	OUTCOME	Outcome	6	C		text		Ref

Validation check identifier	Standard	Source of check	Record identifier used by check	Severity of check	Category of check	SAS macro module name	Check should use source metadata	Domain/data sets to which check applies
1	SDTM001	CDISC-SDTM	WebSDM	Warning	Metadata	cdtcheck_metadata	Y	JALL
2	SDTM002	CDISC-SDTM	SAS	Error	Metadata	cdtcheck_metadata	N	DM-DS-EX
3	SDTM003	CDISC-SDTM	SAS	Warning	Metadata	cdtcheck_metadata	Y	JALL
4	SDTM004	CDISC-SDTM	SAS	Note	Metadata	cdtcheck_metadata	Y	JALL
5	SDTM005	CDISC-SDTM	SAS	Warning	Metadata	cdtcheck_metadata	Y	JALL
6	SDTM006	CDISC-SDTM	SAS	Warning	Metadata	cdtcheck_metadata	Y	JALL

Study Driver Programs
SAS supplied programs designed to submit processes, run validations, and create output.

create_formatsfromcrtds.sas
create_sasdatafromcpt.sas
create_sourcemetadatas.sas
cdt_metadatasreport.sas
cdt_report.sas
validate_data.sas

Study Data
Comprised of SDTM 3.1.2 domains containing study data.

ae.sas7bdat
ce.sas7bdat
cm.sas7bdat
co.sas7bdat
da.sas7bdat
dm.sas7bdat
ds.sas7bdat
dv.sas7bdat
eg.sas7bdat
ex.sas7bdat

Controlled Terminology Dictionaries

- Comprised of Controlled Terminology as supplied by National Cancer Institute. Provided and implemented as a unique standard.
- MedDRA customer supplied and not provided.
- Any customer supplied controlled terminology or coding dictionaries.

Driver
Programs

Dataset	Description	Structure	Purpose	Keys	Location
AE	Adverse Events	Events - One record per adverse event per subject	Tabulation	STUDYID USUBID AEDECOD AESTDTC	Adverse Events SAS transport file
CE	Clinical Events	Events - One record per event per subject	Tabulation	STUDYID USUBID CETERM CESTDTC	Clinical Events SAS transport file
CM	Concomitant Medications	Interventions - One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID USUBID CMTRT CMSTDTC	Concomitant Medications SAS transport file
CO	Comments	Special Purpose Domains - One record per comment per subject	Tabulation	STUDYID USUBID COSEQ	Comments SAS transport file
DA	Drug Accountability	Findings - One record per drug accountability finding per subject	Tabulation	STUDYID USUBID DATESTDTC DADTC	Drug Accountability SAS transport file

CREATE_CRDTS_DEFINE_PDF

Dataset	Description	Class	Structure	Purpose	Keys	Location
AE	Adverse Events	Events	One record per adverse event per subject	Tabulation	STUDYID USUBID AEDECOD AESTDTC	Adverse Events SAS transport file
CE	Clinical Events	Events	One record per event per subject	Tabulation	STUDYID USUBID CETERM CESTDTC	Clinical Events SAS transport file
CM	Concomitant Medications	Interventions	One record per recorded medication occurrence or constant-dosing interval per subject	Tabulation	STUDYID USUBID CMTRT CMSTDTC	Concomitant Medications SAS transport file

SAS Clinical Standards Toolkit 1.5 is designed to run stand-alone with Base SAS. The user interface is SAS Clinical Data Integration. SAS Clinical Standards Toolkit will also run on SAS Drug Development 4.1 and the current release of JMP® Clinical.



Check Invocation	Seq #	Source Data	Result Identifier	Message	Severity	Problem Detected?	Actual Value	Keys
1	1	SDTM001 SUPPAAE	CST005	Data set not found in reference standard - compliance not assessed	Warning	Check incomplete		

Result Identifier	Validation check identifier	Unique invocation of result	Sequence number within results	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=not, 1=yes)	Process status (0=not, 1=aborted)
22	SDTM001	SDTM001	1	1 SRCDATA SUPPAAE	Variable (DVAR) appears in dataset but is not in SDTM standard	Warning	1	0
23	SDTM001	SDTM001	2	2 SRCDATA SUPPAAE	Variable (DVAR) appears in dataset but is not in SDTM standard	Warning	1	0
24	SDTM001	SDTM001	3	3 SRCDATA SUPPAAE	Variable (DVAR) appears in dataset but is not in SDTM standard	Warning	1	0
25	SDTM001	SDTM001	4	4 SRCDATA SUPPAAE	Variable (DVAR) appears in dataset but is not in SDTM standard	Warning	1	0

Validation Check Identifier	Version of Standard	Source of Check	Record Identifier used by Check Source	Ratio Description from Checksource	Severity of Check	Domains/Data Sets to which Check Applies	Columns to which Check Applies
SDTM0001	***	WebSDM	IR5000	Identifies domain table that has zero rows and therefore contains no data	Warning	JALL	
SDTM0002	***	SAS	SAS0017	A load of data into JANUS requires that the DM, DS and EX domains be submitted for each study to be loaded.	Error	DM-DS-EX	
SDTM0003	***	SAS	SAS0018	WebSDM and the SDTM model require only the DM domain be present.	Error	DM	
SDTM0004	***	SAS	SAS0033	Source metadata includes domain data set not found in reference metadata	Note	JALL	
SDTM0005	***	SAS	SAS0034	Custom domain data set does not adhere to specification naming guidelines	Note	JALL	