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SAS® Clinical Standards Toolkit 1.4

Getting Started

SAS® Documentation

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SAS® Clinical Standards Toolkit 1.4: Getting Started

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About This Book

Audience

The SAS Clinical Standards Toolkit and this book are designed for SAS programmers in the clinical research industry. Programmers must have a good understanding of the SAS macro language and must also be knowledgeable of evolving industry data standards, such as the Clinical Data Interchange Standards Consortium (CDISC).

Requirements

This book does not attempt to provide instruction to install the SAS Clinical Standards Toolkit. It is assumed that the SAS Clinical Standards Toolkit has been successfully installed by a SAS Administrator and that the installation has been verified to have been installed correctly and to be properly functioning.

Recommended Reading

Here is the recommended reading list:

- *SAS Clinical Standards Toolkit 1.4: User's Guide*

  This book provides more comprehensive information about the SAS Clinical Standards Toolkit.

- *SAS Clinical Standards Toolkit 1.4: Installation Qualification*

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Chapter 1

Introduction to the SAS Clinical Standards Toolkit

Key SAS Clinical Standards Toolkit Functionality

This book provides a brief introduction to the SAS Clinical Standards Toolkit. The SAS Clinical Standards Toolkit serves two primary purposes:

- Provide SAS implementations, based in SAS, of evolving clinical data standards.
- Provide a framework that exploits these standards to meet common clinical research analysis and submission requirements.

Through the Clinical Standards Toolkit 1.4 release, the SAS Clinical Standards Toolkit supports only standards developed by the Clinical Data Interchange Standards Consortium (CDISC). However, there is nothing in the product design that limits support of other standards, and it is anticipated that both current users and future SAS Clinical Standards Toolkit releases will support non-CDISC clinically-related standards.

The SAS Clinical Standards Toolkit is an open-source solution. Most of the code is either Base SAS or SAS macro code; for XML-based standards some JAVA and XSLT code is used. The SAS Clinical Standards Toolkit is a SAS solution for SAS users.

Given that study design, data collection, and analysis and submission requirements of each research protocol are unique, and that the SAS Clinical Standards Toolkit provides libraries of open-source SAS macros and code, user customization is expected and encouraged.

The SAS Clinical Standards Toolkit File Roadmap

The SAS Clinical Standards Toolkit files can be aggregated into three primary groups:

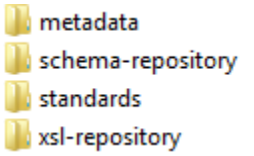
- the SAS Clinical Standards Toolkit Global Library
- SAS program files (!sasroot)

- Clinical study files

The primary function of the SAS Clinical Standards Toolkit Global Library is to provide the metadata that defines each supported Clinical Standards Toolkit standard. This location is specified during product installation and can be subsequently moved to another location. By default, on Microsoft Windows, this location is set to `c:\cstGlobalLibrary`.

Here are the top-level subfolders:

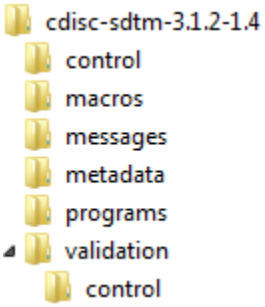
Figure 1.1 *Global Library Top Folder Hierarchy*



The metadata folder contains key metadata about all supported standards and can be updated with each new product release. The metadata folder can also be updated each time you elect to register a new standard or version of a standard. The schema-repository and xsl-repository folders support XML-based standards (such as CDISC-ODM and CDISC-CRTDDS). The standards folder contains a subfolder hierarchy for each supported standard.

This folder hierarchy illustrates the types of metadata supporting the CDISC SDTM 3.1.2 standard:

Figure 1.2 *Global Library Folder Hierarchy, CDISC SDTM 3.1.2*



The **control** folder contains data sets that provide general metadata about the standard. The **macros** folder contains standard-specific SAS macros that are included in the SAS autocall path when working with that standard. The **messages** folder contains standard-specific messages used in reporting or process results. The **metadata** folder contains the "gold-standard" definition of the standard as interpreted and implemented by who registered the standard. The **programs** folder contains programs and property files supporting general use of the standard. The **validation** folder and the **control** folder contain validation check metadata for those standards supporting validation of standard domains or data sets.

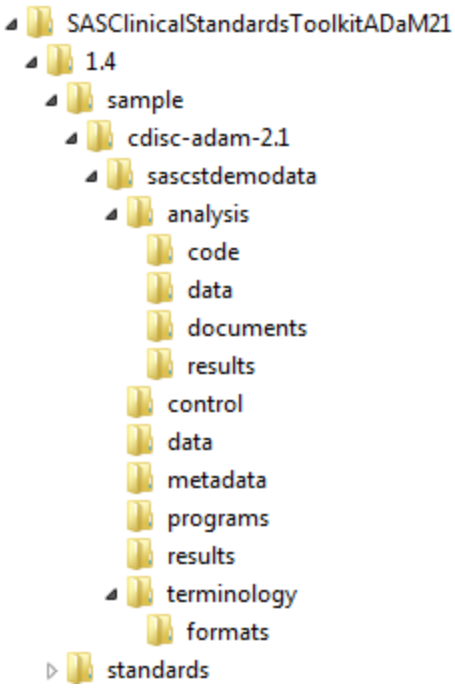
Installation of the SAS Clinical Standards Toolkit places files in the !sasroot tree for both the common SAS Clinical Standards Toolkit framework files and for each supported standard. The generic (cross-standard or standard-independent) framework SAS macros are installed to `!sasroot/cstframework/sasmacros` (Microsoft Windows). The SAS config file has been altered when the SAS Clinical Standards Toolkit was installed to include this folder, by default, in the SASautos path, meaning

that the framework macros are available to you whenever and however you start SAS referencing the default config file.

Within each standard subfolder hierarchy, there is a sample folder and a standards folder. The standards folder is equivalent to the files included in the Global Library and discussed previously. The sample folder hierarchy contains the set of files that represent a sample implementation of the specific standard, sample study data sets, and sample programs and results that illustrate the SAS Clinical Standards Toolkit functionality.

Here is the CDSIC ADaM 2.1 sample folder hierarchy:

Figure 1.3 *!sasroot Folder Hierarchy for CDISC ADaM*



This standard-specific folder hierarchy might be different for different standards. For example, the CDISC ADaM analysis folder and subfolders are unique to ADaM. The !sasroot location of these files merely provides a location for the sample SAS implementation. Your study files might be located anywhere reachable by SAS and need not conform to the folder naming convention illustrated here.

Key SAS Clinical Standards Toolkit Components

Framework and standard-specific SAS macros, as described above, provide the foundation for the SAS Clinical Standards Toolkit functionality. Three other SAS Clinical Standards Toolkit components are also noteworthy:

- driver modules
- properties
- SASReferences data set

The SAS Clinical Standards Toolkit provides a set of driver modules (non-macro SAS code) that illustrate all of the basic Toolkit functions using sample data supplied by SAS. These drivers can serve as templates for the Toolkit processes you want to develop.

These drivers might be submitted as batch or interactive processes. They can be found in the programs subfolder for each standard (for the relative location of this folder, see Figure 1.3 on page 3). For a more complete description of what these drivers do, see "Using the SAS Clinical Standards Toolkit" on page 5.

The SAS Clinical Standards Toolkit also provides a series of framework and standard-specific properties files (such as initialization, validation, and report properties files). You can use these files to both define global macro variables and to set their default values. These typically can be found in the same folders as the driver modules. Use of these property files is optional but recommended, and you can add your own global macro variables as needed.

Perhaps the single most important file used by the SAS Clinical Standards Toolkit is the SASReferences data set. The SASReferences data set captures all the input and output file library and file references associated with any given process. Here is a sample:

Figure 1.4 *Sample SASReferences Data Set (CDISC SDTM 3.1.2 Validation Process)*

	standard	standardversion	type	subtype	SASref	reftype	path	order	memname
1	CST-FRAMEWORK	1.2	messages		messages	libref		1	
2	CDISC-SDTM	3.1.2	autocall		sdtmauto	fileref		1	
3	CDISC-SDTM	3.1.2	control	reference	cntl_s	libref	C:\Local\Temp\SAS Files_TD4444_D72672_	1	sasreferences.sas7bdat
4	CDISC-SDTM	3.1.2	control	validation	cntl_v	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/control	2	validation_control.sas7bdat
5	CDISC-SDTM	3.1.2	fmtsearch		srcfmt	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/terminology/formats	1	formats.sas7bcat
6	CDISC-SDTM	3.1.2	messages		sdtmmsg	libref		2	
7	CDISC-SDTM	3.1.2	properties	initialize	inprop	fileref		1	initialize.properties
8	CDISC-SDTM	3.1.2	properties	validation	valprop	fileref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/programs	2	validation.properties
9	CDISC-SDTM	3.1.2	referencecontrol	validation	refcntl	libref			
10	CDISC-SDTM	3.1.2	referencecterm		ctref	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/terminology/coding-dictionaries		meddra.sas7bdat
11	CDISC-SDTM	3.1.2	referencemetadata	table	refmeta	libref			
12	CDISC-SDTM	3.1.2	referencemetadata	column	refmeta	libref			
13	CDISC-SDTM	3.1.2	results	validationmetrics	results	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/results		validation_metrics.sas7bdat
14	CDISC-SDTM	3.1.2	results	validationresults	results	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/results		validation_results.sas7bdat
15	CDISC-SDTM	3.1.2	sourcedata		srcdata	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/data		
16	CDISC-SDTM	3.1.2	sourcemetadata	column	srcmeta	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/metadata		source_columns.sas7bdat
17	CDISC-SDTM	3.1.2	sourcemetadata	table	srcmeta	libref	!sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata/metadata		source_tables.sas7bdat
18	CDISC-TERMINOLOGY	NCI_THESAURUS	fmtsearch		cstfmt	libref	c:/cstGlobalLibrary/standards/cdisc-terminology-1.4/cdisc-sdtm/201104/formats	1	cterms.sas7bcat

Here are some general observations about the sample SASReferences data set shown above:

- The **type** and **subtype** values are used by the SAS Clinical Standards Toolkit code to find the fileref or libref associated with a particular input or output file type.
- The SASref can be any user-defined value.
- An empty path tells the SAS Clinical Standards Toolkit to look for the default value from the standard-specific metadata in the Global Library (usually a Global Library location).

A complete discussion of the SASReferences data set is provided in Chapter 5, "SASReferences File," of the *SAS Clinical Standards Toolkit 1.4: User's Guide*. The SAS Clinical Standards Toolkit defines a standard SASReferences data set for each supported standard (found in **`<global library>/standards/<standard>/control`**).

Using the SAS Clinical Standards Toolkit

The SAS Clinical Standards Toolkit Global Library contains the SAS metadata definition of all supported standards. This metadata definition, defined primarily as the reference_tables and reference_columns data sets, can be used as defined. The metadata definition also can be modified or used as a template to build your own SAS representation of the CDISC standards supplied by SAS or your own customized standard.

Sample driver modules are provided with each supported standard. These modules can be copied and modified to reflect your own data and metadata sources and the target location for any SAS process output. These drivers all follow the same general process workflow:

- Set any process global macro variable values.
- Define a root path for input and output files (unnecessary if you do not use relative paths and you specify explicit paths).
- Create or reference a SASReferences data set that defines all input/output files.
- Call the cstutil_processsetup() macro that confirms a valid SASReferences structure, allocates any SAS librefs and filerefs, set the process-specific macro autocall and format search paths.
- Call the primary macro of interest (such as validation or define creation macro).
- (Optional) Perform any session cleanup.

For a more complete description of what a driver module does, see “Running a Validation Process” in Chapter 6, “Validation,” of the *SAS Clinical Standards Toolkit 1.4: User's Guide*.

Chapter 2

Sample Scenarios

Validating the CDISC ADaM Data Sets

Assumption

You have a library of CDISC ADaM SAS data sets (for purposes of this example, derived from a library of CDISC SDTM 3.1.2 domains). Derivation of ADaM analysis files from SDTM domains is not a supported function in the SAS Clinical Standards Toolkit. Products such as SAS Clinical Data Integration can be used to create such mapping processes and transformation processes.

Location of ADaM-Specific Driver Modules

The ADaM-specific driver modules are located here:

```
!sasroot/../../SASClinicalStandardsToolkitADaM21/1.4/sample/
cdisc-adam-2.1/sascstdemodata/programs
```

Step 1: Derive Metadata About Your Source Data

Before you can validate your ADaM data sets, you must derive a set of metadata that describes your library of analysis data sets. In the SAS Clinical Standards Toolkit, the metadata that describes your study data sets and columns is generally referred to as "source metadata." To help derive this metadata, the SAS Clinical Standards Toolkit provides a sample driver module (create_sourcemetadata.sas) that calls the SAS macro adamutil_createsrcmetafromsaslib.sas found in the **`<global library>/standards/cdisc-adam-2.1-1.4/macros`** folder. This macro uses Base SAS metadata (proc contents output) and reference metadata (supplied by SAS) describing the CDISC ADaM standard to initialize the source metadata. You might find it necessary to augment or modify this approach based on other metadata you have available or other processes that you adopt.

Step 2: Build Your Own Driver Module

The sample driver that can be run to demonstrate the ADaM validation process is validate_data.sas. Use this driver as a sample to build your own driver module, specifying the locations of source data and metadata. Take note of the SASReferences data set created in the validate_data driver. It references both SDTM and ADaM data and metadata as well as ADaM controlled terminology. Reference to the SDTM metadata supports comparison of ADaM column metadata with SDTM column metadata for those columns derived directly from SDTM. (See "Assumption" on page 7.)

Step 3: Submit the Modified Driver Module

The SAS Clinical Standards Toolkit validation processes generally create two types of output data sets: validation results and validation metrics. The names and locations of these SAS data sets depend on your SASReferences specifications for results management.

Here is a display that illustrates a sample Results data set produced by the validation process:

Figure 2.1 *Partial Sample Results Data Set (CDISC ADaM 2.1 Validation Process)*

resultid	checkid	seqno	srcdata	message	resultseverity	resultflag	actual	keyvalues
CST0100	ADAM0001	1	SRCDATA.ADSL	No errors detected in SRCDATA.ADSL	Info	0		
CST0100	ADAM0048	1	SRCDATA.ADSL	No errors detected in source data	Info	0		
ADAM0053	ADAM0053	1	SRCDATA.ADAE	The values of USUBJID are not present in SDTM.DM	Error	1	STUDYID=SASCSTDEMODATA ,USUBJID=S999P999	USUBJID=S999P999, AETERM=, AESTDY=.
ADAM0053	ADAM0053	2	SRCDATA.ADQS	The values of USUBJID are not present in SDTM.DM	Error	1	STUDYID=SASCSTDEMODATA ,USUBJID=S999P999	USUBJID=S999P999, PARAM=.
ADAM0053	ADAM0053	3	SRCDATA.ADSL	The values of USUBJID are not present in SDTM.DM	Error	1	STUDYID=SASCSTDEMODATA ,USUBJID=S999P999	USUBJID=S999P999
ADAM0054	ADAM0054	1	SRCDATA.ADSL	Within ADSL there is more than one record for a unique value of USUBJID	Error	1	keys=USUBJID	USUBJID=S999P999
ADAM0061	ADAM0061	1	ADSL.TRTSDT+TRTSDTM	SDTM.EX is present and neither TRTSDT or TRTSDTM are present	Error	1		
ADAM0069	ADAM0069	1	SRCDATA.ADSL	A variable with a prefix of TR and containing AG is present and a variable with the same root with a suffix of N is not present	Error	1	TRAG1N	
CST0021	ADAM0102	1	CSTCHECK_COLUMN VARLIST	Table SRCDATA.ADQS does not contain APERIOD column(s)	Warning: Check not run	-1		
ADAM0102	ADAM0102	108	SRCDATA.ADAE	For every unique xx value of APERIOD in BDS datasets, there is not a ADSL variable TRTxxP	Error	1		
ADAM0138	ADAM0138	1	SRCDATA.ADAE	CRITy is populated and CRITyFL is not populated	Error	1	CRIT1=2,CRIT1FL=	USUBJID=S999P999, AETERM=HEARTBURN-LIKE DYSPEPSIA, AESTDY=3
ADAM0143	ADAM0143	2	SRCDATA.ADQS	PARAMCD has more than 8 characters in length	Error	1	PARAMCD=leucocytes	USUBJID=S999P999, PARAM=lcount

The validation results shown above are representative of the range of validation results one might see, from no reported errors (such as ADAM0001) to multiple errors detected (such as ADAM0053) to an inability to run a specific check because of a lack of data or metadata (such as ADAM0102). The validation metrics output data set attempts to summarize the validation results and provide a denominator for each check.

For a more thorough discussion of how validation is performed, see Chapter 6, "Validation," of the *SAS Clinical Standards Toolkit 1.4: User's Guide*.

Creating a define.xml File from CDISC SDTM 3.1.2 Source Data

Overview

The SAS Clinical Standards Toolkit supports the currently published CDISC CRTDDS 1.0 (define.xml) submission standard, which supports representation of the CDISC SDTM 3.1.1/3.1.2 tabulation data sets in metadata form. (Future releases are expected to support updates to the CRTDDS standard that support representation of CDISC ADaM analysis data sets.)

Assumption

You have a library of CDISC SDTM SAS data sets (which are not read by this process) from which a set of metadata (in the form of source_study, source_tables, and source_columns data sets) has been created. This metadata must contain the expected, correctly typed columns created for the sample study supplied by SAS.

Location of the CRTDDS-Specific Driver Modules

```
!sasroot/../../SASClinicalStandardsToolkitCRTDDS10/1.4/sample/
cdisc-crtdds-1.0/programs
```

Step 1: Extract Available SDTM Metadata into CRTDDS Metadata Files

The initial task is to extract available SDTM metadata into CRTDDS metadata files. The SAS representation of CRTDDS involves 39 data sets, but only 12 of these derive directly from SDTM. The sample driver create_crtdds_from_sdtm.sas, modified to point to your specific SDTM study, should be submitted to extract the SDTM metadata. This process builds all 39 data sets but populates only 12 (depending on your study).

Note: The key input (source) files are the SDTM metadata files (source_study, source_tables, and source_columns), not the SDTM domain data sets.

Step 2: (Optional) Populate the Remaining CRTDDS Data Sets

None of the remaining 39 data sets must be populated to create a viable define.xml file using the SAS Clinical Standards Toolkit. However, Value Level metadata and annotated CRF page references are needed to make the define.xml useful for review and

analysis. The next step is to populate the remaining CRTDDS data sets using your own metadata sources and methods.

For more discussion of this step, see FAQ "How Do I Add Supplemental Data (Not Directly Derivable from Other Standards Such as CDISC SDTM) Used to Create a define.xml File?" on page 20. Also, for a discussion of the data sets most critical for successful derivation of the define.xml file, see "Special Topic: A Round Trip Exercise Involving the CDISC CRT-DDS Standard: Importing and Exporting the define.xml File" in Chapter 7 of the *SAS Clinical Standards Toolkit 1.4: User's Guide*.

Note: If you do not have additional metadata, you can skip this step.

Step 3: Create the define.xml File

At this point, all available content for the define.xml file has been captured in the SAS representation (39 data sets) of the CDISC CRTDDS standard. The SAS Clinical Standards Toolkit provides a sample driver module, create_crtdds_define.sas. This module builds and validates the define.xml file. Now, submit the create_crtdds_define.sas driver.

Within this driver, the call to the primary task macro (located in **`<global library>/standards/cdisc-crtdds-1.0-1.4/macros`**):

```
%crtdds_write(_cstCreateDisplayStyleSheet=1);
```

requests that the default style sheet supplied by SAS (source: CDISC) be copied to the folder location containing the generated define.xml file.

Here is a portion of the define.xml file, as rendered by this default style sheet. Hyperlinks among tables, columns, codelists, and other file elements are provided.

Figure 2.2 *Partial Sample define.xml File (as Rendered by the Default Style Sheet)*

Datasets for Study study1

Dataset	Description	Structure	Purpose	Keys	Location
AE	Adverse Events	Events - One record per adverse event per subject	Tabulation	STUDYID USUBJID AEDECOD AESTDTC	Adverse Events SAS transport file
CE	Clinical Events	Events - One record per event per subject	Tabulation	STUDYID USUBJID 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 USUBJID CMTRT CMSTDTC	Concomitant Medications SAS transport file

Step 4: Validate the Generated define.xml File

The final step is to validate the generated define.xml file. As discussed in Chapter 7, "XML-Based Standards", of the *SAS Clinical Standards Toolkit 1.4: User's Guide*, the SAS Clinical Standards Toolkit offers two complementary validation methodologies.

- The first methodology relies on the definition of a master set of validation checks as described in the previous example. This method uses SAS files and SAS code to validate the SAS representation of the standard. Example checks include the assessment of foreign key relationships across data sets and value conformance to a set of expected values.
- The second methodology involves verification that the XML file is valid structurally and syntactically according to the XML schema.

The final task in the sample create_crtdds_define.sas driver is to call the crtdds_xmlvalidate() macro to perform the schema validation.

Here is part of the Results data set:

Figure 2.3 *Partial Sample Results Data Set (CDISC CRTDDS 1.0 Create Process)*

	resultid	seqno	srcdata	message	resultseverity
5	CST0200	1	CRTDDS_WRITE	PROCESS STANDARD: CDISC-CRTDDS	Info
6	CST0200	2	CRTDDS_WRITE	PROCESS STANDARDVERSION: 1.0	Info
7	CST0200	3	CRTDDS_WRITE	PROCESS DRIVER: CREATE_CRTDDS_DEFINE	Info
8	CST0200	4	CRTDDS_WRITE	PROCESS DATE: 2011-08-19T17:47:23	Info
9	CST0200	5	CRTDDS_WRITE	PROCESS TYPE: CREATE CRTDDS DEFINE.XML	Info
10	CST0200	6	CRTDDS_WRITE	PROCESS SASREFERENCES: C:\Local\Temp\SAS Files_TD6216_D72672_/sasreferences	Info
11	CST0200	7	CRTDDS_WRITE	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitCRTDDS10/1.4/sample/cdisc-crtdds-1.0	Info
12	CST0200	8	CRTDDS_WRITE	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info
13	CST0200	9	CRTDDS_WRITE	PROCESS CSTVERSION: 1.4	Info
14	CST0122	1	CST_CREATETABLESFORDATASTANDARD	The tables were created for CDISC-CRTDDS 1.0 in library _cst9152	Info
36	CRT0010	1	CRTDDS_WRITE	The CRT-DDS file was created at C:\Program Files\SASHome\SASClinicalStandardsToolkitCRTDDS10\1.4\sample\cdisc-crtdds-1.0\sourcexml\define.xml	Info
37	CST0200	1	CRTDDS_XMLVALIDATE	Starting XML Validation	Info
38	CST0200	1	JAVA CHECK	No Java issues	Info
39	CRT0001	1	XML TRANSFORMER	Transform starting.	Info
56	CRT0001	18	XML TRANSFORMER	The document validated successfully	Info
57	CRT0115	1	CRTDDS_XMLVALIDATE	No errors were found in the CRT-DDS file.	Info

This Results data set provides process information and the location of the generated define.xml file. The Results data set confirms that no problems were found with the file following validation of the file. Note that the SAS validation of file content was not run in this example.

Importing and Validating a CDISC ODM XML File

Overview

The SAS Clinical Standards Toolkit supports the currently published CDISC ODM 1.3.0 standard, which facilitates the archival and interchange of the metadata and data for clinical research. The SAS Clinical Standards Toolkit can import an ODM XML file into a SAS data set representation of the ODM 1.3.0 standard.

Assumption

You have an ODM XML file (which is not created by this process) from which a SAS representation (in the form of 66 SAS data sets) has to be created.

Location of the ODM-Specific Driver Modules

```
!sasroot/../../SASClinicalStandardsToolkitODM130/1.4/sample/
cdisc-odm-1.3.0/programs
```

Step 1: Validate the ODM XML File against the ODM 1.3.0 XML Schema

The initial task is to validate the ODM XML file against the ODM 1.3.0 XML schema. This involves verification that the ODM XML file is valid structurally and syntactically according to the XML schema. The sample driver create_sasodm_fromxml.sas, modified to point to your specific ODM XML file, contains a call to the odm_xmlvalidate macro to perform this schema validation task.

Here is part of the Results data set:

Figure 2.4 *Partial Sample Results Data Set (CDISC ODM 1.3.0 Schema Validation Process)*

	resultid	seqno	srcdata	message	resultseverity
5	CST0200	1	ODM_XMLVALIDATE	PROCESS STANDARD: CDISC-ODM	Info
6	CST0200	2	ODM_XMLVALIDATE	PROCESS STANDARDVERSION: 1.3.0	Info
7	CST0200	3	ODM_XMLVALIDATE	PROCESS DRIVER: CREATE_ODMXML	Info
8	CST0200	4	ODM_XMLVALIDATE	PROCESS DATE: 2011-08-04T16:23:20	Info
9	CST0200	5	ODM_XMLVALIDATE	PROCESS TYPE: VALIDATE ODM XML	Info
10	CST0200	6	ODM_XMLVALIDATE	PROCESS SASREFERENCES: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7480_L72371_/_cstsasrefs.sas7bdat	Info
11	CST0200	7	ODM_XMLVALIDATE	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0	Info
12	CST0200	8	ODM_XMLVALIDATE	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info
13	CST0200	9	ODM_XMLVALIDATE	PROCESS CSTVERSION: 1.4	Info
14	CST0200	1	JAVA CHECK	No Java issues	Info
15	ODM0001	1	XML TRANSFORMER	Transform starting.	Info
16	ODM0001	2	XML TRANSFORMER	Using JRE: C:\PROGRA~2\Java\jre6	Info
17	ODM0001	3	XML TRANSFORMER PARAMETER	Import Or Export: EXPORT	Info
18	ODM0001	4	XML TRANSFORMER PARAMETER	Standards XML Path: C:/Program Files/SASHome/SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0/sourcexml/odm_sample.xml	Info
19	ODM0001	5	XML TRANSFORMER PARAMETER	Fail on Validation Error: false	Info
20	ODM0001	6	XML TRANSFORMER PARAMETER	Standard Name: CDISC-ODM	Info
21	ODM0001	7	XML TRANSFORMER PARAMETER	Standard Version: 1.3.0	Info
22	ODM0001	8	XML TRANSFORMER PARAMETER	Schema Repository Location: c:/cstGlobalLibrary/schema-repository	Info
23	ODM0001	9	XML TRANSFORMER PARAMETER	XSL Repository Location: null	Info
24	ODM0001	10	XML TRANSFORMER PARAMETER	Output Encoding: UTF-8	Info
25	ODM0001	11	XML TRANSFORMER PARAMETER	Log File Location: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7480_L72371_/_log4810	Info
26	ODM0001	12	XML TRANSFORMER PARAMETER	Header Comment Text: Produced from SAS data using the SAS Clinical Standards Toolkit	Info
27	ODM0001	13	XML TRANSFORMER PARAMETER	Is Validating XML: true	Info
28	ODM0001	14	XML TRANSFORMER PARAMETER	Creating Display Stylesheet: false	Info
29	ODM0001	15	XML TRANSFORMER PARAMETER	Custom Stylesheet: null	Info
30	ODM0001	16	XML TRANSFORMER PARAMETER	Custom Stylesheet Output Shortname: null	Info
31	ODM0001	17	XML TRANSFORMER PARAMETER	Creating Output Folders: true	Info
32	ODM0001	18	XML TRANSFORMER	The document validated successfully	Info
33	ODM0115	1	ODM_XMLVALIDATE	No errors were found in the ODM file.	Info

This Results data set provides process information, the location of the ODM XML file, and confirms that the ODM XML file validated successfully.

Here is a Results data set that shows schema validation issues with an ODM XML file:

Figure 2.5 *Partial Sample Results Data Set (CDISC ODM 1.3.0 Schema Validation Process) – Invalid ODM XML File*

	resultid	seqno	srcdata	message	resultseverity
32	ODM0003	18	XML VALIDATION	(Line 104/Column 152) cvc-enumeration-valid: Value 'N' is not facet-valid with respect to enumeration '[Yes, No]'. It must be a value from the enumeration.	Error
33	ODM0003	19	XML VALIDATION	(Line 104/Column 152) cvc-attribute.3: The value 'N' of attribute 'Repeating' on element 'ItemGroupDef' is not valid with respect to its type, 'YesOrNo'.	Error
34	ODM0003	20	XML VALIDATION	(Line 512/Column 15) The element type "ItemDef" must be terminated by the matching end-tag "</ItemDef>".	Error
35	ODM0003	21	XML TRANSFORMER	The element type "ItemDef" must be terminated by the matching end-tag "</ItemDef>".	Error
36	ODM0011	1	ODM_XMLVALIDATE	Errors were reported in the generation of the ODM file.	Error

Running the odm_xmlvalidate macro is not required to be able to import an ODM XML file. However, importing an invalid ODM XML file can result in an incomplete import, because the odm_read macro ignores elements and attributes in the ODM XML file that are not defined by the XML schema.

Step 2: Import the ODM XML File

The next step is to import the ODM XML file by calling the odm_read macro, which results in 66 SAS data sets describing the CDISC ODM 1.3.0 data model. The odm_read macro is called by the sample driver create_sasodm_fromxml.sas.

Here is the Results data set. It provides process information and the location of the imported ODM XML file. The Results data set also confirms that no problems were

found with the import. And, the Results data set shows that format catalogs and data sets have been created.

Figure 2.6 *Partial Sample Results Data Set (CDISC ODM 1.3.0 Read Process)*

	resultid	seqno	srcdata	message	resultseverity
5	CST0200	1	ODM_READ	PROCESS STANDARD: CDISC-ODM	Info
6	CST0200	2	ODM_READ	PROCESS STANDARDVERSION: 1.3.0	Info
7	CST0200	3	ODM_READ	PROCESS DRIVER: CREATE_SASODM_FROMXML	Info
8	CST0200	4	ODM_READ	PROCESS DATE: 2011-08-22T16:19:08	Info
9	CST0200	5	ODM_READ	PROCESS TYPE: FILEIO	Info
10	CST0200	6	ODM_READ	PROCESS SASREFERENCES: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7340_L72371_/_cstsasrefs.sas7bdat	Info
11	CST0200	7	ODM_READ	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0	Info
12	CST0200	8	ODM_READ	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info
13	CST0200	9	ODM_READ	PROCESS CSTVERSION: 1.4	Info
14	CST0200	1	JAVA CHECK	No Java issues	Info
15	ODM0013	1	ODM_READ	The ODM map file was read from the following location: C:\Program Files\SASHome\SASClinicalStandardsToolkitODM130\1.4\sample\cdisc-odm-1.3.0\referencexml\odm.map	Info
16	CST0200	2	ODM_READ	Destination library for format catalogs set to trgdata	Info
17	CST0200	3	CSTUTIL_BUILDFORMATSFROMXML	trgdata.ODMfmtcat_de catalog and data set created	Info
18	CST0200	4	CSTUTIL_BUILDFORMATSFROMXML	trgdata.ODMfmtcat_en catalog and data set created	Info
19	CST0200	5	CSTUTIL_BUILDFORMATSFROMXML	trgdata.ODMfmtcat_fr_CA catalog and data set created	Info
20	ODM0012	6	ODM_READ	The ODM file C:\Program Files\SASHome\SASClinicalStandardsToolkitODM130\1.4\sample\cdisc-odm-1.3.0\sourcexml\odm_sample.xml was read successfully.	Info

Step 3: Validate the SAS Representation of the ODM XML File

The final step in importing an ODM XML file is to validate the SAS representation of the ODM XML standard. In step 1, we had already validated the ODM XML file against the XML schema. The validation of the SAS representation of the ODM XML standard goes further than XML schema validation.

An example of a check that is part of the validation of SAS representation is the assessment of foreign key relationships across data sets. The SAS Clinical Standards Toolkit provides a sample driver program, validate_odm_data.sas, which validates the SAS representation of an ODM XML file.

Submit the modified driver module. The SAS Clinical Standards Toolkit validation processes generally create two output files: validation results and validation metrics. The names and locations of these SAS data sets depend on your SASReferences specifications for results management.

Here is an example of a Results data set produced by the validation process:

Figure 2.7 *Partial Sample Results Data Set (CDISC ODM 1.3.0 Validation Process)*

	resultid	seqno	srcdata	message	resultseverity	actual	keyvalues
197	ODM0110	1	SRCDATA.ITEMDATA (SRCDATA.ITEMDEFS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDATA	Error	ITEMOID=ID.AETERM	
198	ODM0110	2	SRCDATA.ITEMDATA (SRCDATA.ITEMDEFS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDATA	Error	ITEMOID=ID.AETERM	
199	CST0100	1	SRCDATA.ITEMDATA (SRCDATA.ITEMGROUPDATA)	No errors detected in source data	Info		
200	CST0100	1	SRCDATA.ITEMDATA (SRCDATA.MEASUREMENTUNITS)	No errors detected in source data	Info		
201	CST0100	1	SRCDATA.ITEMDATA (SRCDATA.SIGNATURE)	No errors detected in source data	Info		
202	ODM0110	1	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	CODELISTREF=CodeLists.OID.UNIT	FK_METADATAVERSION=MetaDataVersion.OID.1, OID=ItemDef.OID.LB.LBORRESU
203	ODM0110	2	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	CODELISTREF=CodeLists.OID.UNIT	FK_METADATAVERSION=MetaDataVersion.OID.1, OID=ItemDef.OID.LB.LBSTRESU
204	ODM0110	3	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	CODELISTREF=CodeLists.OID.LBTEST	FK_METADATAVERSION=MetaDataVersion.OID.1, OID=ItemDef.OID.LB.LBTEST
205	ODM0110	4	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	CODELISTREF=CodeLists.OID.UNIT	FK_METADATAVERSION=MetaDataVersion.OID.1, OID=ItemDef.OID.lnr.lborresu
206	CST0100	1	SRCDATA.ITEMDEFS (SRCDATA.METADATAVERSION)	No errors detected in source data	Info		

In this example there are several issues in the foreign key relations across data sets.

Chapter 3

Frequently Asked Questions

Global Library

Does It Matter Where the Global Library is Located?

No. On Microsoft Windows systems, the default location for the Global Library is `c:/cstGlobalLibrary`. This location is assumed (and referenced as <*global library*>) throughout this document. <*global library*> can point to any location that is accessible by SAS.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: For a summary of the cstGlobalLibrary, see “Global Standards Library” in Chapter 2, “Framework.”

How Do I Change the Location of the Global Library?

The value of the variable cstGlobalLibrary is set during installation of the SAS Clinical Standards Toolkit. If you want to change the location after installation, you must modify the framework autocall utility macro cstutil_setcstgroot to point to the new location that you have chosen.

Note: The SAS Clinical Standards Toolkit recognizes and uses only one Global Library at a time.

Process Results

How Do I See Process Results?

The default location for the results of a SAS Clinical Standards Toolkit process is set by the _cstResultsDS property in the framework initialize.properties file. By default, this is set to work._cstresults. Process results can be persisted, if the SASReferences data set has a type=results record.

Note: All SAS Clinical Standards Toolkit process Results data sets have the same structure and all columns have the same meaning.

Standards

How Do I Customize a Registered Standard?

The definition of each standard (and version of each standard) is done in the Global Library. A best practice recommendation is that you do not (permanently) modify the Global Library files, but instead modify copies of the files.

The files and metadata that constitute a standard vary from standard to standard. Use the files that define each standard, located in **<*global library*>/standards/<*standard*>**, as templates, adding your customizations. You can rename or otherwise introduce your own subfolders and files that constitute each standard. If you want to create your own version of an existing registered standard, review the information in the next question.

How Do I Register a New Standard (or a New Version for an Existing Standard)?

Use the SAS Clinical Standards Toolkit framework utility macro cst_registerstandard.sas to register a new standard. A new subfolder hierarchy is added to the **<*global library*>/standards/** location, and the **<*global library*>/metadata/standards.sas7bdat** data set is updated with metadata about the new standard. This metadata is provided in the form of two data sets, standards, and StandardSASReferences. These data sets are passed to the SAS Clinical Standards Toolkit as parameters in the call to the cst_registerstandard macro.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Maintenance Usage Scenarios" in Chapter 2, "Framework."

Does SAS Offer Updates for Previously Released Standards?

New production releases of the SAS Clinical Standards Toolkit routinely provide updates to previously released standards. For information about how these updates are provided, see "Does a New Version of the SAS Clinical Standards Toolkit Automatically Overwrite Files Installed with a Previous Version?" on page 24.

SAS also makes available a SAS support knowledge base focus area (**http://support.sas.com/rnd/base/cdisc/cst/index.html**) to communicate product information, references, and updates. Preproduction files are also available for download.

The SAS Clinical Standards Toolkit development team also supports the early adopter phase and works with development partners on future product releases.

Creating and Modifying Files

Should I Modify SAS Clinical Standards Toolkit Files Supplied by SAS If I Want to Test Changes or Make Permanent Changes to Any of Those Files?

A best practice recommendation is that you do not (permanently) modify framework autocall macros or Global Library files, but instead modify copies of the files. This allows seamless updates to those files supplied by SAS without concern about overwriting or losing your changes.

Note: The SAS Clinical Standards Toolkit provides an internal backup of standard-specific Global Library files supplied by SAS in the !sasroot standard-specific sample subfolders.

How Do I Modify a Sample Driver Program to Point to My Own Study Data?

Each sample driver module sets a &studyRootPath macro variable to point to the root path of the sample study SAS supplies for each standard. This macro enables you to point to your own study root path by resetting the value of this macro variable. You might instead prefer to use explicit paths in your SASReferences data set and not use &studyRootPath at all.

The sample drivers assume a study folder hierarchy like that of the sample study, but this hierarchy is not required. If you have another organization for your study, you might need to make other changes to the paths specified in your driver module.

How Do I Create the Required Study Metadata?

Each supported standard might define study metadata differently. The SAS representation of the 32 standard CDISC SDTM 3.1.2 domains differs from the SAS representation of the three types of tables supported in CDISC ADaM 2.1.

Most users have metadata about their studies in some form and file format other than that used by the SAS Clinical Standards Toolkit. You have to convert or map some of that metadata into the source_study, source_tables, and source_columns format specified in the sample study metadata folder (such as **`!sasroot/../../SASClinicalStandardsToolkitADaM21/1.4/sample/cdisc-adam-2.1/sascstdemodata/metadata`**). Some standards provide sample code that supports this task. For CDISC ADaM, look at the create_sourcemetadata.sas sample driver module as an example.

Note: The structure of the source metadata corresponds to the reference metadata for each standard as defined in the Global Library (such as **`<global library>/standards/cdisc-adam-2.1-1.4/metadata`** reference_tables and reference_columns data sets).

Can I Modify the Check Metadata Columns tableScope and columnScope to Match My Study?

Yes. The initial values are based on the sample data associated with each standard. Your study data almost certainly differs. For CDISC SDTM and CDISC ADaM, your domains and analysis data sets reflect your study protocol. Some checks might not apply to some of your domains because your implementation of that domain might deviate from other domains from the same class (such as Findings).

Be aware that tableScope and columnScope wildcarding is a convenience, and you can instead explicitly reference a specific table or column in any check invocation.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Validation Check Metadata: Validation Master" in Chapter 6, "Validation."

Can I Add My Own New Validation Checks for SDTM or ADaM?

Yes. You can add checks to any SAS Clinical Standards Toolkit standard that supports validation. Each check is defined as a set of metadata (in the validation_master data set found in the **`<global library>/standards/<standard>/validation/control`** folder) and a message to be used when an error is detected (in the messages data set found in the **`<global library>/standards/<standard>/messages`** folder).

For each new check, you must create the check metadata to conform to the validation_master template and an associated message to conform to the messages data set metadata structure.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: For more information about check metadata and the available SAS Clinical Standards Toolkit validation check macros, see Chapter 6, "Validation."

How Do I Use My Own Controlled Terminology?

The SAS Clinical Standards Toolkit permits the use of any set of controlled terminology or any coding dictionaries. Generally, controlled terminology is defined to the SAS Clinical Standards Toolkit as SAS format catalogs; coding dictionaries as SAS data sets. Either format is valid.

The SASReferences data set is used to document these format catalogs and coding dictionaries, and to facilitate run-time references to these reference input sources. In the SAS Clinical Standards Toolkit sample drivers, a SASReferences type=fmtsearch record points to each SAS format catalog (and allows specification of a reference order for like-named formats), and a type=referencecterm record points to each specific coding dictionary to be referenced. The format search path is set with the call to the cstutil_processsetup macro.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: For more information about using controlled terminology in validation processes, see "Special Topic: Using Alternative Controlled Terminologies" in Chapter 6, "Validation."

How Do I Point to My Company's Version of MedDRA?

The sample SDTM SASReferences data set offers an example of referencing the MedDRA dictionary. The type=referencecterm record points to a folder (which can be anywhere) that can contain a MedDRA data set (using any name).

The SDTM validation check (SDTM0451) supplied by SAS that compares AEDECOD to MedDRA preferred terms expects that the MedDRA data set contains the column PT_NAME. If your data set uses other column names, see "If I Disagree with or Choose to Modify the Codelogic of a Specific Validation Check, What Needs to Be Done?" on page 23.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Building a Validation Process" in Chapter 6, "Validation."

How Do I Use My Own Style Sheet with a SAS Clinical Standards Toolkit-Generated define.xml File?

The SAS Clinical Standards Toolkit uses the macro crtdds_write to create a define.xml file. This macro has the optional parameter _cstCreateDisplayStyleSheet that determines two things:

- whether the macro creates a style sheet in the same folder as the output define.xml file
- whether the macro creates a reference to that style sheet in the define.xml file

If you set this macro parameter to **`1`**, the macro looks in the supplied SASreferences file for a record with a type/subtype of **`referencexml/stylesheet`** and uses that file.

By default, the crtdds_write macro creates a style sheet reference in the define.xml file and copies a style sheet in the same folder as the define.xml file. This default style sheet, define1-0-0.xsl, is copied from the **`<global library>/standards/cdisc-crtdds-1.0/stylesheet`** folder and is identical to the style sheet that was originally made available by CDISC as part of the first release of the define.xml file.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Writing XML Files" in Chapter 7, "XML-Based Standards."

Can I Associate a Style Sheet with an ODM XML File Generated by the SAS Clinical Standards Toolkit?

Although it is not common to associate a style sheet with an ODM XML file, the SAS Clinical Standards Toolkit allows this. To do this, you must call the macro odm_write with macro parameter cstCreateDisplayStyleSheet=1 and also add a record to the SASreferences file with type/subtype of **`referencexml/stylesheet`** pointing to the style sheet to be used.

Note: SAS does not supply a default style sheet for ODM.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Module ODM V1.3.0 (Run Time)" in Appendix 3, "Macro Application Programming Interface."

How Do I Add Supplemental Data (Not Directly Derivable from Other Standards Such as CDISC SDTM) Used to Create a define.xml File?

When the SAS Clinical Standards Toolkit creates a define.xml file, it converts the information from a SAS data set representation of the CRT-DDS model into XML. For CDISC CRT-DDS 1.0, this means that 39 data sets (such as ItemDefs) are the source for creating the define.xml element and attribute structure. The content of these 39 data sets can be derived in part from other standards (such as CDISC SDTM).

You can directly maintain these 39 data sets so that you can add additional data that needs to be part of the define.xml. To be able to maintain these 39 data sets, you must be

familiar with the structure of these data sets and the relationships among these data sets. For example, to add Value Level Metadata to the define.xml, add rows to four data sets: itemdefs, valuelists, valuelistitemrefs, and itemvaluelistrefs.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See Appendix 9, "CRT-DDS 1.0 SAS Data Sets," and "Writing XML Files" in Chapter 7, "XML-Based Standards."

How Do I Create the Data Sets That Are Used to Create an ODM XML File?

When the SAS Clinical Standards Toolkit creates an ODM XML file, it converts the information from a SAS data set representation of the ODM model into XML. For CDISC ODM 1.3.0, this means that 66 data sets (such as ItemDefs) are the source for creating the ODM XML element and attribute structure.

You can directly maintain these 66 data sets so that you can add data that needs to be part of the ODM XML file. To be able to maintain these 66 data sets, you must be familiar with the structure of these data sets and the relationships among these data sets.

Normally, you would not use SAS to create an ODM XML file, because it is assumed that there is a workflow in which a data collection and management system exports metadata definitions and data content in the form of a transactional or snapshot ODM XML file. When SAS is used to create an ODM XML file, the initial SAS representation of the ODM model can be created by using one of the following methods:

- Call %cst_createTablesForDataStandard(_cstStandard=CDISC-ODM, _cstStandardVersion=1.3.0, _cstOutputLibrary=work); to build zero-observation SAS data sets.
- Call the %odm_read macro to import an ODM XML file that can serve as a template for the creation of the SAS representation of the ODM XML data model.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Writing XML Files" in Chapter 7, "XML-Based Standards."

How Do I Modify the autocall Path to Point to My Own Macros?

The SAS Clinical Standards Toolkit autocall path is set by default to **`SASAUTOS`**, which includes the SAS Clinical Standards Toolkit framework macros found (on Microsoft Windows) in **`!sasroot\cstframework\sasmacro`**.

A macro library is defined for each standard in the Global Library. (See "Where Do the Framework and Standard-Specific Macros Reside?" on page 23.) In the SASReferences data set, one or more records with type=autocall can be used to reset the SAS autocall path, where the order column specifies the order each macro library is to be referenced. You can use the same strategy to reference any user-defined macro libraries, even if those libraries are not associated with a specific standard.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See Chapter 5, "SASReferences File."

Do I Have to Create and Use a SASReferences Data Set for Any SAS Clinical Standards Toolkit Process That I Run?

No. However, the SAS Clinical Standards Toolkit has adopted this method to define and document the input and output file and library references, to build the macro autocall, and to format search paths for each SAS Clinical Standards Toolkit process. Although

you can perform all library and file allocations and set SAS system options yourself, it is highly recommended that you use the SASReferences approach.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See Chapter 5, "SASReferences File."

Do I Need to Use Properties Files to Define My Own Global Macro Variables?

No. However, doing so standardizes your approach to creating and documenting global macro variables.

Within the SAS Clinical Standards Toolkit, either of these two methods is always used to process properties files:

- adding a type=properties record to the SASReferences data set, which is then processed in the routine call to cstutil_processsetup()
- directly calling cst_setproperties()

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Properties" in Chapter 3, "Metadata File Descriptions."

Validation Process

Do I Have to Run All of the SAS Validation Checks for SDTM?

No. The SAS Clinical Standards Toolkit offers the full set of CDISC SDTM 3.1.2 validation checks in the Global Library data set called validation_master found in the **<*global library*>/standards/cdisc-sdtm-3.1.2-1.4/validation/control** folder.

This set of checks represents an amalgamation of WebSDM, OpenCDISC, and SAS checks. Some checks assess structural (metadata) compliance, and other checks evaluate specific data sets, columns, and data values at the "cell" level.

For any given validation process, the SAS Clinical Standards Toolkit expects that you have defined and referenced (in SASReferences, with type/subtype set to **control/validation**) a run-time set of checks that might be some subset of the validation_master checks. You have the option of both creating this subset and ordering the checks to be run.

The run-time set of checks might well change over time. For example, once the metadata structure of the domains is confirmed, those checks need not be run again.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See "Building a Validation Process" in Chapter 6, "Validation."

Can I Run a Validation Process in the SAS Clinical Standards Toolkit on Multiple Studies Simultaneously?

Yes. The SAS Clinical Standards Toolkit offers several distinct methodologies that support validating multiple studies. However, these methodologies depend on your data accrual processes and workflow. It is important that you maintain relationships between the source study data and the metadata that the SAS Clinical Standards Toolkit requires. Each column in each data set in each study must be uniquely identifiable.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See “Case Study 7: Validation of Multiple Studies” in Chapter 6, “Validation.”

If I Disagree with or Choose to Modify the Codelogic of a Specific Validation Check, What Needs to Be Done?

Create your own copy of the standard-specific validation_master data set (which might be the run-time validation_control data set). Then, make the changes to the copy’s validation check metadata, including codelogic.

If you believe that the codelogic supplied by SAS is in error and you want SAS to correct the error, report the problem through normal Technical Support channels. Approved updates become available with a subsequent hot fix or release of the SAS Clinical Standards Toolkit.

Macros

Is There Any Debugging Help for SAS Macro Errors?

Debugging errors in SAS macros can be difficult. The SAS Clinical Standards Toolkit defines the global macro variable_cstDebug to enable these SAS system options: mprint, mlogic, symbolgen, and mautolocdisplay.

Use these options to significantly increase the number of lines written to the SAS log. By default, _cstDebug is set to 0, and these options are not enabled.

Common errors might be discussed in various parts of the *SAS Clinical Standards Toolkit 1.4: User's Guide*. SAS also maintains a knowledge base that includes product-specific notes regarding installation, problems, and usage. (See “How Do I Report Problems, Ask Questions, or Get More Information about How to Use the SAS Clinical Standards Toolkit?” on page 24.)

Other users might have reported or addressed problems on the SAS and Clinical Trials Community forum (**http://communities.sas.com/community/sas_and_clinical_trials**).

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See “Common Errors and Solutions” in Chapter 5, “SASReferences File.”

Where Do the Framework and Standard-Specific Macros Reside?

The SAS Clinical Standards Toolkit framework macros can be found here:

- Microsoft Windows

  !sasroot\cstframework\sasmacro, where !sasroot is **C:\Program Files\SASHome\SASFoundation\9.3**

- UNIX

  !sasroot/sasautos, where !sasroot is **/usr/local/SASHome/SASFoundation/9.3/**

Standard-specific macros can be found in ***<global library>*/standards/*<standard>*/macros**.

Miscellaneous

How Do I Report Problems, Ask Questions, or Get More Information about How to Use the SAS Clinical Standards Toolkit?

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See Chapter 1, "References."

Can the SAS Clinical Standards Toolkit 1.4 Be Used with Any Release of SAS Besides SAS 9.3?

The SAS Clinical Standards Toolkit 1.4 release is validated only on SAS 9.3, running on these platforms:

- Windows 32
- Windows for x64
- Linux for x64
- Solaris SPARC
- Solaris AMD
- HP-UX Itanium

In general, the code base for the SAS Clinical Standards Toolkit is designed to be backwardly compatible with prior releases of Base SAS, with only limited use of new features introduced with recent SAS releases. The open-source nature of the product allows user updates to all product components. "Off-label" use of the product is at the discretion of the user.

How Is Availability of a New SAS Clinical Standards Toolkit Release Publicized?

Releases of the SAS Clinical Standards Toolkit occur periodically. Please have your site representative contact your unit's SAS account manager for updates on the release schedule.

Availability of product updates is typically announced on the SAS and Clinical Trials Community forum (**http://communities.sas.com/community/sas_and_clinical_trials**). You can use e-mail notifications and RSS feeds to ensure that you do not miss any announcements.

The SAS Clinical Standards Toolkit development team members also report on product updates and availability at industry-specific user conferences such as PharmaSUG and PhUSE.

Does a New Version of the SAS Clinical Standards Toolkit Automatically Overwrite Files Installed with a Previous Version?

No. SAS has a strategy of adding the release number to folder names for both the !sasroot files and the Global Library files. For example:

- SAS Clinical Standards Toolkit 1.3

  !sasroot/../../SASClinicalStandardsToolkitSDTM312/1.3/sample

  <*global library*>/standards/cdisc-sdtm-3.1.2-1.3

- SAS Clinical Standards Toolkit 1.4

  !sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample

  <*global library*>/standards/cdisc-sdtm-3.1.2-1.4

In addition, SAS does not automatically reset the default version of any previously installed version of a standard to the current version. Instead, you must make the decision to upgrade to the current version.

SAS Clinical Standards Toolkit 1.4: User's Guide Reference: See “Unregistering an Old Version of a Standard, and Then Registering a New Version of a Standard” in Chapter 2, “Framework.”