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SAS® Clinical Standards Toolkit 1.7: User's Guide, Second Edition

SAS® Documentation

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What's New

What's New in the SAS Clinical Standards Toolkit

Overview

Here are the significant new features in the SAS Clinical Standards Toolkit 1.7:

- Macro changes
- Support for CDISC CDASH 1.1
- Support for CDISC Dataset-XML 1.0
- Additional support for CDISC Define-XML 2.0
- Reduced and consolidated validation_master data sets for SDTM 3.1.2, 3.1.3, 3.2, and ADaM 2.1
- Support for the Analysis Results Metadata 1.0 extension for Define-XML 2.0

Macro Changes

Here are the changes to macros that have been made in the SAS Clinical Standards Toolkit 1.7:

- The framework macro %CSTUTILMANAGECOLUMNSIZE has been added.

  This macro provides options to change the size of a column to the observed length or the expected length. This macro is useful for reducing the size of a data set to conform to regulatory submission guidelines. For complete information about this macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

- The macro %CSTUTILCOMPAREMETADATASASDEFINE has been added.

  This macro compares the metadata in a CRT-DDS 1.0 or Define-XML 2.0 define.xml file with the metadata in the SAS Version 5 XPORT transport files or in the SAS data sets. For complete information about this macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*. For more information about the standards, see Chapter 9, "XML-Based Standards," on page 291.

- The macros %CSTUTILSQLCOLUMNDEFINITION, %CSTUTILSQLGENERATETABLE, and %CSTUTILFINDFIXEXTDASCIICHARS have been added.

  The macros help you develop content for a new standard or study. Here are the functions that they perform:

  - create SAS Clinical Standards Toolkit metadata files
  - create SQL code that generates data sets based on column definitions in SAS Clinical Standards Toolkit metadata files
  - replace extended ASCII characters with characters that are acceptable to SAS

- The macro %CSTUTILREGISTERCTSUBTYPE has been added.

  This macro supports updates to the SAS Clinical Standards Toolkit metadata. This macro enables the registration of a new set of controlled terminology to the ***global standards library directory*/standards/cdisc-terminology-1.7/control/standardsubtypes.sas7bdat** data set. For more information, see Chapter 4, "Metadata Management," on page 57.

- The standard-specific macros crtdds_xmlvalidate.sas, ct_xmlvalidate.sas, and odm_xmlvalidate.sas are no longer available in the SAS Clinical Standards Toolkit 1.7. These macros have been replaced by the %CSTUTILXMLVALIDATE macro.

Support for CDISC CDASH 1.1

Support for the CDISC CDASH 1.1 standard has been added. This support includes definitions of the 16 domains that are included in the following documents:

- *Clinical Data Acquisition Standards Harmonization (CDASH) Standard* (Version 1.1, January 18, 2011)
- *Clinical Data Acquisition Standards Harmonization (CDASH) User Guide* (Version 1-1.1, April 12, 2012)

For a description of the implementation, see "CDISC CDASH 1.1" on page 130.

Support for CDISC Dataset-XML 1.0

The CDISC Dataset-XML 1.0 data standard has been implemented. It can be used to transport CDISC SDTM, SEND, and ADaM data sets as part of a submission to the FDA. It supports proprietary (non-CDISC) tabular data structure for data transfer between two parties.

The implementation includes these features:

- create Dataset-XML 1.0 files from study data with study data examples from SDTM 3.1.2 and ADaM 2.1
- validate a Dataset-XML 1.0 file against the XML schema definition as published by CDISC
- import Dataset-XML 1.0 files into SAS data sets with study data examples from SDTM 3.1.2 and ADaM 2.1
- compare SAS data sets created from original SAS study data and SAS study data that was imported from Dataset-XML 1.0 files

For a description of the implementation, see "CDISC Dataset-XML" on page 402.

Additional Support for CDISC Define-XML 2.0

Four macros have been added to support creating an initial version of the SAS source metadata data sets source_study, source_tables, source_columns, source_codelists, source_values, and source_documents. These data sets are entered to create a Define-XML 2.0 file.

Here are the macros:

- %DEFINE_CREATESRCMETAFROMSASLIB, which derives source metadata files from a data library that contains SAS study domain data sets
- %DEFINE_CREATESRCMETAFROMDEFINE, which derives source metadata files from a data library that contains the SAS representation of a Define-XML 2.0 define.xml file for a study
- %CSTUTILMIGRATECRTDDS2DEFINE, which migrates source metadata data sets from CRT-DDS 1.0 to Define-XML 2.0
- %CSTUTILGETNCIMETADATA, which creates the source_codelists data set from a list of format catalogs that define the study formats and a SAS data set that contains CDISC/NCI codelist metadata

For more information about these macros, see "Special Topic: Creating Study Source Metadata to Create a CDISC Define-XML 2.0 define.xml File" on page 390.

Note: The macros %DEFINE_CREATESRCMETAFROMSASLIB, %DEFINE_CREATESRCMETAFROMDEFINE, and %CSTUTILMIGRATECRTDDS2DEFINE also create the source_analysisresults SAS data set. This data set is entered to create a Define-XML 2.0 file that includes Analysis Results Metadata.

Reduced and Consolidated validation_master Data Sets for SDTM 3.1.2, 3.1.3, 3.2, and ADaM 2.1

The validation_master data sets for SDTM 3.1.2, 3.1.3, 3.2, and ADaM 2.1 have been reduced and consolidated for each standard to represent only the validation checks provided by SAS. These validation checks enhance third-party checks to provide consistent standard metadata and to ensure data quality for each standard.

1

Introduction to the SAS Clinical Standards Toolkit

What Is the SAS Clinical Standards Toolkit? 1

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What Is the SAS Clinical Standards Toolkit?

The purpose and scope of the SAS Clinical Standards Toolkit can best be described by considering the product name.

Clinical

The SAS Clinical Standards Toolkit focuses primarily on supporting clinical research activities. These activities involve the discovery and development of new pharmaceutical and biotechnology products and medical devices. These activities occur from project initiation through product submission and throughout the full product lifecycle. They do not include non-research patient records or health-care, pharmacy, hospital, and insurance electronic records.

Standards

The SAS Clinical Standards Toolkit initially focuses on standards defined by the Clinical Data Interchange Standards Consortium (CDISC). CDISC is a global, open, multidisciplinary, nonprofit organization that has established standards to support the acquisition, exchange, submission, and archival of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information-system interoperability, which, in turn, improves medical research and related areas of health care. The SAS Clinical Standards Toolkit is not limited to supporting CDISC standards. The SAS Clinical Standards Toolkit framework is designed to support the specification and use of any user-defined standard.

Toolkit

The term *toolkit* connotes a collection of tools, products, and solutions. The SAS Clinical Standards Toolkit provides a set of standards and functionality that will evolve and grow with future product updates and releases. Customer requirements and expectations of the SAS Clinical Standards Toolkit will play a key role in deciding what functionality to provide in future releases.

References

Table 1.1 *References*

Reference	Web Address **	Description
CDISC CDASH 1.1	http://www.cdisc.org/cdash	Provides access to the *Clinical Data Acquisition Standards Harmonization (CDASH)* standard (version 1.1) and the *Clinical Data Acquisition Standards Harmonization (CDASH) User Guide* (version 1-1.1).
CDISC SDTM 3.1.2	http://www.cdisc.org/sdtm	Provides access to the *Study Data Tabulation Model (Version 1.2)* and the *Study Data Tabulation Model Implementation Guide: Human Clinical Trials (Version 3.1.2)*.

Reference	Web Address **	Description
CDISC SDTM 3.1.3	http://www.cdisc.org/sdtm	Provides access to the *Study Data Tabulation Model (Version 1.3)* and the *Study Data Tabulation Model Implementation Guide: Human Clinical Trials (Version 3.1.3)*.
CDISC SDTM 3.2	http://www.cdisc.org/sdtm	Provides access to the *Study Data Tabulation Model Version 1.4*, the *Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.2*, the *Study Data Tabulation Model Implementation Guide: Associated Persons Version 1.0*, and the *Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD) Version 1.0*.
CDISC SEND 3.0	http://www.cdisc.org/send	Provides access to the *Standard for Exchange of Nonclinical Data Implementation Guide: Nonclinical Studies, Version 3.0*.
CDISC CRT-DDS 1.0	http://www.cdisc.org/define-xml	Provides access to the *Case Report Tabulation Data Definition Specification (CRT-DDS, also called define.xml) Final Version 1.0*.
CDISC Define-XML 2.0	http://www.cdisc.org/define-xml	Provides access to the Define-XML 2.0 standard.
CDISC Dataset-XML 1.0	http://www.cdisc.org/dataset-xml	Provides access to the Dataset-XML 1.0 standard.
CDISC ODM 1.3.0	http://www.cdisc.org/odm	Provides access to ODM Version 1.3.0 files and documentation.

Reference	Web Address **	Description
CDISC ODM 1.3.1	http://www.cdisc.org/odm	Provides access to ODM Version 1.3.1 files and documentation.
NCI CDISC Controlled Terminology	http://www.cdisc.org/terminology	Provides access to CDISC Controlled Terminology.
CDISC ADaM 2.1	http://www.cdisc.org/adam	Provides access to the *Analysis Data Model, Version 2.1* and the *ADaM Implementation Guide, Version 1.0*. **Note:** Registration might be required.
CDISC ADaM 2.1 Validation Checks	http://www.cdisc.org/adam-validation	Provides access to the CDISC ADaM Validation Checks **Note:** Access to the CDISC members-only site might be required.
CDISC Analysis Results Metadata 1.0 for Define-XML 2.0	http://www.cdisc.org/adam#armv1	Provides access to the Analysis Results Metadata 1.0 extension for Define-XML 2.0.
Data Structure for Adverse Event Analysis Version 1.0	http://www.cdisc.org/adam	Provides access to the Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis Version 1.0.
Data Structure for Time-to-Event Analyses Version 1.0	http://www.cdisc.org/adam	Provides access to the ADaM Basic Data Structure for Time-to-Event Analyses Version 1.0.
OpenCDISC Validation Rules	http://www.opencdisc.org/projects/validator/cdisc-validation-rules-repository	Provides access to the OpenCDISC CDISC Validation Rules Repository.
Janus Operational Pilot	http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/ucm155327.htm	Provides information about operational pilots to date, including error checks.

Reference	Web Address **	Description
ISO 8601:2004 Data Elements and Interchange Formats—Information Interchange—Representation of Dates and Times	http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=40874	Provides information about the ISO 8601 standard.
FDA Study Data Standards Resources	http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm	Provides access to a variety of resources in support of submission of clinical study data to the FDA.
Advanced Review with Electronic Data Promotion Group (PMDA)	http://www.pmda.go.jp/english/review-services/reviews/advanced-efforts/0002.html	Provides information about the PMDA's new approach to electronic submissions of study data.
SAS Technical Support	Online form: http://support.sas.com/ctx/supportform/createForm	Provides access to a form on which any problems experienced with the product and technical questions should be documented. Or, you can call (in North America) 919-677-8008. Otherwise, contact your local SAS office.
SAS Knowledge Base for the SAS Clinical Standards Toolkit	http://support.sas.com/rnd/base/cdisc/cst/index.html	Provides current information, documentation, technical papers, and presentations about the SAS Clinical Standards Toolkit.
SAS Clinical Standards Toolkit Documentation	http://support.sas.com/documentation/onlinedoc/clinical/index.html	Provides a link to this document and other documents.
SAS Clinical Standard Toolkit: Papers	http://support.sas.com/rnd/base/cdisc/cst/index.html#papers	Provides links to papers written about the SAS Clinical Standards Toolkit.

Reference	Web Address **	Description
SAS Clinical Standards Toolkit Samples and SAS Notes	http://support.sas.com/notes/index.html	Provides a way to search SAS installation problems, usage problems, samples, and SAS Notes that are associated with the SAS Clinical Standards Toolkit. (Type *Clinical Standards Toolkit* in the search field.)
SAS in Health Care and Pharma Community	https://communities.sas.com/t5/Health-Care-and-Pharma/ct-p/sas_health_pharma	Provides access to a primary public discussion forum for the SAS Clinical Standards Toolkit.
SAS Training	http://support.sas.com/training/	Currently, SAS is pursuing the development of SAS Clinical Standards Toolkit training classes. Some information about the SAS Clinical Standards Toolkit is provided in the SAS Clinical Data Integration: Essentials training course.
External Vendor Tutorials		Offers product tutorials from vendors, often as a part of an industry-related user conference.

** Accessed on December 4, 2014.

2

Framework

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Overview

The Framework module of the SAS Clinical Standards Toolkit enables you to manage the registration of standards, and provides the metadata and API infrastructure to interact with those standards.

To understand the Framework module, you must understand the fundamentals of how the files are structured and used. The Framework module has two distinct pieces:

- the components that are installed as part of the SAS Foundation and shared files (SAS macros, JAR files, and so on)
- the global standards library

The following sections describe the structure of the global standards library. The sections use some of the framework macros to show how the shared files are used.

Global Standards Library

The global standards library is the metadata repository for the SAS Clinical Standards Toolkit. By default, the global standards library contains the metadata for the Framework module and the metadata for each data standard that is provided with the SAS Clinical Standards Toolkit (such as the CDISC SDTM 3.1.2 standard).

During the installation and configuration of the SAS Clinical Standards Toolkit, you are prompted for the location where the global standards library should be installed. The configuration process creates a series of directories in this location.

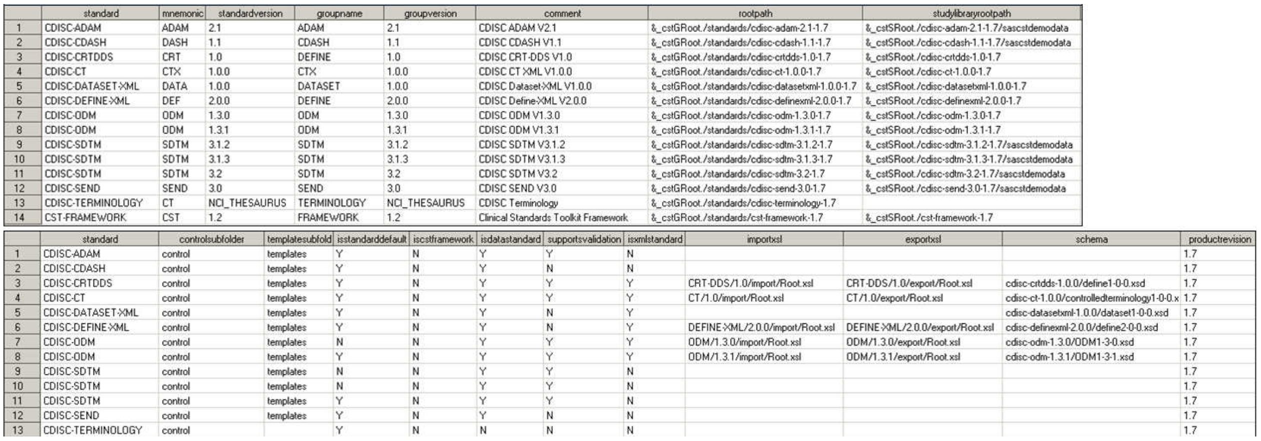
- `logs` contains the transactionlog data set used by the metadata management macros. For more information, see Chapter 4, "Metadata Management," on page 57.
- `metadata` contains data sets that have information about the registered standards. For more information, see "Common Framework Metadata" on page 13.
- `schema-repository` contains the schemas for XML-based standards that are supported.
- `standards` contains a standard-specific directory hierarchy for each of the supported standards.
- `xsl-repository` contains directories and XSL files used in reading and writing XML files.

The `logs` directory contains one data set: transactionlog. This data set is populated only by the metadata management macros. The data set can be updated by one or more users depending on how the SAS Clinical Standards Toolkit is implemented (file server installation or single installation on a laptop). The data set contains metadata update information from all users.

The `metadata` directory contains three data sets and one XML file: Standards, Standardlookup, StandardSASReferences, and availabletransforms.xml. The Standards data set has a list of the registered standards and basic information relating to each standard.

The following display shows the full content of the global standards library Standards data set included with the SAS Clinical Standards Toolkit after a new installation of the application:

Figure 2.1 Global Standards Library: Metadata Standards Data Set



	standard	mnemonic	standardversion	groupname	groupversion	comment	rootpath	studylibraryrootpath
1	CDISC-ADAM	ADAM	2.1	ADAM	2.1	CDISC ADAM V2.1	&_cstGRoot./standards/cdisc-adam-2.1-1.7	&_cstSRoot./cdisc-adam-2.1-1.7/sascstdemodata
2	CDISC-CDASH	DASH	1.1	CDASH	1.1	CDISC CDASH V1.1	&_cstGRoot./standards/cdisc-cdash-1.1-1.7	&_cstSRoot./cdisc-cdash-1.1-1.7/sascstdemodata
3	CDISC-CRTDDS	CRT	1.0	DEFINE	1.0	CDISC CRT-DDS V1.0	&_cstGRoot./standards/cdisc-crtdds-1.0-1.7	&_cstSRoot./cdisc-crtdds-1.0-1.7
4	CDISC-CT	CTX	1.0.0	CTX	1.0.0	CDISC CT XML V1.0.0	&_cstGRoot./standards/cdisc-ct-1.0.0-1.7	&_cstSRoot./cdisc-ct-1.0.0-1.7
5	CDISC-DATASET-XML	DATA	1.0.0	DATASET	1.0.0	CDISC Dataset-XML V1.0.0	&_cstGRoot./standards/cdisc-datasetxml-1.0.0-1.7	&_cstSRoot./cdisc-datasetxml-1.0.0-1.7
6	CDISC-DEFINE-XML	DEF	2.0.0	DEFINE	2.0.0	CDISC Define-XML V2.0.0	&_cstGRoot./standards/cdisc-definexml-2.0.0-1.7	&_cstSRoot./cdisc-definexml-2.0.0-1.7
7	CDISC-ODM	ODM	1.3.0	ODM	1.3.0	CDISC ODM V1.3.0	&_cstGRoot./standards/cdisc-odm-1.3.0-1.7	&_cstSRoot./cdisc-odm-1.3.0-1.7
8	CDISC-ODM	ODM	1.3.1	ODM	1.3.1	CDISC ODM V1.3.1	&_cstGRoot./standards/cdisc-odm-1.3.1-1.7	&_cstSRoot./cdisc-odm-1.3.1-1.7
9	CDISC-SDTM	SDTM	3.1.2	SDTM	3.1.2	CDISC SDTM V3.1.2	&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.7	&_cstSRoot./cdisc-sdtm-3.1.2-1.7/sascstdemodata
10	CDISC-SDTM	SDTM	3.1.3	SDTM	3.1.3	CDISC SDTM V3.1.3	&_cstGRoot./standards/cdisc-sdtm-3.1.3-1.7	&_cstSRoot./cdisc-sdtm-3.1.3-1.7/sascstdemodata
11	CDISC-SDTM	SDTM	3.2	SDTM	3.2	CDISC SDTM V3.2	&_cstGRoot./standards/cdisc-sdtm-3.2-1.7	&_cstSRoot./cdisc-sdtm-3.2-1.7/sascstdemodata
12	CDISC-SEND	SEND	3.0	SEND	3.0	CDISC SEND V3.0	&_cstGRoot./standards/cdisc-send-3.0-1.7	&_cstSRoot./cdisc-send-3.0-1.7/sascstdemodata
13	CDISC-TERMINOLOGY	CT	NCI_THESAURUS	TERMINOLOGY	NCI_THESAURUS	CDISC Terminology	&_cstGRoot./standards/cdisc-terminology-1.7	
14	CST-FRAMEWORK	CST	1.2	FRAMEWORK	1.2	Clinical Standards Toolkit Framework	&_cstGRoot./standards/cst-framework-1.7	&_cstSRoot./cst-framework-1.7

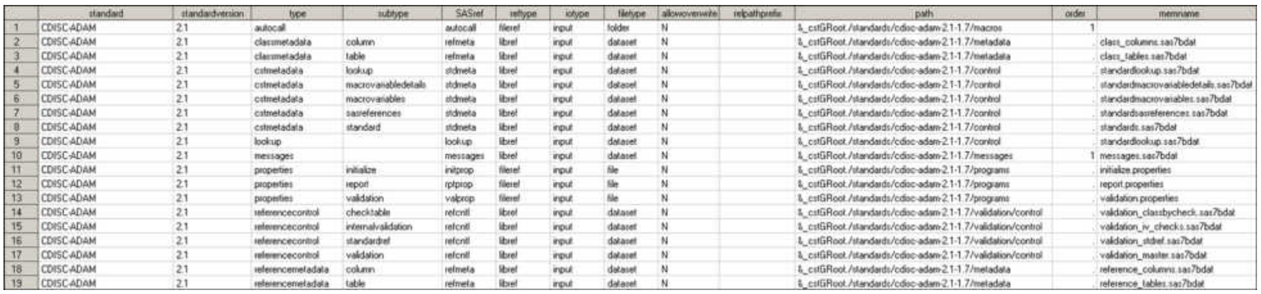
	standard	controlsubfolder	templatesubfold	isstandarddefault	iscstframework	isdatastandard	supportsvalidation	isxmlstandard	importxsl	exportxsl	schema	productrevision
1	CDISC-ADAM	control	templates	Y	N	Y	Y	N				1.7
2	CDISC-CDASH	control	templates	Y	N	Y	N	N				1.7
3	CDISC-CRTDDS	control	templates	Y	N	Y	Y	Y	CRT-DDS/1.0/import/Root.xsl	CRT-DDS/1.0/export/Root.xsl	cdisc-crtdds-1.0.0/define1-0-0.xsd	1.7
4	CDISC-CT	control	templates	Y	N	Y	Y	Y	CT/1.0/import/Root.xsl	CT/1.0/export/Root.xsl	cdisc-ct-1.0.0/controlledterminology1-0-0.x	1.7
5	CDISC-DATASET-XML	control	templates	Y	N	Y	N	Y			cdisc-datasetxml-1.0.0/dataset1-0-0.xsd	1.7
6	CDISC-DEFINE-XML	control	templates	Y	N	Y	N	Y	DEFINE-XML/2.0.0/import/Root.xsl	DEFINE-XML/2.0.0/export/Root.xsl	cdisc-definexml-2.0.0/define2-0-0.xsd	1.7
7	CDISC-ODM	control	templates	N	N	Y	Y	Y	ODM/1.3.0/import/Root.xsl	ODM/1.3.0/export/Root.xsl	cdisc-odm-1.3.0/ODM1-3-0.xsd	1.7
8	CDISC-ODM	control	templates	Y	N	Y	Y	Y	ODM/1.3.1/import/Root.xsl	ODM/1.3.1/export/Root.xsl	cdisc-odm-1.3.1/ODM1-3-1.xsd	1.7
9	CDISC-SDTM	control	templates	N	N	Y	Y	N				1.7
10	CDISC-SDTM	control	templates	N	N	Y	Y	N				1.7
11	CDISC-SDTM	control	templates	Y	N	Y	Y	N				1.7
12	CDISC-SEND	control	templates	Y	N	Y	N	N				1.7
13	CDISC-TERMINOLOGY	control		Y	N	N	N	N				1.7

Note: The `&_cstGRoot` directory in the **rootpath** column maps to the *global standards library directory*.

The StandardSASReferences data set defines the typical inputs and outputs of SAS processes that are associated with each standard.

The following display shows some rows and columns:

Figure 2.2 Global Standards Library: Some Rows and Columns of the Metadata StandardSASReferences Data Set



	standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order	memname
1	CDISC-ADAM	2.1	autocall		autocall	fileref	input	folder	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/macros	1	
2	CDISC-ADAM	2.1	classmetadata	column	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/metadata	.	class_columns.sas7bdat
3	CDISC-ADAM	2.1	classmetadata	table	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/metadata	.	class_tables.sas7bdat
4	CDISC-ADAM	2.1	cstmetadata	lookup	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/control	.	standardlookup.sas7bdat
5	CDISC-ADAM	2.1	cstmetadata	macrovariabledetails	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/control	.	standardmacrovariabledetails.sas7bdat
6	CDISC-ADAM	2.1	cstmetadata	macrovariables	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/control	.	standardmacrovariables.sas7bdat
7	CDISC-ADAM	2.1	cstmetadata	sasreferences	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/control	.	standardsasreferences.sas7bdat
8	CDISC-ADAM	2.1	cstmetadata	standard	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/control	.	standards.sas7bdat
9	CDISC-ADAM	2.1	lookup		lookup	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/control	.	standardlookup.sas7bdat
10	CDISC-ADAM	2.1	messages		messages	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/messages	1	messages.sas7bdat
11	CDISC-ADAM	2.1	properties	initialize	initprop	fileref	input	file	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/programs	.	initialize.properties
12	CDISC-ADAM	2.1	properties	report	rptprop	fileref	input	file	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/programs	.	report.properties
13	CDISC-ADAM	2.1	properties	validation	valprop	fileref	input	file	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/programs	.	validation.properties
14	CDISC-ADAM	2.1	referencecontrol	checktable	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/validation/control	.	validation_classbycheck.sas7bdat
15	CDISC-ADAM	2.1	referencecontrol	internalvalidation	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/validation/control	.	validation_iv_checks.sas7bdat
16	CDISC-ADAM	2.1	referencecontrol	standardref	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/validation/control	.	validation_stdref.sas7bdat
17	CDISC-ADAM	2.1	referencecontrol	validation	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/validation/control	.	validation_master.sas7bdat
18	CDISC-ADAM	2.1	referencemetadata	column	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/metadata	.	reference_columns.sas7bdat
19	CDISC-ADAM	2.1	referencemetadata	table	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-adam-2.1-1.7/metadata	.	reference_tables.sas7bdat

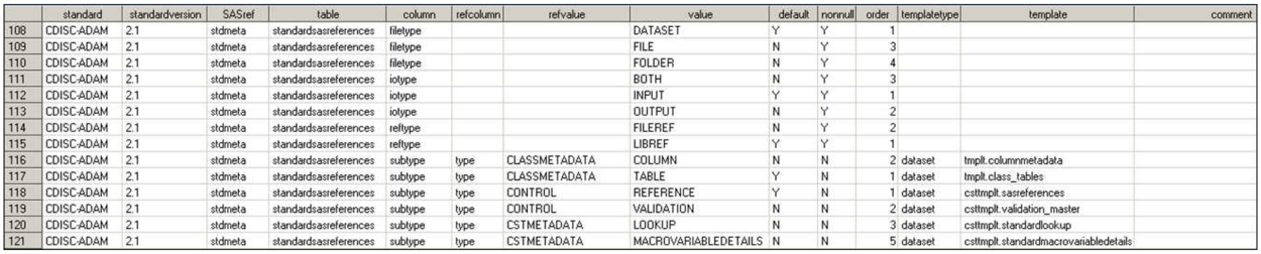
The **type** and **subtype** columns can be used to reference information that the SAS Clinical Standards Toolkit needs. This information is in the directory structures and file naming standards used by the customer. A full list of valid types and subtypes are provided in this document.

The `standards` directory contains subdirectories for each of the standard versions that is provided with the SAS Clinical Standards Toolkit. In addition, there are subdirectories for user-customized versions of these standards and any new user-defined standards. Each subdirectory should be considered a stand-alone module. This is how the SAS Clinical Standards Toolkit can keep parallel standards and reduce the need for revalidation. Within each subdirectory, there might be directories that group the files, data sets, and housekeeping programs.

The Standardlookup data set contains discrete lookup values specific to a SAS Clinical Standards Toolkit registered standard. It provides specific information for column values and data set template names. In addition, this data set is used to perform internal validation of the SAS Clinical Standards Toolkit.

The following display shows the entire column list:

Figure 2.3 *Global Standards Library: Metadata Standardlookup Data Set*

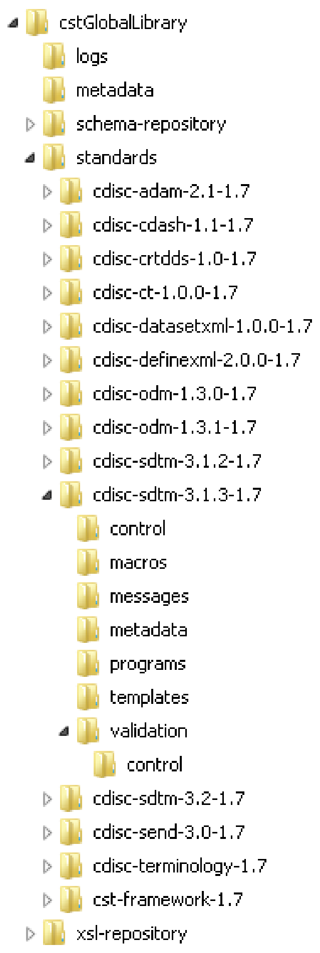


	standard	standardversion	SASref	table	column	refcolumn	refvalue	value	default	nonnull	order	templatetype	template	comment
108	CDISC-ADAM	2.1	stdmeta	standardsasreferences	filetype			DATASET	Y	Y	1			
109	CDISC-ADAM	2.1	stdmeta	standardsasreferences	filetype			FILE	N	Y	3			
110	CDISC-ADAM	2.1	stdmeta	standardsasreferences	filetype			FOLDER	N	Y	4			
111	CDISC-ADAM	2.1	stdmeta	standardsasreferences	iotype			BOTH	N	Y	3			
112	CDISC-ADAM	2.1	stdmeta	standardsasreferences	iotype			INPUT	Y	Y	1			
113	CDISC-ADAM	2.1	stdmeta	standardsasreferences	iotype			OUTPUT	N	Y	2			
114	CDISC-ADAM	2.1	stdmeta	standardsasreferences	reftype			FILEREF	N	Y	2			
115	CDISC-ADAM	2.1	stdmeta	standardsasreferences	reftype			LIBREF	Y	Y	1			
116	CDISC-ADAM	2.1	stdmeta	standardsasreferences	subtype	type	CLASSMETADATA	COLUMN	N	N	2	dataset	tmplt.columnmetadata	
117	CDISC-ADAM	2.1	stdmeta	standardsasreferences	subtype	type	CLASSMETADATA	TABLE	Y	N	1	dataset	tmplt.class_tables	
118	CDISC-ADAM	2.1	stdmeta	standardsasreferences	subtype	type	CONTROL	REFERENCE	Y	N	1	dataset	csttmplt.sasreferences	
119	CDISC-ADAM	2.1	stdmeta	standardsasreferences	subtype	type	CONTROL	VALIDATION	N	N	2	dataset	csttmplt.validation_master	
120	CDISC-ADAM	2.1	stdmeta	standardsasreferences	subtype	type	CSTMETADATA	LOOKUP	N	N	3	dataset	csttmplt.standardlookup	
121	CDISC-ADAM	2.1	stdmeta	standardsasreferences	subtype	type	CSTMETADATA	MACROVARIABLEDETAILS	N	N	5	dataset	csttmplt.standardmacrovariabledetails	

The availabletransforms.xml file is for XML-based standards. It defines the location of the XML schema, the location of the XSL transformation style sheets, and the import and export locations of XML documents.

The following display shows the directory structure for a Microsoft Windows global standards library with **cdisc-sdtm-3.1.3-1.7** expanded:

Figure 2.4 *Directory Structure for a Microsoft Windows Global Standards Library*



```
cstGlobalLibrary
    logs
    metadata
    schema-repository
    standards
        cdisc-adam-2.1-1.7
        cdisc-cdash-1.1-1.7
        cdisc-crtdds-1.0-1.7
        cdisc-ct-1.0.0-1.7
        cdisc-datasetxml-1.0.0-1.7
        cdisc-definexml-2.0.0-1.7
        cdisc-odm-1.3.0-1.7
        cdisc-odm-1.3.1-1.7
        cdisc-sdtm-3.1.2-1.7
        cdisc-sdtm-3.1.3-1.7
            control
            macros
            messages
            metadata
            programs
            templates
            validation
                control
        cdisc-sdtm-3.2-1.7
        cdisc-send-3.0-1.7
        cdisc-terminology-1.7
        cst-framework-1.7
    xsl-repository
```

The **`schema-repository`** directory contains XML schema definitions that are used to validate XML files. Standards that use XML should have their schemas in this directory so that they can be found. For example, the **`schema-repository`** directory for CDISC CRT-DDS 1.0 as defined in the Standards data set maps to this location:

***`global standards library directory`*`/schema-repository/`**
`cdisc-crtdds-1.0.0`

See Figure 2.1 on page 10, row 2, **schema** column.

The **`xsl-repository`** directory contains files that are used to transform XML files from one format to another. For example, the default style sheet directory for CDISC CRT-DDS 1.0 define.xml files created by the SAS Clinical Standards Toolkit as defined in the Standards data set maps to this location:

`global standards library directory`**`/xsl-repository/CRT-DDS/1.0/export`**

See Figure 2.1 on page 10, row 2, **exportxsl** column.

What Is a Standard?

The answer to this question depends on what the standard is supposed to do. In the case of terminology, it might be a format catalog and a data set. In the case of an XML-based standard, it might be metadata that describes the SAS representation of the XML. It might be data sets that control validating the SAS representation of the XML. It might be routines to convert the SAS representation to the actual XML files. Or, it might be initialization files for standard-specific properties.

The minimum number of items that are needed to register a standard to the framework are the data sets that define the standard, as well as the standard's SASReferences data set. The macro to register a standard is described in "Registering a New Version of a Standard" on page 26.

For more information about what a SAS Clinical Standards Toolkit standard is, see Chapter 5, "Supported Standards," on page 87.

Common Framework Metadata

Overview

The following SAS Clinical Standards Toolkit metadata files support the functions and common tasks across multiple standards.

File structure and content for each of these metadata files are fully described in Chapter 3, “Metadata File Descriptions,” on page 33. Use of these metadata files is documented in sections that use the SAS Clinical Standards Toolkit metadata.

Other SAS Clinical Standards Toolkit metadata files specific to supported standards or specific to actions (such as validation) are described in Chapter 3, “Metadata File Descriptions,” on page 33. They are also discussed elsewhere in this document.

Standards Data Set

This data set has a list of the registered standards (for example, CDISC SDTM 3.1.3) and basic information relating to each standard. The Standards data set is in the global standards library metadata folder and within each registered standard folder hierarchy here:

```
global standards library directory/standards/<standard>/control
```

StandardSASReferences

This data set defines the typical inputs and outputs of SAS processes that are associated with each standard. The StandardSASReferences data set is in the global standards library metadata folder and within each registered standard folder hierarchy here:

```
global standards library directory/standards/<standard>/control
```

Standardlookup

This data set contains valid values for discrete variables in the SAS Clinical Standards Toolkit metadata files. The Standardlookup data set is in the *global standards library directory* and within each registered standard folder hierarchy at this location:

```
global standards library directory/standards/<standard>/control
```

SASReferences Data Set

This data set defines generic system and study-specific input and output files that are required by each SAS Clinical Standards Toolkit process. A sample SASReferences data set is provided with each supported standard.

Properties Files

These files provide the set of name-value pairs that are required to establish the environment for each SAS Clinical Standards Toolkit process. Properties are translated into SAS global macro variables at the start of each process. Properties are within each registered standard folder hierarchy here:

***global standards library directory*/standards/*<standard>*/programs**

Messages Data Set

This data set contains a list of codes and associated text that are specific to each standard. It can contain specific actions (such as validation) that are used to report process results. The Messages data set is within each registered standard folder hierarchy here:

***global standards library directory*/standards/*<standard>*/messages**

Results Data Set

This data set summarizes each SAS Clinical Standards Toolkit process. It captures the outcome of specific actions and uses the Messages data set to standardize output.

Common Usage Scenarios for the Framework

Overview

The following sections describe usage scenarios that the framework accommodates. Code that is required to complete the usage scenario is included in each section. All macros that are provided in the usage scenarios are in the primary SAS Clinical Standards Toolkit autocall path:

- Microsoft Windows

  `!sasroot/cstframework/sasmacro`

- UNIX

  `!sasroot/sasautos`

For complete macro documentation, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Initializing the Framework's Global Macro Variables

The framework requires certain global macro variables to execute properly. You should initialize these global macro variables at the start of each SAS Clinical Standards Toolkit session. The same requirement might exist for a standard. The standard might need global macro variables to call its macros. The framework provides a macro to help with this requirement.

```
/*
initialize the global macro variables needed by the framework
*/
%cst_setstandardproperties(
_cstStandard=CST-FRAMEWORK
,_cstSubType=initialize
);
```

This code looks at the global SASReferences data set for a properties entry with a `SubType` value of `initialize`. By default, this entry is located here:

***global standards library directory*/standards/cst-framework-1.7/programs/initialize.properties**

Global macro variables are initialized based on the name-value pairs in this properties file. After this macro has been called once, you do not need to call it again during the SAS session, unless you want to override macro variables or reset them.

Referencing the Default Version of a Standard

If the default version of a standard is to be used, the version information can be omitted. The default version is specified in the global standards library metadata Standards data set. Here is an example of the code to initialize CDISC SDTM 3.2 properties:

```
/*
initialize the global macro variables needed by CDISC SDTM
*/
%cst_setstandardproperties(
_cstStandard=CDISC-SDTM
,_cstSubType=initialize
);
```

In this example, the initialization properties for the default version of the CDISC SDTM standard (currently 3.2) are used without needing to specify a version.

Getting a List of the Standards That Are Installed

It is programmatically possible to get a list of the current standards that are registered to the framework. This code can be used:

```
/*
get a list of the registered standards
*/
%cst_getregisteredstandards(
_cstOutputDS=work.regStds
);
```

The data set work.regStds contains the information from the global standards library metadata Standards data set. The work.regStds data set's content matches the information provided in Figure 2.1 on page 10.

Determining Which Revision (Release) of a Standard Version Is Installed

It is programmatically possible to determine which revision of a standard version is installed. This code can be used:

```
/*
initialize the global macro variables needed by the framework
*/
%cst_setstandardproperties(
    _cstStandard=CST-FRAMEWORK
    ,_cstSubType=initialize
    );
/*
get a list of the registered standards
*/
%cst_getregisteredstandards(
    _cstOutputDS=work.regStds
    );
```

The data set work.regStds contains the information from the global standards library metadata Standards data set. The last column is **productRevision**. This column contains the revision of each standard version. If the **productRevision** column is blank, then the standard was originally registered with SAS Clinical Standards Toolkit 1.2.

Here is another, simpler method to determine the current SAS Clinical Standards Toolkit release:

```
%put CST Version: %cstutil_getcstversion;
```

You can also use the _cstVersion global macro variable:

```
%put &_cstVersion
```

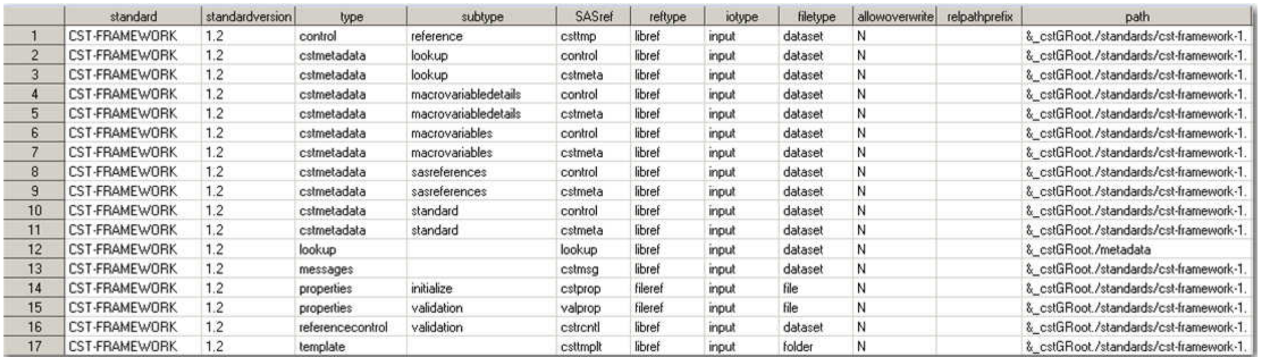
Getting a List of the Files and Data Sets That Are Associated with a Registered Standard

When standards are registered, information about the files and data sets that comprise the standard is registered also. This macro call returns records from the StandardSASReferences data set that are associated with the specified standard. It returns records for standardversion if applicable.

```
%cst_getstandardsasreferences(
_cstStandard=CST-FRAMEWORK
,_cstOutputDS=sasrefs
);
```

The parameters that are used in this macro call specify the standard `CST-FRAMEWORK` and the data set to create to contain the information. Because the standard version is omitted, the default standard version is used. The data set that is returned is a SASReferences data set. For the macro call, this display shows the first few columns of data that are returned.

Figure 2.5 *StandardSASReferences Returned in work.sasrefs Data Set (Column Subset)*



	standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path
1	CST-FRAMEWORK	1.2	control	reference	csttmp	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
2	CST-FRAMEWORK	1.2	cstmetadata	lookup	control	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
3	CST-FRAMEWORK	1.2	cstmetadata	lookup	cstmeta	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
4	CST-FRAMEWORK	1.2	cstmetadata	macrovariabledetails	control	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
5	CST-FRAMEWORK	1.2	cstmetadata	macrovariabledetails	cstmeta	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
6	CST-FRAMEWORK	1.2	cstmetadata	macrovariables	control	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
7	CST-FRAMEWORK	1.2	cstmetadata	macrovariables	cstmeta	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
8	CST-FRAMEWORK	1.2	cstmetadata	sasreferences	control	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
9	CST-FRAMEWORK	1.2	cstmetadata	sasreferences	cstmeta	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
10	CST-FRAMEWORK	1.2	cstmetadata	standard	control	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
11	CST-FRAMEWORK	1.2	cstmetadata	standard	cstmeta	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
12	CST-FRAMEWORK	1.2	lookup		lookup	libref	input	dataset	N		&_cstGRoot./metadata
13	CST-FRAMEWORK	1.2	messages		cstmsg	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
14	CST-FRAMEWORK	1.2	properties	initialize	cstprop	fileref	input	file	N		&_cstGRoot./standards/cst-framework-1.
15	CST-FRAMEWORK	1.2	properties	validation	valprop	fileref	input	file	N		&_cstGRoot./standards/cst-framework-1.
16	CST-FRAMEWORK	1.2	referencecontrol	validation	cstrcntl	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.
17	CST-FRAMEWORK	1.2	template		csttmplt	libref	input	folder	N		&_cstGRoot./standards/cst-framework-1.

Note: If the %CST_SETSTANDARDPROPERTIES macro has not been called before invoking the %CST_GETSTANDARDSASREFERENCES macro, these errors are reported in the SAS log:

```
WARNING: Apparent symbolic reference _CSTDEBUG not resolved.
ERROR: A character operand was found in the %EVAL function or
%IF condition where a numeric operand is required. The condition was:
(&_cstDebug))
```

```
ERROR: The macro CST_GETSTANDARDSASREFERENCES will stop executing.
```

Calling the %CST_SETSTANDARDPROPERTIES macro to create global macro variables for the SAS Clinical Standards Toolkit session is a prerequisite for most SAS Clinical Standards Toolkit tasks.

Creating Data Sets Used by the Framework

Many macro calls to the framework require tables to be passed in or referenced. The structure of these tables can be difficult to build manually, so the SAS Clinical Standards Toolkit provides functionality to create table shells that can be filled in. Here is an example of the macro call:

```
/*
Create the empty SASReferences data set used in the next
step
 */
%cst_createdsfromtemplate(
    _cstStandard=CST-FRAMEWORK,
    _cstType=control,
    _cstSubType=reference,
    _cstOutputDS=work.sasrefs
    );
```

The `Type` and `SubType` identify that it is a SASReferences table. The `Standard` identifies the module to be used. If the standard version is not specified, then the default for standard version is used. The output is a data set named work.sasrefs that contains 0 observations.

Creating Table Shells Based on a Data Standard

Data standards like CDISC SDTM have reference metadata that describes the tables and columns that comprise the data standard. Creating table shells using this metadata is useful and saves time. Here is the code to do this:

```
/*
Create the table shells for CDISC SDTM 3.1.3 in the work library
*/
%cst_createtablesfordatastandard(
    _cstStandard=CDISC-SDTM
    ,_cststandardVersion=3.1.3
    ,_cstOutputLibrary=work
    );
```

This code creates the domains described by CDISC SDTM version 3.1.3 in the Work library. Each domain contains 0 observations.

Getting a Copy of the Reference Metadata for a Data Standard

The SAS representation of many standards (such as CDISC SDTM) includes table and column metadata for all domains that are specific to each standard. The SAS Clinical Standards Toolkit framework provides a way to create and populate the metadata files.

```
/*
Step 1. Create the empty SASReferences data set used in
the next step
 */
%cst_createdsfromtemplate(
    _cstStandard=CST-FRAMEWORK,
    _cstType=control,
    _cstSubType=reference,
    _cstOutputDS=work.sasrefs);
/*
Step 2. Prep the type of information to be returned.
 */
data work.sasrefs;
    if 0 then set work.sasrefs;
    standard='CDISC-SDTM';
    standardVersion='3.1.2';
    * ----- REFERENCE METADATA -----;
    * tables metadata;
    type='referencemetadata';
    subType='table';
    sasRef='work';
    refType='libref';
    memname='refTables';
    iotype='input';
    filetype='dataset';
    allowoverwrite='N';
    output;
    * columns metadata;
    type='referencemetadata';
    subType='column';
    sasRef='work';
    refType='libref';
```

```
        memname='refColumns';
        output;
    run;
    /*
    Step 3. Call the macro to get the metadata.
     */
    %cst_getstandardmetadata(
        _cstSASReferences=work.sasrefs
        );
```

Step 1 uses one macro to create an empty SASReferences data set named `work.sasrefs`.

Step 2 determines the information to be returned. The standard and version is CDISC SDTM 3.1.2. The `type` and `subType` identify the types of metadata to be returned. The `sasRef` and `memname` identify the target library and name for each data set.

Step 3 is the actual macro call that does the processing. The data set `work.sasrefs` is read, and the global metadata is used to fulfill the request.

The outcome of these steps is two data sets. The data set `work.refTables` contains metadata about the CDISC SDTM 3.1.2 domains. The data set `work.refColumns` contains metadata about each of the columns defined in the domains.

Inserting Information from Registered Standards into a SASReferences File

When a standard is registered, information about the data sets and files that comprise the standard is registered. These data sets and files are in a default folder hierarchy within the global standards library. The SAS Clinical Standards Toolkit provides a mechanism to reference the location of, and metadata about, these data sets and files. As a result, you do not have to specify paths and member names in each SASReferences file that you create. When a SAS Clinical Standards Toolkit process encounters an incomplete file reference in a SASReferences file, it looks in the standard-specific folder hierarchy for the information. This mechanism is useful for a number of reasons:

- Programmers do not need to know all of the locations.

- If the global standards library needs to move, it can without having to change all of the SASReferences files that use a standard.
- To change standard versions, you need only to change the contents of the **standardversion** column.

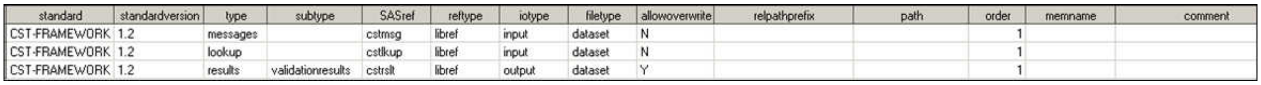
This code creates a partial SASReferences file:

```
/*
Step 1. Initialize the global macro variables needed by the
framework.
*/
%cst_setstandardproperties(
    _cstStandard=CST-FRAMEWORK
    ,_cstSubType=initialize
    );
/*
Step 2. Create the empty SASReferences data set.
*/
%cst_createdsfromtemplate(
    _cstStandard=CST-FRAMEWORK,
    _cstType=control,
    _cstSubType=reference,
    _cstOutputDS=sasrefs
    );
/*
Step 3. Fill in the minimal information for a series of
records
*/
data sasrefs;
    if 0 then set sasrefs;

    standard='CST-FRAMEWORK';
    standardversion='1.2';
    type='messages';
    subtype='';
    sasref='cstmsg';
    reftype='libref';
    order=1;
    iotype='input';
    filetype='dataset';
    allowoverwrite='N';
    output;
    standard='CST-FRAMEWORK';
    standardversion='1.2';
    type='lookup';
    subtype='';
    sasref='cstlkup';
    reftype='libref';
    order=1;
    iotype='input';
    filetype='dataset';
    allowoverwrite='N';
    output;
    standard='CST-FRAMEWORK';
    standardversion='1.2';
    type='results';
    subtype='validationresults';
    sasref='cstrslt';
    reftype='libref';
    order=1;
    iotype='output';
    filetype='dataset';
    allowoverwrite='Y';
    output;
run;
```

The following display shows what the data set looks like:

Figure 2.6 Example SASReferences Data Set



standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order	memname	comment
CST-FRAMEWORK	1.2	messages		cstmsg	libref	input	dataset	N			1		
CST-FRAMEWORK	1.2	lookup		cstlkup	libref	input	dataset	N			1		
CST-FRAMEWORK	1.2	results	validationresults	cstrslt	libref	output	dataset	Y			1		

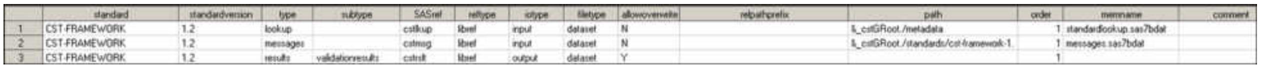
The **path** and **memname** columns are missing. The user has specified the standard, standardversion, type, subtype, SASref, and reftype. This information is sufficient. The rest of the information is available from the registered standard's metadata.

This macro call attempts to insert the missing information if it is found in a registered standard's metadata:

```
/*
Step 4. Insert the missing information from registered
standard.
*/
%cst_insertstandardsasrefs(
    _cstSASReferences=sasrefs
    ,_cstOutputDS=outSASRefs
    );
```

The following display shows what the output data set looks like:

Figure 2.7 *work.outSASRefs Data Set with Added Content*



	standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order	memname	comment
1	CST-FRAMEWORK	1.2	lookup		cstlkup	libref	input	dataset	N		&_cstGRoot./metadata	1	standardlookup.sas7bdat	
2	CST-FRAMEWORK	1.2	messages		cstmsg	libref	input	dataset	N		&_cstGRoot./standards/cst-framework-1.	1	messages.sas7bdat	
3	CST-FRAMEWORK	1.2	results	validationresults	cstrslt	libref	output	dataset	Y			1		

Maintenance Usage Scenarios

Overview

The following sections describe usage scenarios that the framework accommodates. Code that is required to complete the usage scenario is included in each section. All macros that are provided in the usage scenarios are in the primary SAS Clinical Standards Toolkit autocall path:

- Microsoft Windows

  `!sasroot/cstframework/sasmacro`

- UNIX

  `!sasroot/sasautos`

Note: All of the maintenance usage scenarios require that you have Write access to the global standards library.

For complete macro documentation, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

TIP Best Practice Recommendation: Do not modify global standards library files provided with the SAS Clinical Standards Toolkit. Instead, modify copies of these files. Leaving the SAS files intact enables these files to be updated without concern about overwriting or losing your changes.

Registering a New Version of a Standard

This code defines and registers a new standard. The code can also be used to register a new or custom version of an existing standard.

```
/*
Step 1. Ensure that the macro variable pointing to the global standards
library exists.
*/
%cstutil_setcstgroot;
/*
Step 2. Register the standard with the Toolkit global standards
library
*/
%cst_registerstandard(
    _cstRootPath=%nrstr(&_cstGRoot./standards/myStandard),
    _cstControlSubPath=control,
    _cstStdDSName=standards,
    _cstStdSASRefsDSName=StandardSASReferences),
    _cstStdLookupDSName=standardlookup;
```

Step 1 ensures that the macro variable that contains the global standards library path is set. Step 2 registers the standard by passing this information:

- The main path to the directory that contains the standard version's files.
- The path to the registration data sets that are used to populate the global standards library metadata data sets. This is the name of the subfolder in the **`_cstRootPath`** parameter value.

  Note: This subfolder must exist before registering the standard.
- The names of the Standards and StandardSASReferences data sets. These data sets have the same structure as the data sets in the global standards library metadata directory. Both of these data sets are required to define a new standard or a new version of a standard.
- The name of the Standardlookup data set. This data set has the same structure as the data set in the ***`global standards library directory`*****`/metadata`** directory. This data set is optional.

The `_cstRootPath` parameter uses `%nrstr(&_cstGroot)` so that `&_cstGroot` is registered as a macro variable. This specification allows the global standards library to be moved or copied without reregistering the full path of the new standard.

When defining and registering a new standard, you should evaluate which of the metadata files described in "Common Framework Metadata" on page 13 should be provided to support new standard functionality. For example:

- Should a sample SASReferences file be created to perform some task?
- Should a Messages data set be added to provide standard-specific informational messages?
- Should properties files be provided to set standard-specific global macro variables?

For more information about the metadata files that support the SAS Clinical Standards Toolkit, see Chapter 3, "Metadata File Descriptions," on page 33. You can define new metadata types. These new metadata types should be documented in the standard-specific StandardSASReferences and Standardlookup data sets, and in the SAS Clinical Standards Toolkit framework Standardlookup data set.

Setting the Default Version for a Standard

When multiple versions of a standard exist, the first version that is installed is set as the default. The default version is used when multiple versions of a standard have been registered, and a specific version is not provided in a macro call or in a SASReferences file. This code modifies the default version of a specific standard:

```
%cst_setstandardversiondefault(
    _cstStandard=CDISC-SDTM
    ,_cstStandardVersion=3.1.3
    );
```

The version `3.1.3` is set as the default version for the CDISC SDTM standard.

Unregistering a Standard Version

If a standard becomes obsolete and needs to be unregistered, then use the framework to do this. Unregistering a standard might be needed during the development of a custom standard.

This macro call unregisters the CDISC SDTM 3.1.1 standard, removes it from the global standards library metadata Standards data set, and removes all records for 3.1.1 from the StandardSASReferences data set:

```
%cst_unregisterstandard(
    _cstStandard=CDISC-SDTM
    ,_cstStandardVersion=3.1.1
    );
```

Unregistering an Old Version of a Standard, and Then Registering a New Version of a Standard

Suppose that the SAS Clinical Standards Toolkit 1.6 is currently installed and used. The SAS Clinical Standards Toolkit 1.7 is released. You want the product updates for a standard version. In the following steps, the CDISC SDTM standard is used as an example. However, the steps apply to all other standard versions. You want to set version 3.2 as the default version for the CDISC SDTM standard. The SAS Clinical Standards Toolkit installation process does not do this automatically because you might have made updates to the SAS Clinical Standards Toolkit 1.6 code base or metadata that you want to preserve. Or, you might want to test the SAS Clinical Standards Toolkit 1.7 CDISC SDTM 3.2 implementation before declaring it the new default version.

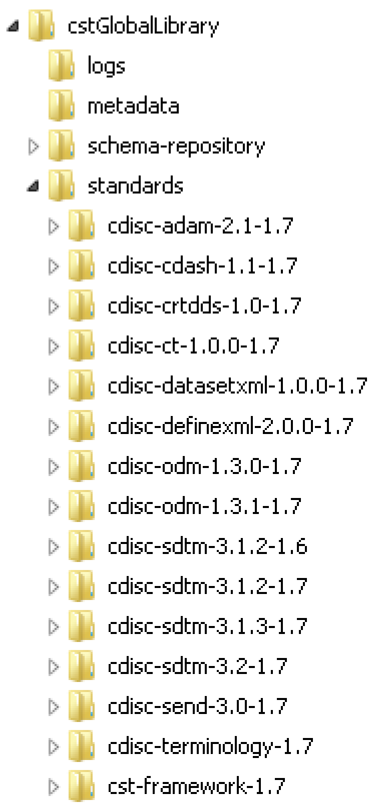
Step 1: Confirm that multiple versions of the standard are available. Confirm that registration of a new version is needed.

1 Navigate to the global standards library Standards directory ***`global standards library directory`*****`/standards`**.

2 Confirm that multiple libraries exist for the same standard version.

In this example, two subdirectories exist for CDISC SDTM 3.1.2.

Figure 2.8 Multiple Versions per Standard in the Global Standards Library



```
cstGlobalLibrary
  logs
  metadata
  schema-repository
  standards
    cdisc-adam-2.1-1.7
    cdisc-cdash-1.1-1.7
    cdisc-crtdds-1.0-1.7
    cdisc-ct-1.0.0-1.7
    cdisc-datasetxml-1.0.0-1.7
    cdisc-definexml-2.0.0-1.7
    cdisc-odm-1.3.0-1.7
    cdisc-odm-1.3.1-1.7
    cdisc-sdtm-3.1.2-1.6
    cdisc-sdtm-3.1.2-1.7
    cdisc-sdtm-3.1.3-1.7
    cdisc-sdtm-3.2-1.7
    cdisc-send-3.0-1.7
    cdisc-terminology-1.7
    cst-framework-1.7
```

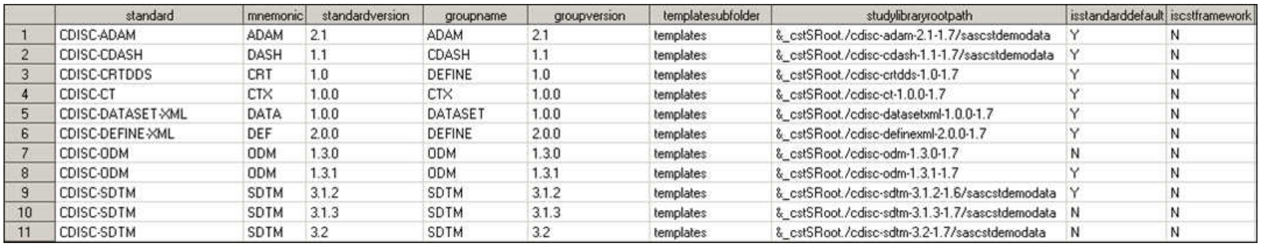
The **`cdisc-sdtm-3.1.2–1.6`** directory contains files installed with the SAS Clinical Standards Toolkit 1.6. The **`cdisc-sdtm-3.1.2-1.7`** directory contains files installed with the SAS Clinical Standards Toolkit 1.7.

3 Confirm which revision of the standard version is currently in use.

- Assign a LIBNAME to the **`metadata`** subdirectory in the global standards library.
- Open the Standards data set in the library, and confirm that the older version is the one being used.

The following display shows that the registered version CDISC SDTM 3.1.2.-1.6 indicates that it is the original version that was shipped with the SAS Clinical Standards Toolkit 1.6:

Figure 2.9 *Global Standards Library Metadata Standards Data Set before Updates*



	standard	mnemonic	standardversion	groupname	groupversion	templatesubfolder	studylibraryrootpath	isstandarddefault	iscstframework
1	CDISC-ADAM	ADAM	2.1	ADAM	2.1	templates	&_cstSRoot./cdisc-adam-2.1-1.7/sascstdemodata	Y	N
2	CDISC-CDASH	DASH	1.1	CDASH	1.1	templates	&_cstSRoot./cdisc-cdash-1.1-1.7/sascstdemodata	Y	N
3	CDISC-CRTDDS	CRT	1.0	DEFINE	1.0	templates	&_cstSRoot./cdisc-crtdds-1.0-1.7	Y	N
4	CDISC-CT	CTX	1.0.0	CTX	1.0.0	templates	&_cstSRoot./cdisc-ct-1.0.0-1.7	Y	N
5	CDISC-DATASET-XML	DATA	1.0.0	DATASET	1.0.0	templates	&_cstSRoot./cdisc-datasetxml-1.0.0-1.7	Y	N
6	CDISC-DEFINE-XML	DEF	2.0.0	DEFINE	2.0.0	templates	&_cstSRoot./cdisc-definexml-2.0.0-1.7	Y	N
7	CDISC-ODM	ODM	1.3.0	ODM	1.3.0	templates	&_cstSRoot./cdisc-odm-1.3.0-1.7	N	N
8	CDISC-ODM	ODM	1.3.1	ODM	1.3.1	templates	&_cstSRoot./cdisc-odm-1.3.1-1.7	Y	N
9	CDISC-SDTM	SDTM	3.1.2	SDTM	3.1.2	templates	&_cstSRoot./cdisc-sdtm-3.1.2-1.6/sascstdemodata	Y	N
10	CDISC-SDTM	SDTM	3.1.3	SDTM	3.1.3	templates	&_cstSRoot./cdisc-sdtm-3.1.3-1.7/sascstdemodata	N	N
11	CDISC-SDTM	SDTM	3.2	SDTM	3.2	templates	&_cstSRoot./cdisc-sdtm-3.2-1.7/sascstdemodata	N	N

CDISC SDTM 3.1.2.-1.6 is defined as the default version for the CDISC SDTM standard.

Step 2: Register the updated CDISC SDTM 3.1.2 metadata in the global standards library to use the SAS Clinical Standards Toolkit 1.7.

1 Navigate to the Standards directory in the global standards library. Go to the **`programs`** directory of the revision of the standard version that needs to be registered. For example, go to ***`global standards library directory/`*** **`standards/cdisc-sdtm-3.1.2-1.7/programs`**.

2 Start a SAS session. Make sure that the current directory is the **`programs`** directory.

3 To unregister the currently installed revision and version, submit this code:

```
%cstutil_setcstgroot;
/*
Set the framework properties used for the uninstall
*/
%cst_setstandardproperties(
    _cstStandard=CST-FRAMEWORK,
    _cstSubType=initialize
    );

/*
If the version to be replaced is the default, you must
make another version the default.
In this case, this is the desired final outcome anyway.
*/
```

```
%cst_setstandardversiondefault(
    _cstStandard=CDISC-SDTM
    ,_cstStandardVersion=3.1.3
    );

/*
Unregister the standard
*/
%cst_unregisterstandard(
    _cstStandard=CDISC-SDTM
    ,_cstStandardVersion=3.1.2
    );
```

Note: The %CST_SETSTANDARDVERSIONDEFAULT macro call needs to be used only if the version being updated is the default version of the standard.

4 Check the Results data set. By default, the data set is work._cstResults. The final line in the data set should report that the standard version is no longer registered as a standard.

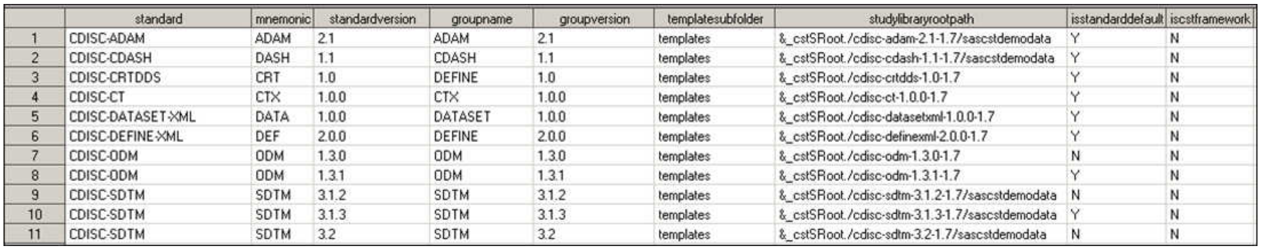
5 Open and submit the registerstandard.sas file from the `programs` directory into the Program Editor.

6 Confirm that the new revision was registered.

- Assign a LIBNAME to the **`metadata`** subdirectory in the global standards library.
- Open the Standards data set in the library, and confirm that the newer revision is the one being used.

The following display shows that the CDISC SDTM 3.1.2 standard is now reregistered, the product revision in use is 1.7, and CDISC SDTM 3.1.3 is registered as the default standard:

Figure 2.10 *Global Standards Library Metadata Standards Data Set after Updates*



	standard	mnemonic	standardversion	groupname	groupversion	templatesubfolder	studylibraryrootpath	isstandarddefault	iscstframework
1	CDISC-ADAM	ADAM	2.1	ADAM	2.1	templates	&_cstSRoot./cdisc-adam-2.1-1.7/sascstdemodata	Y	N
2	CDISC-CDASH	DASH	1.1	CDASH	1.1	templates	&_cstSRoot./cdisc-cdash-1.1-1.7/sascstdemodata	Y	N
3	CDISC-CRTDDS	CRT	1.0	DEFINE	1.0	templates	&_cstSRoot./cdisc-crtdds-1.0-1.7	Y	N
4	CDISC-CT	CTX	1.0.0	CTX	1.0.0	templates	&_cstSRoot./cdisc-ct-1.0.0-1.7	Y	N
5	CDISC-DATASET-XML	DATA	1.0.0	DATASET	1.0.0	templates	&_cstSRoot./cdisc-datasetxml-1.0.0-1.7	Y	N
6	CDISC-DEFINE-XML	DEF	2.0.0	DEFINE	2.0.0	templates	&_cstSRoot./cdisc-definexml-2.0.0-1.7	Y	N
7	CDISC-ODM	ODM	1.3.0	ODM	1.3.0	templates	&_cstSRoot./cdisc-odm-1.3.0-1.7	N	N
8	CDISC-ODM	ODM	1.3.1	ODM	1.3.1	templates	&_cstSRoot./cdisc-odm-1.3.1-1.7	Y	N
9	CDISC-SDTM	SDTM	3.1.2	SDTM	3.1.2	templates	&_cstSRoot./cdisc-sdtm-3.1.2-1.7/sascstdemodata	N	N
10	CDISC-SDTM	SDTM	3.1.3	SDTM	3.1.3	templates	&_cstSRoot./cdisc-sdtm-3.1.3-1.7/sascstdemodata	Y	N
11	CDISC-SDTM	SDTM	3.2	SDTM	3.2	templates	&_cstSRoot./cdisc-sdtm-3.2-1.7/sascstdemodata	N	N

3 Metadata File Descriptions

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Overview

The SAS Clinical Standards Toolkit provides and uses metadata files to support its basic core functions, and to support specific functionality within the SAS Clinical Standards Toolkit. The file content and structure are described in the following sections. The usage of each of these metadata files is described in the document.

Standards

The Standards data set is used by the SAS Clinical Standards Toolkit framework to store information about a standard version. All standards that are provided with the SAS Clinical Standards Toolkit, and standards that you might want to add are defined in the global standards library in the metadata/standards data set. All calls to the %CST_REGISTERSTANDARD macro that are described in Chapter 2 interact directly with the metadata/standards data set.

Table 3.1 *Metadata/Standards Data Set Structure in the Global Standards Library*

Column Name	Column Length	Description
standard	($20)	The name of the registered standard.
mnemonic	($4)	A short mnemonic for the standard.
standardversion	($20)	The version number of the registered standard. Must be unique within the standard.
groupname	($20)	The standard group across versions, such as STDM or TERMINOLOGY.
groupversion	($20)	The version of the groupname, often the same as standardversion.
comment	($200)	A description of the registered standard version.

Column Name	Column Length	Description
rootpath	($200)	The root path for the standard version's directory in the global standards library.
studylibraryrootpath	($200)	The root path to the study repository. This can be used to initialize the studyRootPath and studyOutputPath global macro variables and to use relative paths to study library subfolders. By default, this is set to the sample library that is associated with each standard provided with the SAS Clinical Standards Toolkit.
controlsubfolder	($200)	The control folder path (relative to rootpath). This value provides the location of data sets that are required for standard registration (such as Standards and StandardSASReferences).
templatesubfolder	($200)	The template folder path (relative to rootpath). This value provides the location of data sets that are specific to the standard that serve as templates for standard-specific processes.
isstandarddefault	($1)	A value that identifies whether the version is the default for the standard. More than one version can be registered and you can still have a default version. Valid values are Y and N.
iscstframework	($1)	A value that identifies whether the standard version is part of the framework. This column can be used to subset the list of registered standards. Valid values are Y and N.
isdatastandard	($1)	A value that identifies whether the standard version is a data standard. For example, CDISC SDTM versions are data standards, and CDISC Controlled Terminology is not. Valid values are Y and N.
supportsvalidation	($1)	A value that identifies whether the standard version supports validation. Valid values are Y and N.

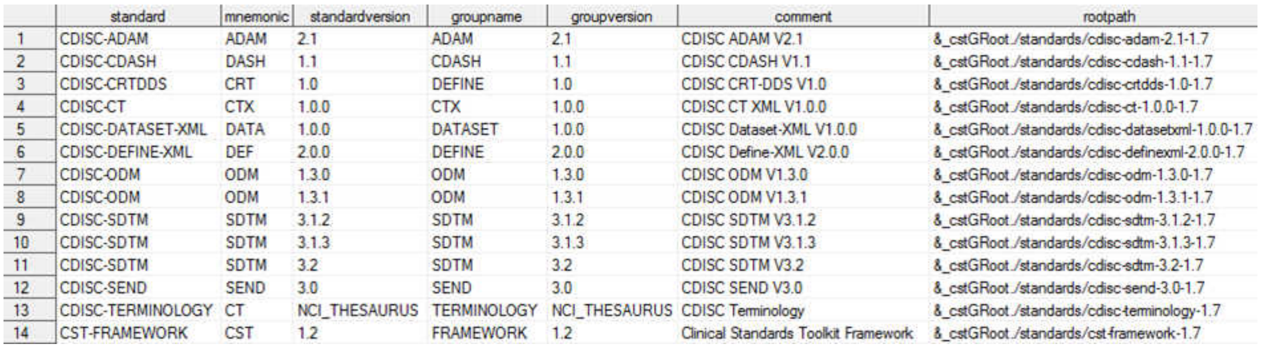
Column Name	Column Length	Description
isxmlstandard	($1)	A value that identifies whether the standard version is based on XML. CDISC SDTM is not, and CDISC CRT-DDS is. Valid values are Y and N.
importxsl	($200)	If the standard version is based on XML, then this is the path to the XSL file to import the XML into the SAS representation.
exportxsl	($200)	If the standard version is based on XML, then this is the path to the XSL file to export the XML file.
schema	($200)	If the standard version is based on XML, then this is the path to the XML schema document that can be used to validate the XML.
productrevision	($10)	The revision of the standard and standardversion that is currently installed.

The global standards library data set provided with the SAS Clinical Standards Toolkit is located here:

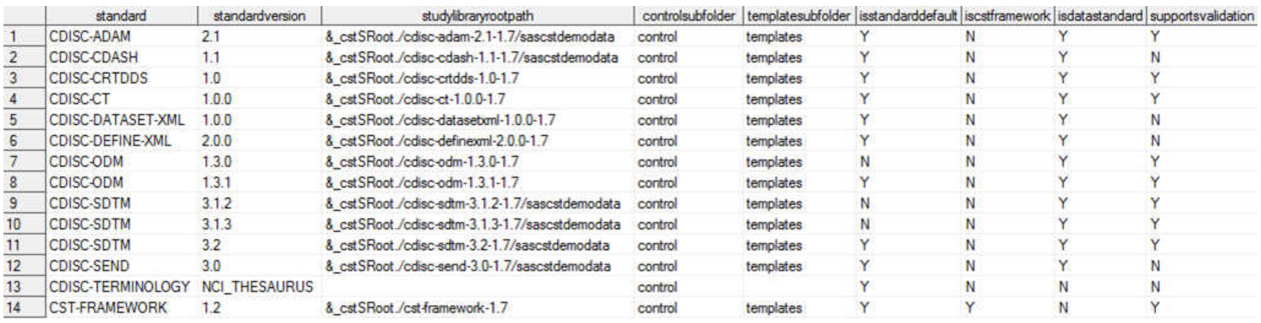
***global standards library directory*/metadata/standards.sas7bdat**

The global standards library data set contains these records, which are provided with the SAS Clinical Standards Toolkit (the columns are continued in the subsequent two images).

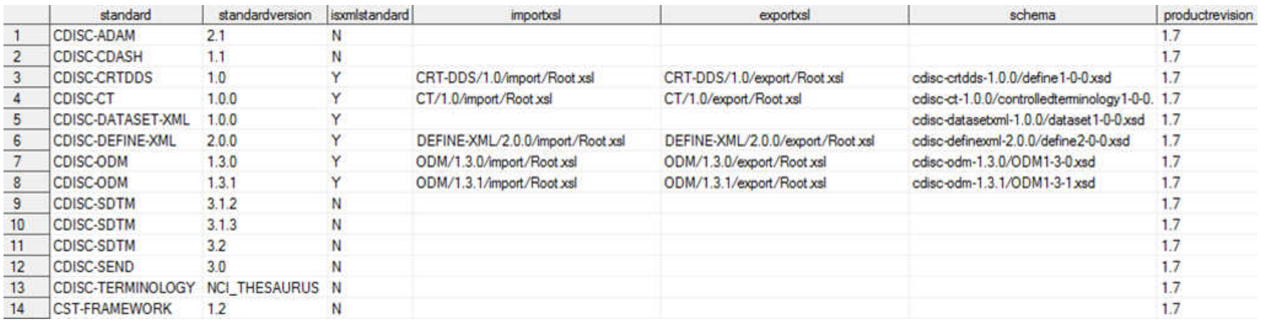
Figure 3.1 *Metadata/Standards Data Set Content in the Global Standards Library*



	standard	mnemonic	standardversion	groupname	groupversion	comment	rootpath
1	CDISC-ADAM	ADAM	2.1	ADAM	2.1	CDISC ADAM V2.1	&_cstGRoot./standards/cdisc-adam-2.1-1.7
2	CDISC-CDASH	DASH	1.1	CDASH	1.1	CDISC CDASH V1.1	&_cstGRoot./standards/cdisc-cdash-1.1-1.7
3	CDISC-CRTDDS	CRT	1.0	DEFINE	1.0	CDISC CRT-DDS V1.0	&_cstGRoot./standards/cdisc-crtdds-1.0-1.7
4	CDISC-CT	CTX	1.0.0	CTX	1.0.0	CDISC CT XML V1.0.0	&_cstGRoot./standards/cdisc-ct-1.0.0-1.7
5	CDISC-DATASET-XML	DATA	1.0.0	DATASET	1.0.0	CDISC Dataset-XML V1.0.0	&_cstGRoot./standards/cdisc-datasetxml-1.0.0-1.7
6	CDISC-DEFINE-XML	DEF	2.0.0	DEFINE	2.0.0	CDISC Define-XML V2.0.0	&_cstGRoot./standards/cdisc-definexml-2.0.0-1.7
7	CDISC-ODM	ODM	1.3.0	ODM	1.3.0	CDISC ODM V1.3.0	&_cstGRoot./standards/cdisc-odm-1.3.0-1.7
8	CDISC-ODM	ODM	1.3.1	ODM	1.3.1	CDISC ODM V1.3.1	&_cstGRoot./standards/cdisc-odm-1.3.1-1.7
9	CDISC-SDTM	SDTM	3.1.2	SDTM	3.1.2	CDISC SDTM V3.1.2	&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.7
10	CDISC-SDTM	SDTM	3.1.3	SDTM	3.1.3	CDISC SDTM V3.1.3	&_cstGRoot./standards/cdisc-sdtm-3.1.3-1.7
11	CDISC-SDTM	SDTM	3.2	SDTM	3.2	CDISC SDTM V3.2	&_cstGRoot./standards/cdisc-sdtm-3.2-1.7
12	CDISC-SEND	SEND	3.0	SEND	3.0	CDISC SEND V3.0	&_cstGRoot./standards/cdisc-send-3.0-1.7
13	CDISC-TERMINOLOGY	CT	NCI_THESAURUS	TERMINOLOGY	NCI_THESAURUS	CDISC Terminology	&_cstGRoot./standards/cdisc-terminology-1.7
14	CST-FRAMEWORK	CST	1.2	FRAMEWORK	1.2	Clinical Standards Toolkit Framework	&_cstGRoot./standards/cst-framework-1.7



	standard	standardversion	studylibraryrootpath	controlsubfolder	templatesubfolder	isstandarddefault	iscstframework	isdatastandard	supportsvalidation
1	CDISC-ADAM	2.1	&_cstSRoot./cdisc-adam-2.1-1.7/sascstdemodata	control	templates	Y	N	Y	Y
2	CDISC-CDASH	1.1	&_cstSRoot./cdisc-cdash-1.1-1.7/sascstdemodata	control	templates	Y	N	Y	N
3	CDISC-CRTDDS	1.0	&_cstSRoot./cdisc-crtdds-1.0-1.7	control	templates	Y	N	Y	Y
4	CDISC-CT	1.0.0	&_cstSRoot./cdisc-ct-1.0.0-1.7	control	templates	Y	N	Y	Y
5	CDISC-DATASET-XML	1.0.0	&_cstSRoot./cdisc-datasetxml-1.0.0-1.7	control	templates	Y	N	Y	N
6	CDISC-DEFINE-XML	2.0.0	&_cstSRoot./cdisc-definexml-2.0.0-1.7	control	templates	Y	N	Y	N
7	CDISC-ODM	1.3.0	&_cstSRoot./cdisc-odm-1.3.0-1.7	control	templates	N	N	Y	Y
8	CDISC-ODM	1.3.1	&_cstSRoot./cdisc-odm-1.3.1-1.7	control	templates	Y	N	Y	Y
9	CDISC-SDTM	3.1.2	&_cstSRoot./cdisc-sdtm-3.1.2-1.7/sascstdemodata	control	templates	N	N	Y	Y
10	CDISC-SDTM	3.1.3	&_cstSRoot./cdisc-sdtm-3.1.3-1.7/sascstdemodata	control	templates	N	N	Y	Y
11	CDISC-SDTM	3.2	&_cstSRoot./cdisc-sdtm-3.2-1.7/sascstdemodata	control	templates	Y	N	Y	Y
12	CDISC-SEND	3.0	&_cstSRoot./cdisc-send-3.0-1.7/sascstdemodata	control	templates	Y	N	Y	N
13	CDISC-TERMINOLOGY	NCI_THESAURUS		control		Y	N	N	N
14	CST-FRAMEWORK	1.2	&_cstSRoot./cst-framework-1.7	control	templates	Y	Y	N	Y



	standard	standardversion	isxmlstandard	importxsl	exportxsl	schema	productrevision
1	CDISC-ADAM	2.1	N				1.7
2	CDISC-CDASH	1.1	N				1.7
3	CDISC-CRTDDS	1.0	Y	CRT-DDS/1.0/import/Root.xsl	CRT-DDS/1.0/export/Root.xsl	cdisc-crtdds-1.0.0/define1-0-0.xsd	1.7
4	CDISC-CT	1.0.0	Y	CT/1.0/import/Root.xsl	CT/1.0/export/Root.xsl	cdisc-ct-1.0.0/controlledterminology1-0-0.	1.7
5	CDISC-DATASET-XML	1.0.0	Y			cdisc-datasetxml-1.0.0/dataset1-0-0.xsd	1.7
6	CDISC-DEFINE-XML	2.0.0	Y	DEFINE-XML/2.0.0/import/Root.xsl	DEFINE-XML/2.0.0/export/Root.xsl	cdisc-definexml-2.0.0/define2-0-0.xsd	1.7
7	CDISC-ODM	1.3.0	Y	ODM/1.3.0/import/Root.xsl	ODM/1.3.0/export/Root.xsl	cdisc-odm-1.3.0/ODM1-3-0.xsd	1.7
8	CDISC-ODM	1.3.1	Y	ODM/1.3.1/import/Root.xsl	ODM/1.3.1/export/Root.xsl	cdisc-odm-1.3.1/ODM1-3-1.xsd	1.7
9	CDISC-SDTM	3.1.2	N				1.7
10	CDISC-SDTM	3.1.3	N				1.7
11	CDISC-SDTM	3.2	N				1.7
12	CDISC-SEND	3.0	N				1.7
13	CDISC-TERMINOLOGY	NCI_THESAURUS	N				1.7
14	CST-FRAMEWORK	1.2	N				1.7

The `&_cstGRoot` in the **rootpath** column maps to the ***`global standards library directory`*** that is set by calling the %CSTUTIL_SETCSTGROOT macro.

&_cstSRoot in the studylibraryrootpath column maps to the *sample study library directory* that is set by calling the %CSTUTIL_SETCSTSROOT macro.

An example of the global standards library data set that is used to register a specific standard is located here:

`global standards library directory``/standards/`
`cdisc-sdtm-3.1.2-1.7/control/standards.sas7bdat`

StandardSASReferences

The StandardSASReferences metadata data set specifies a set of library and file records that are used by most processes that are provided with the SAS Clinical Standards Toolkit implementation of each standard. It contains references to those libraries and files that are installed with each standard that SAS provides. A standard-specific StandardSASReferences data set exists for each SAS Clinical Standards

Toolkit data standard that is supported by SAS. For example, the CDISC SDTM 3.1.2 StandardSASReferences data set is located here:

***global standards library directory*/standards/ cdisc-sdtm-3.1.2-1.7/control/standardsasreferences.sas7bdat**

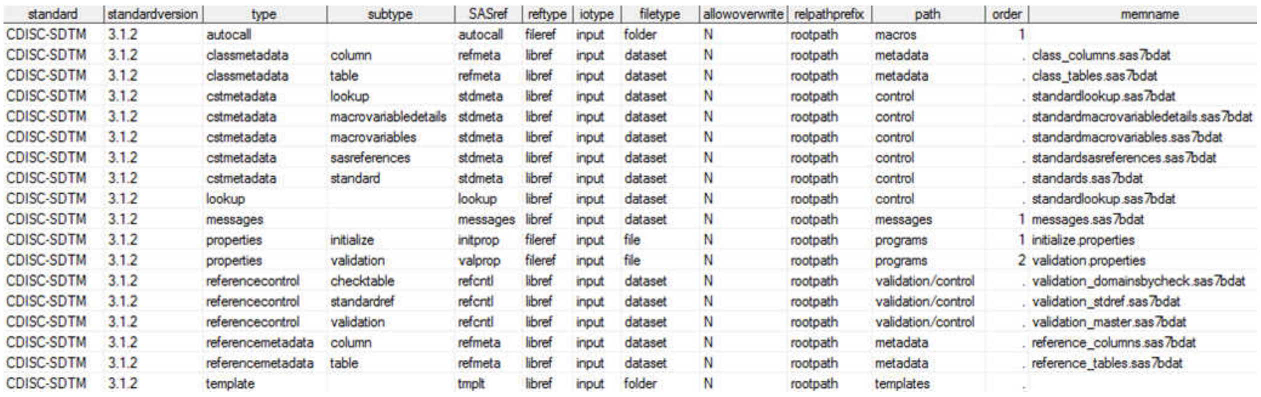


Figure 3.2 *Metadata/StandardSASReferences Data Set Content in the Global Standards Library*

standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order	memname
CDISC-SDTM	3.1.2	autocall		autocall	fileref	input	folder	N	rootpath	macros	1	
CDISC-SDTM	3.1.2	classmetadata	column	refmeta	libref	input	dataset	N	rootpath	metadata	.	class_columns.sas7bdat
CDISC-SDTM	3.1.2	classmetadata	table	refmeta	libref	input	dataset	N	rootpath	metadata	.	class_tables.sas7bdat
CDISC-SDTM	3.1.2	cstmetadata	lookup	stdmeta	libref	input	dataset	N	rootpath	control	.	standardlookup.sas7bdat
CDISC-SDTM	3.1.2	cstmetadata	macrovariabledetails	stdmeta	libref	input	dataset	N	rootpath	control	.	standardmacrovariabledetails.sas7bdat
CDISC-SDTM	3.1.2	cstmetadata	macrovariables	stdmeta	libref	input	dataset	N	rootpath	control	.	standardmacrovariables.sas7bdat
CDISC-SDTM	3.1.2	cstmetadata	sasreferences	stdmeta	libref	input	dataset	N	rootpath	control	.	standardsasreferences.sas7bdat
CDISC-SDTM	3.1.2	cstmetadata	standard	stdmeta	libref	input	dataset	N	rootpath	control	.	standards.sas7bdat
CDISC-SDTM	3.1.2	lookup		lookup	libref	input	dataset	N	rootpath	control	.	standardlookup.sas7bdat
CDISC-SDTM	3.1.2	messages		messages	libref	input	dataset	N	rootpath	messages	1	messages.sas7bdat
CDISC-SDTM	3.1.2	properties	initialize	initprop	fileref	input	file	N	rootpath	programs	1	initialize.properties
CDISC-SDTM	3.1.2	properties	validation	valprop	fileref	input	file	N	rootpath	programs	2	validation.properties
CDISC-SDTM	3.1.2	referencecontrol	checktable	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_domainsbycheck.sas7bdat
CDISC-SDTM	3.1.2	referencecontrol	standardref	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_stdref.sas7bdat
CDISC-SDTM	3.1.2	referencecontrol	validation	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_master.sas7bdat
CDISC-SDTM	3.1.2	referencemetadata	column	refmeta	libref	input	dataset	N	rootpath	metadata	.	reference_columns.sas7bdat
CDISC-SDTM	3.1.2	referencemetadata	table	refmeta	libref	input	dataset	N	rootpath	metadata	.	reference_tables.sas7bdat
CDISC-SDTM	3.1.2	template		tmplt	libref	input	folder	N	rootpath	templates	.	

The **type** and **subtype** values are discussed in the following section. The **SASref** value is the default value that is used in the library and filename allocation process. You can overwrite this value. The **path** value contains a relative path. The **relpathprefix** value **`rootpath`** instructs the code to use the rootpath location that is specified in the standard-specific Standards data set. The resolved path is shown in Figure 3.3 on page 39.

The cross-standard global standards library StandardSASReferences data set that is provided with the SAS Clinical Standards Toolkit is located here:

***global standards library directory*/metadata/ standardsasreferences.sas7bdat**

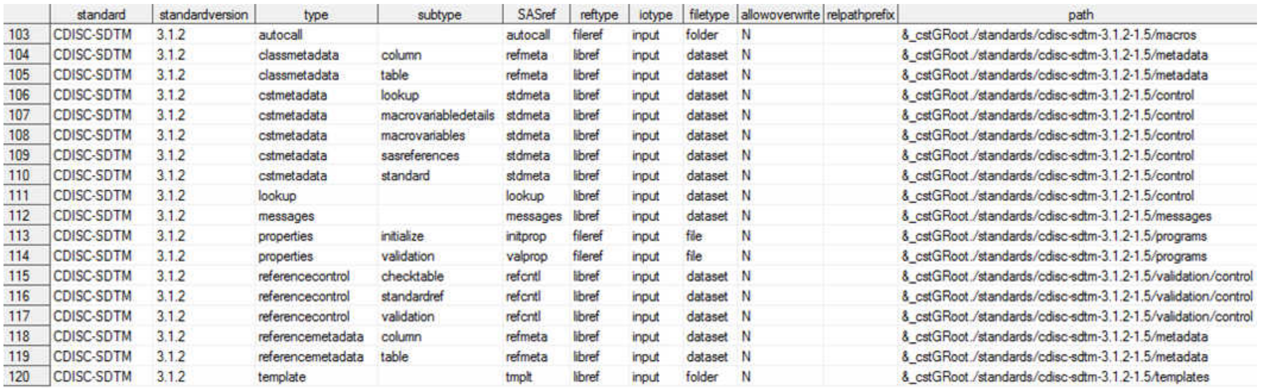
This data set contains the concatenation of each StandardSASReferences data set that is provided for each supported standard in the SAS Clinical Standards Toolkit. The following enhancements are the only enhancements to the data set during concatenation:

- the **path** column is resolved to the full global standards library path for each record, based on the **relpathprefix** value

- the **relpathprefix** column is reset to null

The following display shows the content for the CDISC SDTM StandardSASReferences data set that is described in Figure 3.2 on page 38. In the display, &_cstGRoot maps to the ***global standards library directory*** that is set by calling the %CSTUTIL_SETCSTGROOT macro:

Figure 3.3 *Metadata/StandardSASReferences Data Set in the Global Standards Library (CDISC SDTM 3.1.2 Excerpt)*



	standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path
103	CDISC-SDTM	3.1.2	autocall		autocall	fileref	input	folder	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/macros
104	CDISC-SDTM	3.1.2	classmetadata	column	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/metadata
105	CDISC-SDTM	3.1.2	classmetadata	table	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/metadata
106	CDISC-SDTM	3.1.2	cstmetadata	lookup	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/control
107	CDISC-SDTM	3.1.2	cstmetadata	macrovariabledetails	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/control
108	CDISC-SDTM	3.1.2	cstmetadata	macrovariables	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/control
109	CDISC-SDTM	3.1.2	cstmetadata	sasreferences	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/control
110	CDISC-SDTM	3.1.2	cstmetadata	standard	stdmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/control
111	CDISC-SDTM	3.1.2	lookup		lookup	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/control
112	CDISC-SDTM	3.1.2	messages		messages	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/messages
113	CDISC-SDTM	3.1.2	properties	initialize	initprop	fileref	input	file	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/programs
114	CDISC-SDTM	3.1.2	properties	validation	valprop	fileref	input	file	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/programs
115	CDISC-SDTM	3.1.2	referencecontrol	checktable	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/validation/control
116	CDISC-SDTM	3.1.2	referencecontrol	standardref	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/validation/control
117	CDISC-SDTM	3.1.2	referencecontrol	validation	refcntl	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/validation/control
118	CDISC-SDTM	3.1.2	referencemetadata	column	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/metadata
119	CDISC-SDTM	3.1.2	referencemetadata	table	refmeta	libref	input	dataset	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/metadata
120	CDISC-SDTM	3.1.2	template		tmplt	libref	input	folder	N		&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.5/templates

The structure of all StandardSASReferences data sets is the same for all standards provided with the SAS Clinical Standards Toolkit. This structure is described in "SASReferences" on page 42.

Standardlookup

The Standardlookup data set provides a mechanism to capture valid values for discrete variables in the SAS Clinical Standards Toolkit metadata files. This data set supports such tasks as validating the content of the SAS Clinical Standards Toolkit metadata files and providing selectable values in the user interfaces of other tools and solutions.

***Table 3.2** Standardlookup Data Set Structure in the Global Standards Library*

Column Name	Column Length	Description
standard	($20)	The name of the registered standard.
standardversion	($20)	The version number of the registered standard. This must be unique within the standard.
SASref	($8)	SAS libref
table	($32)	A SAS Clinical Standards Toolkit table name
column	($32)	A SAS Clinical Standards Toolkit column name
refcolumn	($32)	Associated SAS Clinical Standards Toolkit column name
refvalue	($200)	Associated SAS Clinical Standards Toolkit column value
value	($200)	Unique SAS Clinical Standards Toolkit column value
default	($200)	Default SAS Clinical Standards Toolkit column value
nonnull	($1)	Value that specifies whether a SAS Clinical Standards Toolkit column value must be non-null
order	(8.)	A SAS Clinical Standards Toolkit column value order
templatetype	($8)	For the given record, a non-null value (for example, data set) indicates that a template is available. For example, the macro call `%cst_createdsfromtemplate( _cstStandard=CST-FRAMEWORK, _cstType=control,_cstSubType=reference, _cstOutputDS=work.sasreferences)` finds that a template is available as csttmplt.sasreferences.
template	($40)	The SAS reference (libref.dset or fileref) to the templatetype. For example, csttmplt.sasreferences points to ***`global standards library directory/`*** **`standards/cst-framework-1.7/templates/sasreferences.sas7bdat`**.

Column Name	Column Length	Description
comment	($200)	Explanatory comments

A Standardlookup data set is provided for most standards with the SAS Clinical Standards Toolkit. This data set can be used in the definition and registration of custom standards in the SAS Clinical Standards Toolkit.

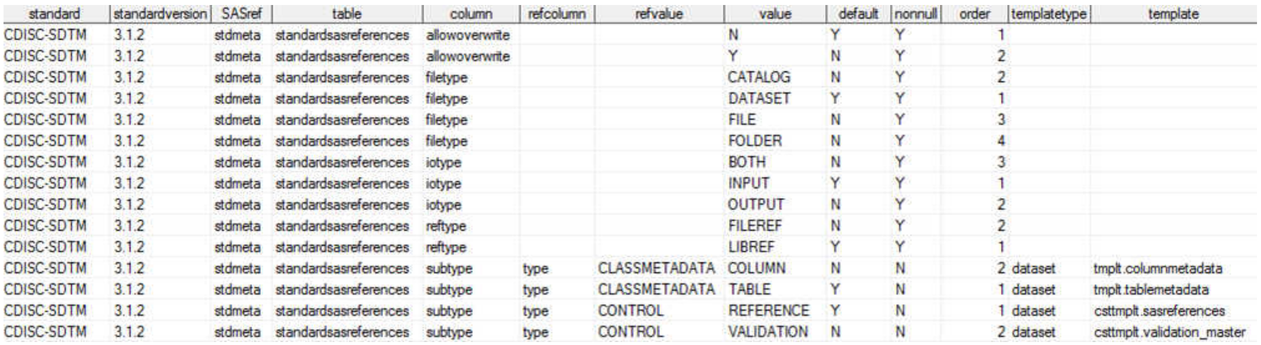
The cross-standard global standards library Standardlookup data set that is provided with the SAS Clinical Standards Toolkit is located here:

***global standards library directory*/metadata/ standardlookup.sas7bdat**

This data set contains the concatenation of each Standardlookup data set that is provided for each supported standard in the SAS Clinical Standards Toolkit.

The following display shows an example of the records in a Standardlookup data set:

Figure 3.4 *Standardlookup Data Set Content in the Global Standards Library*



standard	standardversion	SASref	table	column	refcolumn	refvalue	value	default	nonnull	order	templatetype	template
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	allowoverwrite			N	Y	Y	1		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	allowoverwrite			Y	N	Y	2		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	filetype			CATALOG	N	Y	2		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	filetype			DATASET	Y	Y	1		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	filetype			FILE	N	Y	3		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	filetype			FOLDER	N	Y	4		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	iotype			BOTH	N	Y	3		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	iotype			INPUT	Y	Y	1		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	iotype			OUTPUT	N	Y	2		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	reftype			FILEREF	N	Y	2		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	reftype			LIBREF	Y	Y	1		
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	subtype	type	CLASSMETADATA	COLUMN	N	N	2	dataset	tmplt.columnmetadata
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	subtype	type	CLASSMETADATA	TABLE	Y	N	1	dataset	tmplt.tablemetadata
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	subtype	type	CONTROL	REFERENCE	Y	N	1	dataset	csttmplt.sasreferences
CDISC-SDTM	3.1.2	stdmeta	standardsasreferences	subtype	type	CONTROL	VALIDATION	N	N	2	dataset	csttmplt.validation_master

These records show the valid values for discrete columns in any SDTM 3.1.2 SASReferences (including StandardSASReferences) data set. For example, **filetype** can have values of CATALOG, DATASET, FILE, or FOLDER. These records also show that a SASReferences data set allows two **subtype** values (REFERENCE and VALIDATION) when **type** is CONTROL. When **type** is CONTROL, the **subtype** value must always be non-null.

Templates are available for both the SASReferences data set and the validation_master data sets. For more information about the columns and values in SASReferences data sets, see the following section.

SASReferences

Each SAS Clinical Standards Toolkit process (for example, a primary task or action such as validating source data against a SAS Clinical Standards Toolkit standard) requires using a SASReferences data set. The SASReferences data set identifies all of the inputs required and the outputs that are created by the process. Each process might have its own unique SASReferences data set.

Chapter 6, “SASReferences File,” on page 137, describes the content and usage of SASReferences data sets.

The following table identifies and describes each column within a SASReferences data set:

Table 3.3 *SASReferences Data Set Structure*

Column Name	Column Length	Description
standard	($20)	Standard name. This value should match the **standard** field in the Standards data set in ***global standards library directory*/metadata** and in other metadata files referenced in SASReferences (for example, CDISC SDTM and CDISC CRT-DDS). This column is required.
standardversion	($20)	Specific version of a standard. This value should match one of the standardversion values associated with the **standard** field in the Standards data set in ***global standards library directory*/metadata** and in other metadata files referenced in SASReferences (for example, 3.1.1 or 1.0). This column is required.

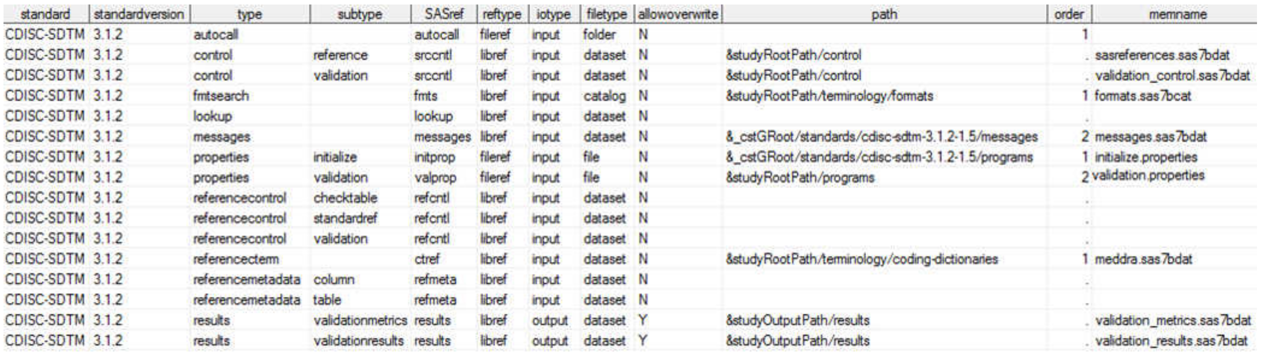
Column Name	Column Length	Description
type	($40)	The type of input and output data or metadata. This is a predefined set of values that are documented in the ***global standards library directory*/standards/cst-framework-1.7/control/standardlookup** data set. These values are also itemized in Table 6.1 on page 140. This column is required.
subtype	($40)	The specific subtype within type of input and output data or metadata. This is a predefined set of values that are documented in the ***global standards library directory*/standards/cst-framework-1.7/control/standardlookup** data set. These values are also itemized in Table 6.1 on page 140. This column is optional, depending on type.
SASref	($8)	The SAS libref or fileref that references the library or file in the SAS Clinical Standards Toolkit SAS process. This value should match the value of sasref that is used in any other associated metadata files (for example, in the Source Columns data set, the value is type=srcmeta). This column is required. It must conform to SAS libref or fileref naming conventions.
reftype	($8)	The reference type. This column is required. Valid values are libref and fileref.
iotype	($8)	The input/output type (input, output, or both) of the entity. Entities defined as “input” or “both” must exist and be accessible. If not, calls to the %CSTUTILVALIDATESASREFERENCES macro report an error condition and halt the process.
filetype	($8)	The file type (folder, dataset, catalog, or file).
allowoverwrite	($1)	Allow the file to be overwritten (Y/N), for files with an iotype value of “output” or “both”.

Column Name	Column Length	Description
relpathprefix	($41)	The relative path prefix (for example, rootpath, studylibraryrootpath, or &mypath). If non-null, the value of the path is assumed to be relative to the resolved relpathprefix. The reserved values rootpath and studylibraryrootpath have special significance: they instruct the SAS Clinical Standards Toolkit to use the standard-specific values for these columns in the ***`global standards library directory/`*** **`metadata/standards.sas7bdat`** data set.
path	($2048)	The path of the library or the path portion of the file reference. If you want to use the default value for a standard, standardversion, type, or subtype, then leave the path blank. The value is added to the &_cstSASRefs working version of the SASReferences data set from the standard-specific StandardSASReferences data set. Specific paths should be provided for any type or subtype that is study- or run-specific. Paths might be relative to an environment variable (for example, !sasroot) or to a SAS macro variable (for example, &studyRootPath).
order	(8.)	Processing or concatenation order within type. If this value exists, then it should be a positive integer with no duplicates within type. This column is optional, depending on type. The order should be specified if one of these is true: 1 Multiple records exist within these types: autocall, fmtsearch, cmplib, messages. 2 Library concatenation is wanted (multiple librefs are within the same value of SASref for a type). 3 There is a need to establish precedence within a type (for example, look first in this library and then look in another library).

Column Name	Column Length	Description
memname	($48)	The name of a specific SAS file (data set or catalog) or file that is not created by SAS (for example, properties or an XML file). The memname column should be blank for library references. This column is optional, depending on type. As a general rule, memname should be provided if the path is provided, except where individual file references are not appropriate (for example, type=autocall and type=sourcedata). If you want to use the default value for a standard, standardversion, type, or subtype, then leave memname blank. The value is added to the &_cstSASRefs working version of the SASReferences data set from the standard-specific StandardSASReferences data set. The file suffix for SAS files is optional.
comment	($200)	Explanatory comments. This column is optional.

The following display shows some information in a typical SAS Clinical Standards Toolkit SASReferences data set:

Figure 3.5 *A Sample SASReferences Data Set*



standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	path	order	memname
CDISC-SDTM	3.1.2	autocall		autocall	fileref	input	folder	N		1	
CDISC-SDTM	3.1.2	control	reference	srccntl	libref	input	dataset	N	&studyRootPath/control	.	sasreferences.sas7bdat
CDISC-SDTM	3.1.2	control	validation	srccntl	libref	input	dataset	N	&studyRootPath/control	.	validation_control.sas7bdat
CDISC-SDTM	3.1.2	fmtsearch		fmts	libref	input	catalog	N	&studyRootPath/terminology/formats	1	formats.sas7bcat
CDISC-SDTM	3.1.2	lookup		lookup	libref	input	dataset	N		.	
CDISC-SDTM	3.1.2	messages		messages	libref	input	dataset	N	&_cstGRoot/standards/cdisc-sdtm-3.1.2-1.5/messages	2	messages.sas7bdat
CDISC-SDTM	3.1.2	properties	initialize	initprop	fileref	input	file	N	&_cstGRoot/standards/cdisc-sdtm-3.1.2-1.5/programs	1	initialize.properties
CDISC-SDTM	3.1.2	properties	validation	valprop	fileref	input	file	N	&studyRootPath/programs	2	validation.properties
CDISC-SDTM	3.1.2	referencecontrol	checktable	refcntl	libref	input	dataset	N		.	
CDISC-SDTM	3.1.2	referencecontrol	standardref	refcntl	libref	input	dataset	N		.	
CDISC-SDTM	3.1.2	referencecontrol	validation	refcntl	libref	input	dataset	N		.	
CDISC-SDTM	3.1.2	referencecterm		ctref	libref	input	dataset	N	&studyRootPath/terminology/coding-dictionaries	1	meddra.sas7bdat
CDISC-SDTM	3.1.2	referencemetadata	column	refmeta	libref	input	dataset	N		.	
CDISC-SDTM	3.1.2	referencemetadata	table	refmeta	libref	input	dataset	N		.	
CDISC-SDTM	3.1.2	results	validationmetrics	results	libref	output	dataset	Y	&studyOutputPath/results	.	validation_metrics.sas7bdat
CDISC-SDTM	3.1.2	results	validationresults	results	libref	output	dataset	Y	&studyOutputPath/results	.	validation_results.sas7bdat

From this display, you can see that the data set contains information about types of data and metadata and where they are located. The SAS Clinical Standards Toolkit imposes a rigid, minimum SASReferences file structure. All columns defined in Table 3.3 on page 42 are expected; additional columns are allowed. No changes to column attributes are allowed (for example, changing column lengths).

Note: SASReferences data sets from the SAS Clinical Standards Toolkit releases prior to version 1.5 can be used in version 1.7 if they do not include any of the columns added in version 1.5 (iotype, filetype, allowoverwrite, and relpathprefix).

Properties

The SAS Clinical Standards Toolkit uses properties files to set default preferences for each process. Properties are name-value pairs that are translated into SAS global macro variables. These macro variables are available for the duration of a SAS Clinical Standards Toolkit process. Properties can be defined in any number of files. Both text file and SAS data set formats are supported. For more information about the SAS Clinical Standards Toolkit global macro variables, see Appendix 1, "Global Macro Variables," on page 459. These macro variables are derived from properties files provided with the SAS Clinical Standards Toolkit.

The following table describes the contents of a sample properties file in ***global standards library directory*/standards/cst-framework/programs/initialize.properties**:

Table 3.4 *Properties File Structure*

Name (Global Macro Variable)	Default Value
_cstDebug	0
_cstDebugOptions	mprint mlogic symbolgen mautolocdisplay
_cst_rc	0
_cst_rcmsg	
_cst_MsgID	
_cst_MsgParm1	
_cst_MsgParm2	

Name (Global Macro Variable)	Default Value
_cstResultSeq	0
_cstSeqCnt	0
_cstSrcData	
_cstResultFlag	0
_cstResultsDS	work._cstresults
_cstMessages	work._cstmessages
_cstReallocateSASRefs	0
_cstFMTLibraries	
_cstMessageOrder	APPEND
_cstSASRefsLoc	
_cstSASRefsName	
_cstSASRefs	work._cstsasrefs
_cstStdSASRefs	
_cstSubjectColumns	_none_
_cstLRECL	LRECL=2048
_cstVersion	1.7

Messages

By default, the SAS Clinical Standards Toolkit provides a Messages data set for the SAS Clinical Standards Toolkit framework and for each data standard provided with the

SAS Clinical Standards Toolkit. Each Messages data set includes a list of codes and associated text that are specific to each standard. In some cases, actions such as validation are used to report process results.

The following table describes the structure of all the message files:

Table 3.5 *Messages Data Set Structure*

Column Name	Column Length	Description	Required
resultid	(\$8)	The message ID. The SAS Clinical Standards Toolkit has adopted a naming convention matching each standard. The resultid values are prefixed with an up to 4-character prefix (CST for framework messaging; CDISC examples: ODM, SDTM, ADAM, and CRT). By convention, the prefix matches the **`mnemonic`** field in the Standards data set in ***`global standards library directory/`*** **`metadata`**. This prefix is followed by a 4-digit numeric that is unique within the standard (for example, SDTM1234). You can use any naming convention limited to eight characters. For CDISC standards supporting validation, the resultid should match the checkid from the Validation Master data set for standard records that support validation.	Yes
standardversion	(\$20)	A specific version of a standard. This value must match one of the standard versions that is associated with a registered standard. This value must also match the **`standardversion`** field in the SASReferences data set. The only exception to this rule is that *** can be used to signify that the check applies to all supported versions of the standard (for example, 3.1.2, 1.0, ***). If a subsequent version of the standard is released, then *** would be applicable if the check is valid for the new version.	Yes

Column Name	Column Length	Description	Required
checksource	($40)	A string that identifies the source of the message. This string is used to provide source-specific messages generated within the SAS Clinical Standards Toolkit. CDISC examples include CDISC, SAS, and WebSDM. This field can contain any user-defined value.	Yes
sourceid	($8)	A reference identifier for this message from the **`checksource`**.	No
checkseverity	($40)	The severity as assigned by **`checksource`**. This value is mapped to these standardized values: Note (Low), Warning (Medium), Error (High). A value is expected, although it is not technically required. It is used in reporting.	No
sourcedescription	($500)	A full description of the validation check that is associated with **`checksource`** if the source is external to the SAS Clinical Standards Toolkit. If **`checksource`** is set to **`CST`**, then this field is null.	No
messagetext	($500)	The default message text to be written to the Results data set. This field can contain 0, 1, or 2 parameters. By convention, parameters are _cstParm1 and _cstParm2, but any _cst prefix parameter is recognized. The fully resolved **`messagetext`** that includes substituted parameter values is written to the Results data set.	Yes
parameter1	($100)	The message parameter1 (_cstParm1) default value. If the code using the message does not provide a parameter value, then this default value is used. This column can be null.	No

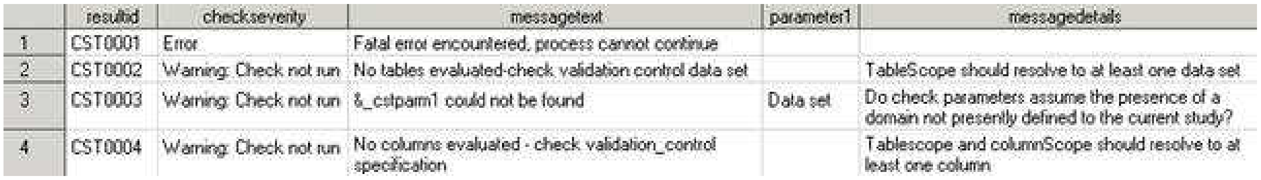
Column Name	Column Length	Description	Required
parameter2	($100)	The message parameter2 (_cstParm2) default value. If the code using the message does not provide a parameter value, then this default value is used. This column can be null.	No
messagedetails	($200)	Any additional information that explains the message.	No

The Messages data set that supports the SAS Clinical Standards Toolkit framework is located here:

***global standards library directory*/standards/cst-framework-1.7/messages/messages.sas7bdat**

The following display provides an excerpt of records and columns from the SAS Clinical Standards Toolkit framework Messages data set:

Figure 3.6 *Framework Messages Data Set*



	resultid	checkseverity	messagetext	parameter1	messagedetails
1	CST0001	Error	Fatal error encountered, process cannot continue		
2	CST0002	Warning: Check not run	No tables evaluated-check validation control data set		TableScope should resolve to at least one data set
3	CST0003	Warning: Check not run	&_cstparm1 could not be found	Data set	Do check parameters assume the presence of a domain not presently defined to the current study?
4	CST0004	Warning: Check not run	No columns evaluated - check validation_control specification		Tablescope and columnScope should resolve to at least one column

Certain message-type data sets that support non-framework standards are described in this document.

Results

Each SAS Clinical Standards Toolkit process generates a Results data set. The Results data set can be persisted beyond the SAS session based on SASReferences data set settings. Each Results data set captures the outcome of specific process actions. Each Results data set uses the Messages data set to standardize output.

The structure of each SAS Clinical Standards Toolkit Results data set is described in this table.

Table 3.6 *Results Data Set Structure*

Column Name	**Column Length**	**Description**
resultid	($8)	Result ID. The resultid is a message ID from the standard Messages data set (for example, framework or CDISC SDTM). The SAS Clinical Standards Toolkit has adopted a naming convention matching a resultid with each standard. The resultid values are prefixed with an up to 4-character prefix (CST for framework messaging; CDISC examples: ODM, SDTM, ADAM, and CRT). By convention, the prefix matches the **`mnemonic`** field in the Standards data set in ***`global standards library directory/`*****`metadata`**. This prefix is followed by a 4-digit numeric that is unique within the standard (for example, SDTM1234). You can use any naming convention limited to eight characters. Value should be non-null.
checkid	($8)	Validation check ID. The SAS Clinical Standards Toolkit has adopted a naming convention matching each standard to be validated. The checkid values are prefixed with an up to 4-character prefix (CDISC examples: ODM, SDTM, ADAM, and CRT). By convention, the prefix matches the **`mnemonic`** field in the Standards data set in ***`global standards library directory/`*****`metadata`**. This prefix is followed by a 4-digit numeric that is unique within the standard (for example, SDTM1234). You can use any naming convention limited to eight characters. Value should be non-null for validation processes. Otherwise, this column is optional.

Column Name	Column Length	Description
resultseq	(8.)	Unique invocation of resultid. For validation processes, a sequence number to indicate the record number relative to checkid in the Validation Control run-time set of checks. If set to 1, then this is incremented only with each repeat invocation of a check. For non-validation processes, this value is generally a constant 1, but is reset to 1 with each new invocation of the SAS Clinical Standards Toolkit macro that is being run when the Results record is generated. Value should be non-null positive integer.
seqno	(8.)	Sequence number relative to resultseq. This value is a unique sequence number for the Results record in each unique value of resultseq. Value should be non-null positive integer.
srcdata	($200)	Source data. This string generally specifies: ■ (for validation) the domains evaluated or the check macro used ■ (otherwise) the SAS Clinical Standards Toolkit macro that is being run when the Results record is generated Value should be non-null.
message	($500)	Resolved message text from Messages data set. The message value includes up to two run-time parameter values in message text. Value should be non-null.

Column Name	Column Length	Description
resultseverity	($40)	Result severity (for example, warning or error). Info — Informational note Note — Problem detected, low severity Warning — Problem detected, medium severity Warning: Check not run — No assessment able to be made Warning: Check not completed — Full compliance assessment could not be made Error — Problem detected, high severity Value should be non-null.
resultflag	(8.)	A value that determines whether a problem has been detected. The values are 0=no, otherwise, yes. -1 Validation check not run 0 No problem detected (value always 0 when resultseverity=Info) 1 Validation check run, error detected Value should be non-null.
_cst_rc	(8.)	Process status. Values are nonzero and aborted. A nonzero value typically indicates that the process ended abnormally. Value should be non-null.
actual	($240)	Actual value observed. This value is generally used for validation reporting. It provides the actual column values that are in error. This column is optional.
keyvalues	($2000)	Record-level keys and values. This value is generally used for validation reporting. It provides domain key values for records that are in error. This column is optional.
resultdetails	($200)	Basis or explanation for result. This column is optional.

For an example of a SAS Clinical Standards Toolkit Results data set, see Figure 7.9 on page 213 and Figure 7.10 on page 214.

Additional Metadata Files

Overview

The following metadata files can be used for specific tasks. In some cases, the file structures might be unique to the supported or referenced standard. These metadata files are provided by the SAS Clinical Standards Toolkit.

Validation Master (Validation Control)

Each standard that supports validation has a Validation Master data set that provides the full set of validation checks defined for that standard. (For a description of the standards.supportsvalidation field, see Table 3.1 on page 34.) This data set should have the columns as defined in Table 7.3 on page 174, though additional columns are permitted for user customizations. For each SAS Clinical Standards Toolkit validation process, the set of run-specific checks is captured in a Validation Control data set. The Validation Control data set is identical in structure to the Validation Master data set, but can be different only in the number of records (checks) included. Use of Validation Control SAS views is supported.

Reference Tables (Source Tables)

Part of the definition of each standard is the itemization of the data tables that define the SAS representation of that standard and version. The reference_tables data set captures table-level metadata about each reference standard data set. The structure of this data set can be standard specific. For example, Table 7.1 on page 167 describes the table metadata for the CDISC SDTM standard. For selected actions, the SAS Clinical Standards Toolkit requires a similarly structured source_tables data set that defines study-specific tables. For example, a SAS Clinical Standards Toolkit validation process compares the study metadata in the source_tables data set with the reference standard metadata in the reference_tables data set.

Reference Columns (Source Columns)

Part of the definition of each standard is the itemization of the columns in each data table that defines the SAS representation of that standard and version. The reference_columns data set captures column-level metadata about each reference standard column. The structure of this data set can be standard specific. For example, Table 7.2 on page 169 describes the column metadata for the CDISC SDTM standard. For selected actions, the SAS Clinical Standards Toolkit requires a similarly structured source_columns data set that defines study-specific columns. For example, a SAS Clinical Standards Toolkit validation process compares the study metadata in the source_columns data set with the reference standard metadata in the reference_columns data set.

Validation Metrics

Each SAS Clinical Standards Toolkit validation process can generate a Summary data set that provides a meaningful denominator for most validation checks. The Summary data set enables you to more accurately assess the relative scope of errors that are detected. The generation of this data set is based on validation property settings. This data set can be persisted beyond the SAS session based on SASReferences data set settings. For example, Table 7.10 on page 193 describes the metrics metadata for the CDISC SDTM standard, and Figure 7.2 on page 195 provides sample content for the CDISC SDTM standard.

CDISC CRT-DDS and CDISC Define-XML 2.0 Style Sheets

Sample XSL style sheets are provided with the CDISC CRT-DDS 1.0 standard and the CDISC Define-XML 2.0 standard. A define.xml file can be rendered in a human-readable form (such as HTML) with an appropriate XSL style sheet. These sample style sheets, define1-0-0.xsl for CDISC CRT-DDS 1.0 and define2-0-0.xsl for CDISC Define-XML 2.0, are based on the style sheets provided by CDISC at http://www.cdisc.org/define-xml.

Updated style sheets from CDISC are available at http://wiki.cdisc.org/display/PUB/Stylesheet+Library.

The SAS implementation of the CDISC CRT-DDS 1.0 standard comes with the style sheet define-v1-updated-html.xsl. This style sheet is an updated version of the stylesheet that was used in the updated version of the CDISC SDTM/ADaM Pilot Project Submission Package in 2013. (See http://www.cdisc.org/sdtmadam-pilot-.) Because XSL style sheets are not part of the official CDISC standards, you can use alternative style sheets for display purposes.

4

Metadata Management

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Overview

Management of metadata is performed using macros and driver programs to add, modify, and delete metadata. Prior to version 1.6 of the SAS Clinical Standards Toolkit, these macros were in three general categories:

- Macros or driver programs that derive entire data sets or catalogs from standard-specific data or metadata. For example:
  - The driver program create_sourcemetadata, which initializes source metadata files from a SAS library of data sets or from a CRT-DDS define.xml file.
  - The %CST_CREATEDSFROMTEMPLATE macro, which creates a zero-observation data set that is based on a template.
  - The %CST_CREATETABLESFORDATASTANDARD macro, which creates domain data sets as defined in reference_tables and reference_columns.
  - The %CSTUTIL_BUILDFORMATSFROMXML macro, which creates format catalogs from codelist information in XML-based standards.
- Macros or driver programs that modify run-time process metadata from standard-specific data or metadata. For example:
  - The %CST_INSERTSTANDARDSASREFS macro, which does a look-through to provide paths and memnames from StandardSASReferences.
  - The %CSTUPDATESTANDARDSASREFS macro, which expands all relative paths to full paths in a SASReferences file.
- Macros or driver programs that register or initialize a new standard or standard version. For example, the %CST_REGISTERSTANDARD macro registers a new standard within the global standards library.

There were no macros or driver programs to support modifying metadata files that are associated with a given standard or standard version at a record level. Beginning with version 1.6 of the SAS Clinical Standards Toolkit provides metadata management macros that enable metadata management to accomplish these goals:

- Make minor modifications to a domain. For example, increase a column length in the reference_columns data set.
- Add or remove columns to or from domain metadata, such as reference_columns or source_columns.
- Update a validation_master record to change the definition of an existing validation check.
- Add one or more records (validation checks) to a validation_master data set.
- Modify a Messages data set record. For example, modify the text or severity values.
- Update a specific CRT-DDS or Define-XML 2.0 data set (in any of the SAS representation data sets).
- Add a record to value-level metadata, such as source_values.
- Retain any metadata modifications in a permanent transaction log data set.
- Enable the registration of a new set of controlled terminology

The SAS Clinical Standards Toolkit has always been an open-source collection of SAS macros, programs, format catalogs, and data sets. Any SAS programmer, with the proper security authorization, can modify any of these components of the product. For this reason, the metadata management macros enable you to make modifications to the metadata data sets and to track these changes in a transaction log data set. Use of these macros preserves the metadata of the SAS Clinical Standard Toolkit data sets, such as data set labels, keys, and sort order.

Metadata management macros are addressed in this chapter. Each macro is briefly described. In addition to the main metadata management macros, a small group of supporting macros is available. All actions performed by the metadata management macros are written to a transaction log data set. Information about all macros is in the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Transaction Log Data Set

To track changes and additions to the SAS Clinical Standards Toolkit, all metadata management macros write one or more transaction records to a transaction log data set.

Note: Transaction records are not written when a macro is run in test mode.

The columns that are written to the transaction log data set are shown in this table.

Table 4.1 Columns Written to the Transaction Log Data Set

Column	Label	Format	Valid Values
cststandard	Name of standard	$20	
cststandardversion	Standard version	$20	
cstuser	SAS user ID	$32	
cstmacro	CST macro used	$32	
cstfilepath	System file path	$2048	
cstmessage	Message text	$500	
cstcurdtm	Date/time of transaction (ISO8601)	E8601DT.	
cstdataset	CST Data set	$41	
cstcolumn	CST Data set column	$32	
cstactiontype	Transaction type ADD|DELETE|UPDATE	$8	ADD|DELETE|UPDATE
cstentity	Transaction entity DATASET|COLUMN|RECORD	$8	DATASET|COLUMN|RECORD

Here are the values for cstactiontype:

- ADD: An entity was added.
- DELETE: An entity was deleted.
- UPDATE: An entity was modified.

Here are the values for cstentity:

- DATASET: A SAS data set was acted on.
- COLUMN: A SAS column was acted on.
- RECORD: A SAS data set record was acted on.

The default transaction log data set is stored in ***global standards library directory*/logs** as transactionlog.sas7bdat. This location and data set name are set in the %CST_GETSTATIC AUTOCALL macro using the static variable names CST_LOGGING_PATH and CST_LOGGING_DS, respectively. This default location and name can be modified by overriding the %CST_GETSTATIC macro or by setting the value of the global macro variable _cstTransactionDS to a reachable libref.dataset value before calling any metadata management macro.

Two support macros (%CSTUTILGETDSLOCK and %CSTUTILLOGEVENT) interact with the transaction log data set to determine whether the data set is locked (by another SAS process or by another user) and to control writing data to the data set.

Metadata Management Macros

Overview

Metadata management macros enable you to customize the metadata of any data standard that is used by the SAS Clinical Standards Toolkit. The macros provide a mechanism, the transaction log data set, to track changes.

The metadata management macros included in SAS Clinical Standards Toolkit are shown in this table.

Table 4.2 Metadata Management Macros

Macro	Description
%CSTUTILADDDATASET	Adds a data set.
%CSTUTILADDDSCOLUMN	Adds a column to a data set.
%CSTUTILAPPENDMETADATARECORDS	Adds records to a data set by either merging or appending.
%CSTUTILDELETEDSCOLUMN	Removes a column from a data set.
%CSTUTILDELETEMETADATARECORDS	Removes a record from a data set.
%CSTUTILMODIFYCOLUMNATTRIBUTE	Changes an attribute of a column in a data set.
%CSTUTILUPDATEMETADATARECORDS	Modifies a record in a data set.
%CSTUTILREGISTERCTSUBTYPE	Enables the registration of a new set of controlled terminology

Note: Information about all macros is in the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Test Mode

To verify changes before they are written to a permanent data set, all of the metadata management macros can be run in test mode except as noted below.

Write access permission is required to the target permanent data set. Write access permission is checked as an initial step in the metadata management macros. If Write access permission is not available, the macro does complete successfully, even in test mode.

Note: cstutiladddataset and cstutiladddscolumn cannot be run in test mode.

All test mode output is generated in the SAS Work directory, and the transaction log data set is not updated. After you have verified that the changes are correct, run the macro again with test mode disabled, and the permanent data set is modified.

Problem Reporting

There are two ways to report problems: in the _cstResults data set or in the SAS log file.

Because a full SAS Clinical Standards Toolkit environment (one in which all global macro variables are defined) is not required for a macro to run, a macro reports problems in one of two locations, in this order:

1. If the _cstResultsDS macro variable and the data set specified by the value of _cstResultsDS exist, problems are reported in the _cstResults data set.
2. If the _cstResultsDS macro variable or the data set specified by the value of _cstResultsDS does not exist, problems are reported in the SAS log file.

Note: After the first submission of a macro, a work._cstresults data set might exist and the _cstResultsDS macro variable might specify the data set. Subsequent macro submissions report problems to the work._cstresults data set instead of to the SAS log file. This happens because some of the macros call other internal macros that generate a work._cstresults data set. This data set is then used by subsequent macros for problem reporting.

If the SAS log file is used to report problems, the SAS Clinical Standards Toolkit distinguishes problems from normal SAS log messages by displaying a message similar to this one:

```
[CSTLOGMESSAGE.CSTUTILDELETEDSCOLUMN] ERROR:
results.transactionlog could not be found.
```

Support Macros

The support macros that enhance the functionality of the metadata management macros are shown in this table.

Table 4.3 Support Macros

Macro	Description
%CSTUTILBUILDATTRFROMDS	Creates an attribute statement for all variables in a data set. (internal macro)
%CSTUTILGETDSLOCK	Verifies whether a transaction log data set is locked or not. (internal macro)
%CSTUTILLOGEVENT	Writes a record to the transaction log data set.

Common Parameters

The metadata management macros share a set of common parameters. These parameters are used by all of the metadata management macros:

- _cstStd: The SAS Clinical Standards Toolkit registered standard name (for example, CDISC-SDTM).
- _cstStdVer: The SAS Clinical Standards Toolkit registered standard version (for example, 3.1.3).
- _cstDS: The target data set to act on. This is specified in *libname.dataset* form, where the LIBNAME has been previously allocated.

The parameter _cstTestMode is used by most of the metadata management macros. _cstTestMode specifies whether a macro is run in test mode. The valid values are `Y` (default) or `N`. For more information, see "Test Mode" on page 62.

Copying a Data Set from One Library to Another Library

The %CSTUTILADDDATASET macro copies a data set from one library to another library.

In this example, the _cstInputDS parameter contains the *libname.dataset* to copy (the source). The _cstDS parameter contains the *libname.dataset* to create (the target). Key variables for the newly created data set are specified in the _cstDSKeys parameter.

```
**************************************************
*  Copy a data set from one library to another  *
**************************************************;

libname newstudy '<directory where new study data sets will reside>';
libname srcmeta '<directory supplying data set to be copied>';
libname log 'C:\cstGlobalLibrary\logs';

%cstutiladddataset(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstInputDS=srcmeta.source_values,
        _cstDSLabel=SDTM Source Value Metadata,
        _cstDSKeys=sasref table column value,
        _cstOverwrite=Y);
```

In this example, newstudy.source_values (_cstDS parameter) is a copy of the data set from srcmeta.source_values (_cstInputDS parameter). A label (_cstDSLabel parameter) is specified for newstudy.source_values with the value **`SDTM Source Value Metadata`**. Data set key variables (sasref, table, column, and value) are specified in the _cstDSKeys parameter. The _cstOverwrite parameter is set to **`Y`**, which allows an existing copy of this data set to be overwritten.

Before running the macro, the Newstudy library is empty. After running the macro, the data set from the Srcmeta library is copied to the Newstudy library.

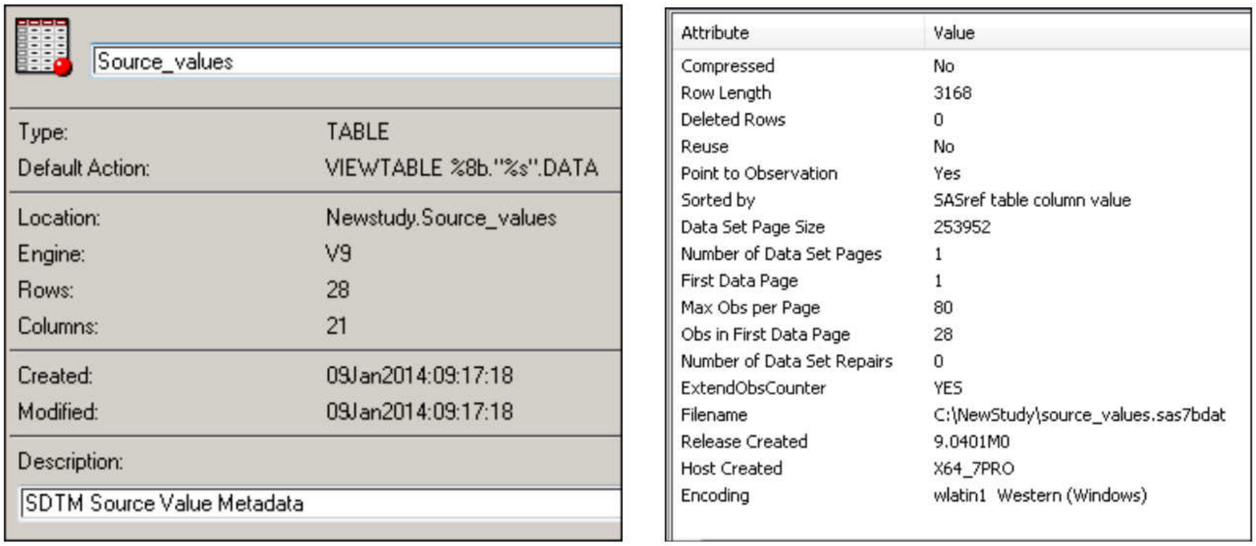
The SAS log file contains a message to inform you that the operation was successful:

```
[CSTLOGMESSAGE.CSTUTILADDDATASET] NOTE: newstudy.source_values
successfully added.
```

Note: If the message is not in the SAS log file, review the contents of the work._cstresults data set.

The following display shows that the properties of the newstudy.source_values data set show that the keys and label parameter values were used:

Figure 4.1 *Keys and Label Parameter Values Were Used*



Source_values

Type:	TABLE
Default Action:	VIEWTABLE %8b."%s".DATA
Location:	Newstudy.Source_values
Engine:	V9
Rows:	28
Columns:	21
Created:	09Jan2014:09:17:18
Modified:	09Jan2014:09:17:18

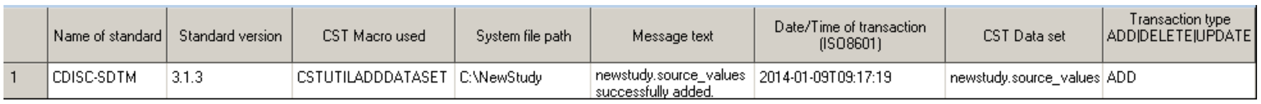
Description:

SDTM Source Value Metadata

Attribute	Value
Compressed	No
Row Length	3168
Deleted Rows	0
Reuse	No
Point to Observation	Yes
Sorted by	SASref table column value
Data Set Page Size	253952
Number of Data Set Pages	1
First Data Page	1
Max Obs per Page	80
Obs in First Data Page	28
Number of Data Set Repairs	0
ExtendObsCounter	YES
Filename	C:\NewStudy\source_values.sas7bdat
Release Created	9.0401M0
Host Created	X64_7PRO
Encoding	wlatin1 Western (Windows)

The following display shows part of the transaction log data set in the Log library, which shows that it was updated:

Figure 4.2 *Transaction Log Data Set Was Updated*



	Name of standard	Standard version	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set	Transaction type ADD|DELETE|UPDATE
1	CDISC-SDTM	3.1.3	CSTUTILADDDATASET	C:\NewStudy	newstudy.source_values successfully added.	2014-01-09T09:17:19	newstudy.source_values	ADD

Note: Not all of the columns are shown.

Adding Records to a Data Set

The %CSTUTILAPPENDMETADATARECORDS macro adds new records to a data set. This macro requires an input data set that contains the records to use to update the target data set. It takes records from the input data set and either appends or merges the records to the target data set.

Note: Appending records to a data set always adds rows to the target data set even if the rows already exist in the target data set. Merging records adds new rows and updates existing rows. If keys are present, the target data set is sorted and duplicate key records are deleted.

In this example, the newstudy.source_values data set is merged (indicated by `_cstUpdateDSType=merge`) with the work.newrecs data set. The _cstOverwriteDup parameter enables duplicate records from work.newrecs to overwrite those records in newstudy.source_values.

```
 *****************************
*  Merge in the dummy data  *
*****************************;
%cstutilappendmetadatarecords(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstNewDS=work.newrecs,
        _cstUpdateDSType=merge,
        _cstOverwriteDup=y,
        _cstTestMode=n);
```

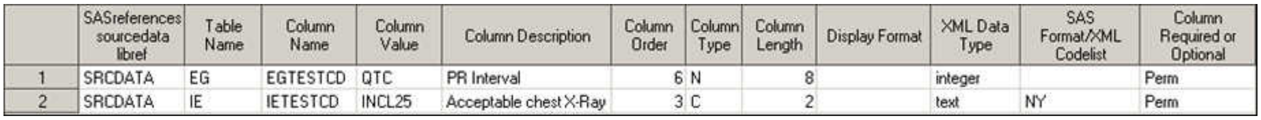
Note: To merge successfully, the keys for the data sets must match. Any discrepancies in the keys are reported either to the SAS log file or to the Results data set.

Before running the macro, the work.newrecs data set was created for the _cstNewDS macro parameter.

Note: The data set (newstudy.source_values) must share the same structure as the target data set (work.newrecs).

The following display shows an example of the work.newrecs data set:

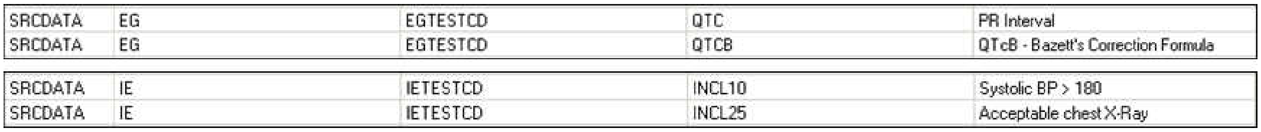
Figure 4.3 *Example work.newrecs Data Set*



	SASreferences sourcedata libref	Table Name	Column Name	Column Value	Column Description	Column Order	Column Type	Column Length	Display Format	XML Data Type	SAS Format/XML Codelist	Column Required or Optional
1	SRCDATA	EG	EGTESTCD	QTC	PR Interval	6	N	8		integer		Perm
2	SRCDATA	IE	IETESTCD	INCL25	Acceptable chest X-Ray	3	C	2		text	NY	Perm

After the macro is run, the newstudy.source_values data set is updated with the new EG record and the IE record. The following display shows an example of the updated data set:

Figure 4.4 *Example of Updated Data Set*



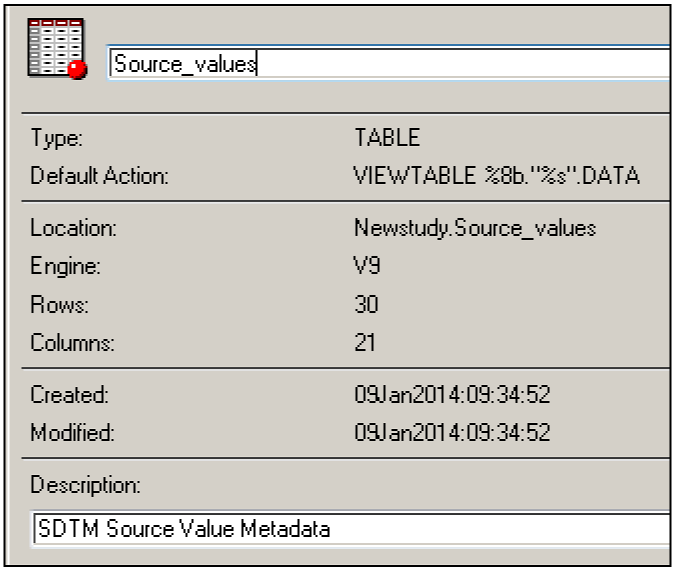
SRCDATA	EG	EGTESTCD	QTC	PR Interval
SRCDATA	EG	EGTESTCD	QTCB	QTcB - Bazett's Correction Formula

SRCDATA	IE	IETESTCD	INCL10	Systolic BP > 180
SRCDATA	IE	IETESTCD	INCL25	Acceptable chest X-Ray

The row count (**Rows**) is increased from 28 to 30 (compare to the image on page 66), which indicates that the two records were added from the work.newrecs data set.

The following display shows the updated properties of the newstudy.source_values data set:

Figure 4.5 Updated Properties of the newstudy.source_values Data Set



Source_values

Type:	TABLE
Default Action:	VIEWTABLE %8b."%s".DATA
Location:	Newstudy.Source_values
Engine:	V9
Rows:	30
Columns:	21
Created:	09Jan2014:09:34:52
Modified:	09Jan2014:09:34:52

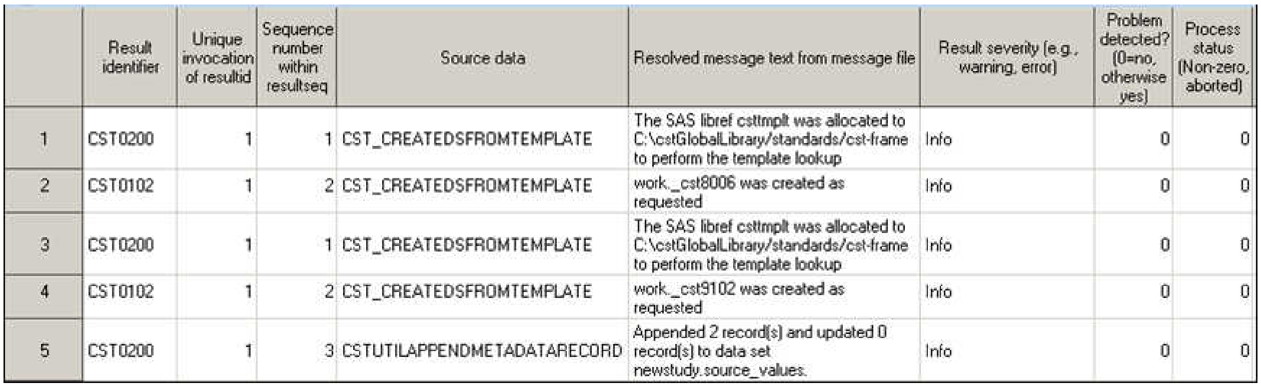
Description:

SDTM Source Value Metadata

The results of running the macro write to the work._cstresults data set because the data set was created by the macro in the previous example.

The following display shows part of the work._cstresults data set, in which row 5 contains the message generated after running the %CSTUTILAPPENDMETADATARECORD macro:

Figure 4.6 *Message Generated After Running the %CSTUTILAPPENDMETADATARECORD Macro*

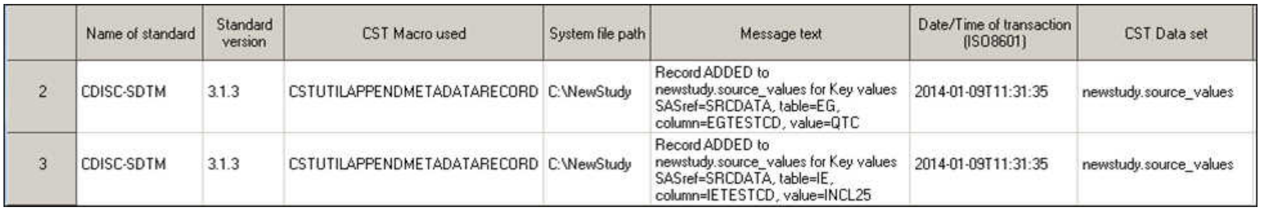


	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
1	CST0200	1	1	CST_CREATEDSFROMTEMPLATE	The SAS libref csttmplt was allocated to C:\cstGlobalLibrary/standards/cst-frame to perform the template lookup	Info	0	0
2	CST0102	1	2	CST_CREATEDSFROMTEMPLATE	work._cst8006 was created as requested	Info	0	0
3	CST0200	1	1	CST_CREATEDSFROMTEMPLATE	The SAS libref csttmplt was allocated to C:\cstGlobalLibrary/standards/cst-frame to perform the template lookup	Info	0	0
4	CST0102	1	2	CST_CREATEDSFROMTEMPLATE	work._cst9102 was created as requested	Info	0	0
5	CST0200	1	3	CSTUTILAPPENDMETADATARECORD	Appended 2 record(s) and updated 0 record(s) to data set newstudy.source_values.	Info	0	0

Note: Not all columns or rows are shown.

The following display shows part of the transaction log data set, which shows that it was updated for each row of data added (rows 2 and 3):

Figure 4.7 *Transaction Log Data Set*



	Name of standard	Standard version	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set
2	CDISC-SDTM	3.1.3	CSTUTILAPPENDMETADATARECORD	C:\NewStudy	Record ADDED to newstudy.source_values for Key values SASref=SRCDATA, table=EG, column=EGTESTCD, value=QTC	2014-01-09T11:31:35	newstudy.source_values
3	CDISC-SDTM	3.1.3	CSTUTILAPPENDMETADATARECORD	C:\NewStudy	Record ADDED to newstudy.source_values for Key values SASref=SRCDATA, table=IE, column=IETESTCD, value=INCL25	2014-01-09T11:31:35	newstudy.source_values

Note: Not all columns or rows are shown.

In this example, the newstudy.source_values data set is appended (indicated by `_cstUpdateDSType=append`) to the work.newrecs data set. When appending rows, the _cstOverwriteDup parameter is ignored.

```
*************************** 
*  Append the dummy data  *
***************************;
```

```
%cstutilappendmetadatarecords(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstNewDS=work.newrecs,
        _cstUpdateDSType=append,
        _cstOverwriteDup=y,
        _cstTestMode=n);
```

Updating a Column in a Data Set

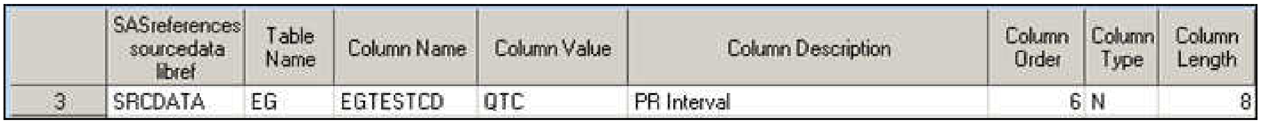
The %CSTUTILUPDATEMETADATARECORDS macro updates column values. Specific records can be retrieved using the _cstDSIfClause parameter.

In this example, the record in newstudy.source_values that matches the _cstDSIfClause parameter (`table='EG'` and `value='QTC'`) is modified. The LABEL column value (_cstColumn) is changed to **`QT Interval (QTc)`**.

```
*********************
*  Update a record  *
*********************;

%cstutilupdatemetadatarecords(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstDSIfClause=table='EG' and value='QTC',
        _cstColumn=label,
        _cstValue=QT Interval (QTc),
        _cstTestMode=n);
```

The following display shows the value of the **Column Description** for **QTC** (**PR Interval**) before running the macro:

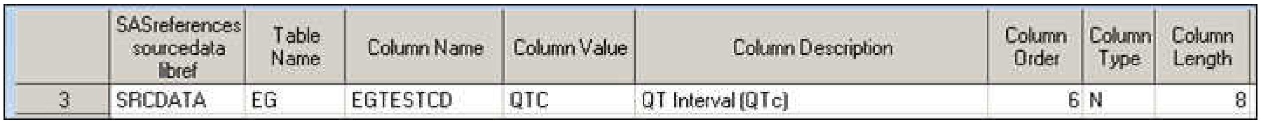
Figure 4.8 Before Running the Macro



	SASreferences sourcedata libref	Table Name	Column Name	Column Value	Column Description	Column Order	Column Type	Column Length
3	SRCDATA	EG	EGTESTCD	QTC	PR Interval	6	N	8

The following display shows the modified value of the **Column Description** for **QTC** (**QT Interval (QTc)**):

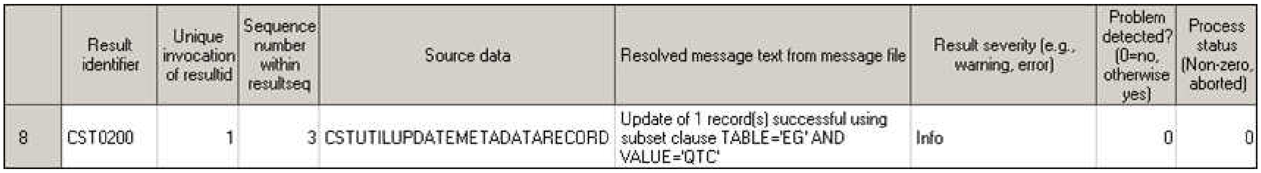
Figure 4.9 Modified Value of the Column Description for QTC



	SASreferences sourcedata libref	Table Name	Column Name	Column Value	Column Description	Column Order	Column Type	Column Length
3	SRCDATA	EG	EGTESTCD	QTC	QT Interval (QTc)	6	N	8

The results of the previous call to the %CSTUTILUPDATEMETADATARECORDS macro are written to the work._cstresults data set in row 8. The following display shows the message that explains that this was an update of one record using the specified WHERE clause:

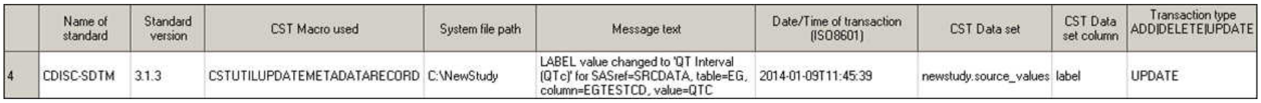
Figure 4.10 Results of Running the Macro



	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
8	CST0200	1	3	CSTUTILUPDATEMETADATARECORD	Update of 1 record(s) successful using subset clause TABLE='EG' AND VALUE='QTC'	Info	0	0

The following display shows the updated transaction log data set in row 4:

Figure 4.11 Updated Transaction Log Data Set



	Name of standard	Standard version	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set	CST Data set column	Transaction type ADD|DELETE|UPDATE
4	CDISC-SDTM	3.1.3	CSTUTILUPDATEMETADATARECORD	C:\NewStudy	LABEL value changed to 'QT Interval (QTc)' for SASref=SRCDATA, table=EG, column=EGTESTCD, value=QTC	2014-01-09T11:45:39	newstudy.source_values	label	UPDATE

Adding a Column to a Data Set

The %CSTUTILADDDSCOLUMN macro adds a new column and any corresponding column attributes used by the SAS Clinical Standards Toolkit. An initial value can be specified for the column if needed.

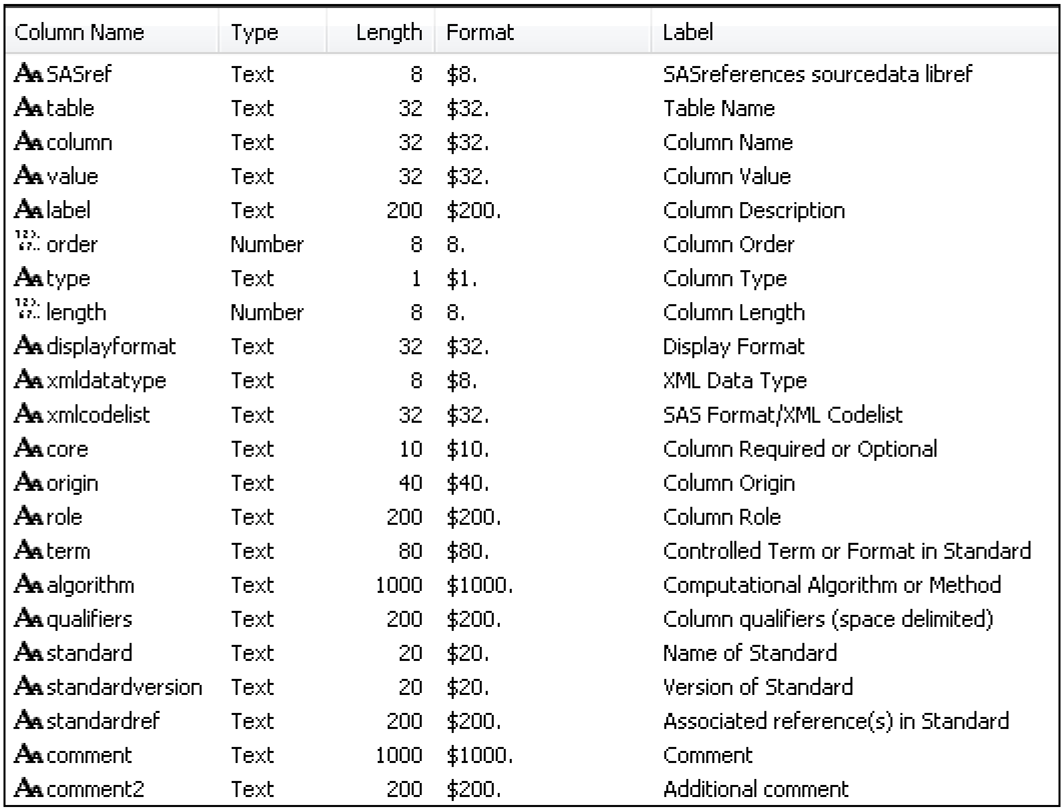
In this example, the new column parameter (_cstColumn) is specified as `comment2`. The other parameters set the label, type, length, format, and initial value for the column. The label is specified as **`Additional comment`**, the type is specified as `C` (character), the length is specified as `200`, the format is specified as `$200`, and the initial value is specified as **`This is a test to add a new variable`**. The initial value is set for the comment2 column for all records.

```
**********************
*  Add a new column  *
**********************;

%cstutiladddscolumn(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstColumn=comment2,
        _cstColumnLabel=Additional comment,
        _cstColumnType=c,
        _cstColumnLength=200,
        _cstColumnFmt=$200.,
        _cstColumnInitValue=This is a test to add a new variable);
```

Before running the macro, the number of columns in the newstudy.source_values data set was 21. After running the macro, the number of columns is 22 and the comment2 column was modified.

The following display shows the full set of columns in the newstudy.source_values data set. The comment2 column is at the bottom of the list with length, format, and label as specified in the macro parameters.

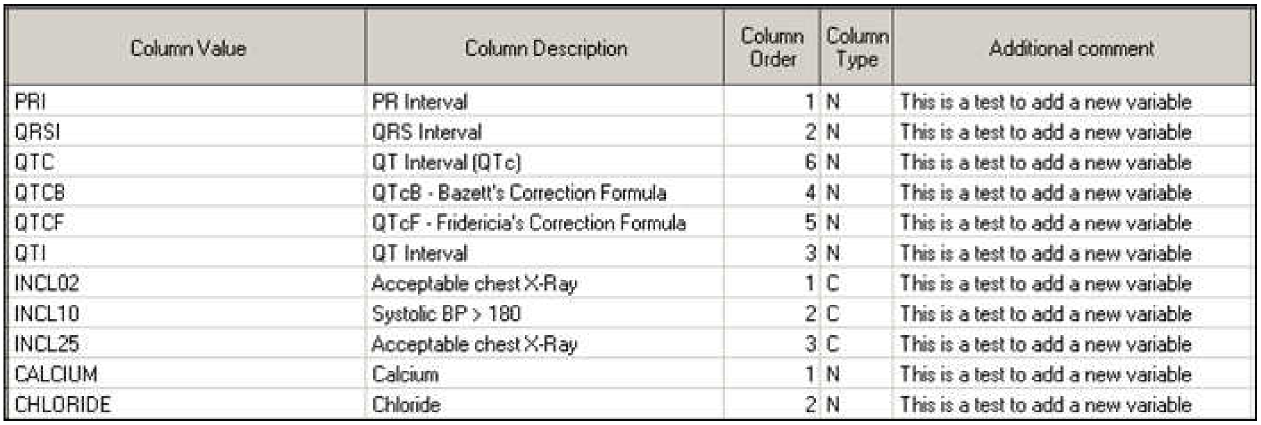
Figure 4.12 Modified Columns in the newstudy.source_values Data Set



Column Name	Type	Length	Format	Label
SASref	Text	8	$8.	SASreferences sourcedata libref
table	Text	32	$32.	Table Name
column	Text	32	$32.	Column Name
value	Text	32	$32.	Column Value
label	Text	200	$200.	Column Description
order	Number	8	8.	Column Order
type	Text	1	$1.	Column Type
length	Number	8	8.	Column Length
displayformat	Text	32	$32.	Display Format
xmldatatype	Text	8	$8.	XML Data Type
xmlcodelist	Text	32	$32.	SAS Format/XML Codelist
core	Text	10	$10.	Column Required or Optional
origin	Text	40	$40.	Column Origin
role	Text	200	$200.	Column Role
term	Text	80	$80.	Controlled Term or Format in Standard
algorithm	Text	1000	$1000.	Computational Algorithm or Method
qualifiers	Text	200	$200.	Column qualifiers (space delimited)
standard	Text	20	$20.	Name of Standard
standardversion	Text	20	$20.	Version of Standard
standardref	Text	200	$200.	Associated reference(s) in Standard
comment	Text	1000	$1000.	Comment
comment2	Text	200	$200.	Additional comment

The following display shows the modified newstudy.source_values data set, which shows that the initial value of `This is a test to add a new variable` was set for the new column on all data set records:

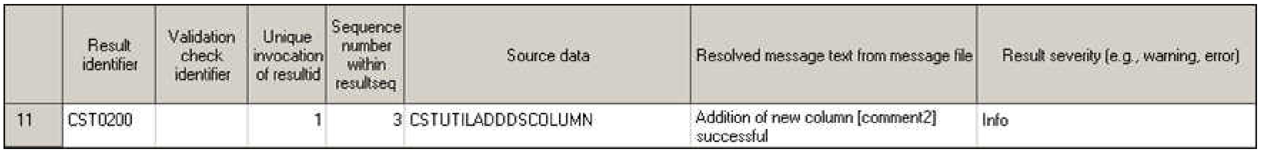
Figure 4.13 Modified newstudy.source_values Data Set



Column Value	Column Description	Column Order	Column Type	Additional comment
PRI	PR Interval	1	N	This is a test to add a new variable
QRSI	QRS Interval	2	N	This is a test to add a new variable
QTC	QT Interval (QTc)	6	N	This is a test to add a new variable
QTCB	QTcB - Bazett's Correction Formula	4	N	This is a test to add a new variable
QTCF	QTcF - Fridericia's Correction Formula	5	N	This is a test to add a new variable
QTI	QT Interval	3	N	This is a test to add a new variable
INCL02	Acceptable chest X-Ray	1	C	This is a test to add a new variable
INCL10	Systolic BP > 180	2	C	This is a test to add a new variable
INCL25	Acceptable chest X-Ray	3	C	This is a test to add a new variable
CALCIUM	Calcium	1	N	This is a test to add a new variable
CHLORIDE	Chloride	2	N	This is a test to add a new variable

The following display shows the modified work.results data set:

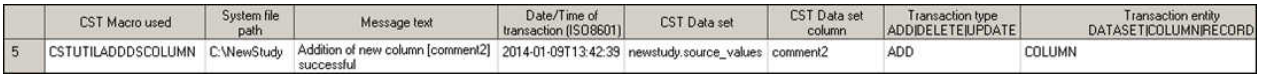
Figure 4.14 Modified work.results Data Set



	Result identifier	Validation check identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)
11	CST0200		1	3	CSTUTILADDDSCOLUMN	Addition of new column [comment2] successful	Info

The following display shows the updated transaction log data set:

Figure 4.15 Updated Transaction Log Data Set



	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set	CST Data set column	Transaction type ADD|DELETE|UPDATE	Transaction entity DATASET|COLUMN|RECORD
5	CSTUTILADDDSCOLUMN	C:\NewStudy	Addition of new column [comment2] successful	2014-01-09T13:42:39	newstudy.source_values	comment2	ADD	COLUMN

Modifying a Column Attribute in a Data Set

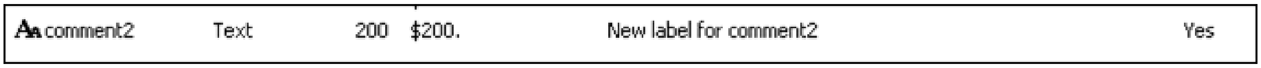
The %CSTUTILMODIFYCOLUMNATTRIBUTE macro modifies the attributes of a column.

In this example, the label attribute is modified for column comment2 (which was added in the previous example). After running the macro, the label (_cstAttr parameter) for comment2 is updated to the value specified in the _cstAttrValue parameter.

```
*******************************
*  Modify a column attribute  *
*******************************;

%cstutilmodifycolumnattribute(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstColumn=comment2,
        _cstAttr=label,
        _cstAttrValue=New label for comment2,
        _cstTestMode=n);
```

The following display shows the modified column:

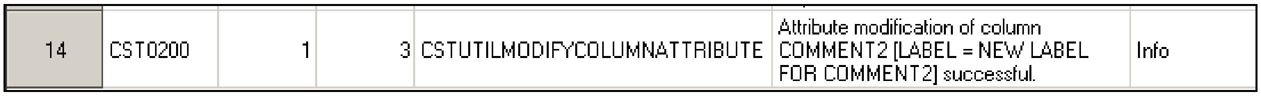
Figure 4.16 Modified Column



comment2	Text	200	$200.	New label for comment2	Yes

The following display shows the modified work._cstresults data set:

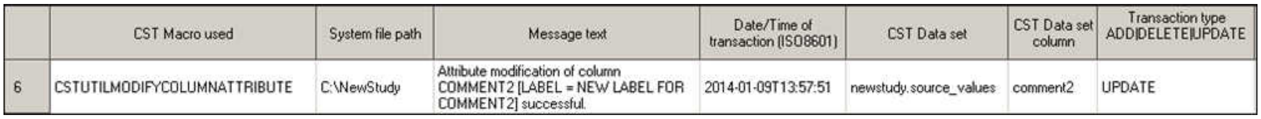
Figure 4.17 Modified work._cstresults Data Set



14	CST0200	1	3	CSTUTILMODIFYCOLUMNATTRIBUTE	Attribute modification of column COMMENT2 [LABEL = NEW LABEL FOR COMMENT2] successful.	Info

The following display shows the updated transaction log data set:

Figure 4.18 Updated Transaction Log Data Set



	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set	CST Data set column	Transaction type ADD|DELETE|UPDATE
6	CSTUTILMODIFYCOLUMNATTRIBUTE	C:\NewStudy	Attribute modification of column COMMENT2 [LABEL = NEW LABEL FOR COMMENT2] successful.	2014-01-09T13:57:51	newstudy.source_values	comment2	UPDATE

Deleting a Column in a Data Set

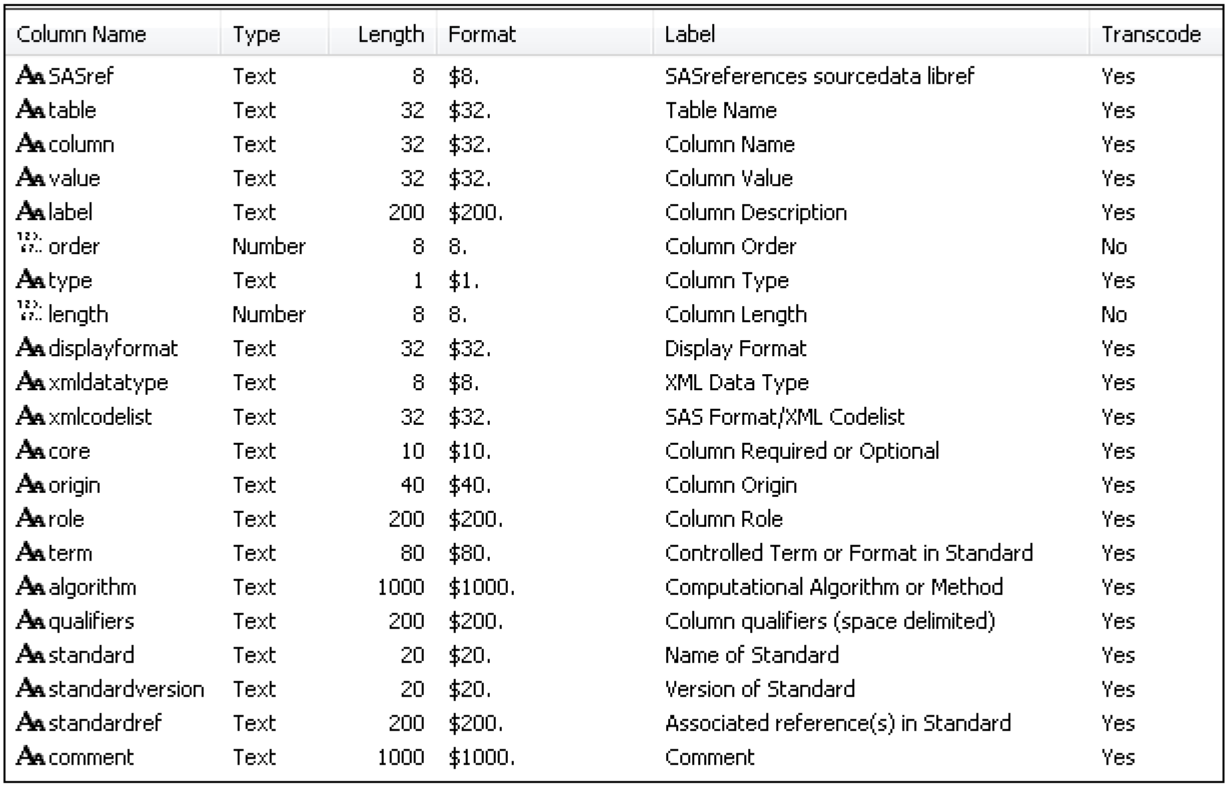
The %CSTUTILDELETEDSCOLUMN macro deletes an existing column from a data set.

In this example, the macro deletes the comment2 column (which was created in the previous example) in the newstudy.source_values data set. The _cstMustBeEmpty parameter is set to **N**, which specifies that the macro should delete the column if values are present.

```
*********************
*  Delete a column  *
*********************;

%cstutildeletedscolumn(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstColumn=comment2,
        _cstMustBeEmpty=n,
        _cstTestMode=n);
```

The following display shows the modified columns in the newstudy.source_values data set. The comment2 column has been removed and the column count is reduced to 21.

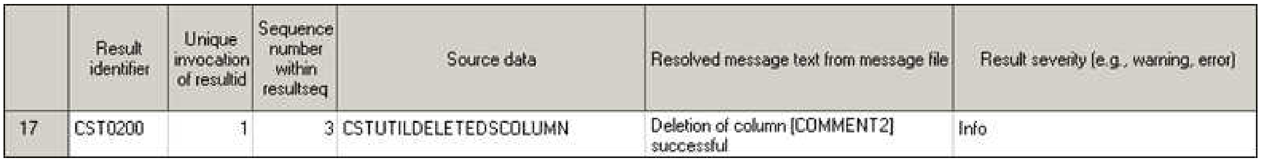
Figure 4.19 *Modified Columns in the newstudy.source_values Data Set*



Column Name	Type	Length	Format	Label	Transcode
SASref	Text	8	$8.	SASreferences sourcedata libref	Yes
table	Text	32	$32.	Table Name	Yes
column	Text	32	$32.	Column Name	Yes
value	Text	32	$32.	Column Value	Yes
label	Text	200	$200.	Column Description	Yes
order	Number	8	8.	Column Order	No
type	Text	1	$1.	Column Type	Yes
length	Number	8	8.	Column Length	No
displayformat	Text	32	$32.	Display Format	Yes
xmldatatype	Text	8	$8.	XML Data Type	Yes
xmlcodelist	Text	32	$32.	SAS Format/XML Codelist	Yes
core	Text	10	$10.	Column Required or Optional	Yes
origin	Text	40	$40.	Column Origin	Yes
role	Text	200	$200.	Column Role	Yes
term	Text	80	$80.	Controlled Term or Format in Standard	Yes
algorithm	Text	1000	$1000.	Computational Algorithm or Method	Yes
qualifiers	Text	200	$200.	Column qualifiers (space delimited)	Yes
standard	Text	20	$20.	Name of Standard	Yes
standardversion	Text	20	$20.	Version of Standard	Yes
standardref	Text	200	$200.	Associated reference(s) in Standard	Yes
comment	Text	1000	$1000.	Comment	Yes

The following display shows the modified work._cstresults data set:

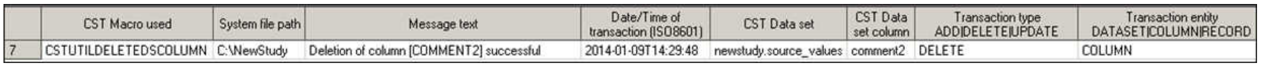
Figure 4.20 *Modified work._cstresults Data Set*



	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)
17	CST0200	1	3	CSTUTILDELETEDSCOLUMN	Deletion of column [COMMENT2] successful	Info

The following display shows the updated transaction log data set:

Figure 4.21 *Updated Transaction Log Data Set*



	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set	CST Data set column	Transaction type ADD|DELETE|UPDATE	Transaction entity DATASET|COLUMN|RECORD
7	CSTUTILDELETEDSCOLUMN	C:\NewStudy	Deletion of column [COMMENT2] successful	2014-01-09T14:29:48	newstudy.source_values	comment2	DELETE	COLUMN

Deleting a Record in a Data Set

The %CSTUTILDELETEMETADATARECORDS macro deletes records based on the records specified by the _cstDSIfClause parameter.

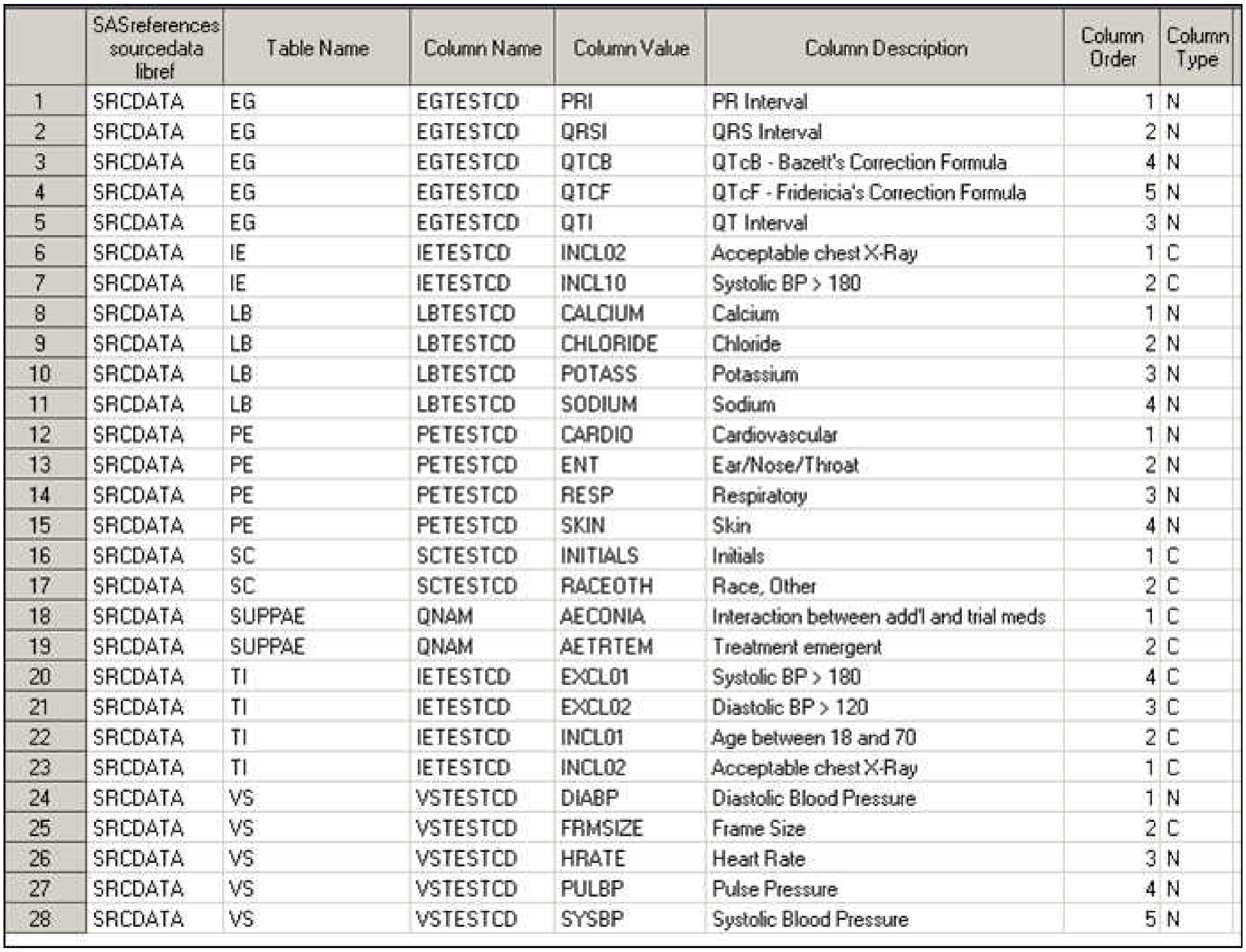
CAUTION! Ensure that the WHERE clause retrieves the correct records to delete. It is highly recommended that this operation initially be performed in test mode. For more information, see “Test Mode” on page 62.

In this example, the two rows of data added from the previous examples are deleted from the newstudy.source_values data set using the same WHERE clause.

```
*********************
*  Delete a record  *
*********************;

%cstutildeletemetadatarecords(
        _cstStd=CDISC-SDTM,
        _cstStdVer=3.1.3,
        _cstDS=newstudy.source_values,
        _cstDSIfClause=(table='EG' and value='QTC') or (table='IE' and value='INCL25'),
        _cstTestMode=n);
```

The following display shows the modified newstudy.source_values data set, which shows that the two rows have been deleted and the record count is reduced from 30 to 28:

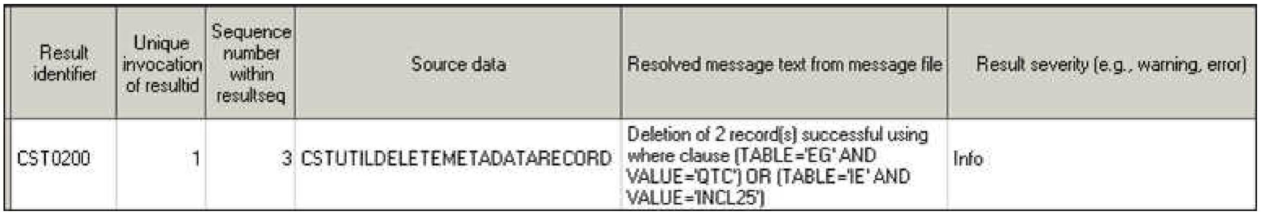
Figure 4.22 Modified newstudy.source_values Data Set



	SASreferences sourcedata libref	Table Name	Column Name	Column Value	Column Description	Column Order	Column Type
1	SRCDATA	EG	EGTESTCD	PRI	PR Interval	1	N
2	SRCDATA	EG	EGTESTCD	QRSI	QRS Interval	2	N
3	SRCDATA	EG	EGTESTCD	QTCB	QTcB - Bazett's Correction Formula	4	N
4	SRCDATA	EG	EGTESTCD	QTCF	QTcF - Fridericia's Correction Formula	5	N
5	SRCDATA	EG	EGTESTCD	QTI	QT Interval	3	N
6	SRCDATA	IE	IETESTCD	INCL02	Acceptable chest X-Ray	1	C
7	SRCDATA	IE	IETESTCD	INCL10	Systolic BP > 180	2	C
8	SRCDATA	LB	LBTESTCD	CALCIUM	Calcium	1	N
9	SRCDATA	LB	LBTESTCD	CHLORIDE	Chloride	2	N
10	SRCDATA	LB	LBTESTCD	POTASS	Potassium	3	N
11	SRCDATA	LB	LBTESTCD	SODIUM	Sodium	4	N
12	SRCDATA	PE	PETESTCD	CARDIO	Cardiovascular	1	N
13	SRCDATA	PE	PETESTCD	ENT	Ear/Nose/Throat	2	N
14	SRCDATA	PE	PETESTCD	RESP	Respiratory	3	N
15	SRCDATA	PE	PETESTCD	SKIN	Skin	4	N
16	SRCDATA	SC	SCTESTCD	INITIALS	Initials	1	C
17	SRCDATA	SC	SCTESTCD	RACEOTH	Race, Other	2	C
18	SRCDATA	SUPPAE	QNAM	AECONIA	Interaction between add'l and trial meds	1	C
19	SRCDATA	SUPPAE	QNAM	AETRTEM	Treatment emergent	2	C
20	SRCDATA	TI	IETESTCD	EXCL01	Systolic BP > 180	4	C
21	SRCDATA	TI	IETESTCD	EXCL02	Diastolic BP > 120	3	C
22	SRCDATA	TI	IETESTCD	INCL01	Age between 18 and 70	2	C
23	SRCDATA	TI	IETESTCD	INCL02	Acceptable chest X-Ray	1	C
24	SRCDATA	VS	VSTESTCD	DIABP	Diastolic Blood Pressure	1	N
25	SRCDATA	VS	VSTESTCD	FRMSIZE	Frame Size	2	C
26	SRCDATA	VS	VSTESTCD	HRATE	Heart Rate	3	N
27	SRCDATA	VS	VSTESTCD	PULBP	Pulse Pressure	4	N
28	SRCDATA	VS	VSTESTCD	SYSBP	Systolic Blood Pressure	5	N

The following display shows the modified work._cstresults data set:

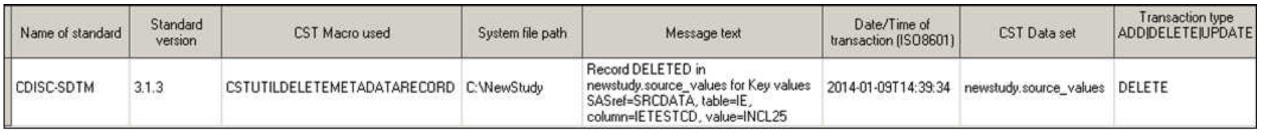
Figure 4.23 *Modified work._cstresults Data Set*



Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)
CST0200	1	3	CSTUTILDELETEMETADATARECORD	Deletion of 2 record(s) successful using where clause (TABLE='EG' AND VALUE='QTC') OR (TABLE='IE' AND VALUE='INCL25')	Info

The following display shows the updated transaction log data set:

Figure 4.24 *Updated Transaction Log Data Set*



Name of standard	Standard version	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set	Transaction type ADD|DELETE|UPDATE
CDISC-SDTM	3.1.3	CSTUTILDELETEMETADATARECORD	C:\NewStudy	Record DELETED in newstudy.source_values for Key values SASref=SRCDATA, table=IE, column=IETESTCD, value=INCL25	2014-01-09T14:39:34	newstudy.source_values	DELETE

Deleting a Data Set

Although it is not a new macro, the %CSTUTIL_DELETEDATASET macro has been updated to write to the transaction log data set. As a result, it can be used as a metadata management macro. With this new capability, any data set that is deleted can be recorded in the transaction log data set if the _cstLogging parameter is set to 1. The default is not to write to the transaction log data set.

The following example deletes the newstudy.source_values data set that was used in these examples:

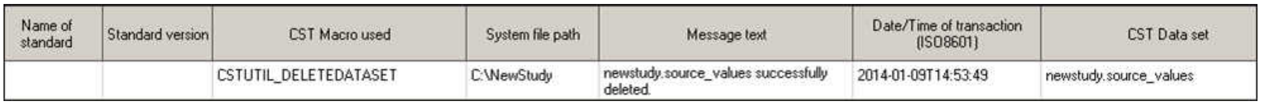
```
**************************
*  Delete the data set   *
**************************;

%cstutil_deletedataset(
        _cstDataSetName=newstudy.source_values,
        _cstLogging=1);
```

After running the macro, the directory no longer contains the data set.

This macro does not write to the work._cstresults data set. Messages are written directly to the SAS log file: `[CSTLOGMESSAGE.CSTUTIL_DELETEDATASET] NOTE: newstudy.source_values successfully deleted.`

The following display shows the updated transaction log data set:

Figure 4.25 *Updated Transaction Log Data Set*



Name of standard	Standard version	CST Macro used	System file path	Message text	Date/Time of transaction (ISO8601)	CST Data set
		CSTUTIL_DELETEDATASET	C:\NewStudy	newstudy.source_values successfully deleted.	2014-01-09T14:53:49	newstudy.source_values

Note: In the image, **Name of standard** and **Standard version** are not populated. The %CSTUTIL_DELETEDATASET macro is an older SAS Clinical Standard Toolkit macro that does not require those parameter values for any data lookups. However, the values for the file path and the data set name are listed in the transaction log data set.

Registering a New Controlled Terminology Subset

SAS Clinical Standards Toolkit supports point-in-time snapshots and subsets of CDISC terminology. They are located here:

***global standards library directory*/standards/cdisc-terminology-1.7**

This data set stores metadata about the snapshots and subsets:

***global standards library directory*/standards/cdisc-terminology-1.7/control/standardsubtypes.sas7bdat**

The %CSTUTILREGISTERCTSUBTYPE macro documents new controlled terminology snapshots or subsets that are registered to the SAS Clinical Standards Toolkit. For more information about the macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Each CDISC terminology standard that is provided by SAS includes a SAS format catalog (cterms.sas7bcat) and a SAS data set (cterms.sas7bdat). The data set is an extract of the NCI EVS controlled terminology for a given CDISC standard and update. A similar data set and catalog that represent your snapshot or subset must be created. The data set and catalog location are identified in the _cstpath parameter of the %CSTUTILREGISTERCTSUBTYPE macro. The snapshot or subset must be registered using the %CSTUTILREGISTERCTSUBTYPE macro, which adds a record to this data set:

***global standards library directory*/standards/cdisc-terminology-1.7/control/standardsubtypes.sas7bdat**

The following example registers a data set and a catalog named myct in the ***global standards library directory*/standards/cdisc-terminology-1.7/cdisc-sdtm/201412/formats** folder:

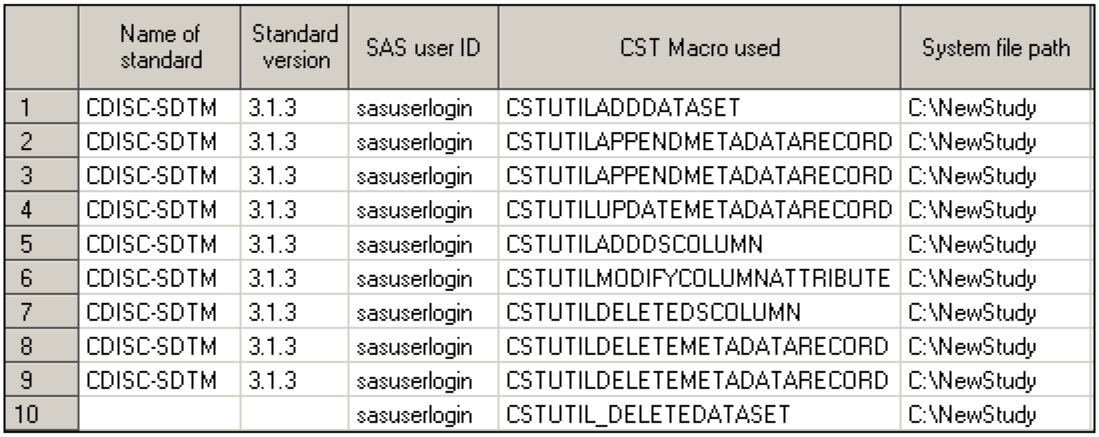
```
%cstutilregisterctsubtype(
     _cststd=CDISC-TERMINOLOGY,
     _cststdver=CDISC-SDTM,
     _cststandardsubtype=NCI_THESAURUS,
     _cststandardsubtypeversion=201412,
     _cstpath=&_cstGRoot./standards/cdisc-terminology-1.7/cdisc-sdtm/201412/formats,
     _cstmemname=myct,
     _cstisstandarddefault=N,
     _cstdescription=%nrbquote(CDISC SDTM Controlled Terminology, released by NCI on 2014-12-20));
```

Example Transaction Log Data Set

This display shows the complete transaction log data set that was created by running all of the example macros in this chapter.

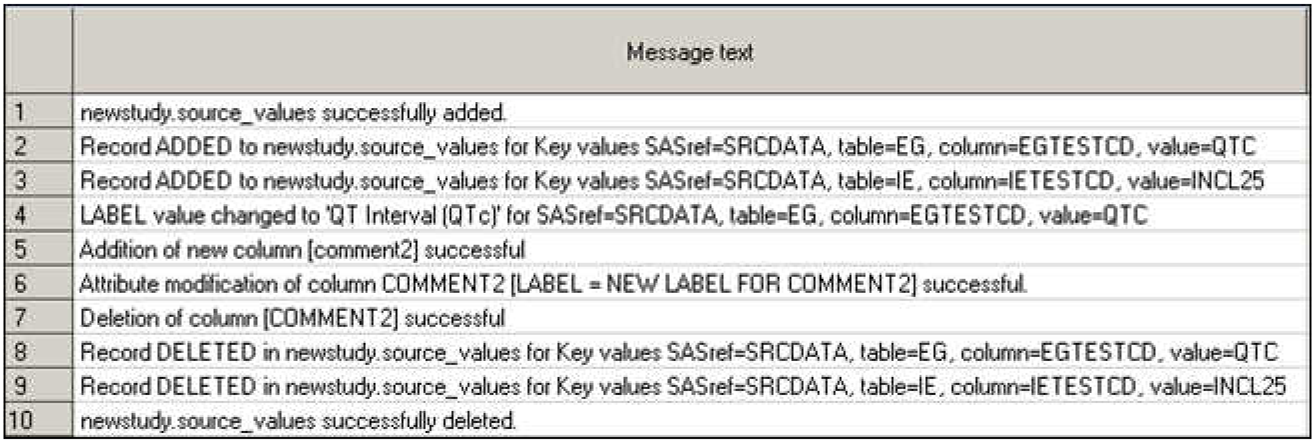
Note: The transaction log data set is broken into three displays for clarity.

Figure 4.26 Example Transaction Log Data Set — Image 1



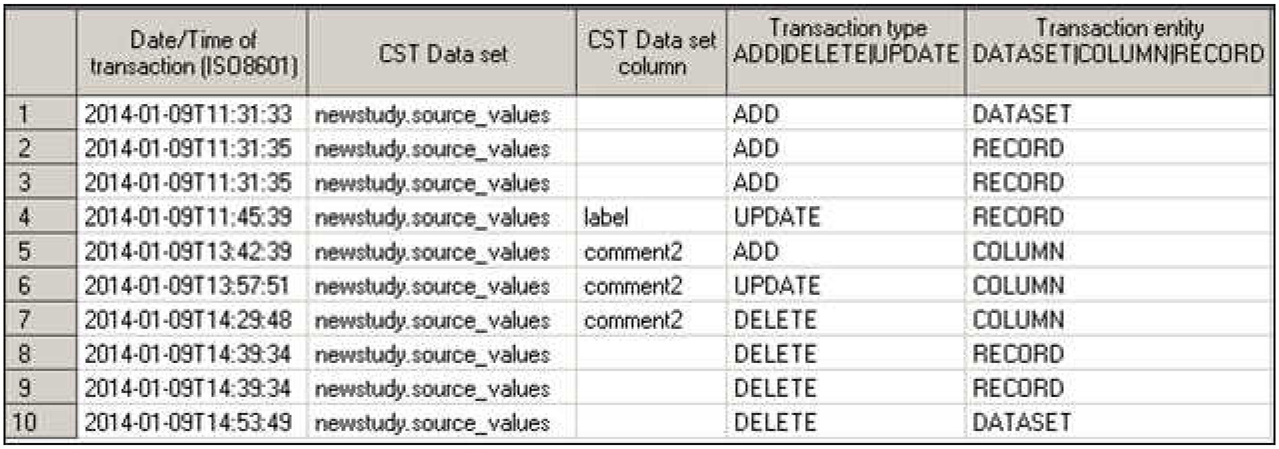
	Name of standard	Standard version	SAS user ID	CST Macro used	System file path
1	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILADDDATASET	C:\NewStudy
2	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILAPPENDMETADATARECORD	C:\NewStudy
3	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILAPPENDMETADATARECORD	C:\NewStudy
4	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILUPDATEMETADATARECORD	C:\NewStudy
5	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILADDDSCOLUMN	C:\NewStudy
6	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILMODIFYCOLUMNATTRIBUTE	C:\NewStudy
7	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILDELETEDSCOLUMN	C:\NewStudy
8	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILDELETEMETADATARECORD	C:\NewStudy
9	CDISC-SDTM	3.1.3	sasuserlogin	CSTUTILDELETEMETADATARECORD	C:\NewStudy
10			sasuserlogin	CSTUTIL_DELETEDATASET	C:\NewStudy

Figure 4.27 Example Transaction Log Data Set — Image 2



	Message text
1	newstudy.source_values successfully added.
2	Record ADDED to newstudy.source_values for Key values SASref=SRCDATA, table=EG, column=EGTESTCD, value=QTC
3	Record ADDED to newstudy.source_values for Key values SASref=SRCDATA, table=IE, column=IETESTCD, value=INCL25
4	LABEL value changed to 'QT Interval (QTc)' for SASref=SRCDATA, table=EG, column=EGTESTCD, value=QTC
5	Addition of new column [comment2] successful
6	Attribute modification of column COMMENT2 [LABEL = NEW LABEL FOR COMMENT2] successful.
7	Deletion of column [COMMENT2] successful
8	Record DELETED in newstudy.source_values for Key values SASref=SRCDATA, table=EG, column=EGTESTCD, value=QTC
9	Record DELETED in newstudy.source_values for Key values SASref=SRCDATA, table=IE, column=IETESTCD, value=INCL25
10	newstudy.source_values successfully deleted.

Figure 4.28 *Example Transaction Log Data Set — Image 3*



	Date/Time of transaction (ISO8601)	CST Data set	CST Data set column	Transaction type ADD|DELETE|UPDATE	Transaction entity DATASET|COLUMN|RECORD
1	2014-01-09T11:31:33	newstudy.source_values		ADD	DATASET
2	2014-01-09T11:31:35	newstudy.source_values		ADD	RECORD
3	2014-01-09T11:31:35	newstudy.source_values		ADD	RECORD
4	2014-01-09T11:45:39	newstudy.source_values	label	UPDATE	RECORD
5	2014-01-09T13:42:39	newstudy.source_values	comment2	ADD	COLUMN
6	2014-01-09T13:57:51	newstudy.source_values	comment2	UPDATE	COLUMN
7	2014-01-09T14:29:48	newstudy.source_values	comment2	DELETE	COLUMN
8	2014-01-09T14:39:34	newstudy.source_values		DELETE	RECORD
9	2014-01-09T14:39:34	newstudy.source_values		DELETE	RECORD
10	2014-01-09T14:53:49	newstudy.source_values		DELETE	DATASET

See Also

“Transaction Log Data Set” on page 60

5

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SAS Representation of Standards

Overview

The SAS Clinical Standards Toolkit is designed to support various clinical standards. The SAS Clinical Standards Toolkit was initially built to support the Clinical Data Interchange Standards Consortium (CDISC) standards. However, the generic framework enables definition of any type of standard.

Each SAS Clinical Standards Toolkit standard provides a SAS representation of the published source guidelines or source specification. The SAS representation is designed to serve as a model or template of the source specification.

Two key design requirements shaped the implementation of the SAS Clinical Standards Toolkit standards.

- Each supported standard is represented in one or more SAS files. This facilitates these points:

  - It provides SAS users with an implementation of data models and standards that are based on SAS.

  - It enables you to use SAS routines to assess how well any user-defined set of data and metadata conforms to the standard.

  - It enables you to use SAS code to read and derive files in other formats (for example, XML).

    Each SAS Clinical Standards Toolkit standard is an optimized reference standard from a SAS perspective.

- You are able to define your own customized standards, or you are able to modify existing SAS standards. For more information about how new standards are registered in the SAS Clinical Standards Toolkit, see "Registering a New Version of a Standard" on page 26.

SAS provides new standards and updates based on customer requirements, changes to source guidelines, and changes to source specifications.

This document uses the term “reference standard” to refer to the SAS representation of each source specification.

The definition of reference standard depends on several factors, including the complexity of the external source standard, the intended use of the standard, and your preferred implementation methodology. Here are three ways to define reference standard:

- A limited SAS representation of an external standard, defined as one or more SAS files.

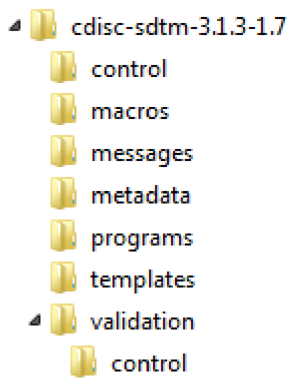
  For example, consider two of the CDISC standards supported in the SAS Clinical Standards Toolkit. Each CDISC Controlled Terminology standard can be represented in its simplest form as either a SAS data set or SAS format catalog of acceptable values. Each CDISC SDTM standard can be represented as a set of domains (SAS data sets), and as an associated set of data sets that describe the data set and column metadata for those domains. For some users, this might be the only information about the standards needed from the SAS Clinical Standards Toolkit.

- A distinct folder hierarchy within the global standards library, comprising the previous definition and any supporting files required by the SAS Clinical Standards Toolkit.

  By default, reference standards are specified in the global standards library that is created when the SAS Clinical Standards Toolkit is deployed. Each reference standard can be unique in regard to the folder hierarchy and supporting files. Consider the CDISC SDTM standard.

The following display shows the global standards library folder hierarchy that is provided for CDISC SDTM:

Figure 5.1 *Global Standards Library Folder Hierarchy*



The `metadata` folder contains the data set and column metadata for each supported domain. The SAS Clinical Standards Toolkit provides a utility macro (%CST_CREATETABLESFORDATASTANDARD) that reads this metadata, and builds an empty data set for each supported SDTM domain. All supporting files required by the SAS Clinical Standards Toolkit to support the specific CDISC SDTM standard are provided in the remaining folders.

- The `control` folder provides these data sets:

Standards	is a single-record file that provides metadata about the standard.
Standardlookup	provides acceptable values for many discrete-value columns for a number of standard metadata files.
StandardSASReferences	is a sample or template specification of records that describes input or output files relevant to using the standard.

- The `macros` folder contains any SAS code specific to the CDISC SDTM standard.

- The `messages` folder contains messages that are associated with tasks (such as validation) that are supported by the SAS Clinical Standards Toolkit.

- ◻ The **`metadata`** folder provides these data sets:

class_tables	identifies a limited set of column collections specific to one or more SDTM domains.
class_columns	identifies the full set of column definitions used in the SDTM domains.
reference_tables	provides metadata for the specific data sets (domains) that are supported for CDISC SDTM. This information is different for each version of the CDISC SDTM standard.
reference_columns	provides metadata for the specific columns in the domains that are supported for CDISC SDTM. This information is different for each version of the CDISC SDTM standard.

- ◻ The **`programs`** folder contains several properties files that specify generic SAS Clinical Standards Toolkit properties and specific CDISC SDTM properties translated into SAS global macro variables for a SAS Clinical Standards Toolkit process.
- ◻ The **`validation/control`** folder provides check metadata that is associated with the primary CDISC SDTM task supported by the SAS Clinical Standards Toolkit.

Each of these folders is discussed in greater detail in this document.

- A logical set of files from multiple SAS libraries and multiple standards as defined in the previous two definitions. These are all collated within a single SASReferences data set.

  Each reference standard can be defined by the files itemized in a SASReferences data set and used to perform a standard task. The SASReferences data set documents all of the input and output files that are associated with a SAS Clinical Standards Toolkit process. These files do not need to be limited to a single standard or be resident in a single standard folder hierarchy. Consider a SASReferences data set that supports a process that builds a CDISC CRT-DDS define.xml file. That SASReferences data set might point to CDISC SDTM source data and metadata, a CDISC controlled terminology SAS format catalog, a set of reference table and column metadata documenting the SAS data sets used to build the define.xml file, and a default style sheet for the generated define.xml file. A broader view of what comprises the CDISC CRT-DDS reference standard must recognize that the standard also references data and metadata from other standards.

TIP Best Practice Recommendation: Instead of changing an existing SAS standard, you should define a new standard. This allows seamless updates to SAS standards, which facilitates operational qualification, demo scripts, and Technical Support debugging a fixed standard. There is a way for you to request a change to an existing standard if there are errors. To define a new standard, which can be just changing an existing standard and saving it as a new standard, see Chapter 2, “Framework,” on page 7.

CDISC SDTM

Purpose

CDISC SDTM defines a standard structure for data tabulations that are submitted as part of a product application to a regulatory authority such as the FDA. The data sets and columns required for a regulatory application are not prescribed by the standard. Instead, these requirements are based on the trial protocol and discussions with the regulatory authority in charge of reviewing the submission. Therefore, any SAS Clinical Standards Toolkit standard, including any CDISC SDTM standard, is only a representative sample or template.

Release Dates

CDISC SDTM 3.1.2

- CDISC SDTM Model, Final Version 1.2, November 12, 2008
- *CDISC SDTM Implementation Guide*, Final Version 3.1.2, November 12, 2008

CDISC SDTM 3.1.3

- CDISC SDTM Model, Final Version 1.3, July 16, 2012
- *CDISC SDTM Implementation Guide*, Final Version 3.1.3, July 16, 2012

CDISC SDTM 3.2

- Study Data Tabulation Model, Final Version 1.4, November 26, 2013
- *Study Data Tabulation Model Implementation Guide: Human Clinical Trials*, Final Version 3.2, November 26, 2013
- *Study Data Tabulation Model Implementation Guide: Associated Persons*, Final Version 1.0, December 12, 2013
- *Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)*, Provisional Version 1.0, December 4, 2012

Description

CDISC standards, including SDTM, allow for the inclusion and exclusion of some columns. (For example, timing variables can be included or excluded.) In addition, CDISC standards do not specify a length for most columns. Therefore, any implementation of a CDISC standard requires interpretation of that standard, which might lead to differences in the implementation of that standard. Reference standards are derived based on internal conventions and experiences, and discussions with regulatory authorities.

The domain and column metadata that constitute the SAS representation of each CDISC SDTM standard are derived from the global standards library in these formats:

- as empty data sets (using the utility macro %CST_CREATETABLESFORDATASTANDARD)
- as table metadata (See Table 5.1 on page 95.)
- as column metadata for each domain (See Table 5.2 on page 96.)

Table 5.1 Sample reference_tables Record (CDISC SDTM 3.2)

Column Name	Column Value
SASref	REFMETA
Table	AE
Label	Adverse Events
Class	Events
XmlPath	.../transport/ae.xpt
XmlTitle	Adverse Events SAS transport file
Structure	One record per adverse event per subject
Purpose	Tabulation
Keys	STUDYID USUBJID AEDECOD AESTDTC
State	Final
Date	2013-11-26
Standard	CDISC-SDTM
StandardVersion	3.2
Standardref	SDTMIG 3.2, section 6.2
Comment	“The Adverse Events dataset includes clinical data describing "any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment" (ICH E2A). The events included in the AE dataset should be consistent with the protocol requirements. Adverse events may be captured either as free text or via a pre-specified list of terms.”

***Table 5.2** Sample reference_columns Record (CDISC SDTM 3.2)*

Column Name	Column Value
sasref	REFMETA
table	AE
column	AESEV
label	Severity/Intensity
order	26
type	C
length	20
displayformat	
xmldatatype	text
xmlcodelist	AESEV
core	Perm
origin	
role	RecordQualifier
term	(AESEV)
algorithm	
qualifiers	UPPERCASE
standard	CDISC-SDTM
standardversion	3.2
standardref	

Column Name	Column Value
comment	The severity or intensity of the event. Examples: MILD, MODERATE, SEVERE.

The SAS Clinical Standards Toolkit CDISC SDTM reference standard provides metadata and code to validate the structure and content of the SDTM domains.

To enable validation, supplemental files supporting SDTM validation processes include these global standards library files:

- The Validation Master data set in the `validation/control` folder contains the superset of checks validating the domain structure and content for each specific SDTM version.
- The Messages data set in the `messages` folder provides error messaging for all Validation Master checks.
- SAS code in the `macros` folder provides code specific to SDTM that augments code that is provided in the primary SAS Clinical Standards Toolkit autocall library (`!sasroot/cstframework/sasmacro`).

It is this set of files, in whole or in part, that defines each of the CDISC SDTM reference standards.

CDISC SDTM 3.1.1 Reference Standard

Note: Effective with SAS Clinical Standards Toolkit 1.7, the CDISC SDTM 3.1.1 reference standard is no longer supported. The SDTM 3.1.1 subfolder hierarchy has been removed from the global standards library and the sample study library.

CDISC SDTM 3.1.2 Reference Standard

Overview of the CDISC SDTM 3.1.2 Domains

The SAS Clinical Standards Toolkit representation of the CDISC SDTM 3.1.2 standard consists of 32 domains (in the reference_tables metadata data set) and 723 columns (in the reference_columns metadata data set).

The 32 supported domains are shown in this table.

Table 5.3 CDISC SDTM 3.1.2 Supported Domains

Adverse Events - AE	PK Concentrations - PC
Clinical Events - CE	Physical Examination - PE
Concomitant Medications - CM	PK Parameters - PP
Comments - CO	Questionnaires - QS
Drug Accountability - DA	Related Records - RELREC
Demographics - DM	Subject Characteristics - SC
Disposition - DS	Subject Elements - SE
Protocol Deviations - DV	Substance Use - SU
ECG Test Results - EG	Supplemental Qualifiers - AE - SUPPAE
Exposure - EX	Subject Visits - SV
Findings About - FA	Trial Arms - TA
Inclusion/Exclusion Criterion Not Met - IE	Trial Elements - TE
Laboratory Test Results - LB	Trial Inclusion/Exclusion Criteria - TI
Microbiology Specimen - MB	Trial Summary - TS
Medical History - MH	Trial Visits - TV
Microbiology Susceptibility Test - MS	Vital Signs - VS

CDISC SDTM 3.1.3 Reference Standard

Overview of the CDISC SDTM 3.1.3 Domains

The SAS Clinical Standards Toolkit representation of the CDISC SDTM 3.1.3 standard consists of 36 domains (in the reference_tables metadata data set) and 821 columns (in the reference_columns metadata data set).

The 36 supported domains are shown in this table.

Table 5.4 *CDISC SDTM 3.1.3 Supported Domains*

Adverse Events - AE	Clinical Events - CE
Concomitant Medications - CM	Comments - CO
Drug Accountability - DA	Demographics - DM
Disposition - DS	Protocol Deviations - DV
ECG Test Results - EG	Exposure - EX
Findings About - FA	Inclusion/Exclusion Criterion Not Met - IE
Laboratory Test Results - LB	Microbiology Specimen - MB
Medical History - MH	Microbiology Susceptibility - MS
PK Concentrations - PC	Physical Examination - PE
Pool Definition - POOLDEF	PK Parameters - PP
Questionnaire - QS	Related Records - RELREC
Disease Response - RS	Subject Characteristics - SC
Subject Elements - SE	Substance Use - SU
Supplemental Qualifiers - AE - SUPPAE	Subject Visits - SV

Trial Arms - TA	Trial Elements - TE
Trial Inclusion/Exclusion Criteria - TI	Tumor Results - TR
Trial Summary - TS	Tumor Identification - TU
Trial Visits - TV	Vital Signs - VS

CDISC SDTM 3.2 Reference Standard

Overview of the CDISC SDTM 3.2 Domains

The SAS Clinical Standards Toolkit representation of the CDISC SDTM 3.2 standard consists of 57 domains (in the reference_tables metadata data set) and 1284 columns (in the reference_columns metadata data set).

The 57 supported domains are shown in this table.

Table 5.5 CDISC SDTM 3.2 Supported Domains

Adverse Events - AE	Morphology - MO
Associated Persons Demographics - APDM	Microbiology Susceptibility - MS
Associated Persons Related to Subjects - APRELSUB	PK Concentrations - PC
Clinical Events - CE	Physical Examination - PE
Concomitant Medications - CM	Pool Definition - POOLDEF
Comments - CO	PK Parameters - PP
Drug Accountability - DA	Procedures - PR
Death Details - DD	Questionnaire - QS
Device Events - DE	Related Records - RELREC

Study Device Identifiers - DI	Related Subjects - RELSUB
Demographics - DM	Reproductive System Findings - RP
Device Properties - DO	Disease Response - RS
Device-Subject Relationships - DR	Subject Characteristics - SC
Disposition - DS	Subject Elements - SE
Device Tracking and Disposition - DT	Skin Response - SR
Device In-Use - DU	Subject Status - SS
Protocol Deviations - DV	Substance Use - SU
Device Exposure - DX	Supplemental Qualifiers - SUPP
Exposure as Collected - EC	Subject Visits - SV
ECG Test Results - EG	Trial Arms - TA
Exposure - EX	Trial Disease Assessments - TD
Findings About - FA	Trial Elements - TE
Healthcare Encounters - HO	Trial Inclusion/Exclusion Criteria - TI
Inclusion/Exclusion Criterion Not Met - IE	Tumor Results - TR
Immunogenicity Specimen Assessment - IS	Trial Summary - TS
Laboratory Test Results - LB	Tumor Identification - TU
Microbiology Specimen - MB	Trial Visits - TV
Medical History - MH	Vital Signs - VS
Microscopic Findings - MI	

CDISC ADaM 2.1

Purpose

The Analysis Data Model (ADaM) specifies the fundamental principles and standards to follow when creating analysis data sets and associated metadata. ADam supports efficient generation, replication, and review of analysis results. The design of analysis data sets is generally driven by the scientific and medical objectives of the clinical trial. A fundamental principle is that the structure and content of the analysis data sets must support clear, unambiguous communication of the scientific and statistical aspects of the clinical trial.

The purpose of ADaM is to provide a framework that enables analysis of the data. At the same time, ADaM enables reviewers and other recipients of the data to have a clear understanding of the data’s lineage from collection to analysis to results. Whereas ADaM is optimized to support data derivation and analysis, CDISC Study Data Tabulation Model (SDTM) is optimized to support data tabulation.

Release Date

CDISC ADaM Analysis Data Model, Final Version 2.1, December 17, 2009

The ADaM Basic Data Structure for Time-to-Event Analyses, Version 1.0, May 8, 2012

Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis, Version 1.0, May 10, 2012

Regulatory Basis

(Source: Submission of Data in CDISC Format to CBER, http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/ucm209137.htm, page updated: October 18, 2013)

Effective December 15, 2010, SDTM and ADaM are being accepted for CBER IND, NDA, and BLA submissions.

(Source: Study Data Specifications, Version 1.5.1, January 4, 2010)

"Prior to submission, sponsors should contact the appropriate center's reviewing division to determine the division's analysis dataset needs. CDISC/ADaM standards for analysis datasets (www.cdisc.org/adam) may be used if acceptable to the review division."

(Source: *CDER Common Data Standards Issues Document*, Version 1.1/December 2011, http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM254113.pdf)

"In determining how to create ADaM analysis datasets for submission to CDER, sponsors should refer to three documents: the Analysis Data Model and the ADaM Implementation Guide (www.CDISC.org), and the FDA Study Data Specifications Document (http://www.fda.gov/downloads/ForIndustry/DataStandards/StudyDataStandards/UCM199599.pdf). Close adherence to the ADaM Implementation Guide is expected and any specific questions that result from attempts to adhere to these documents should be discussed with the review division."

CDISC ADaM 2.1 Reference Standard

Section 2.1 of the *Analysis Data Model Implementation Guide* provides the fundamental principles of the CDISC ADaM model.

- Analysis data sets and associated metadata must clearly and unambiguously communicate the content and source of the data sets supporting the statistical analyses performed in a clinical study.
- Analysis data sets and associated metadata must provide traceability to enable an understanding of where an analysis value came from.
- Analysis data sets must be readily usable with commonly available software tools.
- Analysis data sets must be associated with metadata to facilitate clear and unambiguous communication. Ideally, the metadata is machine-readable.
- Analysis data sets should have a structure and content that enable statistical analyses to be performed with minimal programming. Such data sets are described as analysis-ready.

Implementation of the CDISC ADaM 2.1 reference standard in the SAS Clinical Standards Toolkit supports each of these principles.

The number and structure of analysis data sets are highly dependent on the type of study, the study objectives as defined in the statistical analysis plan, and discussions with the reviewing authority. ADaM data sets incorporate derived and collected data that permit analysis with little or no additional programming. Data can be from various SDTM domains, other ADaM data sets, or any combination thereof.

The CDISC ADaM 2.1 reference standard currently supports these analysis data set structures:

- The subject-level analysis data set (ADSL) provides descriptive information about subjects, such as study disposition, demographic, and baseline characteristics. The ADSL is the primary source for subject-level variables included in other analysis data sets, such as population flags and treatment variables. There is only one ADSL per study, and the ADSL and its related metadata are required in each CDISC-based submission of data from a clinical trial, even if no other analysis data sets are submitted.
- The ADaM Basic Data Structure (BDS) is used for the majority of ADaM data sets, regardless of the therapeutic area or type of analysis. Each BDS data set contains one or more records per subject and analysis parameter. The structure of some BDS data sets might include an analysis time point. A record in a BDS analysis data set can represent an observed, derived, or imputed value required for analysis. Each BDS data set contains a core set of variables that describe the analysis parameter and the value being analyzed. A data value can be derived from any source file, including any combination of SDTM and ADaM data sets. The Time-to-Event analysis data set is an example implementation of the BDS structure.
- The Adverse Event analysis data set (ADAE) structure is built on the nomenclature of the CDISC SDTM Implementation Guides for collected data. The ADAE data set adds attributes, variables, and data structures that are required for statistical analyses. The primary SDTM source domain for the ADAE data set is AE, with the corresponding SUPPAE. Additional variables can be added from the ADaM ADSL data set. The ADAE data set is required when SDTM AE is not sufficient to support all adverse event analyses. The ADAE structure for the standard adverse event

safety data set has at least one record per each AE recorded in the SDTM AE domain.

Metadata for the ADSL, BDS, and ADAE data sets is defined in the SAS Clinical Standards Toolkit reference_tables data set in the standard metadata folder.

The Analysis Data Model identifies four types of metadata that are captured and supported by the SAS Clinical Standards Toolkit.

Table 5.6 *ADaM Metadata Types and SAS Clinical Standards Toolkit Locations*

ADaM Metadata Type	SAS Clinical Standards Toolkit Location
Analysis data set metadata	global standards library reference_tables.sas7bdat
Analysis variable metadata	global standards library reference_columns.sas7bdat
Analysis parameter-value-level metadata	global standards library valuemetadata.sas7bdat template sample library metadata source_values.sas7bdat example
Analysis results metadata	global standards library analysis_results.sas7bdat template sample library metadata analysis_results.sas7bdat example

Version 1.0 of the Analysis Data Model Implementation Guide (ADaMIG) defines a common set of ADSL and BDS columns that can be used as templates for ADaM analysis data sets. This set of ADSL and BDS columns has been supplemented with Version 1.0 of the Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis. Metadata for the 290 columns in the SAS representation of ADSL, BDS, and ADAE is defined in the SAS Clinical Standards Toolkit reference_columns data set in the standard metadata folder. Empty ADSL, BDS, and ADAE data sets containing these columns can be derived from the SAS Clinical Standards Toolkit global standards library using the utility macro %CST_CREATETABLESFORDATASTANDARD.

The SAS Clinical Standards Toolkit CDISC ADaM reference standard also provides metadata and code to validate the structure and content of the ADaM analysis data sets.

To enable validation, supplemental files supporting ADaM validation processes include these SAS Clinical Standards Toolkit global standards library files:

- The Validation Master data set in the **`validation/control`** folder contains the superset of checks validating the structure and content of each analysis data set. These checks are based on versions 1.1 and 1.2 of the CDISC ADaM Validation Checks as prepared by the CDISC ADaM team, as well as selected checks that are unique to the SAS Clinical Standards Toolkit.
- The Messages data set in the **`messages`** folder provides error messaging for all Validation Master checks.
- SAS code in the **`macros`** folder provides code that is specific to ADaM that augments code that is provided in the primary SAS Clinical Standards Toolkit autocall library (**`!sasroot/cstframework/sasmacro`**).

These supplemental files, in whole or in part, define the SAS Clinical Standards Toolkit CDISC ADaM reference standard.

CDISC CRT-DDS 1.0

Purpose

The CDISC CRT-DDS standard defines the metadata structures in a machine-readable XML format. These metadata structures are used to describe tabulation and analysis data sets and variables for regulatory submissions. The XML schema that is used to define the metadata structures in an XML format is based on an extension to the CDISC Operational Data Model (ODM).

Release Date

CDISC CRT-DDS, Final Version 1.0, February 10, 2005

Regulatory Basis

(Source: CDISC Case Report Tabulation Data Definition Specification)

In 1999, the FDA standardized the submission of clinical and non-clinical data and metadata in a set of eSubmission guidelines to include metadata descriptions of the data sets and columns within a Data Definition Document (define.pdf). In 2003, the FDA published a set of guidance documents on receiving electronic product applications per the International Conference on Harmonisation (ICH) electronic Common Technical Document (eCTD) specifications. In these specifications, the FDA expanded the acceptable file types to include the XML format.

CDISC CRT-DDS 1.0 Reference Standard

Overview

The domain and column metadata that constitute the SAS representation of CDISC CRT-DDS 1.0 are derived from the global standards library in these formats:

- as empty data sets (using the utility macro %CST_CREATETABLESFORDATASTANDARD)
- as table metadata (See Table 5.7 on page 107.)
- as column metadata for 176 columns in the 39 data sets (reference_columns in the standard metadata folder)

Table 5.7 *CDISC CRT-DDS 1.0 reference_tables*

AnnotatedCRFs	ItemGroupAliases	MDVLeafTitles
CLItemDecodeTranslatedText	ItemGroupDefItemRefs	MUTranslatedText
CodeListLitems	ItemGroupDefs	MeasurementUnits
CodeLists	ItemGroupLeaf	MetaDataVersion
ComputationMethods	ItemGroupLeafTitles	Presentation

DefineDocument	ItemMURefs	ProtocolEventRefs
ExternalCodeLists	ItemQuestionExternal	RCErrorTranslatedText
FormDefArchLayouts	ItemQuestionTranslatedText	Study
FormDefItemGroupRefs	ItemRangeCheckValues	StudyEventDefs
FormDefs	ItemRangeChecks	StudyEventFormRefs
ImputationMethods	ItemRole	SupplementalDocs
ItemAliases	ItemValueListRefs	ValueListItemRefs
ItemDefs	MDVLeaf	ValueLists

As a general rule, the SAS representation of the CDISC CRT-DDS standard is patterned to match the XML element (data set) and attribute (column) structure of define.xml. For example, for CDISC SDTM, domain-level metadata is represented by a define.xml ItemGroupDef element. This metadata is captured in the ItemGroupDefs SAS data set. The TE domain metadata is shown in this code:

```
<ItemGroupDef OID="docroot.IG.TE"
    Name="TE"
    Repeating="No"
    IsReferenceData="Yes"
    Purpose="Tabulation"
    def:Label="Trial Elements"
    def:Structure="One record per planned element"
    def:DomainKeys="STUDYID,ETCD"
    def:Class="Trial Design"
    def:ArchiveLocationID="ArchiveLocation.te">
    !-- All ItemRefs would be listed here -->
    <def:leaf ID="ArchiveLocation.te"
    xlink:href="te.xpt"> <def:title>te.xpt</def:title>
  </def:leaf>
</ItemGroupDef>
```

The TE domain metadata is shown in this table.

Table 5.8 *Sample Data Set Representation: ItemGroupDefs.sas7bdat*

Column	**Value**
OID	IG.TE
Name	TE
Repeating	No
IsReferenceData	Yes
SASDatasetName	TE
Domain	TE
Origin	
Role	
Purpose	Tabulation
Comment	Elements are the building blocks of Arms. Arms consisting of Elements are the paths subjects will follow.
Label	Trial Elements
Class	Trial Design
Structure	One record per planned element
DomainKeys	STUDYID, ETCD
ArchiveLocationID	Location.TE
FK_MetaDataVersion	MDV.1

Note: Empty or null attributes are not typically included in the XML file.

The highly structured nature of CDISC CRT-DDS data requires that any mapping to a relational format include a large number of data sets, with foreign key relationships to help preserve the intended non-relational object structure. In the SAS Clinical Standards Toolkit, foreign key relationships are enforced when validating the CDISC CRT-DDS data sets.

Field lengths in the CDISC CRT-DDS data sets are consistent by core data type. CDISC has not specified any limit to the length of most character fields. Arbitrary lengths have been chosen by data type. These lengths are listed in this table. In the table, standard data types are distilled into core data types. To be safe, larger lengths have been chosen to ensure that no data loss occurs in the SAS Clinical Standards Toolkit pre-installed data sets. Production tables might be compressed using SAS mechanisms to preserve disk space.

Table 5.9 CDISC CRT-DDS Default Lengths by Data Type

Type Name	Length	Description
oid	128	A unique object identifier or a reference
text	2000	A character field that can accommodate a large number of characters
name	128	A descriptive identifier
value	512	An item of collected or reference data
path	512	An absolute or relative file system path or URL

Note: CRT-DDS and ODM use slightly different lengths.

CDISC CRT-DDS SAS Data Set Construction

The SAS Clinical Standards Toolkit CDISC CRT-DDS reference standard supports reading and representing in SAS a define.xml file, building a define.xml file, and validating the structure and content of the SAS representation of a define.xml file. In addition, the structural integrity of the define.xml file is validated, and a define.pdf file can be generated. To support this functionality, supplemental files include these global standards library files:

- A SAS format catalog (crtddsct.sas7bcat) in the **`formats`** folder provides valid values for selected columns in the 39 data sets of the SAS representation.
- The Validation Master data set in the **`validation/control`** folder contains the superset of checks validating the structure and content of the 39 data sets.
- The Messages data set in the **`messages`** folder provides error messaging for all Validation Master checks.
- SAS code in the **`macros`** folder provides CDISC CRT-DDS-specific code that augments code that is provided in the primary SAS Clinical Standards Toolkit autocall library (**`!sasroot/cstframework/sasmacro`**).
- The **`style sheet`** folder contains the define1-0-0.xsl and define-v1-updated-html.xsl XSL style sheets.

  The define1-0-0.xsl style sheet was the original style sheet published by CDISC in 2005. It can be found at http://www.cdisc.org/define-xml.

  The define-v1-updated-html.xsl style sheet was used in the 2013 update to the first CDISC SDTM/ADaM Pilot Project (http://www.cdisc.org/sdtm-adam-pilot-).

  A define.xml file can be rendered in a human-readable form if it contains an explicit XML style sheet reference, such as a reference to the default style sheet.

CDISC Define-XML 2.0

Purpose

The CDISC Define-XML 2.0 standard defines the metadata structures in a machine-readable XML format. These metadata structures are used to describe tabulation and analysis data sets and variables for regulatory submissions and any proprietary (non-CDISC) data set structure. The XML schema that is used to define the metadata structures in an XML format is based on an extension to the CDISC Operational Data Model (ODM).

Release Date

CDISC Define-XML Version 2.0 specification, Production Version 2.0.0, March 5, 2013.

Regulatory Basis

(Source: CDISC Define-XML Version 2.0 Specification)

“In the United States, the approval process for regulated human and animal health products requires the submission of data from clinical trials and other studies as expressed in the Code of Federal Regulations (CFR). The FDA established the regulatory basis for wholly electronic submission of data in 1997 with the publication of regulations on the use of electronic records in place of paper records (21 CFR Part 11). In 1999, the FDA standardized the submission of clinical and non-clinical data using the SAS Version 5 XPORT Transport Format and the submission of metadata using Portable Document Format (PDF), respectively. In 2005, the Study Data Specifications published by the FDA included the recommendation that data definitions (metadata) be provided as a Define-XML file. In December 2011, the CDER Common Data Standards Issues Document stated that ‘a properly functioning define.xml file is an important part of the submission of standardized electronic datasets and should not be considered optional.’”

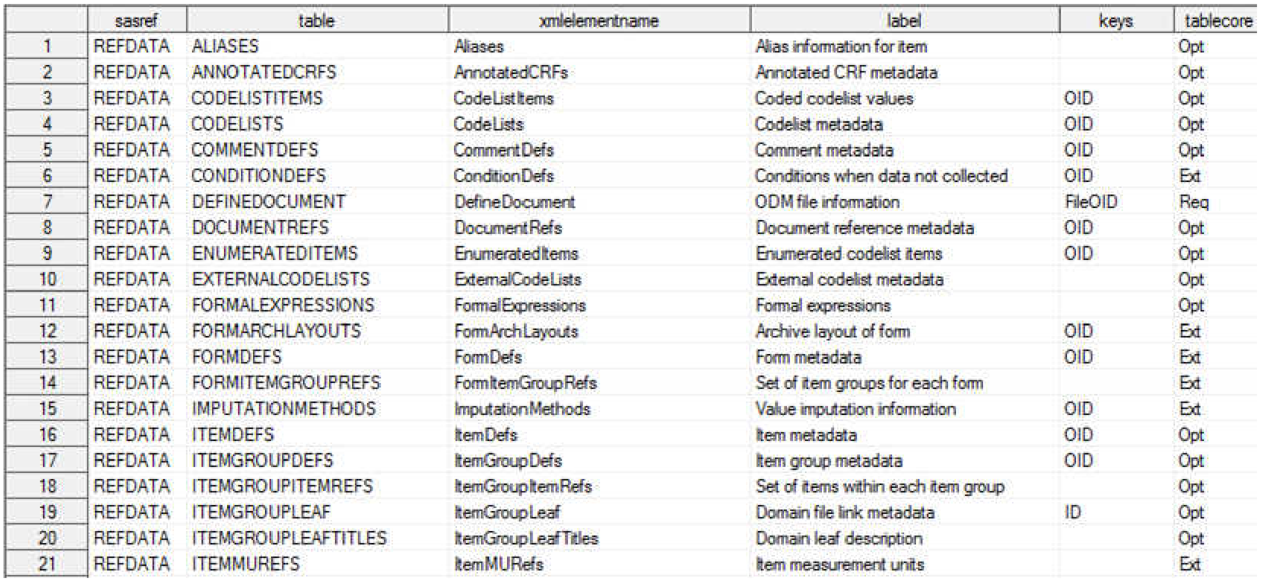
CDISC Define-XML 2.0 Reference Standard

Overview

The domain and column metadata that constitute the SAS representation of the CDISC Define-XML 2.0 standard are derived from the global standards library in these formats:

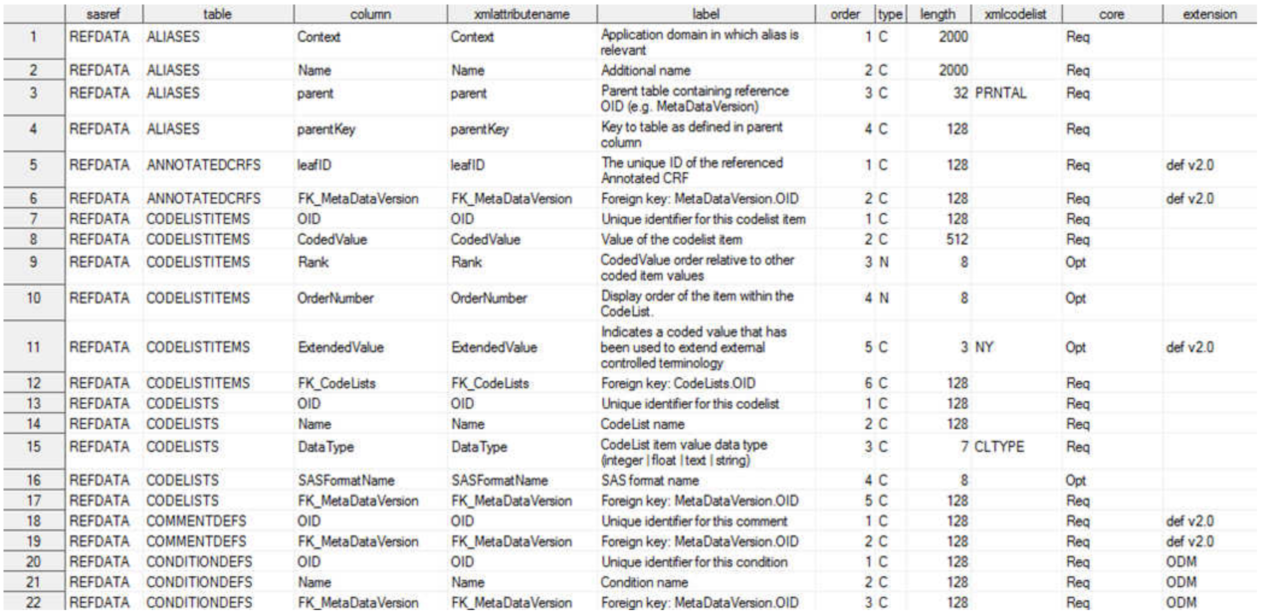
- as empty data sets (using the macro %CST_CREATETABLESFORDATASTANDARD)
- as table metadata (See Figure 5.2 on page 113.)
- as column metadata (See Figure 5.3 on page 113.)

Figure 5.2 *CDISC Define-XML 2.0 reference_tables*



	sasref	table	xmlelementname	label	keys	tablecore
1	REFDATA	ALIASES	Aliases	Alias information for item		Opt
2	REFDATA	ANNOTATEDCRFS	AnnotatedCRFs	Annotated CRF metadata		Opt
3	REFDATA	CODELISTITEMS	CodeListItems	Coded codelist values	OID	Opt
4	REFDATA	CODELISTS	CodeLists	Codelist metadata	OID	Opt
5	REFDATA	COMMENTDEFS	CommentDefs	Comment metadata	OID	Opt
6	REFDATA	CONDITIONDEFS	ConditionDefs	Conditions when data not collected	OID	Ext
7	REFDATA	DEFINEDOCUMENT	DefineDocument	ODM file information	FileOID	Req
8	REFDATA	DOCUMENTREFS	DocumentRefs	Document reference metadata	OID	Opt
9	REFDATA	ENUMERATEDITEMS	EnumeratedItems	Enumerated codelist items	OID	Opt
10	REFDATA	EXTERNALCODELISTS	ExternalCodeLists	External codelist metadata		Opt
11	REFDATA	FORMALEXPRESSIONS	FormalExpressions	Formal expressions		Opt
12	REFDATA	FORMARCHLAYOUTS	FormArchLayouts	Archive layout of form	OID	Ext
13	REFDATA	FORMDEFS	FormDefs	Form metadata	OID	Ext
14	REFDATA	FORMITEMGROUPREFS	FormItemGroupRefs	Set of item groups for each form		Ext
15	REFDATA	IMPUTATIONMETHODS	ImputationMethods	Value imputation information	OID	Ext
16	REFDATA	ITEMDEFS	ItemDefs	Item metadata	OID	Opt
17	REFDATA	ITEMGROUPDEFS	ItemGroupDefs	Item group metadata	OID	Opt
18	REFDATA	ITEMGROUPITEMREFS	ItemGroupItemRefs	Set of items within each item group		Opt
19	REFDATA	ITEMGROUPLEAF	ItemGroupLeaf	Domain file link metadata	ID	Opt
20	REFDATA	ITEMGROUPLEAFTITLES	ItemGroupLeafTitles	Domain leaf description		Opt
21	REFDATA	ITEMMUREFS	ItemMURefs	Item measurement units		Ext

Figure 5.3 *CDISC Define-XML 2.0 reference_columns*



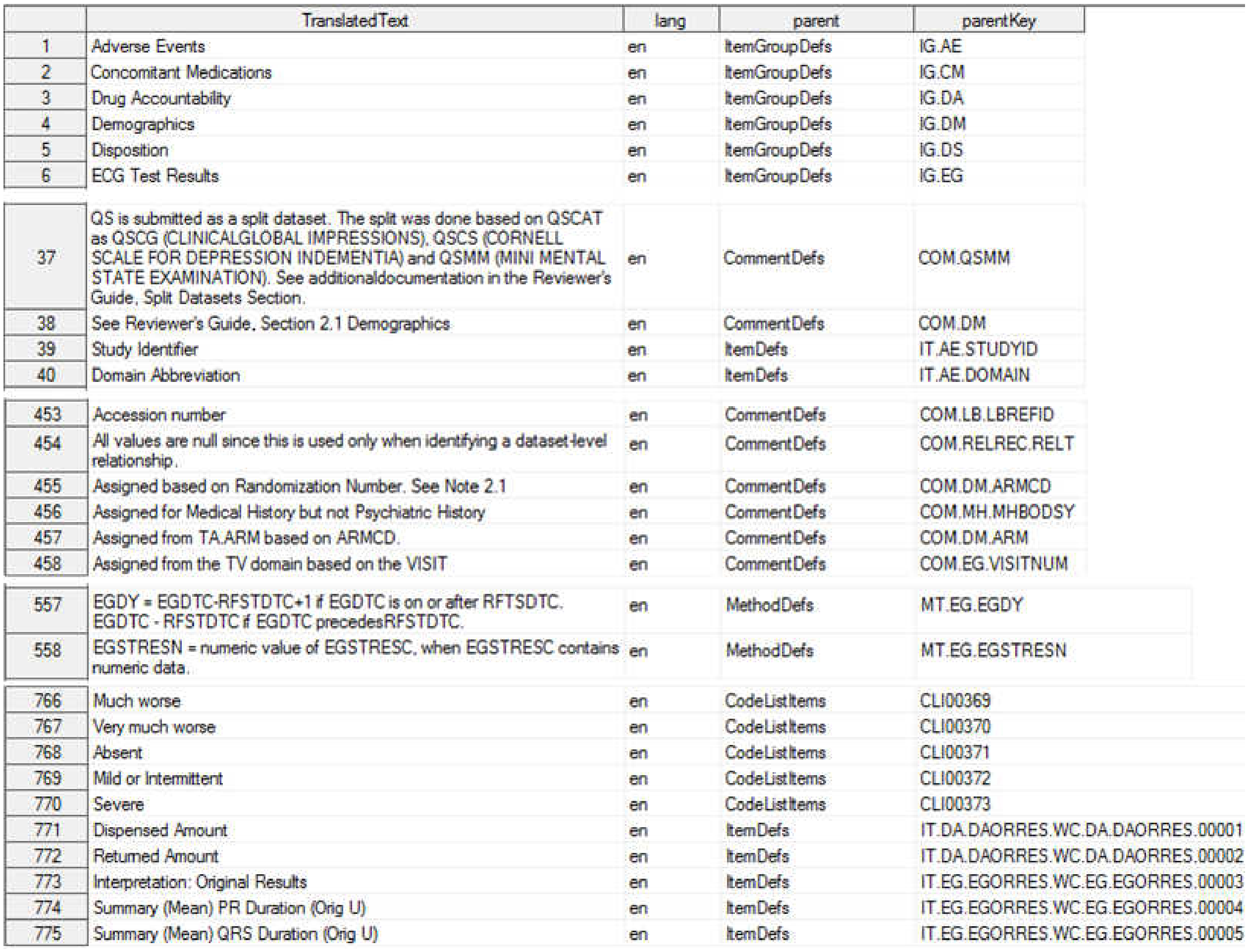
	sasref	table	column	xmlattributename	label	order	type	length	xmlcodelist	core	extension
1	REFDATA	ALIASES	Context	Context	Application domain in which alias is relevant	1	C	2000		Req	
2	REFDATA	ALIASES	Name	Name	Additional name	2	C	2000		Req	
3	REFDATA	ALIASES	parent	parent	Parent table containing reference OID (e.g. MetaDataVersion)	3	C	32	PRNTAL	Req	
4	REFDATA	ALIASES	parentKey	parentKey	Key to table as defined in parent column	4	C	128		Req	
5	REFDATA	ANNOTATEDCRFS	leafID	leafID	The unique ID of the referenced Annotated CRF	1	C	128		Req	def v2.0
6	REFDATA	ANNOTATEDCRFS	FK_MetaDataVersion	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	2	C	128		Req	def v2.0
7	REFDATA	CODELISTITEMS	OID	OID	Unique identifier for this codelist item	1	C	128		Req	
8	REFDATA	CODELISTITEMS	CodedValue	CodedValue	Value of the codelist item	2	C	512		Req	
9	REFDATA	CODELISTITEMS	Rank	Rank	CodedValue order relative to other coded item values	3	N	8		Opt	
10	REFDATA	CODELISTITEMS	OrderNumber	OrderNumber	Display order of the item within the CodeList.	4	N	8		Opt	
11	REFDATA	CODELISTITEMS	ExtendedValue	ExtendedValue	Indicates a coded value that has been used to extend external controlled terminology	5	C	3	NY	Opt	def v2.0
12	REFDATA	CODELISTITEMS	FK_CodeLists	FK_CodeLists	Foreign key: CodeLists.OID	6	C	128		Req	
13	REFDATA	CODELISTS	OID	OID	Unique identifier for this codelist	1	C	128		Req	
14	REFDATA	CODELISTS	Name	Name	CodeList name	2	C	128		Req	
15	REFDATA	CODELISTS	DataType	DataType	CodeList item value data type (integer | float | text | string)	3	C	7	CLTYPE	Req	
16	REFDATA	CODELISTS	SASFormatName	SASFormatName	SAS format name	4	C	8		Opt	
17	REFDATA	CODELISTS	FK_MetaDataVersion	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	5	C	128		Req	
18	REFDATA	COMMENTDEFS	OID	OID	Unique identifier for this comment	1	C	128		Req	def v2.0
19	REFDATA	COMMENTDEFS	FK_MetaDataVersion	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	2	C	128		Req	def v2.0
20	REFDATA	CONDITIONDEFS	OID	OID	Unique identifier for this condition	1	C	128		Req	ODM
21	REFDATA	CONDITIONDEFS	Name	Name	Condition name	2	C	128		Req	ODM
22	REFDATA	CONDITIONDEFS	FK_MetaDataVersion	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	3	C	128		Req	ODM

The **tablecore** column in the reference_tables data set indicates whether the table is a required (**Req**) or optional (**Opt**) part of the Define-XML 2.0 metadata, according to the XML schema. Tables with tablecore equal to **Ext** are part of the underlying ODM metadata model, but they should be considered extensions to the Define-XML 2.0 metadata model. The core column in the reference_columns data set indicates whether a column is required (**Req**) or optional (**Opt**) in a table when the table is part of the metadata.

As a general rule, the SAS representation of the CDISC Define-XML 2.0 standard is patterned to match the XML element (data set) and attribute (column) structure of define.xml. The SAS representation of the CDISC Define-XML 2.0 metadata model contains fewer tables than the CDISC Define-XML 2.0 metadata model. This reduction was accomplished by combining tables with the same structure.

The following display shows an example of combining tables:

Figure 5.4 *CDISC Define-XML 2.0 TranslatedText Table*



	TranslatedText	lang	parent	parentKey
1	Adverse Events	en	ItemGroupDefs	IG.AE
2	Concomitant Medications	en	ItemGroupDefs	IG.CM
3	Drug Accountability	en	ItemGroupDefs	IG.DA
4	Demographics	en	ItemGroupDefs	IG.DM
5	Disposition	en	ItemGroupDefs	IG.DS
6	ECG Test Results	en	ItemGroupDefs	IG.EG
37	QS is submitted as a split dataset. The split was done based on QSCAT as QSCG (CLINICALGLOBAL IMPRESSIONS), QSCS (CORNELL SCALE FOR DEPRESSION INDEMENTIA) and QSMM (MINI MENTAL STATE EXAMINATION). See additionaldocumentation in the Reviewer's Guide, Split Datasets Section.	en	CommentDefs	COM.QSMM
38	See Reviewer's Guide, Section 2.1 Demographics	en	CommentDefs	COM.DM
39	Study Identifier	en	ItemDefs	IT.AE.STUDYID
40	Domain Abbreviation	en	ItemDefs	IT.AE.DOMAIN
453	Accession number	en	CommentDefs	COM.LB.LBREFID
454	All values are null since this is used only when identifying a dataset-level relationship.	en	CommentDefs	COM.RELREC.RELT
455	Assigned based on Randomization Number. See Note 2.1	en	CommentDefs	COM.DM.ARMCD
456	Assigned for Medical History but not Psychiatric History	en	CommentDefs	COM.MH.MHBODSY
457	Assigned from TA.ARM based on ARMCD.	en	CommentDefs	COM.DM.ARM
458	Assigned from the TV domain based on the VISIT	en	CommentDefs	COM.EG.VISITNUM
557	EGDY = EGDTC-RFSTDTC+1 if EGDTC is on or after RFTSDTC. EGDTC - RFSTDTC if EGDTC precedesRFSTDTC.	en	MethodDefs	MT.EG.EGDY
558	EGSTRESN = numeric value of EGSTRESC, when EGSTRESC contains numeric data.	en	MethodDefs	MT.EG.EGSTRESN
766	Much worse	en	CodeListItems	CLI00369
767	Very much worse	en	CodeListItems	CLI00370
768	Absent	en	CodeListItems	CLI00371
769	Mild or Intermittent	en	CodeListItems	CLI00372
770	Severe	en	CodeListItems	CLI00373
771	Dispensed Amount	en	ItemDefs	IT.DA.DAORRES.WC.DA.DAORRES.00001
772	Returned Amount	en	ItemDefs	IT.DA.DAORRES.WC.DA.DAORRES.00002
773	Interpretation: Original Results	en	ItemDefs	IT.EG.EGORRES.WC.EG.EGORRES.00003
774	Summary (Mean) PR Duration (Orig U)	en	ItemDefs	IT.EG.EGORRES.WC.EG.EGORRES.00004
775	Summary (Mean) QRS Duration (Orig U)	en	ItemDefs	IT.EG.EGORRES.WC.EG.EGORRES.00005

The TranslatedText table contains the contents of the TranslatedText child elements of various parent elements (ItemGroupDefs, ItemDefs, ItemOrigin, CodeLists, CodeListItems, MethodDefs, CommentDefs, and others). Other tables that combine similar table structures into one table are the Aliases table, the DocumentRefs table, and the FormalExpressions table.

The highly structured nature of CDISC Define-XML 2.0 data requires that any mapping to a relational format include a large number of data sets. Foreign key relationships help preserve the intended non-relational object structure. In SAS Clinical Standards Toolkit, these foreign key relationships are enforced when validating CDISC Define-XML 2.0 data sets in a way that is similar to the CDISC CRT-DDS 1.0 data sets.

Field lengths in the CDISC Define-XML 2.0 data sets are consistent by core data type. CDISC has not specified a limit to the length of most character fields. Arbitrary lengths have been chosen by data type. Here are the lengths:

Table 5.10 *CDISC Define-XML 2.0 Default Lengths by Data Type*

Type Name	Length	Description
oid	128	A unique object identifier or a reference
text	2000	A character field that can accommodate a large number of characters
name	128	A descriptive identifier
value	512	An item of collected or reference data
path	512	An absolute or relative file system path or URL

Note: CRT-DDS 1.0 and Define-XML 2.0 use the same default lengths

In the table, standard data types are distilled into core data types. Larger lengths have been chosen to ensure that no data loss occurs in the SAS Clinical Standards Toolkit pre-installed data sets. Production tables can be compressed using SAS mechanisms to preserve disk space.

CDISC Define-XML 2.0 SAS Data Set Construction

The SAS Clinical Standards Toolkit CDISC Define-XML 2.0 reference standard supports these actions:

- reading and representing a define.xml file in SAS
- building a define.xml file
- validating the structural integrity of the define.xml file against an XML schema

To support this functionality, supplemental files include these global standards library files:

- A SAS format catalog (defct.sas7bcat) in the **`formats`** folder provides valid values for selected columns in the 46 data sets of the SAS representation.
- The Messages data set in the **`messages`** folder provides unified error messaging for all Define-XML processes.
- SAS code in the **`macros`** folder provides code that is specific to CDISC Define-XML 2.0. This SAS code augments code that is provided in the primary SAS Clinical Standards Toolkit autocall library (**`!sasroot/cstframework/sasmacro`**).
- The **`style sheet`** folder contains the define2-0-0.xsl XSL style sheet. The define2-0-0.xsl style sheet is based on the style sheet that was published by CDISC in 2013. It can be found at http://www.cdisc.org/define-xml.

  A define.xml file can be rendered in a human-readable form (such as HTML) with an XSL style sheet.

CDISC Analysis Results Metadata 1.0 for Define-XML 2.0

Purpose

The CDISC Define-XML 2.0 standard defines the metadata structures in a machine-readable XML format. These metadata structures are used to describe tabulation and analysis data sets and variables for regulatory submissions, as well as any proprietary (non-CDISC) data set structure.

The Analysis Results Metadata extension to the Define-XML 2.0.0 describes a model for the purpose of submissions to regulatory agencies such as the United States Food and Drug Administration (FDA) as well as for the exchange of analysis datasets and key results between other parties. This Analysis Results Metadata extension is based on the metadata model as described in the CDISC ADaM Analysis Data Model Version 2.1 document.

The XML schema that is used to define the metadata structures in an XML format is based on an extension to the CDISC Operational Data Model (ODM).

Release Date

CDISC Analysis Results Metadata Specification for Define-XML Version 2, Production Version 1.0, January 27, 2015.

Regulatory Basis

(Source: Technical Conformance Guide on Electronic Study Data Submissions, Pharmaceuticals and Medical Devices Agency, Provisional Translation [as of July 2015]).

In order for the review of clinical study data to progress smoothly, it is important that the relationship between the analysis results shown in the application documents and the analysis datasets is easily understandable. Therefore, the definition documents of the

ADaM datasets should preferably include Analysis Results Metadata, which shows the relationship between the analysis results and the corresponding analysis dataset and the variables used, for the analyses performed to obtain the main results of efficacy and safety and clinical study results that provide the rationales for setting of the dosage and administration, shown in 4.1.1.3. The Analysis Results Metadata of each analysis should preferably include the following items.

- Figure or table numbers and titles showing the analysis results displayed in the clinical study report
- Purpose and reasons for performing the analysis
- Parameter name and code to be used
- Variables subject to analysis
- Dataset to be used
- Selection criteria for the records subject to analysis
- Corresponding description in the statistical analysis plan, analysis program name, and summary of the analytical methods
- Extract of the analysis program corresponding to the analysis method

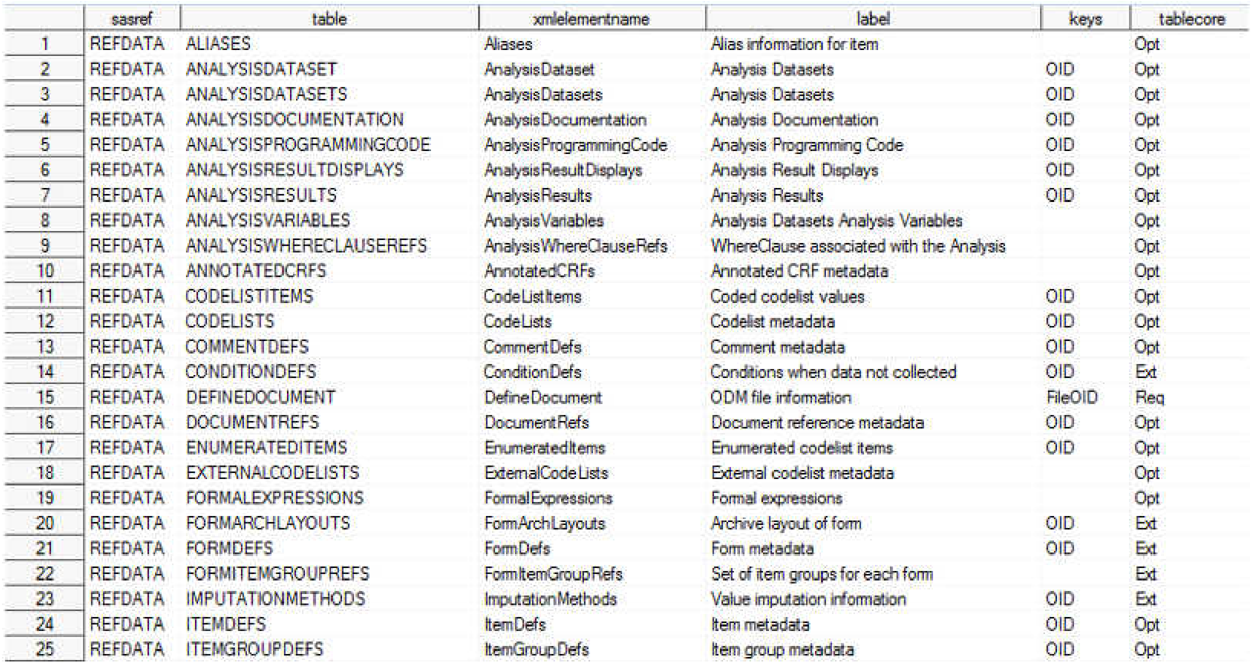
For the format of the Analysis Results Metadata, the applicant should refer to the Analysis Results Metadata Specification for Define-XML by CDISC to the extent possible, but if it is difficult to include it into the definition document, it is possible to submit it as a separated file in PDF format, as specified in “Electronic Specifications of Common Technical Documents”, and “Handling of Electronic Specifications of Common Technical Documents”. The explanations in the definition document may be written in Japanese.

CDISC Define-XML 2.0 Reference Standard (including Analysis Results Metadata)

The domain and column metadata that constitute the SAS representation of the CDISC Define-XML 2.0 standard (including Analysis Results Metadata) are derived from the global standards library in these formats:

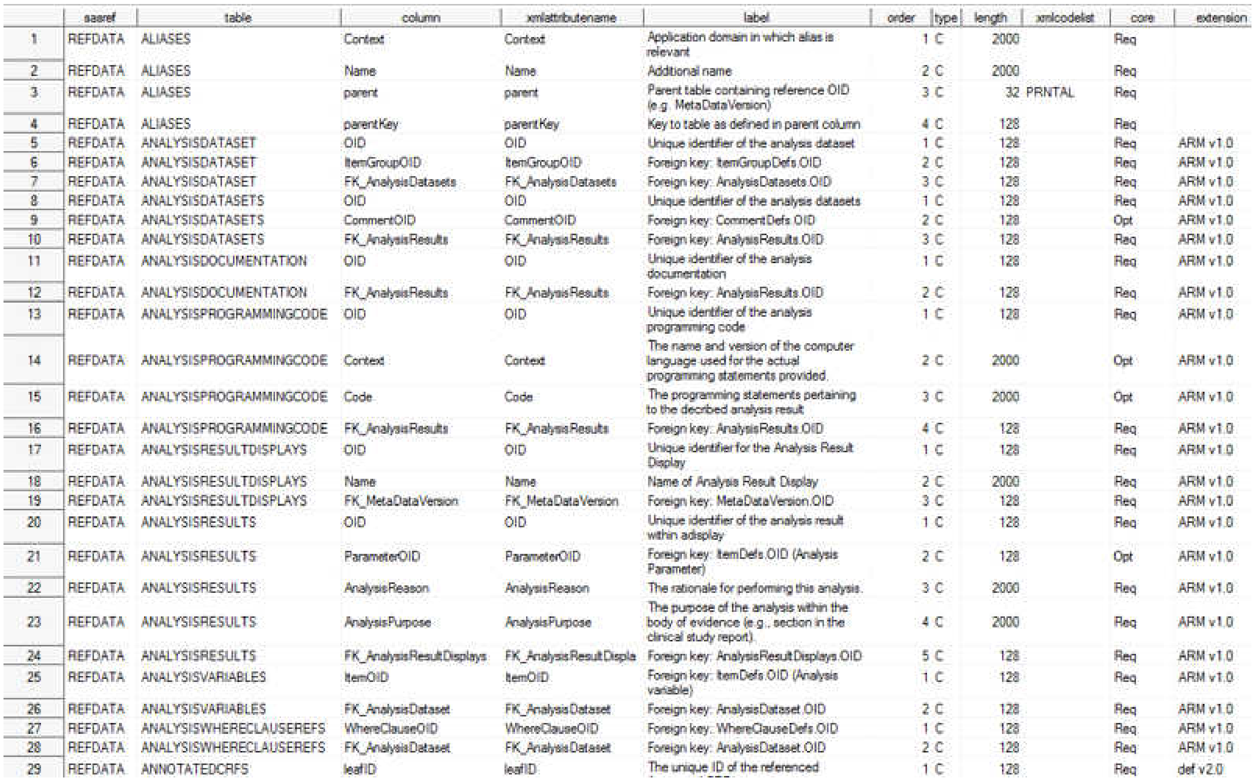
- as empty data sets (using the macro %CST_CREATETABLESFORDATASTANDARD)
- as table metadata for 54 data sets (reference_tables in the standard metadata folder. For more information, see Figure 5.5 on page 119.)
- as column metadata for 239 columns in the 54 data sets (reference_columns in the standard metadata folder. For more information, see Figure 5.6 on page 120.)

Figure 5.5 reference_tables (CDISC Define-XML 2.0 including Analysis Results Metadata)



	sasref	table	xmlelementname	label	keys	tablecore
1	REFDATA	ALIASES	Aliases	Alias information for item		Opt
2	REFDATA	ANALYSISDATASET	AnalysisDataset	Analysis Datasets	OID	Opt
3	REFDATA	ANALYSISDATASETS	AnalysisDatasets	Analysis Datasets	OID	Opt
4	REFDATA	ANALYSISDOCUMENTATION	AnalysisDocumentation	Analysis Documentation	OID	Opt
5	REFDATA	ANALYSISPROGRAMMINGCODE	AnalysisProgrammingCode	Analysis Programming Code	OID	Opt
6	REFDATA	ANALYSISRESULTDISPLAYS	AnalysisResultDisplays	Analysis Result Displays	OID	Opt
7	REFDATA	ANALYSISRESULTS	AnalysisResults	Analysis Results	OID	Opt
8	REFDATA	ANALYSISVARIABLES	AnalysisVariables	Analysis Datasets Analysis Variables		Opt
9	REFDATA	ANALYSISWHERECLAUSEREFS	AnalysisWhereClauseRefs	WhereClause associated with the Analysis		Opt
10	REFDATA	ANNOTATEDCRFS	AnnotatedCRFs	Annotated CRF metadata		Opt
11	REFDATA	CODELISTITEMS	CodeListItems	Coded codelist values	OID	Opt
12	REFDATA	CODELISTS	CodeLists	Codelist metadata	OID	Opt
13	REFDATA	COMMENTDEFS	CommentDefs	Comment metadata	OID	Opt
14	REFDATA	CONDITIONDEFS	ConditionDefs	Conditions when data not collected	OID	Ext
15	REFDATA	DEFINEDOCUMENT	DefineDocument	ODM file information	FileOID	Req
16	REFDATA	DOCUMENTREFS	DocumentRefs	Document reference metadata	OID	Opt
17	REFDATA	ENUMERATEDITEMS	EnumeratedItems	Enumerated codelist items	OID	Opt
18	REFDATA	EXTERNALCODELISTS	ExternalCodeLists	External codelist metadata		Opt
19	REFDATA	FORMALEXPRESSIONS	FormalExpressions	Formal expressions		Opt
20	REFDATA	FORMARCHLAYOUTS	FormArchLayouts	Archive layout of form	OID	Ext
21	REFDATA	FORMDEFS	FormDefs	Form metadata	OID	Ext
22	REFDATA	FORMITEMGROUPREFS	FormItemGroupRefs	Set of item groups for each form		Ext
23	REFDATA	IMPUTATIONMETHODS	ImputationMethods	Value imputation information	OID	Ext
24	REFDATA	ITEMDEFS	ItemDefs	Item metadata	OID	Opt
25	REFDATA	ITEMGROUPDEFS	ItemGroupDefs	Item group metadata	OID	Opt

Figure 5.6 *reference_columns (CDISC Define-XML 2.0 including Analysis Results Metadata)*



	sasref	table	column	xmlattributename	label	order	type	length	xmlcodelist	core	extension
1	REFDATA	ALIASES	Context	Context	Application domain in which alias is relevant	1	C	2000		Req	
2	REFDATA	ALIASES	Name	Name	Additional name	2	C	2000		Req	
3	REFDATA	ALIASES	parent	parent	Parent table containing reference OID (e.g. MetaDataVersion)	3	C	32	PRNTAL	Req	
4	REFDATA	ALIASES	parentKey	parentKey	Key to table as defined in parent column	4	C	128		Req	
5	REFDATA	ANALYSISDATASET	OID	OID	Unique identifier of the analysis dataset	1	C	128		Req	ARM v1.0
6	REFDATA	ANALYSISDATASET	ItemGroupOID	ItemGroupOID	Foreign key: ItemGroupDefs.OID	2	C	128		Req	ARM v1.0
7	REFDATA	ANALYSISDATASET	FK_AnalysisDatasets	FK_AnalysisDatasets	Foreign key: AnalysisDatasets.OID	3	C	128		Req	ARM v1.0
8	REFDATA	ANALYSISDATASETS	OID	OID	Unique identifier of the analysis datasets	1	C	128		Req	ARM v1.0
9	REFDATA	ANALYSISDATASETS	CommentOID	CommentOID	Foreign key: CommentDefs.OID	2	C	128		Opt	ARM v1.0
10	REFDATA	ANALYSISDATASETS	FK_AnalysisResults	FK_AnalysisResults	Foreign key: AnalysisResults.OID	3	C	128		Req	ARM v1.0
11	REFDATA	ANALYSISDOCUMENTATION	OID	OID	Unique identifier of the analysis documentation	1	C	128		Req	ARM v1.0
12	REFDATA	ANALYSISDOCUMENTATION	FK_AnalysisResults	FK_AnalysisResults	Foreign key: AnalysisResults.OID	2	C	128		Req	ARM v1.0
13	REFDATA	ANALYSISPROGRAMMINGCODE	OID	OID	Unique identifier of the analysis programming code	1	C	128		Req	ARM v1.0
14	REFDATA	ANALYSISPROGRAMMINGCODE	Context	Context	The name and version of the computer language used for the actual programming statements provided.	2	C	2000		Opt	ARM v1.0
15	REFDATA	ANALYSISPROGRAMMINGCODE	Code	Code	The programming statements pertaining to the decribed analysis result	3	C	2000		Opt	ARM v1.0
16	REFDATA	ANALYSISPROGRAMMINGCODE	FK_AnalysisResults	FK_AnalysisResults	Foreign key: AnalysisResults.OID	4	C	128		Req	ARM v1.0
17	REFDATA	ANALYSISRESULTDISPLAYS	OID	OID	Unique identifier for the Analysis Result Display	1	C	128		Req	ARM v1.0
18	REFDATA	ANALYSISRESULTDISPLAYS	Name	Name	Name of Analysis Result Display	2	C	2000		Req	ARM v1.0
19	REFDATA	ANALYSISRESULTDISPLAYS	FK_MetaDataVersion	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	3	C	128		Req	ARM v1.0
20	REFDATA	ANALYSISRESULTS	OID	OID	Unique identifier of the analysis result within adisplay	1	C	128		Req	ARM v1.0
21	REFDATA	ANALYSISRESULTS	ParameterOID	ParameterOID	Foreign key: ItemDefs.OID (Analysis Parameter)	2	C	128		Opt	ARM v1.0
22	REFDATA	ANALYSISRESULTS	AnalysisReason	AnalysisReason	The rationale for performing this analysis.	3	C	2000		Req	ARM v1.0
23	REFDATA	ANALYSISRESULTS	AnalysisPurpose	AnalysisPurpose	The purpose of the analysis within the body of evidence (e.g., section in the clinical study report)	4	C	2000		Req	ARM v1.0
24	REFDATA	ANALYSISRESULTS	FK_AnalysisResultDisplays	FK_AnalysisResultDispla	Foreign key: AnalysisResultDisplays.OID	5	C	128		Req	ARM v1.0
25	REFDATA	ANALYSISVARIABLES	ItemOID	ItemOID	Foreign key: ItemDefs.OID (Analysis variable)	1	C	128		Req	ARM v1.0
26	REFDATA	ANALYSISVARIABLES	FK_AnalysisDataset	FK_AnalysisDataset	Foreign key: AnalysisDataset.OID	2	C	128		Req	ARM v1.0
27	REFDATA	ANALYSISWHERECLAUSEREFS	WhereClauseOID	WhereClauseOID	Foreign key: WhereClauseDefs.OID	1	C	128		Req	ARM v1.0
28	REFDATA	ANALYSISWHERECLAUSEREFS	FK_AnalysisDataset	FK_AnalysisDataset	Foreign key: AnalysisDataset.OID	2	C	128		Req	ARM v1.0
29	REFDATA	ANNOTATEDCRFS	leafID	leafID	The unique ID of the referenced	1	C	128		Req	def v2.0

The **tablecore** column in the reference_tables data set indicates whether the table is a required (**Req**) or optional (**Opt**) part of the Define-XML 2.0 metadata, according to the XML schema. Tables with tablecore equal to **Ext** are part of the underlying ODM metadata model, but they should be considered extensions to the Define-XML 2.0 metadata model. The core column in the reference_columns data set indicates whether a column is required (**Req**) or optional (**Opt**) in a table when the table is part of the metadata.

CDISC ODM

Purpose

(Source: CDISC website http://www.cdisc.org/odm)

The CDISC ODM standard facilitates the archival and interchange of the metadata and data for clinical research. ODM is a vendor-neutral, platform-independent format for the interchange and archival of clinical study data. ODM includes the clinical data and its associated metadata, administrative data, reference data, and audit information. All of the information that needs to be shared during setup, operation, analysis, and submission, as well as for long-term retention as part of an archive, is included in ODM.

Release Dates

- CDISC ODM, Version 1.3.0, December 15, 2006
- CDISC ODM, Version 1.3.1, February 11, 2010

CDISC ODM 1.3.0 Reference Standard

The SAS Clinical Standards Toolkit supports this CDISC ODM 1.3.0 functionality:

- reading and representing in SAS a complete odm.xml file (specific limitations are noted below)
- building an odm.xml file from a SAS representation of the ODM standard
- schema-level validating of an odm.xml file
- validating the structure and content of the SAS representation of an odm.xml file
- identifying unsupported (unrecognized) ODM elements and attributes by using a sample tool
- extracting one or more data sets from the ClinicalData or ReferenceData sections of the ODM XML file

The SAS Clinical Standards Toolkit does not support this CDISC ODM 1.3.0 functionality:

- reading or writing the DigitalSignatures section of the ODM
- vendor or customer extensions of the ODM
- processing is limited to a single ODM file (for example, the use of PriorFileOID to reference another file is ignored)

- Full file metadata is expected in each file.
- Effective support only for ODM FileType=Snapshot. The SAS Clinical Standards Toolkit makes no attempt to process multiple transactions per data point; multiple transactions are saved in the SAS ODM representation for subsequent processing

The domain and column metadata that constitute the SAS representation of CDISC ODM 1.3.0 are derived from the global standards library in these formats:

- as empty data sets (using the utility macro %CST_CREATETABLESFORDATASTANDARD)
- as table metadata (See Table 5.12 on page 123.)
- as column metadata for 315 columns in the 66 data sets (reference_columns in the standard metadata folder)

As a general rule, the SAS representation of the CDISC ODM standard is patterned to match the XML element (data set) and attribute (column) structure of odm.xml. For example, consider this XML extract:

```
<ClinicalData StudyOID="P2006-101" MetadataVersionOID="101.01">
 <SubjectData SubjectKey="1000" TransactionType="Insert">
  <StudyEventData StudyEventOID="101.Screen">
   <FormData FormOID="101.DEMOG">
    <ItemGroupData ItemGroupOID="101.DM">
     <ItemDataString ItemOID="101.USUBJID">101-01-01</ItemDataString>
     <ItemDataString ItemOID="101.SEX">F</ItemDataString>
    </ItemGroupData>
   </FormData>
  </StudyEventData>
 </SubjectData>
</ClinicalData>
```

The following table describes how the XML element and attribute information maps to the SAS representation:

Table 5.11 Sample Mapping of odm.xml File to SAS Representation

XML Element or Attribute	SAS Data Set	SAS Column	SAS Column Value
<ClinicalData StudyOID="P2006-101" MetadataVersionOID="101.01" >	ClinicalData	StudyOID MetaDataVersionOID	"P2006-101" "101.01"
<SubjectData SubjectKey="1000" TransactionType="Insert">	SubjectData	SubjectKey TransactionType	"1000" "Insert"
<StudyEventData StudyEventOID="101.Screen" >	StudyEventData	StudyEventOID	"101.Screen"
<FormData FormOID="101.DEMOG">	FormData	FormOID	"101.DEMOG"
<ItemGroupData ItemGroupOID="101.DM">	ItemGroupData	ItemGroupOID	"101.DM"
<ItemDataString ItemOID="101.USUBJID">101-01-01</ItemDataString>	ItemData	ItemOID ItemDataType Value	"101.USUBJID" "ItemDataString" "101-01-01"
<ItemDataString ItemOID="101.SEX">F</ItemDataString>	ItemData	ItemOID ItemDataType Value	"101.SEX" "ItemDataString" "F"

The following table lists the complete set of 66 tables that form the SAS Clinical Standards Toolkit SAS representation of the CDISC ODM 1.3.0 standard:

Table 5.12 CDISC ODM 1.3.0 reference_tables

admindata	itemrangecheckvalues

annotation	itemrcformalexpression
annotationflag	itemrole
association	keyset
auditrecord	location
clinicaldata	locationversion
clitemdecodetranslatedtext	measurementunits
codelistitems	metadataversion
codelists	methoddefformalexpression
conditiondefformalexpression	methoddefs
conditiondefs	methoddeftranslatedtext
conditiondeftranslatedtext	mutranslatedtext
enumerateditems	odm
externalcodelists	presentation
formdata	protocoleventrefs
formdefarchlayouts	protocoltranslatedtext
formdefitemgrouprefs	rcerrortranslatedtext
formdefs	referencedata
formdeftranslatedtext	signature
imputationmethods	signaturedef
itemaliases	study
itemdata	studyeventdata

itemdefs	studyeventdefs
itemdeftranslatedtext	studyeventdeftranslatedtext
itemgroupaliases	studyeventformrefs
itemgroupdata	subjectdata
itemgroupdefitemrefs	user
itemgroupdefs	useraddress
itemgroupdeftranslatedtext	useraddressstreetname
itemmurefs	useremail
itemquestionexternal	userfax
itemquestiontranslatedtext	userlocationref
itemrangechecks	userphone

The highly structured nature of CDISC ODM data requires that any mapping to a relational format include a large number of data sets, with foreign key relationships to help preserve the intended non-relational object structure. In the SAS Clinical Standards Toolkit, foreign key relationships are enforced when validating the CDISC ODM data sets.

Field lengths in the CDISC ODM data sets are consistent by core data type. CDISC has not specified any limit to the length of most character fields. Arbitrary lengths have been chosen by data type. These lengths are listed in this table. In the table, standard data types are distilled into core data types. To be safe, larger lengths have been chosen to ensure that no data loss occurs in the SAS Clinical Standards Toolkit pre-installed data sets. Production tables might be compressed using SAS mechanisms to preserve disk space.

Table 5.13 CDISC ODM Default Lengths by Data Type

Type Name	Length	Description
oid	64	A unique object identifier or a reference
text	2000	A character field that can accommodate a large number of characters
name	128	A descriptive identifier
value	512	An item of collected or reference data
path	512	An absolute or relative file system path or URL

The table metadata for the 66 data sets and the column metadata for the 315 columns in those data sets that comprise the SAS representation of the CDISC ODM 1.3.0 standard are here:

***global standards library directory*/standards/ cdisc-odm-1.3.0-1.7/metadata**

Table metadata is in reference_tables.sas7bdat, and column metadata is in reference_columns.sas7bdat.

Only the ODM data set, which contains valid values for the FileOID, CreationDateTime, and FileType variables, is needed to create a minimal, but valid, CDISC ODM-compliant XML document. This is based on the CDISC ODM standard, which is flexible. All table and column names are case sensitive. They must be specified exactly as shown.

In the SAS implementation of the relational data model, the keys are extended to define a unique record in every SAS data set. For example, a unique record in the EnumeratedItems data set is defined by the variables FK_CODELISTS and CODEDVALUE. These SAS data set keys are in the table metadata in the SAS reference_tables data set.

Starting in ODM 1.3.0, there are two forms of the ItemData element, which is the element used by ODM for transmitting clinical data item values. These two forms are untyped and typed. Here is an example of a typed ItemData element:

<ItemDataFloat ItemOID="ItemDef.OID.VS.VSSTRESN" TransactionType="Insert">76</ItemDataFloat>

Here is an example of an untyped ItemData element:

<ItemData ItemOID="ID.AETERM" Value="HEADACHE" />

Both of these data values are stored in the Value variable in the ItemData SAS data set. In the case of typed data, the ItemDataType variable in the ItemData SAS data set has the data type (for example, Float). In the case of untyped data, the ItemDataType variable in the ItemData SAS data set is null.

Typed and untyped data transmission should not be mixed within a single ODM file. However, in the example provided by the SAS Clinical Standards Toolkit, both types are part of the same example for demonstration purposes.

In the SAS Clinical Standards Toolkit, the CDISC ODM standard supports reading and representing in SAS a complete odm.xml file, and building an odm.xml file. The SAS Clinical Standards Toolkit validates both the structure and content of the SAS representation of each odm.xml file and the structural integrity of that file. The SAS Clinical Standards Toolkit also supports the extraction of subject or reference data for a data set (such as an SDTM AE domain) from the odm.xml file.

To support all of this functionality, supplemental files include these global standards library files:

- A SAS format catalog (odmct.sas7bcat) in the `formats` folder provides valid values for selected columns in the 66 tables of the SAS representation.
- The Messages data set in the `messages` folder provides error messaging for all Validation Master checks.
- The Validation Master data set in the `validation/control` folder contains the superset of checks validating the structure and content of the 66 tables.

- SAS code in the `macros` folder provides CDISC ODM-specific code that augments the code provided in the primary SAS Clinical Standards Toolkit autocall library (`!sasroot/cstframework/sasmacro`).

It is this set of files, in whole or in part, that defines the CDISC ODM 1.3.0 reference standard.

CDISC ODM 1.3.1 Reference Standard

The CDISC ODM 1.3.1 reference standard has the same functionality as CDISC ODM 1.3.0, with the following differences:

- The SAS representation of CDISC ODM 1.3.1 includes 10 data sets in addition to those shown in Table 5.12 on page 123. The 10 additional data sets are listed in this table:

Table 5.14 Additional CDISC ODM 1.3.1 Tables Not Included with CDISC ODM 1.3.0

codelistaliases	formaliases
codelistitemaliases	methodaliases
codelisttranslatedtext	mualiases
conditionaliases	protocolaliases
enumerateditemaliases	studyeventaliases

- The table metadata for these 76 data sets can be found in the reference_tables data set in the standard metadata folder. Column metadata for the 352 columns in these 76 data sets can be found in the reference_columns data set in the standard metadata folder.

This set of files, in whole or in part, defines the CDISC ODM 1.3.1 reference standard.

CDISC SEND 3.0

Purpose

The CDISC SEND standard defines a standard structure for data tabulations that are designed to support single-dose general toxicology studies, repeat-dose general toxicology studies, and carcinogenicity non-clinical studies. CDISC SEND is based on CDISC SDTM. These data tabulations are submitted as part of a product application to a regulatory authority such as the FDA.

The data sets and columns required for a product application are not prescribed by the standard. Instead, requirements are based on the trial protocol and discussions with the regulatory authority in charge of reviewing the application. Therefore, any SAS Clinical Standards Toolkit standard, including the CDISC SEND standard, is only a representative sample or template.

Release Date

CDISC Standard for Exchange of Nonclinical Data (SEND), Final Version 3.0, May 19, 2011

Overview of the CDISC SEND 3.0 Domains

The SAS Clinical Standards Toolkit representation of the CDISC SEND 3.0 standard consists of 28 domains (in the reference_tables metadata data set) and 563 columns (in the reference_columns metadata data set).

The 28 domains are shown in this table.

Table 5.15 *CDISC SEND 3.0 Supported Domains*

Body Weight Gains - BG	Pharmacokinetics Concentrations - PC
Body Weights - BW	Palpable Masses - PM

Clinical Observations - CL	Pool Definition - POOLDEF
Comments - CO	Pharmacokinetics Parameters - PP
Death Diagnosis - DD	Related Records - RELREC
Demographics - DM	Subject Characteristics - SC
Disposition - DS	Subject Elements - SE
ECG Test Results - EG	Supplemental Qualifiers - SUPPQUAL
Exposure - EX	Trial Arms - TA
Food and Water Consumption - FW	Trial Elements - TE
Laboratory Test Results - LB	Tumor Findings - TF
Macroscopic Findings - MA	Trial Summary - TS
Microscopic Findings - MI	Trial Sets - TX
Organ Measurements - OM	Vital Signs - VS

CDISC CDASH 1.1

Purpose

Version 1.1 of the Clinical Data Acquisition Standards Harmonization (CDASH) standard identifies the basic data collection fields needed from a clinical, scientific, and regulatory perspective. The data collection fields enable more efficient and consistent data collection at clinical research sites.

This standard is designed to be used by clinical trials personnel who are responsible for collecting, cleaning, and ensuring the integrity of clinical trials data.

The CDISC CDASH and CDISC SDTM standards are related. The CDISC SDTM standard provides a standard for the submission of data. The CDISC CDASH standard is needed earlier in the data flow process. It defines a basic set of data collection fields (or variables) that are expected to exist in the majority of CRFs. The data collection fields are highly recommended, recommended, or conditional. The CDASH data collection fields facilitate mapping to the CDISC SDTM structure, which is required for the submission of data.

The CDASH 1.1 standard describes the basic recommended data collection fields for 16 domains commonly used in clinical trials.

Release Date

CDISC Clinical Data Acquisition Standards Harmonization (CDASH) Standard, Version 1.1, January 18, 2011

Overview of the CDISC CDASH 1.1 Domains

The SAS Clinical Standards Toolkit representation of the CDISC CDASH 1.1 standard consists of 16 domains. Unlike the SAS Clinical Standards Toolkit representations of other standards, multiple records per domain can be in the reference_tables metadata data set, and multiple records per column can be in the reference_columns metadata data set. These multiple records enable specification for the Findings domains of multiple scenarios (such as whether laboratory data undergoes processing at a local or central lab), multiple views (such as whether data is collected in normalized or de-normalized formats), and multiple languages.

The 16 supported domains are shown in this table.

Table 5.16 *CDISC CDASH 1.1 Supported Domains*

Adverse Events - AE	Inclusion and Exclusion Criteria - IE
Comments - CO	Laboratory Test Results - LB
Prior and Concomitant Medications - CM	Medical History - MH
Demographics - DM	Physical Examination - PE

Disposition - DS	Protocol Deviations - DV
Drug Accountability - DA	Subject Characteristics - SC
ECG Test Results - EG	Substance Use - SU
Exposure - EX	Vital Signs - VS

CDISC Controlled Terminology

Purpose

The CDISC Controlled Terminology standard supports standardizing values for columns in data submitted to the regulatory authorities. Standardization facilitates loads into regulatory databases, data review, and analysis. The initial standardization of values has primarily been in support of SDTM submission data and the CDISC CDASH (Clinical Data Acquisition Standards Harmonization) development of standardized data collection instruments.

CDISC Controlled Terminology Reference Standard

CDISC Controlled Terminology is maintained by and distributed as part of the National Cancer Institute (NCI) Enterprise Vocabulary Services (EVS) Thesaurus. For more information, see “References” on page 2. Periodically, CDISC Controlled Terminology is updated to include the work of numerous terminology project teams. Updates are in the form of new packages or sets of terminology.

The SAS Clinical Standards Toolkit offers snapshots of the NCI EVS Thesaurus. These snapshots are typically coordinated with the release of other CDISC standards that use the thesaurus. Several snapshots are currently supported across several standards.

The SAS Clinical Standards Toolkit offers a tool to import controlled terminology from the ODM XML files that can be downloaded from the NCI CDISC Controlled Terminology FTP site (http://evs.nci.nih.gov/ftp1/CDISC/).

For SDTM, these snapshots are supplied, which support the Study Data Tabulation Model Implementation Guide (SDTMIG):

- The 201212 snapshot was taken from the NCI EVS Controlled Terminology for SDTM, released December 2012.
- The 201312 snapshot was taken from the NCI EVS Controlled Terminology for SDTM, released December 2013.
- The 201406 snapshot was taken from the NCI EVS Controlled Terminology for SDTM, released June 2014.

For SEND, these snapshots are supplied, which support the Standard for the Exchange of Nonclinical Data Implementation Guide Version 3.0 (SENDIG V3.0):

- The 201212 snapshot was taken from the NCI EVS Controlled Terminology for SEND, released December 2012.
- The 201312 snapshot was taken from the NCI EVS Controlled Terminology for SEND, released December 2013.
- The 201406 snapshot was taken from the NCI EVS Controlled Terminology for SEND, released June 2014.

For ADaM, these snapshots are supplied, which support the Analysis Data Model Implementation Guide Version 1.0 (ADaMIG v1.0):

- The 201101 snapshot was taken from the NCI EVS Controlled Terminology for ADaM, released January 2011.
- The 201107 snapshot was taken from the NCI EVS Controlled Terminology for ADaM, released July 2011.
- The 201512 snapshot was taken from the NCI EVS Controlled Terminology for ADaM, released December 2015.

For Questionnaires (QS), the following snapshot is supplied, which supports the Questionnaire Controlled Terminology for the current version of the Study Data Tabulation Model Implementation Guide:

- The 201312 snapshot was taken from the NCI EVS Controlled Terminology for Questionnaires, released December 2013.
- The 201406 snapshot was taken from the NCI EVS Controlled Terminology for Questionnaires, released June 2014.

For CDASH, these snapshots are supplied, which support the Clinical Data Acquisition Standards Harmonization Standard Version 1.0 (CDASH STD v1.0):

- The 201212 snapshot was taken from the NCI EVS Controlled Terminology for CDASH, released December 2012.
- The 201312 snapshot was taken from the NCI EVS Controlled Terminology for CDASH, released December 2013.
- The 201403 snapshot was taken from the NCI EVS Controlled Terminology for CDASH, released April 2014.

Note: Although SAS does not provide the SAS Clinical Standards Toolkit with the CDASH standard, the terminology is provided as a convenience.

Each CDISC Terminology standard includes a SAS format catalog (cterms.sas7bcat) and a SAS data set (cterms.sas7bdat). The catalog and data set are found in this global standards library folder (where *xxxx* is the specific standard (adam, cdash, or sdtm) and YYYYMM is the specific snapshot (201104, 201212, and so on):

```
global standards library directory/standards/
cdisc-terminology1.7/cdisc-xxxx/<current OR YYYYMM>/formats
```

CDISC Dataset-XML 1.0

Purpose

CDISC Dataset-XML defines a standard format for transporting tabular data in XML between any two entities based on CDISC ODM XML. In addition to supporting the transport of data sets as part of a submission to the FDA, Dataset-XML can be used to exchange data between two parties. For example, the Dataset-XML data format can be used by a CRO to transmit SDTM or ADaM data sets to a sponsor organization. Dataset-XML supports SDTM, ADaM, and SEND data sets but can also be used to exchange any other type of tabular data set.

The metadata for a data set in a Dataset-XML file must conform to the Define-XML standard. Each Dataset-XML file contains data for a single data set, but a single Define-XML file describes all of the data sets included in the folder. Both Define-XML 1.0 and Define-XML 2.0 are supported for use with Dataset-XML.

Release Date

CDISC Dataset-XML Version 1.0 Specification, Production Version 1.0.0, April 22, 2014

Regulatory Basis

In the United States, the approval process for regulated human and animal health products requires the submission of data from clinical trials and other studies as expressed in the Code of Federal Regulations (CFR). The FDA established the regulatory basis for wholly electronic submission of data in 1997 with the publication of regulations on the use of electronic records in place of paper records (21 CFR Part 11). In 1999, the FDA standardized the submission of clinical and non-clinical data using the SAS Version 5 XPORT Transport Format and the submission of metadata using Portable Document Format (PDF), respectively. In 2005, the Study Data Specifications published by the FDA included the recommendation that data definitions (metadata) be provided as a Define-XML file.

On November 5, 2012, the FDA held a meeting entitled “Regulatory New Drug Review: Solutions for Study Data Exchange Standards”, the purpose of which was to solicit input regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data. CDISC Dataset-XML was presented as an alternative for consideration.

In 2014, the FDA conducted a pilot to evaluate CDISC Dataset-XML as a solution to the challenges of the SAS Version 5 XPORT transport.

CDISC Dataset-XML 1.0 SAS Data Set Construction

The SAS Clinical Standards Toolkit CDISC Dataset-XML 1.0 standard supports reading a Dataset-XML file, building a Dataset-XML file, and validating the structural integrity of a Dataset-XML file against an XML schema. To support this functionality, supplemental files include these global standards library files:

- The Messages data set in the `messages` folder provides unified error messaging for all Dataset-XML processes.
- SAS code in the `macros` folder provides CDISC Dataset-XML 1.0-specific code that augments code that is provided in the primary SAS Clinical Standards Toolkit autocall library (`!sasroot/cstframework/sasmacro`).
- The `referencexml` folder contains SAS XML map files, which are used to read XML files into SAS data sets.

6

SASReferences File

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Overview

The SAS Clinical Standards Toolkit supports the submission of SAS processes using predefined metadata files. These files are introduced and described in Chapter 3, "Metadata File Descriptions," on page 33. The key metadata file that supports this functionality is the SASReferences file. This SAS data set essentially identifies all of the key inputs and outputs for any SAS Clinical Standards Toolkit process. Each unique process can have an associated, unique SASReferences file. However, the SAS Clinical Standards Toolkit offers many standardization aids, so more generic SASReferences files are preferable.

The required SASReferences file structure is provided in Table 3.3 on page 42 and example content is provided in Figure 3.5 on page 45.

Building a SASReferences File

Each SASReferences file requires content that is specific to its planned use. For example, a SAS Clinical Standards Toolkit process that creates a define.xml file requires the specification of XML and recommends the specification of style sheet information. A SAS Clinical Standards Toolkit process that validates data against a standard requires the specification of the validation checks to be run.

The SAS Clinical Standards Toolkit offers several ways to create a SASReferences file for use in subsequent processes.

1. Use sample SASReferences files that are provided with the SAS Clinical Standards Toolkit. These sample SASReferences files contain the required and optional contents for specific tasks. For example, the task of validating the functionality of CDISC SDTM 3.1.2 uses the SASReferences file found here in SAS 9.3:

   ***sample study library directory*\cdisc-sdtm-3.1.2-1.7\sascstdemodata\control**

   An excerpt of this sample SASReferences file is provided in Figure 3.5 on page 45.

2. The SAS Clinical Standards Toolkit provides SASReferences templates for use. These templates are either zero-observation data sets or data sets containing records that must be modified. A SASReferences data set template is located here:

   ***global standards library directory*/standards/cst-framework-1.7/templates**

   The SAS Clinical Standards Toolkit provides default SASReferences data sets for each supported standard. These default SASReferences data sets contain records that are commonly required for certain SAS Clinical Standards Toolkit tasks (such as validation). However, all records that are required might not be included. Or, all records that are included might not be required for certain tasks. And, SAS librefs, filerefs, paths, and memname values might require modification. For example, see the StandardSASReferences data set found here:

***global standards library directory*/standards/**
cdisc-sdtm-3.1.2-1.7/control

3 The SAS Clinical Standards Toolkit provides the utility macros to build and return many SAS Clinical Standards Toolkit metadata data sets.

- The %CST_GETSTANDARDSASREFERENCES macro returns the StandardSASReferences data set. (See the file description in Chapter 3, "Metadata File Descriptions," on page 33 for the specified standard.)
- The %CST_CREATEDSFROMTEMPLATE macro can be used to return an empty SASReferences data set.

Use of these utility macros is illustrated later in this chapter.

The primary function of the SASReferences file is to define the SAS Clinical Standards Toolkit process inputs and outputs. What information does the process need to reference? What does the process produce? Where does the information come from and go? The "what" information is determined by the use of two SASReferences fields: type and subtype. The "where" information is determined by path and memname. The values for all of these fields are restricted for the SAS Clinical Standards Toolkit to values itemized in the framework Standardlookup data set found here:

***global standards library directory*/standards/cst-framework-1.7/**
control/standardlookup.sas7bdat

Customizing the type and subtype values in the Standardlookup data set is allowed. Customization is a prerequisite if you want to use the field values in any SASReferences data set that is used by the SAS Clinical Standards Toolkit.

The following table lists and describes the acceptable type and subtype values in the framework Standardlookup data set:

Table 6.1 SAS Clinical Standards Toolkit SASReferences Type and Subtype Values

Type	Subtype	Comments
autocall		One record for each library that contains macros to be included in the SAS autocall path. Typically, this includes one record for each standard that is referenced in the SASReferences file, excluding the SAS Clinical Standards Toolkit framework. The framework and cross-standard macros are already included in the autocall path at product deployment. User-written macros, as referenced in one or more additional code libraries, require an autocall record for each library.
classmetadata	column or table	Identifies the SAS data sets (sasref.memname) that contain the column and table metadata for specific CDISC SDTM template data sets that are used to build standard SDTM-compliant data sets. This type is provided by default in StandardSASReferences and is optional.
cmplib		Identifies and sets the compiled library path to include any user-written and user-referenced functions. SAS searches the libraries in the order listed until the desired data set is found.
codemodule		Currently not used and is included only as a placeholder for future ADaM development within the SAS Clinical Standards Toolkit.
cstmetadata	lookup, macrovariabledetails, macrovariables, sasreferences, standard, or standardsubtypes	Identifies the SAS data set templates that are used for SAS Clinical Standards Toolkit Standards Library internal validation

Type	Subtype	Comments
control	validation, reference, or internalvalidation	Identifies any run-time process control file, including the SASReferences data set itself. (In other words, it is a self-documentation record). For the SAS Clinical Standards Toolkit validation processes, the Validation Control data set that specifies the validation checks to be run is identified with subtype=validation.
externalxml	xml or tlfxml	Identifies an external XML file. Depending on the standard version and the subsequent macro that is called, this file can be read or written. Using CDISC CRT-DDS as an example, this type specifies the define.xml file that is created when the %CRTDDS_WRITE macro is called. When the %CRTDDS_READ macro is supported, this type identifies the XML file to be read. TLFXML refers to the tables, listings, and figures XML file that is used in ADaM 2.1.
fmtsearch		Provides a way to build the format search path for a validation process. The SAS Clinical Standards Toolkit sets the SAS fmtsearch type based on each record, specifying a SAS catalog that uses the order=n sequence. This type is not provided by default in StandardSASReferences, so you must specify a value. The type=fmtsearch value is optional unless one or more checks that assess value compliance against a SAS format are to be run.
globalmetadata	sasreferences or standard	Identifies the SAS data set templates that are used for the internal validation of the SAS Clinical Standards Toolkit global standards library.

Type	Subtype	Comments
logging	transaction	Identifies a data set (transactionlog) that is associated with the SAS Clinical Standards Toolkit metadata management macros. The data set contains information about any actions performed on the metadata while using these macros.
lookup	lookup	Identifies a data set (Standardlookup) that is associated with each The SAS Clinical Standards Toolkit standard that contains valid values for discrete metadata fields. This type is provided by default in StandardSASReferences and is required for each standard. For example, the valid values for type and subtype that are documented in this table have been defined in one or more SAS Clinical Standards Toolkit Standardlookup data sets.
messages		Identifies one or more Messages data sets that are associated with each SAS Clinical Standards Toolkit standard. This type is provided by default in StandardSASReferences. You must specify value only with user customizations that require new or modified messages. The SAS Clinical Standards Toolkit populates the data set that is referenced by the global macro variable &_cstMessages with all Messages data sets that are included in SASReferences. This type is required for each standard.

Type	Subtype	Comments
properties	initialize, validation, or report	Initializes a standard version's required macro variables. Specification in SASReferences is optional. (These macro variables can be defined with calls to %CST_SETSTANDARDPROPERTIES or %CST_SETPROPERTIES instead.) Each standard should have at least one properties (initialize) file. Each standard can have any additional files that are needed. A subtype=validation value is specific to SAS Clinical Standards Toolkit validation processes.
referencecontrol	validation, standardref, checktable, or internalvalidation	If subtype=validation, then the value identifies the standard-supplied master superset of supported validation checks. Although this is key metadata, it is not typically referenced at run time and does not need to be included. It is the Validation Control file that is identified with type=control and subtype=validation that must be included. If subtype=standardref, then the value identifies an optional data set that contains a list of references that provide the basis for each validation check that is included in the subtype=validation data set.
referencecterm		Identifies a SAS data set (sasref.memname) that most often contains controlled terminology, as opposed to a SAS format containing controlled terminology (for example, medDRA). The type=referencecterm value is optional unless one or more checks are to be run that assess value compliance against a SAS data set.

Type	Subtype	Comments
referencemetadata	column or table	Identifies the SAS data sets (sasref.memname) that contain the column and table metadata for a standard version. This type is provided by default in StandardSASReferences, so you must specify a value only to override the default for the standard. Records for both subtypes are required.
referencexml	stylesheet, map, tlfxml, datamap, or metamap	If subtype=stylesheet, then this value identifies the directory and filename of an XML style sheet. In the production of CDISC CRT-DDS XML files, this value should point to the style sheet to be copied into the directory with the XML file. If subtype=map, then this value identifies the persisted location of a SAS XML map file. The SAS XML map file reads the Work cube.xml file generated by the SAS Clinical Standards Toolkit that translates an XML file into the SAS representation of the XML-based standard (such as CDISC CRT-DDS and CDISC ODM). If subtype=metamap or subtype=datamap, then this value identifies the map file that supports reading metadata or data from XML files.
report	library or outputfile	Specifies the storage location of the SAS Clinical Standards Toolkit process reports. If a single, specific report is referenced, then it can be specified with a subtype of outputfile, a valid path, and valid memname values. If the process produces multiple reports, then a subtype of library is used with a valid path to the directory or folder. In the latter case, default report names as defined in the code are used.

Type	Subtype	Comments
results	analysis or results or validationresults, metrics or validationmetrics	Specifies the storage location of the Results and Metrics data sets that are generated by the SAS Clinical Standards Toolkit process. The Metrics data set is specific to the SAS Clinical Standards Toolkit validation processes and is optional depending on property settings. A `results/validationresults` record is required. **Note:** Analysis has been added for the SAS Clinical Standards Toolkit, but it is not used.
resultspackage	xml or log	This type is not used in the SAS Clinical Standards Toolkit. This type bundles a set of process inputs and outputs together for later access.
sourcedata		Defines the folder location of the data for a specific study. This type is required for validation processes if one or more checks are to be run that access a specific source data domain.
sourcemetadata	analyses, analysisresult, column, document, value, table, study, codelist, or itemgroup	Identifies the SAS data sets (sasref.memname) that contain the column, document, analyses, analysis result, value (for value level metadata), codelist, itemgroup, study, and table metadata for a study or set of source data. This type is not provided by default in StandardSASReferences, so you must specify a value. Records for both subtypes are required.
standardmetadata	attribute or element	Identifies the SAS data set templates for valid_attributes and valid_elements when validating ODM files.

Type	Subtype	Comments
standards	registeredstandards or registeredsasreferences	Identifies the template for the registered Standards and SASReferences data sets, respectively. This value is used by the framework when the global metadata library is created. This type is not used in post-deployment processes.
studymetadata	analyses, analysisresult, codelist, column, document, value, table, study, or itemgroup	Identifies the SAS data sets (sasref.memname) that contain the table, column, codelists, document, analyses, analysis result, value (for value level metadata), study, and itemgroup metadata for a study. This type is not provided by default in StandardSASReferences, so you must specify a value. Records for both subtypes are required.
targetdata		Defines the location of the data to be derived for a specific standard. For example, for CDISC CTR-DDS, the %CRTDDS_READ macro derives a set of CRT-DDS data sets from the referenced define.xml file. This type is optional.
targetmetadata	analyses, analysisresult, document, value, column, table, study, codelist, or itemgroup	Identifies the SAS data sets (sasref.memname) that contain the analyses, analysis result, document, value (for value level metadata), codelist, itemgroup, study, column, table, and study metadata to be derived for a specific standard. For example, for CDISC CRT-DDS, the %CRTDDS_READ macro derives files that describe metadata about the targetdata data sets that are derived from the referenced define.xml file. If this type is used, then a record for each subtype is required.
template		Identifies the library for metadata template data sets that are used to generate table shells.

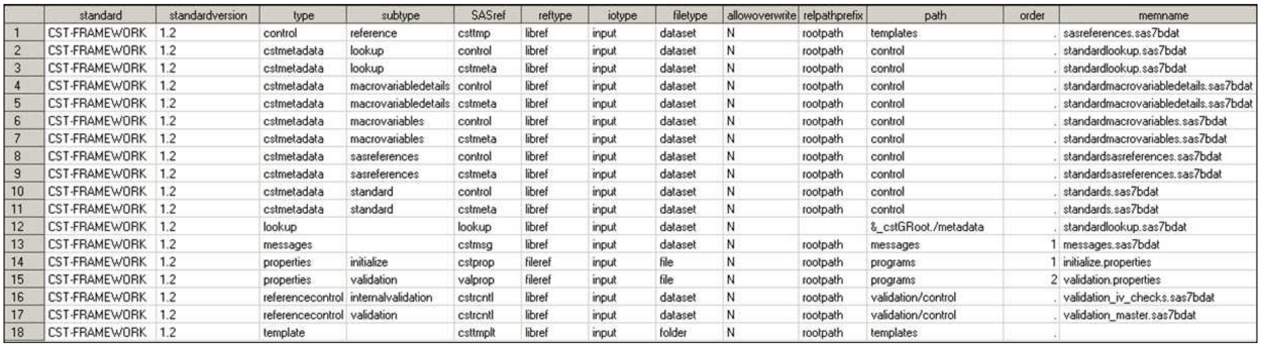
Type	Subtype	Comments
transport		This type is not used in the SAS Clinical Standards Toolkit. This type identifies a library of SAS transport files that are optionally referenced by a define.xml file.

Every instance of the SASReferences file does not require a specific path and filename. At the beginning of this section, a call to this macro was described:

```
%cst_getstandardsasreferences(_cstStandard=CST-FRAMEWORK,
_cstStandardVersion=1.2,_cstOutputDS=sasreferences);
```

The following display shows that this macro call produces this SASReferences file:

Figure 6.1 Standard SASReferences File for CST-FRAMEWORK



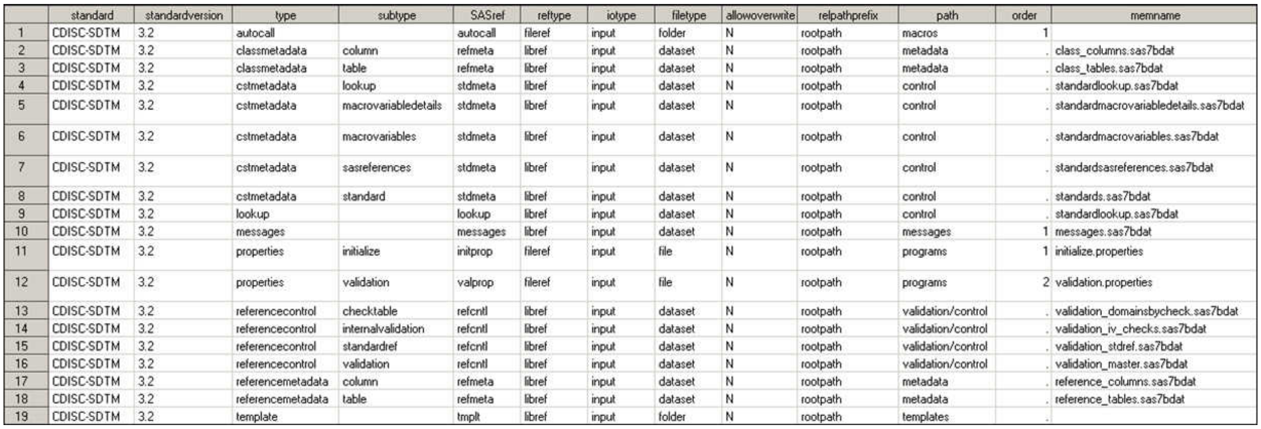
	standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order	memname
1	CST-FRAMEWORK	1.2	control	reference	csttmp	libref	input	dataset	N	rootpath	templates	.	sasreferences.sas7bdat
2	CST-FRAMEWORK	1.2	cstmetadata	lookup	control	libref	input	dataset	N	rootpath	control	.	standardlookup.sas7bdat
3	CST-FRAMEWORK	1.2	cstmetadata	lookup	cstmeta	libref	input	dataset	N	rootpath	control	.	standardlookup.sas7bdat
4	CST-FRAMEWORK	1.2	cstmetadata	macrovariabledetails	control	libref	input	dataset	N	rootpath	control	.	standardmacrovariabledetails.sas7bdat
5	CST-FRAMEWORK	1.2	cstmetadata	macrovariabledetails	cstmeta	libref	input	dataset	N	rootpath	control	.	standardmacrovariabledetails.sas7bdat
6	CST-FRAMEWORK	1.2	cstmetadata	macrovariables	control	libref	input	dataset	N	rootpath	control	.	standardmacrovariables.sas7bdat
7	CST-FRAMEWORK	1.2	cstmetadata	macrovariables	cstmeta	libref	input	dataset	N	rootpath	control	.	standardmacrovariables.sas7bdat
8	CST-FRAMEWORK	1.2	cstmetadata	sasreferences	control	libref	input	dataset	N	rootpath	control	.	standardsasreferences.sas7bdat
9	CST-FRAMEWORK	1.2	cstmetadata	sasreferences	cstmeta	libref	input	dataset	N	rootpath	control	.	standardsasreferences.sas7bdat
10	CST-FRAMEWORK	1.2	cstmetadata	standard	control	libref	input	dataset	N	rootpath	control	.	standards.sas7bdat
11	CST-FRAMEWORK	1.2	cstmetadata	standard	cstmeta	libref	input	dataset	N	rootpath	control	.	standards.sas7bdat
12	CST-FRAMEWORK	1.2	lookup		lookup	libref	input	dataset	N		&_cstGRoot./metadata	.	standardlookup.sas7bdat
13	CST-FRAMEWORK	1.2	messages		cstmsg	libref	input	dataset	N	rootpath	messages	1	messages.sas7bdat
14	CST-FRAMEWORK	1.2	properties	initialize	cstprop	fileref	input	file	N	rootpath	programs	1	initialize.properties
15	CST-FRAMEWORK	1.2	properties	validation	valprop	fileref	input	file	N	rootpath	programs	2	validation.properties
16	CST-FRAMEWORK	1.2	referencecontrol	internalvalidation	cstrcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_iv_checks.sas7bdat
17	CST-FRAMEWORK	1.2	referencecontrol	validation	cstrcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_master.sas7bdat
18	CST-FRAMEWORK	1.2	template		csttmplt	libref	input	folder	N	rootpath	templates	.	

The **SASref** field, with values of **cstmeta** and **control**, points to the same path field value. The **control** SASref was retained to ensure backward compatibility with past releases.

Figure 6.2 on page 148 shows the information returned by this call to %CST_GETSTANDARDSASREFERENCES for the CDISC SDTM standard:

```
%cst_getstandardsasreferences(_cstStandard=CDISC-SDTM,
_cstOutputDS=sasreferences);
```

Figure 6.2 *Standard SASReferences for CDISC SDTM*



	standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order	memname
1	CDISC-SDTM	3.2	autocall		autocall	fileref	input	folder	N	rootpath	macros	1	
2	CDISC-SDTM	3.2	classmetadata	column	refmeta	libref	input	dataset	N	rootpath	metadata	.	class_columns.sas7bdat
3	CDISC-SDTM	3.2	classmetadata	table	refmeta	libref	input	dataset	N	rootpath	metadata	.	class_tables.sas7bdat
4	CDISC-SDTM	3.2	cstmetadata	lookup	stdmeta	libref	input	dataset	N	rootpath	control	.	standardlookup.sas7bdat
5	CDISC-SDTM	3.2	cstmetadata	macrovariabledetails	stdmeta	libref	input	dataset	N	rootpath	control	.	standardmacrovariabledetails.sas7bdat
6	CDISC-SDTM	3.2	cstmetadata	macrovariables	stdmeta	libref	input	dataset	N	rootpath	control	.	standardmacrovariables.sas7bdat
7	CDISC-SDTM	3.2	cstmetadata	sasreferences	stdmeta	libref	input	dataset	N	rootpath	control	.	standardsasreferences.sas7bdat
8	CDISC-SDTM	3.2	cstmetadata	standard	stdmeta	libref	input	dataset	N	rootpath	control	.	standards.sas7bdat
9	CDISC-SDTM	3.2	lookup		lookup	libref	input	dataset	N	rootpath	control	.	standardlookup.sas7bdat
10	CDISC-SDTM	3.2	messages		messages	libref	input	dataset	N	rootpath	messages	1	messages.sas7bdat
11	CDISC-SDTM	3.2	properties	initialize	initprop	fileref	input	file	N	rootpath	programs	1	initialize.properties
12	CDISC-SDTM	3.2	properties	validation	valprop	fileref	input	file	N	rootpath	programs	2	validation.properties
13	CDISC-SDTM	3.2	referencecontrol	checktable	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_domainsbycheck.sas7bdat
14	CDISC-SDTM	3.2	referencecontrol	internalvalidation	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_iv_checks.sas7bdat
15	CDISC-SDTM	3.2	referencecontrol	standardref	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_stdref.sas7bdat
16	CDISC-SDTM	3.2	referencecontrol	validation	refcntl	libref	input	dataset	N	rootpath	validation/control	.	validation_master.sas7bdat
17	CDISC-SDTM	3.2	referencemetadata	column	refmeta	libref	input	dataset	N	rootpath	metadata	.	reference_columns.sas7bdat
18	CDISC-SDTM	3.2	referencemetadata	table	refmeta	libref	input	dataset	N	rootpath	metadata	.	reference_tables.sas7bdat
19	CDISC-SDTM	3.2	template		tmplt	libref	input	folder	N	rootpath	templates	.	

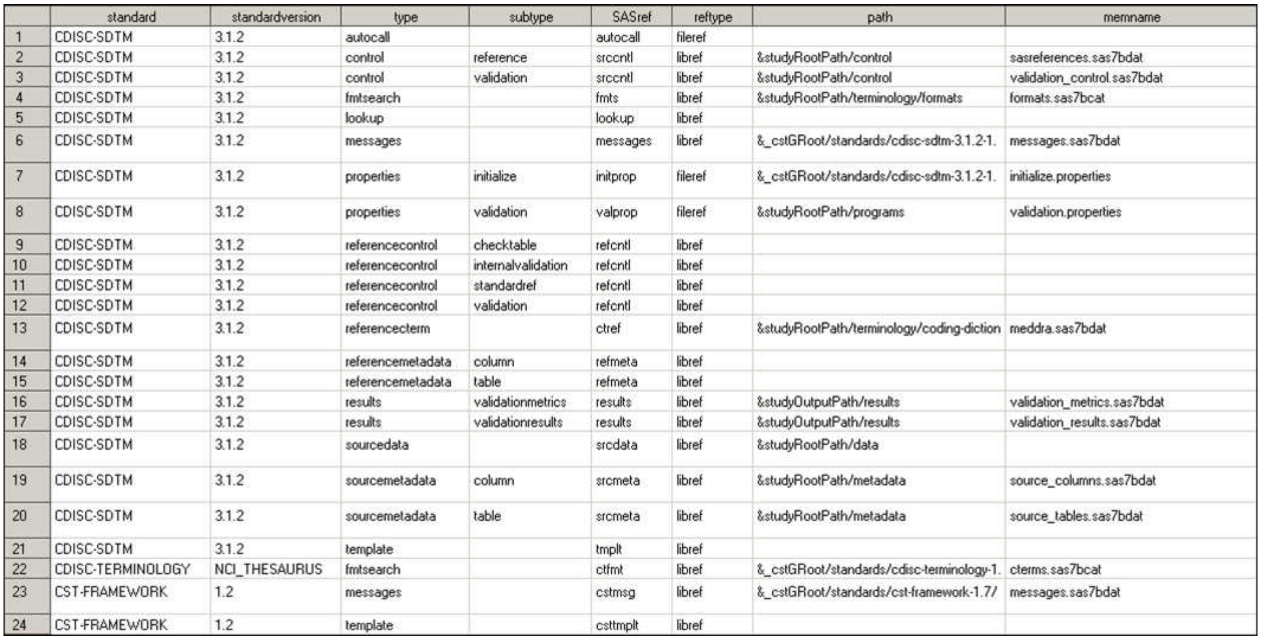
A comparison of Figure 6.1 on page 147 and Figure 6.2 on page 148 shows little similarity in the record types and no overlap in references to specific files. The target inputs and outputs for CDISC SDTM are more focused on the task (for example, validating SDTM domains). The SAS Clinical Standards Toolkit validation processes require specification of a comparative reference standard. Here, there are references to a standard-specific macro library (autocall), Messages data set, and properties files. Unique SASref values by type are provided, pointing to distinct files and folders in the global standards library.

Consider an actual SASReferences file built to support CDISC SDTM 3.1.2 validation. The task of validating the functionality of CDISC SDTM 3.1.2 uses the SASReferences file here in SAS 9.3 and SAS 9.4:

***sample study library directory*\cdisc-sdtm-3.1.2-1.7**
sascstdemodata\control

The following display shows the complete contents of the SASReferences file:

Figure 6.3 Sample SASReferences File for CDISC SDTM Validation



	standard	standardversion	type	subtype	SASref	reftype	path	memname
1	CDISC-SDTM	3.1.2	autocall		autocall	fileref		
2	CDISC-SDTM	3.1.2	control	reference	srccntl	libref	&studyRootPath/control	sasreferences.sas7bdat
3	CDISC-SDTM	3.1.2	control	validation	srccntl	libref	&studyRootPath/control	validation_control.sas7bdat
4	CDISC-SDTM	3.1.2	fmtsearch		fmts	libref	&studyRootPath/terminology/formats	formats.sas7bcat
5	CDISC-SDTM	3.1.2	lookup		lookup	libref		
6	CDISC-SDTM	3.1.2	messages		messages	libref	&_cstGRoot/standards/cdisc-sdtm-3.1.2-1.	messages.sas7bdat
7	CDISC-SDTM	3.1.2	properties	initialize	initprop	fileref	&_cstGRoot/standards/cdisc-sdtm-3.1.2-1.	initialize.properties
8	CDISC-SDTM	3.1.2	properties	validation	valprop	fileref	&studyRootPath/programs	validation.properties
9	CDISC-SDTM	3.1.2	referencecontrol	checktable	refcntl	libref		
10	CDISC-SDTM	3.1.2	referencecontrol	internalvalidation	refcntl	libref		
11	CDISC-SDTM	3.1.2	referencecontrol	standardref	refcntl	libref		
12	CDISC-SDTM	3.1.2	referencecontrol	validation	refcntl	libref		
13	CDISC-SDTM	3.1.2	referencecterm		ctref	libref	&studyRootPath/terminology/coding-diction	meddra.sas7bdat
14	CDISC-SDTM	3.1.2	referencemetadata	column	refmeta	libref		
15	CDISC-SDTM	3.1.2	referencemetadata	table	refmeta	libref		
16	CDISC-SDTM	3.1.2	results	validationmetrics	results	libref	&studyOutputPath/results	validation_metrics.sas7bdat
17	CDISC-SDTM	3.1.2	results	validationresults	results	libref	&studyOutputPath/results	validation_results.sas7bdat
18	CDISC-SDTM	3.1.2	sourcedata		srcdata	libref	&studyRootPath/data	
19	CDISC-SDTM	3.1.2	sourcemetadata	column	srcmeta	libref	&studyRootPath/metadata	source_columns.sas7bdat
20	CDISC-SDTM	3.1.2	sourcemetadata	table	srcmeta	libref	&studyRootPath/metadata	source_tables.sas7bdat
21	CDISC-SDTM	3.1.2	template		tmplt	libref		
22	CDISC-TERMINOLOGY	NCI_THESAURUS	fmtsearch		ctfmt	libref	&_cstGRoot/standards/cdisc-terminology-1.	cterms.sas7bcat
23	CST-FRAMEWORK	1.2	messages		cstmsg	libref	&_cstGRoot/standards/cst-framework-1.7/	messages.sas7bdat
24	CST-FRAMEWORK	1.2	template		csttmplt	libref		

Table 6.2 Explanation of Sample SASReferences File for CDISC SDTM Validation

Lines	Comment
1	Instructs the SAS Clinical Standards Toolkit to add any SDTM-specific macros to the autocall path.
2	Documents the name and location of this file. This information is used in the sample reports that are discussed in this document.
3	Points to the set of validation checks to be run in this validation assessment. The framework default values for SASref, path, and memname have been overridden.
4, 22	Two standards are referenced to create a format search path. Line 4 references the SDTM study-specific formats catalog. Line 22 references the more general CDISC Controlled Terminology cterms catalog. The precedence is set by the order column.
6, 23	These records are identical to the CST-FRAMEWORK and CDISC-SDTM StandardSASReferences records.

Lines	Comment
7	Illustrates the call to a standard-specific properties file that is used to initialize a global macro variable that is specific to that standard. Referencing a standard-specific properties files in the SASReferences data set is recommended. The call to the CST-FRAMEWORK initialize.properties file is a prerequisite setup step outside of SASReferences and performed before processing SASReferences.
8	The validation properties path has been modified to point to a location in the study hierarchy, rather than to the global standards library that is defined in the StandardSASReferences file.
9–12, 14–15, 21, 24	Points to the reference standard for CDISC SDTM 3.1.2, but unlike the template defaults in Figure 6.2 on page 148, path and memname are blank. Leaving them blank tells the SAS Clinical Standards Toolkit to look in the CDISC SDTM 3.1.2 StandardSASReferences file and use the defaults for that standard and version. This convention facilitates portability of the data set by doing a run-time lookup for the current information. The lookup results in the inclusion of the path and memname values as defined in Figure 6.2 on page 148.
13	References a medDRA data set that is maintained in the study-specific hierarchy. A more common implementation might reference a non-study-specific coding dictionary.
16–17	Specifies that process results are to be stored in a location in the study hierarchy.
18	This is a type that is not in the template files (StandardSASReferences). It defines the location of the study (source) data. The use of &studyRootPath, coupled with the assumption of a fixed-folder hierarchy, enables portability across studies. The memname value is not relevant for a library of SAS data sets.
19–20	These values follow the style used in line 18 for source data. The same SASref is used for multiple subtypes in a single type because the subtypes reference two differently named SAS data sets from the same folder.

An alternative way to build the SASReferences file is to use the %CST_CREATEDSFROMTEMPLATE utility macro.

```
%cst_createdsfromtemplate(_cstStandard=CST-FRAMEWORK,_cstType=control,
_cstSubType=reference,_cstOutputDS=work.sasreferences);
proc sql;
insert into work.sasreferences
values(CST-FRAMEWORK 1.2 messages messages libref 1 );
.
```

```
   .
   .
   quit;
```

This macro copies the template. New records can be added various ways, including the previous PROC SQL technique. There is no requirement that the SASReferences file has to live outside the SAS Work area and be kept beyond the SAS Clinical Standards Toolkit process. However, these are best practices that enable future capabilities such as process reruns and reporting.

How Is a SASReferences File Used?

Overview

After a SASReferences file has been created for a task, three key steps occur.

1. The name and location of the file must be communicated to the SAS Clinical Standards Toolkit.
2. The structural integrity and content of the file are assessed.
3. The file content is translated into allocated SAS libraries and filenames, system options are set, and required work files are created.

After these steps are completed, a SAS environment has been properly established to support subsequent SAS Clinical Standards Toolkit tasks.

Communicating the Filename and Location to the SAS Clinical Standards Toolkit

Three global macro variables are used to define the name and location of the SASReferences file:

- The _cstSASRefsLoc macro variable provides the path to the SAS library that contains the file.

- The _cstSASRefsName macro variable provides the SASReferences filename in _cstSASRefsLoc.
- The _cstSASRefs macro variable provides libref.dset for the SASReferences file that is returned from the call to the %CST_INSERTSTANDARDSASREFS macro. The libref.dset is used in the SAS Clinical Standards Toolkit code for the remainder of the process.

Sample driver programs are provided with the SAS Clinical Standards Toolkit. These driver programs show how to perform the necessary setup tasks for SAS Clinical Standards Toolkit processes, and how to reference and use sample data that is provided with the SAS Clinical Standards Toolkit.

The key macro %CSTUTIL_PROCESSSETUP is called in all sample driver programs. This macro interprets information about the location and name of the SASReferences file, and calls the %CSTUTIL_ALLOCATESASREFERENCES macro to allocate SAS librefs and filerefs based on SASReferences content.

Here is the macro code:

```
%macro cstutil_processsetup( _cstSASReferencesSource=SASREFERENCES,
          _cstSASReferencesName=sasreferences,
          _cstSASReferencesLocation=)  /des='CST: Setup Process Metadata';
```

The following table lists the parameters that are supported by the %CSTUTIL_PROCESSSETUP macro:

Table 6.3 Parameters Supported by cstutil_processsetup

Parameter	Description
_cstSASReferencesSource	Specifies the initial source that setup should be based on. Valid values are SASReferences (default) or Results. If Results, then no other parameters are required, setup responsibility is passed to the %CSTUTIL_REPORTSETUP macro, and the Results data set name must be passed to %CSTUTIL_REPORTSETUP as libref.memname.

Parameter	Description
_cstSASReferencesLocation	Specifies the path (folder location) of the SASReferences data set. The default is the path to the Work library. This is the value of the global macro variable.
_cstSASReferencesName	Specifies the name of the SASReferences data set. The default is SASReferences. The value of the global macro variable _cstSASRefsName is set to this parameter value.

Excluding the SAS Clinical Standards Toolkit reporting processes, to communicate with a SASReferences file, use one of these two methods:

Note: The SAS Clinical Standards Toolkit reporting processes might use the _cstSASReferencesSource=RESULTS parameter.

1 Create and reference the SASReferences file in the SAS Work library.

```
%* The following call assumes the existence of work.sasreferences;
%cstutil_processsetup();
```

2 Reference an existing SASReferences file.

```
%cstutil_setcstsroot;
data _null_;
call symput('studyRootPath',cats("&_cstSRoot",
            "/cdisc-sdtm-3.1.2-&_cstVersion/sascstdemodata"));
run;
%* Look for the data set named sasreferences in the specified folder ;
%cstutil_processsetup(_cstSASReferencesLocation=&studyrootpath/control);
```

The call to the %CSTUTIL_SETCSTROOT macro sets the SAS Clinical Standards Toolkit global macro variable &_cstSRoot to the sample library.

Assessing Structural Integrity and Content

Overview

Two SAS Clinical Standards Toolkit framework utility macros perform key functions in assessing whether the SASReferences file is valid.

The %CST_INSERTSTANDARDSASREFS macro looks up missing paths and memnames in the constructed SASReferences file from each StandardSASReferences data set. For example, this macro sets the path and memname values for lines 9 through 12 in the example in Figure 6.3 on page 149. This macro attempts to update only records for a supported standard (and standardversion) that has missing path and memname information. It does not update records with non-null values, and it does not add any records from the StandardSASReferences data set. If this macro runs successfully, then the resulting data set has paths for all records and memnames for all records that require them. This does not include autocall and sourcedata records. By default, the resulting data set is referenced by the &_cstSASRefs global macro variable.

The %CSTUTILVALIDATESASREFERENCES macro checks the structure and content of the SASReferences data set against a defined gold standard.

If you have used previous versions of the SAS Clinical Standards Toolkit, you might see failures when you use the %CSTUTILVALIDATESASREFERENCES macro against SASReferences data sets that were created in a version before the SAS Clinical Standards Toolkit 1.5. These failures are caused by the stricter adherence to the SASReferences metadata model that the %CSTUTILVALIDATESASREFERENCES macro enforces.

Here is the syntax of this macro:

```
%macro cstutilvalidatesasreferences (_cstDSName=,
_cstStandard=,_cstStandardversion=, _cstSASRefsGoldStd=,
_cstallowoverride=, _cstResultsType=, _cstPreAllocated,
_cstVerbose= );
```

_cstDSName specifies the two-level name of the data set to be validated. This value is required. The default value is &_cstSASRefs derived from the process setup macro.

_cstStandard specifies the name of a registered data standard. This value is required. The default value is CST-FRAMEWORK.

_cstStandardversion specifies the version of a registered data standard. This value is required. The default value is 1.2.

_cstSASRefsGoldStd specifies the two-level name of a comparative gold standard against which this SASReferences data set is compared. This value is required. By default, the global standards library metadata StandardSASReferences is assumed.

_cstallowoverride specifies whether to ignore one or more of the values defined above. Specify the check code in a blank-delimited string (for example, CHK01 CHK07). If null, all conditions are tested.

_cstResultsType specifies where to store report findings: in the SAS log or in the Results data set. This value is required. It must be either LOG or RESULTS. The default value is LOG.

_cstPreAllocated specifies whether to allocate librefs and filerefs when this macro is called. If they are not allocated, the validation of data sets and catalogs is performed based on paths and memnames, not on libref.memnames. This value is required. It must be either N or Y. The default value is N.

_cstVerbose specifies whether to report specific problems or the absence of problems in _cst_rc. Otherwise, only success or failure is reported. This value is required. It must be either N or Y. The default value is N.

This macro is typically used as a part of the normal process setup. It is called either before or as a part of %CSTUTIL_ALLOCATESASREFERENCES or as a stand-alone call outside the context of use in the normal process setup. The macro sets the _cst_rc and _cst_rcmsg global macro variables to indicate that the SASReferences data set is valid (_cst_rc=0) or not valid (_cst_rc ne 0).

There are eight checks associated with this macro when validating a SASReferences data set.

- CHK01: The data set is structurally correct.
- CHK02: An unknown standard or standardversion exists.
- CHK03: The referenced input and output files and folders can be accessed.
- CHK04: All required look-throughs to the global standards library defaults work.
- CHK05: All discrete character field values are found in the Standardlookup data set.
- CHK06: For the given context, path and memname macro variables are resolved.
- CHK07: Multiple fmtsearch records exist, but valid ordering is not provided.
- CHK08: Multiple autocall records exist, but valid ordering is not provided.

In the SAS Clinical Standards Toolkit 1.5, additional columns were included in the SASReferences data set to facilitate internal validation. Two of these columns are iotype and filetype. To remain backward compatible, if the SASReferences data set is missing these two columns, CHK03 is ignored because the %CSTUTIL_VALIDATESASREFERENCES macro assumes that the SASReferences data set was created in a version before the SAS Clinical Standards Toolkit 1.5.

Results are written to the Results data set defined by the &_cstResultsDS global macro variable.

Common Errors and Solutions

The following list describes the most common errors detected by the %CSTUTIL_VALIDATESASREFERENCES macro. Solutions are suggested. All errors appear in the Results data set.

- CHK01 - A problem with the structure of the data set exists.

  The macro has detected a structural difference in the data set that needs to be addressed.

  Fix the issues as described in the Results data set.

- CHK02 - An unknown standard or standardversion value exists.

  The macro has detected a standard or standardversion value that does not exist in the SAS Clinical Standards Toolkit. This can be caused by a typographical error for the value or by a standard that has not yet been registered with the SAS Clinical Standards Toolkit.

  Correct the erroneous value or register the unknown standard.

- CHK03 - The referenced input and output files cannot be accessed.

  This check uses a new metadata variable in SASReferences called iotype. This variable is not available in versions of the SAS Clinical Standards Toolkit prior to version 1.5. To maintain backward compatibility, a special Boolean macro variable exists. It is named &_cstCurrentStyle and has a value of 1 (version 1.5 or higher SASReferences) or 0 (previous version [before version 1.5] of SASReferences). When set to 0, the SAS Clinical Standards Toolkit ignores this check.

Based on the value of iotype, the macro has detected a specified input file, data set, or catalog that does not exist in the path provided by SASReferences. For iotype equal to 'output' or 'both,' the specified path is Read-Only and does not allow the SAS Clinical Standards Toolkit to create an output file.

Correct this issue by ensuring that pathnames, filenames, data set names, and catalog names are entered correctly. For output file references, ensure that the user account has Write access permission to the folders that are specified in SASReferences.

- CHK04 - Required look-throughs to the global standards library defaults do not work.

  For this check to be meaningful, ensure that a call to %CST_INSERTSTANDARDSASREFS has been performed before running this check. Otherwise, empty pathnames might exist that are populated with a call to %CST_INSERTSTANDARDSASREFS.

  This check is not applicable to stand-alone use. This check detects pathnames that are missing or null.

  Correct this issue by verifying that the call to %CST_INSERTSTANDARDSASREFS was made before running this check. Otherwise, provide a valid pathname for each missing value.

- CHK05 - Not all discrete character fields were found in the Standardlookup data set.

  This check detects missing or incorrect names for the following columns in SASReferences: reftype, type+subtype combinations, iotype, filetype, and allowoverwrite.

  Note: Because iotype, filetype, and allowoverwrite were introduced in the SAS Clinical Standards Toolkit 1.5, these columns are ignored when &_cstCurrentStyle=0. (See check CHK03.)

  Correct this issue by providing valid values for these columns in SASReferences. If needed, update the Standardlookup data set.

  Note: Updating the Standardlookup data set is an advanced use of the SAS Clinical Standards Toolkit and should be performed by an administrator.

- CHK06 - For the given context, all macro variables have not been resolved.

This check detects unresolved macro variables used in the memname and path columns.

Correct this issue by making sure all macro references used in SASReferences have been resolved.

- CHK07

  To ensure proper FMTSEARCH functionality in SAS, the order in which the fmtsearch string is built is very important for the proper functioning of the SAS Clinical Standards Toolkit. This check detects multiple fmtsearch records with invalid order values. Invalid order values could be missing or duplicate values.

  Correct this issue by assigning valid order values for multiple fmtsearch records.

- CHK08

  To ensure proper AUTOCALL macro functionality in SAS, the order in which the autocall macro string is built is very important for the proper functioning of the SAS Clinical Standards Toolkit. This check detects multiple autocall records with invalid order values. Invalid order values could be missing or duplicate values.

  Correct this issue by assigning valid order values for multiple autocall records.

Translating Content for a SAS Session

After the SASReferences file has been built, its content must be translated for use by a SAS Clinical Standards Toolkit process. A call to the SAS Clinical Standards Toolkit framework utility macro %CSTUTIL_PROCESSSETUP performs the translation. If this macro runs successfully, then the SAS session is properly configured for any tasks (such as validation) that follow.

When the %CSTUTIL_PROCESSSETUP macro is called, these events happen:

1. The %CSTUTIL_ALLOCATESASREFERENCES macro is called.
2. The %CST_INSERTSTANDARDSASREFS macro is called to insert paths into any records that are missing that information. The information is retrieved from the StandardSASReferences data set for each standard.

3. The %CSTUTIL_VALIDATESASREFERENCES macro is called to perform internal validation on the SASReferences data set updated in step 2.

4. All filerefs and librefs are allocated.

5. Any property files are passed to cst_setproperties to create global macro variables.

6. The format search path is set if any type=fmtsearch records are found, based on the order that is specified.

7. The autocall path is set if any type=autocall records are found, based on the order that is specified. By default, the framework macro library was added to the autocall path when the SAS Clinical Standards Toolkit was deployed.

8. A Messages data set is created to contain records from each standard, based on the properties or global macro variables _cstMessages and _cstMessageOrder. The Messages data set is used for the duration of the process to add fully resolved messages to the Results data set.

After all of these steps have been performed, all libraries should be allocated, all paths and global macros should be set, and the global status macro variable _cst_rc should be set to 0. The process is ready to proceed.

CAUTION! SASReferences is key to the process, and any errors cause the process to fail. This is a common process failure point because of the importance of the SASReferences file, and the strict structural and content expectations of the file. For tips on debugging problems with the SASReferences file, see "Common Errors and Solutions" on page 156.

TIP Best Practice Recommendation: Each SASReferences file is customized for the specific task to be completed. Later sections describe SASReferences implementations required by these specific tasks.

7

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Validation Framework Overview

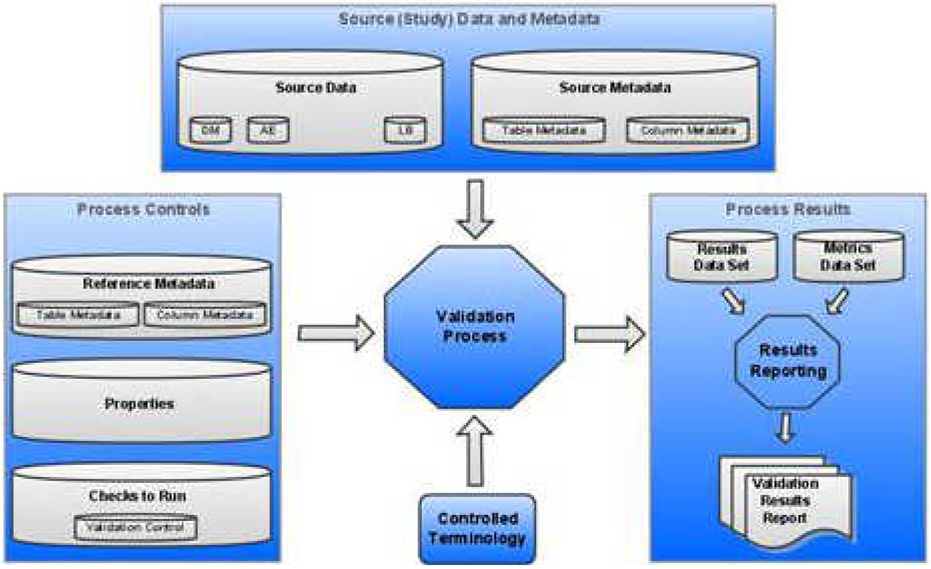
The SAS Clinical Standards Toolkit validation assesses the compliance of data, and the metadata describing the data, with an accepted reference standard. It assesses the consistency of values in a specific column, between columns, across records in a specific data set, and across data sets. The primary output is a Results data set that itemizes the process findings, and an optional Metrics data set that summarizes the results.

The SAS Clinical Standards Toolkit provides a framework to build a process. The process uses inputs or process controls to evaluate the compliance of source data with a reference standard. Each SAS Clinical Standards Toolkit process uses a SAS program file to point to a SASReferences control data set, and to execute a primary action SAS macro (such as %SDTM_VALIDATE). This SAS program file is referred to as a driver program in this document.

Generally, validation is performed by running SAS macros against the standard, which is represented by SAS files. Validation of some standards, such as CDISC CRT-DDS, might include validating files that are not SAS files (such as define.xml).

The following display shows a SAS Clinical Standards Toolkit validation process:

Figure 7.1 *Components of a SAS Clinical Standards Toolkit Validation Process*



Each component is fully described in the following sections.

- *Source Data* is a set of SAS data sets in one or more libraries that collectively represents a clinical study. These SAS data sets are referred to as study domains or study data sets. One or more source data sets are required by a typical SAS Clinical Standards Toolkit validation process. However, it is possible to test only the structural compliance of source metadata by limiting validation to a subset of validation checks.
- *Source Metadata* is a set of SAS data sets in one or more libraries that provide metadata about the source data. The source metadata is typically in a format specific to a standard. For example, metadata about source data sets might be captured in a source_tables data set. Metadata about columns in those source data sets might be captured in a source_columns data set.
- *Process Controls* is the set of instructions that each SAS Clinical Standards Toolkit process uses to perform a specific action. These instructions might be provided in a varied number and in various type of files. For a SAS Clinical Standards Toolkit validation process, these files include:

  - *Reference Metadata* is a set of SAS data sets that provide metadata. This metadata defines a specific standard and is typically in a format specific to a standard. For example, metadata about data sets might be captured in a reference_tables data set. Metadata about columns in those data sets might be captured in a reference_columns data set. For an example, see Table 5.1 on page 95 and Table 5.2 on page 96.
  - *Properties* are a series of name-value pairs that are translated into SAS global macro variables. These macro variables are available for the duration of the SAS Clinical Standards Toolkit process. Properties might be defined in a varied number of files. Both text file format and SAS data set format are supported. For information about a sample validation.properties file, see "Validation Check Metadata: Validation Master" on page 173. For information about the SAS Clinical Standards Toolkit global macro variables, see Appendix 1, "Global Macro Variables," on page 459.
  - *Set of Checks to Run* is a set of checks that represent all or some of the checks defined for a standard. Each check provides metadata that is used by the validation code to perform a specific compliance assessment.
- *Controlled Terminology* is an optional set of lookup values against which source data columns can be evaluated. These values can be in the form of SAS format catalogs or SAS data sets.
- *Results* are presented in a Results data set that itemizes the process findings, and in a Metrics data set that summarizes the results. The Results data set usually contains a record indicating that each check was run successfully without error, or it contains a record that itemizes the errors detected. Information about the process also might be included. The generation of a Metrics data set is conditional based on property file settings.

The SAS Clinical Standards Toolkit validation makes these basic assumptions:

1. There is some combination of source data and metadata available as SAS files that you want to validate.
2. A reference standard has been defined with which the source data and metadata are to be compared. The SAS Clinical Standards Toolkit provides representative reference metadata for each supported standard.

3 The source data can be in a varied number of SAS files, and those SAS files can have any form. However, the metadata describing the source data must accurately represent the source data. The metadata must be in a form specific to a supported standard and defined by the SAS Clinical Standards Toolkit.

4 A set of validation checks must be defined, and the validation checks must conform to a generic SAS Clinical Standards Toolkit SAS data set structure. The SAS Clinical Standards Toolkit provides a representative set of validation checks for each supported standard.

Metadata Requirements

Overview

As noted in Chapter 5, “Supported Standards,” on page 87, a standard consists of properties, messages, and metadata files that collectively represent the standard in the SAS Clinical Standards Toolkit. Each SAS Clinical Standards Toolkit registered standard can support validation if the standards.supportsvalidation flag is set to Y. This setting indicates that the required set of validation files defining the standard exist. By default, the set of validation files that supports the standards that are provided by SAS is in the cstGlobalLibrary folder hierarchy.

For example, validation files that define the CDISC SDTM 3.1.3 standard are in this folder hierarchy:

***global standards library directory*/standards/cdisc-sdtm-3.1.3-1.7**

The following sections describe each metadata type used by typical validation processes. For information about metadata files that are common to all SAS Clinical Standards Toolkit processes, see Chapter 3, “Metadata File Descriptions,” on page 33. Metadata characteristics specific to compliance assessments are described in the sections in this chapter.

Reference Metadata

For CDISC standards, reference metadata about data sets is defined in a reference_tables data set, and metadata about columns is defined in a reference_columns data set. An example of a CDISC SDTM reference_tables record is provided in Table 7.1 on page 167 and an example of a CDISC SDTM reference_columns record is provided in Table 7.2 on page 169.

Note: The structure and content of the reference metadata data sets can vary across standards.

As noted in Chapter 5, “Supported Standards,” on page 87, each standard that is provided by SAS provides a SAS interpretation of the published source guidelines or specification of that standard. Each standard is designed to serve as a representative model or template of the source specification. Each model or template can be modified to establish your own gold standard.

Table 7.1 *reference_tables Data Set*

Column Name	Column Length	Description
sasref	$8	The SAS libref that refers to the table in the SAS Clinical Standards Toolkit process. This value should match the value of the SASReferences.sasref field, where type=referencemetadata and subtype=table. This column is required.
table	$32	The name of the tabulation domain or analysis data set being defined in the standard. The value must conform to SAS naming conventions. This column is required.
label	$200	The label of the domain being defined in the standard. The value must conform to SAS naming conventions. This column is required for standards from which define.xml metadata is derived.

Column Name	Column Length	Description
class	$40	The observation class in the standard. Example CDISC SDTM values are Events, Findings, Interventions, Relates, Special Purpose, and Trial Design. This column is optional and not relevant for all standards.
xmlpath	$200	The path to the SAS transport file. This path can be specified as a relative path. The value can be used when creating define.xml to populate the value for the def:leaf xlink:href link to the domain file. The value should be the pathname and filename of the SAS transport file relative to the location of define.xml file. This column is optional and not relevant for all standards.
xmltitle	$200	The title of the SAS transport file. The value can be used when creating a define.xml file to populate the value for the def:leaf def:title value. It can provide a meaningful description, label, or location of the domain leaf (for example, crt/data sets/Protocol 1234/AE.xpt). This column is optional and not relevant for all standards.
structure	$200	The description of the general structure of the table. An example value is one record per event per subject. This column is optional and not relevant for all standards.
purpose	$20	The description of the general purpose of the table. Examples are Tabulation (required for CDISC SDTM) and Analysis (required for CDISC ADaM). This column is optional and not relevant for all standards.
keys	$200	A space-delimited string of keys that captures the table columns that uniquely define records in the table. This set of keys can also define the sort order of records in the table. Example is STUDYID USUBJID. This column is expected to support SAS Clinical Standards Toolkit functionality but is not required for all standards.
state	$20	A description of the table state, such as Draft or Final. This column is optional.
date	$20	A meaningful, distinguishing date that describes the table, such as the release date, the creation date, or the modified date. This column is optional.

Column Name	Column Length	Description
standard	$20	This value captures the standard name. This value must match the name of a registered standard in the SAS Clinical Standards Toolkit framework. For a discussion of registered standards, see Chapter 2, "Framework," on page 7. This value must match the standard field in the SASReferences data set. Examples are CDISC SDTM and CDISC CRT-DDS. This column is required.
standardversion	$20	This value captures a specific version of a standard. This value must match one of the standard versions associated with a registered standard. This value must match the standardversion field in the SASReferences data set. Examples are 3.2 and 1.0. This column is required.
standardref	$200	Any reference to an associated standard definition, implementation guide, schema, and so on, that provides additional information about the table or describes the table in greater detail. This column is optional.
comment	$500	Any character string that provides comments relevant to the table. This column is optional.

Note: The column length can vary to match submission requirements or corporate conventions.

Table 7.2 *reference_columns Data Set*

Column Name	Column Length	Description
sasref	$8	The SAS libref that refers to the table containing the column in the SAS Clinical Standards Toolkit process. This value should match the value of the SASReferences.sasref field, where type=referencemetadata and subtype=column. This column is required.
table	$32	The name of the tabulation domain or analysis data set being defined in the standard. The value must conform to SAS naming conventions. This column is required.

Column Name	Column Length	Description
column	$32	The name of the column in the table. The value must conform to SAS naming conventions. This column is required.
label	$200	The label of the column. The value must conform to SAS naming conventions. This column is required for standards from which define.xml metadata is derived.
order	8.	The order of the columns in each table. Values must be integers >0 and unique in each table. This column is required.
type	$1	The SAS type, N for numeric, C for character. This column is required.
length	8.	The length of the column. Numeric columns have a length of 8. This column is required.
displayformat	$32	The display format for numeric variables. For example, 8.2 indicates that floating-point variable values should be displayed to the second decimal place. This value is optional and not relevant for all standards.
xmldatatype	$8	The data type of the column as it is defined in the define.xml file. Values are integer | float | date | datetime | time | text. This column is optional and not relevant for all standards.
xmlcodelist	$32	A SAS format name that is used to assess conformance to controlled terminology. This value does not have a $ prefix for character formats and does not have the trailing period. This value is also the codelist name in the define.xml file. The SAS format name must be in the format search path for successful column-value validation. This record is optional and not relevant for all standards.
core	$10	The value indicates whether the column is required. Sample CDISC SDTM values are Req (required), Exp (expected), Perm (permissible), and Dep (deprecated). This column is optional and not relevant for all standards.

Column Name	Column Length	Description
origin	$40	Information about the source of the column. Values can include CRF page numbers and derived or variable references. Values are user extensible. This column is optional and not relevant for all standards.
role	$200	Space-delimited column classification. Examples are Identifier, Topic, Qualifier, Timing, Selection, and Analysis. Columns can have multiple roles. This column is optional and not relevant for all standards.
term	$80	The value indicates whether the column is subject to controlled terminology as defined in each standard source specification. This column is optional and not relevant for all standards.
algorithm	$1000	Imputation or computation method to derive the column value. This column is optional and not be relevant for all standards.
qualifiers	$200	Space-delimited string containing supplemental column attributes. Example CDISC SDTM values are MIXEDCASE, UPPERCASE, DATETIME, and DURATION. This column is optional and not relevant for all standards.
standard	$20	This value captures the standard name. This value must match the name of a registered standard in the SAS Clinical Standards Toolkit framework. For a discussion of registered standards, see Chapter 2, “Framework,” on page 7. This value must match the standard field in the SASReferences data set. Examples are CDISC SDTM and CDISC CRT-DDS. This column is required.
standardversion	$20	This value captures a specific version of a standard. This value must match one of the standard versions associated with a registered standard. This value must match the standardversion field in the SASReferences data set. Examples are 3.2 and 1.0. This column is required.

Column Name	Column Length	Description
standardref	$200	Any reference to an associated standard definition, implementation guide, schema, and so on, that provides additional information about the column or describes the column in greater detail. This column is optional.
comment	$1000	Any character string that provides comments relevant to the column. This column is optional.

Note: The column length can vary to match submission requirements or corporate conventions.

The standard reference metadata provided with the SAS Clinical Standards Toolkit is in the global standards library. By default, this library is located here:

***global standards library directory*/standards/**
***<specific standard>*/metadata**

For example, for the CDISC SDTM 3.1.3 standard, the location is:

***global standards library directory*/standards/**
cdisc-sdtm-3.1.3-1.7/metadata

This global standards library metadata folder can contain other standard-specific metadata. For example, CDISC SDTM includes class_tables and class_columns data sets. These data sets have more generic metadata than specific domain instances like DM or AE, and they are most useful when deriving new, custom domains. For example, if a new CDISC SDTM events domain is required, you can initialize table metadata based on the EVENTS record in class_tables data set, and can initialize column metadata based on the EVENTS, IDENTIFIERS, and TIMING records in the class_columns data set.

Source Metadata

The SAS Clinical Standards Toolkit validation processes require source metadata that describes source (study) domains and columns. This is the study data that is to be validated. The SAS Clinical Standards Toolkit assumes that the reference metadata (that is, reference_tables and reference_columns) for a standard serves as a model or template for the source metadata (that is, source_tables and source_columns). It is recommended that these two sets of metadata be structurally equivalent. However, additional metadata attributes might exist if they are used for other purposes or for custom extensions to the SAS Clinical Standards Toolkit.

The SAS Clinical Standards Toolkit assumes that source_tables and source_columns data sets accurately reflect and are consistent with the source data that they describe. Although some standard-specific validation checks might look for discrepancies and report them in detail, failure to accurately reflect and be consistent with the source data can lead to errors in the SAS Clinical Standards Toolkit validation process. It can even halt the execution of the process.

Validation Check Metadata: Validation Master

The Validation Master data set contains all validation checks defined for a standard. By default, this data set is deployed to this directory in each supported standard:

***global standards library directory*/standards/*<standard>*/ validation/control**

By default, the Validation Master SAS data set's actual name is validation_master.sas7bdat.

The SAS Clinical Standards Toolkit requires that this data set have a fixed structure.

The following table lists the columns in the Validation Master data set:

Table 7.3 Column Descriptions of the Validation Master Data Set

Column Name	Column Length	Description
checkid	$8	Validation check ID. The SAS Clinical Standards Toolkit has adopted a naming convention matching each standard to be validated. The checkid values are prefixed with an up to 4-character prefix (CDISC examples: ODM, SDTM, ADAM, and CRT). By convention, the prefix matches the mnemonic field in the Standards data set in ***`global standards library directory`*****`/metadata`**. This prefix is followed by a 4-digit numeric that is unique within the standard (for example, SDTM1234). You can use any naming convention limited to eight characters. By default, the checkid column is the first (primary) sort field in the Validation Master data set provided with the SAS Clinical Standards Toolkit. Sorting by checkid is not required. This column is required.
standard	$20	This value captures the standard name. This value must match the name of a registered standard in the SAS Clinical Standards Toolkit framework. For a discussion of registered standards, see Chapter 2, "Framework," on page 7. This value must match the standard field in the SASReferences data set. Examples are CDISC SDTM and CDISC CRT-DDS. This column is required.
standardversion	$20	This value captures a specific version of a standard. This value must match one of the standard versions associated with a registered standard. This value must match the standardversion field in the SASReferences data set. The only exception to this rule is that *** can be used to signify that the check applies to all supported versions of the standard. For example, 3.2, 1.0, ***. If a subsequent version of the standard is released, then *** would be applicable if the check is valid for the new version. This column is required.

Column Name	Column Length	Description
checksource	$40	A string that identifies the source of the check. CDISC examples include SAS, WebSDM, and CDISC. This field can contain any user-defined value. A primary use of this field is to subset the full set of checks in the run-time Validation Control data set. This column is required.
sourceid	$8	A reference identifier for this check from the checksource. In the Validation Master data set, a SAS identifier (for example, SAS0001) is used for checks provided with the SAS Clinical Standards Toolkit with no external source. An example is IR5250 (WebSDM identifier). This column is optional.
checkseverity	$40	The severity as assigned by checksource. This value is mapped to these standardized values: Note (Low), Warning (Medium), Error (High). A value is expected, although it is not technically required. It is used in messages and reporting.
checktype	$20	General type of check. This value categorizes checks and helps register customized checks. Values are user extensible and can be standard specific. A primary use of this field is to subset the full set of checks in the run-time Validation Control data set. Example CDISC SDTM values are: Metadata-structural—Checks some metadata-only property (no data access required). ColumnValue-content: Checks a column value or compares two column values. Date-content: Checks ISO 8601 compliance or compares two date values. Multirecord-content: Looks across multiple records in a single domain. Multitable-content: Looks across multiple domains. Controlterm-content: Assesses whether column value is consistent with controlled terminology. This column is optional.

Column Name	Column Length	Description
codesource	$32	The name of the check macro. The name must conform to SAS naming conventions. The value must be in the SAS autocall path. An example is %CSTCHECK_NOTUNIQUE. This column is required.
usesourcemetadata	$1	The value indicates whether to use source metadata rather than reference metadata. The metadata controls the derivation of domains and column lists to be validated, program flow, and looping. Values are Y and N (default). This column is optional.
tablescope	$200	The value specifies the domains to be validated by the check. The domains must exist in either or both of the reference metadata or source metadata. The value can be in the form: _ALL_-DM-DS: Multiple domains that exclude one or more specific domains that are delimited with a -. DM: Any single domain; can be specified as libref.domain. DM+AE: Multiple domains delimited with a +. _ALL_: Multiple DM domains that exclude specific domains delimited with a -. SUPP**: Wildcard to include multiple domains. CLASS:EVENTS: All domains capturing event results. (This syntax specifies to use table metadata column CLASS for EVENTS as the value-similar syntax for all other fields and values.) [_ALL_-DM][DM]: Bracket syntax to define sublists for comparative purposes. In this example, all non-DM domains are compared with the DM domain. See the Validation Master data set for a full set of values. This column is required.

Column Name	Column Length	Description
columnscope	$200	The value specifies one or more space-delimited columns identified for inclusion or exclusion in the specified check. The value can be in the form: _ALL_: All columns (equivalent to ** or a null value). _NA_: Not applicable (that is, domain-level check). AGE: Any single column. This value can be specified as libref.domain.column or domain.column. ARM+ARMCD: Multiple columns delimited with a +. **BLFL-LBBLFL: Multiple columns that exclude specific columns delimited with a -. **DTC: Wildcard to include multiple columns with ** representing the domain name. xxx**: (For example, AE**, where ** is a column wildcard). [**STDTC][**ENDTC]: Bracket syntax to define sublists for comparative purposes. In this example, all start dates are compared with all end dates. The number of columns in each sublist must be equivalent. See the Validation Master data set for a full set of values. This column is optional. (If null, the value is equivalent to _ALL_.)

Column Name	Column Length	Description

codelogic	$2000	Check-specific code segment that is inserted into the check macro defined in codesource and consistent with codetype. The codelogic value enables check-level customization and allows the reuse of more general check macros. The field length of $2000 limits the code to short code segments, although referencing another macro or using `%include` expands this capability. The codelogic value can use global and local macro variables (for example, variables provided as macro input parameters and variables set within the calling code). Examples include:
		`If ( . < &_cstColumn1 <`
		`&_cstColumn2), then _cstError=1;`
		`%include <fileref>`
		`/* where <fileref> can be set outside of the SAS Clinical Standards Toolkit`
		`or in the SASReferences control data set */`
		The previous code is limited to filerefs set outside of the SAS Clinical Standards Toolkit or in the SASReferences control data set.
		`%sdtmcheckutil_recordlookup`
		`data _cstProblems;`
		`set&_cstDSName;`
		`if <`*`some condition`*`>;`
		`run;`
		This column is optional.

Column Name	Column Length	Description
codetype	8.	This value defines whether to use codelogic and what type of codelogic can be used in the validation code. Values include: 0: No codelogic used. 1: DATA step statement level. (For example, if &_cstColumn <0 then _cstError=1.) 2: Full DATA step, PROC SQL step, or multiple steps. 3: Calls a SAS macro or `%include` that can contain only DATA step statement level code. (For example, codetype=1.) 4: Calls a SAS macro or `%include` that can contain only full DATA step or PROC SQL step code. (For example, codetype=2.) This column is required.
lookuptype	$20	This value defines the type of information to use for value comparison to some standard. Values include: Metadata: Use the SAS Clinical Standards Toolkit metadata. Specifically, use the value of the column metadata field xmlcodelist to identify the codelist (rendered as a SAS format). Format: Use a SAS format from the SAS format search path. Dataset: Use a reference SAS data set (for example, medDRA). There are no SAS Clinical Standards Toolkit requirements for the structure and content of the reference SAS data set. <extensible>: Other user-defined values can be used if there are explicitly referenced in user-written code. This column in optional.

Column Name	Column Length	Description
lookupsource	$32	The specific SAS format or file associated with lookuptype. For example: If lookuptype is metadata, then lookupsource should be blank. The code gets the value from the source_columns.xmlcodelist field. If lookuptype is format, then lookupsource should be the SAS format and must be in the format search path if it is specified. This value should generally match any value in source_columns.xmlcodelist for the columns specified in columnscope. This field allows a run-time validation check against another format. If lookuptype is Dataset, then lookupsource should be the name of a SAS data set. This value is specified as the data set name (for example, meddra) or libref.dataset. If a value is provided without a libref, then the SAS Clinical Standards Toolkit looks for any SASReferences type=referencecterm records for the sasref value. This column is optional.
standardref	$200	Any reference to an associated standard definition, implementation guide, schema, and so on, that provides additional information about the check or describes the basis for the check in greater detail. This column is optional.
reportingcolumns	$200	This value includes columns not included in columnscope for code-processing purposes and to help resolve errors. If this value is specified, then it should be a space-delimited list of columns in the domains specified in the tablescope field. The values of these columns can be reported in the Results data set. This column is optional.

Column Name	Column Length	Description
checkstatus	8.	This value determines whether the check is ready to be used and included in any Validation Control run-time data set. If the check is ready, then the value should be set to any positive integer. Values include: 0: (inactive, default) >0: (active) -1: (deprecated, archived) -2: (not implemented in this SAS Clinical Standards Toolkit release) This column is optional, although it is expected.
reportall	$1	This value enables more concise reporting of errors. Values include: Y: (yes, report all records, default) N: (no) This column is required although not all check macro modules support abbreviated (N) reporting.

Column Name	Column Length	Description
uniqueid	$48	This value provides a unique ID for the check. It ensures uniqueness in the data set and in the SAS Clinical Standards Toolkit. This value allows any provided or derived check to be uniquely identifiable over time. An example is SDTM000401CST160SDTM3202014-01-07T16:03:51CST. Legend: characters 1-8: checkid characters 9-10: checkid repeat indicator (00 unless multiple invocations of checkid are included) characters 11-16: the version of the SAS Clinical Standards Toolkit where the check metadata was last materially modified characters 17-23: standard version characters 24-42: implementation datetime of the last metadata update characters 43-48: assigning authority This column is optional, although it is expected.
comment	$200	Any character string that provides comments relevant to the check. This column is optional.

The content of the Validation Master data set is based on a combination of compliance requirements and the SAS representation of the standard.

The following table describes a sample Validation Master data set record for the CDISC SDTM 3.1.3 standard:

Table 7.4 *Sample CDISC SDTM 3.1.3 Validation Master Data Set Record*

Column Name	Column Value	Comment
checkid	SDTM0860	The SAS Clinical Standards Toolkit check identifier used in validation results and reports.

Column Name	Column Value	Comment
standard	CDISC-SDTM	The registered standard.
standardversion	3.1.2	The standard version. A value of *** indicates that the check is applicable to all versions of the standard. 3.1.2 indicates it is applicable for all SDTM versions 3.1.2 and later.
checksource	WebSDM	This check originated as a WebSDM check.
sourceid	R5132	WebSDM check R5132.
checkseverity	Warning	
checktype	Column	
codesource	cstcheck_column	This check uses the %CSTCHECK_COLUMN check macro in the SAS Clinical Standards Toolkit autocall library.
usesourcemetadata	Y	This check is run on source data domains.
tablescope	RELREC	This check is run on the RELREC domain.
columnscope	RELTYPE	This check evaluates only the RELTYPE column values.
codelogic	`if (upcase(&_cstColumn) not in ("","ONE","MANY")) then _cstError=1;`	This logic is used in cstcheck_column. Errors are documented in a work._cstproblems data set.
codetype	1	This code logic is used in the DATA step.

Column Name	Column Value	Comment
lookuptype		
lookupsource		
standardref		
reportingcolumns		
checkstatus	1	
reportall	Y	This check reports all errors that are identified.
uniqueid	SDTM086001CST150SDTM3 122012-06-08T10:49:21CST	
comment		

The Validation Master data set contains all validation checks for a standard, whereas the Validation Control data set is the run-time equivalent and contains just the validation checks to be run in a validation process. The Validation Control data set is structurally equivalent to the Validation Master data set. For additional information about how the validation check metadata in the Validation Control data set is used in the SAS Clinical Standards Toolkit validation processes, see "Special Topic: How the SAS Clinical Standards Toolkit Interprets Validation Check Metadata" on page 236.

Supplemental Validation Check Metadata: Validation Standard References

The validation standard references data set contains additional information about each of the checks in the Validation Master data set. This data set is used in the validation metadata reporting process to provide additional information to you about the origin of the check. It also provides any supporting documentation about the check. By default, this data set is deployed to this directory in each supported standard:

***global standards library directory*/standards/<*standard*>/ validation/control**

***Table 7.5** Column Descriptions of the Validation_StdRef Data Set*

Column Name	Column Length	Description
checkid	$8	The validation check ID, as specified in the Validation Master data set. (See Table 7.3 on page 174.)
standard	$20	This value captures the standard name. This value must match the standard in the associated Validation Master data set. This column is required.
standardversion	$20	This value captures a specific version of a standard. This value should be the version for which the supplemental reference information is applicable. This column is required.
informationsource	$80	This value captures the origin of the reference information. The value can be an implementation guide, website, harmonization document, and so on. It can be any source that can be referenced that provides insight into the check.
sourcelocation	$200	This value contains the location in the information source, such as a page number or a section number.
seqno	8.	This value provides a sequence number for checkid if multiple sources of information are available for a check. This column is required.
sourcetext	$2000	This value captures descriptive information from the source that supports the check. This information attempts to provide a basis for inclusion of the check.

The content of the Validation_StdRef data set is based on information from any source that supports the check.

The following table describes information about a specific check in the Validation_StdRef data set (record 1) for the CDISC SDTM 3.1.3 standard:

Table 7.6 *Sample CDISC SDTM 3.1.3 Validation_StdRef Data Set for Check SDTM0860 — Record 1*

Column Name	Column Value	Comment
checkid	SDTM0860	The SAS Clinical Standards Toolkit check identifier used in results and reports.
standard	CDISC-SDTM	The registered standard.
standardversion	3.1.2	The standard version.
informationsource	*SDTM 3.1.2 Implementation Guide*	This reference information originated from the *SDTM 3.1.2 Implementation Guide*.
sourcelocation	3.2.2, page 20	Section 3.2.2, page 20 of the *SDTM 3.1.2 Implementation Guide*.
seqno	1	The first record for this checkid.
sourcetext	Conformance with the SDTMIG Domain Models is minimally indicated by: Following SDTM-specified controlled terminology and format guidelines for variables, when provided	The text of the information retrieved from section 3.2.2, page 20 of the *SDTM 3.1.2 Implementation Guide*.

The following table describes information about a specific check in the Validation_StdRef data set (record 2) for the CDISC SDTM 3.1.3 standard:

Table 7.7 *Sample CDISC SDTM 3.1.3 Validation_StdRef Data Set for Check SDTM0860 — Record 2*

Column Name	Column Value	Comment
checkid	SDTM0860	The SAS Clinical Standards Toolkit check identifier used in results and reports.
standard	CDISC-SDTM	The registered standard.
standardversion	3.1.2	The standard version.
informationsource	*SDTM 3.1.2 Implementation Guide*	This reference information originated from the *SDTM 3.1.2 Implementation Guide*.
sourcelocation	Convention	Section 6.3.7, page 153 of the *SDTM 3.1.2 Implementation Guide*.
seqno	2	The second record for this checkid.
sourcetext	[RELTYPE] Controlled Terms, Codelist or Format: ONE, MANY	The text of the information retrieved from section 6.3.7, page 153 of the *SDTM 3.1.2 Implementation Guide*.

Supplemental Validation Check Metadata: CDISC SDTM Domains by Check

The SAS Clinical Standards Toolkit validation metadata, as specified in the Validation Master data set, uses the tablescope and columnscope columns to define the scope of the check. The scope being what domains (tables) and what columns to validate when the check is run. The SAS Clinical Standards Toolkit uses a shorthand syntax in these columns that is interpreted by the SAS Clinical Standards Toolkit framework macros to build a list of target tables and columns. For more information, see "Special Topic: How the SAS Clinical Standards Toolkit Interprets Validation Check Metadata" on page 236. The Validation_DomainsByCheck data set is located here:

***global standards library directory*/standards/cdisc-sdtm-3.1.*x*/ validation/control**

It contains records for each domain to be validated by each check in the Validation Master data set. This data set is used by reporting tools that are provided with the SAS Clinical Standards Toolkit to report domain-specific errors. For more information, see Chapter 11, "Reporting," on page 443. It is also available to other programs and applications that might need to subset checks that are applicable to specific domains.

The SDTM version of the Validation_DomainsByCheck data set that is provided by SAS is built from the version of the Validation Master data set that is also provided by SAS. If the tableScope and columnScope columns are modified, then the Validation_DomainsByCheck data set must also be modified or rebuilt.

Table 7.8 *Column Descriptions of the Validation_DomainsByCheck Data Set*

Column Name	Column Length	Description
checkid	$8	The validation check ID, as specified in the Validation Master data set. (See Table 7.3 on page 174.)
table	$32	This value captures the domain or table name. This column is required.
standardversion	$20	This value captures a specific version of a standard. This value must match standardversion in the associated Validation Master data set.
checksource	$40	A string that identifies the source of the check. This value must match checksource in the associated Validation Master data set.
resultseq	8.	The unique invocation of a check within the Validation Master data set. This value is incremented if multiple record or domain combinations exist.

For CDISC SDTM 3.1.3 validation check SDTM0860, the Validation_DomainsByCheck data set contains a record only for the RELREC domain because the tableScope for this check is only RELREC. However, the SDTM0606 check looks for non-numeric values in all tables (tableScope=_ALL_). Based on the sample study provided by SAS, 36 records (domains) are included in the Validation_DomainsByCheck data set for SDTM0606.

Supplemental Validation Check Metadata: CDISC ADaM Class by Check

For CDISC ADaM, the supplemental data set is called Validation_ClassByCheck. It is located here:***global standards library directory*/standards/cdisc-adam-2.1-1.7/validation/control**.

This data set is patterned after the data set that is described in Table 7.8 on page 188. However, the column class ($40, Observation Class within Standard) has been added. This addition accommodates the different way that the ADaM reference standard is defined. For example, the reference_tables data set, located in **/standards/cdisc-adam-2.1-1.7/metadata**, includes a BDS record that serves as a class template for all specific implementations of BDS that are required for a study. The SAS Clinical Standards Toolkit does not know each of the specific analysis data sets, so the Validation_ClassByCheck data set includes records by class, not by domain, for each check in the ADaM Validation Master data set.

Validation.Properties

Properties specific to validation processes are provided with the SAS Clinical Standards Toolkit. These properties enable you to specify how validation checks are to be processed and whether metrics are to be reported.

As with all SAS Clinical Standards Toolkit properties files, a call to the %CST_SETPROPERTIES macro is required to translate the properties into SAS global macro variables. This call can be explicitly made as a driver program setup task, or it can be made by including the Validation.Properties file as a record in the SASReferences data set. For all standards that support validation, the Validation.Properties file is required, even if no metrics are wanted because the SAS

Clinical Standards Toolkit validation process does expect, and uses, the metrics global macro variables.

The following table describes the properties in the Validation.Properties file:

Table 7.9 Properties in the Validation.Properties File

Property Name	Description
_cstCheckSortOrder	This property determines the order in which validation checks are processed. If no value is provided, or the default value _DATA_ is used, then the data set order is assumed. Or, _cstCheckSortOrder can be set to sort the Validation Control data set at run time by any fields in that data set (for example, CHECKSOURCE CHECKID).
_cstMetrics	This property determines whether to calculate and report metrics. An example value is 1=Yes.
_cstMetricsDS	This property sets the SAS data set name to use to accumulate metrics during the process. The default value is work._cstmetrics.
_cstMetricsNumSubj _cstMetricsCntNumSubj	This property determines whether to calculate and report subject-level counts. An example value is 1=Yes, initialize _cstMetricsCntNumSubj to 0. The calculation of subject-level counts might not be appropriate for all check macros.
_cstMetricsNumRecs _cstMetricsCntNumRecs	This property determines whether to calculate and report record-level counts. An example value is 1=Yes, initialize cstMetricsCntNumRecs to 0.
_cstMetricsNumChecks _cstMetricsCntNumChecks	This property determines whether to summarize and report the number of checks run. An example value is 1=Yes, initialize cstMetricsCntNumChecks to 0.
_cstMetricsNumBadChecks _cstMetricsCntNumBadChecks	This property determines whether to summarize and report the number of check invocations that failed. An example is 1=Yes, initialize cstMetricsCntNumBadChecks to 0.

Property Name	Description
_cstMetricsNumErrors _cstMetricsCntNumErrors	This property determines whether to summarize and report the total number of errors (resultseverity=Error) found. An example is 1=Yes, initialize cstMetricsCntNumErrors to 0.
_cstMetricsNumWarnings _cstMetricsCntNumWarnings	This property determines whether to summarize and report the total number of warnings (resultseverity=Warning) found. An example is 1=Yes, initialize cstMetricsCntNumWarnings to 0.
_cstMetricsNumNotes _cstMetricsCntNumNotes	This property determines whether to summarize and report the total number of notes (resultseverity=Note) found. An example value is 1=Yes, initialize cstMetricsCntNumNotes to 0.
_cstMetricsNumStructural _cstMetricsCntNumStructural	This property determines whether to summarize and report the total number of structural (metadata) errors found. An example value is 1=Yes, initialize cstMetricsCntNumStructural to 0.
_cstMetricsNumContent _cstMetricsCntNumContent	This property determines whether to summarize and report the total number of content (data) errors found. An example value is 1=Yes, initialize cstMetricsCntNumContent to 0.
_cstMetricsTimer	This property determines whether to report the elapsed time for each check invocation. An example value is 1=Yes.

By default, for all standards that support validation, Validation.Properties is located here:

***global standards library directory*/standards/*<standard>*/programs**

Properties can logically be associated with each study. Using the CDISC SDTM 3.1.3 sample study provided with the SAS Clinical Standards Toolkit as an example, a study-specific instance of the Validation.Properties file is located here: ***sample study library directory*/cdisc-sdtm-3.1.3-1.7**.

Messages

Each SAS Clinical Standards Toolkit registered standard that supports validation has a Validation Master data set, and an associated Messages data set. The Validation Master data set provides the super-set of checks defined for that standard. The Messages data set provides messages to be generated during the execution of each validation process. A distinct Messages data set record is expected for each set of checkid and checksource values in the Validation Master data set. Messages can be parameterized and internationalized.

By default, the standard-specific Messages data set is deployed to this directory in each supported standard:

***global standards library directory*/standards/*<standard>*/messages**

All Messages data sets in the SAS Clinical Standards Toolkit should have the same structure. The structure is defined in Chapter 3, "Metadata File Descriptions," on page 33.

During a process, the SAS Clinical Standards Toolkit appends any standard-specific messages that are required by the process to any generic SAS Clinical Standards Toolkit framework messages that are available to all processes. This appended Messages data set follows the naming convention that is defined within the global macro variable _cstMessages.

Validation Metrics

Generating the SAS Clinical Standards Toolkit validation metrics provides a meaningful denominator for most validation checks. This enables you to more accurately assess the relative scope of errors that are detected. Generally, the calculated denominator is a count of the number of records processed in a domain.

This code segment, which is extracted from a validation check macro, shows a typical calculation of the number of records in a domain. It also shows the macro call to add the count to the Validation Metrics data set:

```
data _null_;
if 0 then set &_cstDSName nobs=_numobs;
```

```
call symputx('_cstMetricsCntNumRecs',_numobs);
stop;
run;

* Write applicable metrics *;
%if &_cstMetrics %then %do;
%if &_cstMetricsNumRecs %then
   %cstutil_writemetric(
     _cstMetricParameter=# of records tested,
     _cstResultID=&_cstCheckID,
     _cstResultSeqParm=&_cstResultSeq,
     _cstMetricCnt=&_cstMetricsCntNumRecs,
     _cstSrcDataParm=&_cstDSname
   );
%end;
```

Because a check can evaluate multiple columns in a domain, the count will be greater. In addition, a metadata-level check that does not access the domain data directly might report the number of metadata records instead.

Metrics processing is enabled based on settings in the Validation.Properties file. See Table 7.9 on page 190.

The following table provides a description of the Validation Metrics data set, including the meaning of each field:

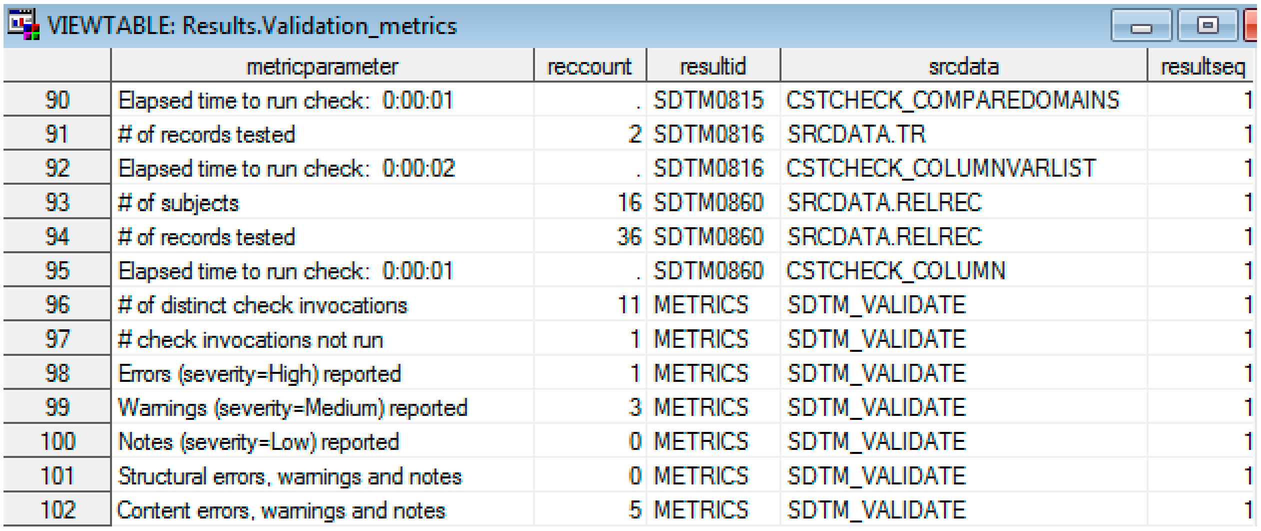
Table 7.10 Column Descriptions of the Validation Metrics Data Set

Column Name	Column Length	Description
metricparameter	$40	A descriptive text string that specifies the metric of interest. This string is hardcoded in the check macro and cannot be modified without code changes. Values should be non-null.
reccount	8.	A count of the number of records specific to the combination of metricparameter and resultid. This number is derived in the check macro and cannot be modified without code changes. This column can contain a summary count of records written to the Results data set (resultid=METRICS). Reccount can be null for selected metricparameters, such as the assessment of elapsed time for each check.

Column Name	Column Length	Description
resultid	$8	The resultid is either the checkid or a hardcoded constant such as METRICS. The SAS Clinical Standards Toolkit has adopted a naming convention matching each standard. The checkid (resultid) values are prefixed with an up to 4-character prefix (CST for framework messaging; CDISC examples: ODM, SDTM, ADAM, and CRT). By convention, the prefix matches the mnemonic field in the Standards data set in ***global standards library directory*/metadata**. This prefix is followed by a 4-digit numeric that is unique within the standard (for example, SDTM1234). You can use any naming convention limited to eight characters. Values should be non-null.
srcdata	$200	The string that specifies the domain or check macro to which the metricparameter applies. Values should be non-null.
resultseq	8.	A counter that indicates the record number in checkid in the Validation Control run-time set of checks. If set to 1, then this counter is incremented only with each repeat invocation of a check. This value enables you to link to the Validation Control and Results data sets. Values should be non-null.

The following display shows the Validation Metrics output from a SAS Clinical Standards Toolkit validation process running CDISC SDTM validation. The Validation Control data set contains 11 validation checks.

Figure 7.2 *Sample Validation Metrics Data Set*



VIEWTABLE: Results.Validation_metrics

	metricparameter	reccount	resultid	srcdata	resultseq
90	Elapsed time to run check: 0:00:01	.	SDTM0815	CSTCHECK_COMPAREDOMAINS	1
91	# of records tested	2	SDTM0816	SRCDATA.TR	1
92	Elapsed time to run check: 0:00:02	.	SDTM0816	CSTCHECK_COLUMNVARLIST	1
93	# of subjects	16	SDTM0860	SRCDATA.RELREC	1
94	# of records tested	36	SDTM0860	SRCDATA.RELREC	1
95	Elapsed time to run check: 0:00:01	.	SDTM0860	CSTCHECK_COLUMN	1
96	# of distinct check invocations	11	METRICS	SDTM_VALIDATE	1
97	# check invocations not run	1	METRICS	SDTM_VALIDATE	1
98	Errors (severity=High) reported	1	METRICS	SDTM_VALIDATE	1
99	Warnings (severity=Medium) reported	3	METRICS	SDTM_VALIDATE	1
100	Notes (severity=Low) reported	0	METRICS	SDTM_VALIDATE	1
101	Structural errors, warnings and notes	0	METRICS	SDTM_VALIDATE	1
102	Content errors, warnings and notes	5	METRICS	SDTM_VALIDATE	1

The missing reccount value in line 90 and the absence of other metrics for SDTM0815 indicate that the check was not run. (SDTM0815 evaluates the value of the POOLID column, which is not used in any non-POOLDEF domain in the sample study provided by SAS.) This should be reported in the Results data set.

Lines 93 through 95 report metrics on the SDTM0860 validation check. Two problems are reported in the Results data set for a single subject, and these metrics (16 subjects and 36 records tested) provide denominator information to assess how common the problems are.

Lines 96 through 102 are summary metrics reported at the end of the SDTM validation process in the %SDTM_VALIDATE macro. The following five problems are noted:

- one check (SDTM0815) could not be run
- two of the three warnings were for SDTM0860
- one other warning and one error condition were found

The Validation Results and Validation Metrics data sets, when used in tandem, provide a more complete picture of each compliance assessment.

For more information about the Validation Metrics data set, see Table 7.10 on page 193.

Cross-Standard Validation

Overview

The implementation of the ADaM 2.1 standard in the SAS Clinical Standards Toolkit requires the use of a number of cross-standard validation checks. These cross-standard validation checks compare data and metadata between two different standards, such as ADaM 2.1 and SDTM 3.1.2.

The SAS Clinical Standards Toolkit provides two macros that enable cross-standard comparisons: cstcheck_crossstdcomparedomains.sas and cstcheck_crossstdmetamismatch.sas. These macros are located here: **`!sasroot/cstframework/sasmacro`**.

The %CSTCHECK_CROSSSTDCOMPAREDOMAINS Macro

The %CSTCHECK_CROSSSTDCOMPAREDOMAINS macro compares values for one or more columns in one table with those same columns in another domain in another standard. Or, it compares the values against metadata from the comparison standard. The macro requires use of _cstCodeLogic as a full DATA step or PROC SQL invocation. This DATA or SQL step assumes as input a work copy of the column metadata data set returned by the %CSTUTIL_BUILDCOLLIST macro. Any resulting records in the derived data set represent errors to be reported.

Here are example validation checks that use the %CSTCHECK_CROSSSTDCOMPAREDOMAINS macro:

- ADaM subject not found in the SDTM DM domain

- ADaM SDTM domain reference (for traceability), but the SDTM domain is unknown

An ADaM 2.1 validation check that uses this macro is ADAM0653. Here is the rule description for this check:

“Specified record not found in SDTM for this subject.”

Here is the message text for this check:

`Corresponding SDTM record not found based on STUDYID, USUBJID and AESEQ`

Here is sample code from the codelogic field from the ADaM 2.1 Validation Master data set for validation check ADAM0653. In this example, &_cstDSName (ADaM data set name) and &_cstCrossDataLib (SDTM library) are generated by the macro prior to execution of codelogic.

```
%let _cstCheckVar=AETERM;
    proc sql noprint;
      create table work._cstproblems as
      select adam.studyid, adam.usubjid, adam.aeseq, adam.&_cstCheckVar
      from &_cstDSName as adam
         left join
           &_cstCrossDataLib..ae as sdtm
         on adam.studyid=sdtm.studyid and adam.usubjid=sdtm.usubjid and
            adam.aeseq=sdtm.aeseq
      where adam.&_cstCheckVar ne sdtm.&_cstCheckVar
    quit;
```

The %CSTCHECK_CROSSSTDMETAMISMATCH Macro

The %CSTCHECK_CROSSSTDMETAMISMATCH macro identifies inconsistencies in metadata across registered standards. The macro requires use of _cstCodeLogic as a full DATA step or PROC SQL invocation. This DATA step or SQL step assumes as input a work copy of the column metadata data set returned by the %CSTUTIL_BUILDCOLLIST macro. Any resulting records in the derived data set represent errors to be reported.

Assumptions:

1. No data content is accessed for this check.
2. Both study and reference metadata are available to assess compliance.
3. The _cstProblems data set includes at least two columns. The mnemonics are from the global standards library data set:
   - &_cstStMnemonic._value (for example, ADAM_value containing the value of the column of interest from the primary standard)
   - &_cstCrMnemonic._value (for example, SDTM_value containing the value of the column of interest from the comparison standard)

Required global macro variables:

- _cstcrossstd: The name of the comparison standard. It is also used as a parameter to initialize _cstCrMnemonic.
- _cstcrossstdver: The version of the comparison standard.
- _cstrunstd: The primary standard. It is also used as a parameter to initialize _cstStMnemonic.
- _cstrunstdver: The version of the primary standard.

An ADaM 2.1 validation check that uses this macro is ADAM0651. Here is the rule description for this check, taken from the CDISC ADaM Validation document:

“ADaM column with a column name prefix of 'AE' not found in SDTM”

Here is the message text for this check:

```
ADaM column name starting with AE found having no like-named SDTM
column
```

The full codeLogic PROC SQL step for ADAM0653 is located here:

global standards library
directory

```
/standards/cdisc-adam-2.1-1.7/validation/control/validation_
master.sas7bdat
```

Building a Validation Process

Overview

Building a SAS Clinical Standards Toolkit validation process is similar to building any SAS Clinical Standards Toolkit process. The differences are the validation process inputs and outputs, as defined in the SASReferences data set, can differ, a standard-specific validate macro is called, and process output can include an optional Metrics data set.

This table shows the standard-specific validation macros for all SAS Clinical Standards Toolkit standards that support validation.

Table 7.11 Standard-Specific Validation Macros for Standards Supporting Validation

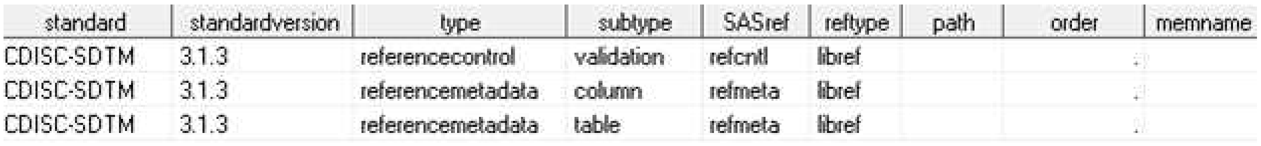
Standard and Version	Validation Macro
CDISC-ADAM 2.1	adam_validate
CDISC-CRTDDS 1.0	crtdds_validate
CDISC-CT 1.0.0	ct_validate
CDISC-ODM (all)	odm_validate
CDISC-SDTM (all)	sdtm_validate
CST-FRAMEWORK 1.2	cstvalidate

The remainder of this section uses SDTM 3.1.3 as an example.

SASReferences Customizations

A SAS Clinical Standards Toolkit validation process requires that you specify a reference standard with which the source data and metadata can be compared. The following display shows the three records, specific to the standard and standardversion of interest, that should be included in the SASReferences data set:

Figure 7.3 *Defining the Reference Standard in the SASReferences Data Set*



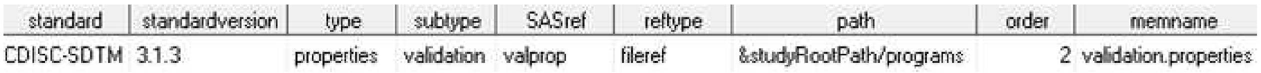
standard	standardversion	type	subtype	SASref	reftype	path	order	memname
CDISC-SDTM	3.1.3	referencecontrol	validation	refcntl	libref		.	
CDISC-SDTM	3.1.3	referencemetadata	column	refmeta	libref		.	
CDISC-SDTM	3.1.3	referencemetadata	table	refmeta	libref		.	

The empty **path** field signals that the path and memname information should be derived from the StandardSASReferences data set associated with the standard and standardversion. Including the referencecontrol and referencemetadata records is unique to validation process in the SAS Clinical Standards Toolkit.

The SAS Clinical Standards Toolkit validation can include references to these files:

1 A validation-specific properties file.

Figure 7.4 *Defining the Validation-Specific Properties File in the SASReferences Data Set*



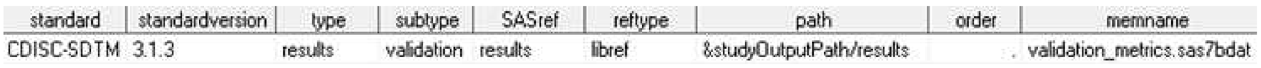
standard	standardversion	type	subtype	SASref	reftype	path	order	memname
CDISC-SDTM	3.1.3	properties	validation	valprop	fileref	&studyRootPath/programs	2	validation.properties

The Validation.Properties file sets process global macro variables specific to validation, such as metrics. For a complete discussion of these properties, see "Validation.Properties" on page 189. For information about the derived global macro variables, see Appendix 1, "Global Macro Variables," on page 459. The Validation.Properties file is a required file to support the SAS Clinical Standards Toolkit validation.

Validation properties do not need to be separately referenced in SASReferences.

2 The output location of any process-generated Metrics data set.

Figure 7.5 *Defining the Metrics Output Location in the SASReferences Data Set*

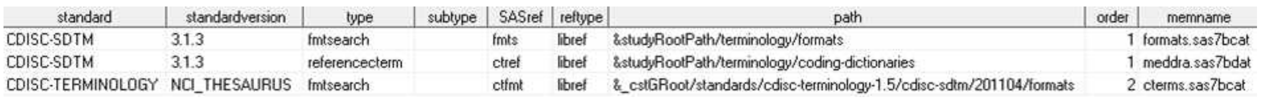


standard	standardversion	type	subtype	SASref	reftype	path	order	memname
CDISC-SDTM	3.1.3	results	validation	results	libref	&studyOutputPath/results	.	validation_metrics.sas7bdat

The Metrics data set provides a summary of the validation process, including error counts, processing time, and denominators for specific checks. For a complete discussion of validation metrics, see "Validation Metrics" on page 192 and "Validation Results and Metrics" on page 212. For information about the global macro variables that govern metrics output, see Appendix 1, "Global Macro Variables," on page 459. The Metrics data set is typically output to the same location as the validation Results data set. This location is common to all SAS Clinical Standards Toolkit processes.

3 The location of any libraries containing controlled terminology, format catalogs, and coding dictionary data sets.

Figure 7.6 *Defining the Location of Controlled Terminology in the SASReferences Data Set*

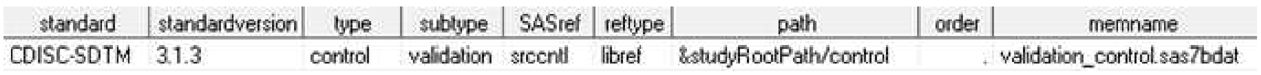


standard	standardversion	type	subtype	SASref	reftype	path	order	memname
CDISC-SDTM	3.1.3	fmtsearch		fmts	libref	&studyRootPath/terminology/formats	1	formats.sas7bcat
CDISC-SDTM	3.1.3	referencecterm		ctref	libref	&studyRootPath/terminology/coding-dictionaries	1	meddra.sas7bdat
CDISC-TERMINOLOGY	NCI_THESAURUS	fmtsearch		ctfmt	libref	&_cstGRoot/standards/cdisc-terminology-1.5/cdisc-sdtm/201104/formats	2	cterms.sas7bcat

The type=fmtsearch records enable you to specify multiple format catalogs (for example, company-wide, compound, group-level, and study-level). Order in the format search path is set by the **order** field. The type=referencecterm record enables you to specify one or more lookup data sets (such as dictionary lookups like LOINC and MedDRA). These lookup data sets do not need to conform to a specific structure, and they do not need to be in a structure that can be read into a SAS format. Customized code (typically in the Validation Master **codelogic** field) is required to join domain data with each associated lookup data set.

4 The location of the run-time Validation Control data set.

Figure 7.7 *Defining the Run-Time Validation Control Location in the SASReferences Data Set*



standard	standardversion	type	subtype	SASref	reftype	path	order	memname
CDISC-SDTM	3.1.3	control	validation	srccntl	libref	&studyRootPath/control	.	validation_control.sas7bdat

The Validation Control data set is required and discussed in the following section.

Validation Control: Specification of Run-Time Checks

Each SAS Clinical Standards Toolkit validation process requires you to specify the validation checks to be run. This is accomplished by cloning, subsetting, or building a set of validation checks based on the Validation Master data set. (See "Validation Check Metadata: Validation Master" on page 173.) The SAS Clinical Standards Toolkit assumes that each Validation Control data set is structurally equivalent to the Validation Master data set.

A sample CDISC SDTM 3.1.3 Validation Control data set is deployed to this directory:

***sample study library directory*/cdisc-sdtm-3.1.3–1.7/ sascstdemodata/control**

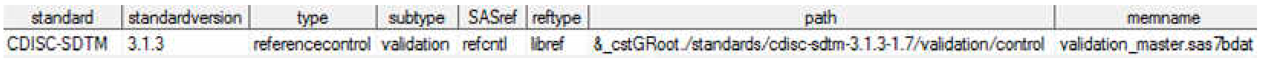
By default, the Validation Control data set name is validation_control.sas7bdat.

As a required input to a validation process, the Validation Control data set must be referenced in the run-time SASReferences file. (See Figure 7.7 on page 201.)

The &studyRootPath value is assumed to have been set to ***sample study library directory*/cdisc-sdtm-3.1.3/sascstdemodata**.

The Validation Master data set (illustrated in Figure 7.3 on page 200 and in this display) serves as the source for Validation Control content. Note that in this display, the **path** and **memname** information have been derived from the StandardSASReferences data set and points to the global standards library.

Figure 7.8 Defining Validation Control Data Set Location



standard	standardversion	type	subtype	SASref	reftype	path	memname
CDISC-SDTM	3.1.3	referencecontrol	validation	refcntl	libref	&_cstGRoot./standards/cdisc-sdtm-3.1.3-1.7/validation/control	validation_master.sas7bdat

The following table provides examples of how to create a Validation Control data set from the Validation Master data set. The sample code is written assuming that the code will be submitted in a context where libraries have been allocated and the format search and autocall paths have been set.

Table 7.12 Sample Code to Create Validation Control Data Set

Check Subset	Sample Code
All checks provided with the SAS Clinical Standards Toolkit.	`data control.validation_control;` `set refcntl.validation_master;` `run;`
Structural checks (metadata-only checks that do not require access to the domain data).	`data control.validation_control;` `set refcntl.validation_master (where=(upcase(checktype)="METADATA"));run;`
Content checks (checks that require access to the domain data).	`data control.validation_control;` `set refcntl.validation_master (where=(upcase(checktype) ne "METADATA"));` `run;`
Checks with a production status.	`data control.validation_control;` `set refcntl.validation_master (where=(checkstatus>0));` `run;`

Check Subset	Sample Code

Sampling of checks, one for each check macro.	`proc sort data=refcntl.validation_master out=work.control;`
	`by codesource checkid;`
	`run;`
	`data work.control;`
	`set work.control;`
	`by codesource;`
	`if first.codesource;`
	`run;`
	`proc sort data=work.control out=control.validation_control (label="Check sampler");`
	`by checkid;`
	`run;`

Checks new to CDISC SDTM 3.1.3.	`data control.validation_control;`
	`set refcntl.validation_master (where=(standardVersion = "3.1.3"));`
	`run;`

All codelist-related checks (checks that use the %CSTCHECK_NOTINCODELIST macro).	`data control.validation_control;`
	`set refcntl.validation_master (where=(upcase(checksource)="CSTCHECK_NOTINCODELIST"));`
	`run;`

Generally, the SAS Clinical Standards Toolkit processes validation checks in the order in which they appear in the Validation Control data set. Each validation process honors the default validation property _cstCheckSortOrder. If this property is not set, then the data set order is assumed. As a part of the Validation Control derivation, checks can be sorted in any user-defined order. Or, _cstCheckSortOrder can be set to sort the Validation Control data set at run time by any fields in that data set.

TIP Best Practice Recommendation: You might find the prioritization of checks to be helpful in identifying problems early in the process, or for using as prerequisites for checks that follow.

Setting Properties for the Validation Process

Across all standards, the set of properties that are available for a validation process is extensive. (For more information about the full set of validation properties, see Appendix 1, "Global Macro Variables," on page 459.) However, only a few properties are modified on a regular basis. These include:

- _cstSASRefsLoc, If you want to point to another location for the SASReferences file.
- _cstSASRefsName, which points to another SASReferences filename.
- _cstSASRefs, which points to a specific libref.sasreferences file to use. (This file is typically in Work.)
- _cstSubjectColumns, which provides a space-delimited list of the columns that identify a subject.
- _cstReallocateSASRefs, which reallocates SAS librefs and filerefs in the same SAS session, which is important when changing studies or standards.
- _cstFMTLibraries, which modifies the format search path built from SASReferences. This change is most often used to add a reference to a Work format catalog.
- _cstCheckSortOrder, which provides a set of Validation Control columns to re-sort the check processing order.
- _cstMetrics, set to 1 to enable metrics calculations and reporting.
- _cstDebug, which turns on or off debugging for the session.
- _cstDebugOptions, which alters the SAS options when debugging.

These changes should be made before the process setup begins (as changes to the properties file), or after the process setup ends (as a series of `%let` statements in the code stream).

TIP Best Practice Recommendation: Centralizing property changes in properties files, rather than distributing them in code segments, offers advantages for debugging and documenting processes. Properties are translated to global macro variables by calls to the %CST_SETSTANDARDPROPERTIES or %CST_SETPROPERTIES framework utility macros during process setup. They are reported in the SAS log, and are generally documented in the process SASReferences file.

Running a Validation Process

Sample CDISC SDTM 3.1.3 Driver Program: validate_data.sas

Overview

Each SAS Clinical Standards Toolkit process uses a SAS driver program to set up the program execution flow. The following steps show the execution flow in a typical SAS driver program to perform the SAS Clinical Standards Toolkit validation. For example, the CDISC SDTM 3.1.3 validation driver program is here: ***sample study library directory*/cdisc-sdtm-3.1.3-1.7**.

Step 1: Define macro variables required by the validation process.

```
%let _cstStandard=CDISC-SDTM;
%let _cstStandardVersion=3.1.3;
%let _cstVersion=;
%let _cstCTPath=;
%let _cstCTMemname=;
%let _cstCTDescription=;
```

These macro variables are used as substitution parameters later in the driver program to reduce the number of code changes required.

```
%cst_setStandardProperties(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);
```

Initialize the minimum set of global macro variables used to run any SAS Clinical Standards Toolkit process. This includes the names of work data sets, default locations of files, and metadata used to populate the process Results data set.

Each registered standard should have its own initialize.properties. For each standard that is included in a specific process, the %CST_SETSTANDARDPROPERTIES macro can be called at this point. Alternatively, type=properties records can be added to the SASReferences data set, and the properties are processed when the %CSTUTIL_ALLOCATESASREFERENCES macro is called. This latter approach is followed in the SDTM validate_data.sas driver program.

```
%cst_getRegisteredStandards(_cstOutputDS=work._cstStandards);
data _null_;
  set work._cstStandards (where=(standard="CST-FRAMEWORK"));
  call symputx('_cstVersion',strip(productrevision));
run;
```

Get the list of registered standards to determine the version of the SAS Clinical Standards Toolkit.

```
* Set Controlled Terminology version for this process  *;
%cst_getstandardsubtypes(_cstStandard=CDISC-TERMINOLOGY,_cstOutputDS=work._cstStdSubTypes);
data _null_;
  set work._cstStdSubTypes (where=(standardversion="&_cstStandard" and isstandarddefault='Y'));
  * User can override CT version of interest by specifying a different where clause:        *;
  * Example: (where=(standardversion="&_cstStandard" and standardsubtypeversion='201104'))   *;
  call symputx('_cstCTPath',path);
  call symputx('_cstCTMemname',memname);
  call symputx('_cstCTDescription',description);
run;


proc datasets lib=work nolist;
  delete _cstStandards _cstStdSubTypes;
quit;
```

Choose the default controlled terminology that is associated with the _cstStandard and _cstStandardVersion. Cleanup work files.

```
*********************************************************************************************;
* The following data step sets (at a minimum) the studyrootpath and studyoutputpath.  These *;
* are used to make the driver programs portable across platforms and allow the code to be   *;
* run with minimal modification. These macro variables by default point to locations within *;
* the cstSampleLibrary, set during install but modifiable thereafter.  The cstSampleLibrary *;
* is assumed to allow write operations by this driver module.                              *;
*******************************************************************************************;

%cstutil_setcstsroot;
data _null_;
  call symput('studyRootPath',cats("&_cstSRoot",
              "/cdisc-sdtm-3.1.3-&_cstVersion/sascstdemodata"));
  call symput('studyOutputPath',cats("&_cstSRoot",
              "/cdisc-sdtm-3.1.3-&_cstVersion/sascstdemodata"));
run;
```

Note: &_cstSRoot is set by the call to %CSTUTIL_SETCSTSROOT to the location of the cstSampleLibrary that was defined during the product installation.

```
%let workPath=%sysfunc(pathname(work));
```

The workPath value provides the path to the Work directory. This directory is referenced within the sample study SASReferences data set path column. It is not required.

Step 2: Build and populate the SASReferences data set

```
%let _cstSetupSrc=SASREFERENCES;

*************************************************************************************;
* One strategy to defining the required library and file metadata for a CST process     *;
*  is to optionally build SASReferences in the WORK library.  An example of how to do   *;
*  this follows.                                                                        *;
*                                                                                       *;
* The call to cstutil_processsetup below tells CST how SASReferences will be provided   *;
*  and referenced.  If SASReferences is built in work, the call to cstutil_processsetup *;
*  may, assuming all defaults, be as simple as  %cstutil_processsetup()                 *;
*************************************************************************************;


*************************************************************************************;
* Build the SASReferences data set                                                       *;
* column order:  standard, standardversion, type, subtype, sasref, reftype, iotype,      *;
*                filetype, allowoverwrite, relpathprefix, path, order, memname, comment  *;
* note that &_cstGRoot points to the Global Library root directory                       *;
* path and memname are not required for Global Library references - defaults will be used*;
**************************************************************************************;
%cst_createdsfromtemplate(_cstStandard=CST-FRAMEWORK, _cstType=control,_cstSubType=reference,
                          _cstOutputDS=work.sasreferences);
proc sql;
  insert into work.sasreferences
  values ("CST-FRAMEWORK" "1.2" "messages" "" "messages" "libref"  "input"  "dataset"
          "N"   "" "" 1 "" "")
  values ("&_cstStandard" "&_cstStandardVersion" "control" "validation" "cntl_v" "libref"
          "input" "dataset" "N" "" "&studyRootPath/control" . "validation_control.sas7bdat" "")
  [etc.]
  ;
quit;
```

The %CST_CREATEDSFROMTEMPLATE macro initializes the SASReferences data set that is required for SDTM validation. The SASReferences data set defines the location and name of each input metadata source, input data source, and output file that is created by the validation process, including the Validation Control data set. The Validation Control data set contains the set of checks to include in the validation process. The sample validate_data.sas driver program sets the path of the Validation Control data set to **`&studyRootPath/control`** and sets the name to validation_control.sas7bdat. Based on the code executed in step 1, this is the path:

`sample study library directory`**`/cdisc-sdtm-3.1.3/`**
`sascstdemodata/control/validation_control.sas7bdat`.

For an explanation of the purpose and content of each SASReferences file, see Chapter 6, “SASReferences File,” on page 137. For a fully initialized SASReferences data set for SDTM validation, see Figure 6.3 on page 149.

Step 3: Call the %CSTUTIL_PROCESSSETUP macro.

The %CSTUTIL_PROCESSSETUP macro completes process setup. It ensures that all SAS librefs and filerefs are allocated; all system options, macro autocall paths, and format search paths are set; and that all global macro variables that are required by the process have been appropriately initialized.

Note: For more information about the %CSTUTIL_PROCESSSETUP macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

The %CSTUTIL_PROCESSSETUP macro call:

```
   %cstutil_processsetup();
```

in the validate_data.sas driver reflects the acceptance of the macro parameter defaults listed above.

The %CSTUTIL_PROCESSSETUP macro parameter values tell the process where to find the SASReferences data set.

```
**********************************************************************;
* Set global macro variables for the location of the sasreferences  *;
* file (overrides default properties initialized above              *;
**********************************************************************;

%let _cstSASRefsName=&_cstSASReferencesName;
%let _cstSASRefsLoc=&_cstSASReferencesLocation;
```

The final setup step for the %CSTUTIL_PROCESSSETUP macro is a call to the %CSTUTIL_ALLOCATESASREFERENCES utility macro. The SASReferences data set is now interpreted by the SAS Clinical Standards Toolkit. These actions complete the process:

1 The %CST_INSERTSTANDARDSASREFS macro is called to insert paths into any records that are missing path information. The information is captured from the StandardSASReferences data set for each standard. For more information about how this works, see “Inserting Information from Registered Standards into a SASReferences File” on page 22.

2 Multiple calls to the %CSTUTILVALIDATESASREFERENCES macro are made to perform internal validation on the SASReferences data set.

   The validation performed by the %CSTUTILVALIDATESASREFERENCES macro is described in the“Assessing Structural Integrity and Content” on page 153.

3 All filerefs and librefs are allocated. (This action is contingent on the _cstReallocateSASRefs property or global macro variable value).

4 Any property files are passed to the %CST_SETPROPERTIES macro to create global macro variables.

5 The format search path is set if any type=fmtsearch records are found. This is based on the order specified.

6 The autocall path is set if any type=autocall records are found. This is based on the order specified.

7 A Messages data set is created to contain records from each referenced standard. This data set is based on the _cstMessages and _cstMessageOrder properties or

global macro variable values. This data set is used for the duration of the process to add fully resolved messages to the Results data set.

At this point, all libraries should be allocated, all paths and global macros should be set, and the global status macro variable _cst_rc should be set to 0. The process is ready to proceed.

CAUTION! The SASReferences data set is key to the process, and any errors will cause the process to fail. This is a common process failure point because of the importance of the SASReferences data set. For tips on debugging problems with the SASReferences data set, see "Special Topic: Debugging a Validation Process" on page 244 and "Assessing Structural Integrity and Content" on page 153.

Step 4: Run validation tasks.

```
* Run the standard-specific validation macro. ;
%sdtm_validate;
```

The %SDTM_VALIDATE macro performs these tasks:

1 The macro looks up the Validation Control data set reference from SASReferences.

2 The macro re-sorts the Validation Control data set based on the _cstCheckSortOrder property or global macro variable value. This step is optional.

3 Metadata about the validation process, such as the standard/version, key files referenced, and process datetimes, is added to the process Results data set.

4 For each check in the Validation Control data set with a checkstatus > 0, this macro calls the check macro specified in the Validation Control codesource field. It passes all of the check metadata to the check macro.

5 After all of the checks are run, these events happen:

- The results are saved to the file specified in SASReferences (type=results, subtype=validationresults).
- Any process results are summarized in the Metrics data set if specified.
- The metrics are saved to the file specified in SASReferences (type=results, subtype=validationmetrics).

- Various SAS Work files are cleaned up if needed.

For tips on debugging if unexpected errors occur, see "Special Topic: Debugging a Validation Process" on page 244.

Step 5: Clean up the session.

```
* Clean up the SAS Clinical Standards Toolkit process
files, macro variables and macros.;
%cstutil_cleanupcstsession(
    _cstClearCompiledMacros=0,
    _cstClearLibRefs=0,
    _cstResetSASAutos=0,
    _cstResetCmpLib=0,
    _cstResetFmtSearch=0,
    _cstResetSASOptions=1,
    _cstDeleteFiles=1,
    _cstDeleteGlobalMacroVars=0);
```

This step is optional, and it is unnecessary with batch processing. You should not clean up prematurely or aggressively if additional SAS Clinical Standards Toolkit processes are to be run in the same interactive SAS session.

Note: For more information about the %CSTUTIL_CLEANUPCSTSESSION macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Validation Results and Metrics

For SAS Clinical Standards Toolkit validation processes, the primary products of each validation process are the Results data set and the Metrics data set. These data sets itemize and summarize the findings of the validation process.

Figure 7.9 on page 213 summarizes a sample validation process. Here are a few facts about the sample validation process:

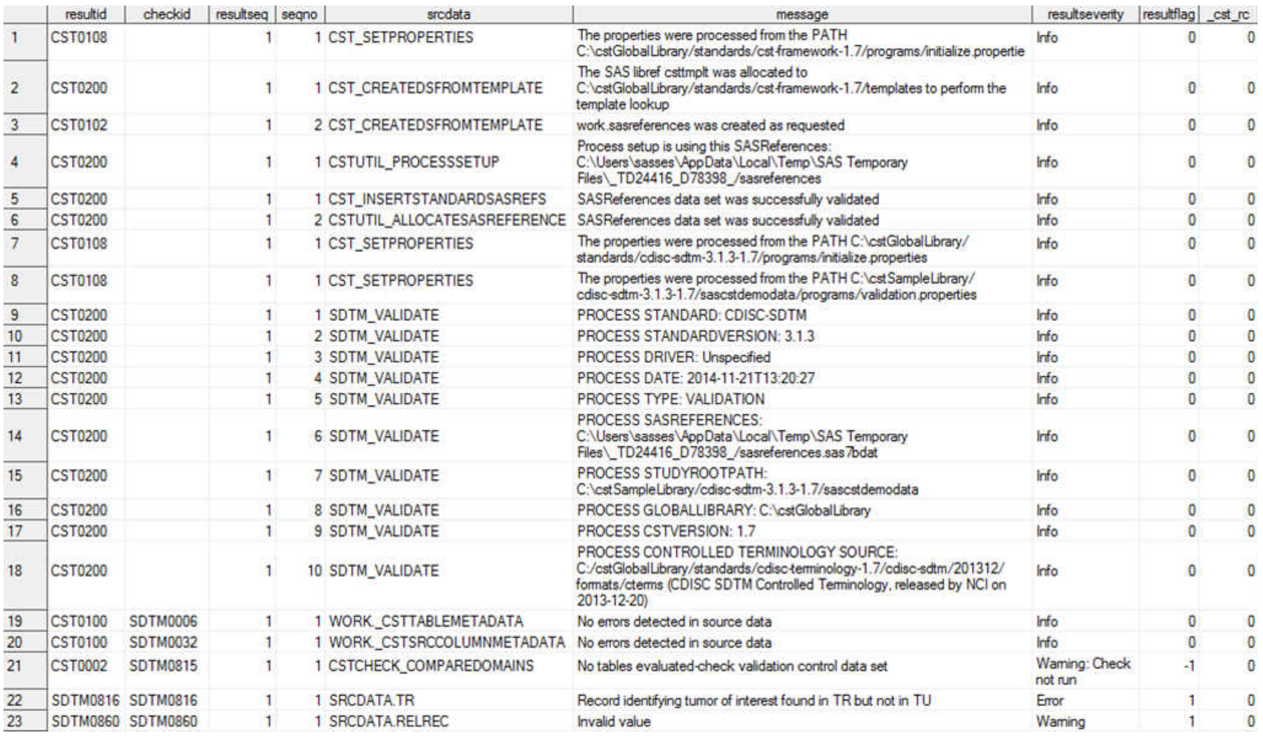
1. The validation process was run on CDISC SDTM 3.1.3 source data.

2. It referenced a Validation Control data set that contained metadata for four checks.

3. It included SASReferences records to persist the results as results.validation_results and results.validation_metrics.

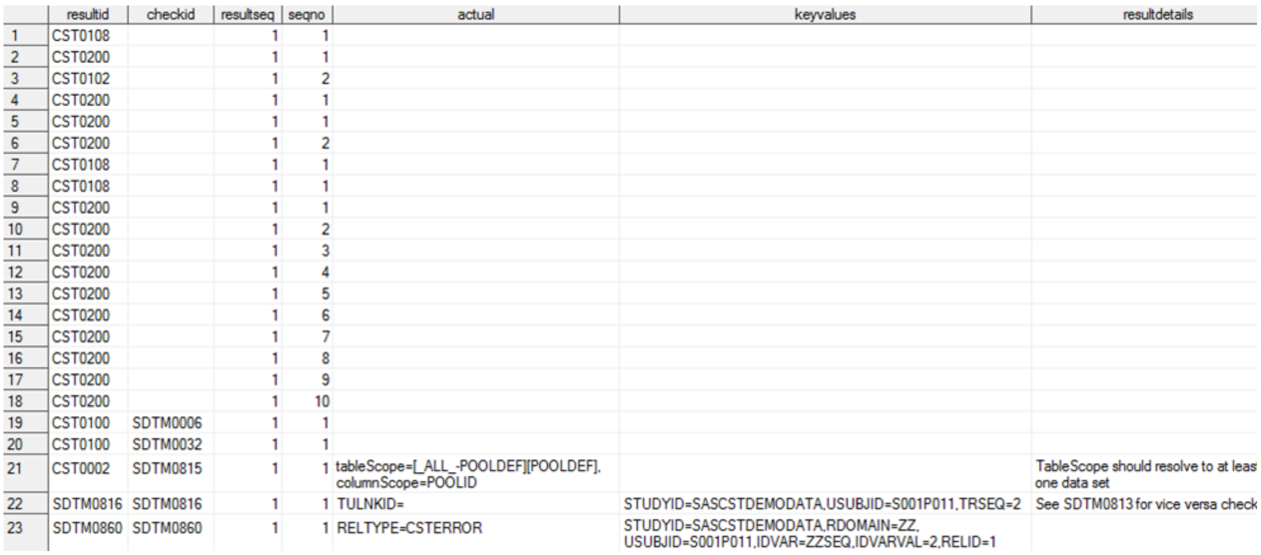
Note: In these displays, some rows have been hidden to reduce redundant examples.

Figure 7.9 *Example of a Validation Results Data Set (#1)*



	resultid	checkid	resultseq	seqno	srcdata	message	resultseverity	resultflag	_cst_rc
1	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cst-framework-1.7/programs/initialize.propertie	Info	0	0
2	CST0200		1	1	CST_CREATEDSFROMTEMPLATE	The SAS libref csttmplt was allocated to C:\cstGlobalLibrary/standards/cst-framework-1.7/templates to perform the template lookup	Info	0	0
3	CST0102		1	2	CST_CREATEDSFROMTEMPLATE	work.sasreferences was created as requested	Info	0	0
4	CST0200		1	1	CSTUTIL_PROCESSSETUP	Process setup is using this SASReferences: C:\Users\sasses\AppData\Local\Temp\SAS Temporary Files_TD24416_D78398_/sasreferences	Info	0	0
5	CST0200		1	1	CST_INSERTSTANDARDSASREFS	SASReferences data set was successfully validated	Info	0	0
6	CST0200		1	2	CSTUTIL_ALLOCATESASREFERENCE	SASReferences data set was successfully validated	Info	0	0
7	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cdisc-sdtm-3.1.3-1.7/programs/initialize.properties	Info	0	0
8	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata/programs/validation.properties	Info	0	0
9	CST0200		1	1	SDTM_VALIDATE	PROCESS STANDARD: CDISC-SDTM	Info	0	0
10	CST0200		1	2	SDTM_VALIDATE	PROCESS STANDARDVERSION: 3.1.3	Info	0	0
11	CST0200		1	3	SDTM_VALIDATE	PROCESS DRIVER: Unspecified	Info	0	0
12	CST0200		1	4	SDTM_VALIDATE	PROCESS DATE: 2014-11-21T13:20:27	Info	0	0
13	CST0200		1	5	SDTM_VALIDATE	PROCESS TYPE: VALIDATION	Info	0	0
14	CST0200		1	6	SDTM_VALIDATE	PROCESS SASREFERENCES: C:\Users\sasses\AppData\Local\Temp\SAS Temporary Files_TD24416_D78398_/sasreferences.sas7bdat	Info	0	0
15	CST0200		1	7	SDTM_VALIDATE	PROCESS STUDYROOTPATH: C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata	Info	0	0
16	CST0200		1	8	SDTM_VALIDATE	PROCESS GLOBALLIBRARY: C:\cstGlobalLibrary	Info	0	0
17	CST0200		1	9	SDTM_VALIDATE	PROCESS CSTVERSION: 1.7	Info	0	0
18	CST0200		1	10	SDTM_VALIDATE	PROCESS CONTROLLED TERMINOLOGY SOURCE: C:/cstGlobalLibrary/standards/cdisc-terminology-1.7/cdisc-sdtm/201312/formats/cterms (CDISC SDTM Controlled Terminology, released by NCI on 2013-12-20)	Info	0	0
19	CST0100	SDTM0006	1	1	WORK._CSTTABLEMETADATA	No errors detected in source data	Info	0	0
20	CST0100	SDTM0032	1	1	WORK._CSTSRCCOLUMNMETADATA	No errors detected in source data	Info	0	0
21	CST0002	SDTM0815	1	1	CSTCHECK_COMPAREDOMAINS	No tables evaluated-check validation control data set	Warning: Check not run	-1	0
22	SDTM0816	SDTM0816	1	1	SRCDATA.TR	Record identifying tumor of interest found in TR but not in TU	Error	1	0
23	SDTM0860	SDTM0860	1	1	SRCDATA.RELREC	Invalid value	Warning	1	0

Figure 7.10 Example of a Validation Results Data Set (#2)



	resultid	checkid	resultseq	seqno	actual	keyvalues	resultdetails
1	CST0108		1	1			
2	CST0200		1	1			
3	CST0102		1	2			
4	CST0200		1	1			
5	CST0200		1	1			
6	CST0200		1	2			
7	CST0108		1	1			
8	CST0108		1	1			
9	CST0200		1	1			
10	CST0200		1	2			
11	CST0200		1	3			
12	CST0200		1	4			
13	CST0200		1	5			
14	CST0200		1	6			
15	CST0200		1	7			
16	CST0200		1	8			
17	CST0200		1	9			
18	CST0200		1	10			
19	CST0100	SDTM0006	1	1			
20	CST0100	SDTM0032	1	1			
21	CST0002	SDTM0815	1	1	tableScope=[_ALL_-POOLDEF][POOLDEF], columnScope=POOLID		TableScope should resolve to at leas one data set
22	SDTM0816	SDTM0816	1	1	TULNKID=	STUDYID=SASCSTDEMODATA,USUBJID=S001P011,TRSEQ=2	See SDTM0813 for vice versa check
23	SDTM0860	SDTM0860	1	1	RELTYPE=CSTERROR	STUDYID=SASCSTDEMODATA,RDOMAIN=ZZ, USUBJID=S001P011,IDVAR=ZZSEQ,IDVARVAL=2,RELID=1	

Table 7.13 Comments about the Validation Results Data Sets in Displays 7.9 and 7.10

Lines	Comment
1,7,8	Informational notes about processing the properties files.
3	Informational note saying that the creation of work.sasreferences was successful.
4	Informational note from cstutil_processsetup that informs you of the location of the SASReferences data set.
5-6	Informational notes that inform you that the process SASReferences data set passed internal validation using the %CSTUTILVALIDATESASREFERENCES macro called from two different macros.
9-18	Informational summary that provides internal documentation about the process.
19-20	Checks SDTM0006 and SDTM0032 ran without error.
21	Check SDTM0815 did not run. The check scope as defined in tableScope and columnScope found no domains other than POOLDEF in the sample study that contained the column of interest (POOLID).

Lines	Comment
22-23	A single problem was detected for each of the SDTM0816 and SDTM0860 checks. Actual column values and key values for the problem records are reported to aid in problem resolution.

For a description of the Validation Metrics data set that is associated with this example compliance assessment, see Figure 7.2 on page 195..

Here are some general observations:

- The absence of a value in the results.checkid field can be used as an indicator of whether messaging has been set up. If the checkid field is nonmissing in a Results record, then messaging related to a specific validation check is available.
- A resultseq value > 1 indicates a repeat invocation of a specific validation check. There should be differences in the Validation Control metadata for the specific validation check.
- The seqno field is intended to be a record (message) counter in each specific check invocation. Generally, this value starts with 1 on the first record, and increments by 1 until the last record for each checkid and resultseq combination. One exception is with the Validation Control column reportAll=N. This signals the code to not write a record to the Results data set for each record in error. However, seqno continues to increment in this case, resulting in a gap in seqno values, with the last seqno approximating the total number of records in error.

A set of sample validation reports is available to summarize the SAS Clinical Standards Toolkit validation process results and metrics. For more information, see Chapter 11, “Reporting,” on page 443.

Validation Checks by Standard

Overview

The SAS Clinical Standards Toolkit provides a set of defined checks for each standard, where the *global standards library directory*/metadata standards data set supportsvalidation flag is set to “Y”. By default, each Validation Master data set is located here:

```
global standards library directory/standards/<standard>/
validation/control
```

The following table summarizes the content of each standard-specific validation_master data set that is provided with the SAS Clinical Standards Toolkit:

Table 7.14 Summary of Checks in Each validation_master Data Set That Is Provided with the SAS Clinical Standards Toolkit

CDISC Standard and Version	Total Number of Check Records	Number of Unique Checks	Number of Check Macros Used
ADaM 2.1	63	56	13
CRT-DDS 1.0	83	12	7
CT 1.0.0	34	14	7
ODM 1.3.0	179	39	10
ODM 1.3.1	190	38	10
SDTM 3.1.2	26	26	8
SDTM 3.1.3	48	46	11
SDTM 3.2	52	49	11

CDISC Standard and Version	Total Number of Check Records	Number of Unique Checks	Number of Check Macros Used
Define-XML 2.0	N/A	N/A	N/A
Dataset-XML 1.0	N/A	N/A	N/A
CST-FRAMEWORK	137	92	11

Note: Starting with the SAS Clinical Standards Toolkit 1.7, OpenCDISC checks have been removed from the validation_master data sets for CDISC-SDTM and CDISC-ADaM.

ADaM 2.1

The CDISC ADaM validation checks are derived from the SAS interpretation of the CDISC ADaM Validation Checks Version 1.0 (final production version dated September 20, 2010) and the CDISC ADaM Validation Checks Version 1.1 maintenance release (dated and released January 21, 2011 to correct errors and remove duplicate checks). Excluding the OpenCDISC checks leaves 11 CDISC-defined checks in the SAS Clinical Standards Toolkit.

In addition, SAS has added 45 unique checks (52 total records) to the Validation Master data set. These checks can be identified where checksource="SAS".

ADaM data sets are typically derived from a tabulation study, such as SDTM or SEND. Some checks require the comparison of ADaM content with data and metadata from the tabulation source. Of the 63 validation_master records, 10 involve a comparison with another CDISC standard such as SDTM 3.1.3.

CDISC CRT-DDS 1.0

The SAS Clinical Standards Toolkit provides check macros that validate the data in the SAS data sets representing CDISC CRT-DDS data. The goal of these check macros is to ensure that all data is correctly specified and that referential integrity is maintained. As a result, a standards-compliant CDISC define.xml file can be produced from these data sets.

The validity of CRT-DDS data is determined by the standard in the form of XML schema definitions. These XML schema definitions must be translated into checks appropriate for the relational and tabular format.

Checks fall into these general categories:

- Ensures that all cross-table references are satisfied and that the referenced item actually exists (referential integrity).
- Ensures that required variables are not missing or empty for an observation or row.
- Ensures that character data conforms to a particular format.

Formats are specified in the standard in one of two ways:

- an enumeration
- a regular expression

The SAS Clinical Standards Toolkit provides 83 CDISC CRT-DDS validation checks. These validation checks were developed by SAS and are based on CRT-DDS and ODM implementation experience and careful review of the associated implementation guides, with special emphasis on the occurrence of “should” within each implementation guide. Table 7.15 on page 218 lists the types of checks for CRT-DDS data.

Each check type is assumed to operate on data that exists in a source column in a source data set. A check type can reference one or more parameters that validate the source column data. A parameter can be a character string or a representation of some column other than the source column against which the source column data must be compared.

All character comparisons are case sensitive. Character data is assumed to have been trimmed of leading or trailing white space.

Table 7.15 *CRT-DDS Validation Check Types*

Check Type	Category	Description
Unique in data set	Structural	No two values for the source column can be the same in the same source data set.

Check Type	Category	Description
Required character value	Data	The trimmed (white space removed) value of the character data must consist of one or more characters.
Required numeric value	Data	The numeric value of the column cannot be missing.
Enumeration(s0,s1,...)	Data	If character data exists, its value must match one of the enumerated character strings. All string comparisons are case sensitive.
Foreign key(targetColumn)	Structural	Each existing value in this column must have an equivalent value in the target column.
Foreign key required(targetColumn)	Structural	A value is required for this column in every row. Each value must have an equivalent value in the target column. This check is the equivalent of running the required character value check, and this check failing if that check fails. If the required character value passes, the foreign key check is run.
Character format: language	Data	The character data must consist of 1 to 8 alphabetical characters of any case. It can be followed by a hyphen and any sequence of 1 to 8 alphabetical characters in any case or numeric digits after that hyphen. For example, e is a legal value, as is en-us, english, and english-d842. Invalid values include 1en, mumblespeak, and en_us. The hyphen character sequence can be repeated, making a value such as english-mumbly-growly-47 a legal value. Regular expression: [a-zA-Z]{1,8}(-[a-zA-Z0-9]{1,8})*.
Character format: fileName	Data	The character data must not contain any characters other than uppercase and lowercase letters of the alphabet, numeric digits, an underscore (_), or a period. Regular expression: [A-Za-z0-9_.]+.

Check Type	Category	Description
Character format: sasFormat	Data	The first character must be either a lowercase or uppercase letter, an underscore (_), or the dollar sign ($). Any subsequent character must be either an uppercase or lowercase letter, a numeric digit, an underscore (_), or a period. Regular expression: [A-Za-z_$][A-Za-z0-9_.]*.
Character format: sasName	Data	The first character must be either a lowercase or uppercase letter or an underscore (_). Any subsequent character must be either an uppercase or lowercase letter, a numeric digit, or an underscore (_). Regular expression: [A-Za-z_][A-Za-z0-9_]*.
Unique across data sets(targetcolumn0,...)	Structural	No value in this column can be the same as any value in any of the data set columns.
Primary key	Data	Must be unique in data set check type and the required character value check type.
Must Have Corresponding Value(targetColumn)	Structural	For each distinct value in this column, there must be at least one equivalent value in the target column.
No Duplicates Per Unique Value(targetColumn)	Structural	For each distinct value in the target column, each value in the source column must be unique. That is, the same value cannot appear more than once in the source column for each distinct value in the target column.

(1) This validation is a combination of checks CRT0101 and CRT0110.

(2) This validation is a combination of checks CRT0100 and CRT0101.

Each check type belongs to one of two categories.

1 Data checks have no dependencies on data outside of the source table. An example is ensuring that a value exists in a column in which values cannot be missing.

2 Structural checks deal with relationships and data integrity between tables. Foreign key enforcement is an example of a structural check. Structural conditions must be

met for the successful generation of a define.xml file. You might want to defer structural checks until later in the process of populating the CRT-DDS data sets. This is because foreign key relationships require that the data be made available in a particular order (that is, a referenced key must be available before the foreign key to it can exist).

The CDISC CRT-DDS validation also checks the data against a set of expected values. The expected values have been stored in a format catalog (crtddsct.sas7bcat) and a data set (crtddsct.sas7bdat). They are in the ***`global standards library directory`***`/standards/cdisc-crtdds-1.0-1.7/formats` folder.

The SASReferences data set needs to contain a row for **fmtsearch**, with **SAS libref** set to **crtfmt** and the **Filename** should refer to **crtddsct.sas7bcat**.

CDISC ODM 1.3.0 and 1.3.1

The SAS Clinical Standards Toolkit provides check macros that validate the data in the SAS data sets representing CDISC ODM data. The structure of this data is similar to CDISC CRT-DDS. Therefore, the process for validating the data is similar. The goal of these check macros is to ensure that all data is correctly specified, and that referential integrity is maintained. As a result, a standards-compliant CDISC define.xml file can be produced from these data sets.

As in CRT-DDS, the validity of ODM data is determined by the standard in the form of XML schema definitions. These XML schema definitions must be translated into checks appropriate for the relational and tabular formats.

Checks fall into these general categories:

- Ensures that all cross-table references are satisfied and that the referenced item actually exists (referential integrity).
- Ensures that required variables are not missing or empty for an observation or row.
- Ensures that character data conforms to a particular format.
- Formats are specified in the standard in one of two ways:
    - an enumeration

- a regular expression

The SAS Clinical Standards Toolkit provides 179 ODM 1.3.0 and 190 ODM 1.3.1 validation checks. These validation checks were developed by SAS and are based on ODM implementation experience and careful review of the *CDISC ODM Implementation Guide*, with special emphasis on the occurrence of "should" within the Implementation Guide.

By default, the ODM 1.3.0 Validation Master data sets are here:

***global standards library directory*/standards/cdisc-odm-1.3.0-1.7/validation/control** and the

***global standards library directory*/standards/cdisc-odm-1.3.1-1.7/validation/control**

Table 7.16 on page 222 lists the types of checks for ODM data.

Each check type is assumed to operate on data that exists in a source column in a source data set. A check type can reference one or more parameters that validate the source column data. A parameter can be a character string or a representation of a column other than the source column against which the source column data must be compared.

All character comparisons are case sensitive. Character data is assumed to have been trimmed of leading and trailing white space.

Table 7.16 *ODM Validation Check Types*

Check Type	Category	Description
Unique in data set	Structural	No two values for the source column can be equivalent within the same source data set.
	Structural	Duplicate OrderNumber element. The OrderNumber attribute must be unique within the same source data set when not null.
Required character value	Data	The trimmed (white space removed) value of the character data must consist of one or more characters.

Check Type	Category	Description
Required numeric value	Data	The numeric value of the column cannot be missing.
Enumeration(s0,s1,…)	Data	If character data exists, its value must match one of the given enumerated character strings. All string comparisons are case sensitive.
Foreign key(targetColumn)	Structural	Each existing value in this column must have an equivalent value in the given target column.
Foreign key required(targetColumn)	Structural	A value is required for this column in every row and each value must have an equivalent value in the given target column. This check is the equivalent of running the required character value check, and failing if that check fails. If a required character value passes, the foreign key check is run.
Character format: language	Data	The character data must consist of 1-8 alphabetical characters of either case, followed optionally by a hyphen character and any sequence of 1-8 alphabetical characters of either case or numeric after that hyphendigits. For example, **`e`** is a legal value, as are **`en-us`** and **`english`** and **`english-d842`**. Invalid values include **`1en`**, **`mumblespeak`**, and **`en_us`**. The hyphen character sequence can be repeated any number of times also making a value such as **`english-mumbly-growly-47`** a legal value. Regular expression: “[a-zA-Z]{1,8}(-[a-zA-Z0-9]{1,8})*”.
Character format: fileName	Data	The character data must not contain any characters other than uppercase and lowercase letters of the alphabet, numeric digits, the underscore (_) character, or a period. Regular expression: [A-Za-z0-9_.]+.

Check Type	Category	Description
Character format: sasName	Data	The first character must be either a lowercase or uppercase letter or an underscore (_). Any subsequent character must be either an uppercase or lowercase letter, a numeric digit, or the underscore (_). Regular expression: [A-Za-z_][A-Za-z0-9_]*.
Character format: sasFormat	Data	The first character must be either a lowercase or uppercase letter, an underscore (_), or the dollar sign ($). Any subsequent character must be either an uppercase or lowercase letter, a numeric digit, the underscore (_), or a period. Regular expression: [A-Za-z_$][A-Za-z0-9_.]*.
Must Have Corresponding Value(targetColumn)	Structural	For each distinct value in this column, there must be at least one equivalent value in the supplied target column.
Unique across data sets(targetcolumn0,…)	Structural	No value in this column can be equal to any value in any of the given data set columns.
Primary key	Data	Must satisfy the Unique in data set check type and the required character value check type.

Check Type	Category	Description
Invalid Value	Data	Documents based on ODM 1.3 should have the ODM version set to 1.3.
	Data	An invalid SAS format name. If the data type is character, the format name needs to start with the $ character.
	Data	An invalid integer value. The attribute is defined as an integer, but the text string does not match the named data format. The allowed string pattern for an integer is: -?digit+.
	Data	An invalid float value. The attribute is defined a float, but the text string does not match the named data format. The allowed string pattern for a float is: -?digit+(.digit+)?.
	Data	An invalid date value. The attribute is defined as a date, but the text string does not match the named data format. The allowed string pattern for a date is: YYYY-MM-DD.
	Data	An invalid time value. The attribute is defined a time, but the text string does not match the named data format. The allowed string pattern for a time is: hh:mm:ss(.n+)?((+|-)hh:mm)?.
	Data	An invalid datetime value. The attribute is defined as a datetime, but the text string does not match the named data format. The allowed string pattern for a datetime is: YYYY-MMM-DD T hh:mm:ss(.n+)?((+|-)hh:mm)?.
External File Reference Found	Data	External file reference found because the prior file OID is not missing (for example, ODM.PriorFileOID ne ‘’)

Check Type	Category	Description
Referenced OID Not Found	Data	If Metadata version IncludedOID is non-null, the referenced OID must be found in this XML file.
	Data	If Metadata version IncludedStudyOID is non-null, the referenced OID must be found in this XML file.
Attribute is Required	Column	The ItemDef length attribute is required when data type is text, string, integer, or float and can be ignored for the other types.
	Column	The required attribute SignificantDigits cannot be empty or missing when Data type is Float.
	Column	Only numeric (integer or float) items should have measurement units. The MeasurementUnitRefs list the acceptable measurement units for this type of item. If only one MeasurementUnitRef is present, all items of this type carry this measurement unit by default. If no MeasurementUnitRef is present, the item's value is scalar (for example., a pure number).
Data Set Does Not Exist	Metadata	Invalid root element. The ODM file must contain a root element called ODM. In other words, the ODM data set must exist.
Mixed Data Exists	Multirecord	Typed and Untyped data transmission should not be mixed within a single ODM file.
Multiple Records Exists	Column	To avoid ambiguity, a particular language tag should not occur more than once in a series of TranslatedText elements

(1) This validation is a combination of checks ODM0101 and ODM0110.

(2) This validation is a combination of checks ODM0100 and ODM0101.

Each check type belongs to one of two categories:

1. Data checks have no dependencies on data outside of the source table. An example is ensuring that a value exists in a column in which values cannot be missing.
2. Structural checks deal with relationships and data integrity between tables. An example is foreign key enforcement. Structural conditions must be met for the successful generation of an ODM XML file. You might want to defer structural checks until later in the process when populating the ODM data sets. This is because foreign key relationships require that the data is made available in a particular order (that is, a referenced key must be available before the foreign key to it can exist).

For the CDISC ODM validation checks that compare the data against a set of expected values, the expected values are stored in a format catalog (odmct.sas7bcat) and a data set (odmct.sas7bdat). For ODM 1.3.0, these are in the ***global standards library directory*/standards/cdisc-odm-1.3.0-1.7/formats** folder. Case-sensitivity compliance is required by the XML schema validation.

CDISC SDTM

The SAS Clinical Standards Toolkit provides validation checks in support of CDISC SDTM 3.1.2, 3.1.3, and 3.2. These checks are derived from multiple sources that have evolved over time. Most checks in the SAS Clinical Standards Toolkit are based on SAS data management and cleaning experiences building CDISC SDTM domains.

Each version of the CDISC SDTM Validation Master data set (such as SDTM 3.1.3) contains a different number of checks based on the rules that are in effect at the time of each version and the number and type of supported tabulation domains. For more information about the distribution of checks by version, see Table 7.14 on page 216.

By default, the Validation Master data set is located here:

***global standards library directory*/standards/*<specific standard and version>*/validation/control**

It is named validation_master.sas7bdat.

Each Validation Master data set is built with multiple instances of the checks. This better supports check selection by version or checksource (that is, WebSDM, SAS, or customer-defined checks) and enables unique check logic and messaging by version or checksource.

Multiple instances of a specific check are provided to handle different sets of SDTM domains. For example, consider a check that assesses whether sequence numbers (**SEQ) are consecutively numbered. For most domains, this is assessed in each patient (USUBJID). However, the trial summary (TS) domain does not contain patient-level data, so the check logic differs for this domain. The Validation Master metadata would differ for these two instances of the check, but the check would report the same error message for each check.

Note: The validation check data set column checkstatus indicates the state of each check. It indicates that the check is ready to be run in its current defined state, or that the check can be run based on some external criteria. Current valid values are 1 (active), 0 (inactive), -1 (deprecated), and -2 (not yet implemented). Values are extensible to meet your requirements. You can choose to use other values such as 1 (draft), 2 (test), and 3 (production). If a check is included in the run-time Validation Control data set, the SAS Clinical Standards Toolkit attempts to run the check as defined if the checkstatus value is > 0.

Consider the interrelationships among the SAS Clinical Standards Toolkit validation check metadata. All run-time Validation Control data sets, any programs that build or derive from these data sets, corresponding Messages data sets, and the Validation_StdRef data set are examples of how interconnected many SAS Clinical Standards Toolkit metadata files are. For more information, see "Messages" on page 192. By default, the Validation_StdRef data set is located here:

***global standards library directory*/standards/<*specific standard and version*>/validation/control**

CDISC CT 1.0.0

The CDISC CT validation checks are patterned in part after the CDISC ODM checks. The checks ensure that SAS rules for format names and non-duplicate values are followed. A total of 34 records are defined in the Validation Master data set, which, by default, is located here:***global standards library directory*/standards/cdisc-ct-1.0.0-1.7/validation/control**.

The SAS Clinical Standards Toolkit Framework

Validation of the SAS Clinical Standards Toolkit framework files is referred to as internal validation. For more information, see Chapter 8, “Internal Validation,” on page 269.

Special Topic: Validation Check Macros

These SAS Clinical Standards Toolkit design requirements shape the implementation of the SAS Clinical Standards Toolkit validation code:

1. Code modules should be generic and reusable across standards. Twenty-one check macros have been defined in the SAS autocall library to support compliance assessments across supported standards.
2. Code must run with SAS 9.3.
3. Code should be written as SAS macros.
4. SAS macros should have simple parameter signatures. All macros accept a single parameter, _cstControl, which is a single-observation data set that contains check-specific metadata.
5. SAS macros should be implemented as non-compiled open code.
6. SAS macros should be callable using the SAS autocall facility. The SAS Clinical Standards Toolkit framework supports a single SAS macros library. Each SAS Clinical Standards Toolkit standard supports an additional macros library, and the macro library is available using the SAS autocall path.
7. Code modules should be generic and reusable with multiple validation checks. For example, the check macros %CSTCHECK_COLUMN, %CSTCHECK_NOTINCODELIST, and %CSTCHECK_NOTUNIQUE are used by every standard provided with the SAS Clinical Standards Toolkit that supports validation.

8 To support code generalization, use metadata-driven techniques to provide check-specific information to the check macros, even including which check macro to call.

9 Code should write processing results to a single validation Results data set. This Results data set should be available for post-process review and reporting.

These design requirements should be used when developing custom validation check macros. The following table identifies and describes the purpose of each of the check macros provided with the SAS Clinical Standards Toolkit:

Table 7.17 SAS Clinical Standards Toolkit Validation Check Macros

Check Macro	Code Logic Style	Description of Purpose
%CSTCHECK_COLUMN		
	Statement	Identifies any invalid column values or attributes.
%CSTCHECK_COLUMNCOMPARE		
	Step	Supports comparison of column values.
%CSTCHECK_COLUMNEXISTS		
	By default, this check does not require the use of codeLogic. If the check metadata includes a non-null value of codeLogic, then DATA step code logic is required.	Determines whether one or more of the columns defined in columnScope exist in each of the tables defined in tableScope.
%CSTCHECK_COLUMNVARLIST		
	Step	Supports comparison of multiple columns within the same data set or across multiple data sets.
%CSTCHECK_COMPAREDOMAINS		

Check Macro	Code Logic Style	Description of Purpose
	Step	Compares values for one or more columns in one domain with values for those same columns in another domain.
%CSTCHECK_CROSSSTDCOMPAREDOMAINS		
	Step	Generally, compares values for 1+ columns in one table against either those same columns in another domain in another standard, or compares values against metadata from the comparison standard.
%CSTCHECK_CROSSSTDMETAMISMATCH		
	Step	Identifies inconsistencies between metadata across registered standards.
%CSTCHECK_DSMISMATCH		
	Step	Identifies any data set mismatches between study and template metadata and the source data library.
%CSTCHECK_METAMISMATCH		
	Step	Identifies inconsistencies between study and reference column metadata.
%CSTCHECK_NOTCONSISTENT		
	Step	Identifies any inconsistent column values across records.
%CSTCHECK_NOTIMPLEMENTED		
	(not used)	Placeholder to report that a check is not yet implemented.
%CSTCHECK_NOTINCODELIST		

Check Macro	Code Logic Style	Description of Purpose
	If lookuptype=DATASET, DATA step code logic required Else, DATA step code logic is optional	Identifies any column values inconsistent with controlled terminologies. Requires reference to the SAS format search path built based on type=FMTSEARCH records in the SASReferences control file. Example is a **STAT value is found other than 'NOT DONE.'
%CSTCHECK_NOTSORTED		
	(not used)	Identifies any domain that is not sorted by the keys defined in the metadata.
%CSTCHECK_NOTUNIQUE		
	Not used for functions 1 through 3; DATA step for function 4	A multi-function macro that assesses the uniqueness of data sets, columns, or value-pairs from two columns. Function 1: Is data set unique by a set of columns? Function 2: For any subject, are column values unique? Function 3: Does a combination of two columns have unique values? Function 4: Are the values in one column (Column2) consistent in each value of another column (Column1)?
%CSTCHECK_RECMISMATCH		
	Step	Identifies any record mismatches across domains (domain as referenced in another domain).
%CSTCHECK_RECNOTFOUND		

Check Macro	Code Logic Style	Description of Purpose
	Step	Compares the consistency of one or more columns across two tables or enables the comparison of the consistency of one <table>.<column> with another <table>.<column>.
%CSTCHECK_VIOLATESSTD		
	Statement	Identifies any invalid column values defined in a reference standard.
%CSTCHECK_ZEROOBS		
	(not used)	Identifies any data set with zero observations.
%CSTCHECKCOMPAREALLCOLUMNS		
	Step	Compares all columns in one domain with the same columns in other domains.
%CSTCHECKENTITYNOTFOUND		
	Step	Reports that an entity, typically a file, folder, or column, cannot be found.
%CSTCHECKFOREIGNKEYNOTFOUND		
	Step	Compares the consistency of one or more columns across two tables, where a column in the first table is a foreign key that points to a primary key in the second table.

Each validation check macro follows a standard basic workflow. Several of the validation check macros perform more complex operations and multiple functions. The basic workflow includes these events:

1. Call the %CSTUTIL_READCONTROL utility macro, which translates the validation check metadata passed as the input parameter into local macro variables for check macro processing.

2. Evaluate required check macro-specific metadata values.

3. Call the %CSTUTIL_BUILDCOLLIST utility macro (or, if processing only domains, %CSTUTIL_BUILDDOMLIST), which evaluates the requested scope of the specific validation check (that is, which tables and columns are to be included when running the check).

4. Loop through the target tables and columns identified in step 3.

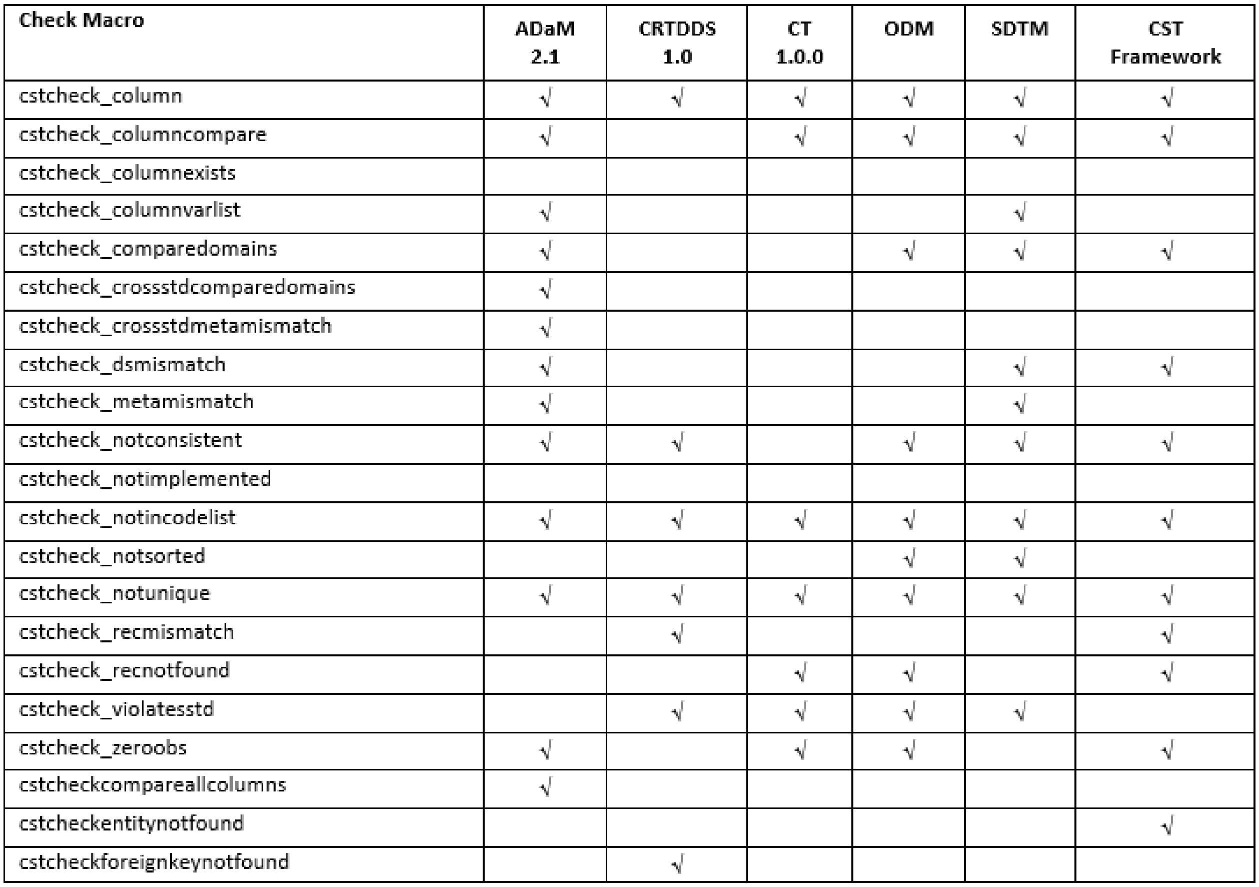
5. Perform the logic required to properly assess the validation check. This might be the check macro code itself, or the code in the validation check metadata codeLogic field.

6. Write any informational or error messages to the Results data set. Metrics are written to the Metrics data set.

7. Clean up any Work files local to the check macro processing.

The following display shows the use of each check macro, by standard and version:

Figure 7.11 Use of Validation Check Macros by Standard



Check Macro	ADaM 2.1	CRTDDS 1.0	CT 1.0.0	ODM	SDTM	CST Framework
cstcheck_column	√	√	√	√	√	√
cstcheck_columncompare	√		√	√	√	√
cstcheck_columnexists						
cstcheck_columnvarlist	√				√	
cstcheck_comparedomains	√			√	√	√
cstcheck_crossstdcomparedomains	√					
cstcheck_crossstdmetamismatch	√					
cstcheck_dsmismatch	√				√	√
cstcheck_metamismatch	√				√	
cstcheck_notconsistent	√	√		√	√	√
cstcheck_notimplemented						
cstcheck_notincodelist	√	√	√	√	√	√
cstcheck_notsorted				√	√	
cstcheck_notunique	√	√	√	√	√	√
cstcheck_recmismatch		√				√
cstcheck_recnotfound			√	√		√
cstcheck_violatesstd		√	√	√	√	
cstcheck_zeroobs	√		√	√		√
cstcheckcompareallcolumns	√					
cstcheckentitynotfound						√
cstcheckforeignkeynotfound		√				

More complete documentation is provided for each check macro in the *SAS Clinical Standards Toolkit: Macro API Documentation*. This information is derived from the code headers. See "Special Topic: Validation Customization" on page 252.

Special Topic: How the SAS Clinical Standards Toolkit Interprets Validation Check Metadata

Overview

Four Validation Master metadata fields are key to how the SAS Clinical Standards Toolkit processes source data and source metadata: usesourcemetadata, tablescope, columnscope, and codelogic.

The SAS Clinical Standards Toolkit uses usesourcemetadata to point to the correct metadata. If usesourcemetadata is set to Y, then the SAS Clinical Standards Toolkit knows that the source metadata (source_tables and source_columns) is to be used to derive the domains and columns to be evaluated for compliance to the standard. If usesourcemetadata is set to N, reference metadata (reference_tables and reference_columns) is to be used.

The SAS Clinical Standards Toolkit uses the tablescope and columnscope values to build the work._csttablemetadata and work._cstcolumnmetadata data sets. Based on the values of these fields, the SAS Clinical Standards Toolkit creates a subset of source metadata or reference metadata that represents the union of tablescope and columnscope. The SAS Clinical Standards Toolkit builds columns specified in columnscope that also exist in the tables specified in tablescope.

For those checks that use codelogic, the SAS Clinical Standards Toolkit builds local macro variables to communicate tablescope and columnscope settings to the code. Simple examples are each domain is interpreted as &_cstDSName, and each column is interpreted as &_cstColumn.

Code logic is run. If the check code logic is a statement (codetype=1 or 3), then _cstError=1 is generally set. If the check code logic is a DATA step or PROC SQL code segment (codetype=2 or 4), then work.cstproblems is created.

Special Topic: SAS Implementation of ISO 8601

Overview

ISO 8601 is a widely used data standard for dates, times, durations, and intervals. The values are stored as text strings. They are formatted in a way that ensures that all of the components are always unambiguous. ISO 8601 is both platform and software independent, which makes it suitable for data interchange.

Many data standards use a simplified subset of ISO 8601 for specifying their own dates, times, and durations. This is true of several CDISC standards, including SDTM.

A complete discussion of ISO 8601 and the CDISC subset of ISO 8601 is beyond the scope of this document. The following tables provide a general idea of what the text strings look like and how to interpret their values. Additional information is in the references.

This list provides a summary of the SAS Clinical Standards Toolkit support of ISO 8601:

- Consistent with CDISC SDTM guidelines, the SAS Clinical Standards Toolkit does not support the ISO 8601 basic format. This means that the text strings must contain the hyphen delimiter for parts of the dates, and the colon delimiter for parts of the time.
- The SAS Clinical Standards Toolkit does not support some of the rarely used formats allowed by ISO 8601. The week (W) formats for dates, Julian dates, and extended dates (used to denote years greater than 9999) are not supported.

SAS provides capabilities for processing ISO 8601 text strings that are far beyond those capabilities required by the SAS Clinical Standards Toolkit and CDISC standards.

- The SAS informats $N8601B. and $N8601E. convert an ISO 8601 text string to a special string called an ISO 8601 entity.

  The ISO 8601 entity is a complex binary value that is stored as a hexadecimal value in a SAS string variable.

The ISO 8601 entity string is useful for reporting in the ISO 8601 format because it prevents the loss of valuable information from the input ISO 8601 text string.

- The ISO 8601 entity value should not be confused with the traditional numeric SAS date, time, or datetime value.
- The ISO 8601 entity should not be used in calculations or comparisons.
- The CALL IS8601_CONVERT routine can be used to generate traditional numeric SAS dates, times, and datetime values from an ISO 8601 string.
- For additional information, see the online SAS documentation.

Example ISO 8601 Values

Overview

The tables in this section provide an overview of some commonly used values. It groups the comments based on the ISO 8601 string type.

Dates and Times: Template

Table 7.18 Example ISO 8601 Values for Dates and Times: Template

String	Interpretation	Comment
YYYY-MM-DDTHH:MM:SS	A specific date and time	YYYY: Four-digit year. MM: # of month (01-12). DD: # of day of month (01-31). T: What follows is a time in a 24-hour clock. HH: Hours. MM: Minutes. SS: Seconds.

Dates and Times: Full Datetime Examples

Table 7.19 *Example ISO 8601 Values for Dates and Times: Full Datetime Examples*

String	Interpretation	Comment
2009-03-25	March 25, 2009	Year must have four digits. Month, day, hour, minute, and second each must have two digits. Single-digit values must be preceded by a leading zero.
2009-03-25T22:29:30	March 25, 2009 10:29 and 30 seconds p.m.	T is always required before a time. Times must always be in military time (for example, 24-hour clock). Midnight must be written as 00:00. 24:00 is not valid. The individual parts of a date value must be separated by a hyphen (-). The individual parts of a time value must be separated by a colon (:).
2009-03-25T22:29:30.333+05:00	March 25, 2009 10:29 and 30.333 seconds p.m. in the time zone GMT + 5 hours	If provided, the time zone must be in HH:MM format. It cannot be truncated or a partial value. Some values in ISO 8601 formats can have decimal places. Most commonly, this is seen in seconds. The decimal place can be denoted as either a period (.) or a comma (,). When a time zone is provided, it must be accompanied by a complete date. The date cannot be truncated or a partial value. This is necessary because the 24 global time zones force the date to be considered as part of the time.
2009-03-25T22:29Z	March 25, 2009 10:29 p.m. Zulu time	Z can be used to substitute for times in GMT (or Zulu) time.

Dates and Times: Partial Datetime Examples

One or more components of the date or time are not known. Partial values are denoted by a single -, no matter how many digits are absent. Partial values can be expressed by truncating the missing parts.

Table 7.20 Example ISO 8601 Values for Dates and Times: Partial Datetime Examples

String	Interpretation	Comment
-----T22:29	The time 10:29 p.m. No value for the date is provided.	A time value must always be prefixed by a date value. In this example, the date value is completely missing, which would be appropriate for time-only fields.
2009	Year 2009.	Trailing values can be truncated when the values are missing.
2009---25	The 25th day of an unknown month in the year 2009. The month is missing.	If a missing value is embedded in the string, then it must always be denoted by a hyphen (-).
--03-25	The 25th day of March in an unknown year.	Missing year.
--03--T-:15	The 15th minute of an unknown hour of an unknown day of the third month of an unknown year.	Missing year, day, and hour.
2009-03	Month of March 2009.	Trailing partial values can be omitted (truncated). If time is omitted, then T must also be omitted.
2009-03--T12	The 12th hour of an unknown day in March 2009.	Missing day of month.

Durations: Template

Table 7.21 Example ISO 8601 Values for Durations: Template

String	Interpretation	Comment
PnYnMnDTnHnMnS	Duration	A span of time where n is the number of the unit that follows the unit. P: indicates that the value is a duration (period) nY: n elapsed years nM: n elapsed months nD: n elapsed days T: the elapsed time in hours, minutes, and seconds nH: n elapsed hours nM: n elapsed minutes nS: n elapsed seconds Typically, only the units with actual values are given. For example, P0Y1M would be P1M.

Durations: Examples

Table 7.22 Example ISO 8601 Values for Durations: Examples

String	Interpretation	Comment
P1D	The span of one day.	Durations always start with P for a period of time. Units of time that are not known are usually omitted. If time is omitted, then T must also be omitted.

String	Interpretation	Comment
P0000-00-01	The span of zero years + zero months + one day.	Durations can be expressed in an alternative format. When expressed, the length of time is stored in the same format as date and time, but preceded by a P. Instead of expressing a specific point in time, it expresses a period of time.
P1Y2M3DT4H5M6S	The span of 1 year, 2 months, 3 days, 4 hours, 5 minutes, and 6 seconds.	The units must be in the correct order. The T is required for all time values, but it should not be specified if no time value is given.

Intervals: Template

Table 7.23 *Example ISO 8601 Values for Intervals: Template*

String	Interpretation	Comment
PnYnMnDTnHnMnS/YYYY-MM-DDTHH:MM:SS or YYYY-MM-DDTHH:MM:SS/PnYnMnDTnHnMnS or YYYY-MM-DDTHH:MM:SS/PnYnMnDTnHnMnS or YYYY-MM-DDTHH:MM:SS/YYYY-MM-DDTHH:MM:SS	Intervals	This is a duration that is anchored to a specific point in time.

Intervals: Examples

Table 7.24 *Example ISO 8601 Values for Intervals: Examples*

String	Interpretation	Comment
2009-03-25T22:29/P1Y	The span of one year starting on March 25, 2009 at 10:29 p.m.	Intervals can express the period of time that starts at a given point in time. The end time is implied.
P0001-00-00/2009-03-25 T22:29	The span of one year ending on March 25, 2009 at 10:29 p.m.	Intervals can express the period of time that ends at a given point in time. The start time is implied.
2008-03-25/2009-03-25	The span of time between March 25, 2008 and March 25, 2009, which happens to be one year.	Intervals can express the period of time that starts at a given point in time and ends at a given point in time. The duration value itself is implied.

SAS ISO 8601 References

The following table lists additional references for SAS ISO 8601:

Table 7.25 *SAS ISO 8601 References*

Topic	Link
SAS 9.3 Language Reference: Concepts	http://support.sas.com/documentation/cdl/en/lrcon/62753/HTML/default/viewer.htm#titlepage.htm
Working with Dates and Times Using the ISO 8601 Basic and Extended Notations	http://support.sas.com/documentation/cdl/en/leforinforref/63324/HTML/default/viewer.htm#p1a0qt18rxydrkn1b0rtdfh2t8zs.htm
CALL IS8601_CONVERT Routine	http://support.sas.com/documentation/cdl/en/lefunctionsref/63354/HTML/default/viewer.htm#p0bhy7ndmdivmmn10b2okmbgiqmj.htm

Topic	Link
$N8601Bw.d Informat	http://support.sas.com/documentation/cdl/en/leforinforref/63324/HTML/default/viewer.htm#n1mqdr981wjxx3n11kqndfer2ei5.htm
$N8601Ew.d Informat	http://support.sas.com/documentation/cdl/en/leforinforref/63324/HTML/default/viewer.htm#p17xoiovjnngtrn1p8yw1r0xyyep.htm
Reading Dates and Times Using the ISO 860 Basic and Extended Notations	http://support.sas.com/documentation/cdl/en/leforinforref/63324/HTML/default/viewer.htm#n09mk4h1ba9wp1n1tc3e7x0eow8q.htm

Special Topic: Debugging a Validation Process

Overview

The SAS Clinical Standards Toolkit provides two properties or global macro variables for debugging problems occurring with all processes. These are _cstDebug and _cstDebugOptions.

The _cstDebug global macro variable toggles debugging options on and off. Many SAS Clinical Standards Toolkit code modules have conditional branching such as:

```
%if &_cstDebug %then
%do;
    /* perform some action */
end;
```

If debugging is toggled on (_cstDebug=1), several things can happen.

- If code is in place, like this excerpt from the sample driver program (validate_data.sas for SDTM 3.1.3) documented in "Running a Validation Process" on page 206, additional messaging to the SAS log can be enabled.

```
%let _cstDebug=0;
```

```
data _null_;
  _cstDebug = input(symget('_cstDebug'),8.);
  if _cstDebug then
    call execute("options &_cstDebugOptions;");
  else
    call execute(("%sysfunc(tranwrd(options %cmpres(&_cstDebugOptions),
                  %str( ), %str( no)));"));
run;
```

By default, the &_cstDebugOptions global macro variable is set to:

mprint mlogic symbolgen mautolocdisplay

These SAS global macro variables generate a lot of information, and they quickly fill the SAS log when running interactively. To increase the default log size permitted, use the option DMSLOGSIZE . You might consider running the process in batch or use PROC PRINTTO to redirect the SAS log to a file.

- Many Work files created during the process are not deleted. They remain available in the Work library to help with debugging.

Each SAS Clinical Standards Toolkit process consists of two primary tasks. The first task is to use set up routines to establish the SAS Clinical Standards Toolkit environment. The second task is to perform some primary SAS Clinical Standards Toolkit action. Your debugging focus is different for these two tasks.

Errors in Setting Up the SAS Clinical Standards Toolkit Environment

In the SAS Clinical Standards Toolkit environment setup, errors most often occur because of problems with the SASReferences data set. For recommendations on configuring the SASReferences data set appropriately, see "Building a SASReferences File" on page 138.

The following table lists common setup errors and possible causes:

Table 7.26 Debugging Process Setup Errors

Error	Location Where Error Is Reported	Possible Cause and Corrective Action
Expected libraries are not allocated.	SAS Log, Libraries window, SAS DMS	(1) An invalid physical name for the libref has been used. Is the libref a valid SAS name? A SAS name can contain one to 32 characters. It must start with a letter or an underscore (_), not a number. Subsequent characters must be letters, numbers, or underscores. Blanks cannot appear in SAS names. Is the libref a reserved SAS libref name? You should not use Work, Sasuser, or Sashelp. (2) The path specified for the libref is invalid; it points to a nonexistent directory. Check the path in your SASReferences data set.
Error: SAS system library WORK cannot be reassigned.	SAS Log	Work is being used as a sasref value with or without a path being designated. A similar error occurs if Sasuser or Sashelp is used.
WARNING: One or more libraries specified in the concatenated library CSTTMP do not exist.	SAS Log	One of the paths specified for a libref is invalid; it points to a nonexistent directory.

Error	Location Where Error Is Reported	Possible Cause and Corrective Action
Warning: Process ending prematurely for CST0090-there were problems with the SASReferences data set.	SAS Log	There is a problem with the SASReferences data set being used. Check for these potential problems: The SASReferences data set does not exist. The SASReferences data set exists but it is empty. The structure of the SASReferences data set is incorrect. For example, it might have an extra column that is not required or an expected column that is missing. A column type might be incorrect. For example, the Order column might be character instead of numeric. An invalid TYPE or SUBTYPE or combination is used in the SASReferences data set. Valid TYPE and SUBTYPE values are provided in the Standardlookup data set found in ***`global standards library directory`*****`/metadata`**. A TYPE value is missing. A SASREF value is missing or invalid. A REFTYPE value is missing or is not equal to libref or fileref (case insensitive).
Error: Physical file does not exist.	SAS Log	(1) The SASReferences data set references a file that does not exist. (2) The filename is not a valid SAS name.

Error	Location Where Error Is Reported	Possible Cause and Corrective Action
WARNING: Apparent invocation of macro SDTM_VALIDATE not resolved.	SAS Log	(1) The macro is misnamed or has not been added to the expected autocall library. Does the macros folder for this standard exist in the cstGlobalLibrary, in the !sasroot hierarchy, or in some correctly designated custom location? (2) The expected autocall path was not created correctly in the call to %CSTUTIL_ ALLOCATESASREFERENCES. Check that the SASReferences data set contains a type=autocall record, defined as a fileref, and points to the correct folder location. Check for an error occurring earlier in the SAS log suggesting that cstutil_allocatesasreferences failed before setting the autocall path.

Errors in Performing Some Primary SAS Clinical Standards Toolkit Action

If the task to perform the primary SAS Clinical Standards Toolkit action begins (that is, the standard-specific validation macro, such as %SDTM_VALIDATE or %CRTDDS_VALIDATE, is found and begins processing), then setup has completed successfully. The remaining process failures are likely because of problems with the various validation components.

Most errors that halt a validation process are reported in the Results data set. As a general rule, these Results data set fields signal process failures and provide information about the cause of the failure:

- the Process status field (_cst_rc), when the value is set to a nonzero value
- the Problem detected field (resultflag), when the value is set to -1

- the Source Data field (srcdata) identifies the macro reporting the problem
- the Resolved Message text field (message) provides a problem cause
- the Basis for Result field (resultdetails) can provide additional information pertinent to the problem

Depending on the severity of the problem and when it occurs, the Results data set might not be saved to the persisted location if that location was requested using a type=results record in the SASReferences data set. In this case, the Results data set defined with the &_cstResultsDS global macro variable might be referenced for the previous information. By default, &_cstResultsDS is set to work._cstresults.

Generally, the SAS Clinical Standards Toolkit does not halt the validation process when an error is detected in a specific check. The error is noted in the Results data set, the resultflag value for that check is set to -1, _cst_rc is set to 0, and processing continues with the next check. A validation process is most likely to be halted (by setting _cst_rc to 1) when there is a significant metadata error that suggests subsequent checks would likely fail to run.

The following table lists common causes for premature process failure or the failure of specific checks to run:

Table 7.27 *Debugging Validation Process Errors*

Error	Resultid in Results Data Set	Possible Cause or Corrective Action
No tables evaluated-check validation control data set.	CST0002	No tables interpreted from the tablescope value could be found in the work._csttablemetadata data set.
<Data set> could not be found	CST0003	This error usually indicates that a specific source column or data set could not be found. The code loops through a set of domains or columns built from the source metadata data sets. This error might result when the source metadata does not accurately reflect the source data.

Error	Resultid in Results Data Set	Possible Cause or Corrective Action
No columns evaluated-check Validation Control specification.	CST0004	No columns interpreted from the columnscope value could be found in the work._cstcolumnmetadata data set. The SAS Clinical Standards Toolkit looks at the union of both tablescope and columnscope to build work._cstcolumnmetadata. The specified column might exist in a domain, but not in any column specified in a tablescope domain.
Lookup to SASReferences control data set failed.	CST0006	The SAS Clinical Standards Toolkit code has a call to the %CSTUTIL_GETSASREFERENCE utility macro for a type or type and subtype combination that cannot be found in the SASReferences data set. This indicates that SASReferences has been incompletely defined for the SAS Clinical Standards Toolkit validation process.
Validation Control parsing of tablescope/ column results in inconsistent sublist lengths.	CST0023	This check involves a comparison of tables or columns, as indicated by multiple sets of brackets in tablescope or columnscope. Each set of brackets constitutes a sublist. However, the number of items in the specified sublist is inconsistent or unexpected by the check macro. Options typically include a more accurate specification of sublist items, either using explicit table or column names or more restrictive tablescope syntax (that is, removing the domain causing the inconsistency using minus sign (-) syntax, such as _ALL_-DM).
One or more check metadata column values is invalid.	CST0026	A value in the Validation Control data set for the check being run is invalid in the context of the specific check macro. Examples include conditions that are required by the check macro but are not found, such as no code logic found, an unexpected usesourcemetadata value, or no lookuptype or lookupsource for valid value assessments.

Error	Resultid in Results Data Set	Possible Cause or Corrective Action
Code failed due to SAS error-see log.	CST0050	A SAS DATA step or SAS procedure failed and the cause is reported in the SAS log. This most commonly occurs because of missing data sets, missing columns, incorrectly sorted data sets, and unexpected macro variable values.
<Message lookup failed to find matching record>	<varies>	The check macro code generates a resultid value that does not find a match in the Messages data set. Either the wrong resultid has been specified, or the standard-specific Messages data set has not been updated to include the resultid.

Other Debugging Tips

Here are some debugging tips that you might find useful:

- Review available Work files for information about the errors (for example, _cstresults, _csttablemetadata, and _cstcolumnmetadata). These files might remain in the Work directory after a process by default. Toggling the _cstDebug global macro variable to 1 forces the Work files to remain after the process ends.
- When debugging, avoid setting the parameter flags in cstutil_cleanupcstsession to 1 (if that cleanup macro is called).

```
%cstutil_cleanupcstsession(_cstClearCompiledMacros=0,
_cstClearLibRefs=0, _cstResetSASAutos=0, _cstResetFmtSearch=0,
_cstResetSASOptions=0,_cstDeleteFiles=0,_cstDeleteGlobalMacroVars=0);
```

- Use work._cstcolumnmetadata and work._csttablemetadata to resolve missing domain and column issues. These data sets can also be used to resolve sublist length differences for checks using sublist syntax [] in tablescope and columnscope.
- Use the resultid code (for example, CST0003) in the Results data set to search the check macro code module used for a specific check for information about the error. The name of the macro code module is set in the Validation Control codesource field.

Special Topic: Validation Customization

Overview

One of the significant benefits of the SAS Clinical Standards Toolkit is that you can customize the solution to meet your needs. From a validation perspective, this includes:

- modifying an existing standard or defining a new reference standard
- using any set of source data and metadata
- modifying the SAS validation checks for supported standards
- adding new validation checks for supported standards
- modifying existing validation check macros or adding new macros
- modifying the SAS Clinical Standards Toolkit messaging, including internationalization
- attempting to validate multiple studies in a single validation process

Each of these customizations is described in these case studies:

- "Case Study 1: Modifying an Existing Standard or Defining a New Reference Standard" on page 253
- "Case Study 2: Using Any Set of Source Data and Metadata" on page 254
- "Case Study 3: Modifying the SAS Validation Checks for Supported Standards" on page 254
- "Case Study 4: Adding New Validation Checks for Supported Standards" on page 255
- "Case Study 5: Modifying Existing Validation Check Macros or Adding New Macros" on page 257
- "Case Study 6: Modifying the SAS Clinical Standards Toolkit Messaging, Including Internationalization" on page 258

- “Case Study 7: Validation of Multiple Studies” on page 260

Case Study 1: Modifying an Existing Standard or Defining a New Reference Standard

Source data and metadata are validated in the SAS Clinical Standards Toolkit against a reference standard. For CDISC standards, the SAS Clinical Standards Toolkit provides a SAS interpretation of the supported CDISC standards. Because CDISC standards are guidelines, they are open to interpretation and customer-specific implementations. Not all clinical studies have all CDISC-defined standard domains, and most clinical studies have additional domains reflecting the focus of the clinical study. In addition, CDISC SDTM domain classes (findings, events, and interventions) enable the inclusion and exclusion of most columns, depending on the clinical data points collected in the study. CDISC guidelines generally do not specify column lengths.

Each of these factors suggests that the SAS Clinical Standards Toolkit CDISC reference standards will be modified or replaced with customer-derived standards. The SAS Clinical Standards Toolkit offers the option of building a reference standard to encompass domain and column customizations. Or, you can customize check macros and check logic to perform specific compliance assessments to a standard. For example, in CDISC SDTM, it is not uncommon to build multiple supplemental qualifier domains (for example, SUPPAE) associated with a core reference domain (for example, AE). It is at the customer's discretion whether the reference standard is modified to include each unique supplemental qualifier domain, or to use existing SAS Clinical Standards Toolkit validation check macros with unique code logic or custom check macros to validate the custom domains. These latter options are discussed in the following case studies.

It is likely that you will derive multiple reference standards. From a SAS Clinical Standards Toolkit validation perspective, the only relevant reference standard is the one defined in the SASReferences data set (as type=referencemetadata).

For information about registering a new standard in the SAS Clinical Standards Toolkit, see “Registering a New Version of a Standard” on page 26.

Case Study 2: Using Any Set of Source Data and Metadata

From a SAS Clinical Standards Toolkit perspective, a source study is defined by the study domains, the study metadata represented in the source_tables and source_columns data sets, and anything that might be unique to a specific study, including controlled terminologies, properties, validation checks, and associated messages.

One key SAS Clinical Standards Toolkit requirement is that source study elements should be kept in synchronization. Another key requirement is that all relevant source study elements should be accurately represented in a SASReferences data set. The synchronization of study elements is a task that is often performed outside the SAS Clinical Standards Toolkit. The study data libraries must contain the domains of interest, the study metadata must provide the complete set of table-level and column-level metadata necessary to describe the source data, and any format catalogs and coding dictionaries supporting the study must be available.

TIP Best Practice Recommendation: If a standard folder hierarchy is adopted for source studies, such as in the SAS Clinical Standards Toolkit CDISC SDTM 3.1.3 sample study (***`sample study library directory`*****`/cdisc-sdtm-3.1.3-1.7/sascstdemodata`**), using generic SASReferences files that use &studyRootPath in the path field might facilitate referencing new source studies.

Case Study 3: Modifying the SAS Validation Checks for Supported Standards

This case study addresses adding multiple instances of existing checks. The most common ways to modify SAS validation checks include:

- Altering the scope of the domains and columns to be validated. Many checks are defined to be run against specific domains or columns, against specific classes of domains (for example, CDISC SDTM findings, events, or interventions), or against all available domains or columns. As you find it useful to modify a reference standard (for example, to include other domains you consistently use) or you have one or more studies that have new domains, changes are likely to involve alterations to the Validation Master and Validation Control (run time) tablescope or columnscope fields.

- Changing the Validation Control codelogic field to alter the logic used to identify error conditions. This might be a necessary change if a check needs to be generalized to accommodate new domains or columns. Or, customer conventions might differ from those in the SAS Clinical Standards Toolkit checks.
- If customer code changes are sufficiently significant, then it might be better to create a new validation check macro. (See "Case Study 5: Modifying Existing Validation Check Macros or Adding New Macros" on page 257.) If a new validation check macro is required, then the Validation Control codesource field needs to be modified to contain the name of the new check macro.
- The Validation Control uniqueid field provides a way to uniquely identify a specific validation check for reference. Any substantive change to any Validation Control data set check field normally leads to a new uniqueid. For information about the structure of uniqueid, see Table 7.3 on page 174.
- The Validation Control checkstatus field provides an easy way to identify selected checks with a user-defined status (for example, draft, deprecated, or not available for a given study). The SAS Clinical Standards Toolkit does not reference this field within any validation check macro.
- The Validation Control lookupsource field can be changed to reference a different SAS format or lookup data set (for example, a new version of MedDRA). In the latter case, a change to the pathname, memname, or both fields in the SASReferences data set might be a more appropriate action.

Case Study 4: Adding New Validation Checks for Supported Standards

To add a new validation check, consider this checklist:

- Check metadata must conform to the Validation Master structure. (For more information, see Chapter 2, "Framework," on page 7.)

- Certain Validation Master fields accept any user-defined value (for example, checksource, sourceid, checktype, standardref, and checkstatus). These fields are not referenced by the validation check macros. The remaining fields are used in the validation check macros, so you must abide by the SAS Clinical Standards Toolkit conventions. These conventions are described in Chapter 2, “Framework,” on page 7.
- A new check should be added to the (run time) Validation Control data set for testing. After testing, it can be promoted to the Validation Master data set to be available to applications and processes. These requirements follow a typical development process.
- For each new validation check, a matching message is required. This is the message that you want written to the Results data set when an error condition is detected. For details, see “Messages” on page 192.
- Use a similar validation check as a template to build the check metadata required by the SAS Clinical Standards Toolkit. Ask yourself the following types of questions:
  - What category or type of check is it?

    Look at the Validation Master data set checktype column. Does it look only at table or column metadata, and not at data values (Metadata)? Does it require a specific raw column value (ColumnValue), or a value that complies with some controlled terminology (Cntlterm)? Must the assessment look across multiple records (Multirecord) or multiple tables (Multitable)?
  - Does the check compare columns within a single table?

    Consider Validation Master records where the codesource column is cstcheck_columncompare, cstcheck_columnvarlist, or cstcheck_notunique.
  - Does the check compare tables?

    Consider Validation Master records where the codesource column is cstcheck_comparedomains or cstcheck_recnotfound.
  - Does the check look across multiple standards?

    Consider Validation Master records where the codesource column is cstcheck_crossstdcomparedomains or cstcheck_crossstdmetamismatch.

- What tablescope and columnscope values are appropriate?
  - Tablescope

    Does the check apply to a specific class of tables (for example, Class:Findings)? Does the check apply to all tables for the standard (_ALL_)? Does the check apply only to one or more specific tables (for example, DM +TA)? Does the check apply to all tables except one (for example, _ALL_-DM)? Does the check compare the same column in two tables (for example, [DM][TA])?
  - Columnscope

    Does the check apply to all columns in the selected tables (_ALL_)? Does the check apply only to one column (for example, USUBJID)? Does the check compare two columns in the same table (for example, [AESDTH][AEOUT])? Does the check apply to all column names that end in a particular suffix (for example, **DTC)?
- If column values are to be compared against an external source (coding dictionary or specific codelist), how are these values referenced for other checks in the lookuptype and lookupsource Validation Master columns?

Case Study 5: Modifying Existing Validation Check Macros or Adding New Macros

The SAS Clinical Standards Toolkit provides 21 validation check macros. These macros, located in the primary SAS Clinical Standards Toolkit autocall library, offer a variety of code examples that are available to all standards supporting validation. For information about the purpose and use of each check macro, see "Special Topic: Validation Check Macros" on page 229 and the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Some validation scenarios might require modifications to the SAS Clinical Standards Toolkit check macros or the derivations of new macros. If so, these guidelines should be followed. These guidelines facilitate the use of these macros in the general SAS Clinical Standards Toolkit framework and in the specific SAS Clinical Standards Toolkit validation framework.

- Follow the current naming convention or adopt a consistent naming convention that conforms to SAS naming conventions.
- Use the current autocall library or use a customized autocall library that has been defined in the SASReferences data set (type=autocall).
- Conform to the basic check macro workflow. This workflow is described in "Special Topic: Validation Check Macros" on page 229.
- Ensure that the macro correctly accepts and interprets the metadata provided as input from the Validation Control data set. If the new macro fails to do so, then it can be hardcoded to provide any specific functionality that is desired.
- Ensure that the macro writes appropriate output to the Results and Metrics data sets.

Case Study 6: Modifying the SAS Clinical Standards Toolkit Messaging, Including Internationalization

This case study considers these three issues related to the support of the SAS Clinical Standards Toolkit messaging:

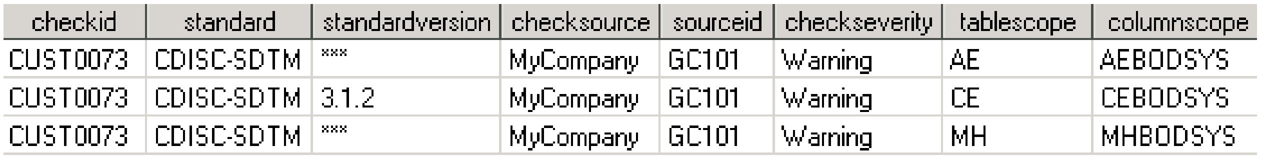
1. Maintain the relationship between the SAS Clinical Standards Toolkit standard-specific messages and standard-specific validation checks.
2. Maintain the relationship between messages and validation check macro code.

   (Deviations are acceptable to the extent that missing parameters have suitable defaults.)
3. Internationalize messages.

A SAS Clinical Standards Toolkit message is created for each distinct combination of the Validation Master standard and checksource fields. This allows the SAS Clinical Standards Toolkit to support checksource-specific messaging and severity. A unique SAS Clinical Standards Toolkit message is required for each value of the Validation Master standardversion field if that value is not the wildcard ***.

Consider the CDISC SDTM Validation Master record excerpt in this display.

Figure 7.12 *Validation Master Data Set Excerpt for Check CUST0073*

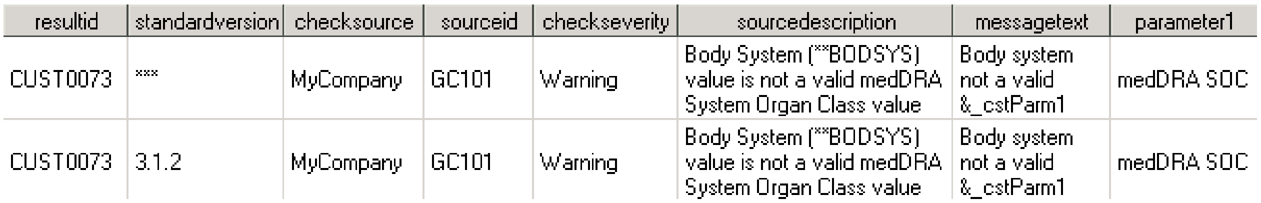


checkid	standard	standardversion	checksource	sourceid	checkseverity	tablescope	columnscope
CUST0073	CDISC-SDTM	***	MyCompany	GC101	Warning	AE	AEBODSYS
CUST0073	CDISC-SDTM	3.1.2	MyCompany	GC101	Warning	CE	CEBODSYS
CUST0073	CDISC-SDTM	***	MyCompany	GC101	Warning	MH	MHBODSYS

Three separate invocations of CUST0073 are represented. Each record points to a different domain (tablescope). This example assumes that the CDISC SDTM 3.1.2 standard has been registered. The first and third records (AE and MH domains) indicate that this specific implementation of the check is applicable to all versions of CDISC SDTM. However, the second record is applicable to only CDISC SDTM 3.1.2 (because CE is a new domain in SDTM 3.1.2).

The following display shows that only two Messages data set records are required:

Figure 7.13 *Messages Data Set Excerpt for Check CUST0073*



resultid	standardversion	checksource	sourceid	checkseverity	sourcedescription	messagetext	parameter1
CUST0073	***	MyCompany	GC101	Warning	Body System (**BODSYS) value is not a valid medDRA System Organ Class value	Body system not a valid &_cstParm1	medDRA SOC
CUST0073	3.1.2	MyCompany	GC101	Warning	Body System (**BODSYS) value is not a valid medDRA System Organ Class value	Body system not a valid &_cstParm1	medDRA SOC

It is the distinct combinations of the Validation Master checkid, standardversion, and checksource fields that control the associated Messages data set records.

It is important to maintain the relationship between messages and validation check macro code. If the validation check macro code references an unknown resultid, the text `<Message lookup failed to find matching record>` is written to the Results data set.

The CUST0073 check defines a substitution parameter (&_cstParm1). (The SAS Clinical Standards Toolkit code assumes that message substitution parameters begin with the string &_cst.) For the calling validation check macro to support parameters when writing output to the Results data set, the parameters that are passed should be syntactically consistent with the messagetext field in the Messages data set.

Building the message record to use a default value (as specified in the parameter1 field) solves the problem when the calling macro fails to pass a substitution value. Using parameters is optional. Parameters might be needed only if the message is to be used in multiple contexts where substitutions of parameter values help interpret the message.

The SAS Clinical Standards Toolkit supports the internationalization of messages through specifying message file references in the SASReferences data set (type=messages). If referenced message files conform to the structure expected by the SAS Clinical Standards Toolkit, any text, including internationalized text, can be included.

Case Study 7: Validation of Multiple Studies

Most illustrations and discussions in this chapter assume a reference to a single clinical study. But, what if you need to validate multiple clinical studies at one time? A key consideration is the information that source data libraries and source metadata files contain, and how they should be referenced in the SASReferences data set used by the validation process.

Consider these methodologies, which are ordered based on estimated rates of adoption. Other candidate methodologies are possible.

- A common methodology is to build single source data and metadata libraries that contain pooled data sets where metadata reconciliation has already occurred. (This is frequently done in integrated summaries of efficacy and safety.) In this case, the SASReferences data set contains a single type=sourcedata record pointing to the pooled integrated data library. The SASReferences SAS librefs (where type=sourcemetadata) must match the source metadata library references in the sasref column of the table and column metadata data sets.
- A second methodology is to build a SAS Clinical Standards Toolkit process that daisy-chains multiple job streams, where each study is defined in a unique SASReferences data set and validated independently. Within the same SAS session, unless your validation process deletes work files, the results and metrics files are appended. The files at the end of the process contain results for all studies.
- An alternative approach defines a single SASReferences libref for multiple type=sourcedata records, each pointing to a different study source library. The SAS

Clinical Standards Toolkit supports library concatenation, but SAS only reads data sets from the first defined library when the same data set name occurs in multiple libraries. Because standard domain names are expected, this approach does not work unless a unique domain-naming convention across studies is used. A similar approach is required for source metadata. These constraints make this approach less tenable.

- Another alternative methodology is to use multiple SASReferences librefs (multiple type=sourcedata records). You have one for each study source library, and a single source metadata library (with one table and one column metadata data set, setting the SASRef column to each libref used in SASReferences). This methodology works for any validation check that does not compare columns across domains or compares domains.

  Source data libraries are considered when tablescope and columnscope parsing occurs in the SAS Clinical Standards Toolkit. However, if tablescope does not include the libref, unintended comparisons of multiple columns or multiple domains from different studies can occur. As a result, this methodology is not recommended unless you consistently use multiple librefs in the source metadata and validation check metadata.

Special Topic: Using Alternative Controlled Terminologies

The SAS Clinical Standards Toolkit supports using any set of controlled terminology or any coding dictionaries such as MedDRA or WHO Drug.

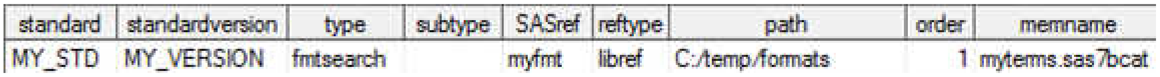
Generally, controlled terminology is defined to the SAS Clinical Standards Toolkit as SAS format catalogs, and coding dictionaries as SAS data sets, although either format is allowed. A SASReferences data set documents all of these, and facilitates run-time references to the input sources. In the SAS 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 a call to the %CSTUTIL_PROCESSSETUP utility macro.

Consider these scenarios and how each one can be handled using the SAS Clinical Standards Toolkit:

- Scenario 1: You want to create and manage codelists (SAS formats) independent of the CDISC Controlled Terminology standard provided with SAS Clinical Standards Toolkit.

  This scenario assumes you have one or more user-defined SAS format catalogs that contain valid values associated with your data columns. These user-defined format catalogs might include extensions to existing CDISC Controlled Terminology codelists or to new formats associated with columns in custom domains. The SAS Clinical Standards Toolkit SASReferences data set enables you to specify references to multiple catalogs and to manage the order in which these appear in the format search path. For example, if you have a catalog named MYTERMS that contains all formats of interest for your study, your SASReferences data set can contain a single type=fmtsearch record:

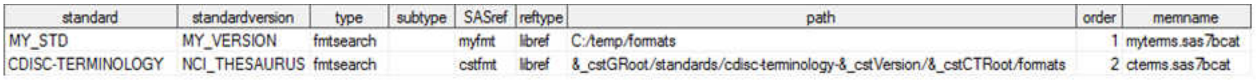
Figure 7.14 *Single type=fmtsearch Record Example*



standard	standardversion	type	subtype	SASref	reftype	path	order	memname
MY_STD	MY_VERSION	fmtsearch		myfmt	libref	C:/temp/formats	1	myterms.sas7bcat

  However, if you prefer to keep your customizations in a separate format catalog, but you want to use the CDISC Controlled Terminology codelists provided with the SAS Clinical Standards Toolkit, your SASReferences data set will have multiple type=fmtsearch records, with the order column value set to establish the format search path precedence:

Figure 7.15 *Multiple type=fmtsearch Records Example*



standard	standardversion	type	subtype	SASref	reftype	path	order	memname
MY_STD	MY_VERSION	fmtsearch		myfmt	libref	C:/temp/formats	1	myterms.sas7bcat
CDISC-TERMINOLOGY	NCI_THESAURUS	fmtsearch		cstfmt	libref	&_cstGRoot/standards/cdisc-terminology-&_cstVersion/&_cstCTRoot/formats	2	cterms.sas7bcat

  In this case, any extended, like-named formats in MYTERMS are used instead of the original formats in CTERMS provided with the SAS Clinical Standards Toolkit.

- Scenario 2: You want to manage codelist (SAS format) customizations as a registered standard in the global standards library of the SAS Clinical Standards Toolkit.

SAS provides snapshots of the CDISC Controlled Terminology standard, as provided by the National Cancer Institute (NCI) Enterprise Vocabulary Services (EVS). These snapshots are defined in the global standards library. In the SAS Clinical Standards Toolkit, these are provided (by CDISC model and snapshot date) in the following location:

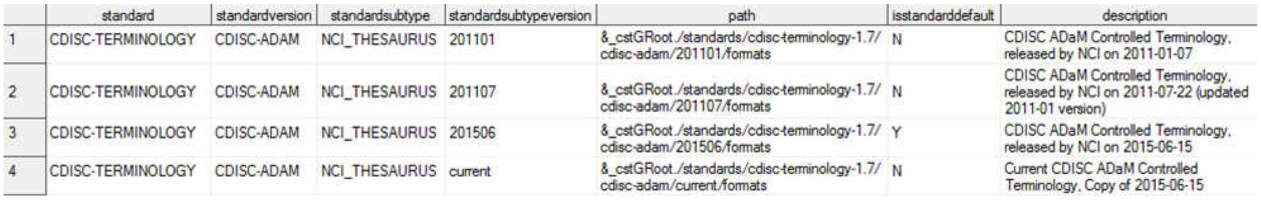
***global standards library directory*/standards/ cdisc-terminology-1.7/**

Consider whether you want to add a new version (such as a dated snapshot) or a completely new set of terminology to the global standards library. To add a new version, follow the snapshot folder hierarchy in the global standards library, and register your new standard in the standardsubstypes data set is located here:

***global standards library directory*/standards/ cdisc-terminology-1.7/control**

For example, suppose you want to add a new CDISC ADaM controlled terminology snapshot released on 15June2015. A new 201506 folder hierarchy is created in the global standards library, a new record is added to the standardsubstypes data set, and the format catalog in the Current subfolder is replaced with the 201506 catalog.

Figure 7.16 *New Controlled Terminology Record*



	standard	standardversion	standardsubtype	standardsubtypeversion	path	isstandarddefault	description
1	CDISC-TERMINOLOGY	CDISC-ADAM	NCI_THESAURUS	201101	&_cstGRoot./standards/cdisc-terminology-1.7/ cdisc-adam/201101/formats	N	CDISC ADaM Controlled Terminology, released by NCI on 2011-01-07
2	CDISC-TERMINOLOGY	CDISC-ADAM	NCI_THESAURUS	201107	&_cstGRoot./standards/cdisc-terminology-1.7/ cdisc-adam/201107/formats	N	CDISC ADaM Controlled Terminology, released by NCI on 2011-07-22 (updated 2011-01 version)
3	CDISC-TERMINOLOGY	CDISC-ADAM	NCI_THESAURUS	201506	&_cstGRoot./standards/cdisc-terminology-1.7/ cdisc-adam/201506/formats	Y	CDISC ADaM Controlled Terminology, released by NCI on 2015-06-15
4	CDISC-TERMINOLOGY	CDISC-ADAM	NCI_THESAURUS	current	&_cstGRoot./standards/cdisc-terminology-1.7/ cdisc-adam/current/formats	N	Current CDISC ADaM Controlled Terminology, Copy of 2015-06-15

The SAS Clinical Standards Toolkit provides sample programs that create the data sets that are needed to register controlled terminology. The programs also register these data sets. The programs are called create_terminology_standarddatasets.sas and registerstandard.sas and are here:

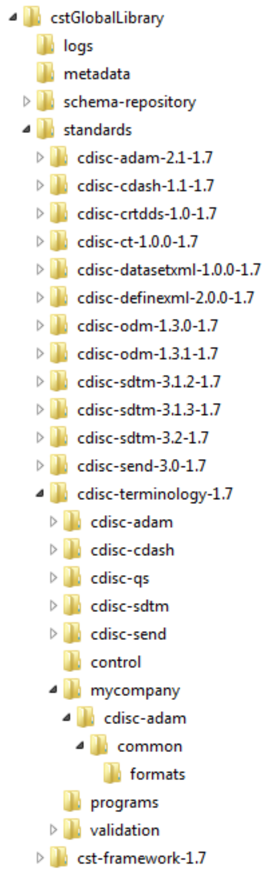
***global standards library directory*/standards/cdisc- terminology-1.7/programs**

Note: You must have Write access to the global standards library.

If you want to add a completely new set of terminology to the global standards library, you must follow the information in “Maintenance Usage Scenarios” on page 25.

Assume that your organization has created its own comprehensive set of CDISC controlled terminology, and you have created the global standards library subfolder hierarchy (with CDISC ADaM fully expanded) shown in this display.

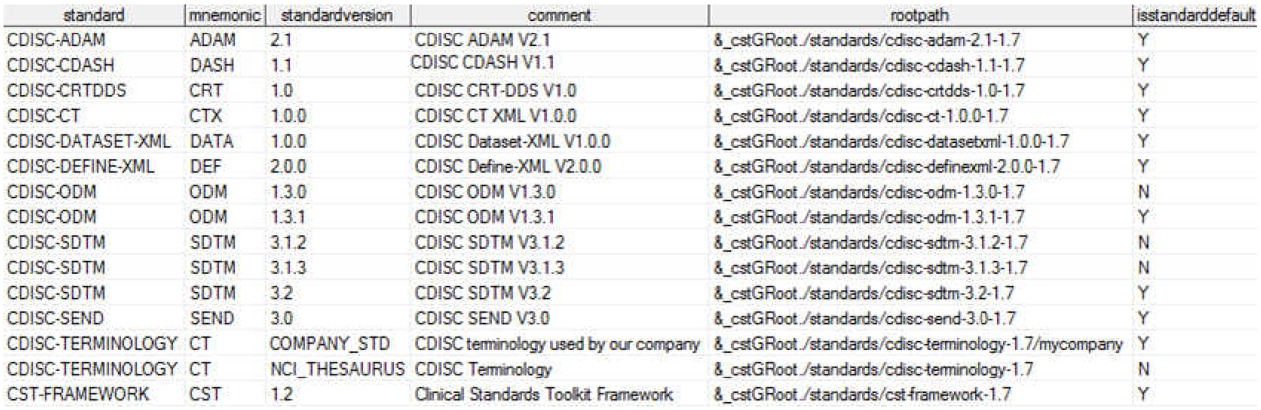
Figure 7.17 Global Standards Library Subfolder Hierarchy Example



```
cstGlobalLibrary
  logs
  metadata
  schema-repository
  standards
    cdisc-adam-2.1-1.7
    cdisc-cdash-1.1-1.7
    cdisc-crtdds-1.0-1.7
    cdisc-ct-1.0.0-1.7
    cdisc-datasetxml-1.0.0-1.7
    cdisc-definexml-2.0.0-1.7
    cdisc-odm-1.3.0-1.7
    cdisc-odm-1.3.1-1.7
    cdisc-sdtm-3.1.2-1.7
    cdisc-sdtm-3.1.3-1.7
    cdisc-sdtm-3.2-1.7
    cdisc-send-3.0-1.7
    cdisc-terminology-1.7
      cdisc-adam
      cdisc-cdash
      cdisc-qs
      cdisc-sdtm
      cdisc-send
      control
      mycompany
        cdisc-adam
          common
            formats
      programs
      validation
    cst-framework-1.7
```

After the registration process, this display shows how your global standards library data set might look (using the folder hierarchy above).

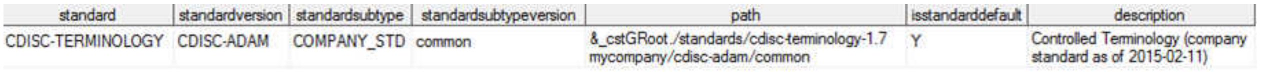
Figure 7.18 Global Standards Library Standards Data Set Example



standard	mnemonic	standardversion	comment	rootpath	isstandarddefault
CDISC-ADAM	ADAM	2.1	CDISC ADAM V2.1	&_cstGRoot./standards/cdisc-adam-2.1-1.7	Y
CDISC-CDASH	DASH	1.1	CDISC CDASH V1.1	&_cstGRoot./standards/cdisc-cdash-1.1-1.7	Y
CDISC-CRTDDS	CRT	1.0	CDISC CRT-DDS V1.0	&_cstGRoot./standards/cdisc-crtdds-1.0-1.7	Y
CDISC-CT	CTX	1.0.0	CDISC CT XML V1.0.0	&_cstGRoot./standards/cdisc-ct-1.0.0-1.7	Y
CDISC-DATASET-XML	DATA	1.0.0	CDISC Dataset-XML V1.0.0	&_cstGRoot./standards/cdisc-datasetxml-1.0.0-1.7	Y
CDISC-DEFINE-XML	DEF	2.0.0	CDISC Define-XML V2.0.0	&_cstGRoot./standards/cdisc-definexml-2.0.0-1.7	Y
CDISC-ODM	ODM	1.3.0	CDISC ODM V1.3.0	&_cstGRoot./standards/cdisc-odm-1.3.0-1.7	N
CDISC-ODM	ODM	1.3.1	CDISC ODM V1.3.1	&_cstGRoot./standards/cdisc-odm-1.3.1-1.7	Y
CDISC-SDTM	SDTM	3.1.2	CDISC SDTM V3.1.2	&_cstGRoot./standards/cdisc-sdtm-3.1.2-1.7	N
CDISC-SDTM	SDTM	3.1.3	CDISC SDTM V3.1.3	&_cstGRoot./standards/cdisc-sdtm-3.1.3-1.7	N
CDISC-SDTM	SDTM	3.2	CDISC SDTM V3.2	&_cstGRoot./standards/cdisc-sdtm-3.2-1.7	Y
CDISC-SEND	SEND	3.0	CDISC SEND V3.0	&_cstGRoot./standards/cdisc-send-3.0-1.7	Y
CDISC-TERMINOLOGY	CT	COMPANY_STD	CDISC terminology used by our company	&_cstGRoot./standards/cdisc-terminology-1.7/mycompany	Y
CDISC-TERMINOLOGY	CT	NCI_THESAURUS	CDISC Terminology	&_cstGRoot./standards/cdisc-terminology-1.7	N
CST-FRAMEWORK	CST	1.2	Clinical Standards Toolkit Framework	&_cstGRoot./standards/cst-framework-1.7	Y

The following display shows that the standardsubstypes data set located in the ***global standards library directory*/standards/cdisc-terminology-1.7/control** folder now contains this CDISC ADaM record:

Figure 7.19 CDISC ADaM Record Example



standard	standardversion	standardsubtype	standardsubtypeversion	path	isstandarddefault	description
CDISC-TERMINOLOGY	CDISC-ADAM	COMPANY_STD	common	&_cstGRoot./standards/cdisc-terminology-1.7 mycompany/cdisc-adam/common	Y	Controlled Terminology (company standard as of 2015-02-11)

- Scenario 3: You use multiple versions of the MedDRA dictionary to code Adverse Events across multiple studies within a submission.

  The SAS Clinical Standards Toolkit does not provide copies of the MedDRA coding dictionary as maintained and distributed by the Maintenance and Support Services Organization. Your organization more than likely maintains the multiple updates to MedDRA, and you might need to reference multiple versions of MedDRA in a single SAS Clinical Standards Toolkit process.

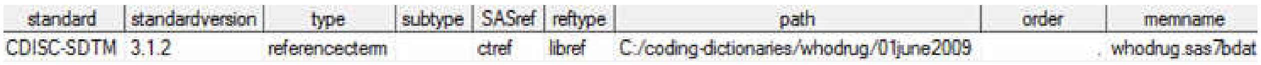
  Although it is possible to create and use SAS format catalogs for MedDRA lookups (and similar coding dictionary lookups), the SAS Clinical Standards Toolkit provides a mechanism to reference and use a data set lookup methodology in the SASReferences data set using one or more type=referencecterm records. Each record points to a specific MedDRA version using a unique SAS libref, with the resulting libref.dataset available for use, as needed.

- Scenario 4: You use the WHO Drug dictionary to ensure that your coding of Concomitant Medications in CMDECOD and CMCLASCD includes valid terms and class codes.

  The SAS Clinical Standards Toolkit does not provide copies of the WHO Drug dictionary as created by the World Health Organization and managed by the Uppsala Monitoring Centre. As in Scenario 3, the SAS Clinical Standards Toolkit provides a mechanism to reference and use a data set lookup methodology in the SASReferences data set using one or more type=referencecterm records.

  The following display shows how your WHO Drug reference might look:

Figure 7.20 *WHO Drug Reference Example*

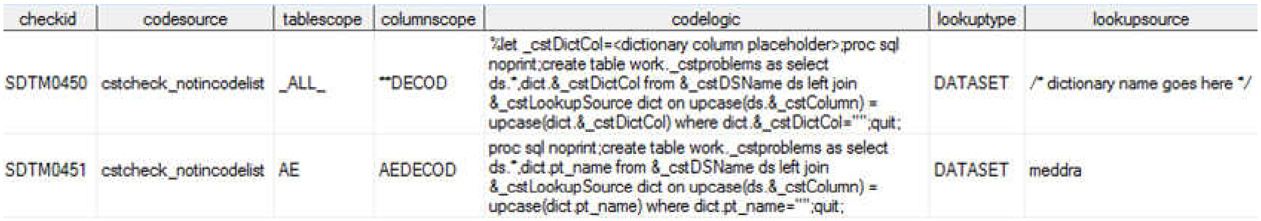


standard	standardversion	type	subtype	SASref	reftype	path	order	memname
CDISC-SDTM	3.1.2	referencecterm		ctref	libref	C:/coding-dictionaries/whodrug/01june2009	.	whodrug.sas7bdat

The SAS Clinical Standards Toolkit provided, in releases prior to version 1.7, several CDISC SDTM validation checks that involved lookups to coding dictionaries. This methodology can still be used in the SAS Clinical Standards Toolkit 1.7.

The following display shows the relevant metadata columns from the validation check data set:

Figure 7.21 *Metadata Columns Example*



checkid	codesource	tablescope	columnscope	codelogic	lookuptype	lookupsource
SDTM0450	cstcheck_notincodelist	_ALL_	**DECOD	%let _cstDictCol=<dictionary column placeholder>;proc sql noprint;create table work._cstproblems as select ds.*,dict.&_cstDictCol from &_cstDSName ds left join &_cstLookupSource dict on upcase(ds.&_cstColumn) = upcase(dict.&_cstDictCol) where dict.&_cstDictCol="";quit;	DATASET	/* dictionary name goes here */
SDTM0451	cstcheck_notincodelist	AE	AEDECOD	proc sql noprint;create table work._cstproblems as select ds.*,dict.pt_name from &_cstDSName ds left join &_cstLookupSource dict on upcase(ds.&_cstColumn) = upcase(dict.pt_name) where dict.pt_name="";quit;	DATASET	meddra

The codelogic value is specific to the coding dictionary. In a WHO Drug lookup, drugname and atc_code (or their equivalents) are used. The %CSTCHECK_NOTINCODELIST check macro retrieves and uses the lookup data set named in the lookupsource metadata column based on information stored in the SASReferences data set records where type=referencecterm.

Special Topic: Performance Considerations

Here are some best practice recommendations:

- You should first run the SAS Clinical Standards Toolkit validation on a subset of source data to identify general process problems, missing or inconsistent process control metadata, and common (and perhaps correctable) data errors.
- You should subset the SAS Clinical Standards Toolkit standard-specific Validation Master data set to remove duplicate checks. For example, CDISC SDTM Janus checks are generally duplicates of WebSDM checks with occasionally different resultseverity values.
- You should be toggled off the _cstDebug option, except for when you want to debug specific program errors to avoid exceeding the SAS log-size limitations or to avoid generating large SAS log files.
- You should run in batch or using PROC PRINTTO any SAS Clinical Standards Toolkit validation process that involves a large number of checks. This is also true for a SAS Clinical Standards Toolkit validation process that is run with the _cstDebug option toggled on. Doing so avoids exceeding the SAS log-size limitations.

8

Internal Validation

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Overview

Each standard as defined in the SAS Clinical Standards Toolkit includes numerous SAS metadata files and SAS macros. For the SAS Clinical Standards Toolkit to function properly, each file must contain a core set of columns that have an expected variable type. Each macro is designed to use these core columns to perform certain functions.

The term *internal validation* refers to a set of tools that checks the consistency of the SAS metadata files. The tools use the SAS Clinical Standards Toolkit validation framework and methodology that assess standard-specific files against a defined reference standard. The tools determine whether the metadata that the SAS Clinical Standards Toolkit expects is correctly defined.

The primary design goals of internal validation include:

- Verify that the metadata files that are provided with the SAS Clinical Standards Toolkit are consistent and correct.
- Use this functionality to facilitate definition, registration, and validation of new user-defined custom standards.
- Use the SAS Clinical Standards Toolkit validation framework whenever possible.
- Limit the amount of new metadata that is required to support internal validation.
- Enable the use of the functionality during product development as a part of the installation qualification process and operational qualification process and as users add new metadata or modify existing metadata.
- Significantly expand the internal validation of SASReferences data sets beyond the use of the %CSTUTIL_CHECKDS autocall macro used in previous releases of the SAS Clinical Standards Toolkit.
- Develop a suite of internal validation programs, tools, and validation processes that can be run independently or as part of a SAS Clinical Standards Toolkit process provided by SAS.

The SAS Clinical Standards Toolkit provides a representative sample of programs, tools, and validation processes to support internal validation, which are summarized in these scenarios:

Table 8.1 Supported Internal Validation Scenarios

Scenario
Support installation qualification and operational qualification assessment and reporting
Assess metadata consistency across files

Scenario
Determine the structural validity of a metadata file
Confirm valid content of a metadata file
Validate a SASReferences data set

Supporting Macros

The following macros support SAS Clinical Standards Toolkit internal validation. Many of these macros are also used for other purposes.

These macros are located in the primary SAS Clinical Standards Toolkit autocall path:

- Microsoft Windows

  ```
  !sasroot/cstframework/sasmacro
  ```

- UNIX

  ```
  !sasroot/sasautos
  ```

For complete macro documentation, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Table 8.2 *Autocall Macros That Support Internal Validation*

Macro	Primary Purpose
%CSTCHECKENTITYNOTFOUND	Reports that a SAS Clinical Standards Toolkit entity (typically a file, folder, or column) cannot be found.
%CSTCHECKUTILCHECKFILE	Determines whether a file exists as defined by columns in a source data set.
%CSTCHECKUTILCHECKFOLDER	Determines whether a folder exists as defined by columns in a source data set.

Macro	Primary Purpose
%CSTCHECKUTILCHECKSTRUCTURE	Compares the structure of data sets referenced within StandardSASReferences or SASReferences data sets against a template.
%CSTCHECKUTILFINDSASREFSFILE	Determines whether designated files in the referenced SASReferences data set exist.
%CSTCHECKUTILLOOKUPVALUES	Determines whether metadata column values for discrete columns exist in the Standardlookup data set.
%CSTUTILBUILDMETADATAFROMSASREFS	Builds the framework reference_tables and reference_columns data sets.
%CSTUTILBUILDSTDVALIDATIONCODE	Generates the validation-specific macro _cstreadStds to build the workflow.
%CSTUTILCHECKFORPROBLEM	Handles any error condition that sets error condition _cst_rc to 1.
%CSTUTILCHECKWRITEACCESS	Checks for Write access for an output object.
%CSTUTILCOMPARESTRUCTURE	Compares the metadata structure of two data sets.
%CSTUTILFINDVALIDFILE	Checks whether a folder, file, data set, catalog, or catalog member exists.
%CSTUTILPROCESSFAILED	Returns a Boolean value to report whether a process failed.
%CSTUTILVALIDATESASREFERENCES	Validates the structure and content of a SASReferences data set.
%CSTUTILVALIDATIONSUMMARY	Summarizes the contents of the validation process results data set.

Validating a SASReferences Data Set

A key internal validation design goal is to verify the content of each SASReferences data set. Each SAS Clinical Standards Toolkit process requires the use of a SASReferences data set. The SASReferences data set identifies all of the inputs that are required and the outputs that are created by the process. Each process might have its own unique SASReferences data set. For a description of the content and usage of SASReferences data sets, see Chapter 6, “SASReferences File,” on page 137.

In most driver programs that are provided with the SAS Clinical Standards Toolkit, a call to the %CSTUTIL_PROCESSSETUP macro initiates a series of steps to establish the environment to perform a subsequent task, such as validating a study or building a define.xml file. SAS file and library references are allocated. Updates to the SAS autocall and format search paths are completed. These steps are completed based solely on the content of a SASReferences data set.

With the SAS Clinical Standards Toolkit, the SASReferences data set is automatically validated through a series of calls to the %CSTUTILVALIDATESASREFERENCES macro. These calls to %CSTUTILVALIDATESASREFERENCES are made within macros called in the %CSTUTIL_PROCESSSETUP macro workflow. The following error conditions are reported by default:

Table 8.3 *SASReferences Data Set Error Conditions Reported by the %CSTUTILVALIDATESASREFERENCES Macro*

Error Flag	Error Condition	Details
CHK01	The data set is structurally incorrect.	A structural comparison with the template that is provided with the SAS Clinical Standards Toolkit is performed using cstutilcomparestructure. Minor differences involving labels, informats, and formats are generally ignored.
CHK02	An unknown standard or standardversion exists.	The standard and standardversion must be registered in the <*global standards library directory*>/metadata/standards data set.

Error Flag	Error Condition	Details
CHK03	A referenced input or output file or folder cannot be accessed.	If filetype="input" or "both", the file or folder must exist. If filetype="output", Write access to the output folder must be enabled.
CHK04	A required look-through to the global standards library defaults fails.	You might choose to leave the path or memname blank in your SASReferences data set, which indicates that you want to use the defaults as specified in the standard-specific StandardSASReferences data set. If the path or memname remains blank (unresolved) after the final call to %CSTUTILVALIDATESASREFERENCES in %CSTUTIL_ALLOCATESASREFERENCES, this error is reported.
CHK05	One or more discrete character field values cannot be found in the Standardlookup data set.	Columns with discrete values (reftype, type +subtype combinations, iotype, filetype, allowoverwrite) must have values as defined in the standard-specific Standardlookup data set.
CHK06	For the given context, path or memname macro variables are not resolved.	If macro variables are used as part of the path or memname value, they must resolve to an accessible folder or file.
CHK07	Multiple fmtsearch records exist, but valid ordering is not provided.	To properly set the format search path, an unambiguous ordering of multiple type=fmtsearch records must be provided.
CHK08	Multiple autocall records exist, but valid ordering is not provided.	To properly set the autocall path, an unambiguous ordering of multiple type=autocall records must be provided.

The occurrence of any of these errors causes the process to terminate. The rationale is that if the process setup is incomplete, and the SAS Clinical Standards Toolkit cannot recognize a SASReferences column value or find a specified file, the process output might be unreliable. Correct problems reported in the process results data set (as typically defined by the _cstResultsDS global macro variable) and resubmit the process.

Sample Driver Programs

Overview

The SAS Clinical Standards Toolkit internal validation addresses these primary use cases:

1 Perform installation qualification and operational qualification.

   This is implemented with and illustrated by the use of the validate_iqoq sample driver, which is located here:

   ***sample study library directory*/cst-framework-1.7/programs**

   This is a two-step process:

   a Select the CST-FRAMEWORK standard, and run the checks that are defined in the validation_control_glmeta view of the internal validation validation_master data set.

      This is a set of 64 checks (checkid < CSTV100) that look only at the global standards library metadata folder.

   b Select 1 to *n* specific standards, and run the checks that are defined in the validation_control_stdiqoq view of the internal validation validation_master data set.

      This is a set of 50 checks (checkid > CSTV100 that are relevant to installation qualification and operational qualification issues) that look only at metadata libraries other than the global standards library metadata folder.

2 Perform validation on standard-specific metadata.

   This is implemented with and illustrated by the use of the validate_standard sample driver. Select 1 to *n* specific standards, and run the checks that are defined in the validation_control_std view of the internal validation validation_master data set.

This is a set of 73 checks (checkid > CSTV100) that look only at metadata libraries other than the global standards library metadata folder.

The sample drivers that support internal validation are described in the following sections. The SASReferences data set is validated automatically as part of these sample driver programs during the call to the %CSTUTIL_PROCESSSETUP macro.

Internal Validation Driver Programs That Are Provided with the SAS Clinical Standards Toolkit

A summary of the driver programs that support internal validation, including these two specific use cases, is here:

- validate_iqoq

  SASReferences: stdvalidation_sasrefs (modified in driver)

  validation_control files used: validation_control_glmeta view, validation_control_stdiqoq view, checktype in (‘GLMETA’ ‘STDIQOQ’)

  Purpose: First, runs checks only on CST-FRAMEWORK global standards library metadata (n=64 checks). Then, runs checks on one or more standards as specified in the driver. Fifty checks are run for each selected standard. These are the checks that support installation qualification and operational qualification for the SAS Clinical Standards Toolkit.

- validate_standard

  SASReferences: stdvalidation_sasrefs (modified in driver)

  validation_control files used: validation_control_std view, checktype in (‘STD’ ‘STDIQOQ’)

  Purpose: Runs checks on one or more standards as specified in the driver. Seventy-three checks are run for each selected standard.

- validate_glmetadata

  SASReferences: stdvalidation_sasrefs (modified in driver) validation_control files used: validation_control_glmeta view, checktype in ('GLMETA')

Purpose: Runs checks only on CST-FRAMEWORK global standards library metadata (n=64 checks).

- validate_data

  SASReferences: sasreferences

  validation_control files used: validation_control data set

  Purpose: Runs checks only against CST-FRAMEWORK metadata. The validation_control data set is currently the same as the validation_master data set that is provided with the SAS Clinical Standards Toolkit. Each of these data sets contains 137 checks.

The files are stored in these locations:

- Drivers: ***sample study library directory*/cst-framework-1.7/programs/<*driver*>.sas**
- SASReferences: ***sample study library directory*/cst-framework-1.7/control/<*SASReferences*>.sas7bdat**
- validation_control: ***sample study library directory*/cst-framework-1.7/control/<*data set of view*>**

The validate_data driver is similar in functionality to other standard-specific drivers (such as the CDISC-SDTM validate_data driver). It runs against a validation_control data set with no subsetting by standard or by check. For the simpler workflow, see the validate_data driver program in the *SAS Clinical Standards Toolkit: Macro API Documentation*.

A complete discussion of the use of the validate_iqoq driver program is provided in *SAS Clinical Standards Toolkit: Installation Qualification*, which is available here: http://support.sas.com/documentation/onlinedoc/clinical/index.html.

Internal Validation Driver Program Workflow: validate_standard

Driver location: ***sample study library directory*/cst-framework-1.7/ programs/validate_standard.sas**

This driver program performs all standard-specific validation checks. This excludes checks that target the ***global standards library directory*/metadata** folder files. Essentially, this is any check defined in validation_master, where checktype NE ‘GLMETA’.

Here is the validate_standard driver workflow:

1 Select the standards of interest in work._cstStandardsforIV:

```
*******************************************************************;
* User defines standard(s) of interest in the following data step *;
*******************************************************************;
%cst_getRegisteredStandards(_cstOutputDS=work._cstAllStandards);

data work._cstStandardsforIV;
  set work._cstAllStandards (where=(
       (upcase(standard) = 'CDISC-ADAM'        and standardversion='2.1')
    or (upcase(standard) = 'CDISC-CRTDDS'      and standardversion='1.0')
    or (upcase(standard) = 'CDISC-CDASH'       and standardversion='1.1')
/*
    or (upcase(standard) = 'CDISC-DATASET-XML' and standardversion='1.0.0')
    or (upcase(standard) = 'CDISC-DEFINE-XML'  and standardversion='2.0.0')
    or (upcase(standard) = 'CDISC-CT'          and standardversion='1.0.0')
    or (upcase(standard) = 'CDISC-ODM'         and standardversion='1.3.0')
    or (upcase(standard) = 'CDISC-ODM'         and standardversion='1.3.1')
    or (upcase(standard) = 'CDISC-SDTM'        and standardversion='3.1.2')
    or (upcase(standard) = 'CDISC-SDTM'        and standardversion='3.1.3')
    or (upcase(standard) = 'CDISC-SDTM'        and standardversion='3.2')
    or (upcase(standard) = 'CDISC-SEND'        and standardversion='3.0')
    or (upcase(standard) = 'CDISC-TERMINOLOGY' and standardversion='NCI_THESAURUS')
    or (upcase(standard) = 'CST-FRAMEWORK'     and standardversion='1.2')
*/
  ));
run;
```

In this example, validation is performed only for the CDISC ADaM, CDISC CDASH, and CDISC CRT-DDS standards.

2 Modify the standard validation SASReferences data set to point to the validation_control view of interest.

In the SAS Clinical Standards Toolkit, views have been provided to make defining the various check subsets more dynamic. Physical SAS data sets can be used, if preferred.

```
**************************************************************************;
* Modify the sample SASReferences data set to point to the run-time       *;
* validation_control data set identifying the validation checks of interest. *;
*                                                                         *;
* The validation_control_std view of the validation_master data set includes *;
* just those checks specific to one or more standards and excludes those core*;
* framework checks that look only within the <cstGlobalLibrary>/metadata    *;
* folder.                                                                 *;
 *************************************************************************;
libname _cstTemp "&studyrootpath/control";

data work.stdvalidation_sasrefs;
   set _cstTemp.stdvalidation_sasrefs;
     if type='control' and subtype='validation' then
     do;
       filetype='view';
       memname='validation_control_std.sas7bvew';
     end;
 run;
```

Note: Alternate views might be used. See “Internal Validation Driver Programs That Are Provided with the SAS Clinical Standards Toolkit” on page 276.

3 Call the process setup macro to perform all CST-FRAMEWORK file and library allocations.

The returned &_cstSASRefs data set contains fully resolved path and memname values.

```
%cstutil_processsetup(_cstSASReferencesLocation=&workpath,
_cstSASReferencesName=stdvalidation_sasrefs);
```

4 (Optional) Re-create work.stdvalidation_sasrefs, and replace _srcfile=‘STDVAL’ with_srcfile=‘FWVAL’

```
*************************************************************************;
* work.stdvalidation_sasrefs will accumulate SASReferences records from all *;
*  sources for later use by cstvalidate().                               *;
```

```
****************************************************************************;

data work.stdvalidation_sasrefs;
  set &_cstSASRefs
    attrib _srcfile format=$8. label='File source for record';
    **********************************************************************;
    * Framework validation sasreferences:  cstcntl.stdvalidation_sasrefs *;
    **********************************************************************;
    _srcfile='STDVAL';
run;
```

Note: This step is optional because it merely provides an indication of the sources and purposes of specific SASReferences data set records.

5 Call the code-generator macro to build the job stream for each standard:

```
filename incCode CATALOG "work._cstCode.stds.source" LRECL=255;
%cstutilbuildstdvalidationcode(_cstStdDS=work._cstStandardsforIV,
_cstSampleRootPath=_DEFAULT_, _cstSampleSASRefDSPath=_DEFAULT_,
_cstSampleSASRefDSName=_DEFAULT_);
```

This macro call populates the work._cstCode.stds.source catalog entry with standard-specific code, which is subsequently used in an `%include` statement. For information about macro parameters, see the %CSTUTILBUILDSTDVALIDATIONCODE macro header comments in the *SAS Clinical Standards Toolkit: Macro API Documentation*.

The workflow of this catalog entry is summarized in the following steps:

a Initialize work._cstTempSASRefDS to accumulate SASReferences records from all of the standards of interest for later use by cstvalidate.

b Look for the standard-specific StandardSASReferences data set from the global standards library. If found, run cstutil_processsetup using this data set.

c Append the fully resolved work._cstSASRefs to the work._cstTempSASRefDS that was created in validate_standard driver workflow step 1. Set _srcfile=‘STD’.

d Look for the standard-specific sdtvalidation_sasrefs data set from the sample library. If found, run cstutil_processsetup using this data set.

e Append the fully resolved work._cstSASRefs to the work._cstTempSASRefDS that was created in step a. Set _srcfile=‘STUDY’.

f Remove any duplicate records from work._cstTempSASRefDS using these key values: standard, standardversion, type, and subtype.

  This significantly reduces the number of records given the commonalities of SASReferences data sets, but it is assumed that it is irrelevant which record is retained.

g Run `%cstutilbuildmetadatafromsasrefs(cstSRefsDS=work._cstTempSASRefDS,cstSrcTabDS=work.source_tables, cstSrcColDS=work.source_columns).`

  This macro dynamically builds reference_tables and reference_columns data sets from a SASReferences data set. For examples, see Figure 8.1 on page 282 and Figure 8.2 on page 283.

h Set _cstSASRefs=work._cstTempSASRefDS, which is the cumulative ready-to-go SASReferences data set.

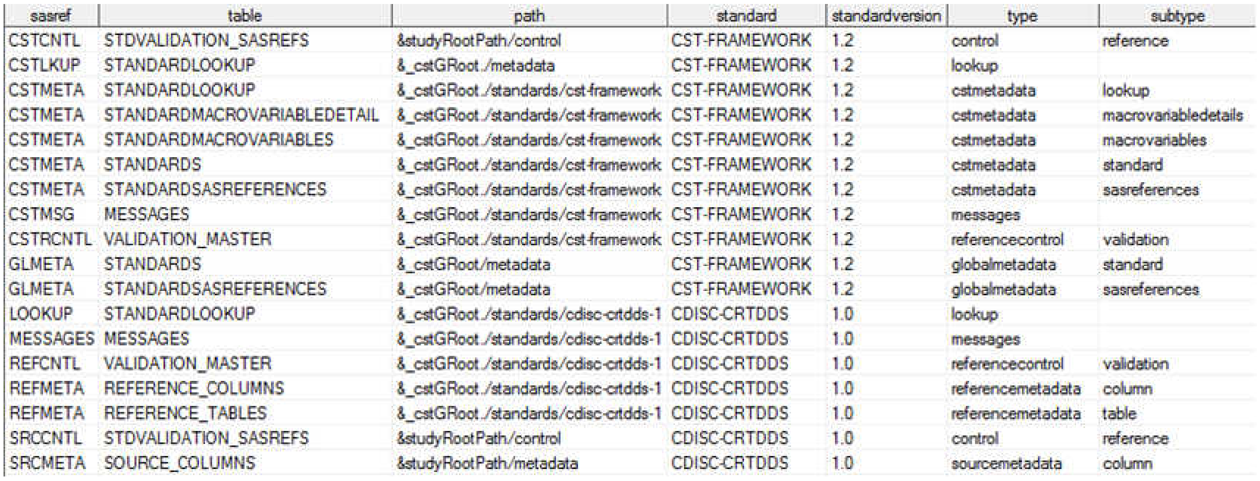
i Call cstvalidate, which uses the validation_control view specific to the driver focus (in this case, validation_control_std) as specified in "Internal Validation Driver Programs That Are Provided with the SAS Clinical Standards Toolkit" on page 276.

j Remove standard-specific records from work._cstTempSASRefDS to anticipate appending new records for the next standard to the remaining framework records.

6 For each standard selected in validate_standard driver workflow step 1, repeat steps a through j in step 5.

  Results are collated in cstrslt.validation_results. For excerpts of the results, see Figure 8.3 on page 284.

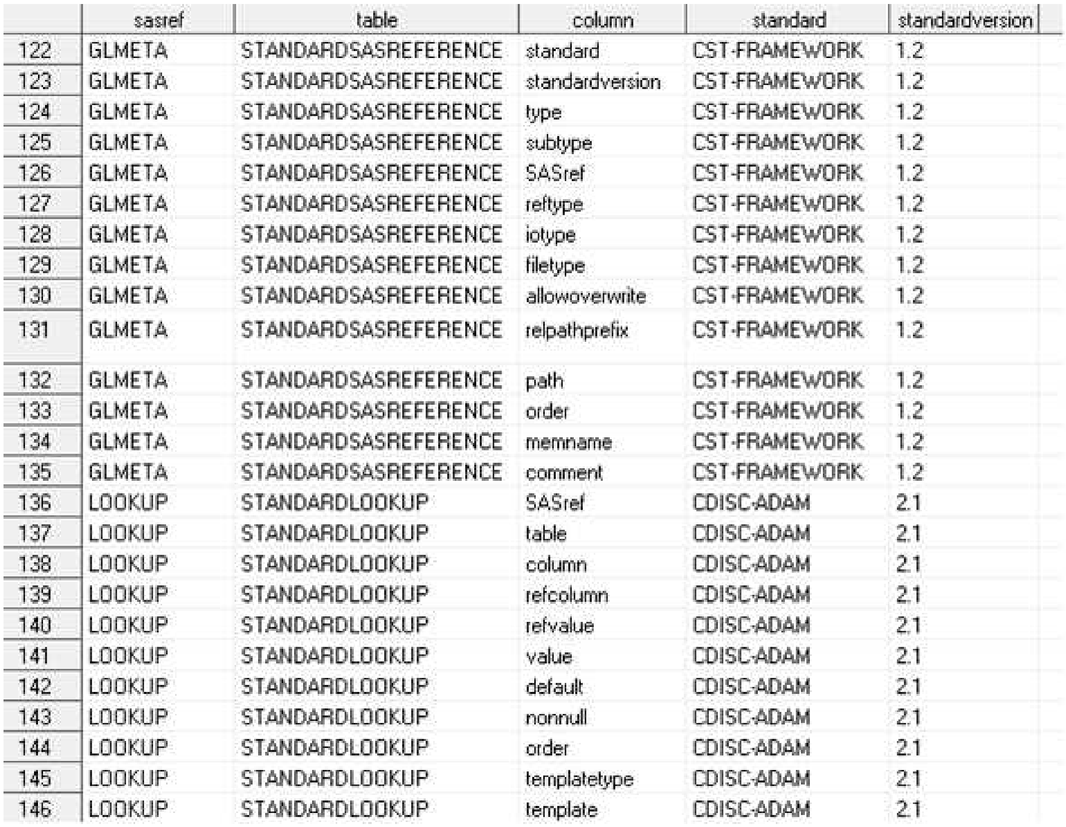
Figure 8.1 *Sample of Dynamically Derived work.reference_tables***



sasref	table	path	standard	standardversion	type	subtype
CSTCNTL	STDVALIDATION_SASREFS	&studyRootPath./control	CST-FRAMEWORK	1.2	control	reference
CSTLKUP	STANDARDLOOKUP	&_cstGRoot./metadata	CST-FRAMEWORK	1.2	lookup	
CSTMETA	STANDARDLOOKUP	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	cstmetadata	lookup
CSTMETA	STANDARDMACROVARIABLEDETAIL	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	cstmetadata	macrovariabledetails
CSTMETA	STANDARDMACROVARIABLES	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	cstmetadata	macrovariables
CSTMETA	STANDARDS	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	cstmetadata	standard
CSTMETA	STANDARDSASREFERENCES	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	cstmetadata	sasreferences
CSTMSG	MESSAGES	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	messages	
CSTRCNTL	VALIDATION_MASTER	&_cstGRoot./standards/cst-framework	CST-FRAMEWORK	1.2	referencecontrol	validation
GLMETA	STANDARDS	&_cstGRoot/metadata	CST-FRAMEWORK	1.2	globalmetadata	standard
GLMETA	STANDARDSASREFERENCES	&_cstGRoot/metadata	CST-FRAMEWORK	1.2	globalmetadata	sasreferences
LOOKUP	STANDARDLOOKUP	&_cstGRoot./standards/cdisc-crtdds-1	CDISC-CRTDDS	1.0	lookup	
MESSAGES	MESSAGES	&_cstGRoot./standards/cdisc-crtdds-1	CDISC-CRTDDS	1.0	messages	
REFCNTL	VALIDATION_MASTER	&_cstGRoot./standards/cdisc-crtdds-1	CDISC-CRTDDS	1.0	referencecontrol	validation
REFMETA	REFERENCE_COLUMNS	&_cstGRoot./standards/cdisc-crtdds-1	CDISC-CRTDDS	1.0	referencemetadata	column
REFMETA	REFERENCE_TABLES	&_cstGRoot./standards/cdisc-crtdds-1	CDISC-CRTDDS	1.0	referencemetadata	table
SRCCNTL	STDVALIDATION_SASREFS	&studyRootPath./control	CDISC-CRTDDS	1.0	control	reference
SRCMETA	SOURCE_COLUMNS	&studyRootPath./metadata	CDISC-CRTDDS	1.0	sourcemetadata	column

Note: **This is an excerpt only. Not all records and columns are shown.

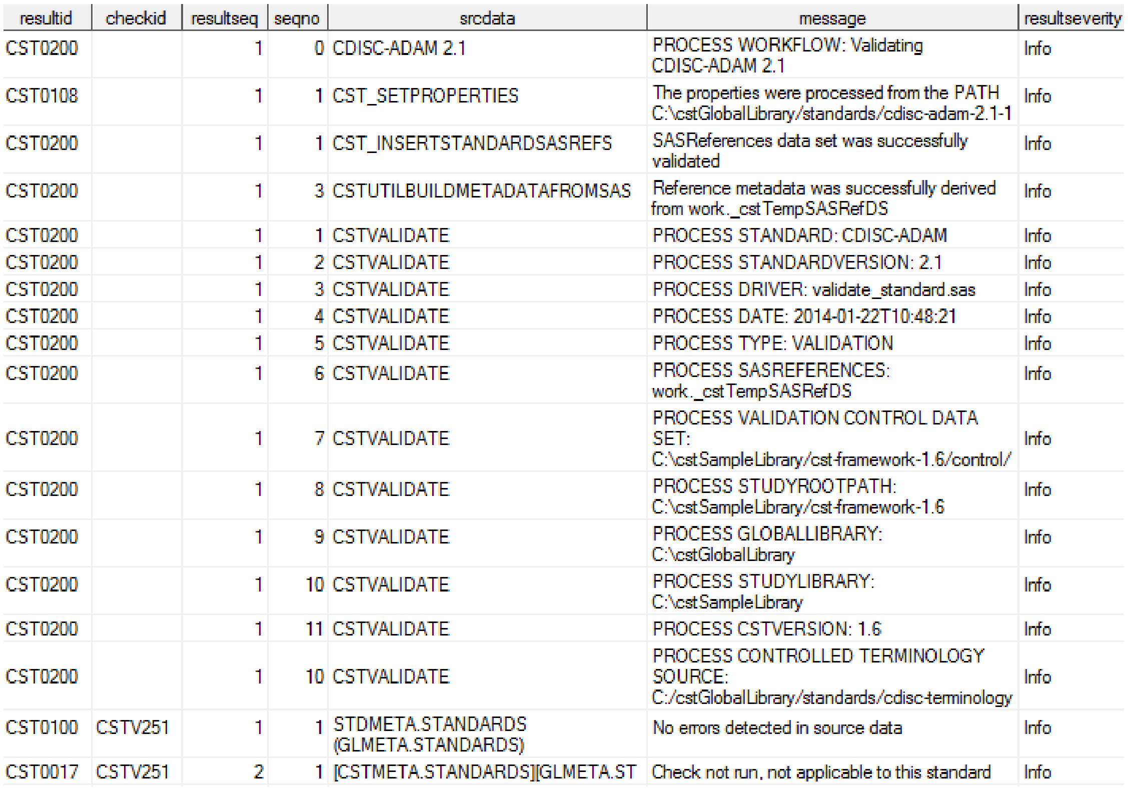
*Figure 8.2 Sample of Dynamically Derived work.reference_columns***



	sasref	table	column	standard	standardversion
122	GLMETA	STANDARDSASREFERENCE	standard	CST-FRAMEWORK	1.2
123	GLMETA	STANDARDSASREFERENCE	standardversion	CST-FRAMEWORK	1.2
124	GLMETA	STANDARDSASREFERENCE	type	CST-FRAMEWORK	1.2
125	GLMETA	STANDARDSASREFERENCE	subtype	CST-FRAMEWORK	1.2
126	GLMETA	STANDARDSASREFERENCE	SASref	CST-FRAMEWORK	1.2
127	GLMETA	STANDARDSASREFERENCE	reftype	CST-FRAMEWORK	1.2
128	GLMETA	STANDARDSASREFERENCE	iotype	CST-FRAMEWORK	1.2
129	GLMETA	STANDARDSASREFERENCE	filetype	CST-FRAMEWORK	1.2
130	GLMETA	STANDARDSASREFERENCE	allowoverwrite	CST-FRAMEWORK	1.2
131	GLMETA	STANDARDSASREFERENCE	relpathprefix	CST-FRAMEWORK	1.2
132	GLMETA	STANDARDSASREFERENCE	path	CST-FRAMEWORK	1.2
133	GLMETA	STANDARDSASREFERENCE	order	CST-FRAMEWORK	1.2
134	GLMETA	STANDARDSASREFERENCE	memname	CST-FRAMEWORK	1.2
135	GLMETA	STANDARDSASREFERENCE	comment	CST-FRAMEWORK	1.2
136	LOOKUP	STANDARDLOOKUP	SASref	CDISC-ADAM	2.1
137	LOOKUP	STANDARDLOOKUP	table	CDISC-ADAM	2.1
138	LOOKUP	STANDARDLOOKUP	column	CDISC-ADAM	2.1
139	LOOKUP	STANDARDLOOKUP	refcolumn	CDISC-ADAM	2.1
140	LOOKUP	STANDARDLOOKUP	refvalue	CDISC-ADAM	2.1
141	LOOKUP	STANDARDLOOKUP	value	CDISC-ADAM	2.1
142	LOOKUP	STANDARDLOOKUP	default	CDISC-ADAM	2.1
143	LOOKUP	STANDARDLOOKUP	nonnull	CDISC-ADAM	2.1
144	LOOKUP	STANDARDLOOKUP	order	CDISC-ADAM	2.1
145	LOOKUP	STANDARDLOOKUP	templatetype	CDISC-ADAM	2.1
146	LOOKUP	STANDARDLOOKUP	template	CDISC-ADAM	2.1

Note: **This is an excerpt only. Not all records and columns are shown.

*Figure 8.3 Sample Results Data Set: validate_standard***



resultid	checkid	resultseq	seqno	srcdata	message	resultseverity
CST0200		1	0	CDISC-ADAM 2.1	PROCESS WORKFLOW: Validating CDISC-ADAM 2.1	Info
CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cdisc-adam-2.1-1	Info
CST0200		1	1	CST_INSERTSTANDARDSASREFS	SASReferences data set was successfully validated	Info
CST0200		1	3	CSTUTILBUILDMETADATAFROMSAS	Reference metadata was successfully derived from work._cstTempSASRefDS	Info
CST0200		1	1	CSTVALIDATE	PROCESS STANDARD: CDISC-ADAM	Info
CST0200		1	2	CSTVALIDATE	PROCESS STANDARDVERSION: 2.1	Info
CST0200		1	3	CSTVALIDATE	PROCESS DRIVER: validate_standard.sas	Info
CST0200		1	4	CSTVALIDATE	PROCESS DATE: 2014-01-22T10:48:21	Info
CST0200		1	5	CSTVALIDATE	PROCESS TYPE: VALIDATION	Info
CST0200		1	6	CSTVALIDATE	PROCESS SASREFERENCES: work._cstTempSASRefDS	Info
CST0200		1	7	CSTVALIDATE	PROCESS VALIDATION CONTROL DATA SET: C:\cstSampleLibrary/cst-framework-1.6/control/	Info
CST0200		1	8	CSTVALIDATE	PROCESS STUDYROOTPATH: C:\cstSampleLibrary/cst-framework-1.6	Info
CST0200		1	9	CSTVALIDATE	PROCESS GLOBALLIBRARY: C:\cstGlobalLibrary	Info
CST0200		1	10	CSTVALIDATE	PROCESS STUDYLIBRARY: C:\cstSampleLibrary	Info
CST0200		1	11	CSTVALIDATE	PROCESS CSTVERSION: 1.6	Info
CST0200		1	10	CSTVALIDATE	PROCESS CONTROLLED TERMINOLOGY SOURCE: C:/cstGlobalLibrary/standards/cdisc-terminology	Info
CST0100	CSTV251	1	1	STDMETA.STANDARDS (GLMETA.STANDARDS)	No errors detected in source data	Info
CST0017	CSTV251	2	1	[CSTMETA.STANDARDS][GLMETA.ST	Check not run, not applicable to this standard	Info

Note: **This is an excerpt only. Not all records and columns are shown.

Validation Checks

validation_master Data Set

A total of 137 validation checks are provided in support of internal validation for the SAS Clinical Standards Toolkit. These can be found in ***global standards library directory*/standards/cst-framework-1.7/validation/control/validation_master.sas7bdat**.

The validation_master data set column checktype is used to specify the primary focus of each check. The following table shows the distribution of records by checktype:

Table 8.4 *Distribution of Internal Validation Checks by Checktype*

Focus	Checktype	Total Number of Checks (Unique)
Global standards library metadata	GLMETA	64 (62)
Standard-specific metadata in global standards library and sample library	STDIQOQ	73 (30)
Standard-specific content	STD	23(8)

The 137 validation checks use 11 of the SAS Clinical Standards Toolkit framework check macros. The following table shows the distribution of these checks by check macro:

Table 8.5 *Distribution of Internal Validation Checks by Check Macro*

Check Macro	Number of Records
%CSTCHECK_COLUMN	38
%CSTCHECK_COLUMNCOMPARE	50
%CSTCHECK_COMPAREDOMAINS	8
%CSTCHECK_DSMISMATCH	7
%CSTCHECK_NOTCONSISTENT	5
%CSTCHECK_NOTINCODELIST	2
%CSTCHECK_NOTUNIQUE	2
%CSTCHECK_RECMISMATCH	4
%CSTCHECK_RECNOTFOUND	11

Check Macro	Number of Records
%CSTCHECK_ZEROOBS	3
%CSTCHECKENTITYNOTFOUND	7

A review of the validation_master tablescope and columnscope values shows a reference to the dynamically derived table and column metadata that is shown in Figure 8.1 on page 282 and Figure 8.2 on page 283.

Note: work.source_tables is a copy of the derived work.reference_tables.work.source_columns is a copy of the derived work.reference_columns.

For internal validation, using the SAS libref is usually required in the validation_master tablescope value. Each SAS libref is associated with a specific SAS library through the SASReferences record that identifies the library (or specific SAS file) as an input to the process.

As with all validation check data sets in the SAS Clinical Standards Toolkit, you can add your own checks or modify existing checks to meet your validation requirements.

validation_control SAS Views

As with any SAS Clinical Standards Toolkit validation process, a key step is the specification of a validation_control data set, which is the definition of a subset of defined validation checks that are the focus of that specific validation process. For internal validation, multiple SAS views have been defined against the superset of internal validation checks that are provided with the SAS Clinical Standards Toolkit.

These SAS views have been created with the code shown in Example Code 8.1 on page 287, where SAS librefs have been defined based on the SASReferences data set references as follows:

```
libname refcntl 'c:/cstGlobalLibrary/standards/cst-framework-1.7/validation/
                  control';
libname cstcntl 'c:/cstSampleLibrary/cst-framework-1.7/control';
```

(The SAS Clinical Standards Toolkit global standards library and sample study library have been set to the path that is indicated.)

Note: The SASReferences filetype column should be set to "view".

Example Code 8.1 *SAS Code to Build Internal Validation Views*

```
proc sql;
  create view cstcntl.validation_control_glmeta
    as select *
    from cstrcntl.validation_master as a
    where upcase(a.checktype)="GLMETA";

  create view cstcntl.validation_control_std
    as select *
    from cstrcntl.validation_master as a
    where upcase(a.checktype) in ("STD","STDIQOQ");

  create view cstcntl.validation_control_stdiqoq
    as select *
    from cstrcntl.validation_master as a
    where upcase(a.checktype) in ("STDIQOQ");
quit;
```

The location of the views can vary based on where your global standards library and sample study library are located.

Example Internal Validation Check: CSTV026

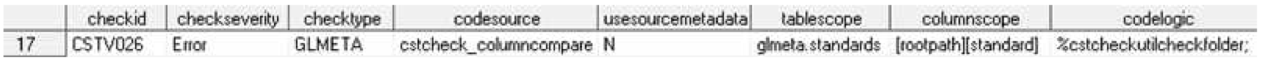
Validation check CSTV026 reports the following condition:

```
Root path does not exist for standard as defined in metadata
standards data set
```

This check reports each instance where the Standards data set column rootpath cannot be found. This value is important to support the use of relative paths, which are indicated by a non-null value in the SASReferences relpathprefix column.

The following display shows a portion of the check metadata for this check:

Figure 8.4 *Internal Validation Check CSTV026 Metadata from validation_master*



	checkid	checkseverity	checktype	codesource	usesourcemetadata	tablescope	columnscope	codelogic
17	CSTV026	Error	GLMETA	cstcheck_columncompare	N	glmeta.standards	[rootpath][standard]	%cstcheckutilcheckfolder;

Each of the column values shown in Figure 8.4 on page 287 is explained in the following table:

*Table 8.6 Column Descriptions for Internal Validation Check CSTV026***

Column	Value	Description
checkid	CSTV026	Specifies the check identifier used to return the correct message from the CST-FRAMEWORK messages data set.
checkseverity	Error	Specifies that the condition is deemed to be serious, which warrants an Error condition.
checktype	GLMETA	Indicates that this check targets the global standards library metadata folder contents. This check is included in the validation_control_glmeta SAS view.
codesource	cstcheck_columncompare	Indicates the check macro to use for processing. All check macros can be found in the primary SAS Clinical Standards Toolkit autocall library.
usesourcemetadata	N	Specifies that the check macro should use work.reference_tables and work.reference_columns to find the tablescope and columnscope values.
tablescope	glmeta.standards	Indicates the specific data set of interest. The SAS libref has been defined in the SASReferences data set (row 10 in Figure 8.1 on page 282) and is included in work.reference_tables.
columnscope	[rootpath][standard]	Specifies the two columns of primary interest in glmeta.standards. The syntax matches what is expected by the %CSTCHECK_COLUMNCOMPARE check macro.
codelogic	%cstcheckutilcheckfolder;	Uses a new check utility macro included in Table 8.2 on page 271.

Note: **Not all check metadata columns are described.

9

XML-Based Standards

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SAS Support of XML-Based Standards

When processing XML-based standards (such as CDISC ODM, CDISC CRT-DDS, and CDISC Define-XML), the SAS Clinical Standards Toolkit attempts to create a representation in SAS that is based on the standard. This typically includes a combination of metadata data sets, content data sets, and SAS format catalogs. Once the standard is represented in SAS, additional processing in SAS, such as model validation and reporting, is facilitated.

In general, when representing an XML-based standard in SAS, an XML element is mapped to a SAS data set, and its associated attributes are mapped to the columns of the SAS data set. The SAS Clinical Standards Toolkit reads a file (CDISC ODM 1.3.0, CDISC ODM 1.3.1, CDISC ODM controlled terminology, CDISC Define-XML 2.0, or CDISC CRT-DDS 1.0 XML [define.xml]) and converts the information into a SAS representation of each model.

For CDISC CRT-DDS 1.0, this means that 39 data sets (such as ItemDefs) containing 176 columns are derived from the define.xml element and attribute structure.

For CDISC Define-XML 2.0, there are 46 data sets (such as ItemDefs) containing 215 columns that are derived from the define.xml element and attribute structure. For the CDISC Analysis Results Metadata extension for Define-XML 2.0, the SAS representation was extended to 54 data sets containing 239 columns.

For CDISC ODM 1.3.0, there are 66 data sets containing 315 columns in the SAS representation of the model.

For ODM 1.3.1, there are 76 data sets containing 352 columns in the SAS representation of the model.

For CDISC CT 1.0, there are 15 data sets containing 73 columns in the SAS representation of the model.

The SAS representation of each standard can be derived in part from other standards (such as CDISC SDTM or CDISC ADaM) and can include supporting metadata from other sources. The SAS Clinical Standards Toolkit can create a CDISC CRT-DDS 1.0 XML file, a CDISC Define-XML 2.0 file (including Analysis Results Metadata), a CDISC ODM 1.3.0 file, a CDISC ODM 1.3.1 XML file, a Dataset-XML 1.0 file, or a CDISC CT XML 1.0 file.

Reading XML Files

Overview

Support of CDISC XML-based standards, such as CDISC Define-XML 2.0, CDISC CRT-DDS (define.xml), and CDISC ODM, includes the ability to read XML files into SAS data set format. In the SAS Clinical Standards Toolkit, you can read these types of files:

- a CDISC CRT-DDS 1.0
- a CDISC Define-XML 2.0 define.xml file (including Analysis Results Metadata 1.0)
- a CDISC ODM 1.3.0 or CDISC ODM 1.3.1 XML file

- the Controlled Terminology files as they are published by the NCI in ODM XML format

Basic Workflow

Here is the basic workflow for reading XML files:

1. Determine the existence of a valid XML file.
2. Use valid XSL style sheets for each target data set (such as ItemDefs.xsl).
3. Use the SAS DATA step component JavaObj to create a standardized intermediate cubeXML file using the XSL style sheets.
4. Read the standardized cubeXML file using the SAS XML LIBNAME engine and XMLMAP processing.

This basic workflow is used by all XML-based standards that are supported by the SAS Clinical Standards Toolkit.

Reading CDISC ODM XML Files: %ODM_READ Macro

Note: The process for reading ODM XML files is the same for all ODM versions that are supported by the SAS Clinical Standards Toolkit. The process is explained using ODM version 1.3.0.

To read an ODM XML file, a specialized macro named %ODM_READ is available in the ODM 1.3.0 standards macro folder. This folder is located here:

***global standards library directory*/standards/ cdisc-odm-1.3.0-1.7/macros**

This macro is referenced from the create_sasodm_fromxml.sas driver program (described more fully below).

File references and other metadata that are required by the macro are set as global macro variable values. Currently, these global macro variable values are set through the framework initialization properties and the CDISC ODM 1.3.0 initialization properties. Throughout the processing of the %ODM_READ macro, the Results data set contains all framework and ODM 1.3.0 specific messages generated during run time.

Based on file references defined in the SASReferences data set, the %ODM_READ macro accesses the ODM XML file.

Here is a partial listing of a sample ODM XML file:

```
<?xml version="1.0" encoding="ISO-8859-1"?>
<ODM
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  FileOID="Study1234"
  ODMVersion="1.3"
  FileType="Snapshot"
  CreationDateTime="2004-07-28T12:34:13-06:00"
  SourceSystem="ss00"
  AsOfDateTime="2004-07-29T12:34:13-06:00"
  Granularity="SingleSite"
  Description="Study to determine existence of ischemic stroke"
  Archival="Yes"
  PriorFileOID="Study-4321"
  Originator="SAS Institute"
  SourceSystemVersion="Version 0.0.0"
  Id="DSSignature123">
  <Study OID="1234"
    <GlobalVariables>
      <StudyName>1234</StudyName>
      <StudyDescription>1234 Data Definition</StudyDescription>
      <ProtocolName>1234</ProtocolName>
    </GlobalVariables>
      <MeasurementUnit OID="MeasurementUnits.OID.MMHG" Name="MMHG"
        <Symbol>
          <TranslatedText xml:lang="en">mmHG</TranslatedText>
          <TranslatedText xml:lang="fr-CA">mmHG</TranslatedText>
        </Symbol>
      </MeasurementUnit>
      <MeasurementUnit OID="MeasurementUnits.OID.YRS" Name="YEARS">
        <Symbol>
          <TranslatedText xml:lang="de">Jahren</TranslatedText>
          <TranslatedText xml:lang="en">Years of age</TranslatedText>
          <TranslatedText xml:lang="fr-CA">Ans</TranslatedText>
        </Symbol>
    </BasicDefinitions>
    <MetaDataVersion MetaDataVersion OID="CDISC.SDTM.3.1.0"
```

```
        Name="Study 1234, Data Definitions"
        Description="Study 1234, Data Definitions">
        <Include StudyOID="1234" MetaDataVersionOID="MDV000">
        </Include>
        <Protocol>
          <Description>
```

After the %ODM_READ macro confirms that the ODM XML file exists, a call is made to the SAS DATA step component JavaObj. JavaObj processing converts the ODM XML file into the cubeXML file through transformations using XSL files and processes. The cubeXML file is created in the Work library. The name of the cubeXML file is _cub**nnnn**.xml, where **nnnn** is a randomly generated number. The cubeXML file is accessed using the SAS XML LIBNAME engine and XMLMAP processing. A default XMLMAP file is stored in the sample ODM 1.3.0 study folder hierarchy under **/referencexml** as odm.map. The odm.map file is required to process the cubeXML file. If it does not exist, then the %ODM_READ macro attempts to create one using the ODM reference metadata.

Here is a partial listing of the odm.map file.

```
<?xml version="1.0" encoding="windows-1252"?>
<SXLEMAP name="ODM130" version="1.2">

<TABLE name="ItemDefs">
   <TABLE-PATH syntax="XPath">/LIBRARY/ItemDefs</TABLE-PATH>
   <TABLE-DESCRIPTION>Item metadata</TABLE-DESCRIPTION>

   <COLUMN name="OID">
     <PATH syntax="Xpath">/LIBRARY/ItemDefs/OID</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>Unique identifier for this item</DESCRIPTION>
     <LENGTH>64</LENGTH>
   </COLUMN>
   <COLUMN name="Name">
     <PATH syntax="Xpath">/LIBRARY/ItemDefs/Name</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>Item (variable) name</DESCRIPTION>
     <LENGTH>128</LENGTH>
   </COLUMN>
   <COLUMN name="DataType">
     <PATH syntax="Xpath">/LIBRARY/ItemDefs/DataType</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
```

```
      <DESCRIPTION>Item (variable) data type (text, integer, float)</DESCRIPTION>
      <LENGTH>18</LENGTH>
    </COLUMN>
    <COLUMN name="Length">
      <PATH syntax="Xpath">/LIBRARY/ItemDefs/Length</PATH>
      <TYPE>numeric</TYPE>
      <DATATYPE>numeric</DATATYPE>
      <DESCRIPTION>Item (variable) length</DESCRIPTION>
      <LENGTH>8</LENGTH>
    </COLUMN>
```

When the cubeXML is processed, each of the 66 data sets (such as ItemDefs) that are included in the SAS representation of the CDISC ODM 1.3.0 model is derived.

Note: For more information about the %ODM_READ macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

By default, if a null-parameter %ODM_READ macro call is made, source metadata files and SAS format catalogs for each language found in the clitemdecodetranslatedtext data set are created after the SAS data sets representing the ODM XML metadata and data content are derived. The target location of the derived metadata files is defined in the SASReferences data set. The target location of any derived SAS format catalogs is the SAS Work library unless defined in the SASReferences data set.

Sample Driver Program: create_sasodm_fromxml.sas

Overview

Each primary SAS Clinical Standards Toolkit task, such as reading CDISC ODM XML files, is guided by a sample driver program that is provided with the SAS Clinical Standards Toolkit. For reading ODM XML files, this program is create_sasodm_fromxml.sas.

The driver program is located here:

***sample study library directory*/cdisc-odm-1.3.0-1.7/programs**

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are two input file references and five output data set references that are key to the successful completion of the driver program. Table 9.1 on page 299 lists these files and data sets, and they are discussed in separate sections. In the sample create_sasodm_fromxml.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

```
&studyRootPath=&_cstSRoot/cdisc-odm-&_cstStandardVersion.
-&_cstVersion
```

```
&studyOutputPath=&_cstSRoot/cdisc-odm-&_cstStandardVersion.
-&_cstVersion
```

Table 9.1 Key Components of the SASReferences Data Set for the create_sasodm_fromxml.sas Driver Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
Input				
externalxml	odmxml	fileref	&studyRootPath/ sourcexml	odm_sample.xml
referencexml	odmmap	fileref	&studyRootPath/ referencexml	odm.map
Output				
sourcedata	srcdata	libref	&studyOutputPath/ derived/data	*.*
sourcemetadata	srcmeta	libref	&studyOutputPath/ derived/metadata	source_ tables.sas7bdat
sourcemetadata	srcmeta	libref	&studyOutputPath/ derived/metadata	source_ columns.sas7bdat

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
targetdata	trgdata	libref	&studyOutputPath/derived/formats	
results	results	libref	&studyOutputPath/results	read_results.sas7bdat

Process Inputs

The externalxml type refers to the ODM XML file to read. The filename reference odmxml is defined in the SASReferences data set. This filename reference is used in the submitted SAS code when referring to the ODM XML file.

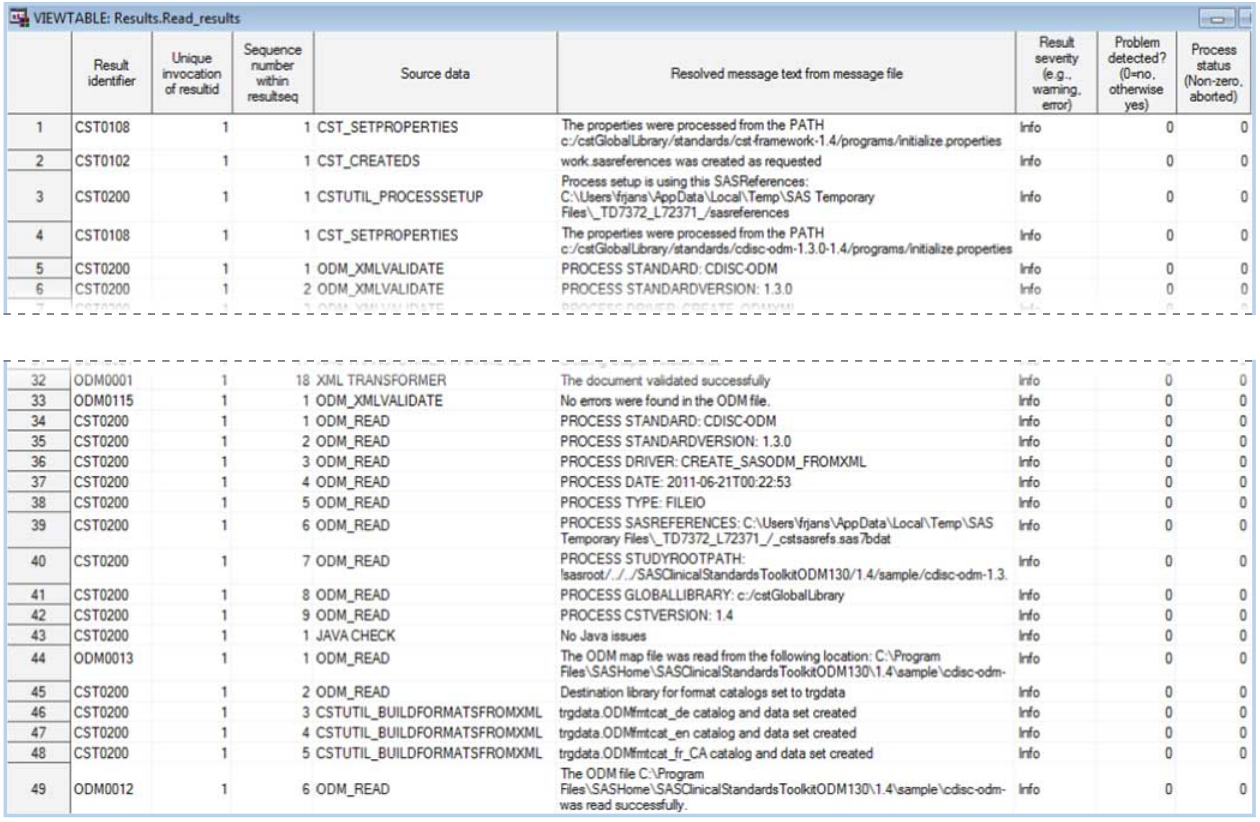
The referencexml type refers to the SAS map file that is used to generate the SAS data sets that represent the ODM file metadata and content. The filename reference odmmap is defined in the SASReferences data set. This filename reference is used in the submitted SAS code when referring to the SAS map file. If a path and filename for the map file are not specified, a temporary map file is created as part of the odm_read processing.

Process Outputs

When the driver program finishes running, the read_results data set is created in the Results library. This data set contains informational, warning, and error messages that were generated by the driver program.

The following display shows an example of the contents of a Results data set that was created while reading the sample ODM XML file that was provided with the SAS Clinical Standards Toolkit:

Figure 9.1 *Example of a Partial Results Data Set Created by the create_sasodm_fromxml.sas Driver Program*

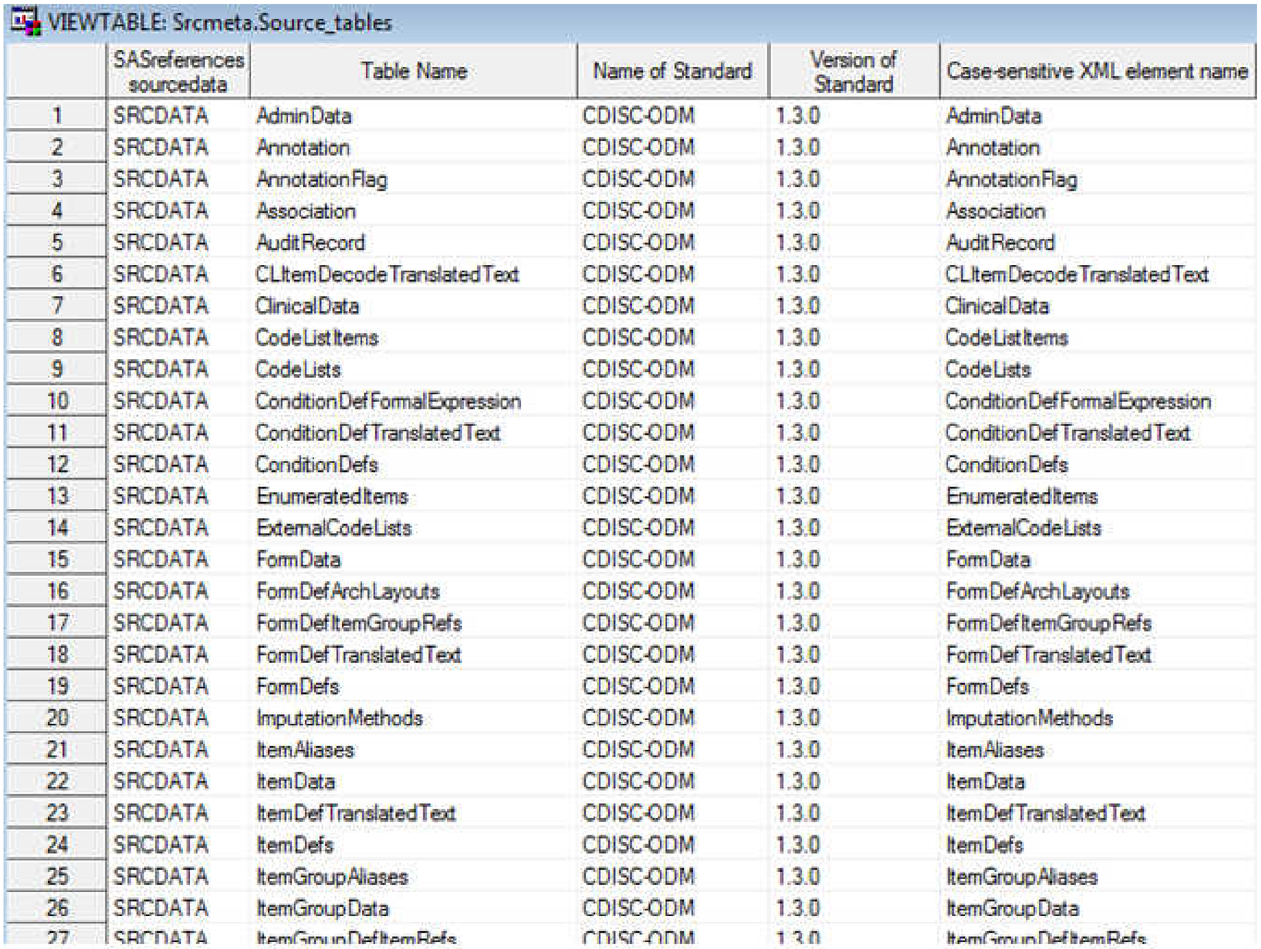


VIEWTABLE: Results.Read_results

	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
1	CST0108	1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-framework-1.4/programs/initialize.properties	Info	0	0
2	CST0102	1	1	CST_CREATEDS	work.sasreferences was created as requested	Info	0	0
3	CST0200	1	1	CSTUTIL_PROCESSSETUP	Process setup is using this SASReferences: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7372_L72371_/sasreferences	Info	0	0
4	CST0108	1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-odm-1.3.0-1.4/programs/initialize.properties	Info	0	0
5	CST0200	1	1	ODM_XMLVALIDATE	PROCESS STANDARD: CDISC-ODM	Info	0	0
6	CST0200	1	2	ODM_XMLVALIDATE	PROCESS STANDARDVERSION: 1.3.0	Info	0	0
32	ODM0001	1	18	XML TRANSFORMER	The document validated successfully	Info	0	0
33	ODM0115	1	1	ODM_XMLVALIDATE	No errors were found in the ODM file.	Info	0	0
34	CST0200	1	1	ODM_READ	PROCESS STANDARD: CDISC-ODM	Info	0	0
35	CST0200	1	2	ODM_READ	PROCESS STANDARDVERSION: 1.3.0	Info	0	0
36	CST0200	1	3	ODM_READ	PROCESS DRIVER: CREATE_SASODM_FROMXML	Info	0	0
37	CST0200	1	4	ODM_READ	PROCESS DATE: 2011-06-21T00:22:53	Info	0	0
38	CST0200	1	5	ODM_READ	PROCESS TYPE: FILEIO	Info	0	0
39	CST0200	1	6	ODM_READ	PROCESS SASREFERENCES: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7372_L72371_/_cstsasrefs.sas7bdat	Info	0	0
40	CST0200	1	7	ODM_READ	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.	Info	0	0
41	CST0200	1	8	ODM_READ	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0
42	CST0200	1	9	ODM_READ	PROCESS CSTVERSION: 1.4	Info	0	0
43	CST0200	1	1	JAVA CHECK	No Java issues	Info	0	0
44	ODM0013	1	1	ODM_READ	The ODM map file was read from the following location: C:\Program Files\SASHome\SASClinicalStandardsToolkitODM130\1.4\sample\cdisc-odm-	Info	0	0
45	CST0200	1	2	ODM_READ	Destination library for format catalogs set to trgdata	Info	0	0
46	CST0200	1	3	CSTUTIL_BUILDFORMATSFROMXML	trgdata.ODMfmtcat_de catalog and data set created	Info	0	0
47	CST0200	1	4	CSTUTIL_BUILDFORMATSFROMXML	trgdata.ODMfmtcat_en catalog and data set created	Info	0	0
48	CST0200	1	5	CSTUTIL_BUILDFORMATSFROMXML	trgdata.ODMfmtcat_fr_CA catalog and data set created	Info	0	0
49	ODM0012	1	6	ODM_READ	The ODM file C:\Program Files\SASHome\SASClinicalStandardsToolkitODM130\1.4\sample\cdisc-odm- was read successfully.	Info	0	0

The %ODM_READ macro creates the source_tables and source_columns data sets in the Srcmeta library. These data sets contain the table and column metadata for each of the SAS data sets that is derived from the ODM XML file.

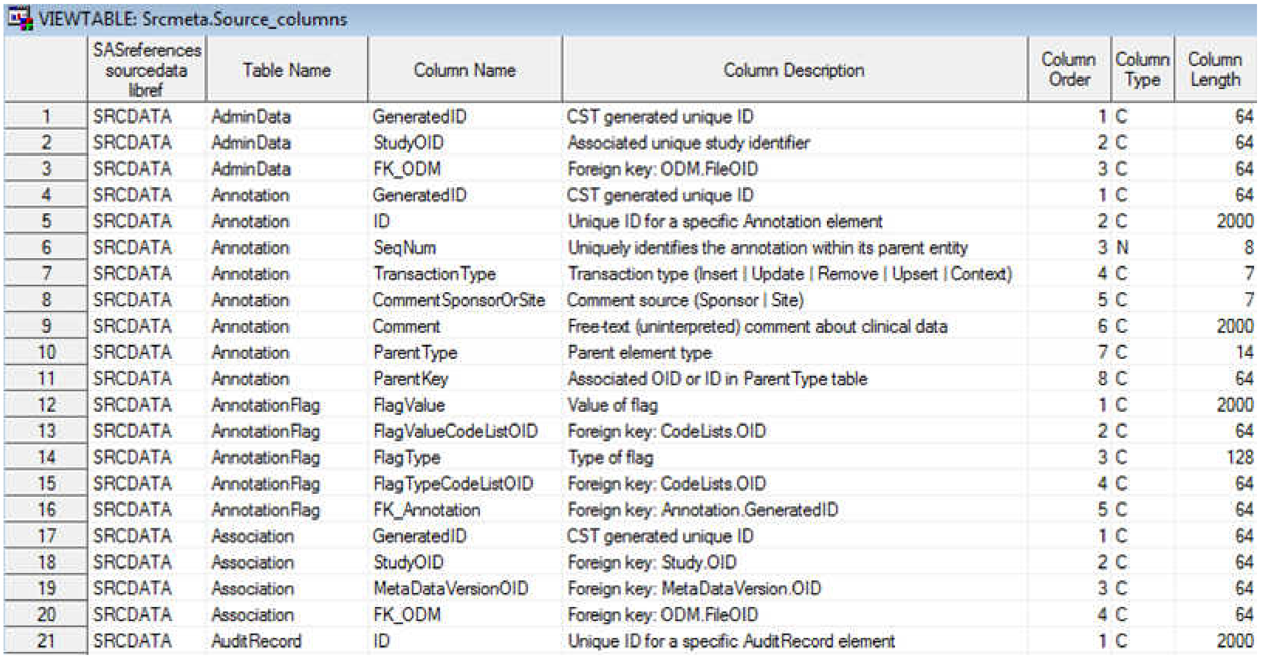
Figure 9.2 Example of Partial Source_Tables Data Set Derived from the %ODM_READ Macro



VIEWTABLE: Srcmeta.Source_tables

	SASreferences sourcedata	Table Name	Name of Standard	Version of Standard	Case-sensitive XML element name
1	SRCDATA	AdminData	CDISC-ODM	1.3.0	AdminData
2	SRCDATA	Annotation	CDISC-ODM	1.3.0	Annotation
3	SRCDATA	AnnotationFlag	CDISC-ODM	1.3.0	AnnotationFlag
4	SRCDATA	Association	CDISC-ODM	1.3.0	Association
5	SRCDATA	AuditRecord	CDISC-ODM	1.3.0	AuditRecord
6	SRCDATA	CLItemDecodeTranslatedText	CDISC-ODM	1.3.0	CLItemDecodeTranslatedText
7	SRCDATA	ClinicalData	CDISC-ODM	1.3.0	ClinicalData
8	SRCDATA	CodeListItems	CDISC-ODM	1.3.0	CodeListItems
9	SRCDATA	CodeLists	CDISC-ODM	1.3.0	CodeLists
10	SRCDATA	ConditionDefFormalExpression	CDISC-ODM	1.3.0	ConditionDefFormalExpression
11	SRCDATA	ConditionDefTranslatedText	CDISC-ODM	1.3.0	ConditionDefTranslatedText
12	SRCDATA	ConditionDefs	CDISC-ODM	1.3.0	ConditionDefs
13	SRCDATA	EnumeratedItems	CDISC-ODM	1.3.0	EnumeratedItems
14	SRCDATA	ExternalCodeLists	CDISC-ODM	1.3.0	ExternalCodeLists
15	SRCDATA	FormData	CDISC-ODM	1.3.0	FormData
16	SRCDATA	FormDefArchLayouts	CDISC-ODM	1.3.0	FormDefArchLayouts
17	SRCDATA	FormDefItemGroupRefs	CDISC-ODM	1.3.0	FormDefItemGroupRefs
18	SRCDATA	FormDefTranslatedText	CDISC-ODM	1.3.0	FormDefTranslatedText
19	SRCDATA	FormDefs	CDISC-ODM	1.3.0	FormDefs
20	SRCDATA	ImputationMethods	CDISC-ODM	1.3.0	ImputationMethods
21	SRCDATA	ItemAliases	CDISC-ODM	1.3.0	ItemAliases
22	SRCDATA	ItemData	CDISC-ODM	1.3.0	ItemData
23	SRCDATA	ItemDefTranslatedText	CDISC-ODM	1.3.0	ItemDefTranslatedText
24	SRCDATA	ItemDefs	CDISC-ODM	1.3.0	ItemDefs
25	SRCDATA	ItemGroupAliases	CDISC-ODM	1.3.0	ItemGroupAliases
26	SRCDATA	ItemGroupData	CDISC-ODM	1.3.0	ItemGroupData
27	SRCDATA	ItemGroupDefItemRefs	CDISC-ODM	1.3.0	ItemGroupDefItemRefs

Figure 9.3 *Example of Partial Source_Columns Data Set Derived from the %ODM_READ Macro*

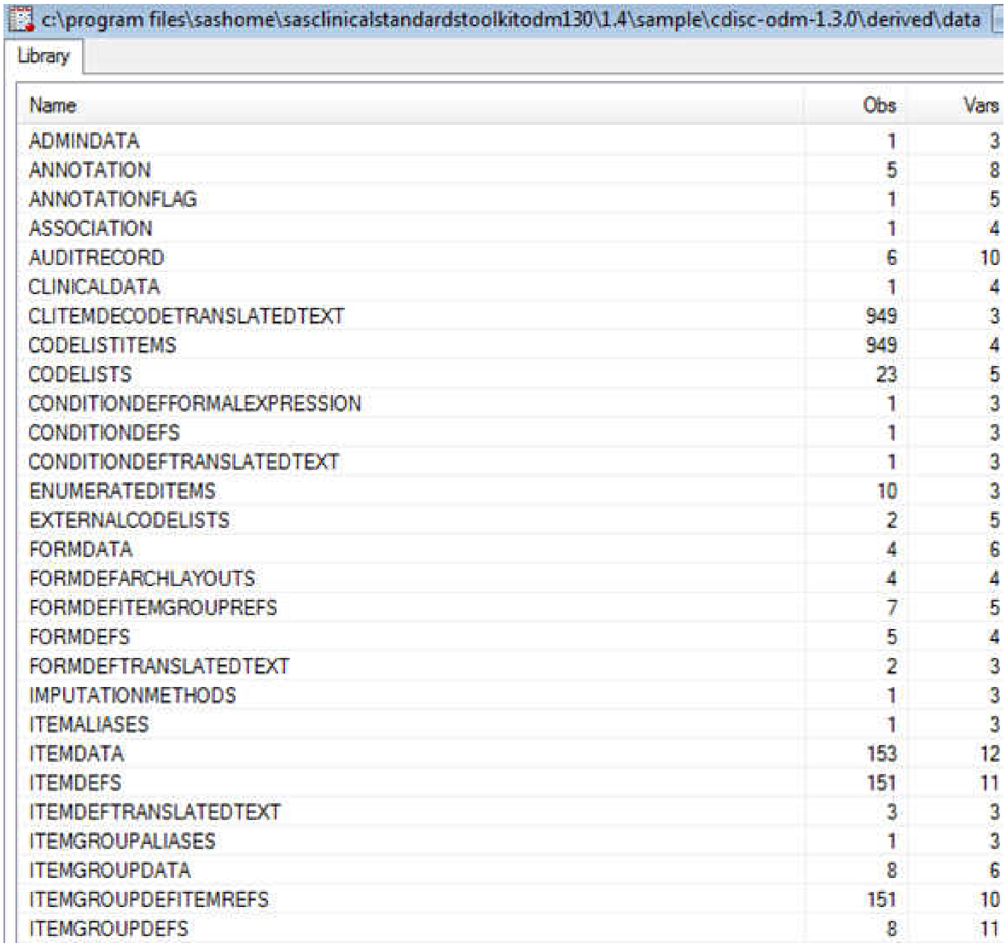


VIEWTABLE: Srcmeta.Source_columns

	SASreferences sourcedata libref	Table Name	Column Name	Column Description	Column Order	Column Type	Column Length
1	SRCDATA	AdminData	GeneratedID	CST generated unique ID	1	C	64
2	SRCDATA	AdminData	StudyOID	Associated unique study identifier	2	C	64
3	SRCDATA	AdminData	FK_ODM	Foreign key: ODM.FileOID	3	C	64
4	SRCDATA	Annotation	GeneratedID	CST generated unique ID	1	C	64
5	SRCDATA	Annotation	ID	Unique ID for a specific Annotation element	2	C	2000
6	SRCDATA	Annotation	SeqNum	Uniquely identifies the annotation within its parent entity	3	N	8
7	SRCDATA	Annotation	TransactionType	Transaction type (Insert | Update | Remove | Upsert | Context)	4	C	7
8	SRCDATA	Annotation	CommentSponsorOrSite	Comment source (Sponsor | Site)	5	C	7
9	SRCDATA	Annotation	Comment	Free-text (uninterpreted) comment about clinical data	6	C	2000
10	SRCDATA	Annotation	ParentType	Parent element type	7	C	14
11	SRCDATA	Annotation	ParentKey	Associated OID or ID in ParentType table	8	C	64
12	SRCDATA	AnnotationFlag	FlagValue	Value of flag	1	C	2000
13	SRCDATA	AnnotationFlag	FlagValueCodeListOID	Foreign key: CodeLists.OID	2	C	64
14	SRCDATA	AnnotationFlag	FlagType	Type of flag	3	C	128
15	SRCDATA	AnnotationFlag	FlagTypeCodeListOID	Foreign key: CodeLists.OID	4	C	64
16	SRCDATA	AnnotationFlag	FK_Annotation	Foreign key: Annotation.GeneratedID	5	C	64
17	SRCDATA	Association	GeneratedID	CST generated unique ID	1	C	64
18	SRCDATA	Association	StudyOID	Foreign key: Study.OID	2	C	64
19	SRCDATA	Association	MetaDataVersionOID	Foreign key: MetaDataVersion.OID	3	C	64
20	SRCDATA	Association	FK_ODM	Foreign key: ODM.FileOID	4	C	64
21	SRCDATA	AuditRecord	ID	Unique ID for a specific AuditRecord element	1	C	2000

The Srcdata library contains the SAS data sets that represent the ODM file metadata and content. By default, the %ODM_READ macro creates 66 unique data sets in the SAS Clinical Standards Toolkit for ODM 1.3.0. Some of these data sets might be empty if no associated content was derived from the ODM XML file. There is a one-to-one correspondence between the tables listed in the Srcdata library and the tables contained in the source_tables metadata file in the Srcmeta library.

Figure 9.4 Example of Partial Srcdata Library Derived from the %ODM_READ Macro



c:\program files\sashome\sasclinicalstandardstoolkitodm130\1.4\sample\cdisc-odm-1.3.0\derived\data

Library

Name	Obs	Vars
ADMINDATA	1	3
ANNOTATION	5	8
ANNOTATIONFLAG	1	5
ASSOCIATION	1	4
AUDITRECORD	6	10
CLINICALDATA	1	4
CLITEMDECODETRANSLATEDTEXT	949	3
CODELISTITEMS	949	4
CODELISTS	23	5
CONDITIONDEFFORMALEXPRESSION	1	3
CONDITIONDEFS	1	3
CONDITIONDEFTRANSLATEDTEXT	1	3
ENUMERATEDITEMS	10	3
EXTERNALCODELISTS	2	5
FORMDATA	4	6
FORMDEFARCHLAYOUTS	4	4
FORMDEFITEMGROUPREFS	7	5
FORMDEFS	5	4
FORMDEFTRANSLATEDTEXT	2	3
IMPUTATIONMETHODS	1	3
ITEMALIASES	1	3
ITEMDATA	153	12
ITEMDEFS	151	11
ITEMDEFTRANSLATEDTEXT	3	3
ITEMGROUPALIASES	1	3
ITEMGROUPDATA	8	6
ITEMGROUPDEFITEMREFS	151	10
ITEMGROUPDEFS	8	11

Extracting Clinical Data and Reference Data from the SAS Representation of an ODM XML File: %ODM_EXTRACTDOMAINDATA Macro

As the primary interchange format for CDISC, ODM XML is a common format for electronic data capture (EDC) data management views of clinical data. This format often does not closely approximate submission (SDTM) and analysis (ADaM) data structures unless the EDC views have been built using the CDISC CDASH standard. From a SAS perspective, you might want to extract clinical data from an ODM XML file to serve as source data for transformations that derive SDTM domain data sets.

The %ODM_EXTRACTDOMAINDATA macro supports extracting clinical data or reference data from the SAS data sets that were created by the %ODM_READ macro.

The %ODM_EXTRACTDOMAINDATA macro makes the following assumptions:

- An ODM XML file is available that contains sufficient metadata and content for extractable clinical data and reference data.
- A full SAS representation of an ODM XML file is available (for example, the %ODM_READ macro has been run against the XML file).
- The SAS representation of an ODM XML file contains both metadata and data.

  By default, the driver assumes all source data files reside in the sample derived folder or the data folder that is typically populated by running the %ODM_READ macro. However, the source data files and the source metadata files can be in different folders.
- Any codelists defined in the ODM XML file and associated with extracted data set columns are available as part of the output of the %ODM_READ macro.

ODM integer and float data types are converted to SAS numeric data. All other ODM data types are converted to SAS character data. If an integer or float data value cannot be converted, a warning appears in the SAS log and Results data set.

Here is a partial listing of the metadata in a sample ODM XML file:

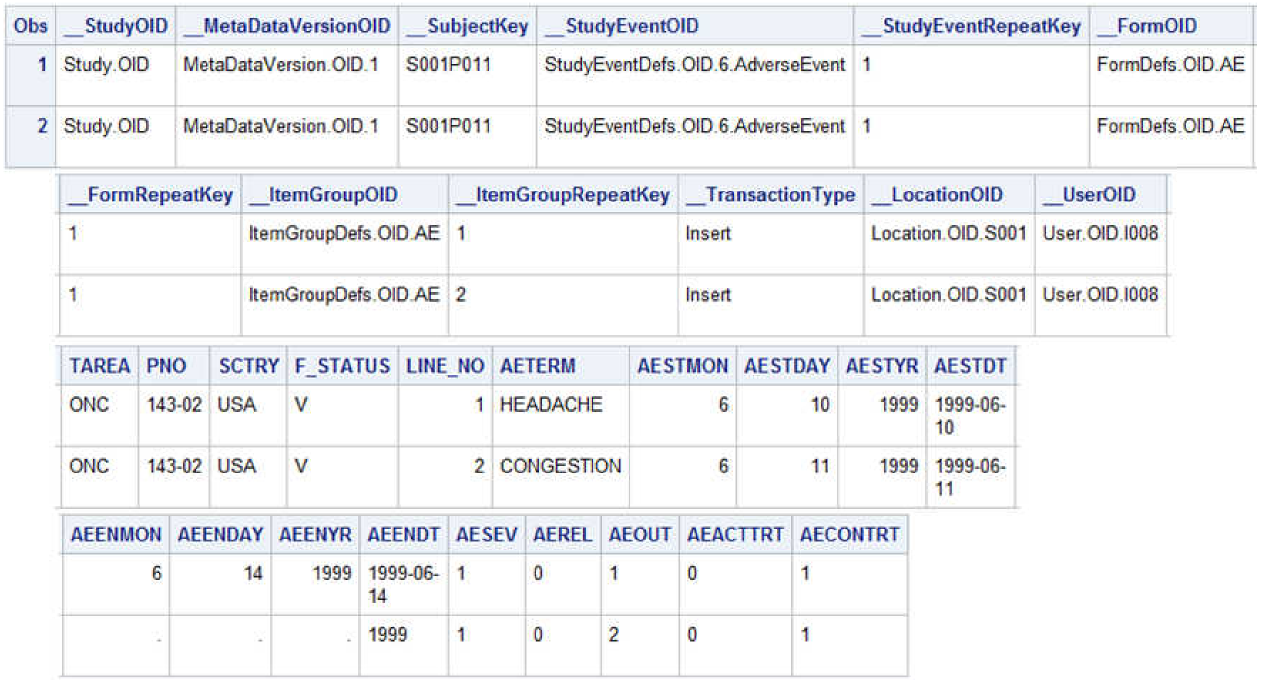
```
<ItemGroupDef OID="ItemGroupDefs.OID.AE" Repeating="Yes"
    SASDatasetName="AE" Name="Adverse Events" Domain="AE"
    Comment="Some adverse events from this trial">
    <ItemRef ItemOID="ID.TAREA"    OrderNumber="1"  Mandatory="No" />
    <ItemRef ItemOID="ID.PNO"      OrderNumber="2"  Mandatory="No" />
    <ItemRef ItemOID="ID.SCTRY"    OrderNumber="3"  Mandatory="No" />
    <ItemRef ItemOID="ID.F_STATUS" OrderNumber="4"  Mandatory="No" />
    <ItemRef ItemOID="ID.LINE_NO"  OrderNumber="5"  Mandatory="No" />
    <ItemRef ItemOID="ID.AETERM"   OrderNumber="6"  Mandatory="No" />
    <ItemRef ItemOID="ID.AESTMON"  OrderNumber="7"  Mandatory="No" />
    <ItemRef ItemOID="ID.AESTDAY"  OrderNumber="8"  Mandatory="No" />
    <ItemRef ItemOID="ID.AESTYR"   OrderNumber="9"  Mandatory="No" />
    <ItemRef ItemOID="ID.AESTDT"   OrderNumber="10" Mandatory="No" />
    <ItemRef ItemOID="ID.AEENMON"  OrderNumber="11" Mandatory="No" />
    <ItemRef ItemOID="ID.AEENDAY"  OrderNumber="12" Mandatory="No" />
    <ItemRef ItemOID="ID.AEENYR"   OrderNumber="13" Mandatory="No" />
    <ItemRef ItemOID="ID.AEENDT"   OrderNumber="14" Mandatory="No" />
    <ItemRef ItemOID="ID.AESEV"    OrderNumber="15" Mandatory="No" />
    <ItemRef ItemOID="ID.AEREL"    OrderNumber="16" Mandatory="No" />
    <ItemRef ItemOID="ID.AEOUT"    OrderNumber="17" Mandatory="No" />
    <ItemRef ItemOID="ID.AEACTTRT" OrderNumber="18" Mandatory="No" />
    <ItemRef ItemOID="ID.AECONTRT" OrderNumber="19" Mandatory="No" />
</ItemGroupDef>
...
<ItemDef OID="ID.AESTDT" SASFieldName="AESTDT"
    Name="Derived Start Date" DataType="date"/>
<ItemDef OID="ID.AEENMON" SASFieldName="AEENMON"
    Name="Stop Month - Enter Two Digits 01-12" DataType="integer" Length="2" />
<ItemDef OID="ID.AEENDAY" SASFieldName="AEENDAY"
    Name="Stop Day - Enter Two Digits 01-31" DataType="integer" Length="2" />
<ItemDef OID="ID.AEENYR" SASFieldName="AEENYR"
    Name="Stop Year - Enter Four Digit Year" DataType="integer" Length="4" />
<ItemDef OID="ID.AEENDT" SASFieldName="AEENDT"
    Name="Derived Stop Date" DataType="date"/>
<ItemDef OID="ID.AESEV" SASFieldName="AESEV"
    Name="Severity" DataType="text" Length="1">
<CodeListRef CodeListOID="CL.$AESEV" />
</ItemDef>
<ItemDef OID="ID.AEREL" SASFieldName="AEREL"
      Name="Relationship to study drug" DataType="text" Length="1">
       <CodeListRef CodeListOID="CL.$AEREL" />
    </ItemDef>
```

Here is a partial listing of the data in the same sample ODM XML file:

```
<ClinicalData StudyOID="Study.OID" MetaDataVersionOID="MetaDataVersion.OID.1">
<SubjectData SubjectKey="S001P011" TransactionType="Insert">
    <StudyEventData StudyEventOID="StudyEventDefs.OID.6.AdverseEvent"
          StudyEventRepeatKey="1">
        <FormData FormOID="FormDefs.OID.AE" FormRepeatKey="1">
        <ItemGroupData ItemGroupOID="ItemGroupDefs.OID.AE"
              ItemGroupRepeatKey="1">
            <ItemData ItemOID="ID.TAREA" Value="ONC" />
            <ItemData ItemOID="ID.PNO" Value="143-02" />
            <ItemData ItemOID="ID.SCTRY" Value="USA" />
            <ItemData ItemOID="ID.F_STATUS" Value="V" />
            <ItemData ItemOID="ID.LINE_NO" Value="1" />
            <ItemData ItemOID="ID.AETERM" Value="HEADACHE" />
            <ItemData ItemOID="ID.AESTMON" Value="06" />
            <ItemData ItemOID="ID.AESTDAY" Value="10" />
            <ItemData ItemOID="ID.AESTYR" Value="1999" />
            <ItemData ItemOID="ID.AESTDT" Value="1999-06-10" />
            <ItemData ItemOID="ID.AEENMON" Value="06" />
            <ItemData ItemOID="ID.AEENDAY" Value="14" />
            <ItemData ItemOID="ID.AEENYR" Value="1999" />
            <ItemData ItemOID="ID.AEENDT" Value="1999-06-14" />
            <ItemData ItemOID="ID.AESEV" Value="1" />
            <ItemData ItemOID="ID.AEREL" Value="0" />
            <ItemData ItemOID="ID.AEOUT" Value="1" />
            <ItemData ItemOID="ID.AEACTTRT" Value="0" />
            <ItemData ItemOID="ID.AECONTRT" Value="1" />
        </ItemGroupData>
```

The %ODM_EXTRACTDOMAINDATA macro creates the data set shown in Figure 9.5 on page 307 and Figure 9.6 on page 308. The first 12 columns in this data set are the data set keys. The macro parameter _cstODMMinimumKeyset determines whether these keys are part of the extracted data set.

Figure 9.5 *AE SAS Data Set (Unformatted) Created by the %ODM_EXTRACTDOMAINDATA Macro*



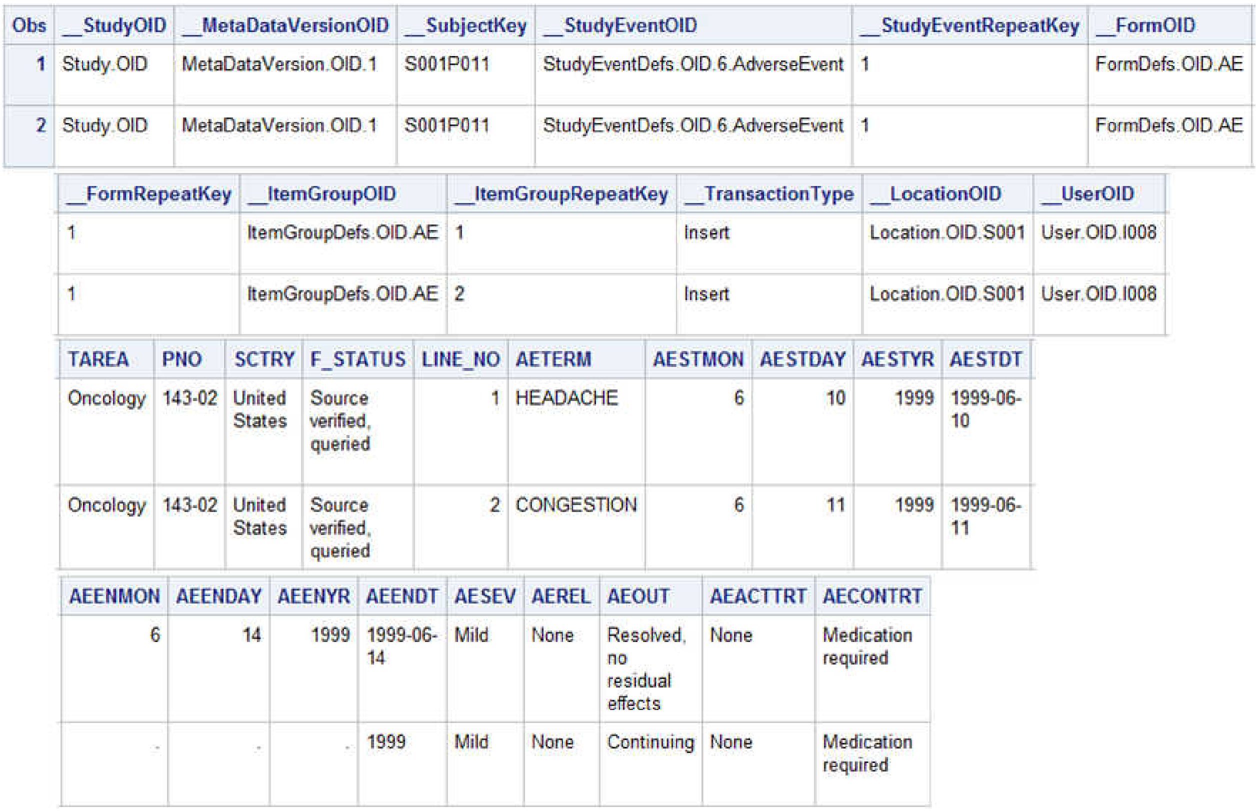
Obs	__StudyOID	__MetaDataVersionOID	__SubjectKey	__StudyEventOID	__StudyEventRepeatKey	__FormOID
1	Study.OID	MetaDataVersion.OID.1	S001P011	StudyEventDefs.OID.6.AdverseEvent	1	FormDefs.OID.AE
2	Study.OID	MetaDataVersion.OID.1	S001P011	StudyEventDefs.OID.6.AdverseEvent	1	FormDefs.OID.AE

__FormRepeatKey	__ItemGroupOID	__ItemGroupRepeatKey	__TransactionType	__LocationOID	__UserOID
1	ItemGroupDefs.OID.AE	1	Insert	Location.OID.S001	User.OID.I008
1	ItemGroupDefs.OID.AE	2	Insert	Location.OID.S001	User.OID.I008

TAREA	PNO	SCTRY	F_STATUS	LINE_NO	AETERM	AESTMON	AESTDAY	AESTYR	AESTDT
ONC	143-02	USA	V	1	HEADACHE	6	10	1999	1999-06-10
ONC	143-02	USA	V	2	CONGESTION	6	11	1999	1999-06-11

AEENMON	AEENDAY	AEENYR	AEENDT	AESEV	AEREL	AEOUT	AEACTTRT	AECONTRT
6	14	1999	1999-06-14	1	0	1	0	1
.	.	.	1999	1	0	2	0	1

Figure 9.6 AE SAS Data Set (Formatted) Created by the %ODM_EXTRACTDOMAINDATA Macro



Obs	__StudyOID	__MetaDataVersionOID	__SubjectKey	__StudyEventOID	__StudyEventRepeatKey	__FormOID
1	Study.OID	MetaDataVersion.OID.1	S001P011	StudyEventDefs.OID.6.AdverseEvent	1	FormDefs.OID.AE
2	Study.OID	MetaDataVersion.OID.1	S001P011	StudyEventDefs.OID.6.AdverseEvent	1	FormDefs.OID.AE

__FormRepeatKey	__ItemGroupOID	__ItemGroupRepeatKey	__TransactionType	__LocationOID	__UserOID
1	ItemGroupDefs.OID.AE	1	Insert	Location.OID.S001	User.OID.I008
1	ItemGroupDefs.OID.AE	2	Insert	Location.OID.S001	User.OID.I008

TAREA	PNO	SCTRY	F_STATUS	LINE_NO	AETERM	AESTMON	AESTDAY	AESTYR	AESTDT
Oncology	143-02	United States	Source verified, queried	1	HEADACHE	6	10	1999	1999-06-10
Oncology	143-02	United States	Source verified, queried	2	CONGESTION	6	11	1999	1999-06-11

AEENMON	AEENDAY	AEENYR	AEENDT	AESEV	AEREL	AEOUT	AEACTTRT	AECONTRT
6	14	1999	1999-06-14	Mild	None	Resolved, no residual effects	None	Medication required
.	.	.	1999	Mild	None	Continuing	None	Medication required

The %ODM_EXTRACTDOMAINDATA macro has this signature:

```
%macro odm_extractdomaindata(
  _cstSourceMetadata=,
  _cstSourceData=,
  _cstIsReferenceData=No,
  _cstSelectAttribute=Name,
  _cstSelectAttributeValue=,
  _cstLang=en,
  _cstMaxLabelLength=256,
  _cstAttachFormats=Yes,
  _cstODMMinimumKeyset=No,
  _cstOutputLibrary=,
  _cstOutputDS=
  );
```

Here are the parameters:

- _cstSourceMetadata and _cstSourceData contain the SAS libref for the SAS ODM metadata representation data.

  If this is not specified, the macro looks for type=sourcedata in SASReferences. If this is not provided, the data set source is assumed to be in the SAS Work library.

- _cstIsReferenceData indicates whether the data to extract is reference data or clinical data. Examples of reference data are laboratory reference ranges or trial design data.

- _cstSelectAttribute contains the ItemGroup attribute that identifies which ItemGroup to extract. Valid values are OID, Name, SASDatasetName, and Domain.

- _cstSelectAttributeValue contains the value of the attribute defined by _cstSelectAttribute that identifies the ItemGroup to extract.

- _cstLang specifies a language identifier for the language tag attribute (xml:lang) in the ODM TranslatedText elements.

- _cstMaxLabelLength determines the maximum value of labels to be created.

  If this is not provided, 256 is assumed. Formats are attached to the data set variables in case the parameter _cstAttachFormats has a value of ‘Yes’.

- _cstODMMinimumKeyset determines the creation of data set keys. If this is not provided, ‘No’ is assumed.

- _cstOutputLibrary defines the SAS library where the extracted data sets are written.

  If this is not specified, the macro looks for type=targetdata in SASReferences. If this is not provided, the data sets are written to the SAS Work library.

- _cstOutputDS contains the name of the extracted data set.

  If this is an invalid SAS data set name, an error is generated. If the data set name is not provided, the macro looks for type=targetdata in SASReferences.

Two sample driver programs for ODM 1.3.0 are provided with the SAS Clinical Standards Toolkit to demonstrate the use of the %ODM_EXTRACTDOMAINDATA macro:

***sample study library directory*/cdisc-odm-1.3.0-1.7/ programs/extract_domaindata_all.sas**

***sample study library directory*/cdisc-odm-1.3.0-1.7/ programs/extract_domaindata.sas**

Two sample driver programs for ODM 1.3.1 are provided with the SAS Clinical Standards Toolkit to demonstrate the use of the %ODM_EXTRACTDOMAINDATA macro:

***sample study library directory*/cdisc-odm-1.3.1-1.7/ programs/extract_domaindata_all.sas**

***sample study library directory*/cdisc-odm-1.3.1-1.7/ programs/extract_domaindata.sas**

The extract_domaindata_all.sas sample driver programs demonstrate how all data sets can be extracted at once. The following shows a code fragment:

```
filename incCode CATALOG "work._cstCode.domains.source" lrecl=255;

data _null_;
 set srcdata.itemgroupdefs(keep=OID Name IsReferenceData SASDatasetName Domain);
  file incCode;
  length macrocall $400 _cstOutputName $100;

  _cstOutputName=SASDatasetName;
  * If we have to use the Name, Only use letters and digits;
  if missing(_cstOutputName) then _cstOutputName=cats(compress(Name, 'adk'));
  * If first character a digit, prepend an underscore;
  if anydigit(_cstOutputName)=1 then _cstOutputName=cats('_', _cstOutputName);
  * Cut long names;
  if length(_cstOutputName) > 32 then _cstOutputName=substr(_cstOutputName, 1, 32);

  macrocall=cats('%odm_extractdomaindata(_cstSelectAttribute=OID',
                                    ', _cstSelectAttributeValue=', OID,
                                    ', _cstIsReferenceData=', IsReferenceData,
                                    ', _cstMaxLabelLength=256',
                                    ', _cstAttachFormats=Yes',
                                    ', _cstODMMinimumKeyset=No',
                                    ', _cstLang=en',
                                    ', _cstOutputDS=', _cstOutputName, ');');
  put macrocall;
run;
```

```
%include incCode;
filename incCode clear;
```

Reading CDISC ODM Controlled Terminology XML Files: %CT_READ Macro

To read an ODM controlled terminology XML file as published quarterly by NCI, a specialized macro named %CT_READ is available in the CDISC controlled terminology 1.0 standards macros folder. This folder is located here:

***global standards library directory*/standards/cdisc-ct-1.0-1.7/macros**

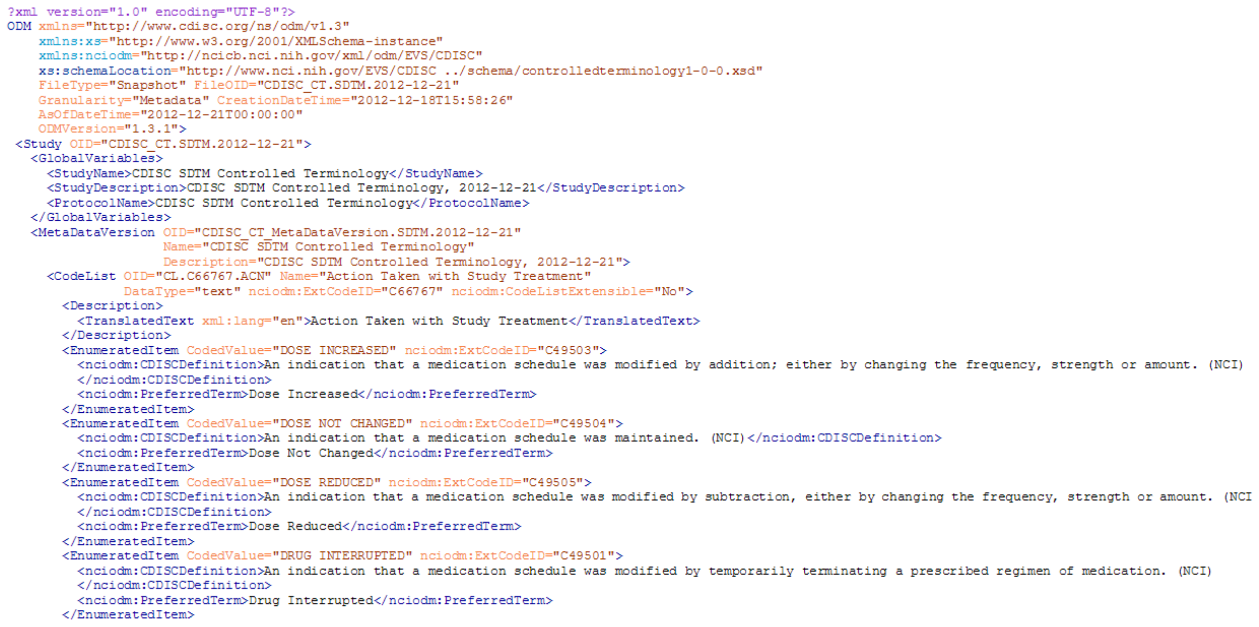
This macro is referenced from the create_sasct_fromxml.sas driver program. For more information, see "Sample Driver Program: create_sasct_fromxml.sas " on page 314.

File references and other metadata that are required by the macro are set as global macro variable values. These global macro variable values are set through the framework initialization properties and the CDISC controlled terminology 1.0 initialization properties. Throughout the processing of the %CT_READ macro, the Results data set contains all framework-specific messages and CDISC controlled terminology 1.0-specific messages that were generated during run time.

Based on file references defined in the SASReferences data set, the %CT_READ macro accesses the ODM controlled terminology XML file.

The following display shows a partial listing of a sample ODM controlled terminology XML file:

Figure 9.7 Partial Listing of a Sample ODM Controlled Terminology XML File



```
?xml version="1.0" encoding="UTF-8"?>
ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
    xmlns:xs="http://www.w3.org/2001/XMLSchema-instance"
    xmlns:nciodm="http://ncicb.nci.nih.gov/xml/odm/EVS/CDISC"
    xs:schemaLocation="http://www.nci.nih.gov/EVS/CDISC ../schema/controlledterminology1-0-0.xsd"
    FileType="Snapshot" FileOID="CDISC_CT.SDTM.2012-12-21"
    Granularity="Metadata" CreationDateTime="2012-12-18T15:58:26"
    AsOfDateTime="2012-12-21T00:00:00"
    ODMVersion="1.3.1">
 <Study OID="CDISC_CT.SDTM.2012-12-21">
   <GlobalVariables>
     <StudyName>CDISC SDTM Controlled Terminology</StudyName>
     <StudyDescription>CDISC SDTM Controlled Terminology, 2012-12-21</StudyDescription>
     <ProtocolName>CDISC SDTM Controlled Terminology</ProtocolName>
   </GlobalVariables>
   <MetaDataVersion OID="CDISC_CT_MetaDataVersion.SDTM.2012-12-21"
                    Name="CDISC SDTM Controlled Terminology"
                    Description="CDISC SDTM Controlled Terminology, 2012-12-21">
     <CodeList OID="CL.C66767.ACN" Name="Action Taken with Study Treatment"
               DataType="text" nciodm:ExtCodeID="C66767" nciodm:CodeListExtensible="No">
       <Description>
         <TranslatedText xml:lang="en">Action Taken with Study Treatment</TranslatedText>
       </Description>
       <EnumeratedItem CodedValue="DOSE INCREASED" nciodm:ExtCodeID="C49503">
         <nciodm:CDISCDefinition>An indication that a medication schedule was modified by addition; either by changing the frequency, strength or amount. (NCI)
         </nciodm:CDISCDefinition>
         <nciodm:PreferredTerm>Dose Increased</nciodm:PreferredTerm>
       </EnumeratedItem>
       <EnumeratedItem CodedValue="DOSE NOT CHANGED" nciodm:ExtCodeID="C49504">
         <nciodm:CDISCDefinition>An indication that a medication schedule was maintained. (NCI)</nciodm:CDISCDefinition>
         <nciodm:PreferredTerm>Dose Not Changed</nciodm:PreferredTerm>
       </EnumeratedItem>
       <EnumeratedItem CodedValue="DOSE REDUCED" nciodm:ExtCodeID="C49505">
         <nciodm:CDISCDefinition>An indication that a medication schedule was modified by subtraction, either by changing the frequency, strength or amount. (NCI
         </nciodm:CDISCDefinition>
         <nciodm:PreferredTerm>Dose Reduced</nciodm:PreferredTerm>
       </EnumeratedItem>
       <EnumeratedItem CodedValue="DRUG INTERRUPTED" nciodm:ExtCodeID="C49501">
         <nciodm:CDISCDefinition>An indication that a medication schedule was modified by temporarily terminating a prescribed regimen of medication. (NCI)
         </nciodm:CDISCDefinition>
         <nciodm:PreferredTerm>Drug Interrupted</nciodm:PreferredTerm>
       </EnumeratedItem>
```

After the %CT_READ macro confirms that the ODM controlled terminology XML file exists, a call is made to the SAS DATA step component JavaObj. JavaObj processing converts the ODM controlled terminology XML file into a cubeXML file through transformations using XSL files and processes.

The cubeXML file is created in the SAS Work library. The name of the cubeXML file is _cub**nnnn**.xml, where **nnnn** is a randomly generated number.

The cubeXML file is accessed using the SAS XML LIBNAME engine and XMLMap processing. A default XMLMap file is stored in the sample CDISC controlled terminology 1.0 study folder hierarchy (**referencexml/odm.map**). An odm.map file is required to process the cubeXML file. If it does not exist, the %CT_READ macro attempts to create one using the CDISC controlled terminology reference metadata.

Here is a partial listing of the odm.map file.

```
<?xml version="1.0" encoding="UTF-8"?>
<SXLEMAP name="CT100" version="1.2">
```

```
<TABLE name="CodeLists">
   <TABLE-PATH syntax="XPath">/LIBRARY/CodeLists</TABLE-PATH>
   <TABLE-DESCRIPTION>Codelist metadata</TABLE-DESCRIPTION>

   <COLUMN name="OID">
     <PATH syntax="Xpath">/LIBRARY/CodeLists/OID</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>Unique identifier for this codelist</DESCRIPTION>
     <LENGTH>128</LENGTH>
   </COLUMN>
   <COLUMN name="Name">
     <PATH syntax="Xpath">/LIBRARY/CodeLists/Name</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>CodeList name</DESCRIPTION>
     <LENGTH>128</LENGTH>
   </COLUMN>
   <COLUMN name="DataType">
     <PATH syntax="Xpath">/LIBRARY/CodeLists/DataType</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>CodeList item value data type (integer | float | text | string)</DESCRIPTION>
     <LENGTH>7</LENGTH>
   </COLUMN>
   <COLUMN name="SASFormatName">
     <PATH syntax="Xpath">/LIBRARY/CodeLists/SASFormatName</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>SAS format name</DESCRIPTION>
     <LENGTH>8</LENGTH>
   </COLUMN>
   <COLUMN name="ExtCodeID">
     <PATH syntax="Xpath">/LIBRARY/CodeLists/ExtCodeID</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>Unique numeric code randomly generated by NCI Thesaurus (NCIt)</DESCRIPTION>
     <LENGTH>64</LENGTH>
   </COLUMN>
   <COLUMN name="CodeListExtensible">
     <PATH syntax="Xpath">/LIBRARY/CodeLists/CodeListExtensible</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>Defines if controlled terms may be added to the codelist (Yes | No)</DESCRIPTION>
     <LENGTH>3</LENGTH>
   </COLUMN>
```

```
<COLUMN name="CDISCSubmissionValue">
  <PATH syntax="Xpath">/LIBRARY/CodeLists/CDISCSubmissionValue</PATH>
  <TYPE>character</TYPE>
  <DATATYPE>character</DATATYPE>
  <DESCRIPTION>Specific value expected for submissions</DESCRIPTION>
  <LENGTH>512</LENGTH>
</COLUMN>
```

When the cubeXML file is processed, each of the 15 data sets (such as CodeLists) that are included in the SAS representation of the CDISC controlled terminology model is derived. One input parameter can be specified in the call to the %CT_READ macro. The parameter offers the option to create source metadata files.

Note: For more information about the %CT_READ macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

By default, if a %CT_READ macro call is made with null parameters, source metadata is derived. The target location of the derived metadata files is defined in the SASReferences data set.

Sample Driver Program: create_sasct_fromxml.sas

Overview

Each primary SAS Clinical Standards Toolkit task, such as reading CDISC ODM controlled terminology XML files, is guided by a sample driver program that is provided with the SAS Clinical Standards Toolkit. For reading ODM controlled terminology XML files, this driver program is create_sasct_fromxml.sas.

This driver program is located here:

***sample study library directory*/cdisc-ct-1.0-1.7/programs**

The SASReferences Data Set

As part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. The SASReferences data set references the input files that are needed (such as the ODM controlled terminology XML file), the librefs and filenames to use, and the names and locations of the data sets to create. The SASReferences data set can be modified to point to study-specific files.

For more information, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are two input file references and five output data set references that are key to the successful completion of the driver program. Table 9.2 on page 315 lists these files and data sets. In the sample create_sasct_fromxml.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

```
&studyRootPath=sample study library directory/cdisc-ct-1.0-1.7
```

```
&studyOutputPath=sample study library directory/cdisc-ct-1.0-1.7
```

Table 9.2 Key Components of the SASReferences Data Set for the create_sasct_fromxml.sas Driver Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
externalxml	crtxml	fileref	&studyRootPath/ sourcexml/sdtm/201212	sdtm_terminology.xml
referencexml	ctmap	fileref	&studyRootPath/ referencexml	ct-1.0.0.map
		Output		
sourcedata	srcdata	libref	&studyOutputPath/data/ sdtm/201212	*.*
results	results	libref	&studyOutputPath/results	read_results_sdtm_ 2012.sas7bdat

Process Inputs

The externalxml type refers to the ODM controlled terminology XML file to read. The filename reference crtxml is defined in the SASReferences data set. This filename reference is used in the submitted SAS code when referring to the ODM controlled terminology XML file.

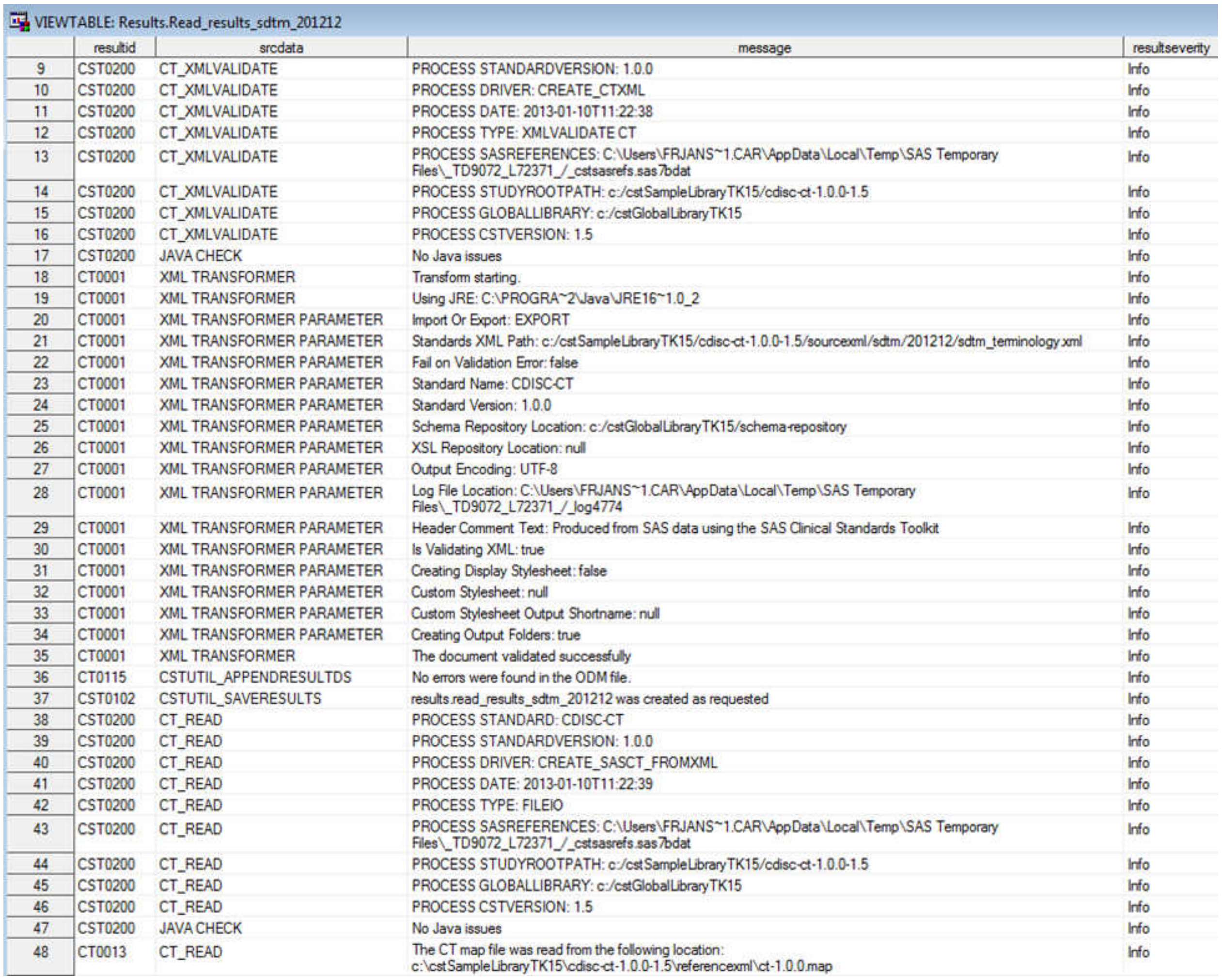
The referencexml type refers to the SAS map file that is used to generate the SAS data sets that represent the ODM file metadata and content. The filename reference ctmap is defined in the SASReferences data set. This filename reference is used in the submitted SAS code when referring to the SAS map file. If a path and filename for the map file are not specified, a temporary map file is created as part of the %CT_READ macro processing.

Process Outputs

When the driver program finishes running, the read_results_sdtm_201212 data set is created in the Results library. This data set contains informational messages, warnings, and error messages that were generated by the driver program.

The following display shows an example of the contents of a Results data set that was created while reading the sample ODM controlled terminology XML file as released by NCI that was provided with the SAS Clinical Standards Toolkit:

Figure 9.8 *Example of a Partial Results Data Set Created by the create_sasct_fromxml.sas Driver Program*

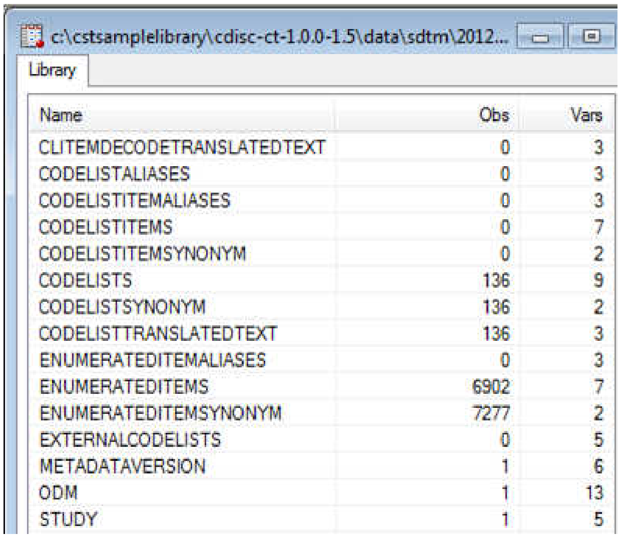


VIEWTABLE: Results.Read_results_sdtm_201212

	resultid	srcdata	message	resultseverity
9	CST0200	CT_XMLVALIDATE	PROCESS STANDARDVERSION: 1.0.0	Info
10	CST0200	CT_XMLVALIDATE	PROCESS DRIVER: CREATE_CTXML	Info
11	CST0200	CT_XMLVALIDATE	PROCESS DATE: 2013-01-10T11:22:38	Info
12	CST0200	CT_XMLVALIDATE	PROCESS TYPE: XMLVALIDATE CT	Info
13	CST0200	CT_XMLVALIDATE	PROCESS SASREFERENCES: C:\Users\FRJANS~1.CAR\AppData\Local\Temp\SAS Temporary Files_TD9072_L72371_/_cstsasrefs.sas7bdat	Info
14	CST0200	CT_XMLVALIDATE	PROCESS STUDYROOTPATH: c:/cstSampleLibraryTK15/cdisc-ct-1.0.0-1.5	Info
15	CST0200	CT_XMLVALIDATE	PROCESS GLOBALLIBRARY: c:/cstGlobalLibraryTK15	Info
16	CST0200	CT_XMLVALIDATE	PROCESS CSTVERSION: 1.5	Info
17	CST0200	JAVA CHECK	No Java issues	Info
18	CT0001	XML TRANSFORMER	Transform starting.	Info
19	CT0001	XML TRANSFORMER	Using JRE: C:\PROGRA~2\Java\JRE16~1.0_2	Info
20	CT0001	XML TRANSFORMER PARAMETER	Import Or Export: EXPORT	Info
21	CT0001	XML TRANSFORMER PARAMETER	Standards XML Path: c:/cstSampleLibraryTK15/cdisc-ct-1.0.0-1.5/sourcexml/sdtm/201212/sdtm_terminology.xml	Info
22	CT0001	XML TRANSFORMER PARAMETER	Fail on Validation Error: false	Info
23	CT0001	XML TRANSFORMER PARAMETER	Standard Name: CDISC-CT	Info
24	CT0001	XML TRANSFORMER PARAMETER	Standard Version: 1.0.0	Info
25	CT0001	XML TRANSFORMER PARAMETER	Schema Repository Location: c:/cstGlobalLibraryTK15/schema-repository	Info
26	CT0001	XML TRANSFORMER PARAMETER	XSL Repository Location: null	Info
27	CT0001	XML TRANSFORMER PARAMETER	Output Encoding: UTF-8	Info
28	CT0001	XML TRANSFORMER PARAMETER	Log File Location: C:\Users\FRJANS~1.CAR\AppData\Local\Temp\SAS Temporary Files_TD9072_L72371_/_log4774	Info
29	CT0001	XML TRANSFORMER PARAMETER	Header Comment Text: Produced from SAS data using the SAS Clinical Standards Toolkit	Info
30	CT0001	XML TRANSFORMER PARAMETER	Is Validating XML: true	Info
31	CT0001	XML TRANSFORMER PARAMETER	Creating Display Stylesheet: false	Info
32	CT0001	XML TRANSFORMER PARAMETER	Custom Stylesheet: null	Info
33	CT0001	XML TRANSFORMER PARAMETER	Custom Stylesheet Output Shortname: null	Info
34	CT0001	XML TRANSFORMER PARAMETER	Creating Output Folders: true	Info
35	CT0001	XML TRANSFORMER	The document validated successfully	Info
36	CT0115	CSTUTIL_APPENDRESULTDS	No errors were found in the ODM file.	Info
37	CST0102	CSTUTIL_SAVERESULTS	results.read_results_sdtm_201212 was created as requested	Info
38	CST0200	CT_READ	PROCESS STANDARD: CDISC-CT	Info
39	CST0200	CT_READ	PROCESS STANDARDVERSION: 1.0.0	Info
40	CST0200	CT_READ	PROCESS DRIVER: CREATE_SASCT_FROMXML	Info
41	CST0200	CT_READ	PROCESS DATE: 2013-01-10T11:22:39	Info
42	CST0200	CT_READ	PROCESS TYPE: FILEIO	Info
43	CST0200	CT_READ	PROCESS SASREFERENCES: C:\Users\FRJANS~1.CAR\AppData\Local\Temp\SAS Temporary Files_TD9072_L72371_/_cstsasrefs.sas7bdat	Info
44	CST0200	CT_READ	PROCESS STUDYROOTPATH: c:/cstSampleLibraryTK15/cdisc-ct-1.0.0-1.5	Info
45	CST0200	CT_READ	PROCESS GLOBALLIBRARY: c:/cstGlobalLibraryTK15	Info
46	CST0200	CT_READ	PROCESS CSTVERSION: 1.5	Info
47	CST0200	JAVA CHECK	No Java issues	Info
48	CT0013	CT_READ	The CT map file was read from the following location: c:\cstSampleLibraryTK15\cdisc-ct-1.0.0-1.5\referencexml\ct-1.0.0.map	Info

The Srcdata library contains the SAS data sets that represent the ODM controlled terminology XML file metadata and content. By default, the %CT_READ macro creates 15 unique data sets in the SAS Clinical Standards Toolkit. Some of these data sets might be empty if no associated content was derived from the ODM controlled terminology XML file. There is a one-to-one correspondence between the tables listed in the Srcdata library and the tables contained in the source_tables metadata file in the Srcmeta library.

Figure 9.9 *Example of Partial Srcdata Library Derived from the %CT_READ Macro*



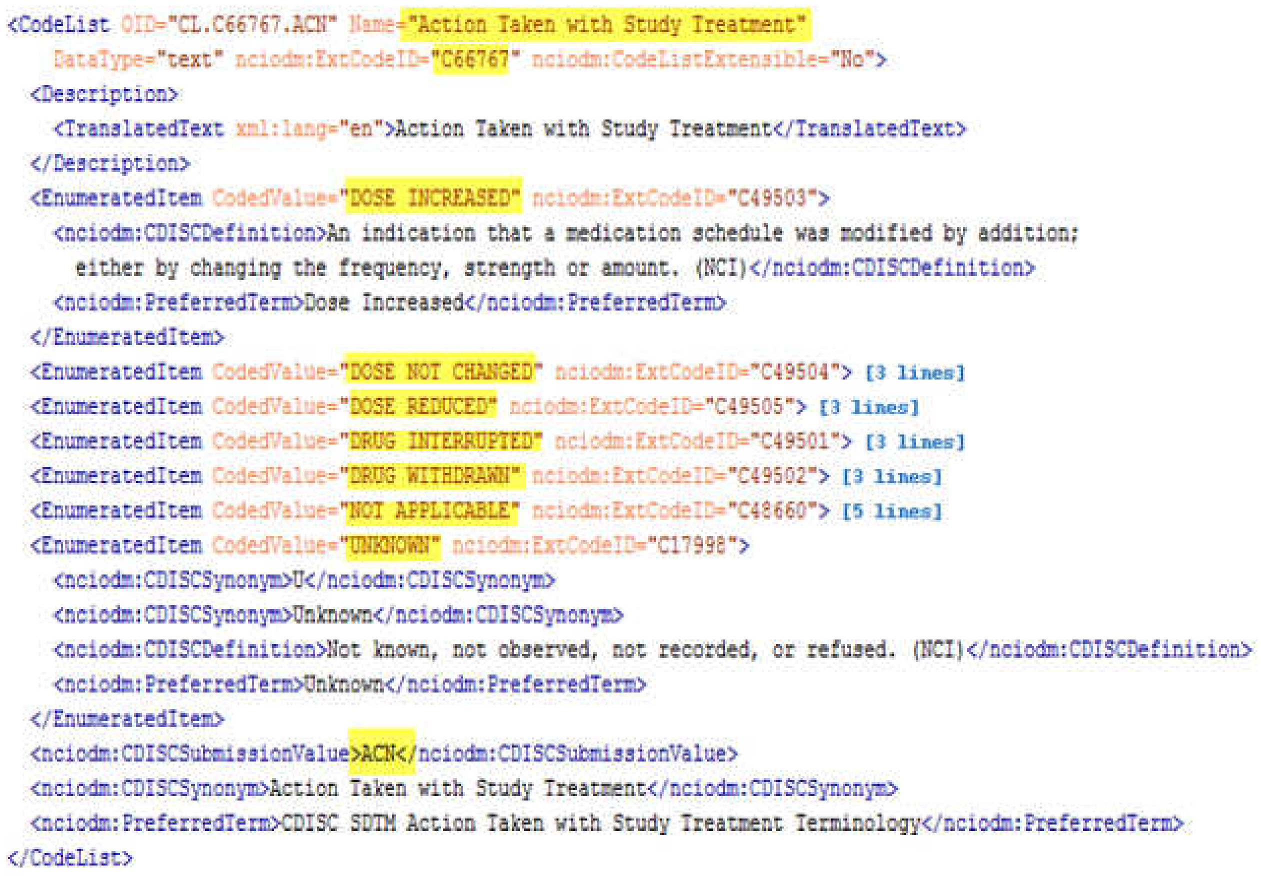
Name	Obs	Vars
CLITEMDECODETRANSLATEDTEXT	0	3
CODELISTALIASES	0	3
CODELISTITEMALIASES	0	3
CODELISTITEMS	0	7
CODELISTITEMSYNONYM	0	2
CODELISTS	136	9
CODELISTSYNONYM	136	2
CODELISTTRANSLATEDTEXT	136	3
ENUMERATEDITEMALIASES	0	3
ENUMERATEDITEMS	6902	7
ENUMERATEDITEMSYNONYM	7277	2
EXTERNALCODELISTS	0	5
METADATAVERSION	1	6
ODM	1	13
STUDY	1	5

Creating a Format Catalog and a Controlled Terminology Data Set from the SAS Representation of a CDISC ODM Controlled Terminology XML File: %CT_CREATEFORMATS Macro

To use the NCI CDISC controlled terminology in a SAS Clinical Standards Toolkit process, the SAS data sets created by the %CT_READ macro must be converted to a SAS format catalog. To enable SAS Clinical Data Integration to import controlled terminology, the SAS data set representation created by the %CT_READ macro must be combined into one SAS data set.

The following display shows an example of controlled terminology in ODM XML (the Action Taken with Study Treatment codelist):

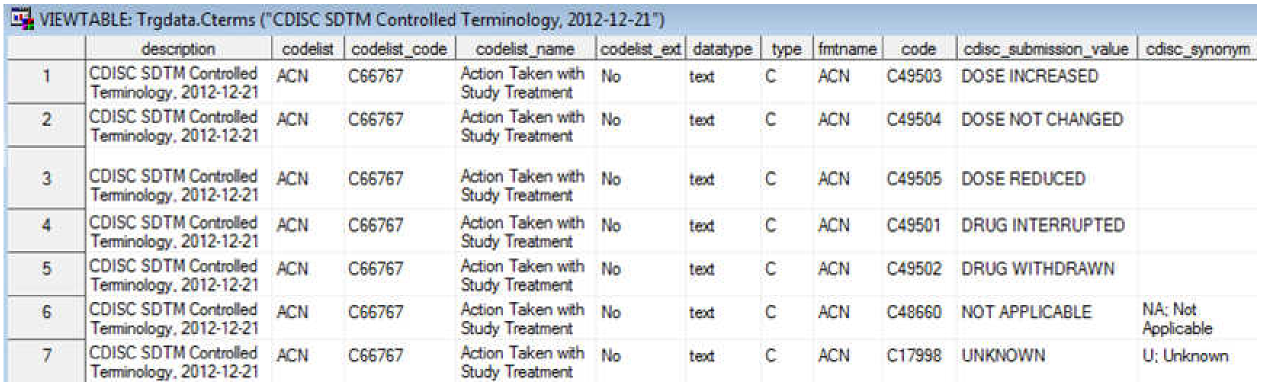
Figure 9.10 *Example of Controlled Terminology in ODM XML*



```
<CodeList OID="CL.C66767.ACN" Name="Action Taken with Study Treatment"
    DataType="text" nciodm:ExtCodeID="C66767" nciodm:CodeListExtensible="No">
  <Description>
    <TranslatedText xml:lang="en">Action Taken with Study Treatment</TranslatedText>
  </Description>
  <EnumeratedItem CodedValue="DOSE INCREASED" nciodm:ExtCodeID="C49503">
    <nciodm:CDISCDefinition>An indication that a medication schedule was modified by addition;
      either by changing the frequency, strength or amount. (NCI)</nciodm:CDISCDefinition>
    <nciodm:PreferredTerm>Dose Increased</nciodm:PreferredTerm>
  </EnumeratedItem>
  <EnumeratedItem CodedValue="DOSE NOT CHANGED" nciodm:ExtCodeID="C49504"> [3 lines]
  <EnumeratedItem CodedValue="DOSE REDUCED" nciodm:ExtCodeID="C49505"> [3 lines]
  <EnumeratedItem CodedValue="DRUG INTERRUPTED" nciodm:ExtCodeID="C49501"> [3 lines]
  <EnumeratedItem CodedValue="DRUG WITHDRAWN" nciodm:ExtCodeID="C49502"> [3 lines]
  <EnumeratedItem CodedValue="NOT APPLICABLE" nciodm:ExtCodeID="C48660"> [5 lines]
  <EnumeratedItem CodedValue="UNKNOWN" nciodm:ExtCodeID="C17998">
    <nciodm:CDISCSynonym>U</nciodm:CDISCSynonym>
    <nciodm:CDISCSynonym>Unknown</nciodm:CDISCSynonym>
    <nciodm:CDISCDefinition>Not known, not observed, not recorded, or refused. (NCI)</nciodm:CDISCDefinition>
    <nciodm:PreferredTerm>Unknown</nciodm:PreferredTerm>
  </EnumeratedItem>
  <nciodm:CDISCSubmissionValue>ACN</nciodm:CDISCSubmissionValue>
  <nciodm:CDISCSynonym>Action Taken with Study Treatment</nciodm:CDISCSynonym>
  <nciodm:PreferredTerm>CDISC SDTM Action Taken with Study Treatment Terminology</nciodm:PreferredTerm>
</CodeList>
```

The following display shows the data set created by the %CT_CREATEFORMATS macro:

Figure 9.11 Partial cterms SAS Data Set Created by the %CT_CREATEFORMATS Macro

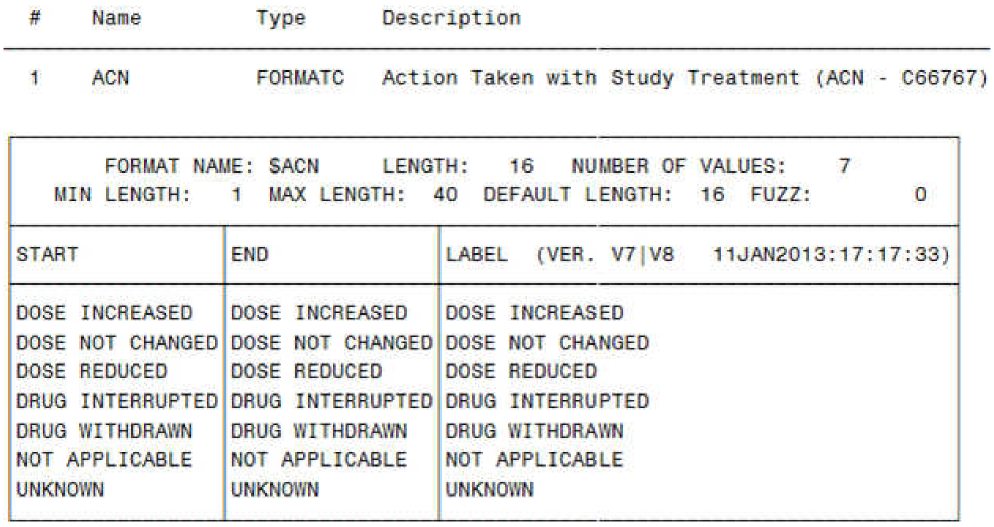


VIEWTABLE: Trgdata.Cterms ("CDISC SDTM Controlled Terminology, 2012-12-21")

	description	codelist	codelist_code	codelist_name	codelist_ext	datatype	type	fmtname	code	cdisc_submission_value	cdisc_synonym
1	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C49503	DOSE INCREASED	
2	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C49504	DOSE NOT CHANGED	
3	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C49505	DOSE REDUCED	
4	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C49501	DRUG INTERRUPTED	
5	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C49502	DRUG WITHDRAWN	
6	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C48660	NOT APPLICABLE	NA; Not Applicable
7	CDISC SDTM Controlled Terminology, 2012-12-21	ACN	C66767	Action Taken with Study Treatment	No	text	C	ACN	C17998	UNKNOWN	U; Unknown

The following display shows that the %CT_CREATEFORMATS macro uses the data set to create the $ACN SAS format:

Figure 9.12 $ACN SAS Format Created by the %CT_CREATEFORMATS Macro



```
  #    Name         Type       Description
-----------------------------------------------------------------------------
  1    ACN          FORMATC    Action Taken with Study Treatment (ACN - C66767)

-------------------------------------------------------------------------
|      FORMAT NAME: $ACN      LENGTH:   16   NUMBER OF VALUES:    7     |
|   MIN LENGTH:   1  MAX LENGTH:  40  DEFAULT LENGTH:  16  FUZZ:       0|
|-----------------------------------------------------------------------|
|START           |END             |LABEL  (VER. V7|V8   11JAN2013:17:17:33)|
|----------------+----------------+-------------------------------------|
|DOSE INCREASED  |DOSE INCREASED  |DOSE INCREASED                       |
|DOSE NOT CHANGED|DOSE NOT CHANGED|DOSE NOT CHANGED                     |
|DOSE REDUCED    |DOSE REDUCED    |DOSE REDUCED                         |
|DRUG INTERRUPTED|DRUG INTERRUPTED|DRUG INTERRUPTED                     |
|DRUG WITHDRAWN  |DRUG WITHDRAWN  |DRUG WITHDRAWN                       |
|NOT APPLICABLE  |NOT APPLICABLE  |NOT APPLICABLE                       |
|UNKNOWN         |UNKNOWN         |UNKNOWN                              |
-------------------------------------------------------------------------
```

The %CT_CREATEFORMATS macro has this signature:

```
%macro ct_createformats(
  _cstLang=en,                /* Language tag in TranslatedText to use      */
  _cstCreateCatalog=1,        /* Create format catalog                      */
  _cstKillCatFirst=0,         /* Empty catalog first                        */
  _cstUseExpression=,         /* Expression to create the SAS format name   */
  _cstAppendChar=F,           /* Letter to append in case SAS format name
                                 ends with digit                            */
  _cstDeleteEmptyColumns=1,   /* Delete columns in output data set that are
                                 completely missing                         */
  _cstTrimCharacterData=1     /* Truncate character data in output data set
                                 to the minimum value needed.               */
  );
```

The %CT_CREATEFORMATS macro attempts to map the CodeList/ nciodm:CDISCSubmissionValue in the codelist variable to the fmtname variable. The fmtname variable value must contain a valid SAS format name. The %CT_CREATEFORMATS macro uses the following steps to create a valid SAS format name:

1 Apply a user-defined expression to create the fmtname variable.

2 If the value of fmtname is empty, use the CodeList/SASFormatName attribute (typically empty in NCI EVS ODM XML files).

3 If the value of fmtname is empty, use the CodeList/nciodm:CDISCSubmissionValue value in the codelist variable.

4 If the value of fmtname ends with a digit, add the character specified by the _cstAppendChar macro parameter (default=F).

After these steps, the value of the fmtname variable is validated against the following regular expression:

```
'm/^(?=.{1,32}$)([\$a-zA-Z_][a-zA-Z0-9_]*[a-zA-Z_])$/'
```

If the value of the fmtname variable fails validation, the fmtname variable value does not contain a valid SAS format name. The value is set to missing. Then, the codelist is not used to create a SAS format.

Two sample driver programs are provided with the SAS Clinical Standards Toolkit to demonstrate the use of the %CT_CREATEFORMATS macro:

***sample study library directory*/cdisc-ct-1.0-1.7/programs/ create_ctformats.sas**

sample study library directory**/cdisc-ct-1.0-1.7/programs/create_ctformats_qs.sas**

Both of these sample driver programs demonstrate how CDISCSubmissionValue can be mapped to a valid SAS format name.

Reading CDISC CRT-DDS 1.0 or Define-XML 2.0 define.xml Files: %CRTDDS_READ and %DEFINE_READ Macros

The process for reading CDISC CRT-DDS 1.0 and CDISC Define-XML 2.0 define.xml files is similar to reading CDISC ODM XML files.

Note: This section demonstrates reading CDISC CRT-DDS 1.0 define.xml files as an example. The CDISC Define-XML 2.0 process is similar, but uses the define_read macro instead of the crtdds_read macro.

The SAS Clinical Standards Toolkit supports reading a define.xml file and translating the file metadata into a SAS representation of the CDISC CRT-DDS model. To read the define.xml file, a specialized macro named %CRTDDS_READ is available in the CRT-DDS 1.0 standards macros folder. This folder is located in ***global standards library directory*****/standards/cdisc-crtdds-1.0-1.7/macros**.

This macro is referenced from the create_sascrtdds_fromxml.sas driver program. There are no input parameters in the call to the %CRTDDS_READ macro.

File references and other metadata that are required by the macro are set as global macro variables. These global macro variables are set through the framework initialization properties and the CDISC CRT-DDS 1.0 initialization properties. Throughout the processing of the %CRTDDS_READ macro, the Results data set contains all framework-specific messages and CRT-DDS 1.0-specific messages that were generated during run time.

Based on file references defined in the SASReferences data set, the %CRTDDS_READ macro accesses the define.xml file.

Here is a partial listing of a sample define.xml file.

```
<ODM xmlns:xlink="http://www.w3.org/1999/xlink"
  xmlns:def="http://www.cdisc.org/ns/def/v1.0"
```

```
      xmlns="http://www.cdisc.org/ns/odm/v1.2" FileOID="1"
      CreationDateTime="2011-07-13T17:15:43-04:00"
      AsOfDateTime="2011-07-13T17:12:42"
      Description="define1" FileType="Snapshot" Id="define1"
      ODMVersion="1.0">
   <Study OID="1">
     <GlobalVariables>
       <StudyName>study1</StudyName>
       <StudyDescription>first study</StudyDescription>
       <ProtocolName>Protocol abc</ProtocolName>
     </GlobalVariables>
     <MetaDataVersion OID="1" Name="CDISC-SDTM 3.1.2"
                      Description="CDISC-SDTM 3.1.2"
                      def:DefineVersion="1.0.0"
                      def:StandardName="CDISC SDTM"
                      def:StandardVersion="3.1.2">
      <ItemGroupDef
        OID="AE1" Name="AE" Repeating="Yes"
        IsReferenceData="No"
        SASDatasetName="AE" Domain="AE"
        Purpose="Tabulation" def:Label="Adverse Events"
        def:Class="Events"
        def:Structure="One record per adverse event per subject"
        def:DomainKeys="STUDYID USUBJID AEDECOD AESTDTC"
        def:ArchiveLocationID="AE1">
         <ItemRef ItemOID="COL1" Mandatory="Yes"
           OrderNumber="1" KeySequence="1" Role="Identifier"/>
         <ItemRef ItemOID="COL2" Mandatory="Yes"
           OrderNumber="2" Role="Identifier"/>
         <ItemRef ItemOID="COL3" Mandatory="Yes"
           OrderNumber="3" KeySequence="2" Role="Identifier"/>
         <ItemRef ItemOID="COL4" Mandatory="Yes"
           OrderNumber="4" Role="Identifier"/>
         <ItemRef ItemOID="COL5" Mandatory="No"
           OrderNumber="5" Role="Identifier"/>
         <ItemRef ItemOID="COL6" Mandatory="No"
           OrderNumber="6" Role="Identifier"/>
         <ItemRef ItemOID="COL7" Mandatory="No"
           OrderNumber="7" Role="Identifier"/>
```

After the %CRTDDS_READ macro confirms that the define.xml file exists, a call is made to the SAS DATA step component JavaObj. JavaObj processing converts the define.xml file into a cubeXML file through transformations using XSL files and processes.

The cubeXML file is created in the Work library. The name of the cubeXML file is _cub**nnnn**.xml , where **nnnn** is a randomly generated number.

The cubeXML file is accessed using the SAS XML LIBNAME engine and XMLMap processing. A default XMLMap file is stored in the sample CRT-DDS 1.0 study folder hierarchy (**referencexml/define.map**). The define.map file is required to process the cubeXML file. If it does not exist, the crtdds_read attempts to create one using the CRT-DDS reference metadata.

Here is a partial listing of the define.map file.

```
<?xml version="1.0" encoding="windows-1252"?>
<SXLEMAP version="1.2">

<TABLE name="AnnotatedCRFs">
   <TABLE-PATH syntax="XPath">/LIBRARY/AnnotatedCRFs</TABLE-PATH>
   <TABLE-DESCRIPTION>Annotated CRF metadata</TABLE-DESCRIPTION>

   <COLUMN name="DocumentRef">
     <PATH syntax="Xpath">/LIBRARY/AnnotatedCRFs/DocumentRef</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>The referenced Annotated CRF document</DESCRIPTION>
     <LENGTH>2000</LENGTH>
   </COLUMN>
   <COLUMN name="leafID">
     <PATH syntax="Xpath">/LIBRARY/AnnotatedCRFs/leafID</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>The unique ID of the referenced Annotated CRF</DESCRIPTION>
     <LENGTH>128</LENGTH>
   </COLUMN>
   <COLUMN name="FK_MetaDataVersion">
     <PATH syntax="Xpath">/LIBRARY/AnnotatedCRFs/FK_MetaDataVersion</PATH>
     <TYPE>character</TYPE>
     <DATATYPE>character</DATATYPE>
     <DESCRIPTION>Foreign key: MetaDataVersion.OID</DESCRIPTION>
     <LENGTH>128</LENGTH>
   </COLUMN>

</TABLE>
```

Processing of the cubeXML file results in the derivation of the data sets (such as ItemDefs) currently included in the SAS representation of the CDISC CRT-DDS model.

The final step in the %CRTDDS_READ macro is the derivation of table and column metadata that describe the data sets in the SAS representation of the define.xml file. At this point, the %CRTDDS_READ macro is ready to create the source_tables and source_columns data sets. The tables in the source_tables data set are created and copied to the output library as defined in the SASReferences data set.

Sample Driver Program: create_sascrtdds_fromxml.sas and create_sasdefine_fromxml.sas

Overview

Each primary SAS Clinical Standards Toolkit task, such as reading CDISC CRT-DDS 1.0 or CDISC Define-XML 2.0 XML files, is guided by a sample driver program that is provided with the SAS Clinical Standards Toolkit.

Note: CDISC CRT-DDS 1.0 is discussed in this section. The process is similar for CDISC Define-XML 2.0.

The create_sascrtdds_fromxml.sas driver program is used to read define.xml files.

The driver program is located here:

```
sample study library directory/cdisc-crtdds-1.0–1.7/programs
```

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are two input file references and four output data set references that are key to the successful completion of the driver program. Table 9.3 on page 326 lists these files and data sets, and they are discussed in separate sections. In the sample create_sascrtdds_fromxml.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

```
&studyRootPath=&_cstSRoot/cdisc-crtdds-1.0-&_cstVersion
```

```
&studyOutputPath=&_cstSRoot/cdisc-crtdds-1.0-&_cstVersion
```

Table 9.3 Key Components of the SASReferences Data Set for the create_sascrtdds_fromxml.sas Driver Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
Input				
externalxml	crtxml	fileref	&studyRootPath/sourcexml	define.xml
referencexml	crtmap	fileref	&studyRootPath/referencexml	define.map
Output				
sourcedata	srcdata	libref	&studyOutputPath/deriveddata	*.*
sourcemetadata	srcmeta	libref	&studyOutputPath/derivedmetadata	source_tables.sas7bdat
sourcemetadata	srcmeta	libref	&studyOutputPath/derivedmetadata	source_columns.sas7bdat
sourcemetadata	srcmeta	libref	&studyOutputPath/derivedmetadata	source_study.sas7bdat
results	results	libref	&studyOutputPath/results	read_results.sas7bdat

Process Inputs

The externalxml type refers to the define.xml file to read. The filename reference crtxml is defined in the SASReferences data set. This filename reference is used in the submitted SAS code when referring to the define.xml file.

The referencexml type refers to the SAS map file that is used to generate the SAS data sets that represent the define.xml file metadata and content. The filename reference crtmap is defined in the SASReferences data set. This filename is used in the submitted

SAS code when referring to the SAS map file. If a path and filename for the map file are not specified, a temporary map file is created as part of the crtdds_read processing.

Process Outputs

The sourcedata type is the library where the metadata files are created. These metadata files are the data sets that comprise the CRT-DDS information.

The sourcemetadata type refers to two data sets that are created from the cubeXML file, source_tables, and source_columns. Both data sets are stored in the same library. The source_tables data set contains metadata about each table that is derived from the CRT-DDS macro. The source_columns data set contains similar metadata but it is at the column level. Both of the data sets are written to the Srcmeta library. The sourcemetadata type refers to a data set source_study. The source_study data set is created in the Srcmeta library and contains study metadata.

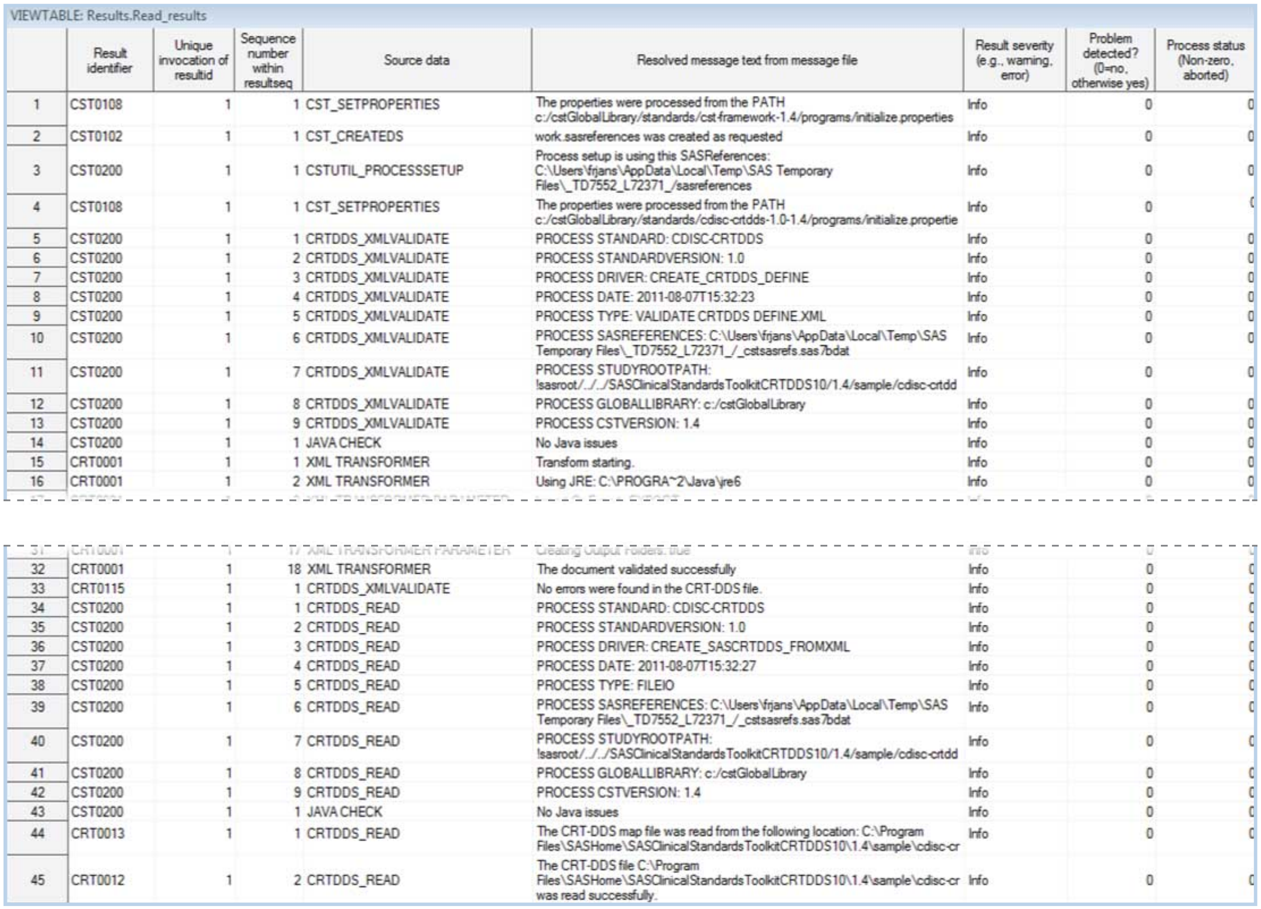
The results type refers to the Results data set that contains information from running the CRT-DDS macro. This information is written to the read_results data set in the Results library.

Process Results

When the driver program finishes running, the read_results data set is created in the Results library. This data set contains informational, warning, and error messages that were generated by the driver program.

The following display shows an example of the contents of a Results data set in the CRT-DDS sample study:

Figure 9.13 *Example of a Partial Results Data Set Created by the create_sascrtdds_fromxml.sas Driver Program*

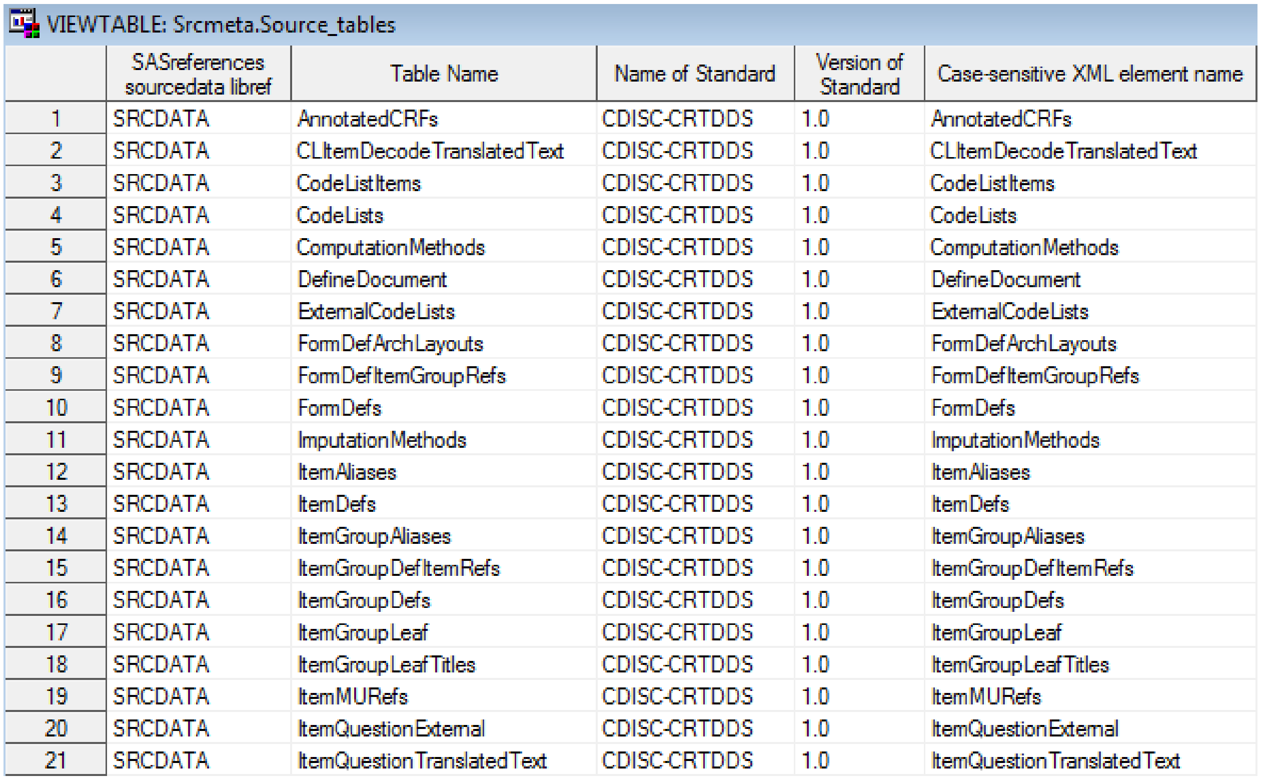


VIEWTABLE: Results.Read_results

	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
1	CST0108	1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-framework-1.4/programs/initialize.properties	Info	0	0
2	CST0102	1	1	CST_CREATEDS	work.sasreferences was created as requested	Info	0	0
3	CST0200	1	1	CSTUTIL_PROCESSSETUP	Process setup is using this SASReferences: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7552_L72371_/sasreferences	Info	0	0
4	CST0108	1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-crtdds-1.0-1.4/programs/initialize.propertie	Info	0	0
5	CST0200	1	1	CRTDDS_XMLVALIDATE	PROCESS STANDARD: CDISC-CRTDDS	Info	0	0
6	CST0200	1	2	CRTDDS_XMLVALIDATE	PROCESS STANDARDVERSION: 1.0	Info	0	0
7	CST0200	1	3	CRTDDS_XMLVALIDATE	PROCESS DRIVER: CREATE_CRTDDS_DEFINE	Info	0	0
8	CST0200	1	4	CRTDDS_XMLVALIDATE	PROCESS DATE: 2011-08-07T15:32:23	Info	0	0
9	CST0200	1	5	CRTDDS_XMLVALIDATE	PROCESS TYPE: VALIDATE CRTDDS DEFINE.XML	Info	0	0
10	CST0200	1	6	CRTDDS_XMLVALIDATE	PROCESS SASREFERENCES: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7552_L72371_/_cstsasrefs.sas7bdat	Info	0	0
11	CST0200	1	7	CRTDDS_XMLVALIDATE	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitCRTDDS10/1.4/sample/cdisc-crtdd	Info	0	0
12	CST0200	1	8	CRTDDS_XMLVALIDATE	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0
13	CST0200	1	9	CRTDDS_XMLVALIDATE	PROCESS CSTVERSION: 1.4	Info	0	0
14	CST0200	1	1	JAVA CHECK	No Java issues	Info	0	0
15	CRT0001	1	1	XML TRANSFORMER	Transform starting.	Info	0	0
16	CRT0001	1	2	XML TRANSFORMER	Using JRE: C:\PROGRA~2\Java\jre6	Info	0	0
31	CRT0001	1	17	XML TRANSFORMER PARAMETER	Creating Output Folders: true	Info	0	0
32	CRT0001	1	18	XML TRANSFORMER	The document validated successfully	Info	0	0
33	CRT0115	1	1	CRTDDS_XMLVALIDATE	No errors were found in the CRT-DDS file.	Info	0	0
34	CST0200	1	1	CRTDDS_READ	PROCESS STANDARD: CDISC-CRTDDS	Info	0	0
35	CST0200	1	2	CRTDDS_READ	PROCESS STANDARDVERSION: 1.0	Info	0	0
36	CST0200	1	3	CRTDDS_READ	PROCESS DRIVER: CREATE_SASCRTDDS_FROMXML	Info	0	0
37	CST0200	1	4	CRTDDS_READ	PROCESS DATE: 2011-08-07T15:32:27	Info	0	0
38	CST0200	1	5	CRTDDS_READ	PROCESS TYPE: FILEIO	Info	0	0
39	CST0200	1	6	CRTDDS_READ	PROCESS SASREFERENCES: C:\Users\frjans\AppData\Local\Temp\SAS Temporary Files_TD7552_L72371_/_cstsasrefs.sas7bdat	Info	0	0
40	CST0200	1	7	CRTDDS_READ	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitCRTDDS10/1.4/sample/cdisc-crtdd	Info	0	0
41	CST0200	1	8	CRTDDS_READ	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0
42	CST0200	1	9	CRTDDS_READ	PROCESS CSTVERSION: 1.4	Info	0	0
43	CST0200	1	1	JAVA CHECK	No Java issues	Info	0	0
44	CRT0013	1	1	CRTDDS_READ	The CRT-DDS map file was read from the following location: C:\Program Files\SASHome\SASClinicalStandardsToolkitCRTDDS10\1.4\sample\cdisc-cr	Info	0	0
45	CRT0012	1	2	CRTDDS_READ	The CRT-DDS file C:\Program Files\SASHome\SASClinicalStandardsToolkitCRTDDS10\1.4\sample\cdisc-cr was read successfully.	Info	0	0

The %CRTDDS_READ macro creates the source_tables and source_columns data sets in the Srcmeta library. These data sets contain the table and column metadata for the SAS representation of CRT-DDS that is derived from the define.xml file. The Srcmeta library corresponds to the location specified in SASReferences (**`&studyOutputPath/derivedmetadata`**).

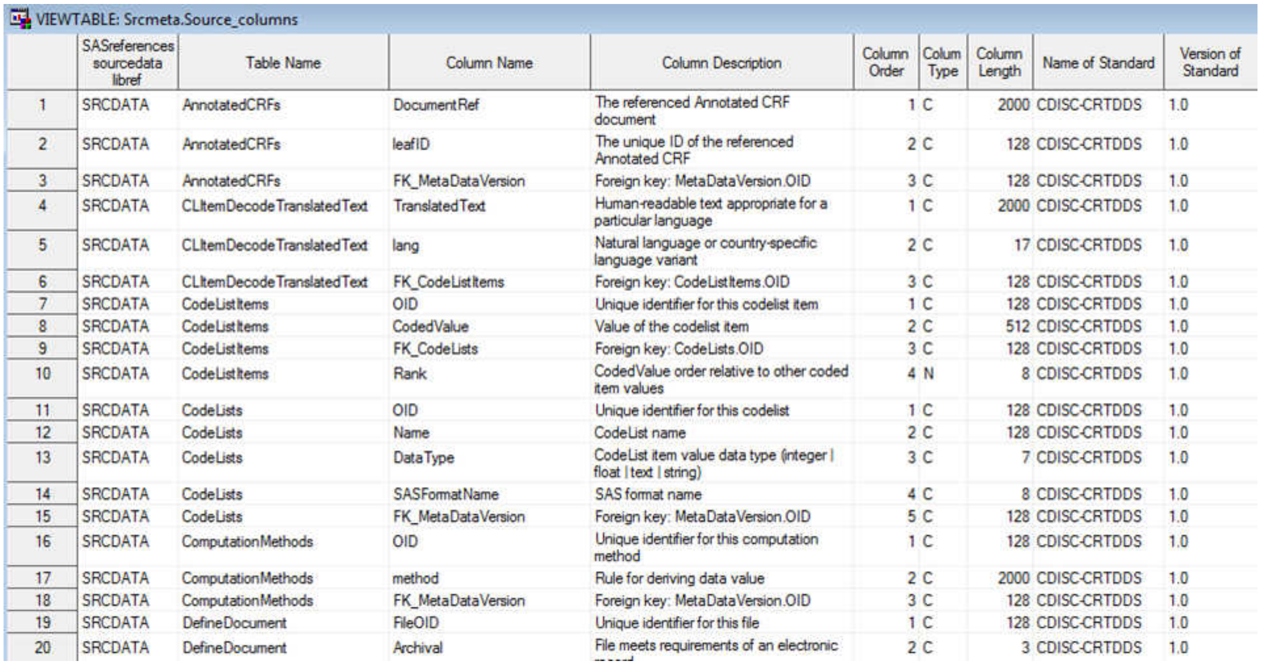
Figure 9.14 *Example of Partial Source_Tables Data Set Derived from the %CRTDDS_READ Macro*



VIEWTABLE: Srcmeta.Source_tables

	SASreferences sourcedata libref	Table Name	Name of Standard	Version of Standard	Case-sensitive XML element name
1	SRCDATA	AnnotatedCRFs	CDISC-CRTDDS	1.0	AnnotatedCRFs
2	SRCDATA	CLItemDecodeTranslatedText	CDISC-CRTDDS	1.0	CLItemDecodeTranslatedText
3	SRCDATA	CodeListItems	CDISC-CRTDDS	1.0	CodeListItems
4	SRCDATA	CodeLists	CDISC-CRTDDS	1.0	CodeLists
5	SRCDATA	ComputationMethods	CDISC-CRTDDS	1.0	ComputationMethods
6	SRCDATA	DefineDocument	CDISC-CRTDDS	1.0	DefineDocument
7	SRCDATA	ExternalCodeLists	CDISC-CRTDDS	1.0	ExternalCodeLists
8	SRCDATA	FormDefArchLayouts	CDISC-CRTDDS	1.0	FormDefArchLayouts
9	SRCDATA	FormDefItemGroupRefs	CDISC-CRTDDS	1.0	FormDefItemGroupRefs
10	SRCDATA	FormDefs	CDISC-CRTDDS	1.0	FormDefs
11	SRCDATA	ImputationMethods	CDISC-CRTDDS	1.0	ImputationMethods
12	SRCDATA	ItemAliases	CDISC-CRTDDS	1.0	ItemAliases
13	SRCDATA	ItemDefs	CDISC-CRTDDS	1.0	ItemDefs
14	SRCDATA	ItemGroupAliases	CDISC-CRTDDS	1.0	ItemGroupAliases
15	SRCDATA	ItemGroupDefItemRefs	CDISC-CRTDDS	1.0	ItemGroupDefItemRefs
16	SRCDATA	ItemGroupDefs	CDISC-CRTDDS	1.0	ItemGroupDefs
17	SRCDATA	ItemGroupLeaf	CDISC-CRTDDS	1.0	ItemGroupLeaf
18	SRCDATA	ItemGroupLeafTitles	CDISC-CRTDDS	1.0	ItemGroupLeafTitles
19	SRCDATA	ItemMURefs	CDISC-CRTDDS	1.0	ItemMURefs
20	SRCDATA	ItemQuestionExternal	CDISC-CRTDDS	1.0	ItemQuestionExternal
21	SRCDATA	ItemQuestionTranslatedText	CDISC-CRTDDS	1.0	ItemQuestionTranslatedText

Figure 9.15 Example of Partial Source_Columns Data Set Derived from the %CRTDDS_READ Macro



VIEWTABLE: Srcmeta.Source_columns

	SASreferences sourcedata libref	Table Name	Column Name	Column Description	Column Order	Colum Type	Column Length	Name of Standard	Version of Standard
1	SRCDATA	AnnotatedCRFs	DocumentRef	The referenced Annotated CRF document	1	C	2000	CDISC-CRTDDS	1.0
2	SRCDATA	AnnotatedCRFs	leafID	The unique ID of the referenced Annotated CRF	2	C	128	CDISC-CRTDDS	1.0
3	SRCDATA	AnnotatedCRFs	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	3	C	128	CDISC-CRTDDS	1.0
4	SRCDATA	CLItemDecodeTranslatedText	TranslatedText	Human-readable text appropriate for a particular language	1	C	2000	CDISC-CRTDDS	1.0
5	SRCDATA	CLItemDecodeTranslatedText	lang	Natural language or country-specific language variant	2	C	17	CDISC-CRTDDS	1.0
6	SRCDATA	CLItemDecodeTranslatedText	FK_CodeListItems	Foreign key: CodeListItems.OID	3	C	128	CDISC-CRTDDS	1.0
7	SRCDATA	CodeListItems	OID	Unique identifier for this codelist item	1	C	128	CDISC-CRTDDS	1.0
8	SRCDATA	CodeListItems	CodedValue	Value of the codelist item	2	C	512	CDISC-CRTDDS	1.0
9	SRCDATA	CodeListItems	FK_CodeLists	Foreign key: CodeLists.OID	3	C	128	CDISC-CRTDDS	1.0
10	SRCDATA	CodeListItems	Rank	CodedValue order relative to other coded item values	4	N	8	CDISC-CRTDDS	1.0
11	SRCDATA	CodeLists	OID	Unique identifier for this codelist	1	C	128	CDISC-CRTDDS	1.0
12	SRCDATA	CodeLists	Name	CodeList name	2	C	128	CDISC-CRTDDS	1.0
13	SRCDATA	CodeLists	DataType	CodeList item value data type (integer | float | text | string)	3	C	7	CDISC-CRTDDS	1.0
14	SRCDATA	CodeLists	SASFormatName	SAS format name	4	C	8	CDISC-CRTDDS	1.0
15	SRCDATA	CodeLists	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	5	C	128	CDISC-CRTDDS	1.0
16	SRCDATA	ComputationMethods	OID	Unique identifier for this computation method	1	C	128	CDISC-CRTDDS	1.0
17	SRCDATA	ComputationMethods	method	Rule for deriving data value	2	C	2000	CDISC-CRTDDS	1.0
18	SRCDATA	ComputationMethods	FK_MetaDataVersion	Foreign key: MetaDataVersion.OID	3	C	128	CDISC-CRTDDS	1.0
19	SRCDATA	DefineDocument	FileOID	Unique identifier for this file	1	C	128	CDISC-CRTDDS	1.0
20	SRCDATA	DefineDocument	Archival	File meets requirements of an electronic	2	C	3	CDISC-CRTDDS	1.0

The Srcdata library contains the driver program-generated tables that comprise the SAS representation of the CRT-DDS model. There is a one-to-one correspondence between the tables listed in the Srcdata library and the tables contained in the source_tables metadata file in the Srcmeta library. The Srcdata library corresponds to the location specified in SASReferences (&studyOutputPath/deriveddata).

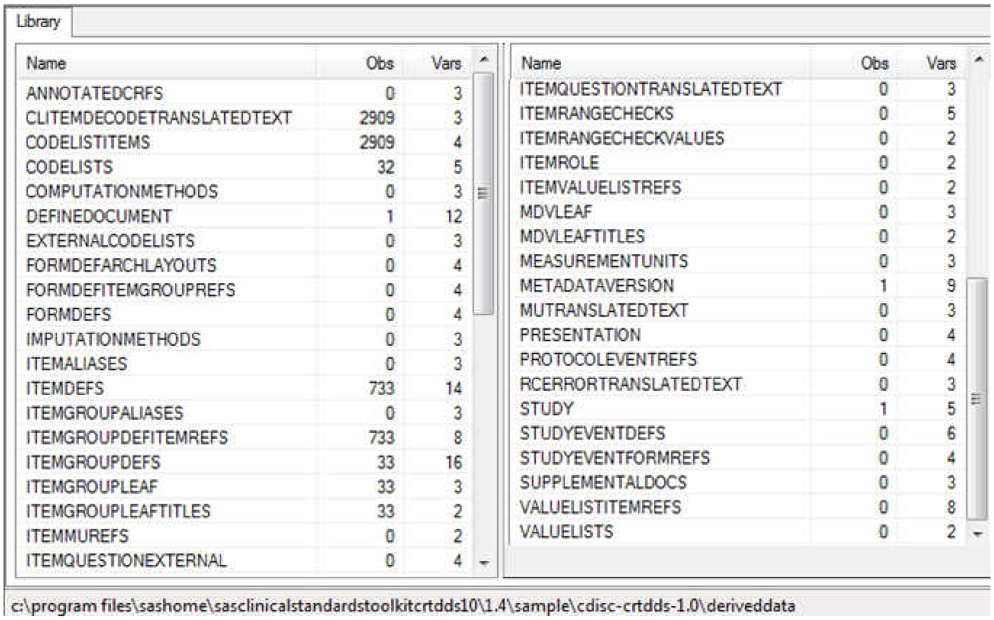


Figure 9.16 *Example of Partial Srcdata Library Derived from the %CRTDDS_READ Macro*

Name	Obs	Vars
ANNOTATEDCRFS	0	3
CLITEMDECODETRANSLATEDTEXT	2909	3
CODELISTITEMS	2909	4
CODELISTS	32	5
COMPUTATIONMETHODS	0	3
DEFINEDOCUMENT	1	12
EXTERNALCODELISTS	0	3
FORMDEFARCHLAYOUTS	0	4
FORMDEFITEMGROUPREFS	0	4
FORMDEFS	0	4
IMPUTATIONMETHODS	0	3
ITEMALIASES	0	3
ITEMDEFS	733	14
ITEMGROUPALIASES	0	3
ITEMGROUPDEFITEMREFS	733	8
ITEMGROUPDEFS	33	16
ITEMGROUPLEAF	33	3
ITEMGROUPLEAFTITLES	33	2
ITEMMUREFS	0	2
ITEMQUESTIONEXTERNAL	0	4

Name	Obs	Vars
ITEMQUESTIONTRANSLATEDTEXT	0	3
ITEMRANGECHECKS	0	5
ITEMRANGECHECKVALUES	0	2
ITEMROLE	0	2
ITEMVALUELISTREFS	0	2
MDVLEAF	0	3
MDVLEAFTITLES	0	2
MEASUREMENTUNITS	0	3
METADATAVERSION	1	9
MUTRANSLATEDTEXT	0	3
PRESENTATION	0	4
PROTOCOLEVENTREFS	0	4
RCERRORTRANSLATEDTEXT	0	3
STUDY	1	5
STUDYEVENTDEFS	0	6
STUDYEVENTFORMREFS	0	4
SUPPLEMENTALDOCS	0	3
VALUELISTITEMREFS	0	8
VALUELISTS	0	2

c:\program files\sashome\sasclinicalstandardstoolkitcrtdds10\1.4\sample\cdisc-crtdds-1.0\deriveddata

When running the driver programs against non-sample data, you must populate the SASReferences data set in the driver program with the proper values. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

Writing XML Files

Overview

Support of CDISC XML-based standards, such as CDISC CRT-DDS 1.0, CDISC Define-XML 2.0, and CDISC ODM, includes the ability to render these files in SAS data set format and the ability to create model-specific XML files from a SAS data set representation of those standards.

In the SAS Clinical Standards Toolkit, you can create a CDISC CRT-DDS 1.0 define.xml file or CDISC Define-XML 2.0 file (including Analysis Results Metadata 1.0) that references a CDISC SDTM study, a SEND study, or a CDISC ADaM study. You can also create a CDISC ODM 1.3.0 XML file or a CDISC ODM 1.3.1 file.

The next section outlines the basic workflow for the creation of model-specific XML files.

Basic Workflow

Here is the basic workflow for writing XML files:

1. Build the SAS representation of a given XML-based standard by referencing an existing set of data and metadata about a clinical study, or by creating data and metadata about a new clinical study in the standard-specific SAS format.
2. (Optional) Validate the SAS representation of the XML-based standard (to include foreign key relationships, value conformance to a set of expected values, and so on).
3. Create a standardized intermediate cubeXML file using the data and metadata contained in the SAS representation of the standard.
4. (Build and) reference a set of valid XSL style sheets for each target data set (such as ItemDefs.xsl).
5. Use the SAS DATA step component JavaObj to read the cubeXML file using the XSL style sheets to create the target standard-specific XML file.
6. (Optional) Validate the structure and syntax of the XML file that was created against an XML schema.

Creating a CDISC CRT-DDS 1.0 define.xml File

There are four key macros that are provided with the SAS Clinical Standards Toolkit that support creation of a CDISC CRT-DDS 1.0 define.xml file. The four macros are listed in the order in which they are executed:

1 The %CRTDDS_SDTMTODEFINE macro creates the 39 tables for the SAS representation of the CRT-DDS files from SDTM metadata. This macro, using SDTM table and column metadata as its source, populates a subset of 19 CRT-DDS data sets.

  The %CRTDDS_ADAMTODEFINE macro is similar to the %CRTDDS_SDTMTODEFINE macro but uses ADaM table and column metadata.

2 The %CRTDDS_VALIDATE macro submits a set of validation checks based on what is defined in the Validation Control data set to validate the referenced SAS representation of the CRT-DDS files.

3 The %CRTDDS_WRITE macro creates the define.xml file from the SAS representation of the CRT-DDS files.

4 The %CSTUTILXMLVALIDATE macro validates that the XML file is structurally and syntactically correct according to the XML schema for the CRT-DDS 1.0 standard. This macro is important if you customize the define.xml file outside of the workflow. For example, if you edit the define.xml file to add links for annotated CRF pages, this macro validates the syntax.

These macros are called by driver programs that are responsible for properly setting up each SAS Clinical Standards Toolkit process to perform a specific SAS Clinical Standards Toolkit task. Several sample driver programs are provided with the SAS Clinical Standards Toolkit CDISC CRT-DDS standard related to the creation of the define.xml file.

Here is the purpose of each of these driver programs:

- The create_crtdds_from_sdtm.sas driver program sets up the required metadata and SASReferences data set for the sample study. It runs the %CRTDDS_SDTMTODEFINE macro. It creates the SAS representation of the CRT-DDS data sets from the sample study SDTM data sets.
- The validate_crtdds_data.sas driver program validates the SAS representation of the CRT-DDS define data sets based on the selected CRT-DDS validation checks. This driver program can be run multiple times until data validation has been reconciled.

- The create_crtdds_define.sas driver program creates the CDISC CRT-DDS 1.0 define.xml file. It runs the %CRTDDS_WRITE and %CSTUTILXMLVALIDATE macros. This driver program creates and validates the XML syntax for the define.xml file.

These driver programs are examples that are provided with the SAS Clinical Standards Toolkit. You can use these driver programs or create your own. The names of these driver programs are not important. However, the content is important and demonstrates how the various SAS Clinical Standards Toolkit framework macros are used to generate the required metadata files.

The driver programs create a define.xml based on SDTM metadata. Similar programs are provided with the SAS Clinical Standards Toolkit for the creation of a define.xml based on ADaM metadata.

Sample Driver Program: create_crtdds_from_sdtm.sas

Overview

The create_crtdds_from_sdtm.sas driver program sets up the required environment variables and library references to initiate the %CRTDDS_SDTMTODEFINE macro. This macro extracts data from the SDTM metadata files. (For more information about the source_tables and source_columns data sets, see "Source Metadata" on page 172.) Depending on the available source information, the macro attempts to convert the information into the 39 tables that represent the SAS interpretation of the CDISC CRT-DDS 1.0 model. All 39 data sets are created, but only those data sets with available data are populated. The other tables contain zero observations.

The following table lists the parameters for the driver program:

Table 9.4 Parameters for the create_crtdds_from_sdtm.sas Driver Program

Parameter	Required	Description
_cstOutLib	Yes	The library reference (LIBNAME) where the tables are created.

Parameter	Required	Description
_cstSourceTables	Yes	The data set that contains the SDTM metadata for the domains to include in the CRT-DDS file.
_cstSourceColumns	Yes	The data set that contains the SDTM metadata for the domain columns to include in the CRT-DDS file.
_cstSourceStudy	Yes	The data set that contains the SDTM metadata for the studies to include in the CRT-DDS file.
_cstSourceValues	No	The data set that contains the SDTM metadata for the Value Level columns to include in the CRT-DDS file.
_cstSourceDocuments	No	The data set that contains the SDTM metadata for the Document references to include in the CRT-DDS file.

Here is an example of a call to the %CRTDDS_SDTMTODEFINE macro:

```
%crtdds_sdtmtodefine(
  _cstOutLib=srcdata,
  _cstSourceTables=sampdata.source_tables,
  _cstSourceColumns=sampdata.source_columns,
  _cstSourceValues=sampdata.source_values,
  _cstSourceDocuments=sampdata.source_documents,
  _cstSourceStudy=sampdata.source_study
  );
```

In the example, the %CRTDDS_SDTMTODEFINE macro writes all of the CRT-DDS 1.0 defined tables to the Srcdata library.

The create_crtdds_from_sdtm.sas driver program is provided with the SAS Clinical Standards Toolkit, and it is ready to run on any of the SDTM sample studies. The driver program can be run interactively or in batch. To run the driver program interactively, start a SAS session, and load the driver program into the SAS editor.

The driver program is located here:

***sample study library directory*/cdisc-crtdds-1.0–1.7/programs**

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, "SASReferences File," on page 137.

In the SASReferences data set, there are five input file references and one output data set reference that are key to the successful completion of the create_crtdds_from_sdtm.sas driver program. Table 9.5 on page 336 lists these files and data sets, and they are discussed in separate sections. In the sample create_crtdds_from_sdtm.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

```
&studyRootPath=sample study library directory/cdisc-sdtm-3.1.3-
1.7/sascstdemodata
```

```
&studyOutputPath=sample study library directory/cdisc-crtdds-1.0-
1.7
```

Table 9.5 Key Components of the SASReferences Data Set for the create_crtdds_from_sdtm.sas Driver Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
sourcemetadata	sampdata	libref	&studyRootPath/ metadata	source_tables. sas7bdat
sourcemetadata	sampdata	libref	&studyRootPath/ metadata	source_columns. sas7bdat
sourcemetadata	sampdata	libref	&studyRootPath/ metadata	source_study. sas7bdat
sourcemetadata	sampdata	libref	&studyRootPath/ metadata	source_values. sas7bdat

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
sourcemetadata	sampdata	libref	&studyRootPath/ metadata	source_documents. sas7bdat
		Output		
sourcedata	srcdata	libref	&studyOutputPath/ data	

Process Inputs

The sourcemetadata type refers to three data sets that contain the SDTM domain metadata: source_tables, source_columns, and source_values. These data sets are stored in the same library.

The sample create_crtdds_from_sdtm.sas driver program provided with the SAS Clinical Standards Toolkit references a source CDISC SDTM 3.1.3 study. So, the source_tables data set contains SDTM 3.1.3 metadata about each standard domain defined in the *Study Data Tabulation Model Implementation Guide: Human Clinical Trials (Version 3.1.3)* and includes any customizations that you have added. The source_columns data set contains similar metadata but it is at the column level. The source_values data set contains Value Level metadata. The source metadata is read from this location:

***sample study library directory*/cdisc-sdtm-3.1.3–1.7/ sascstdemodata/metadata**

This location is represented in the driver program by the sampdata library name.

A source study data set (source_study) is required by this driver program. The following table lists the variables that are required in this data set:

Table 9.6 *Variables Required in the Source Study Data Set (source_study)*

Variable*	Required	Description
StudyName	Yes	The name of the study. This value is used to populate the srcdata.study.studyname column.

Variable*	Required	Description
DefineDocumentName	Yes	The name of the define document to create. This value is used to populate the srcdata.definedocument.FileOID.
SASref	Yes	The reference that ties the study name to the corresponding domains that are associated with this study in the source_tables and source_columns data sets.
ProtocolName	Yes	The name of the protocol for the study. This value is used to populate the srcdata.study.protocolname column.
StudyDescription	Yes	The description of the study. This value is used to populate the srcdata.study.studydescription column. **Note:** You cannot use commas, semicolons, or quotation marks in the description.
Standard	Yes	The name of the standard in the SAS Clinical Standards Toolkit. (For example, CDISC-SDTM.)
StandardVersion	Yes	The version of the standard in the SAS Clinical Standards Toolkit. (For example, 3.1.3.)
FormalStandard	Yes	The formal name of the standard as used in CRT-DDS. (For example, CDISC SDTM.)
FormalStandardVersion	Yes	The formal version of the standard as used in CRT-DDS. (For example, 3.1.3.)

*All variables are required to be non-blank.

Only a single study can be referenced in the source study data set.

Process Outputs

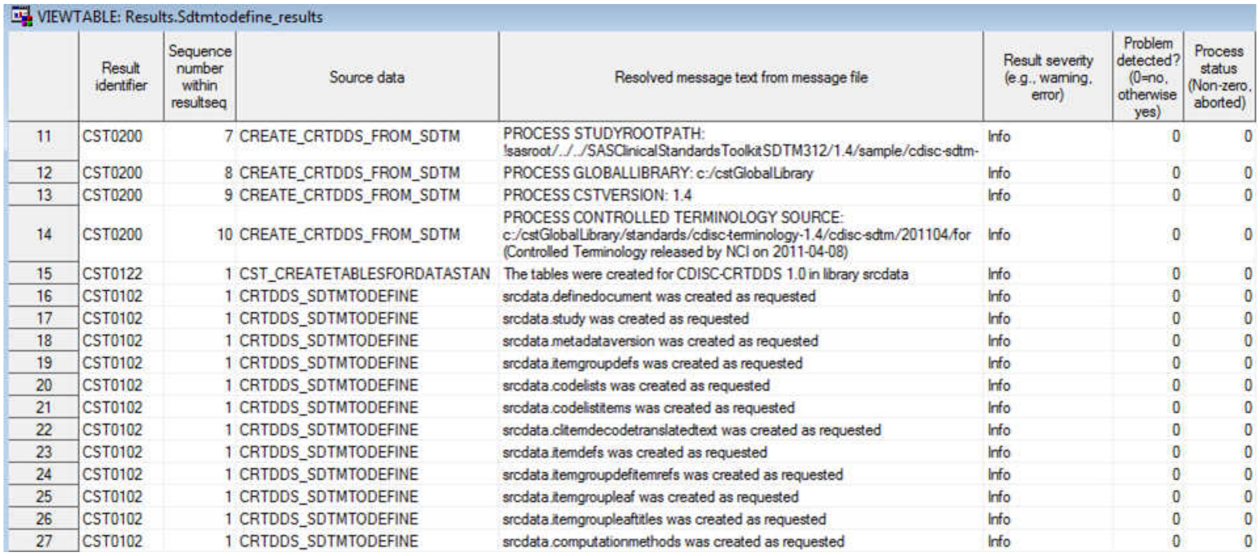
The sourcedata type is the library where the metadata files are created. These metadata files are the data sets that comprise the SAS representation of the CDISC CRT-DDS 1.0 standard. The create_crtdds_from_sdtm.sas driver program creates 39 data sets. Most of these data sets have zero observations because there is no default

SDTM metadata source. In the SAS Clinical Standards Toolkit sample study, these data sets are written to the ***sample study library directory*/cdisc-crtdds-1.0-1.7/data** directory. This location is represented in the driver program by the srcdata library name.

Process Results

When the driver program finishes running, the sdtmtodefine_results data set is created. This data set contains informational, warning, and error messages that were generated by the submitted driver program.

Figure 9.17 *Example of a Partial Results Data Set from CRT-DDS Sample Study*



VIEWTABLE: Results.Sdtmtodefine_results

	Result identifier	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
11	CST0200	7	CREATE_CRTDDS_FROM_SDTM	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-	Info	0	0
12	CST0200	8	CREATE_CRTDDS_FROM_SDTM	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0
13	CST0200	9	CREATE_CRTDDS_FROM_SDTM	PROCESS CSTVERSION: 1.4	Info	0	0
14	CST0200	10	CREATE_CRTDDS_FROM_SDTM	PROCESS CONTROLLED TERMINOLOGY SOURCE: c:/cstGlobalLibrary/standards/cdisc-terminology-1.4/cdisc-sdtm/201104/for (Controlled Terminology released by NCI on 2011-04-08)	Info	0	0
15	CST0122	1	CST_CREATETABLESFORDATASTAN	The tables were created for CDISC-CRTDDS 1.0 in library srcdata	Info	0	0
16	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.definedocument was created as requested	Info	0	0
17	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.study was created as requested	Info	0	0
18	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.metadataversion was created as requested	Info	0	0
19	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.itemgroupdefs was created as requested	Info	0	0
20	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.codelists was created as requested	Info	0	0
21	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.codelistitems was created as requested	Info	0	0
22	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.clitemdecodetranslatedtext was created as requested	Info	0	0
23	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.itemdefs was created as requested	Info	0	0
24	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.itemgroupdefitemrefs was created as requested	Info	0	0
25	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.itemgroupleaf was created as requested	Info	0	0
26	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.itemgroupleaftitles was created as requested	Info	0	0
27	CST0102	1	CRTDDS_SDTMTODEFINE	srcdata.computationmethods was created as requested	Info	0	0

Sample Driver Program: create_crtdds_define.sas

Overview

The create_crtdds_define.sas driver program sets up the required environment variables and library references to initiate the %CRTDDS_WRITE macro. This macro reads the 39 data sets that comprise the SAS representation of the CDISC CRT-DDS 1.0 model, and it converts that information to the required define.xml structure. If source metadata or data are missing, then empty elements and attributes are not created in the define.xml file. The inputs and outputs are specified in the SASReferences data set.

Note: For more information about the %CRTDDS_WRITE macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Here is an example of a call to the %CRTDDS_WRITE macro:

```
%crtdds_write(_cstCreateDisplayStyleSheet=1,
              _cstOutputEncoding=UTF-16,
              _cstResultsOverrideDS=&_cstResultsDS);
```

In this example, a default style sheet is generated in the same directory as the XML output based on the information in the SASReferences data set. XML encoding is set to UTF-16, and process results are written to the default &_cstResultsDS data set.

Here is the call to the macro from the sample create_crtdds_define.sas driver program:

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

The call creates a display style sheet and uses default values for the parameters.

The create_crtdds_define.sas driver program is ready to run on any of the CDISC SDTM sample studies. The driver program can be run interactively or in batch.

The driver program is located here:

***sample study library directory*/cdisc-crtdds-1.0-1.7/programs**

Multiple tasks can be executed in any SAS Clinical Standards Toolkit driver program. The create_crtdds_define.sas driver program calls both the %CRTDDS_WRITE macro to create the define.xml file, and the %CSTUTILXMLVALIDATE macro to validate the syntax of the generated define.xml file. For more information about the %CSTUTILXMLVALIDATE macro, see "Validation of XML-Based Standards" on page 366.

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, "SASReferences File," on page 137.

In the SASReferences data set, there are two input file references and three output data set references that are key to the successful completion of the create_crtdds_define.sas driver program. Table 9.7 on page 341 lists these files and data sets, and they are discussed in separate sections. In the sample create_crtdds_define.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

`&studyRootPath=`*`sample study library directory`*`/cdisc-crtdds-1.0-1.7`

`&studyOutputPath=`*`sample study library directory`*`/cdisc-crtdds-1.0-1.7`

***Table 9.7** Key Components of the SASReferences Data Set for the %CRTDDS_WRITE Macro*

Metadata Type	LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
control	control	libref	&workpath	sasreferences.sas7bdat
sourcedata	srcdata	libref	&studyRootPath/data	
		Output		
referencexml	xslt01	filename	&studyOutputPath/sourcexml	define-v1-updated-html.xsl
results	results	LIBNAME	&studyOutputPath/results	write_results.sas7bdat
externalxml	extxml	filename	&studyOutputPath/sourcexml	define.xml

Process Inputs

Use of the control library name that points to the path in the &workpath macro variable demonstrates a technique of documenting the derivation of the SASReferences data set in the SAS Work library. The driver program initiates the macro variable &workpath with this SAS code:

```
%let workPath=%sysfunc(pathname(work));
```

The sourcedata type is the library that contains the 39 data sets that might have been populated by the create_crtdds_from_sdtm.sas driver program. These metadata files are the data sets that constitute the SAS representation of the CDISC CRT-DDS 1.0 standard. In the SAS Clinical Standards Toolkit sample study, these data sets are read from the ***sample study library directory*****/cdisc-crtdds-1.0-1.7/data** directory. This location is represented in the driver program by the Srcdata library name.

Process Outputs

The externalxml type refers to the define.xml file. This file is accessed in the driver program from the extxml filename statement, and is written to the ***sample study library directory*****/cdisc-crtdds-1.0-1.7/sourcexml** directory.

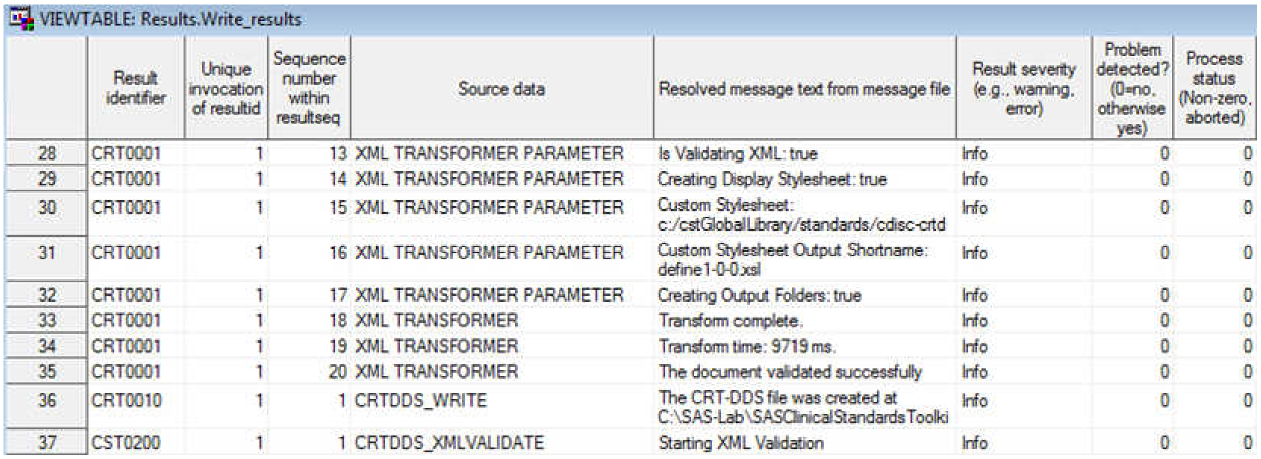
The referencexml type can serve as either an input or output file reference. If the path and filename are not specified, the %CRTDDS_WRITE macro interprets the _cstCreateDisplayStyleSheet=1 parameter to indicate the default style sheet that is provided by the SAS Clinical Standards Toolkit in the global standards library. If a path and filename are specified, the referencexml type serves as an output file reference for the %CRTDDS_WRITE macro. The default style sheet is copied from the global standards library to the path and filename that are specified.

The results type refers to the write_results data set that documents the results of the create_crtdds_define.sas driver program. In the SAS Clinical Standards Toolkit CDISC CRT-DDS folder hierarchy, this information is written to the ***sample study library directory*****/cdisc-crtdds-1.0-1.7/results** directory.

Process Results

Inclusion of the results record (row) in the SASReferences data set indicates that the process results are to be copied to a write_results data set located in the specified SAS library.

Figure 9.18 *Example of a Partial Results Data Set from the CRT-DDS Sample Study*



VIEWTABLE: Results.Write_results

	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
28	CRT0001	1	13	XML TRANSFORMER PARAMETER	Is Validating XML: true	Info	0	0
29	CRT0001	1	14	XML TRANSFORMER PARAMETER	Creating Display Stylesheet: true	Info	0	0
30	CRT0001	1	15	XML TRANSFORMER PARAMETER	Custom Stylesheet: c:/cstGlobalLibrary/standards/cdisc-crtd	Info	0	0
31	CRT0001	1	16	XML TRANSFORMER PARAMETER	Custom Stylesheet Output Shortname: define1-0-0.xsl	Info	0	0
32	CRT0001	1	17	XML TRANSFORMER PARAMETER	Creating Output Folders: true	Info	0	0
33	CRT0001	1	18	XML TRANSFORMER	Transform complete.	Info	0	0
34	CRT0001	1	19	XML TRANSFORMER	Transform time: 9719 ms.	Info	0	0
35	CRT0001	1	20	XML TRANSFORMER	The document validated successfully	Info	0	0
36	CRT0010	1	1	CRTDDS_WRITE	The CRT-DDS file was created at C:\SAS-Lab\SASClinicalStandardsToolki	Info	0	0
37	CST0200	1	1	CRTDDS_XMLVALIDATE	Starting XML Validation	Info	0	0

Creating a define.pdf File from the SAS Representation of the CDISC CRT-DDS 1.0 Standard

The *CDER Data Standards Common Issues Document* (Version 1.1/December 2011) states:

“A critical component of data submission is the define file. A properly functioning define.xml file is an important part of the submission of standardized electronic datasets and should not be considered optional. As a transition step, CDER prefers that sponsors submit both the define.pdf and define.xml formats. The define.pdf is primarily for printing purposes and need not include hyperlinks. CDER will advise when it is ready to only receive define.xml.”

The SAS Clinical Standards Toolkit has a macro that supports the creation of a define.pdf file from the SAS representation of a CDISC CRT-DDS 1.0 standard. This macro is called %CRTDDS_WRITEPDF and is located here:

***global standards library directory*/standards/cdisc-crtdds-1.0-1.7/macros**

The %CRTDDS_WRITEPDF macro supports the creation of a define.pdf file for the CDISC ADaM, SDTM, and SEND standards. The contents of the sections (which attributes are printed) is based on the Study Data Tabulation Model Metadata Submission Guidelines (SDTM-MSG) (http://www.cdisc.org/sdtm, 2011-12-31).

The define.pdf file has an optional table of contents and these sections:

- Dataset level metadata
- Variable level metadata
- Value level metadata
- Algorithms (Computational Methods)
- Controlled Terminology

The following parameters are the most important parameters for the %CRTDDS_WRITEPDF macro:

- _cstCDISCStandard

  The CDISC standard for which the define.pdf is created. Valid values: SDTM, SEND, and ADAM. The default is SDTM.

- _cstSourceLib

  The library that contains the CRT-DDS SAS data sets. If not provided, the code looks in SASReferences for type=sourcedata.

- _cstReportOutput

  The name of the PDF to create. If not provided, the code looks in SASReferences for type=report.

- _cstLinks

  Indicates whether the macro creates internal hyperlinks in the PDF. Valid values: Y or N. The default is N.

- _cstTOC

Indicates that the macro creates a table of contents in the PDF. Valid values: Y or N. The default is N.

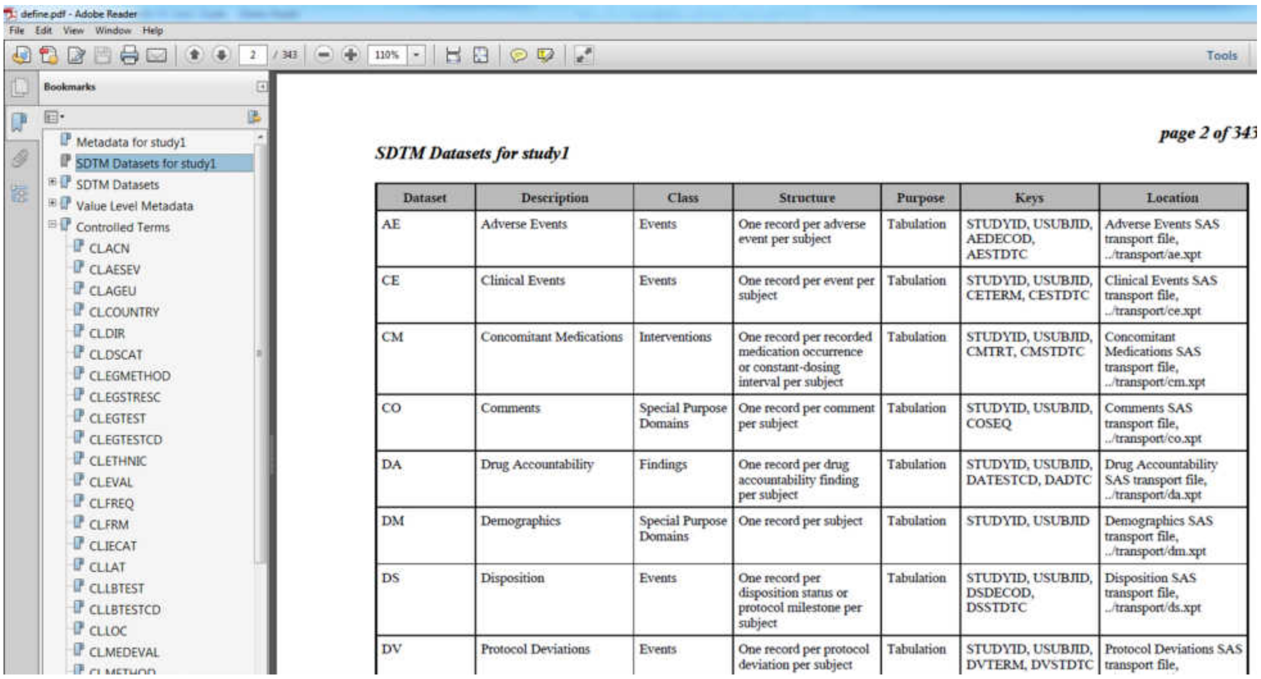
Two sample driver programs are provided with the SAS Clinical Standards Toolkit to demonstrate the use of the %CRTDDS_WRITEPDF macro:

***sample study library directory*/cdisc-crtdds-1.0-1.7/programs/ create_crtdds_define_pdf.sas**

***sample study library directory*/cdisc-crtdds-1.0-1.7/programs/ create_crtdds_define_pdf_adam.sas**

The following displays show examples of define.pdf files that were created by the %CRTDDS_WRITEPDF macro:

Figure 9.19 *Example define.pdf File for SDTM*



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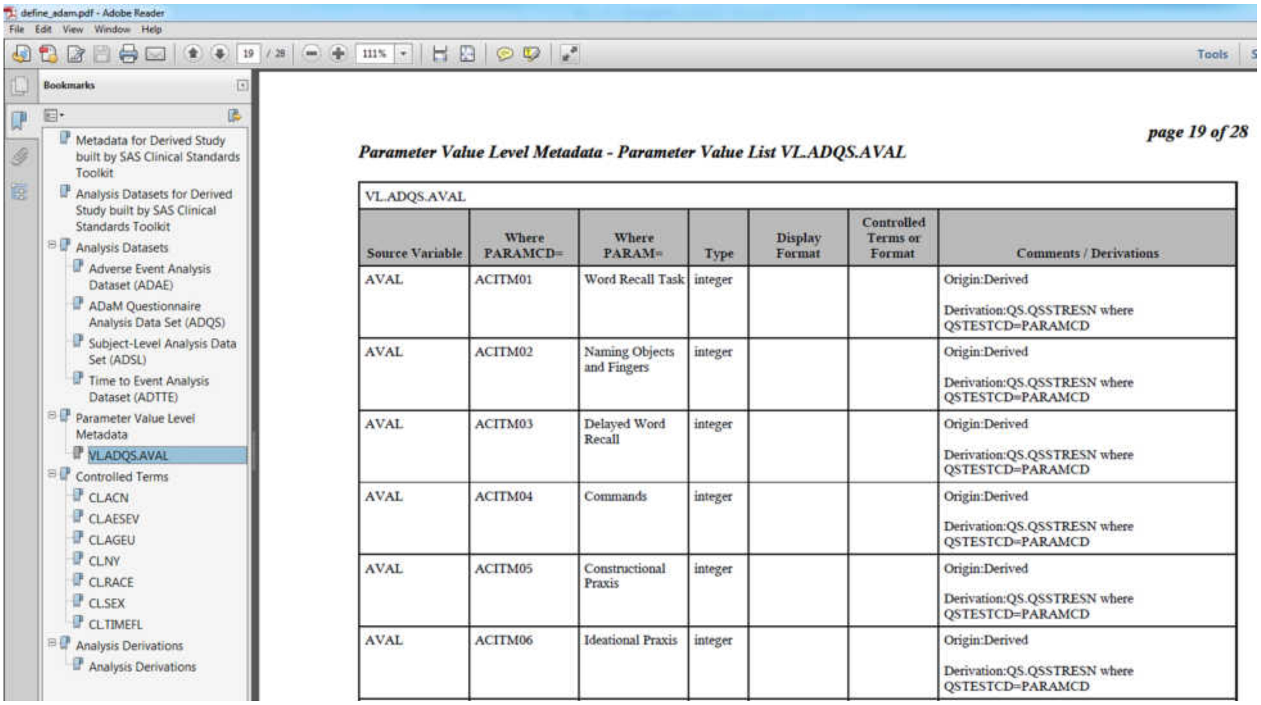
SDTM Datasets for study1

Dataset	Description	Class	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, ../transport/ae.xpt
CE	Clinical Events	Events	One record per event per subject	Tabulation	STUDYID, USUBJID, CETERM, CESTDTC	Clinical Events SAS transport file, ../transport/ce.xpt
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, ../transport/cm.xpt
CO	Comments	Special Purpose Domains	One record per comment per subject	Tabulation	STUDYID, USUBJID, COSEQ	Comments SAS transport file, ../transport/co.xpt
DA	Drug Accountability	Findings	One record per drug accountability finding per subject	Tabulation	STUDYID, USUBJID, DATESTCD, DADTC	Drug Accountability SAS transport file, ../transport/da.xpt
DM	Demographics	Special Purpose Domains	One record per subject	Tabulation	STUDYID, USUBJID	Demographics SAS transport file, ../transport/dm.xpt
DS	Disposition	Events	One record per disposition status or protocol milestone per subject	Tabulation	STUDYID, USUBJID, DSDECOD, DSSTDTC	Disposition SAS transport file, ../transport/ds.xpt
DV	Protocol Deviations	Events	One record per protocol deviation per subject	Tabulation	STUDYID, USUBJID, DVTERM, DVSTDTC	Protocol Deviations SAS transport file,

Figure 9.20 Example define.pdf File for ADaM


define_adam.pdf - Adobe Reader
File Edit View Window Help
19 / 28
111%
Tools
Bookmarks
Metadata for Derived Study built by SAS Clinical Standards Toolkit
Analysis Datasets for Derived Study built by SAS Clinical Standards Toolkit
Analysis Datasets
Adverse Event Analysis Dataset (ADAE)
ADaM Questionnaire Analysis Data Set (ADQS)
Subject-Level Analysis Data Set (ADSL)
Time to Event Analysis Dataset (ADTTE)
Parameter Value Level Metadata
VLADQS.AVAL
Controlled Terms
CLACN
CLAESEV
CLAGEU
CLNY
CLRACE
CLSEX
CLTIMEFL
Analysis Derivations
Analysis Derivations

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Parameter Value Level Metadata - Parameter Value List VLADQS.AVAL

VLADQS.AVAL

Source Variable	Where PARAMCD=	Where PARAM=	Type	Display Format	Controlled Terms or Format	Comments / Derivations
AVAL	ACITM01	Word Recall Task	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM02	Naming Objects and Fingers	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM03	Delayed Word Recall	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM04	Commands	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM05	Constructional Praxis	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD
AVAL	ACITM06	Ideational Praxis	integer			Origin:Derived Derivation:QS.QSSTRESN where QSTESTCD=PARAMCD

Creating a CDISC Define-XML 2.0 define.xml File (Including Analysis Results Metadata 1.0)

There are three key macros that are provided with the SAS Clinical Standards Toolkit that support creation of a CDISC Define-XML 2.0 define.xml file. The three macros are listed in the order in which they are executed:

1. The %DEFINE_SOURCETODEFINE macro creates the tables for the SAS representation of the CDISC Define-XML 2.0 files from study metadata. This macro, using SDTM or ADaM table metadata and column metadata as its source, populates a subset of the Define-XML 2.0 data sets.

2. The %DEFINE_WRITE macro creates the define.xml file from the SAS representation of the CDISC Define-XML 2.0 files.

3 The %CSTUTILXMLVALIDATE macro validates that the XML file is structurally and syntactically correct according to the XML schema for the CDISC Define-XML 2.0 standard.

These macros are called by driver programs that are responsible for properly setting up each SAS Clinical Standards Toolkit process to perform a specific SAS Clinical Standards Toolkit task. Several sample driver programs are provided with the SAS Clinical Standards Toolkit CDISC Define-XML 2.0 standard related to the creation of the define.xml file.

Here is the purpose of each of these driver programs:

1 The create_sasdefine_from_source.sas driver program sets up the required metadata and SASReferences data set for the sample study. It runs the %DEFINE_SOURCETODEFINE macro. It creates the SAS representation of the CDISC Define-XML 2.0 data sets from the sample study data sets.

2 The create_definexml.sas driver program creates the CDISC Define-XML 2.0 define.xml file. It runs the %DEFINE_WRITE and %CSTUTILXMLVALIDATE macros. This driver program creates and validates the XML syntax for the define.xml file.

Note: The create_definexml_from_source.sas and create_definexml_from_source_adam.sas driver programs combine the two purposes into one driver program.

These driver programs are examples that are provided with the SAS Clinical Standards Toolkit. You can use these driver programs or create your own. The names of these driver programs are not important. However, the content is important and demonstrates how the various SAS Clinical Standards Toolkit framework macros are used to generate the required metadata files.

The driver programs create a define.xml file based on SDTM or ADaM metadata.

Sample Driver Program: create_sasdefine_from_source.sas

Overview

The create_sasdefine_from_source.sas driver program sets up the required environment variables and library references to initiate the %DEFINE_SOURCETODEFINE macro. This macro extracts data from the SDTM or ADaM metadata files. (For more information about the source_tables and source_columns data sets, see "Source Metadata" on page 172.) Depending on the available source information, the macro attempts to convert the information into the tables that represent the SAS interpretation of the CDISC Define-XML 2.0 model.

When the macro parameter _cstFullModel has the value **N**, only the 31 Define-XML 2.0 core tables are created. Otherwise, all 46 tables in the Define-XML 2.0 reference standard are created, but only those tables with available data are populated. The other tables contain zero observations. When the macro parameter _cstCheckLengths has the value Y, the macro checks the actual value lengths of variables with DataType=text against the lengths defined in the metadata templates. If the lengths are short, a warning is written to the log file and the Results data set.

Note: For more information about the %DEFINE_SOURCETODEFINE macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Here is an example of a call to the %DEFINE_SOURCETODEFINE macro:

```
%define_sourcetodefine(
   _cstOutLib=srcdata,
   _cstSourceStudy=sampdata.source_study,
   _cstSourceTables=sampdata.source_tables,
   _cstSourceColumns=sampdata.source_columns,
   _cstSourceCodeLists=sampdata.source_codelists,
   _cstSourceDocuments=sampdata.source_documents,
   _cstSourceValues=sampdata.source_values,
   _cstFullModel=N,
   _cstCheckLengths=Y,
   _cstLang=en
   );
```

In this example, the %DEFINE_SOURCETODEFINE macro writes all of the Define-XML 2.0 tables to the Srcdata library.

Here is an example that uses analysis results metadata:

```
%define_sourcetodefine(
    _cstOutLib=srcdata,
    _cstSourceStudy=sampdata.source_study,
    _cstSourceTables=sampdata.source_tables,
    _cstSourceColumns=sampdata.source_columns,
    _cstSourceCodeLists=sampdata.source_codelists,
    _cstSourceDocuments=sampdata.source_documents,
    _cstSourceValues=sampdata.source_values,
    _cstSourceAnalysisResults=sampdata.source_analysisresults,
   _cstFullModel=N,
   _cstCheckLengths=Y,
   _cstLang=en
  );
```

In this example, eight extra tables are created with metadata for analysis results.

The create_sasdefine_from_source.sas driver program is provided with the SAS Clinical Standards Toolkit, and it is ready to run on any of the SDTM or ADaM sample studies. The driver program can be run interactively or in batch. To run the driver program interactively, start a SAS session, and load the driver program into the SAS editor.

The driver program is located here:

***sample study library directory*/cdisc-definexml-2.0.0-1.7/programs**

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are seven input file references and one output data set reference that are key to the successful completion of the create_sasdefine_from_source.sas driver program. Table 9.8 on page 350 lists these files and data sets, and they are discussed in separate sections. In the sample create_sasdefine_from_source.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

&studyRootPath=*sample study library directory*/cdisc-definexml-2.0.0–1.7/sascstdemodata

&studyOutputPath=*sample study library directory*/cdisc-definexml-2.0.0–1.7

Here is the specification of &_cstSrcMetaDataFolder in the SASReferences data set in the create_sasdefine_from_source.sas driver program:

```
&_cstSrcMetaDataFolder=%lowcase(&_cstTrgStandard)-&_cstTrgStandardVersion/metadata
```

Here are the macro variable assignments in the sample driver program to work with the sample SDTM 3.1.2 metadata:

```
%let _cstTrgStandard=CDISC-SDTM;
%let _cstTrgStandardVersion=3.1.2;
```

Here is how to use the sample driver program create_sasdefine_from_source.sas for ADaM metadata:

```
%let _cstTrgStandard=CDISC-ADAM;
%let _cstTrgStandardVersion=2.1;
```

Table 9.8 Key Components of the SASReferences Data Set for the create_sasdefine_from_source.sas Driver Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_study
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_tables
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_colums

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_ codelists
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_values
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_ documents
sourcemetadata	sampdata	libref	&studyRootPath/ &_cstSrcMetaDataFolder	source_ analysisresults
Output				
sourcedata	srcdata	libref	&studyOutputPath/data/%lowcase(&_ cstTrgStandard)-&_ cstTrgStandardVersion	

Process Inputs

The sourcemetadata type refers to the data sets that contain the SDTM study metadata: source_study, source_tables, source_columns, source_values, source_codelists, source_documents, and source_analysisresults. . These data sets are stored in the same library.

The sample create_sasdefine_from_source.sas driver program provided with the SAS Clinical Standards Toolkit references a source CDISC SDTM 3.1.2 study. So, the source_tables data set contains SDTM 3.1.2 metadata about each standard domain defined in the *CDISC SDTM Implementation Guide V3.1.2* and includes any customizations that you have added. The source_columns data set contains similar metadata but it is at the column level. The source_values data set contains Value Level metadata. The source_analysisresults data set would typically only be referenced in a CDISC ADaM study.The source metadata is read from this location:

```
sample study library directory/cdisc-definexml-2.0.0-1.7/
sascstdemodata/cdisc-sdtm-3.1.2/metadata
```

This location is represented in the driver program by the sampdata library name.

A source study data set (source_study) can have only one record, and it is required by this macro. The following table lists the variables that are required in this data set:

Table 9.9 Variables Required in the Source Study Data Set (source_study)

Variable*	Required	Description
SASref	Yes	The reference that ties the study name to the corresponding domains that are associated with this study in the source_tables and source_columns data sets.
StudyName	Yes	The name of the study. This value is used to populate the srcdata.study.studyname column.
StudyDescription	Yes	The description of the study. This value is used to populate the srcdata.study.studydescription column. **Note:** You cannot use commas, semicolons, or quotation marks in the description.
ProtocolName	Yes	The name of the protocol for the study. This value is used to populate the srcdata.study.protocolname column.
StudyVersion	Yes	The name of the define document to create. This value is used to populate the srcdata.metadataversion.oid column.
FormalStandardVersion	Yes	The formal version of the standard as used in Define-XML 2.0. This value is used to populate the srcdata.definedocument.standardversion column. (For example, 3.1.2.)
FormalStandardName	Yes	The formal name of the standard as used in Define-XML 2.0. This value is used to populate the srcdata.definedocument.standardname column. (For example, SDTM-IG.)
Standard	Yes	The name of the standard in the SAS Clinical Standards Toolkit. (For example, CDISC-SDTM.)

Variable*	Required	Description
StandardVersion	Yes	The version of the standard in the SAS Clinical Standards Toolkit. (For example, 3.1.2.)

*All variables are required to be non-blank.

Only a single study can be referenced in a source study data set. The %DEFINE_SOURCETODEFINE macro selects records from only the source_tables, source_colums, source_codelists, source_values, source_documents, and source_analysisresults data sets whose StudyVersion column value is equal to the value of the StudyVersion column in the source_study data set.

Process Outputs

The sourcedata type is the library where the metadata files are created. These metadata files are the data sets that constitute the SAS representation of the CDISC Define-XML 2.0 standard. The create_sasdefine_from_source.sas driver program creates 46 or 31 data sets, depending on the value of the _cstFullModel macro parameter. Most of these data sets have zero observations because there is no default SDTM metadata source. In the SAS Clinical Standards Toolkit sample driver program create_sasdefine_from_source.sas, these data sets are written to this location:

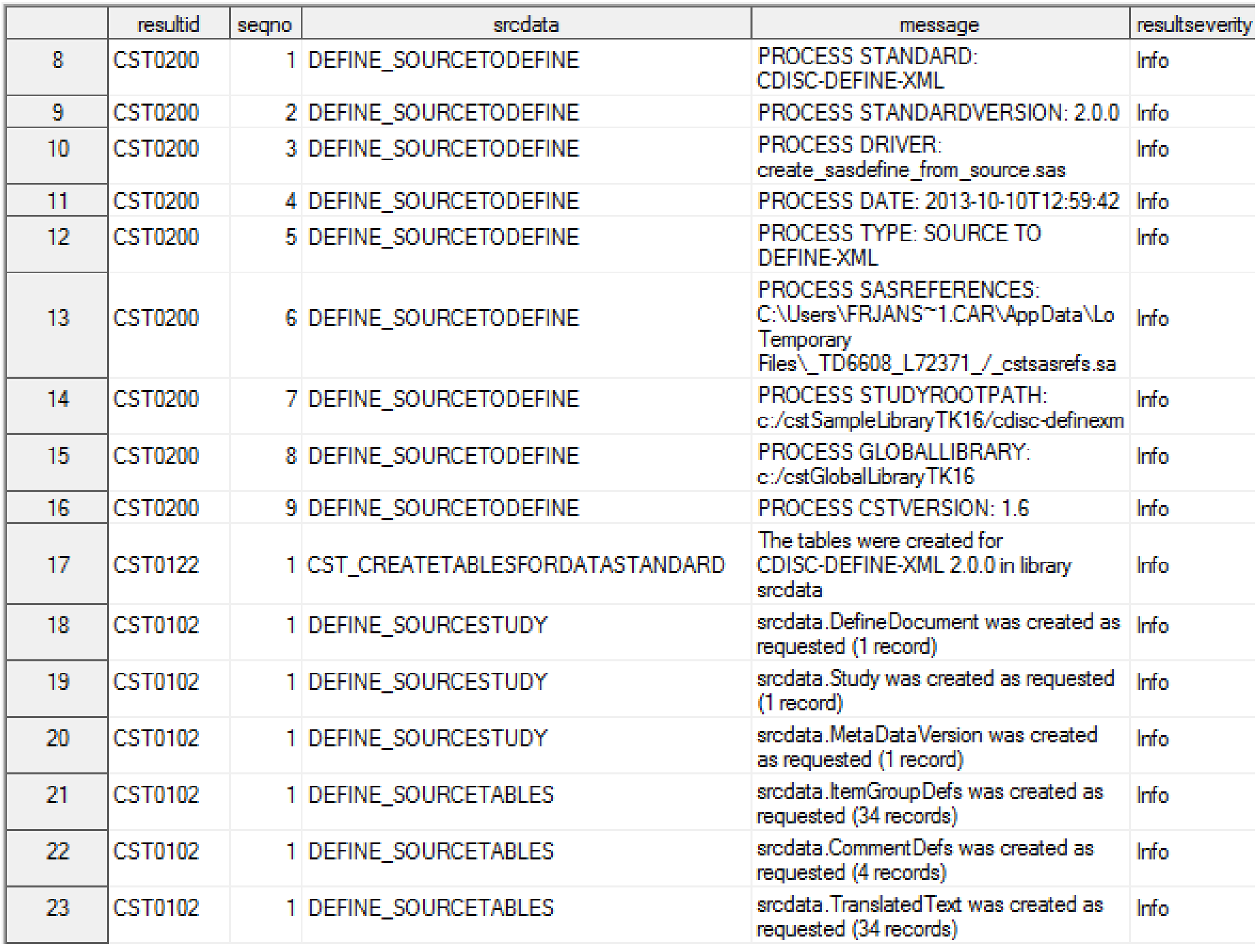
***sample study library directory*/cdisc-definexml-2.0.0-1.7/data/cdisc-sdtm-3.1.2**

This location is represented in the driver program by the srcdata library name.

Process Results

When the driver program finishes running, the sourcetodefine_results data set is created in the Results library. This data set contains informational, warning, and error messages that were generated by the driver program.

Figure 9.21 Example of a Partial Results Data Set from Define-XML 2.0 Sample Study



	resultid	seqno	srcdata	message	resultseverity
8	CST0200	1	DEFINE_SOURCETODEFINE	PROCESS STANDARD: CDISC-DEFINE-XML	Info
9	CST0200	2	DEFINE_SOURCETODEFINE	PROCESS STANDARDVERSION: 2.0.0	Info
10	CST0200	3	DEFINE_SOURCETODEFINE	PROCESS DRIVER: create_sasdefine_from_source.sas	Info
11	CST0200	4	DEFINE_SOURCETODEFINE	PROCESS DATE: 2013-10-10T12:59:42	Info
12	CST0200	5	DEFINE_SOURCETODEFINE	PROCESS TYPE: SOURCE TO DEFINE-XML	Info
13	CST0200	6	DEFINE_SOURCETODEFINE	PROCESS SASREFERENCES: C:\Users\FRJANS~1.CAR\AppData\Lo Temporary Files_TD6608_L72371_/_cstsasrefs.sa	Info
14	CST0200	7	DEFINE_SOURCETODEFINE	PROCESS STUDYROOTPATH: c:/cstSampleLibraryTK16/cdisc-definexm	Info
15	CST0200	8	DEFINE_SOURCETODEFINE	PROCESS GLOBALLIBRARY: c:/cstGlobalLibraryTK16	Info
16	CST0200	9	DEFINE_SOURCETODEFINE	PROCESS CSTVERSION: 1.6	Info
17	CST0122	1	CST_CREATETABLESFORDATASTANDARD	The tables were created for CDISC-DEFINE-XML 2.0.0 in library srcdata	Info
18	CST0102	1	DEFINE_SOURCESTUDY	srcdata.DefineDocument was created as requested (1 record)	Info
19	CST0102	1	DEFINE_SOURCESTUDY	srcdata.Study was created as requested (1 record)	Info
20	CST0102	1	DEFINE_SOURCESTUDY	srcdata.MetaDataVersion was created as requested (1 record)	Info
21	CST0102	1	DEFINE_SOURCETABLES	srcdata.ItemGroupDefs was created as requested (34 records)	Info
22	CST0102	1	DEFINE_SOURCETABLES	srcdata.CommentDefs was created as requested (4 records)	Info
23	CST0102	1	DEFINE_SOURCETABLES	srcdata.TranslatedText was created as requested (34 records)	Info

Sample Driver Program: create_definexml.sas

Overview

The create_definexml.sas driver program sets up the required environment variables and library references to initiate the %DEFINE_WRITE macro. This macro reads the data sets that comprise the SAS representation of the CDISC Define-XML 2.0 model, and it converts that information to the required XML structure. If source metadata or data are missing, then empty elements and attributes are not created in the XML file. The inputs and outputs are specified in the SASReferences data set.

Note: For more information about the %DEFINE_WRITE macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Here is an example of a call to the %DEFINE_WRITE macro:

```
%define_write(_cstCreateDisplayStyleSheet=1,
              _cstOutputEncoding=UTF-8,
              _cstResultsOverrideDS=&_cstResultsDS);
```

In this example, a default style sheet is generated in the same directory as the XML output based on the information in the SASReferences data set. XML encoding is set to UTF-16, and process results are written to the default &_cstResultsDS data set.

Here is the call to the macro from the sample create_definexml.sas driver program:

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

The call creates a display style sheet and uses default values for the parameters.

The create_definexml.sas driver program is ready to run on any of the CDISC SDTM sample studies. The driver program can be run interactively or in batch.

The driver program is located here:

***sample study library directory*/cdisc-definexml-2.0.0-1.7/programs**

Multiple tasks can be executed in any SAS Clinical Standards Toolkit driver program. The create_definexml.sas driver program calls both the %DEFINE_WRITE macro to create the Define-XML file and the %CSTUTILXMLVALIDATE macro to validate the syntax of the generated Define-XML file. For more information about the

%CSTUTILXMLVALIDATE macro, see "Validating an XML File against an XML Schema: %CSTUTILXMLVALIDATE Macro" on page 366.

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, "SASReferences File," on page 137.

In the SASReferences data set, there are two input file references and three output data set references that are key to the successful completion of the create_definexml.sas driver program. Table 9.10 on page 356 lists these files and data sets, and they are discussed in separate sections. In the sample create_definexml.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

```
&studyRootPath=sample study library directory/cdisc-
definexml-2.0.0-1.7
```

```
&studyOutputPath=sample study library directory/cdisc-
definexml-2.0.0-1.7
```

Table 9.10 Key Components of the SASReferences Data Set for the %DEFINE_WRITE Macro

Metadata Type	LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
control	control	libref	&workpath	sasreferences
sourcedata	srcdata	libref	&studyRootPath/ data/&_cstSrcDataFolder	
		Output		
referencexml	xslt01	filename		define-2-0-0.xsl
results	results	libref	&studyOutputPath/results	write_results

Metadata Type	LIBNAME or Fileref to Use	Reference Type	Path	Name of File
externalxml	extxml	filename	&studyOutputPath/ sourcexml	&_cstDefineFile..xml
report	html	filename	&studyOutputPath/ sourcexml	&_cstDefineFile..html

Here is the specification of &_cstSrcMetaDataFolder in the SASReferences data set in the create_sasdefine_from_source.sas driver program:

```
_cstSrcDataFolder=%lowcase(&_cstTrgStandard)-&_cstTrgStandardVersion
```

Here are the variable assignments in the sample driver program to work with the sample SDTM 3.1.2 metadata:

```
%let _cstTrgStandard=CDISC-SDTM;
%let _cstTrgStandardVersion=3.1.2;
%let _cstDefineFile=define-sdtm-3.1.2.xml;
```

Process Inputs

Use of the control library name that points to the path in the &workpath macro variable demonstrates a technique of documenting the derivation of the SASReferences data set in the SAS Work library. The driver program initiates the macro variable &workpath with this SAS code:

```
%let workPath=%sysfunc(pathname(work));
```

The sourcedata type is the library that contains the Define-XML data sets that might have been populated by the create_sasdefine_from_source.sas driver program. These metadata files are the data sets that constitute the SAS representation of the CDISC Define-XML 2.0 standard. In the SAS Clinical Standards Toolkit sample study, these data sets are read from the ***sample study library directory*/cdisc-definexml-2.0.0-1.7/data/cdisc-sdtm-3.1.2** directory. This location is represented in the driver program by the Srcdata library name.

Process Outputs

The externalxml type refers to the define-sdtm-3.1.2.xml file. This file is accessed in the driver program from the extxml filename statement, and is written to the ***sample study library directory*****/cdisc-definexml-2.0-1.7/sourcexml** directory.

The referencexml type can serve as either an input or output file reference. If the path and filename are not specified, the %DEFINE_WRITE macro interprets the _cstCreateDisplayStyleSheet=1 parameter to indicate the default style sheet that is provided by the SAS Clinical Standards Toolkit in the global standards library. If a path and filename are specified, the referencexml type serves as an output file reference for the %DEFINE_WRITE macro. The default style sheet is copied from the global standards library to the path and filename that are specified.

The results type refers to the write_results data set that documents the results of the create_definexml.sas driver program. In the SAS Clinical Standards Toolkit CDISC Define-XML folder hierarchy, this information is written to the ***sample study library directory*****/cdisc-definexml-2.0-1.7/results** directory.

In Microsoft Windows, the define-sdtm-3.1.2.xml file can be viewed by double-clicking it in the SAS Program Editor. This renders the file in your default web browser or in any other application that has been associated with XML files.

On UNIX, if you have not set up your browser configuration in SAS, you need to copy define-sdtm-3.1.2.xml and define2-0-0.xsl to an environment where you can display the XML file in a web browser.

Note: The style sheet information in define2-0-0.xsl is not guaranteed to work for all browser types and versions to produce the correct HTML. But, it does work with Internet Explorer 6.0 and higher. The Chrome browser, for example, does not allow local XML and XSLT processing.

The sample driver program also creates the HTML rendition in the same folder as the XML file using this code:

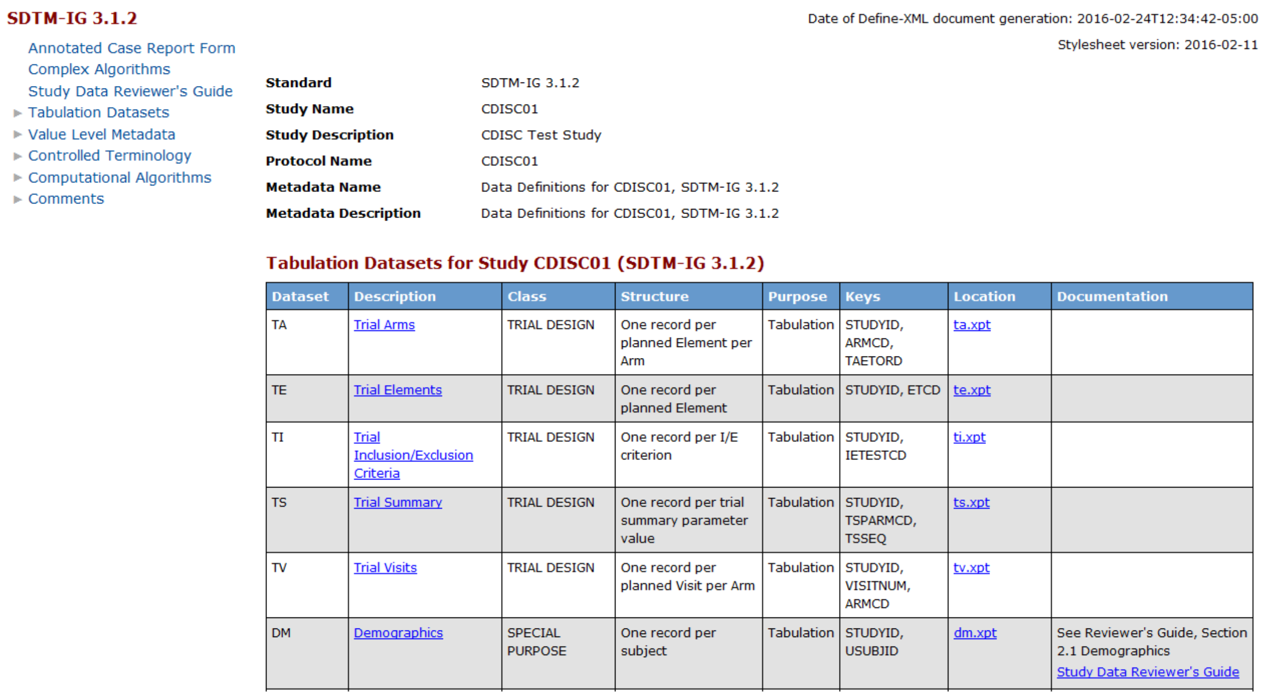
```
proc xsl
   in=extxml
   xsl=xslt01
   out=html;
run;
```

Instead of opening the XML file in a browser and letting the browser use the XSL file to render the HTML, you can directly open the HTML file.

Depending on your browser, you might see a security warning because the style sheet uses JavaScript.

The following display shows the define-sdtm-3.1.2.xml file in a web browser:

Figure 9.22 *define-sdtm-3.1.2.xml File in a Web Browser*



SDTM-IG 3.1.2

Date of Define-XML document generation: 2016-02-24T12:34:42-05:00

Stylesheet version: 2016-02-11

Annotated Case Report Form
Complex Algorithms
Study Data Reviewer's Guide
▸ Tabulation Datasets
▸ Value Level Metadata
▸ Controlled Terminology
▸ Computational Algorithms
▸ Comments

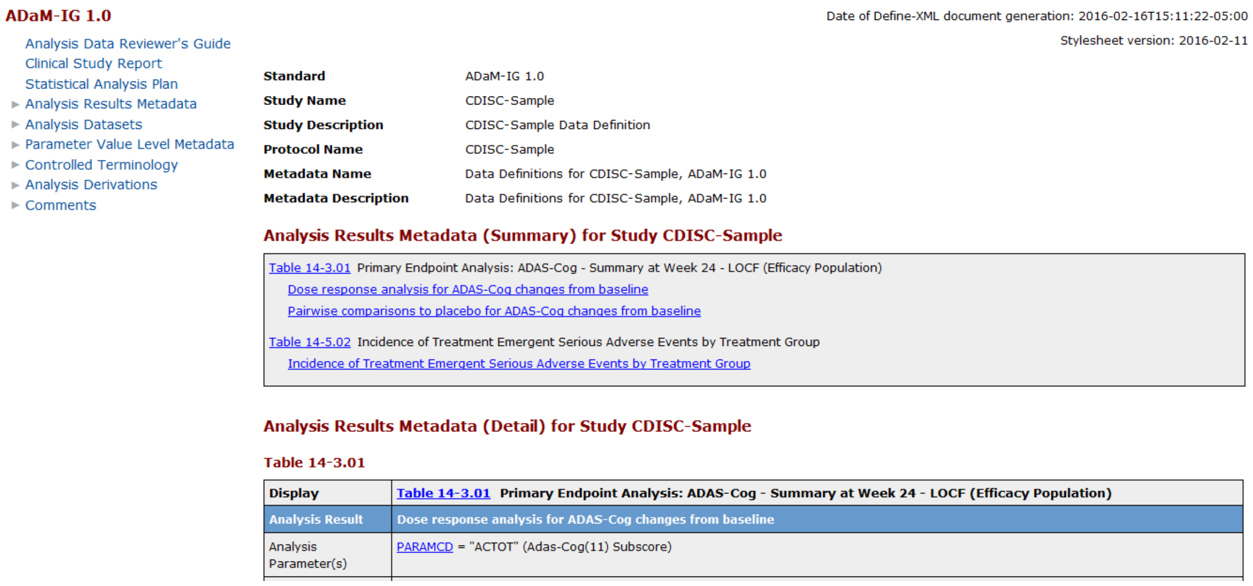
Standard	SDTM-IG 3.1.2
Study Name	CDISC01
Study Description	CDISC Test Study
Protocol Name	CDISC01
Metadata Name	Data Definitions for CDISC01, SDTM-IG 3.1.2
Metadata Description	Data Definitions for CDISC01, SDTM-IG 3.1.2

Tabulation Datasets for Study CDISC01 (SDTM-IG 3.1.2)

Dataset	Description	Class	Structure	Purpose	Keys	Location	Documentation
TA	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD	ta.xpt	
TE	Trial Elements	TRIAL DESIGN	One record per planned Element	Tabulation	STUDYID, ETCD	te.xpt	
TI	Trial Inclusion/Exclusion Criteria	TRIAL DESIGN	One record per I/E criterion	Tabulation	STUDYID, IETESTCD	ti.xpt	
TS	Trial Summary	TRIAL DESIGN	One record per trial summary parameter value	Tabulation	STUDYID, TSPARMCD, TSSEQ	ts.xpt	
TV	Trial Visits	TRIAL DESIGN	One record per planned Visit per Arm	Tabulation	STUDYID, VISITNUM, ARMCD	tv.xpt	
DM	Demographics	SPECIAL PURPOSE	One record per subject	Tabulation	STUDYID, USUBJID	dm.xpt	See Reviewer's Guide, Section 2.1 Demographics Study Data Reviewer's Guide

The following display shows the define-adam-2.1.xml file in a web browser:

Figure 9.23 *define-adam-2.1.xml File in a Web Browser*



ADaM-IG 1.0

- Analysis Data Reviewer's Guide
- Clinical Study Report
- Statistical Analysis Plan
- ▸ Analysis Results Metadata
- ▸ Analysis Datasets
- ▸ Parameter Value Level Metadata
- ▸ Controlled Terminology
- ▸ Analysis Derivations
- ▸ Comments

Date of Define-XML document generation: 2016-02-16T15:11:22-05:00

Stylesheet version: 2016-02-11

Standard	ADaM-IG 1.0
Study Name	CDISC-Sample
Study Description	CDISC-Sample Data Definition
Protocol Name	CDISC-Sample
Metadata Name	Data Definitions for CDISC-Sample, ADaM-IG 1.0
Metadata Description	Data Definitions for CDISC-Sample, ADaM-IG 1.0

Analysis Results Metadata (Summary) for Study CDISC-Sample

Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)
- Dose response analysis for ADAS-Cog changes from baseline
- Pairwise comparisons to placebo for ADAS-Cog changes from baseline

Table 14-5.02 Incidence of Treatment Emergent Serious Adverse Events by Treatment Group
- Incidence of Treatment Emergent Serious Adverse Events by Treatment Group

Analysis Results Metadata (Detail) for Study CDISC-Sample

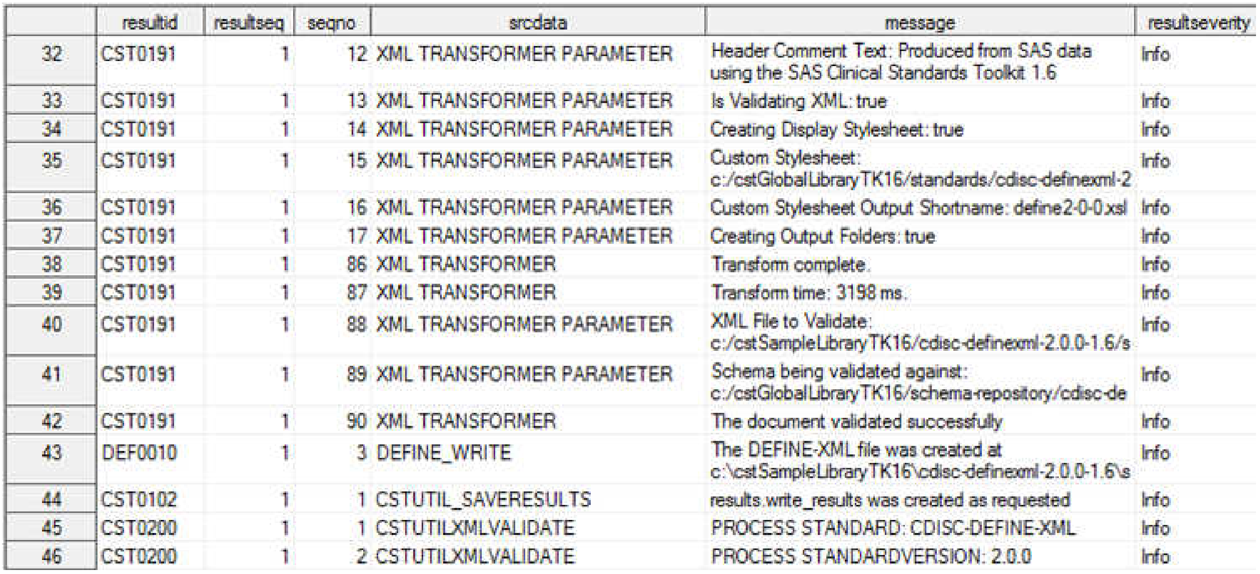
Table 14-3.01

Display	**Table 14-3.01 Primary Endpoint Analysis: ADAS-Cog - Summary at Week 24 - LOCF (Efficacy Population)**
Analysis Result	**Dose response analysis for ADAS-Cog changes from baseline**
Analysis Parameter(s)	PARAMCD = "ACTOT" (Adas-Cog(11) Subscore)

Process Results

Inclusion of the results record (row) in the SASReferences data set indicates that the process results are to be copied to a write_results data set located in the specified SAS library.

Figure 9.24 *Example of a Partial Results Data Set from the Define-XML 2.0 Sample Study*



	resultid	resultseq	seqno	srcdata	message	resultseverity
32	CST0191	1	12	XML TRANSFORMER PARAMETER	Header Comment Text: Produced from SAS data using the SAS Clinical Standards Toolkit 1.6	Info
33	CST0191	1	13	XML TRANSFORMER PARAMETER	Is Validating XML: true	Info
34	CST0191	1	14	XML TRANSFORMER PARAMETER	Creating Display Stylesheet: true	Info
35	CST0191	1	15	XML TRANSFORMER PARAMETER	Custom Stylesheet: c:/cstGlobalLibraryTK16/standards/cdisc-definexml-2	Info
36	CST0191	1	16	XML TRANSFORMER PARAMETER	Custom Stylesheet Output Shortname: define2-0-0.xsl	Info
37	CST0191	1	17	XML TRANSFORMER PARAMETER	Creating Output Folders: true	Info
38	CST0191	1	86	XML TRANSFORMER	Transform complete.	Info
39	CST0191	1	87	XML TRANSFORMER	Transform time: 3198 ms.	Info
40	CST0191	1	88	XML TRANSFORMER PARAMETER	XML File to Validate: c:/cstSampleLibraryTK16/cdisc-definexml-2.0.0-1.6/s	Info
41	CST0191	1	89	XML TRANSFORMER PARAMETER	Schema being validated against: c:/cstGlobalLibraryTK16/schema-repository/cdisc-de	Info
42	CST0191	1	90	XML TRANSFORMER	The document validated successfully	Info
43	DEF0010	1	3	DEFINE_WRITE	The DEFINE-XML file was created at c:\cstSampleLibraryTK16\cdisc-definexml-2.0.0-1.6\s	Info
44	CST0102	1	1	CSTUTIL_SAVERESULTS	results.write_results was created as requested	Info
45	CST0200	1	1	CSTUTILXMLVALIDATE	PROCESS STANDARD: CDISC-DEFINE-XML	Info
46	CST0200	1	2	CSTUTILXMLVALIDATE	PROCESS STANDARDVERSION: 2.0.0	Info

Creating a CDISC ODM XML File

Note: The process to create a CDISC ODM XML file is the same for all ODM versions that are supported by the SAS Clinical Standards Toolkit. The process is explained using ODM version 1.3.0.

There are several key macros that are provided with the SAS Clinical Standards Toolkit that support the creation of an ODM XML file. The macros are listed in the order in which they are executed:

1 The %ODM_VALIDATE macro submits a set of validation checks based on what is defined in the Validation Control data set to validate the referenced SAS representation of each ODM XML file.

2 The %ODM_WRITE macro creates the ODM XML file from the SAS representation of the ODM files and validates that the XML file is structurally and syntactically correct. This macro is important if you customize the XML file outside of the workflow.

3 The %CSTUTILXMLVALIDATE macro validates that the XML file is structurally and syntactically correct, according to the XML schema for the ODM standard. This macro is important if you customize the ODM XML file outside of the workflow.

These macros are called by driver programs that are responsible for properly setting up each SAS Clinical Standards Toolkit process to perform a specific SAS Clinical Standards Toolkit task. Two sample driver programs are provided with the SAS Clinical Standards Toolkit CDISC ODM standard related to the creation of the XML file.

Here is the purpose of each of these driver programs:

1 The validate_odm_data.sas driver program validates the SAS representation of the ODM data sets based on the selected ODM validation checks. This driver program can be run multiple times until data validation has been reconciled.

2 The create_odmxml.sas driver program calls the %ODM_WRITE macro to create the XML file. This driver program creates and validates the syntax for the XML file.

These driver programs are examples that are provided with the SAS Clinical Standards Toolkit. You can use these driver programs or create your own. The names of these driver programs are not important. However, the content is important and demonstrates how the various SAS Clinical Standards Toolkit framework macros are used to generate the required metadata files.

Sample Driver Program: create_odmxml.sas

Overview

The create_odmxml.sas driver program sets up the required environment variables and library references to initiate the %ODM_WRITE macro. This macro reads the 66 data sets that comprise the default SAS representation of the CDISC ODM 1.3.0 model, and it converts that information to the required ODM XML structure. If source metadata or data are missing, then empty elements and attributes are not created in the ODM XML file. The inputs and outputs are specified in the SASRferences data set.

For more information about the %ODM_WRITE macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Here is an example of a call to the %ODM_WRITE macro:

```
%odm_write(_cstOutputEncoding=UTF-16, _cstResultsOverrideDS=&_cstResultsDS);
```

In this example, no default style sheet is generated for the XML output, XML encoding is set to UTF-16, and process results are written to the default &_cstResultsDS data set.

Here is the call to the macro from the sample create_odmxml.sas driver program:

```
%odm_write();
```

The call uses default values for the parameters. The create_odmxml.sas driver program is ready to run on the CDISC ODM sample study provided with the SAS Clinical Standards Toolkit. The driver program can be run interactively or in batch.

The driver program is located here:

***sample study library directory*/cdisc-odm-1.3.0-1.7/programs**

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are one input file reference and two output data set references that are key to the successful completion of the create_odmxml.sas driver program. Table 9.11 on page 364 lists these files and data sets, and they are discussed in separate sections. In the sample create_odmxml.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

&studyRootPath=*sample study library directory*/cdisc-odm-1.3.0-1.7

&studyOutputPath=*sample study library directory*/cdisc-odm-1.3.0-1.7

Table 9.11 Key Components of the SASReferences Data Set for the %ODM_WRITE Macro

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
Input				
sourcedata	srcdata	libref	&studyRootPath/data	
Output				
results	results	libref	&studyOutputPath/ results	write_results. sas7bdat
externalxml	extxml	filename	&studyOutputPath/ sourcexml	odm_sample_ out.xml

Process Inputs

The sourcedata type is the library that contains the default 66 data sets that comprise the SAS representation of an ODM XML file. These data sets might have been populated by a previous odm_read task, or you might have processes in place that build these data sets from source files. In the SAS Clinical Standards Toolkit sample study, these data sets are read from the ***sample study library directory*/cdisc-odm-1.3.0-1.7/data** directory. This location is represented in the driver program by the Srcdata library name.

Process Outputs

The externalxml type refers to the ODM XML file that is to be derived by the process. This file is accessed in the driver program from the extxml filename statement, and is written to the ***sample study library directory*/cdisc-odm-1.3.0-1.7/sourcexml** directory.

Note: Unlike CDISC CRT-DDS or CDISC Define-XML, CDISC does not supply a default style sheet for ODM and one is not provided as part of the SAS Clinical Standards Toolkit. However, you can use the %ODM_WRITE macro, which provides the _cstCreateDisplayStyleSheet parameter, to use information that you provide in the Metadata Type referencexml record of the SASReferences file.

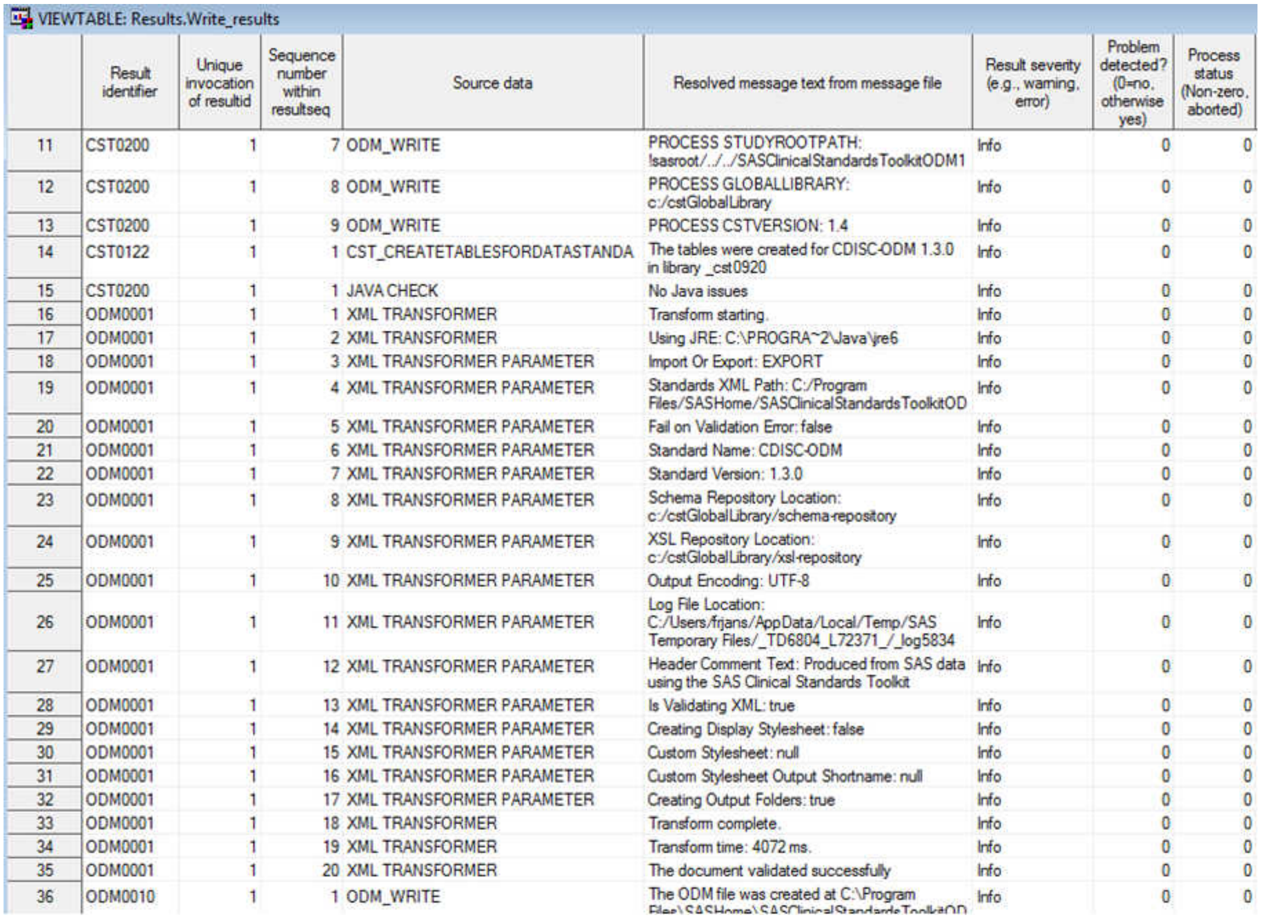
The results type refers to the write_results data set that documents the results of the create_odmxml driver program. In the SAS Clinical Standards Toolkit CDISC CRT-DDS folder hierarchy, this information is written to this location:

```
sample study library directory/cdisc-odm-1.3.0-1.7/results
```

Process Results

Inclusion of the results record (row) in the SASReferences data set indicates that the process results are to be copied to a write_results data set located in the specified SAS library.

Figure 9.25 *Example of a Partial Results Data Set from the ODM Sample Data Hierarchy*



VIEWTABLE: Results.Write_results

	Result identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)
11	CST0200	1	7	ODM_WRITE	PROCESS STUDYROOTPATH: !sasroot/../../SASClinicalStandardsToolkitODM1	Info	0	0
12	CST0200	1	8	ODM_WRITE	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0
13	CST0200	1	9	ODM_WRITE	PROCESS CSTVERSION: 1.4	Info	0	0
14	CST0122	1	1	CST_CREATETABLESFORDATASTANDA	The tables were created for CDISC-ODM 1.3.0 in library _cst0920	Info	0	0
15	CST0200	1	1	JAVA CHECK	No Java issues	Info	0	0
16	ODM0001	1	1	XML TRANSFORMER	Transform starting.	Info	0	0
17	ODM0001	1	2	XML TRANSFORMER	Using JRE: C:\PROGRA~2\Java\jre6	Info	0	0
18	ODM0001	1	3	XML TRANSFORMER PARAMETER	Import Or Export: EXPORT	Info	0	0
19	ODM0001	1	4	XML TRANSFORMER PARAMETER	Standards XML Path: C:/Program Files/SASHome/SASClinicalStandardsToolkitOD	Info	0	0
20	ODM0001	1	5	XML TRANSFORMER PARAMETER	Fail on Validation Error: false	Info	0	0
21	ODM0001	1	6	XML TRANSFORMER PARAMETER	Standard Name: CDISC-ODM	Info	0	0
22	ODM0001	1	7	XML TRANSFORMER PARAMETER	Standard Version: 1.3.0	Info	0	0
23	ODM0001	1	8	XML TRANSFORMER PARAMETER	Schema Repository Location: c:/cstGlobalLibrary/schema-repository	Info	0	0
24	ODM0001	1	9	XML TRANSFORMER PARAMETER	XSL Repository Location: c:/cstGlobalLibrary/xsl-repository	Info	0	0
25	ODM0001	1	10	XML TRANSFORMER PARAMETER	Output Encoding: UTF-8	Info	0	0
26	ODM0001	1	11	XML TRANSFORMER PARAMETER	Log File Location: C:/Users/frjans/AppData/Local/Temp/SAS Temporary Files/_TD6804_L72371_/_log5834	Info	0	0
27	ODM0001	1	12	XML TRANSFORMER PARAMETER	Header Comment Text: Produced from SAS data using the SAS Clinical Standards Toolkit	Info	0	0
28	ODM0001	1	13	XML TRANSFORMER PARAMETER	Is Validating XML: true	Info	0	0
29	ODM0001	1	14	XML TRANSFORMER PARAMETER	Creating Display Stylesheet: false	Info	0	0
30	ODM0001	1	15	XML TRANSFORMER PARAMETER	Custom Stylesheet: null	Info	0	0
31	ODM0001	1	16	XML TRANSFORMER PARAMETER	Custom Stylesheet Output Shortname: null	Info	0	0
32	ODM0001	1	17	XML TRANSFORMER PARAMETER	Creating Output Folders: true	Info	0	0
33	ODM0001	1	18	XML TRANSFORMER	Transform complete.	Info	0	0
34	ODM0001	1	19	XML TRANSFORMER	Transform time: 4072 ms.	Info	0	0
35	ODM0001	1	20	XML TRANSFORMER	The document validated successfully	Info	0	0
36	ODM0010	1	1	ODM_WRITE	The ODM file was created at C:\Program Files\SASHome\SASClinicalStandardsToolkitOD	Info	0	0

Validation of XML-Based Standards

XML Validation

When validating XML-based standards (such as CDISC ODM, CDISC CT, CDISC CRT-DDS 1.0, and CDISC Define-XML 2.0,), the SAS Clinical Standards Toolkit offers two complementary methodologies.

The first methodology is described in Chapter 7, “Compliance Assessment Against a Reference Standard,” on page 161. It relies on the definition of a master set of validation checks that are specific to the table and column metadata that define a set of data and on checks that are specific to the data itself. This method uses SAS files and SAS code to validate the SAS representation of the XML-based 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 an XML file is valid structurally and syntactically according to the XML schema for that standard.

The SAS Clinical Standards Toolkit provides both methodologies to support the validation of CDISC CRT-DDS 1.0 and CDISC ODM 1.3.0 and 1.3.1 files.

For CDISC Define-XML 2.0 files, SAS Clinical Standards Toolkit supports validation against an XML schema.

Validating an XML File against an XML Schema: %CSTUTILXMLVALIDATE Macro

The %CSTUTILXMLVALIDATE macro validates the structure and syntax of an XML file against the XML schema associated with the XML file. It can be run at any time.

Note: This macro replaces the standard-specific macros crtdds_xmlvalidate.sas,ct_xmlvalidate.sas, and odm_xmlvalidate.sas. These macros are deprecated and are deleted in SAS Clinical Standards Toolkit 1.7. It is recommended that you replace calls to these macros with a call to the %CSTUTILXMLVALIDATE macro.

The SAS Clinical Standards Toolkit includes a call to the %CSTUTILXMLVALIDATE macro immediately following a call to create a specific XML file (for example, the %DEFINE_WRITE macro to create a CDISC Define-XML 2.0 file). This is typically the last step of the sample driver program (for example, create_definexml.sas). If you customize the XML file after it is generated, this macro can be used to validate the customizations. The SAS Clinical Standards Toolkit includes a call to the %CSTUTILXMLVALIDATE macro immediately before a call to read a specific XML file (for example, the crtdds_read macro to read a CDISC CRT-DDS 1.0 file) from the associated sample driver program (for example, create_sascrtdds_fromxml.sas).

Here is an example of a call to the %CSTUTILXMLVALIDATE macro:

```
%cstutilxmlvalidate(_cstSASReferences=work.sasreferences,_cstLogLevel=info);
```

In this example, the %CSTUTILXMLVALIDATE macro is being submitted with a log level of Info.

Note: For more information about the %CSTUTILXMLVALIDATE macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

XML schema validation results are logged using four log-level settings. These log levels refer to the XML-generated log, not the log that is generated by SAS.

The following table shows the log levels:

Table 9.12 *Log Levels for the %CSTUTILXMLVALIDATE Macro*

Log Level	Description
Info	Messages such as the system properties of the current Java environment and progress messages. This is the default value.
Warning	Messages that indicate that there might be an issue with the CRT-DDS document or with the execution of the validation process.
Error	Messages that indicate that something in the define.xml document is invalid with respect to the normal XML schema for CRT-DDS. Or, a non-fatal error has occurred during processing.

Log Level	Description
Fatal Error	Messages that indicate that the XML document could not be processed at all. There are many causes, including file system access errors, incorrect file paths, and malformed XML.

Each message that is generated during XML validation is associated with one of these levels. The level that you choose determines what other messages are generated. For example, if you choose the Warning level, then all Warning messages and anything more severe, such as Error and Fatal error messages, are generated. If you choose the Error level, then only Error and Fatal Error messages are generated.

Validating the SAS Representation of a CDISC CRT-DDS 1.0 XML File: %CRTDDS_VALIDATE Macro

Overview

The %CRTDDS_VALIDATE macro supports the first XML validation methodology. This method is based on SAS and validates the SAS representation of the XML-based standard.

In the SAS Clinical Standards Toolkit, CDISC CRT-DDS validation uses the same types of metadata and the same workflow process that is common to validation of all data standards. SAS provides a set of validation checks for CDISC CRT-DDS that are designed to verify the metadata definitions and values of the 39 data sets that comprise the SAS representation of the CRT-DDS model. These checks were created by SAS. For more information about these checks, see Chapter 7, “Compliance Assessment Against a Reference Standard,” on page 161. Metadata about each check is provided in the Validation Master data set in ***global standards library directory/*** **`standards/cdisc-crtdds-1.0-1.7/validation/control`**.

The %CRTDDS_VALIDATE macro controls the validation workflow for CRT-DDS. As each check is processed from the run-time validation check data set, the check determines the source of the table and column metadata to use. The reference_tables and reference_columns data sets contain the metadata for the 39 data sets that comprise the SAS representation for CDISC CRT-DDS. Unless you make customizations or run-time modifications, the source metadata source_tables and source_columns data sets contain the same content as the reference metadata reference_tables and reference_columns data sets.

If all 39 CRT-DDS tables contribute information to the define.xml file, then the validation process can run directly against the reference_tables and reference_columns data sets. In this case, the Use source data flag in the validation check data set needs to be set to **N**. However, you are likely to run validation against a subset of the 39 tables. In this case, a source_tables data set that contains the subset needs to be created from the reference_tables data set. And, a corresponding source_columns data set needs to be created from the reference_columns data set. The run-time validation check data set can contain all of the checks, and Use source data can be set to **Y**, which is the default value.

There are no parameters for the %CRTDDS_VALIDATE macro.

Sample Driver Program: validate_crtdds_data.sas

The validate_crtdds_data.sas driver program sets up the required environment variables and library references before a call is made to the %CRTDDS_VALIDATE macro.

The driver program is located here:

***sample study library directory*/cdisc-crtdds-1.0–1.7/programs**

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are four input file references, one input library reference, and one output data set reference that are key to the successful completion of the validation process. Table 9.13 on page 370 lists these files, libraries, and data sets, and they are discussed in separate sections. In the sample validate_crtdds_data.sas driver program, these values are set for &studyRootPath and &studyOutputPath:

Note: The &studyRootPath and &studyOutputPath paths are the same for this driver program. Two macro variables have been retained to maintain consistency across the SAS Clinical Standards Toolkit driver programs.

&studyRootPath=*sample study library directory*/cdisc-crtdds-1.0-1.7

&studyOutputPath=*sample study library directory*/cdisc-crtdds-1.0-1.7

Table 9.13 Key Components of the SASReferences Data Set for the validate_crtdds_data.sas Driver Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
control	cntl_s	libref	&workpath	sasreferences.sas7bdat
control	cntl_v	libref	&studyRootPath/ control	validation_control. sas7bdat
sourcemetadata	srcmeta	libref	&studyRootPath/ metadata	source_tables.sas7bdat
sourcemetadata	srcmeta	libref	&studyRootPath/ metadata	source_columns. sas7bdat
sourcedata	srcdata	libref	&studyRootPath/ data	
		Output		
results	results	libref	&studyOutputPath/ results	validation_results. sas7bdat

Process Inputs

The use of the cntl_s LIBNAME that points to the &workpath path demonstrates a technique of documenting the derivation of the SASReferences data set in the SAS

Work library. The driver program initiates the macro variable &workPath with this statement:

```
%let workPath=%sysfunc(pathname(work));
```

In this case, the cntl_s LIBNAME points to the same directory as the Work LIBNAME. The second control record points to the validation_control data set (run-time validation check data set), and is accessed by the cntl_v LIBNAME statement. This LIBNAME is assigned to the ***`sample study library directory`*****`/cdisc-crtdds-1.0-1.7/control`** directory.

The sourcemetadata type references two metadata data sets that describe the table (source_tables) and column (source_columns) metadata for the 39 data sets that comprise the SAS representation of the CRT-DDS model. Both data sets are stored in the same library. In the SAS Clinical Standards Toolkit, this source metadata is read from the ***`sample study library directory`*****`/cdisc-crtdds-1.0-1.7/metadata`** directory. This location is represented in the driver program by the Srcmeta library name.

The sourcedata type is the library where the 39 data sets that comprise the SAS representation of the CRT-DDS model are stored. These are the data sets that are being validated. In the SAS Clinical Standards Toolkit, this library is read from the ***`sample study library directory`*****`/cdisc-crtdds-1.0-1.7/data`** directory. This location is represented in the driver program by the Srcdata library name.

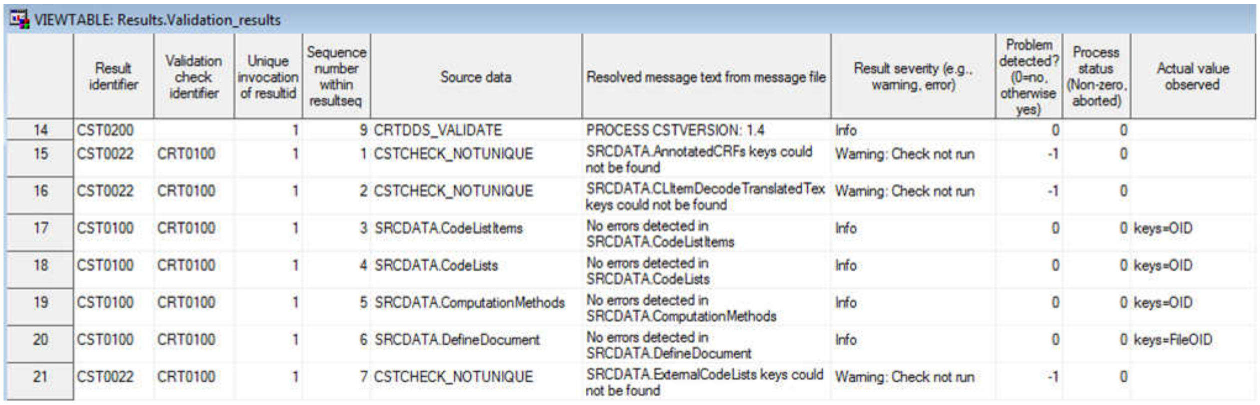
Process Outputs

For the SAS Clinical Standards Toolkit validation processes, the only process outputs that are generated are the Validation Results and Validation Metrics data sets. These data sets are described in the following section.

Process Results

When the validate_crtdds_data.sas driver program finishes running, the validation_results data set is created in the Results library. The Results data set contains informational, warning, and error messages that were generated by the driver program. Reporting of validation process metrics is supported, although it is not implemented for CDISC CRT-DDS validation.

Figure 9.26 *Example of a CDISC CRT-DDS Results Data Set*



VIEWTABLE: Results.Validation_results

	Result identifier	Validation check identifier	Unique invocation of resultid	Sequence number within resultseq	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)	Actual value observed
14	CST0200		1	9	CRTDDS_VALIDATE	PROCESS CSTVERSION: 1.4	Info	0	0	
15	CST0022	CRT0100	1	1	CSTCHECK_NOTUNIQUE	SRCDATA.AnnotatedCRFs keys could not be found	Warning: Check not run	-1	0	
16	CST0022	CRT0100	1	2	CSTCHECK_NOTUNIQUE	SRCDATA.CLItemDecodeTranslatedTex keys could not be found	Warning: Check not run	-1	0	
17	CST0100	CRT0100	1	3	SRCDATA.CodeListItems	No errors detected in SRCDATA.CodeListItems	Info	0	0	keys=OID
18	CST0100	CRT0100	1	4	SRCDATA.CodeLists	No errors detected in SRCDATA.CodeLists	Info	0	0	keys=OID
19	CST0100	CRT0100	1	5	SRCDATA.ComputationMethods	No errors detected in SRCDATA.ComputationMethods	Info	0	0	keys=OID
20	CST0100	CRT0100	1	6	SRCDATA.DefineDocument	No errors detected in SRCDATA.DefineDocument	Info	0	0	keys=FileOID
21	CST0022	CRT0100	1	7	CSTCHECK_NOTUNIQUE	SRCDATA.ExternalCodeLists keys could not be found	Warning: Check not run	-1	0	

Validating the SAS Representation of ODM Files: %ODM_VALIDATE Macro

Overview

The %ODM_VALIDATE macro supports the second XML validation methodology. This method relies on the definition of a master set of validation checks that are specific to the table and column metadata that define a set of data and on checks that are specific to the data itself. This method uses SAS files and SAS code to validate the SAS representation of the XML-based standard.

In the SAS Clinical Standards Toolkit, CDISC ODM validation uses the same types of metadata and the same workflow process that is common to validation of all data standards. SAS provides a set of validation checks for CDISC ODM that are designed to verify the metadata definitions and values of the default 66 data sets that comprise the SAS representation of the ODM model. These checks were created by SAS. For more information about these checks, see Chapter 7, “Compliance Assessment Against a Reference Standard,” on page 161. Metadata about each check is provided in the Validation Master data set in the ***`global standards library directory/`*** **`standards/cdisc-odm-1.3.0-1.7/validation/control`** directory.

The %ODM_VALIDATE macro controls the validation workflow for ODM. As each check is processed from the run-time validation check data set, the check determines the source of the table and column metadata to use. The reference_tables and reference_columns data sets contain the metadata for the 66 data sets that comprise the SAS representation for CDISC ODM. Unless you make customizations or run-time modifications, the source metadata source_tables and source_columns data sets contain the same content as the reference metadata reference_tables and reference_columns data sets.

If all 66 ODM tables contribute information to the ODM XML file, then the validation process can run directly against the reference_tables and reference_columns data sets. In this case, the Use source data flag in the validation check data set needs to be set to **`N`**. However, you can choose to run validation against a subset of the 66 tables. In this case, a source_tables data set that contains the subset needs to be created from the reference_tables data set. And, a corresponding source_columns data set needs to be created from the reference_columns data set. The run-time validation check data set can contain all of the checks, and the Use source data flag can be set to **`Y`**, which is the default value.

There are no parameters for the %ODM_VALIDATE macro.

Sample Driver Program: validate_odm_data.sas

The validate_odm_data.sas driver program sets up the required environment variables and library references before a call is made to the %ODM_VALIDATE macro.

The driver program is located here:

***sample study library directory*/cdisc-odm-1.3.0–1.7/programs**

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, there are three input file references, one input library reference, and one output data set reference that are key to the successful completion of the validation process. These files, libraries, and data sets are listed in Table 9.14 on page 374, and they are discussed in separate sections. In the sample validate_odm_data.sas driver program, these values are set for &studyRootPath and &studyOutputPath.

Note: The &studyRootPath and &studyOutputPath paths are the same for this driver program. These two macro variables have been retained to maintain consistency across the SAS Clinical Standards Toolkit driver programs.

```
&studyRootPath=sample study library directory/cdisc-odm-1.3.0-1.7
```

```
&studyOutputPath=sample study library directory/cdisc-odm-1.3.0-
1.7
```

Table 9.14 Key Components of the SASReferences Data Set for the validate_odm_data.sas Driver Program

Metadata Type	LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
control	cntl_v	libref	&studyRootPath/ control	validation_ control.sas7bdat
sourcemetadata	srcmeta	libref	&studyRootPath/ metadata	source_tables.sas7bdat
sourcemetadata	srcmeta	libref	&studyRootPath/ metadata	source_ columns.sas7bdat
sourcedata	srcdata	libref	&studyRootPath/ data	
		Output		
results	results	libref	&studyOutputPath/ results	validation_ results.sas7bdat

Process Inputs

The control record points to the validation_control data set (run-time validation check data set) data set. It is accessed by the cntl_v LIBNAME statement. This LIBNAME is assigned to the ***sample study library directory*/cdisc-odm-1.3.0–1.7/control** directory.

The sourcemetadata type references two metadata data sets that describe the table (source_tables) and column (source_columns) metadata for the 66 data sets that comprise the SAS representation of the ODM model. Both data sets are stored in the same library. In the SAS Clinical Standards Toolkit, this source metadata is read from the ***sample study library directory*/cdisc-odm-1.3.0–1.7/metadata** directory. This location is represented in the driver program by the Srcmeta library name.

The sourcedata type is the library where the 66 data sets that comprise the SAS representation of the ODM model are stored. These are the data sets that are being validated. In the SAS Clinical Standards Toolkit, this library is read from the ***sample study library directory*/cdisc-odm-1.3.0–1.7/data** directory. This location is represented in the driver program by the Srcdata library name.

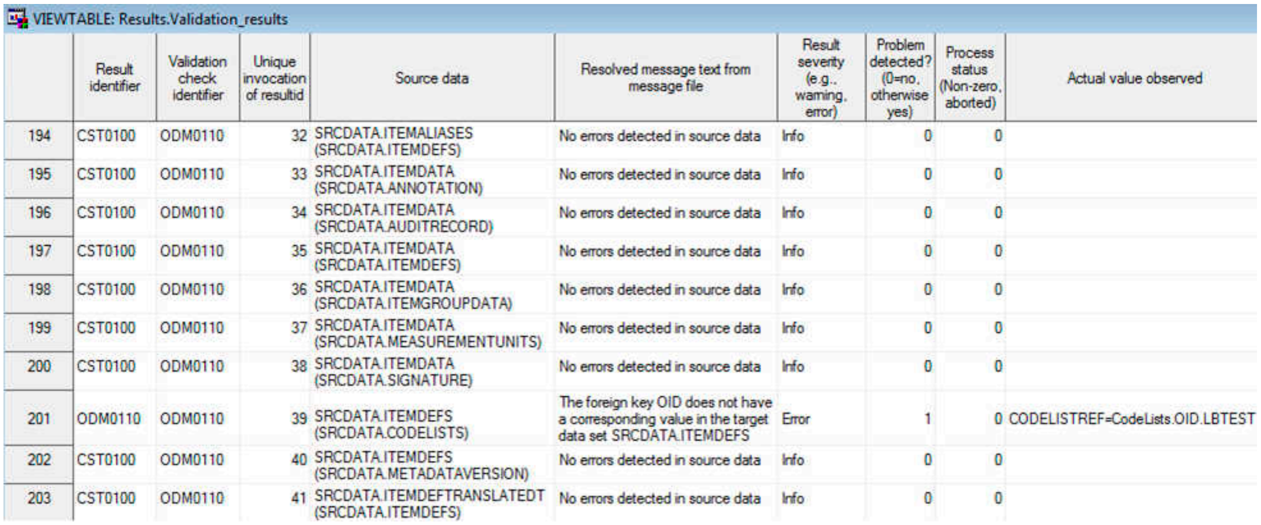
Process Outputs

For the SAS Clinical Standards Toolkit validation processes, the only process outputs that are generated are the Validation Results and Validation Metrics data sets. These data sets are described in the following section.

Process Results

When the validate_odm_data driver program finishes running, the validation_results data set is created in the Results library. The Results data set contains informational, warning, and error messages that were generated by the driver program. Reporting of validation process metrics is supported, although it is not implemented for CDISC ODM validation.

Figure 9.27 *Example of a CDISC ODM Validation Results Data Set*



VIEWTABLE: Results.Validation_results

	Result identifier	Validation check identifier	Unique invocation of resultid	Source data	Resolved message text from message file	Result severity (e.g., warning, error)	Problem detected? (0=no, otherwise yes)	Process status (Non-zero, aborted)	Actual value observed
194	CST0100	ODM0110	32	SRCDATA.ITEMALIASES (SRCDATA.ITEMDEFS)	No errors detected in source data	Info	0	0	
195	CST0100	ODM0110	33	SRCDATA.ITEMDATA (SRCDATA.ANNOTATION)	No errors detected in source data	Info	0	0	
196	CST0100	ODM0110	34	SRCDATA.ITEMDATA (SRCDATA.AUDITRECORD)	No errors detected in source data	Info	0	0	
197	CST0100	ODM0110	35	SRCDATA.ITEMDATA (SRCDATA.ITEMDEFS)	No errors detected in source data	Info	0	0	
198	CST0100	ODM0110	36	SRCDATA.ITEMDATA (SRCDATA.ITEMGROUPDATA)	No errors detected in source data	Info	0	0	
199	CST0100	ODM0110	37	SRCDATA.ITEMDATA (SRCDATA.MEASUREMENTUNITS)	No errors detected in source data	Info	0	0	
200	CST0100	ODM0110	38	SRCDATA.ITEMDATA (SRCDATA.SIGNATURE)	No errors detected in source data	Info	0	0	
201	ODM0110	ODM0110	39	SRCDATA.ITEMDEFS (SRCDATA.CODELISTS)	The foreign key OID does not have a corresponding value in the target data set SRCDATA.ITEMDEFS	Error	1	0	CODELISTREF=CodeLists.OID.LBTEST
202	CST0100	ODM0110	40	SRCDATA.ITEMDEFS (SRCDATA.METADATAVERSION)	No errors detected in source data	Info	0	0	
203	CST0100	ODM0110	41	SRCDATA.ITEMDEFTRANSLATEDT (SRCDATA.ITEMDEFS)	No errors detected in source data	Info	0	0	

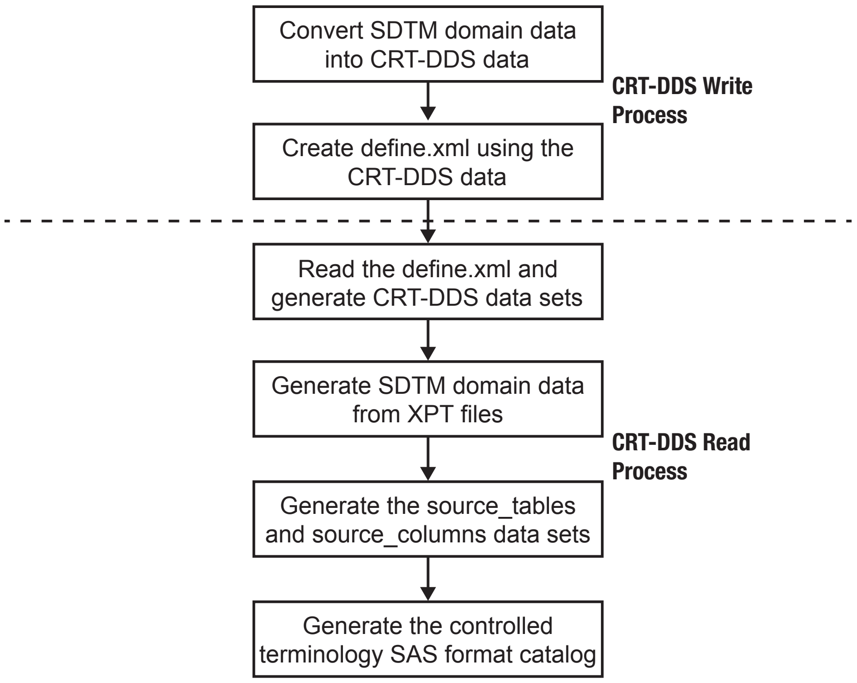
Special Topic: A Round-Trip Exercise Involving the CDISC SDTM and CDISC CRT-DDS Standards

Overview

The typical SAS Clinical Standards Toolkit workflow in support of the CDISC standards includes the definition and validation of SDTM submission data and the creation and validation of a define.xml file based on the SDTM domain data. This exercise demonstrates how you can read a define.xml file to extract the data and metadata for the purposes of re-creating the original source SDTM study. Re-creating the original source study has value as a stand-alone exercise, either to extract a new SDTM study from a define.xml file or to create a new SDTM study using information in a define.xml file as a template.

As a round-trip exercise, this task validates the performance of the %CRTDDS_WRITE and %CRTDDS_READ macros and allows a comparison of original and re-created SDTM metadata and data. This display details the high-level workflow for this exercise.

Figure 9.28 *Round-Trip Process*


Convert SDTM domain data into CRT-DDS data
Create define.xml using the CRT-DDS data
CRT-DDS Write Process
Read the define.xml and generate CRT-DDS data sets
Generate SDTM domain data from XPT files
CRT-DDS Read Process
Generate the source_tables and source_columns data sets
Generate the controlled terminology SAS format catalog

The Workflow

These steps describe the workflow in more detail. The first five steps describe the derivation of the CDISC CRT-DDS 1.0 define.xml file.

Note: Steps 1 to 6 can be used with CDISC Define-XML 2.0. However, steps 7 to 9 have not been implemented in the SAS Clinical Standards Toolkit for Define-XML 2.0.

1 Access a study that contains valid CDISC SDTM data and metadata. This is a study that contains domain data (AE, DM, CO, and so on) and the SAS Clinical Standards Toolkit metadata about that SDTM study, such as source_tables and source_columns. The SAS Clinical Standards Toolkit also includes XSL style sheets,

XMLMap files, and any metadata that is provided by SAS during the SAS Clinical Standards Toolkit installation.

2 Use the set of sample driver programs that are provided in the SAS Clinical Standards Toolkit to define the input and output files for each process task and to invoke the macros that support each standard-specific task. The driver programs are designed to run with the sample studies, but can be modified as needed. New custom drivers can be created and used.

3 Submit the create_crtdds_fromsdtm.sas driver program to access the %CRTDDS_SDTMTODEFINE macro, and create the 39 data sets that comprise the SAS representation of the CRT-DDS model. These 39 output data sets are written to the ***`sample study library directory`***`/cdisc-crtdds-1.0–1.7/data` directory.

4 Validate the CRT-DDS data sets by submitting the validate_crtdds_data.sas driver program. This step is optional.

5 Create the define.xml file by submitting the create_crtdds_define.sas driver program. This driver program generates the define.xml file from the 39 CRT-DDS data sets that were created in step 3. It calls the %CSTUTILXMLVALIDATE macro to validate the XML file structure. The define.xml file is written to the ***`sample study library directory`***`/cdisc-crtdds-1.0–1.7/sourcexml` directory.

At this point, a valid define.xml file has been created from the SAS representation of the CRT-DDS model. In the next steps, the SDTM data and metadata is re-created using the XML read process.

6 Submit the create_sascrtdds_fromxml.sas driver program. This driver program reads the define.xml file created in step 5, and generates the SAS representation of the CRT-DDS model using the %CRTDDS_READ macro. The data sets created in this step should match the data sets created in step 3. These data sets are written to the ***`sample study library directory`***`/cdisc-crtdds-1.0–1.7/deriveddata` directory. This driver program generates the source_tables and source_columns data sets in the ***`sample study library directory`***`/cdisc-crtdds-1.0–1.7/derivedmetadata` directory. By specifying new target folder

locations (deriveddata and derivedmetadata), the data sets can be validated against the data sets that were created or referenced in step 3.

7 SDTM domain data sets are created based on a reachable set of SAS transport files that are specified in the define.xml file. Submit the create_sasdata_fromxpt.sas SDTM driver program. For SDTM 3.1.2, the program is in the ***sample study library directory*****/cdisc-sdtm-3.1.3-1.7/sascstdemodata/programs** directory. This driver program accesses the %SDTMUTIL_CREATESASDATAFROMXPT macro to generate the SDTM domain data sets from the SAS transport files. Creation of the SAS transport files is not performed by the SAS Clinical Standards Toolkit. These files would have been produced as a prerequisite to the generation of the define.xml file as a part of the Electronic Common Technical Document preparation process. The %SDTMUTIL_CREATESASDATAFROMXPT macro assumes that the SAS transport files are reachable from a folder relative to the location of the referenced define.xml file. In the create_sasdata_fromxpt.sas SDTM driver program, the XPT files are read from the ***sample study library directory*****/cdisc-crtdds-1.0-1.7/transport** directory. The generated data sets are written to the ***sample study library directory*****/cdisc-sdtm-3.1.3-1.7/sascstdemodata/derived/data** directory. At this point, the SDTM domain data sets should contain the same information as the original domain data sets that were accessed at the beginning of this process. By specifying a new target folder location, the SDTM data sets can be validated against those referenced in steps 1 and 3.

8 Source metadata that describes the SDTM domains and columns is derived using information contained in the CRT-DDS data sets derived in step 6. Submit the create_sourcemetadata.sas SDTM driver program. For SDTM 3.1.2, it is installed in the ***sample study library directory*****/cdisc-sdtm-3.1.3-1.7/sascstdemodata/programs** directory. In this exercise, this driver program calls the %SDTMUTIL_CREATESRCMETAFROMCRTDDS macro, which uses a library of SAS data sets that capture define.xml metadata (typically derived using the %CRTDDS_READ macro). The output of this step is a set of SDTM metadata in the source_tables, source_columns, and source_study data sets. These data sets are written to the ***sample study library directory*****/cdisc-sdtm-3.1.3-1.7/sascstdemodata/derived/metadata** directory. At this point, the SDTM metadata should contain the same information as the original metadata that was

accessed at the beginning of this process. By specifying a new target folder location, the SDTM metadata data sets can be validated against those referenced in steps 1 and 3.

9 SAS formats that support SDTM controlled terminology are derived using information contained in the CRT-DDS data sets that were derived in step 6. Submit the create_formatsfromcrtdds.sas SDTM driver program. For SDTM 3.1.2, this program is installed in the ***sample study library directory*/cdisc-sdtm-3.1.3-1.7/sascstdemodata/programs** directory. The driver program accesses the %SDTMUTIL_CREATEFORMATSFROMCRTDDS macro and generates the controlled terminology SAS format catalog based on codelists specified in the define.xml file. The derived SAS format catalog is written to the ***sample study library directory*/cdiscsdtm-3.1.3-1.7/sascstdemodata/derived/formats** directory. These formats should match those formats that were referenced by the SDTM columns at the beginning of this process. By specifying a new target folder location, the SAS format catalog can be validated against the catalog referenced in steps 1 and 3.

Once the round-trip exercise is complete, data derived from the process should match the original data. There might be some metadata collected that does not match exactly (particularly any date and time fields that collect real-time information). Differences can be detected by submitting PROC COMPARE on any of the derived data and metadata data sets against the original data and metadata data sets.

Running Multiple Driver Programs

CAUTION! When running multiple driver programs, be aware that the SAS Clinical Standards Toolkit uses autocall macro libraries to contain and reference standard-specific code libraries. Once the autocall path is set and one or more macros have been used in an autocall macro library, deallocation or reallocation of the autocall file reference cannot occur unless the autocall path is reset to exclude the specific file reference.

This becomes a problem with repeated calls to %CSTUTIL_PROCESSSETUP or %CSTUTIL_ALLOCATESASREFERENCES in the same SAS session. You might receive SAS errors, such as this one, unless you submit some specific SAS code:

```
ERROR - At least one file associated with fileref SDTMAUTO is
still in use. ERROR - Error in the FILENAME statement.
```

If you call %CSTUTIL_PROCESSSETUP or %CSTUTIL_ALLOCATESASREFERENCES more than once in the same SAS session, by default the SAS Clinical Standards Toolkit does not attempt to reallocate SAS librefs and filerefs. Records are written to the process results data set noting (for example):

```
SAS libref from SASref=refmeta sasreferences record not allocated
```

Generally, if you are resubmitting the same process code again without changing the &_cststandard or &_cststandardversion global macro variables and you do not have references to different data or metadata libraries, there are no consequences. However, if you are attempting to change the standard or standard version in the same SAS session or you are attempting to reference different studies, code libraries, or terminology libraries, you must use the following code between each code submission:

```
   %let _cstReallocateSASRefs=1;
   %include "&_cstGRoot/standards/cst-framework-1.7/programs/resetautocallpath.sas";
```

In the driver programs provided with the SAS Clinical Standards Toolkit, the previous code is commented so that it is not submitted during run time.

Special Topic: Comparing the Metadata Defined in a Define-XML File with the Metadata from the SAS Version 5 XPORT Transport Files

When you receive a Define-XML file combined with a folder of SAS Version 5 XPORT SAS transport files or a library of SAS data sets, it is important to ensure that the Define-XML file accurately defines the data in the SAS Version 5 XPORT transport files or SAS data sets.

The %CSTUTILCOMPAREMETADATASASDEFINE macro compares the metadata in the SAS Version 5 XPORT transport files or in the SAS data sets with the metadata in the Define-XML file. This macro supports both CRT-DDS 1.0 and Define-XML 2.0.

Before you can use the %CSTUTILCOMPAREMETADATASASDEFINE macro, convert the metadata in the Define-XML file into a SAS representation. For more information about this process, see “Reading CDISC CRT-DDS 1.0 or Define-XML 2.0 define.xml Files: %CRTDDS_READ and %DEFINE_READ Macros” on page 322.

The %CSTUTILCOMPAREMETADATASASDEFINE macro compares metadata between two different sources:

- Metadata extracted from the SAS representation of a CRT-DDS 1.0 or Define-XML 2.0 file. This metadata must be created using either the %CRTDDS_READ or %DEFINE_READ macro to import a define.xml file.
- Metadata extracted from a folder of XPORT files or a library of SAS data sets.

The results of the comparison are presented in a SAS data set that contains the columns shown in the following table:

Table 9.15 SAS Data Set Columns Created by the %CSTUTILCOMPAREMETADATASASDEFINE Macro

Column Name	Column Description
StandardName	Standard Name
StandardVersion	Standard Version
MetadataLib	Metadata Library
DataLib	Data Library
XPTFolder	XPORT Folder
Table	Table
Column	Column
Issue	Issue
define_value	Define Value
data_value	SAS Value

Column Name	Column Description
Comment	Comment

The Issue column summarizes issues that are found. The issue is identified by a keyword.

The following table shows the Issue column keywords and their meanings:

Table 9.16 *Issue Column Keywords*

Issue Column Keyword	Meaning
DSLABEL	The data set label does not match the data set description in the Define-XML metadata.
LABEL	The variable label does not match the variable description in the Define-XML metadata.
DEFINE_COLUMN	The Define-XML metadata defines a variable that is not in the data set.
DATA_COLUMN	A data set column does not have a definition in the Define-XML metadata.
LENGTH	Inconsistencies exist between the length of the SAS variable and the length defined in the Define-XML metadata. **Note:** This check is performed only for SAS character variables because the definition of the length of a numerical variable is not compatible between SAS and Define-XML.
TYPE	Inconsistencies exist between the type of the SAS variable and the DataType defined in the Define-XML metadata.

Here is an example of the code to check the metadata for a CRT-DDS 1.0 file:

```
%cst_setStandardProperties(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);
%cstutil_setcstsroot;

%let studyRootPath=&_cstSRoot/cdisc-crtdds-1.0-&_cstVersion;
%let studyOutputPath=&_cstSRoot/cdisc-crtdds-1.0-&_cstVersion;
```

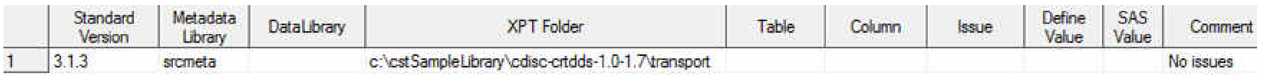
```
filename srcdata "&studyRootPath/transport";
libname srcmeta "&studyRootPath/data";
libname results "&studyOutputPath/results";

%cstutilcomparemetadatasasdefine(
  _cstSourceXPTFolder=%sysfunc(pathname(srcdata)),
  _cstSourceMetadataLibrary=srcmeta,
  _cstRptDS=results.compare_metadata_results
  );
```

This example is located here:

sample study library directory**\cdisc-crtdds-1.0-1.7\programs\compare_metadata_sascrtdds_xpt.sas**

The Results data set indicates no issues.

Figure 9.29 Results Data Set Indicates No Issues



	Standard Version	Metadata Library	DataLibrary	XPT Folder	Table	Column	Issue	Define Value	SAS Value	Comment
1	3.1.3	srcmeta		c:\cstSampleLibrary\cdisc-crtdds-1.0-1.7\transport						No issues

Here is an example of the code to check the metadata for a Define-XML 2.0 file:

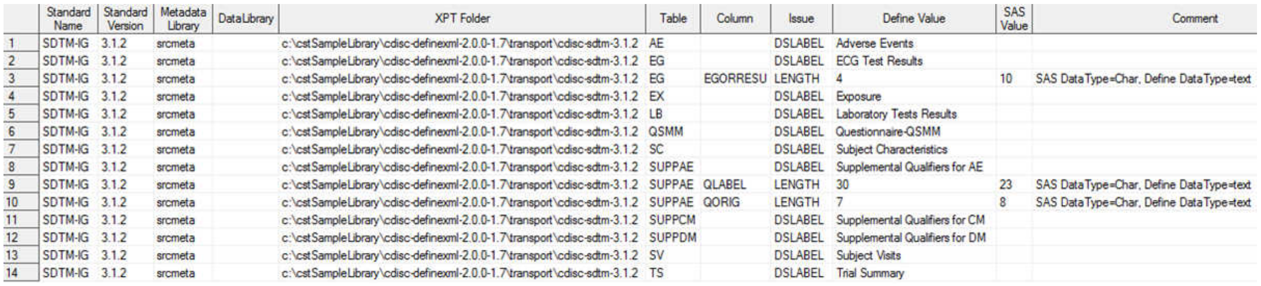
```
%cst_setStandardProperties(_cstStandard=CST-FRAMEWORK,_cstSubType=initialize);
%cstutil_setcstsroot;

%let studyRootPath=&_cstSRoot/cdisc-crtdds-1.0-&_cstVersion;
%let studyOutputPath=&_cstSRoot/cdisc-crtdds-1.0-&_cstVersion;

filename srcdata "&studyRootPath/transport";
libname srcmeta "&studyRootPath/data";
libname results "&studyOutputPath/results";

%cstutilcomparemetadatasasdefine(
  _cstSourceXPTFolder=%sysfunc(pathname(srcdata)),
  _cstSourceMetadataLibrary=srcmeta,
  _cstRptDS=results.compare_metadata_results
  );
```

Instead of specifying a folder that contains XPORT files in the _cstSourceXPTFolder parameter, you can specify a library with SAS data sets in the _cstSourceDataLibrary parameter. This example is located here:

sample study library directory**cdisc-definexml-2.0.0-1.7\programs\compare_metadata_sasdefine_xpt.sas**

The Results data set indicates several issues.

Figure 9.30 *Results Data Set Indicates Several Issues*



	Standard Name	Standard Version	Metadata Library	DataLibrary	XPT Folder	Table	Column	Issue	Define Value	SAS Value	Comment
1	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	AE		DSLABEL	Adverse Events		
2	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	EG		DSLABEL	ECG Test Results		
3	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	EG	EGORRESU	LENGTH	4	10	SAS DataType=Char, Define DataType=text
4	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	EX		DSLABEL	Exposure		
5	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	LB		DSLABEL	Laboratory Tests Results		
6	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	QSMM		DSLABEL	Questionnaire-QSMM		
7	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SC		DSLABEL	Subject Characteristics		
8	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SUPPAE		DSLABEL	Supplemental Qualifiers for AE		
9	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SUPPAE	QLABEL	LENGTH	30	23	SAS DataType=Char, Define DataType=text
10	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SUPPAE	QORIG	LENGTH	7	8	SAS DataType=Char, Define DataType=text
11	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SUPPCM		DSLABEL	Supplemental Qualifiers for CM		
12	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SUPPDM		DSLABEL	Supplemental Qualifiers for DM		
13	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	SV		DSLABEL	Subject Visits		
14	SDTM-IG	3.1.2	srcmeta		c:\cstSampleLibrary\cdisc-definexml-2.0.0-1.7\transport\cdisc-sdtm-3.1.2	TS		DSLABEL	Trial Summary		

Special Topic: Identifying Unsupported Elements and Attributes in a CDISC ODM File

Overview

Note: The following process is the same for all ODM versions that are supported by the SAS Clinical Standards Toolkit. The process is explained using ODM version 1.3.0.

In practice, vendor and custom extensions to ODM are common. For example, Electronic Data Capture (EDC) vendors use data management features and flags that might be exported using ODM XML extensions. By default, these extensions are ignored by the SAS Clinical Standards Toolkit. Recall that the SAS Clinical Standards Toolkit uses XSL style sheets for each of the default, supported 66 ODM data sets (such as ItemDefs). These style sheets look for specifically named tags and hierarchical paths based on the CDISC ODM 1.3.0 published specification. If elements or attributes exist in the XML file but not in the specification, they are ignored.

For example, in this XML code fragment, note the `Vendor:`*`<name>`* syntax. This represents a hypothetical extension to the ODM XML, presumably accompanied by a namespace reference supporting the Vendor naming convention.

```
    <FormData FormOID=" FormDefs.OID.Death" FormRepeatKey="00-01"
```

```
                TransactionType="Remove" Vendor:Revised="No">
           <Vendor:DataQuery DQOID="DQ.OID.001"
                             QueryText="Premature report of patients demise?">
                <Flag>Y</Flag>
                 <AuditRecord>
                   <UserRef UserOID="User.OID.I024" />
                   <LocationRef LocationOID="Location.OID.S001" />
                   <DateTimeStamp>2011-01-24T15:13:22</DateTimeStamp>
                 </AuditRecord>
           </Vendor:DataQuery>
       </FormData>
```

In this code fragment, the `Vendor:DataQuery` syntax specifies a new element with several new attributes and references to other existing (supported) elements. Note the additional Vendor:Revised attribute for FormData.

The SAS Clinical Standards Toolkit provides a macro to parse the ODM XML file to identify currently unsupported elements and tags. This macro, %CSTUTIL_READXMLTAGS, is located in the primary SAS Clinical Standards Toolkit autocall library (**`!sasroot/cstframework/sasmacro`**).

Here is an example of a call to the %CSTUTIL_READXMLTAGS macro:

```
%cstutil_readxmltags(
      _cstxmlfilename=inxml
     ,_cstxmlreporting=Dataset
     ,_cstxmlelementds=work.cstodmelements
     ,_cstxmlattrds=work.cstodmattributes);
```

In this call, the XML file to be parsed is specified with the inxml fileref. The results of parsing are to be written to two data sets: work.cstodmelements for all unique elements found in the XML file and work.cstodmattributes for all unique attributes found that are associated with each unique element.

Note: For more information about the %CSTUTIL_READXMLTAGS macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Sample Program: find_unsupported_tags.sas

Overview

The SAS Clinical Standards Toolkit provides the program find_unsupported_tags.sas to demonstrate the assessment of the ODM XML file elements and attributes. This program is located here:

***sample study library directory*/cdisc-odm-1.3.0-1.7/programs**

This program provides the same process setup functionality supported in most SAS Clinical Standards Toolkit driver programs, builds a SASReferences data set that defines process inputs and outputs, and allocates all SAS librefs and filerefs.

Here is the general workflow of this program:

1 Build a process-specific SASReferences data set.

2 Call the %CSTUTIL_PROCESSSETUP macro to set process paths and perform required library and file allocations.

3 Call the %CSTUTIL_READXMLTAGS macro to create a data set of element names and a data set of attribute names.

4 Compare elements and attributes to a set of known (for example, supported) elements and attributes.

5 Report discrepancies.

The SASReferences Data Set

As a part of each SAS Clinical Standards Toolkit process setup, a valid SASReferences data set is required. It references the input files that are needed, the librefs and filenames to use, and the names and locations of data sets to be created by the process. It can be modified to point to study-specific files. For an explanation of the SASReferences data set, see Chapter 6, “SASReferences File,” on page 137.

In the SASReferences data set, three input file references and one output data set reference are key to the successful completion of the find_unsupported_tags.sas program. Table 9.17 on page 388 lists these files and data sets, and they are discussed in separate sections. In the sample find_unsupported_tags.sas program, these values are set for &studyRootPath and &studyOutputPath:

```
&studyRootPath=sample study library directory/cdisc-odm-1.3.0-1.7
```

```
&studyOutputPath=sample study library directory/cdisc-odm-1.3.0-
1.7
```

Table 9.17 Key Components of the SASReferences Data Set for the find_unsupported_tags.sas Program

Metadata Type	SAS LIBNAME or Fileref to Use	Reference Type	Path	Name of File
		Input		
externalxml	odmxml	fileref	&studyRootPath/ sourcexml	odm_extended.xml
standardmetadata (element)	odmmeta	libref		
standardmetadata (attribute)	odmmeta	libref		
		Output		
results	results	libref	&studyOutputPath/ results	readxmltags_ results.sas7bdat

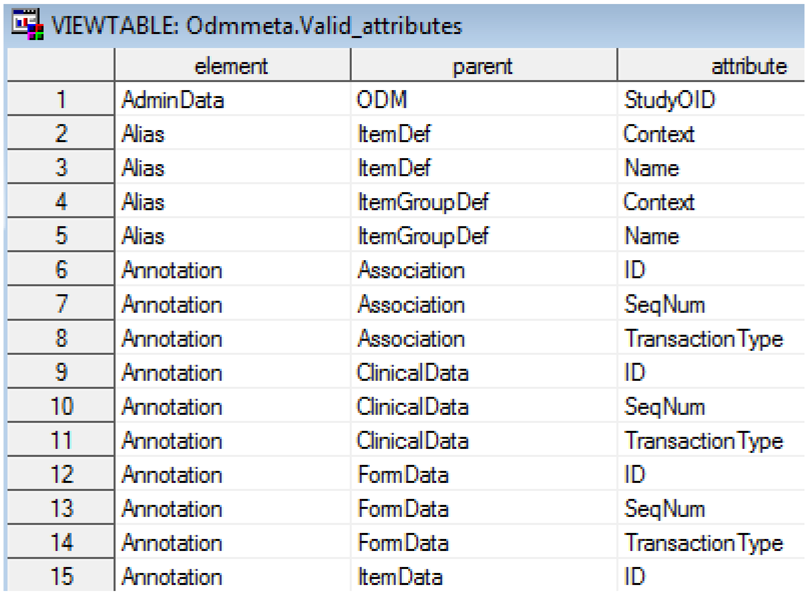
Process Inputs

The externalxml type refers to the ODM XML file to read. The filename odmxml is defined in the SASReferences data set. This filename is used in the submitted SAS code when referring to the XML file. The ODM XML file odm_extended.xml contains sample extensions to the core ODM 1.3.0 model.

The standardmetadata type, referenced by the odmmeta SAS libref, references the ***global standards library directory*/standards/cdisc-odm-1.3.0-1.7/ metadata** folder. This folder includes the two data sets valid_elements and valid_attributes, which contain the full list of ODM core elements and attributes supported by the SAS Clinical Standards Toolkit. The valid_elements data set contains a single column element itemizing the ODM core elements. The valid_attributes data set contains each attribute within the context of its parent tag and containing element.

The following display shows a partial listing of the valid_attributes data set:

Figure 9.31 *Partial Listing of the valid_attributes Data Set*



VIEWTABLE: Odmmeta.Valid_attributes

	element	parent	attribute
1	AdminData	ODM	StudyOID
2	Alias	ItemDef	Context
3	Alias	ItemDef	Name
4	Alias	ItemGroupDef	Context
5	Alias	ItemGroupDef	Name
6	Annotation	Association	ID
7	Annotation	Association	SeqNum
8	Annotation	Association	TransactionType
9	Annotation	ClinicalData	ID
10	Annotation	ClinicalData	SeqNum
11	Annotation	ClinicalData	TransactionType
12	Annotation	FormData	ID
13	Annotation	FormData	SeqNum
14	Annotation	FormData	TransactionType
15	Annotation	ItemData	ID

Process Outputs

The results type refers to the Results data set that contains information from running the process. In the SAS Clinical Standards Toolkit sample code hierarchy, this information is written to the ***`sample study library directory`*****`/cdisc-odm-1.3.0-1.7/results`** directory. This location is represented in the program by the Results library name.

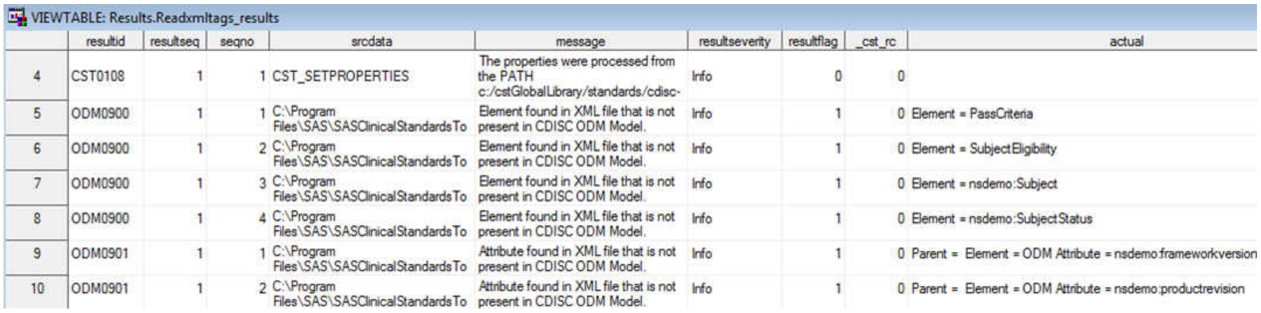
Depending on the parameter values associated with the call to the %CSTUTIL_READXMLTAGS macro, two additional process outputs might be persisted at the conclusion of the process. If the _cstxmlreporting parameter is set to Dataset, any unsupported elements are documented in the data set referenced by the _cstxmlelementds parameter and any unsupported attributes are documented in the data set referenced by the _cstxmlattrds parameter.

Process Results

When the program finishes running, the readxmltags_results data set is created in the Results library. This data set contains informational, warning, and error messages that were generated by the program.

The following display shows an example of the contents of a Results data set run against the customized odm_extended.xml input file (with the _cstxmlreporting parameter set to Results):

Figure 9.32 Example of a Partial Results Data Set Created by the find_unsupported_tags.sas Program



VIEWTABLE: Results.Readxmltags_results

	resultid	resultseq	seqno	srcdata	message	resultseverity	resultflag	_cst_rc	actual
4	CST0108	1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-	Info	0	0	
5	ODM0900	1	1	C:\Program Files\SAS\SASClinicalStandardsTo	Element found in XML file that is not present in CDISC ODM Model.	Info	1	0	Element = PassCriteria
6	ODM0900	1	2	C:\Program Files\SAS\SASClinicalStandardsTo	Element found in XML file that is not present in CDISC ODM Model.	Info	1	0	Element = SubjectEligibility
7	ODM0900	1	3	C:\Program Files\SAS\SASClinicalStandardsTo	Element found in XML file that is not present in CDISC ODM Model.	Info	1	0	Element = nsdemo:Subject
8	ODM0900	1	4	C:\Program Files\SAS\SASClinicalStandardsTo	Element found in XML file that is not present in CDISC ODM Model.	Info	1	0	Element = nsdemo:SubjectStatus
9	ODM0901	1	1	C:\Program Files\SAS\SASClinicalStandardsTo	Attribute found in XML file that is not present in CDISC ODM Model.	Info	1	0	Parent = Element = ODM Attribute = nsdemo:frameworkversion
10	ODM0901	1	2	C:\Program Files\SAS\SASClinicalStandardsTo	Attribute found in XML file that is not present in CDISC ODM Model.	Info	1	0	Parent = Element = ODM Attribute = nsdemo:productrevision

Special Topic: Creating Study Source Metadata to Create a CDISC Define-XML 2.0 define.xml File

Overview

The typical SAS Clinical Standards Toolkit workflow that supports the creation of a Define-XML 2.0 file includes the definition of metadata that describes the study, domains, columns, codelists, value-level metadata, and supporting documents. A CDISC ADaM study can also include analysis results metadata.

This metadata is in the following SAS data sets:

- source_study

- source_tables
- source_colums
- source_codelists
- source_values
- source_documents
- source_analysisresults

The %CST_CREATEDSFROMTEMPLATE macro can create these source metadata data sets with zero observations and based on a template. Here is the syntax:

```
%cst_createdsfromtemplate(
   _cstStandard=CDISC-DEFINE-XML,
   _cstStandardVersion=2.0.0,
   _cstType=studymetadata,
   _cstSubType=study,
   _cstOutputDS=work.source_study
   );
```

The valid values for the _cstSubType parameter are study, table, column, codelist, value, analysisresults, and document.

Part of the metadata in these data sets can be derived by macros in the SAS Clinical Standards Toolkit based on various inputs such as these:

- the study domain data sets

  For more information, see "Creating Study Source Metadata from Study Domain Data Sets" on page 392.

- metadata data from an imported Define-XML 2.0 file from a similar study

  For more information, see "Deriving Study Source Metadata from an Imported Define-XML 2.0 File for a Similar Study" on page 394.

- metadata converted from source study metadata that was previously used for the creation of a CRT-DDS 1.0 define.xml file for a study

  For more information, see "Migrating Study Source Metadata Used for the Creation of a CRT-DDS 1.0 define.Xml File for the Study" on page 397.

Note: These macros attempt to create an approximation of source metadata. No assumptions should be made that the result completely represents the study metadata. Incomplete reference metadata might not enable imputation of missing metadata. You might need to add or update some metadata.

These macros are called by driver programs that are responsible for properly setting up each SAS Clinical Standards Toolkit process to perform a specific task. These driver programs are examples that are provided with the SAS Clinical Standards Toolkit. You can use these driver programs or create your own. The names of these driver programs are not important. However, the content is important and demonstrates how the various SAS Clinical Standards Toolkit framework macros are used to generate the required metadata files.

Creating Study Source Metadata from Study Domain Data Sets

The %DEFINE_CREATESRCMETAFROMSASLIB macro derives source metadata files from a data library that contains SAS study domain data sets.

Here is the general strategy:

1. Use PROC CONTENTS output as the primary source of the information.
2. Use reference_tables,reference_columns,class_tables, and class_columns for matching the columns to impute missing metadata when _cstUseRefLib=Y is specified.

The source data is read from a single SAS library. You can modify the code to reference multiple libraries by using library concatenation. Only one study reference can be specified. Multiple study references require modification of the code.

The create_sourcemetadata_fromsaslib.sas driver program is provided by SAS. It is ready to run on any of the SDTM or ADaM study data samples. The driver program can be run interactively or in batch. To run the driver program interactively, start a SAS session, and load the driver program into the SAS editor.

The driver program is located here:

***sample study library directory*/cdisc-definexml-2.0.0-1.7/programs**

To create the source_codelists study metadata data set, you must specify two items: a list of format catalogs that define the study formats and a SAS data set that contains CDISC/NCI codelist metadata.

You might need to specify study metadata in the driver program.

Here is an example:

```
data work.studymetadata;
   studyname="CDISC01";
   studydescription="CDISC Test Study";
   protocolname="CDISC01";
   studyversion="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2";
run;
```

The parameters can be specified by using a SASReferences file or by specifying the parameters in the macro call.

Here are examples of calls to the %DEFINE_CREATESRCMETAFROMSASLIB macro using the two methods to specify the parameters:

```
%define_createsrcmetafromsaslib(
  _cstTrgStandard=&_cstTrgStandard,
  _cstTrgStandardVersion=&_cstTrgStandardVersion,
  _cstLang=en,
  _cstUseRefLib=Y,
  _cstKeepAllCodeLists=N
);

%define_createsrcmetafromsaslib(
  _cstSASDataLib=srcdata,
  _cstStudyMetadata=work.studymetadata,
  _cstTrgStandard=&_cstTrgStandard,
  _cstTrgStandardVersion=&_cstTrgStandardVersion,
  _cstTrgStudyDS=trgmeta.source_study,
  _cstTrgTableDS=trgmeta.source_tables,
  _cstTrgColumnDS=trgmeta.source_columns,
  _cstTrgCodeListDS=trgmeta.source_codelists,
  _cstTrgValueDS=trgmeta.source_values,
  _cstTrgDocumentDS=trgmeta.source_documents,
  _cstTrgAnalysisResultDS=trgmeta.source_analysisresults,
  _cstLang=en,
  _cstUseRefLib=Y,
  _cstRefTableDS=refmeta.reference_tables,
  _cstRefColumnDS=refmeta.reference_columns,
  _cstClassTableDS=refmeta.class_tables,
  _cstClassColumnDS=refmeta.class_columns,
  _cstKeepAllCodeLists=Y,
  _cstFormatCatalogs=cstfmt.formats ncifmt.cterms,
  _cstNCICTerms=ncifmt.cterms
  );
```

For more information about the %DEFINE_CREATESRCMETAFROMSASLIB macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

After the driver program runs, the srcmeta_saslib_results data set is created. This data set contains informational, warning, and any error messages that were generated by the driver program.

Deriving Study Source Metadata from an Imported Define-XML 2.0 File for a Similar Study

The %DEFINE_CREATESRCMETAFROMDEFINE macro derives source metadata files from a data library that contains the SAS representation of a Define-XML V2.0.0 define.xml file for a study.

Here is the general strategy:

1. Use the SAS representation of a Define-XML V2.0.0 define.xml file as the primary source of the information.
2. Use reference_tables,reference_columns,class_tables, and class_columns for matching the columns to impute missing metadata when _cstUseRefLib=Y is specified.

The following SAS data sets must exist in this Define-XML V2.0.0 SAS data set library:

aliases	itemrefwhereclauserefs
codelistitems	itemvaluelistrefs
codelists	mdvleaf
definedocument	mdvleaftitles
documentrefs	metadataversion

enumerateditems	methoddefs
externalcodelists	pdfpagerefs
formalexpressions	study
itemdefs	translatedtext
itemgroupdefs	valuelistitemrefs
itemgroupitemrefs	valuelists
itemgroupleaf	whereclausedefs
itemgroupleaftitles	whereclauserangechecks
itemorigin	whereclauserangecheckvalues

When creating the source_analysisresults data set, the following SAS data sets must exist in this Define-XML V2.0.0 SAS data set library:

analysisdataset	analysisresultdisplays
analysisdatasets	analysisresults
analysisdocumentation	analysisvariables
analysisprogrammingcode	analysiswhereclauserefs

The create_sourcemetadata_fromsasdefine.sas driver program is provided by SAS. It is ready to run on any SAS representation of a Define-XML V2.0.0 define.xml file for an ADaM or SDTM study. The driver program can be run interactively or in batch. To run the program interactively, start a SAS session, and load the driver program into the SAS editor.

The driver program is located here:

***sample study library directory*/cdisc-definexml-2.0.0-1.7/programs**

The parameters can be specified by using a SASReferences file or by specifying the parameters in the macro call.

Here are examples of calls to the %DEFINE_CREATESRCMETAFROMSASLIB macro using the two methods to specify the parameters:

```
%define_createsrcmetafromdefine(
  _cstTrgStandard=&_cstTrgStandard,
  _cstTrgStandardVersion=&_cstTrgStandardVersion,
  _cstLang=en,
  _cstUseRefLib=Y
);

%define_createsrcmetafromdefine(
  _cstDefineDataLib=srcdata,
  _cstTrgStandard=&_cstTrgStandard,
  _cstTrgStandardVersion=&_cstTrgStandardVersion,
  _cstTrgMetaLibrary=trgmeta,
  _cstTrgStudyDS=trgmeta.source_study,
  _cstTrgTableDS=trgmeta.source_tables,
  _cstTrgColumnDS=trgmeta.source_columns,
  _cstTrgCodeListDS=trgmeta.source_codelists,
  _cstTrgValueDS=trgmeta.source_values,
  _cstTrgDocumentDS=trgmeta.source_documents,
  _cstTrgAnalysisResultDS=trgmeta.source_analysisresults,
  _cstLang=en,
  _cstUseRefLib=Y,
  _cstRefTableDS=refmeta.reference_tables,
  _cstRefColumnDS=refmeta.reference_columns,
  _cstClassTableDS=refmeta.class_tables,
  _cstClassColumnDS=refmeta.class_columns,
  _cstReturn=_cst_rc,
  _cstReturnMsg=_cst_rcmsg
  );
```

For more information about the %DEFINE_CREATESRCMETAFROMDEFINE macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

After the driver program runs, the srcmeta_define_results data set is created. This data set contains informational, warning, and error messages that were generated by the driver program.

Migrating Study Source Metadata Used for the Creation of a CRT-DDS 1.0 define.Xml File for the Study

The %CSTUTILMIGRATECRTDDS2DEFINE macro migrates source metadata data sets from CRT-DDS v1.0 to Define-XML v2.0.

For CRT-DDS 1.0.0, the following source metadata SAS data sets are defined in SAS Clinical Standards Toolkit starting with version 1.5:

- source_study
- source_tables
- source_columns
- source_values
- source_documents

For Define-XML 2.0.0, the source metadata SAS data set source_codelists contains all metadata needed to create codelists in the define.xml file. The metadata includes external codelists (for example, MedDRA and WHODRUGG) and NCI metadata (for example, the so-called C-codes).

To create the source_codelists study metadata data set, you must specify two items: a list of format catalogs that define the study formats and a SAS data set that contains CDISC/NCI codelist metadata.

The migrate_crtdds_to_definexml_sdtm.sas and migrate_crtdds_to_definexml_adam.sas sample driver programs provide examples of migrating CRT-DDS 1.0.0 source metadata to Define-XML 2.0.0 source metadata. The drivers for ADaM and SDTM are similar in structure, so only the SDTM driver program is explained.

The driver program is located here:

***sample study library directory*/cdisc-definexml-2.0.0-1.7/programs**

Here is an example of the librefs that are defined after the initial setup:

```
%*************************************************************************************;
%* Define libnames for input                                                        *;
%*************************************************************************************;
%* Original CRT-DDS v1 source metadata for SDTM 3.1.2 in CST 1.7;
libname crtdds "&studyRootPath/sascstdemodata/metadata";

%*************************************************************************************;
%* Define libnames for output                                                       *;
%*************************************************************************************;
%* Migrated Define-XML v2 source metadata;
libname defv2 "&studyOutputPath/derivedstudymetadata_crtdds/%lowcase(&_cstTrgStandard)-
               &_cstTrgStandardVersion";
%*************************************************************************************;
%* Define formats                                                                   *;
%*************************************************************************************;

**********************************************************************;
* Set CDISC NCI Controlled Terminology version for this process.    *;
**********************************************************************;
%cst_getstandardsubtypes(_cstStandard=CDISC-TERMINOLOGY,_cstOutputDS=work._cstStdSubTypes);
data _null_;
  set work._cstStdSubTypes (where=(standardversion="&_cstTrgStandard" and isstandarddefault='Y'));
 * User can override CT version of interest by specifying a different where clause:         *;
 * Example: (where=(standardversion="&_cstTrgStandard" and standardsubtypeversion='201104'))*;
  call symputx('_cstCTPath',path);
  call symputx('_cstCTMemname',memname);
run;

proc datasets lib=work nolist;
  delete _cstStdSubTypes;
quit;
run;

%* SDTM Study formats in CST 1.7;
libname studyfmt "&studyRootPath/sascstdemodata/terminology/formats";

%* CDISC-NCI Terminology to be used in CST 1.7;
libname ncisdtm "&_cstCTPath";

%* Formats to be used for SDTM;
options fmtsearch = (studyfmt.formats ncisdtm.&_cstCTMemname);
```

Note: You might need to modify the librefs.

Here is an example of some of the CRT-DDS 1.0.0 metadata that must be mapped to values as expected by Define-XML 2.0.0:

```
%*******************************************************************************;
%* Create some formats for mapping                                             *;
%*******************************************************************************;
proc format;
  value $_cststd
   /* Maps from CRT-DDS values to required Define-XML v2 values */
   "CDISC SDTM"="SDTM-IG"
   "CDISC SEND"="SEND-IG"
   "CDISC ADAM"="ADAM-IG"
  ;
  value $_cstdom
   /* Map to ItemGroup/@Domain attribute */
   "QSCG" = "QS"
   "QSCS" = "QS"
   "QSMM" = "QS"
  ;
  value $_cstdomd
   /* Map to ItemGroup/Alias[@Context='DomainDescription']/@Name attribute */
   "QSCG" = "Questionnaires"
   "QSCS" = "Questionnaires"
   "QSMM" = "Questionnaires"
  ;
  value $_cstcls
   /* Maps from CRT-DDS values to required Define-XML v2 values */
   "SPECIAL PURPOSE DOMAINS" = "SPECIAL PURPOSE"
   "SPECIAL PURPOSE DATASETS" = "SPECIAL PURPOSE"
   "FINDINGS ABOUT" = "FINDINGS"
   "ADSL" = "SUBJECT LEVEL ANALYSIS DATASET"
   "ADAE" = "ADAM OTHER"
   "BDS" = "BASIC DATA STRUCTURE"
  ;
  value $_cstvlm
   /* For SDTM maps to variables that are being described by Value Level Metadata */
   "EG.EGTESTCD" = "EGORRES"
   "IE.IETESTCD" = "IEORRES"
   "TI.IETESTCD" = "IECAT"
   "LB.LBTESTCD" = "LBORRES"
   "PE.PETESTCD" = "PEORRES"
   "SC.SCTESTCD" = "SCORRES"
   "VS.VSTESTCD" = "VSORRES"
   "SUPPAE.QNAM" = "QVAL"
  ;
run;
```

Note: It is likely that you must modify some mappings based on the specific data values. It is important to use the format names as specified because these formats are used in the conversion macros.

Here is an example of the metadata conversion:

```
%*****************************************************************************;
%* Define the studyversion macro variable.                                   *;
%* This will become the MetaDataVersion/@OID attribute                       *;
%* In CRT-DDS this was the source_study.definedocumentname column            *;
%* Also define the SASRef macro variable to use for the SASRef column in the *;
%* source_xxx data sets.                                                     *;
%*****************************************************************************;
proc sql noprint;
 select definedocumentname, SASRef into :studyversion, :SASRef
 from crtdds.source_study;
quit;

%*****************************************************************************;
%* Migrate source tables                                                     *;
%*****************************************************************************;
%cstutilmigratecrtdds2define(_cstSrcLib=crtdds, _cstSrcDS=source_study,
                             _cstTrgDS=defv2.source_study, _cstStudyVersion=&studyversion,
                             _cstStandard=&_cstTrgStandard, _cstCheckValues=Y);
%cstutilmigratecrtdds2define(_cstSrcLib=crtdds, _cstSrcDS=source_tables,
                             _cstTrgDS=defv2.source_tables, _cstStudyVersion=&studyversion,
                             _cstStandard=&_cstTrgStandard, _cstCheckValues=Y);
%cstutilmigratecrtdds2define(_cstSrcLib=crtdds, _cstSrcDS=source_columns,
                             _cstTrgDS=defv2.source_columns, _cstStudyVersion=&studyversion,
                             _cstStandard=&_cstTrgStandard, _cstCheckValues=Y);
%cstutilmigratecrtdds2define(_cstSrcLib=crtdds, _cstSrcDS=source_values,
                             _cstTrgDS=defv2.source_values, _cstStudyVersion=&studyversion,
                             _cstStandard=&_cstTrgStandard, _cstCheckValues=Y);
%cstutilmigratecrtdds2define(_cstSrcLib=crtdds, _cstSrcDS=source_documents,
                             _cstTrgDS=defv2.source_documents, _cstStudyVersion=&studyversion,
                             _cstStandard=&_cstTrgStandard, _cstCheckValues=Y);
```

The creation of the source_codelists table is a separate task because this table was not available in the CRT-DDS 1.0.0 source metadata.

Here is an example of the call to the %CSTUTILGETNCIMETADATA macro, in which the _cstFormatCatalogs parameter is blank. This indicates that the format catalogs that define the code lists to include in the source_codelists table are taken from the value of the FMTSEARCH option.

```
%*****************************************************************************;
```

```
%* Create source_codelists                                                      *;
%*******************************************************************************;

%* Get formats ;
 %cstutilgetncimetadata(
  _cstFormatCatalogs=,
  _cstNCICTerms=ncisdtm.cterms,
  _cstLang=en,
  _cstStudyVersion=&studyversion,
  _cstStandard=&_cstTrgStandard,
  _cstStandardVersion=&_cstTrgStandardVersion,
  _cstFmtDS=work._cstformats,
  _cstSASRef=&SASRef,
  _cstReturn=_cst_rc,
  _cstReturnMsg=_cst_rcmsg
  );

%* Create a data set with all applicable formats. ;
data work.cl_column_value(keep=xmlcodelist);
  set defv2.source_columns defv2.source_values;
    xmlcodelist=upcase(xmlcodelist);
    if xmlcodelist ne '';
run;

proc sort data=work.cl_column_value nodupkey;
  by xmlcodelist;
run;

%* Only keep applicable formats. ;
proc sql;
  create table defv2.source_codelists
  as select
    nci.*
  from
    work._cstformats nci, work.cl_column_value cv
  where (upcase(compress(nci.codelist, '$')) =
         upcase(compress(cv.xmlcodelist, '$')))
  ;
quit;
```

Here is an example of the last part of the sample driver program, in which metadata for external controlled terminology is added to the source_codelists data set:

```
%*******************************************************************************;
%* Updates for External Controlled Terminology                                  *;
%*******************************************************************************;
```

```
proc sql;
 insert into defv2.source_codelists
   (sasref, codelist, codelistname, codelistdatatype, dictionary, version,
    studyversion, standard, standardversion)
    values ("&SASRef", "CL.AEDICT", "Adverse Event Dictionary", "text", "MEDDRA", "8.0",
            "&studyversion", "&_cstTrgStandard", "&_cstTrgStandardVersion")
    values ("&SASRef", "CL.DRUGDCT", "Drug Dictionary", "text", "WHODRUG", "200204",
            "&studyversion", "&_cstTrgStandard", "&_cstTrgStandardVersion")
            ;
quit;

data defv2.source_columns;
  set defv2.source_columns;
  if table="AE" and column in ("AEDECOD" "AEBODSYS") then xmlcodelist="CL.AEDICT";
  if table="CM" and column in ("CMDECOD" "CMCLAS" "CMCLASCD")
    then xmlcodelist="CL.DRUGDCT";
run;
```

For more information about the %CSTUTILMIGRATECRTDDS2DEFINE macro and the cstutilgetncimetadata macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

CDISC Dataset-XML

Overview

CDISC Dataset-XML defines a standard format for transporting tabular data in XML between any two entities based on CDISC ODM XML. In addition to supporting the transport of data sets as part of a submission to the FDA, Dataset-XML can be used to exchange data between two parties. For example, the Dataset-XML data format can be used by a CRO to transmit SDTM or ADaM data sets to a sponsor organization. Dataset-XML supports SDTM, ADaM, and SEND data sets but can also be used to exchange any other type of tabular data set.

Dataset-XML and Define-XML

The metadata for a data set in a Dataset-XML file must conform to the Define-XML standard. Each Dataset-XML file contains data for a single data set, but a single Define-

XML file describes all of the data sets included in the folder. Both Define-XML 1.0 and Define-XML 2.0 are supported for use with Dataset-XML.

Creating Dataset-XML Files from SAS Data Sets: %DATASETXML_WRITE Macro

The %DATASETXML_WRITE macro creates a Dataset-XML file from a SAS data set or from a library of SAS data sets.

Here is an example:

```
libname srcdata  "&studyRootPath/data";
filename srcmeta "&studyRootPath/sourcexml/define.xml";
libname xmldata  "&studyOutputPath/sourcexml";

%datasetxml_write(
  _cstSourceLibrary=srcdata,
  _cstOutputLibrary=xmldata
  _cstSourceMetadataDefineFileRef=srcmeta,
  _cstCheckLengths=Y,
  _cstIndent=N,
  _cstZip=Y,
  _cstDeleteAfterZip=N
  );
```

In this example, the Dataset-XML files are compressed into ZIP files, with one ZIP file per Dataset-XML file. But, the Dataset-XML files are not deleted after compression.

Instead of specifying inputs (_cstSourceLibrary and _cstSourceMetadataDefineFileRef) and outputs (_cstOutputLibrary) for the process with the parameters, you can use the more traditional SASReferences data set. These different ways of specifying parameters are demonstrated in two sample programs: create_datasetxml_standalone.sas and create_datasetxml.sas. These sample programs are located here:

***sample study library directory*/cdisc-datasetxml-1.0.0-1.7/programs**

Note: The create_datasetxml_standalone.sas sample program does not use a SASReferences data set and writes reports only in the SAS log file.

The Define-XML file that describes the SAS data sets must contain metadata about all SAS data sets and all variables to convert. The Dataset-XML files by themselves do not have any information about the SAS data sets (name and label) or the SAS variables (name, label, data type, length, and display format). When the Dataset-XML file is converted back to SAS data sets, this information must be provided by the Define-XML file.

Here is an example of a Dataset-XML file:

```
<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:data="http://www.cdisc.org/ns/Dataset-XML/v1.0"
  ODMVersion="1.3.2" FileType="Snapshot" FileOID="cdisc01.AE"
  PriorFileOID="www.cdisc.org.Studycdisc01-Define-XML_2.0.0"
  CreationDateTime="2014-06-23T13:18:18"
  data:DatasetXMLVersion="1.0.0">
  <ClinicalData StudyOID="cdisc01"
    MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
    <ItemGroupData ItemGroupOID="IG.AE" data:ItemGroupDataSeq="1">
    ...
      <ItemData ItemOID="IT.AE.AETERM" Value="AGITATED"/>
```

Here is an example of a Define-XML file:

```
<ODM ... >

  <Study OID="cdisc01">
    ...
    <MetaDataVersion OID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2"
      Name="Study CDISC01, Data Definitions"
      Description="Study CDISC01, Data Definitions"
      def:DefineVersion="2.0.0" def:StandardName="SDTM-IG"
      def:StandardVersion="3.1.2">
  ...
      <ItemGroupDef OID="IG.AE"
        Domain="AE" Name="AE" Repeating="Yes" IsReferenceData="No"
        SASDatasetName="AE" Purpose="Tabulation"
        def:Structure="One record per adverse event per subject"
        def:Class="EVENTS" def:ArchiveLocationID="LF.AE">
 ...
         <ItemRef ItemOID="IT.AE.AETERM" OrderNumber="6" Mandatory="Yes"/>
  ...
<ItemDef OID="IT.AE.AETERM" Name="AETERM" DataType="text" Length="25"
         SASFieldName="AETERM">
```

A Dataset-XML file must satisfy these requirements:

- The ClinicalData attributes StudyOID and MetaDataVersionOID must be the same value as the corresponding OID attributes in the define.xml document.
- The ItemGroupOID value must be the same value as the corresponding ItemGroup OID attribute in the define.xml document.
- All ItemOID attributes in the ItemData elements must have values identical to the values of the corresponding ItemOID attributes in the ItemRef elements that are child elements of the corresponding ItemGroupDef element in the define.xml document.

It would be an error to try to extract from the Dataset-XML file the SAS data set name from an ItemGroup object identifier (ItemGroupOID="IG.AE"). It would also be an error to try to extract the variable name from an object identifier (ItemOID="IT.AE.AETERM"). There is no requirement concerning the values of the identifiers.

SAS tables and columns are matched to @SASDatasetName (or, if this value is not specified, @Name) and @SASFieldName (or, if this value is not specified, @Name). SASDatasetName and SASFieldName are optional but @Name is required. So, @Name is always available.

If the ItemGroup or ItemDef is not found, the XML is generated with this pattern for @ItemGroupOID and @ItemOID:

```
ItemGroupOID = "IG.<table>"
ItemOID = "IT.<table>.<column>"
```

Although ItemGroupOID and ItemOID are generated for missing ItemGroups or ItemDefs, it is important to realize that this can lead to problems later when converting Dataset-XML files to SAS data sets. For example, when converting a Dataset-XML file into a SAS data set, ItemGroupOIDs or ItemOIDs that cannot be matched in the corresponding Define-XML file can lead to missing SAS data sets or missing SAS data set variables.

Warnings are written to the SAS log file and the write_results data set in the results folder.

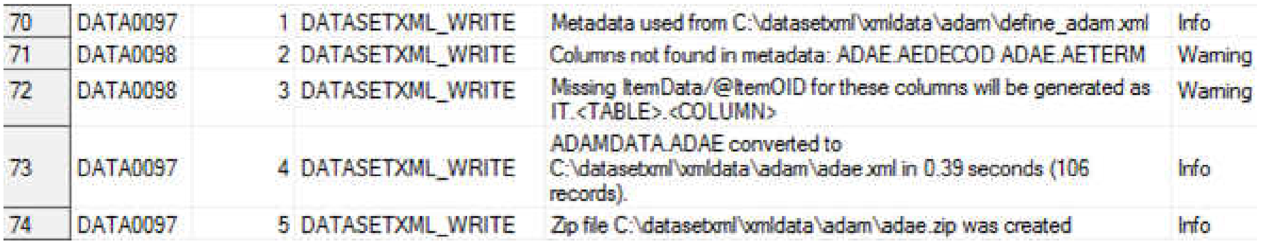
Here is an example of the SAS log file:

```
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Columns not found in metadata:
         ADAE.AEDECOD ADAE.AETERM
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Missing ItemData/@ItemOID for column=AEDECOD
```

```
         has been set to IT.ADAE.AEDECOD
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Missing ItemData/@ItemOID for column=AETERM
         has been set to IT.ADAE.AETERM
```

The following display shows an example of the write_results data set as created by the create_datasetxml.sas sample program:

Figure 9.33 *Example write_results Data Set*



70	DATA0097	1	DATASETXML_WRITE	Metadata used from C:\datasetxml\xmldata\adam\define_adam.xml	Info
71	DATA0098	2	DATASETXML_WRITE	Columns not found in metadata: ADAE.AEDECOD ADAE.AETERM	Warning
72	DATA0098	3	DATASETXML_WRITE	Missing ItemData/@ItemOID for these columns will be generated as IT.<TABLE>.<COLUMN>	Warning
73	DATA0097	4	DATASETXML_WRITE	ADAMDATA.ADAE converted to C:\datasetxml\xmldata\adam\adae.xml in 0.39 seconds (106 records).	Info
74	DATA0097	5	DATASETXML_WRITE	Zip file C:\datasetxml\xmldata\adam\adae.zip was created	Info

The @IsReferenceData attribute in the Define-XML file determines whether the data set is considered ReferenceData or ClinicalData. Here is an example:

```
   <ReferenceData StudyOID="cdisc01"
       MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
       <ItemGroupData ItemGroupOID="IG.TE" data:ItemGroupDataSeq="1">
         <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
         <ItemData ItemOID="IT.TE.DOMAIN" Value="TE"/>
         <ItemData ItemOID="IT.TE.ETCD" Value="EOS"/>
         <ItemData ItemOID="IT.TE.ELEMENT" Value="End of Study"/>
         <ItemData ItemOID="IT.TE.TESTRL" Value="Study Termination"/>
         <ItemData ItemOID="IT.TE.TEDUR" Value="P1D"/>
       </ItemGroupData>

     <ClinicalData StudyOID="cdisc01"
       MetaDataVersionOID="MDV.CDISC01.SDTMIG.3.1.2.SDTM.1.2">
       <ItemGroupData ItemGroupOID="IG.AE" data:ItemGroupDataSeq="1">
         <ItemData ItemOID="IT.STUDYID" Value="CDISC01"/>
         <ItemData ItemOID="IT.AE.DOMAIN" Value="AE"/>
         <ItemData ItemOID="IT.USUBJID" Value="CDISC01.100008"/>
         <ItemData ItemOID="IT.AE.AESEQ" Value="1"/>
         <ItemData ItemOID="IT.AE.AESPID" Value="1"/>
         <ItemData ItemOID="IT.AE.AETERM" Value="AGITATED"/>
```

The _cstCheckLengths macro parameter enables the %DATASETXML_WRITE macro to determine whether the lengths defined in the metadata are long enough for character data. This check is important to avoid data truncation problems when importing the

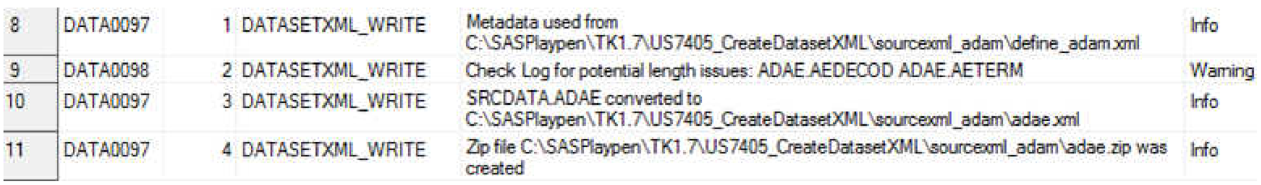
Dataset-XML files into SAS data set with the %DATASETXML_READ macro. Warnings are written to the SAS log file and the write_results data set in the results folder.

Here is an example of the SAS log file:

```
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Length too short: __ItemGroupOID=IG.ADAE
        __ItemOID=IT.ADAE.AETERM Length=20 _valueLength=24 value=HEARTBURN-LIKE DYSPEPSIA
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Length too short: __ItemGroupOID=IG.ADAE
        __ItemOID=IT.ADAE.AETERM Length=20 _valueLength=25 value=ACID REFLUX (OESOPHAGEAL)
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Length too short: __ItemGroupOID=IG.ADAE
        __ItemOID=IT.ADAE.AEDECOD Length=20 _valueLength=32 value=Gastrooesophageal reflux disease
WARNING: [CSTLOGMESSAGE.DATASETXML_WRITE] Length too short: __ItemGroupOID=IG.ADAE
        __ItemOID=IT.ADAE.AETERM Length=20 _valueLength=25 value=ACID REFLUX (OESOPHAGEAL)
```

The following display shows an example of the write_results data set:

Figure 9.34 *Example write_results Data Set*



8	DATA0097	1	DATASETXML_WRITE	Metadata used from C:\SASPlaypen\TK1.7\US7405_CreateDatasetXML\sourcexml_adam\define_adam.xml	Info
9	DATA0098	2	DATASETXML_WRITE	Check Log for potential length issues: ADAE.AEDECOD ADAE.AETERM	Warning
10	DATA0097	3	DATASETXML_WRITE	SRCDATA.ADAE converted to C:\SASPlaypen\TK1.7\US7405_CreateDatasetXML\sourcexml_adam\adae.xml	Info
11	DATA0097	4	DATASETXML_WRITE	Zip file C:\SASPlaypen\TK1.7\US7405_CreateDatasetXML\sourcexml_adam\adae.zip was created	Info

The %DATASETXML_WRITE macro also checks that numeric variables in ADaM data sets that represent date and time information have a DisplayFormat defined in the Define-XML file.

Creating SAS Data Sets from Dataset-XML Files: %DATASETXML_READ Macro

The %DATASETXML_READ macro creates a SAS data set or a library of SAS data sets from Dataset-XML files.

Here is an example:

```
%datasetxml_read(
  _cstSourceDatasetXMLLibrary=dataxml,
  _cstOutputLibrary=sdtmdata,
  _cstSourceMetadataDefineFileRef=defxml,
  _cstDatetimeLength=64,
  _cstAttachFormats=Y,
  _cstNumObsWrite=10000
  );
```

Instead of specifying inputs (_cstSourceDatasetXMLLibrary and _cstSourceMetadataDefineFileRef) and outputs (_cstOutputLibrary) for the process with parameters, you can use the more traditional SASReferences data set. These different ways of specifying parameters are demonstrated in two sample programs: create_sas_from_datasetxml_standalone.sas and create_sas_from_datasetxml.sas. These sample programs are located here:

***sample study library directory*/cdisc-datasetxml-1.0.0-1.7/programs**

Note: The create_sas_from_datasetxml_standalone.sas sample program does not use a SASReferences data set and writes reports only in the SAS log file.

The Define-XML file that describes the Dataset-XML files must contain metadata information about all Dataset-XML files and all variables to convert to SAS data sets. The Dataset-XML files by themselves do not have any information about the SAS data sets (name and label) or the SAS variables (name, label, data type, length, and display format).

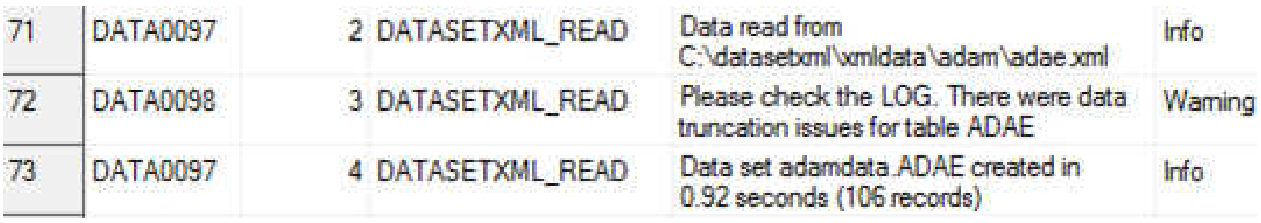
Character variables that represent date- and time-related information in ADaM or SDTM data conform to the ISO 8601 standard and do not have a length specified in the Define-XML file. The _cstDateTimeLength parameter specifies the length to use for these variables when they are converted to SAS data sets. If the lengths of character variables are too short to hold the data, warnings are written to the SAS log file and the read_results data set in the results folder.

Here is an example of the SAS log file:

```
WARNING: [CSTLOGMESSAGE.DATASETXML_READ] TRUNCATION occurred: Length=20 too short for
         ItemGroupDataSeq=12 IT.ADAE.AETERM value=HEARTBURN-LIKE DYSPEPSIA (length=24)
WARNING: [CSTLOGMESSAGE.DATASETXML_READ] TRUNCATION occurred: Length=20 too short for
         ItemGroupDataSeq=25 IT.ADAE.AETERM value=HEARTBURN-LIKE DYSPEPSIA (length=24)
WARNING: [CSTLOGMESSAGE.DATASETXML_READ] TRUNCATION occurred: Length=20 too short for
         ItemGroupDataSeq=28 IT.ADAE.AETERM value=ACID REFLUX (OESOPHAGEAL)
WARNING: [CSTLOGMESSAGE.DATASETXML_READ] TRUNCATION occurred: Length=20 too short for
         ItemGroupDataSeq=28 IT.ADAE.AEDECOD value=Gastrooesophageal reflux disease (length=32)
```

The following display shows an example of the read_results data set as created by the create_sas_from_datasetxml.sas sample program:

Figure 9.35 *Example read_results Data Set*



71	DATA0097	2	DATASETXML_READ	Data read from C:\datasetxml\xmldata\adam\adae.xml	Info
72	DATA0098	3	DATASETXML_READ	Please check the LOG. There were data truncation issues for table ADAE	Warning
73	DATA0097	4	DATASETXML_READ	Data set adamdata.ADAE created in 0.92 seconds (106 records)	Info

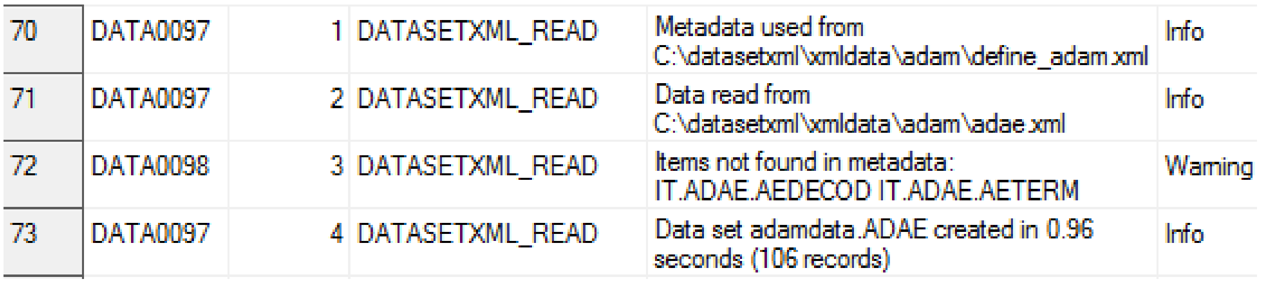
Inconsistencies between the Dataset-XML file and the Define-XML file, which can lead to issues with matching data to metadata, are written to the SAS log file and the read_results data set in the results folder.

Here is an example of the SAS log file:

```
WARNING: [CSTLOGMESSAGE.DATASETXML_READ] Items not found in metadata:
         IT.ADAE.AEDECOD IT.ADAE.AETERM
```

The following display shows an example of the read_results data set:

Figure 9.36 *Example read_results Data Set*



70	DATA0097	1	DATASETXML_READ	Metadata used from C:\datasetxml\xmldata\adam\define_adam.xml	Info
71	DATA0097	2	DATASETXML_READ	Data read from C:\datasetxml\xmldata\adam\adae.xml	Info
72	DATA0098	3	DATASETXML_READ	Items not found in metadata: IT.ADAE.AEDECOD IT.ADAE.AETERM	Warning
73	DATA0097	4	DATASETXML_READ	Data set adamdata.ADAE created in 0.96 seconds (106 records)	Info

In the following example, the ADAE data set is created without the AETERM and AEDECOD variables, as shown in this PROC COMPARE output:

```
Dataset                     Created          Modified  NVar     NObs  Label

DATABASE.ADAE   23JUN14:09:01:29  23JUN14:09:01:29    61      106  Adverse Event Analysis Dataset
DATACOMP.ADAE   02JUL14:12:58:14  02JUL14:12:58:14    59      106  Adverse Event Analysis Dataset


Variables Summary
```

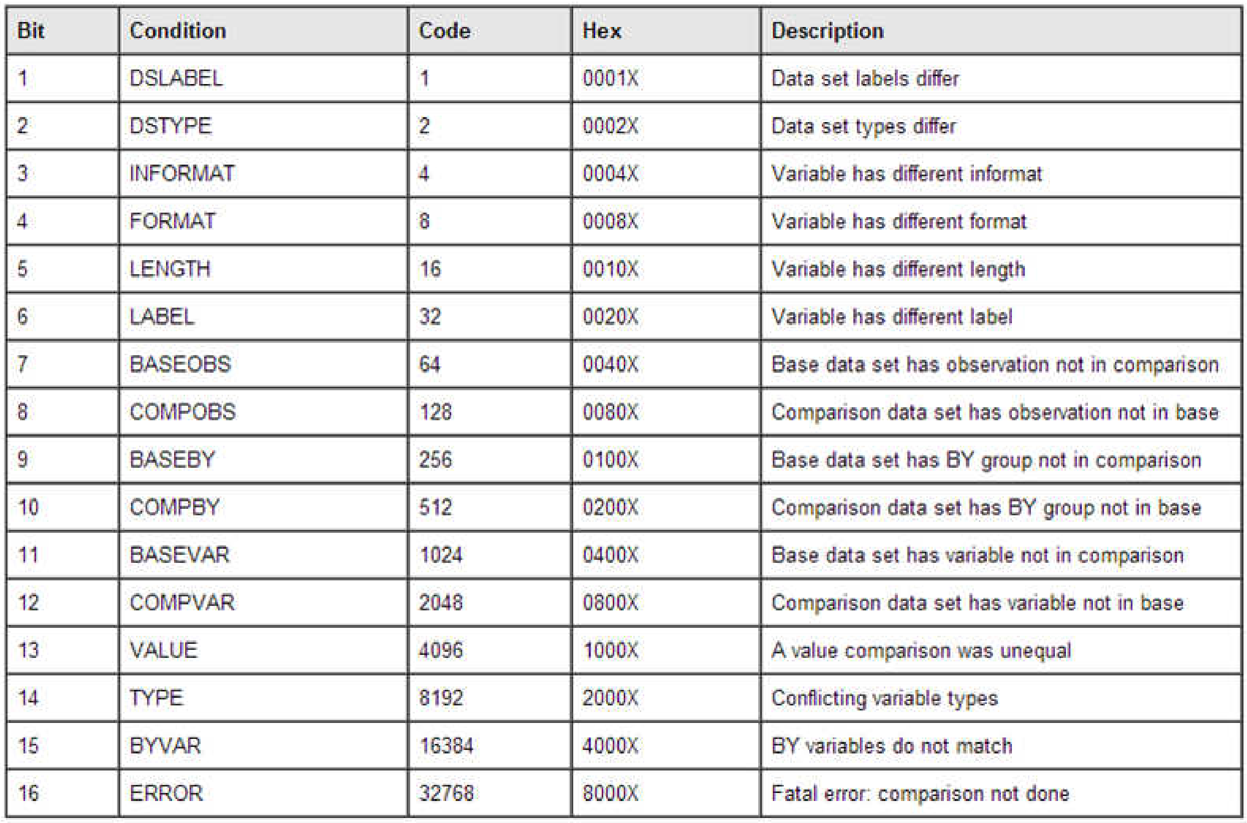
```
Number of Variables in Common: 59.
Number of Variables in DATABASE.ADAE but not in DATACOMP.ADAE: 2.


Listing of Variables in DATABASE.ADAE but not in DATACOMP.ADAE

Variable  Type  Length  Label

AETERM    Char     200  Reported Term for the Adverse Event
AEDECOD   Char     200  Dictionary-Derived Term
```

The sample programs create_sas_from_datasetxml.sas and create_sas_from_datasetxml_standalone.sas also contain a call to the %CSTUTILCOMPAREDATASETS macro. This call compares the original SAS data sets to the SAS data sets that were created from the Dataset-XML files.

```
%cstutilcomparedatasets(
  _cstLibBase=sdtmdat0,
  _cstLibComp=sdtmdata,
  _cstCompareLevel=0,
  _cstCompOptions=%str(criterion=0.00000000000001),
  _cstCompDetail=Y
  );
```

For every SAS data set that is compared, the macro reports the error code as returned by PROC COMPARE. The following table shows the error codes:

Figure 9.37 *Error Codes Returned by PROC COMPARE*



Bit	Condition	Code	Hex	Description
1	DSLABEL	1	0001X	Data set labels differ
2	DSTYPE	2	0002X	Data set types differ
3	INFORMAT	4	0004X	Variable has different informat
4	FORMAT	8	0008X	Variable has different format
5	LENGTH	16	0010X	Variable has different length
6	LABEL	32	0020X	Variable has different label
7	BASEOBS	64	0040X	Base data set has observation not in comparison
8	COMPOBS	128	0080X	Comparison data set has observation not in base
9	BASEBY	256	0100X	Base data set has BY group not in comparison
10	COMPBY	512	0200X	Comparison data set has BY group not in base
11	BASEVAR	1024	0400X	Base data set has variable not in comparison
12	COMPVAR	2048	0800X	Comparison data set has variable not in base
13	VALUE	4096	1000X	A value comparison was unequal
14	TYPE	8192	2000X	Conflicting variable types
15	BYVAR	16384	4000X	BY variables do not match
16	ERROR	32768	8000X	Fatal error: comparison not done

For example, `code=40 (8+32)` indicates that a format and a label are different. This message is written to the SAS log file:

```
WARNING: [CSTLOGMESSAGE.CSTUTILCOMPAREDATASETS] Comparing srcdata.adqs and
         trgdata.adqs  - Differences: FORMAT/LABEL (SysInfo=40)
```

When converting SAS data sets to Dataset-XML and then converting back to SAS data sets, here are difference to expect:

- Date- and time-related columns do not have a length defined in the Define-XML metadata.

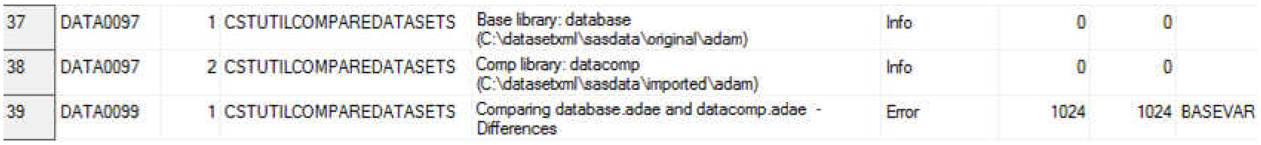
Specify a length to assign in the macro (for example, `_cstdatetimeLength=64`). The length is used to create the date- and time-related columns but can be different from the original lengths.

- SAS numeric variables are created with a length of 8 to avoid loss of precision, even when the original length or the length specified in the Define-XML file is less than 8.
- Character variables (DataType="text") that do not have a length specified in the Define-XML file are created with a length of 200.
- Small differences in precision can be expected around the machine precision for numeric variables that represent real numbers.
- Character data that contains leading spaces or trailing spaces loses the leading and trailing spaces.

By specifying PROC COMPARE options with the _cstCompOptions parameter, you can specify that the comparison be less precise. For example, `_cstCompOptions=%str(criterion=0.00000000000001)`. Lesser precision prevents differences close to machine precision from being reported as errors.

The following display shows an example of data set differences reported in the read_results data set:

Figure 9.38 *Example read_results Data Set*



37	DATA0097	1	CSTUTILCOMPAREDATASETS	Base library: database (C:\datasetxml\sasdata\original\adam)	Info	0	0	
38	DATA0097	2	CSTUTILCOMPAREDATASETS	Comp library: datacomp (C:\datasetxml\sasdata\imported\adam)	Info	0	0	
39	DATA0099	1	CSTUTILCOMPAREDATASETS	Comparing database.adae and datacomp.adae - Differences	Error	1024	1024	BASEVAR

10

CDISC ADaM Data

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Overview

The SAS Clinical Standards Toolkit provides the following support for the CDISC ADaM 2.1 standard:

- A metadata representation of the CDISC ADaM standard in a set of SAS data sets.

  For more information, see "SAS Representation of CDISC ADaM Metadata" on page 414.

- The ability to derive template (zero-observation) data sets for the ADaM subject-level Analysis (ADSL) data set, a representative Basic Data Structure (BDS) data set, and an ADaM Adverse Event (ADAE) data set.

  Note: Templates for additional ADaM data structures will be provided in future releases after the CDISC ADaM team approves them for use.

- Implementation of version 1.2 CDISC ADaM validation checks as prepared by the CDISC ADaM team.

  In addition, SAS has provided validation checks for the ADAE and ADaM Time-to-Event (ADTTE) domains. These validation checks are derived from individual implementation guides provided by CDISC. For the ADAE domain, the release of the implementation guide is *Analysis Data Model (ADaM) Data Structure for Adverse Event Analysis, Version 1.0*. For the ADTTE domain, the release of the implementation guide is *ADaM Basic Data Structure for Time-to-Event Analyses, Version 1.0*.

- A sample reporting methodology that combines the analysis results metadata with a sample set of tables, listings, and figures (TLF) metadata to create example clinical study reports.

SAS Representation of CDISC ADaM Metadata

The SAS Clinical Standards Toolkit provides a SAS metadata representation of each supported standard. The SAS Clinical Standards Toolkit implementation of the CDISC ADaM 2.1 standard provides an interpretation of the *Analysis Data Model (ADaM), Version 2.1* document and the *Analysis Data Model (ADaM) Implementation Guide, Version 1.0*. The Analysis Data Model identifies four types of ADaM metadata that are captured and supported by the SAS Clinical Standards Toolkit.

The specific sources from the ADaM document for each metadata type are shown in the following table:

Table 10.1 *ADaM Document Sources for Each Metadata Type*

Metadata Type	ADaM Document Source
Analysis Data Set	Section 5.1, Analysis Data Set Metadata, Table 5.1.1
Analysis Variable	Section 5.2, Analysis Variable Metadata, Table 5.2.1
Analysis Parameter	Section 5.2.1, Analysis Parameter Value-Level Metadata
Analysis Results	Section 5.3, Analysis Results Metadata, Table 5.3.1

In the SAS Clinical Standards Toolkit, the Analysis data set metadata is captured in the reference_tables and class_tables data sets, which are located here:

***global standards library directory*/standards/ cdisc-adam-2.1-1.7/metadata**

The SAS Clinical Standards Toolkit captures more metadata than might be specified for a standard. This helps support SAS Clinical Standards Toolkit functionality and provides greater consistency across supported standards.

The following table shows the mapping of the Analysis data set metadata defined by the CDISC ADaM team to the SAS metadata representation in the reference_tables data set:

Table 10.2 *Analysis Data Set Metadata*

Analysis Data Set Metadata Field**	Description**	reference_tables Column Mapping
DATASET NAME	The file name of the dataset, hyperlinked to the corresponding analysis dataset variable descriptions (that is, the data definition table) within the define file.	table
DATASET DESCRIPTION	A short descriptive summary of the contents of the dataset	label

Analysis Data Set Metadata Field**	Description**	reference_tables Column Mapping
DATASET LOCATION	The folder and filename where the dataset can be found, ideally hyperlinked to the actual dataset (that is, XPT file)	xmlpath
DATASET STRUCTURE	The level of detail represented by individual records in the dataset (for example,, “One record per subject,” “One record per subject per visit,” “One record per subject per event”).	structure
KEY VARIABLES OF DATASET	A list of variable names that parallels the structure, ideally uniquely identifies and indexes each record in the dataset.	keys
CLASS OF DATASET	Identification of the general class of the dataset using the name of the ADaM structure (that is, “ADAE”, “ADSL,” “BDS”) or “OTHER” if not an ADaM-specified structure	class
DOCUMENTATION	Description of the source data, processing steps, and analysis decisions pertaining to the creation of the dataset. Software code of various levels of functionality and complexity, such as pseudo-code or actual code fragments might be provided. Links or references to external documents (for example, protocol, statistical analysis plan, software code) might be used.	documentation

**Source: *Analysis Data Model (ADaM), Version 2.1*, Section 5.1, Analysis Dataset Metadata, Table 5.1.1

The reference_tables data set provided with the SAS Clinical Standards Toolkit contains three records for the ADaM ADAE data set, ADaM ADSL data set, and a representative ADaM BDS data set. CDISC ADaM specifies that only the ADSL data set is required. Any number of BDS data sets can be defined as required for each study.

In the SAS Clinical Standards Toolkit, Analysis Variable metadata is captured in the reference_columns and class_columns data sets in the global standards library folder:

***global standards library directory*/standards/ cdisc-adam-2.1-1.7/metadata**

The following table shows the mapping of Analysis Variable metadata defined by the CDISC ADaM team to the SAS metadata representation in the reference_columns data set:

Table 10.3 *Analysis Variable Metadata*

Analysis Variable Metadata Field**	Description**	reference_ columns Column Mapping
DATASET NAME	The filename of the analysis dataset	table
VARIABLE NAME	The name of the variable	column
VARIABLE LABEL	A brief description of the variable	label
VARIABLE TYPE	The variable type. Valid values are as defined in the Case Report Tabulation Data Definition Specification Standard (for example, in version 1.0.0 they include “text,” “integer,” and “float”).	xmldatatype
DISPLAY FORMAT	The variable display information (that is, the format used for the variable in a tabular or graphical presentation of results). It is suggested that the syntax be consistent with the format terminology incorporated in the software application used for analysis (for example, $16 or 3.1 if using SAS).	displayformat
CODELIST / CONTROLLED TERMS	A list of valid values or allowable codes and their corresponding decodes for the variable. The field can include a reference to an external codelist (identified by name and version) or a hyperlink to a list of the values in the codelist/controlled terms section of the define file.	xmlcodelist

Analysis Variable Metadata Field**	Description**	reference_columns Column Mapping
SOURCE / DERIVATION	Provides details about the variable's lineage – what was the predecessor, where the variable came from in the source data (SDTM or other analysis dataset) or how the variable was derived. This field is used to identify the immediate predecessor source and/or a brief description of the algorithm or process applied to that sourceand can contain hyperlinked text that refers readers to additional information. The source / derivation can be as simple as a two-level name (for example, ADSL.AGEGR)identifying the data file and variable that is the source of the variable (that is, a variable copied with no change). It can be a simple description of a derivation and the variable used in the derivation (for example, "categorization of ADSL.BMI"). It can also be a complex algorithm, where the element contains a complete description of the derivation algorithm and/or a link to a document containing it and/or a link to the analysis dataset creation program.	origin comment (supplemented by origin and algorithm from the source metadata, such as SDTM)

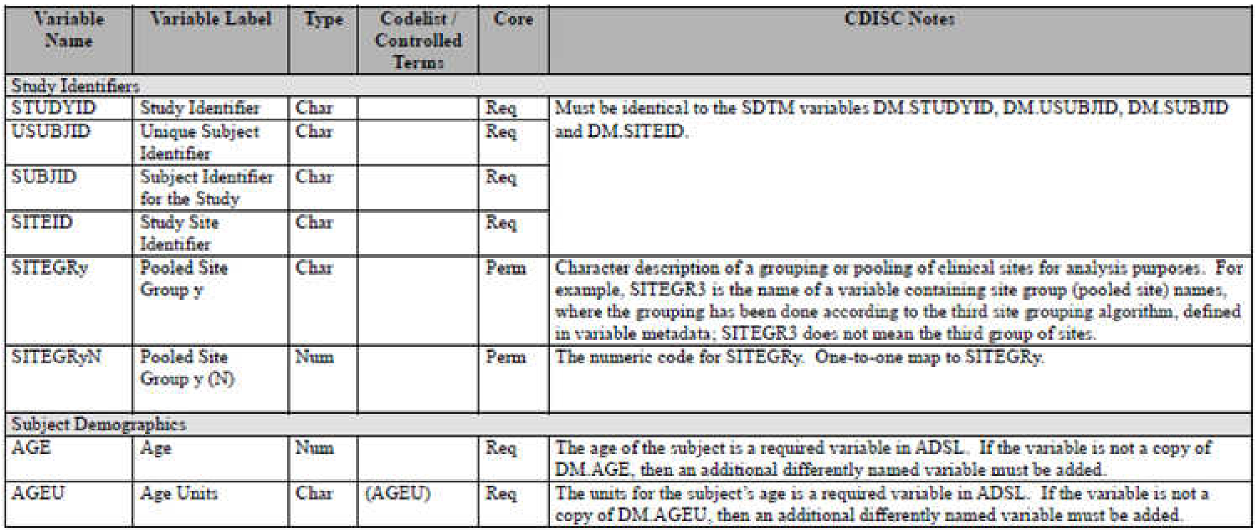
**Source: *Analysis Data Model (ADaM), Version 2.1*, Section 5.2, Analysis Variable Metadata, Table 5.2.1

The reference_columns data set provided with the SAS Clinical Standards Toolkit contains one record for each column in each of the three data sets (ADSL, BDS, and ADAE) in the reference_tables data set. This results in 63 records (columns) for ADSL, 142 records (columns) for BDS, and 85 records (columns) for the ADAE data set.

Core reference_columns metadata for each column is in the *Analysis Data Model (ADaM) Implementation Guide, Version 1.0*. Figure 10.1 on page 419 provides an excerpt of ADSL column metadata as itemized in Table 3.1.1 of the *Analysis Data Model*

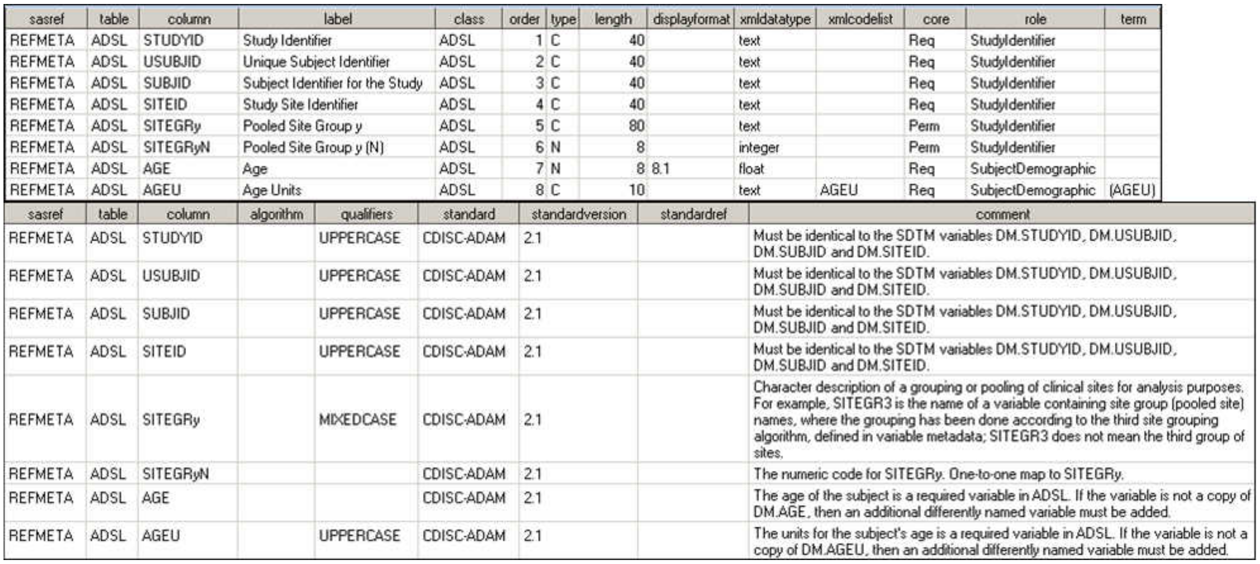
(ADaM) Implementation Guide, Version 1.0. This metadata has been translated into the SAS representation of ADSL as shown in Figure 10.2 on page 419.

Figure 10.1 *ADSL Columns as Specified in the Analysis Data Model (ADaM) Implementation Guide*



Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
Study Identifiers					
STUDYID	Study Identifier	Char		Req	Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
USUBJID	Unique Subject Identifier	Char		Req	
SUBJID	Subject Identifier for the Study	Char		Req	
SITEID	Study Site Identifier	Char		Req	
SITEGRy	Pooled Site Group y	Char		Perm	Character description of a grouping or pooling of clinical sites for analysis purposes. For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site grouping algorithm, defined in variable metadata; SITEGR3 does not mean the third group of sites.
SITEGRyN	Pooled Site Group y (N)	Num		Perm	The numeric code for SITEGRy. One-to-one map to SITEGRy.
Subject Demographics					
AGE	Age	Num		Req	The age of the subject is a required variable in ADSL. If the variable is not a copy of DM.AGE, then an additional differently named variable must be added.
AGEU	Age Units	Char	(AGEU)	Req	The units for the subject's age is a required variable in ADSL. If the variable is not a copy of DM.AGEU, then an additional differently named variable must be added.

Figure 10.2 *ADSL Columns as Defined in reference_columns Data Set*



sasref	table	column	label	class	order	type	length	displayformat	xmldatatype	xmlcodelist	core	role	term
REFMETA	ADSL	STUDYID	Study Identifier	ADSL	1	C	40		text		Req	StudyIdentifier	
REFMETA	ADSL	USUBJID	Unique Subject Identifier	ADSL	2	C	40		text		Req	StudyIdentifier	
REFMETA	ADSL	SUBJID	Subject Identifier for the Study	ADSL	3	C	40		text		Req	StudyIdentifier	
REFMETA	ADSL	SITEID	Study Site Identifier	ADSL	4	C	40		text		Req	StudyIdentifier	
REFMETA	ADSL	SITEGRy	Pooled Site Group y	ADSL	5	C	80		text		Perm	StudyIdentifier	
REFMETA	ADSL	SITEGRyN	Pooled Site Group y (N)	ADSL	6	N	8		integer		Perm	StudyIdentifier	
REFMETA	ADSL	AGE	Age	ADSL	7	N	8	8.1	float		Req	SubjectDemographic	
REFMETA	ADSL	AGEU	Age Units	ADSL	8	C	10		text	AGEU	Req	SubjectDemographic	(AGEU)

sasref	table	column	algorithm	qualifiers	standard	standardversion	standardref	comment
REFMETA	ADSL	STUDYID		UPPERCASE	CDISC-ADAM	2.1		Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
REFMETA	ADSL	USUBJID		UPPERCASE	CDISC-ADAM	2.1		Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
REFMETA	ADSL	SUBJID		UPPERCASE	CDISC-ADAM	2.1		Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
REFMETA	ADSL	SITEID		UPPERCASE	CDISC-ADAM	2.1		Must be identical to the SDTM variables DM.STUDYID, DM.USUBJID, DM.SUBJID and DM.SITEID.
REFMETA	ADSL	SITEGRy		MIXEDCASE	CDISC-ADAM	2.1		Character description of a grouping or pooling of clinical sites for analysis purposes. For example, SITEGR3 is the name of a variable containing site group (pooled site) names, where the grouping has been done according to the third site grouping algorithm, defined in variable metadata; SITEGR3 does not mean the third group of sites.
REFMETA	ADSL	SITEGRyN			CDISC-ADAM	2.1		The numeric code for SITEGRy. One-to-one map to SITEGRy.
REFMETA	ADSL	AGE			CDISC-ADAM	2.1		The age of the subject is a required variable in ADSL. If the variable is not a copy of DM.AGE, then an additional differently named variable must be added.
REFMETA	ADSL	AGEU		UPPERCASE	CDISC-ADAM	2.1		The units for the subject's age is a required variable in ADSL. If the variable is not a copy of DM.AGEU, then an additional differently named variable must be added.

The SAS representation of ADaM analysis metadata in reference_tables and reference_columns provides a study template based on the *Analysis Data Model (ADaM), Version 2.1* document and the *Analysis Data Model (ADaM) Implementation Guide, Version 1.0*. Each specific study implementation of ADaM creates multiple BDS data sets. The number of data sets is determined by the study design, the statistical analysis plan, and the available source data (for example, SDTM). Each analysis data set (including ADSL) might contain a different subset of columns defined by the CDISC ADaM model.

The SAS implementation makes assumptions about the data type and length of each column. These assumptions represent a typical implementation consistent with SDTM metadata and conventions for specific types of columns. For example, most identifiers have a default length of 40, most flags have a length of 1, and columns using controlled terminology are defined with a length that is long enough to capture the longest controlled term.

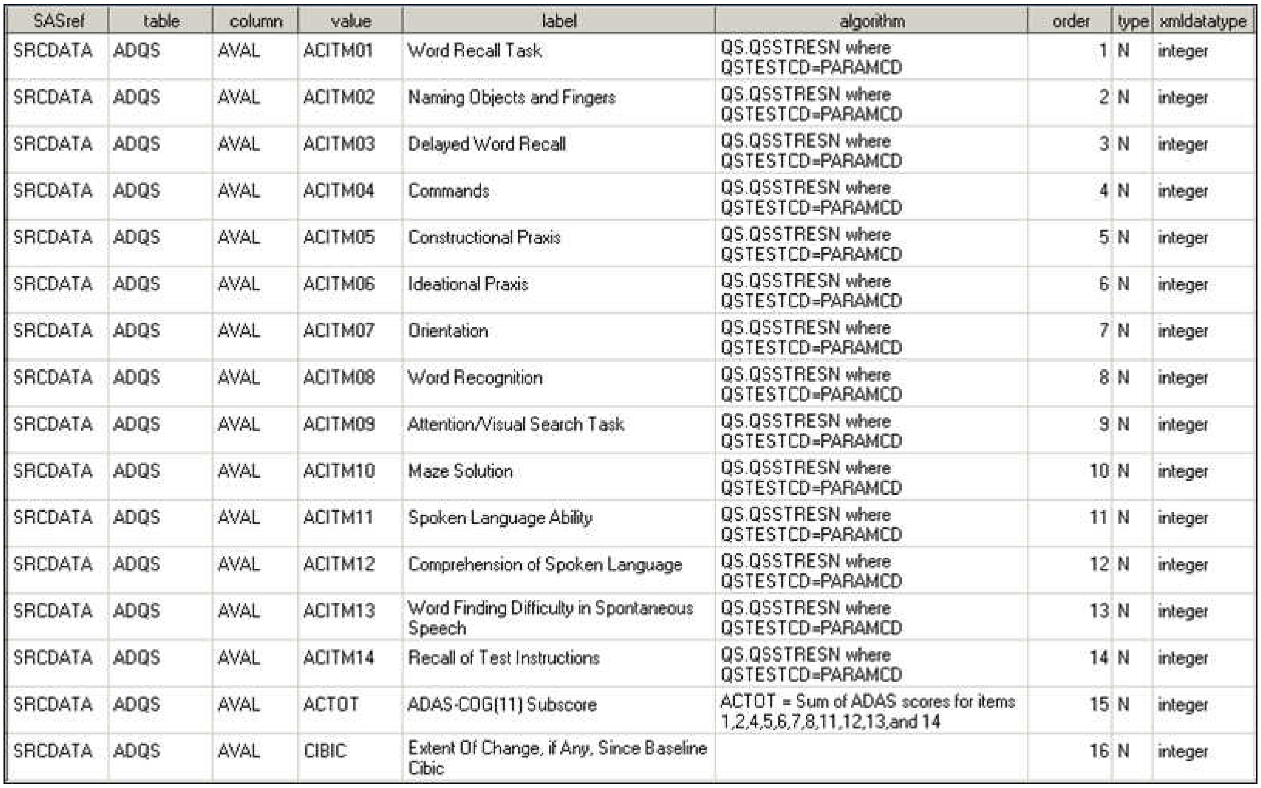
A third type of metadata identified in the *Analysis Data Model (ADaM), Version 2.1* (see Table 10.1 on page 415) is analysis parameter value-level metadata. As noted in the ADaM document:

“Each BDS data set can contain multiple analysis parameters. In a BDS analysis dataset, the variable PARAM contains a unique description for every analysis parameter included in that dataset. Each value of PARAM identifies a set of one or more rows in the dataset. To describe how variable metadata vary by PARAM/PARAMCD, the metadata element PARAMETER IDENTIFIER is required in variable-level metadata for a BDS analysis dataset. This PARAMETER IDENTIFIER metadata element identifies which variables have metadata that vary depending on PARAM/PARAMCD, and links the metadata for a variable to the appropriate value of PARAM/PARAMCD.”

The SAS Clinical Standards Toolkit CDISC ADaM sample study provides a source_values data set that captures analysis parameter information. This data set offers a consistent approach for all CDISC standards that contribute metadata to the derivation of CRT-DDS (ADaM, SDTM, and SEND).

The following display shows an excerpt of the sample ADaM source_values data set:

Figure 10.3 *Excerpt of the Sample source_values Data Set*



SASref	table	column	value	label	algorithm	order	type	xmldatatype
SRCDATA	ADQS	AVAL	ACITM01	Word Recall Task	QS.QSSTRESN where QSTESTCD=PARAMCD	1	N	integer
SRCDATA	ADQS	AVAL	ACITM02	Naming Objects and Fingers	QS.QSSTRESN where QSTESTCD=PARAMCD	2	N	integer
SRCDATA	ADQS	AVAL	ACITM03	Delayed Word Recall	QS.QSSTRESN where QSTESTCD=PARAMCD	3	N	integer
SRCDATA	ADQS	AVAL	ACITM04	Commands	QS.QSSTRESN where QSTESTCD=PARAMCD	4	N	integer
SRCDATA	ADQS	AVAL	ACITM05	Constructional Praxis	QS.QSSTRESN where QSTESTCD=PARAMCD	5	N	integer
SRCDATA	ADQS	AVAL	ACITM06	Ideational Praxis	QS.QSSTRESN where QSTESTCD=PARAMCD	6	N	integer
SRCDATA	ADQS	AVAL	ACITM07	Orientation	QS.QSSTRESN where QSTESTCD=PARAMCD	7	N	integer
SRCDATA	ADQS	AVAL	ACITM08	Word Recognition	QS.QSSTRESN where QSTESTCD=PARAMCD	8	N	integer
SRCDATA	ADQS	AVAL	ACITM09	Attention/Visual Search Task	QS.QSSTRESN where QSTESTCD=PARAMCD	9	N	integer
SRCDATA	ADQS	AVAL	ACITM10	Maze Solution	QS.QSSTRESN where QSTESTCD=PARAMCD	10	N	integer
SRCDATA	ADQS	AVAL	ACITM11	Spoken Language Ability	QS.QSSTRESN where QSTESTCD=PARAMCD	11	N	integer
SRCDATA	ADQS	AVAL	ACITM12	Comprehension of Spoken Language	QS.QSSTRESN where QSTESTCD=PARAMCD	12	N	integer
SRCDATA	ADQS	AVAL	ACITM13	Word Finding Difficulty in Spontaneous Speech	QS.QSSTRESN where QSTESTCD=PARAMCD	13	N	integer
SRCDATA	ADQS	AVAL	ACITM14	Recall of Test Instructions	QS.QSSTRESN where QSTESTCD=PARAMCD	14	N	integer
SRCDATA	ADQS	AVAL	ACTOT	ADAS-COG(11) Subscore	ACTOT = Sum of ADAS scores for items 1,2,4,5,6,7,8,11,12,13,and 14	15	N	integer
SRCDATA	ADQS	AVAL	CIBIC	Extent Of Change, if Any, Since Baseline Cibic		16	N	integer

This data set can be found in ***`sample study library directory`*****`/cdisc-adam-2.1-1.7/sascstdemodata/metadata`**.

For more information about analysis parameter value-level metadata, see sections 5.2.1 and 5.2.2 of the *Analysis Data Model (ADaM) Version 2.1* document.

The final set of metadata prescribed by the *Analysis Data Model (ADaM) Version 2.1* document is analysis results metadata. Analysis results metadata is described in the ADaM document:

"These metadata provide traceability from a result used in a statistical display to the data in the analysis data sets. Analysis results metadata are not required. Analysis results metadata describe the major attributes of a specified analysis result found in a clinical study report or submission."

The metadata fields used to describe an analysis result are listed in Table 10.4 on page 422. The analysis results metadata is illustrated in the SAS Clinical Standards Toolkit CDISC ADaM sample study analysis_results.sas7bdat data set found in ***sample study library directory*****/cdisc-adam-2.1-1.7/sascstdemodata/metadata**. This sample file can serve as a template to initialize your analysis results data set, or see "ADaM Data Set Templates" on page 425.

Table 10.4 Analysis Results Metadata

Analysis Results Metadata Field**	Description**	analysis_results Data Set Column Mapping
DISPLAY IDENTIFIER	A unique identifier for the specific analysis display (such as a table or figure number)	dispid
DISPLAY NAME	Title of display, including additional information if needed to describe and identify the display (for example, analysis population)	dispname
RESULT IDENTIFIER	Identifies the specific analysis result within a display. For example, if there are multiple p-values on a display and the analysis results metadata specifically refers to one of them, this field identifies the p-value of interest. When combined with the display identifierprovides a unique identification of a specific analysis result.	resultid
PARAM	The analysis parameter in the BDS analysis dataset that is the focus of the analysis result. Does not apply if the result is not based on a BDS analysis dataset.	param
PARAMCD	Corresponds to PARAM in the BDS analysis dataset. Does not apply if the result is not based on a BDS analysis dataset.	paramcd
ANALYSIS VARIABLE	The analysis variable being analyzed	analvar

Analysis Results Metadata Field**	Description**	analysis_results Data Set Column Mapping
REASON	The rationale for performing this analysis. It indicates when the analysis was planned (for example, "Pre-specified in Protocol," "Pre-specified in SAP," "Data Driven," "Requested by Regulatory Agency") and the purpose of the analysis within the body of evidence (for example,, "Primary Efficacy," "Key Secondary Efficacy," "Safety"). The terminology used is sponsor defined. An example of a reason is "Primary Efficacy Analysis as Pre-specified in Protocol."	reason
DATASET	The name of the dataset used to generate the analysis result. In most cases, this is a single dataset. However, if multiple datasets are used, they are all listed here.	datasets
SELECTION CRITERIA	Specific and sufficient selection criteria for analysis subset and / or numerator–a complete list of the variables and their values used to identify the records selected for the analysis. Though the syntax is not ADaM-specified, the expectation is that the information could easily be included in a WHERE clause or something equivalent to ensureselecting the exact set of records appropriate for an analysis. This information is required if the analysis does not include every record in the analysis dataset.	selcrit

Analysis Results Metadata Field**	Description**	analysis_results Data Set Column Mapping
DOCUMENTATION	Textual description of the analysis performed. This information could be a text description, pseudo code, or a link to another document such as the protocol or statistical analysis plan, or a link to an analysis generation program (that is, a statistical software program used to generate the analysis result). The contents of the documentation metadata element contains depends on the level of detail required to describe the analysis itself, whether the sponsor is providing a corresponding analysis generation program, and sponsor-specific requirements and standards. This documentation metadata element will remain free form, meaning it will not become subject to a rigid structure or controlled terminology.	document
PROGRAMMING STATEMENTS	The software programming code used to perform the specific analysis. This includes, for example, the model statement (using the specific variable names) and all technical specifications needed for reproducing the analysis (for example, covariance structure). The name and version of the applicable software application should be specified either as part of this metadata element or in another document, such as a Reviewer's Guide. (See Appendix B for more information about a Reviewer 's Guide.)	progstmt

**Source: *Analysis Data Model (ADaM), Version 2.1*, Section 5.3, Analysis Results Metadata, Table 5.3.1

Note: The structure of the analysis results metadata as described in Table 10.4 on page 422 is different from the structure of the metadata that is needed for creating

Analysis Results Metadata 1.0 for Define-XML 2.0 because the latter is based on the 2013 implementation for Define-XML v2.

ADaM Data Set Templates

The SAS Clinical Standards Toolkit implementation of the CDISC ADaM 2.1 standard provides metadata templates for creating analysis data sets that conform to the structure prescribed in the *Analysis Data Model (ADaM) Implementation Guide, Version 1.0*. You can use the SAS Clinical Standards Toolkit metadata in the reference_tables and reference_columns data sets to create these templates.

A framework utility macro, %CST_CREATETABLESFORDATASTANDARD, builds empty ADAE, ADSL, and BDS data sets using the reference_tables and reference_columns metadata.

Submit this code to create the three data sets:

```
%cst_setstandardproperties(_cstStandard=CST-FRAMEWORK,
_cstSubType=initialize);
%cst_createtablesfordatastandard(_cstStandard=CDISC-ADAM,
_cstStandardVersion=2.1, _cstOutputLibrary=work);
```

The successful creation of the data sets is reported in the SAS log:

```
NOTE: The data set WORK.ADSL has 0 observations and 63 variables.
NOTE: The data set WORK.BDS has 0 observations and 142 variables.
NOTE: The data set WORK.ADAE has 0 observations and 85 variables.
```

Specifying additional data sets or columns in the global standards library folder results in the %CST_CREATETABLESFORDATASTANDARD macro building a different set of zero-observation data sets. The global standards library folder is located here:

***global standards library directory*/standards/cdisc-adam-2.1-1.7/metadata**

A zero-observation template data set for the analysis_results data set is located here:

***global standards library directory*/standards/cdisc-adam-2.1-1.7/templates**.

Validation of ADaM Data Sets

Overview

Validation of CDISC ADaM data sets in the SAS Clinical Standards Toolkit uses the same validation methodology used for other standards. Within the global standards library, registering each standard includes setting the flag supportsvalidation in the Metadata Standards data set. All standards that support validation, including ADaM, use the same validation framework and processes described in Chapter 7, "Compliance Assessment Against a Reference Standard," on page 161.

ADaM validation of ADSL and BDS data sets is based on the *CDISC ADaM Validation Checks Version 1.2 Maintenance Release* (dated and released July 5, 2012 to correct errors and to add and remove checks). This documentation was prepared by the CDISC ADaM team.

Note: In SAS Clinical Standards Toolkit 1.7, ADaM validation of ADSL and BDS data sets changed from previous releases. The validation checks covered by OpenCDISC have been removed, and only checks developed by SAS and 11 CDISC checks remain (63 total). In SAS Clinical Standards Toolkit 1.7, these remaining 63 checks have no corresponding checks in OpenCDISC and are provided solely to expand the validation of ADaM domains.

The SAS Clinical Standards Toolkit defines validation checks using a combination of these files:

- the Validation Master data set, which is located here:

  ***global standards library directory*/standards/cdisc-adam-2.1-1.7/validation/control**

  This data set contains 63 records, 11 of which are CDISC validation checks.

- the Messages data set, which is located here:

  ***global standards library directory*/standards/cdisc-adam-2.1-1.7/messages**

This data set contains 56 observations. Some messages in this data set are used across several checks in the Validation Master data set.

Unique Validation Properties

Two validation properties have been added to the SAS Clinical Standards Toolkit to support ADaM validation:

- _cstParseLengthOverride

  By default, the value is set to `1` and is used only by the SAS Clinical Standards Toolkit framework macro %CSTUTIL_PARSESCOPESEGMENT when evaluating the validation check data set fields tablescope and columnscope. For ADaM validation, it is recommended that this value always be set to `1`.

- _cstCaseMgmt

  By default, the value is set to **`<blank>`**. A value of **`UPCASE`** is also allowed. This property (global macro variable) is used only in the validation check data set field codelogic. For example, consider this codelogic:

  ```
  if (&_cstCaseMgmt(&_cstColumn) not in ("","Y")) then _cstError=1;
  ```

  When _cstCaseMgmt=UPCASE, the column value is case insensitive, and the values “y” and “Y” are equivalent. When _cstCaseMgmt=, the value “y” is reported as an error.

Validation Check Macros

ADaM validation uses the following check macros from the autocall library in the defined checks:

%CSTCHECK_COLUMN	%CSTCHECK_CROSSSTDCOMPAREDOMAINS*
%CSTCHECK_COLUMNCOMPARE	%CSTCHECK_CROSSSTDMETAMISMATCH*
%CSTCHECK_COLUMNVARLIST	%CSTCHECK_METAMISMATCH
%CSTCHECK_COMPAREDOMAINS	%CSTCHECK_NOTINCODELIST

%CSTCHECK_DSMISMATCH	%CSTCHECK_NOTUNIQUE
%CSTCHECK_NOTCONSISTENT	%CSTCHECK_ZEROOBS
%CSTCHECKCOMPAREALLCOLUMNS*	

* These macros are used only for CDISC ADaM validation, although they are available to all standards.

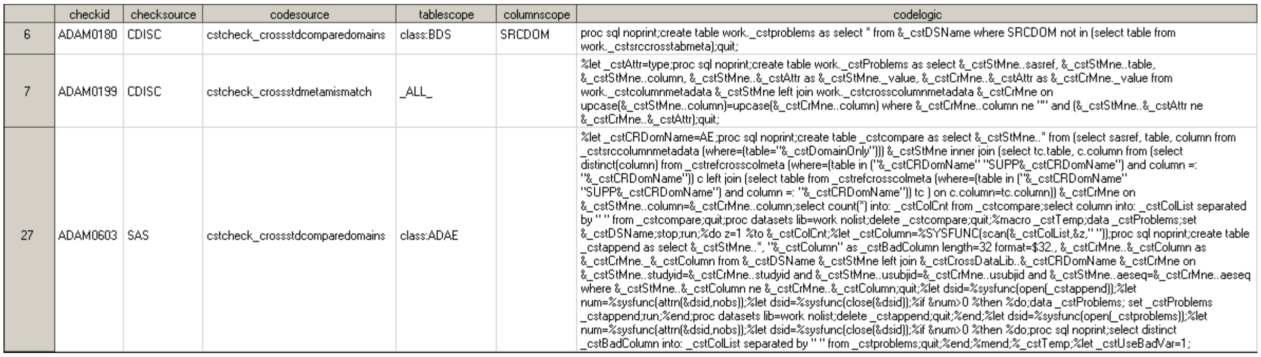
Note: This list represents a subset of check macros that are available to all standards to be validated.

For information about the purpose and use of each check macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Cross-Standard Validation Checks

Several ADaM validation checks require a comparison of ADaM data or metadata with SDTM data or metadata. These checks require the availability of table and column metadata from two different standards. To support this comparison, two check macros (%CSTCHECK_CROSSSTDCOMPAREDOMAINS and %CSTCHECK_CROSSSTDMETAMISMATCH) are available in the SAS Clinical Standards Toolkit. Part of the metadata available in the Validation Master data set for the ADaM cross-standard validation checks is shown in Figure 10.4 on page 428.

Figure 10.4 *Partial Metadata for the CDISC ADaM Cross-Standard Validation Checks*



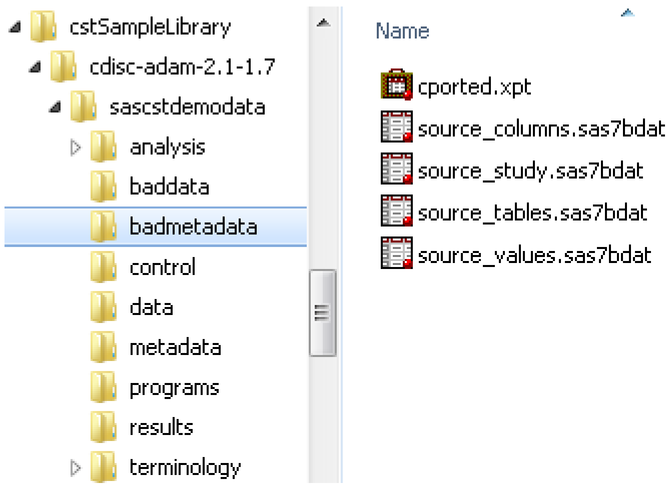
	checkid	checksource	codesource	tablescope	columnscope	codelogic
6	ADAM0180	CDISC	cstcheck_crossstdcomparedomains	class:BDS	SRCDOM	proc sql noprint;create table work._cstproblems as select * from &_cstDSName where SRCDOM not in (select table from work._cstsrccrosstabmeta);quit;
7	ADAM0199	CDISC	cstcheck_crossstdmetamismatch	_ALL_		%let _cstAttr=type;proc sql noprint;create table work._cstProblems as select &_cstStMne..sasref, &_cstStMne..table, &_cstStMne..column, &_cstStMne..&_cstAttr as &_cstStMne._value, &_cstCrMne..&_cstAttr as &_cstCrMne._value from work._cstcolumnmetadata &_cstStMne left join work._cstcrosscolumnmetadata &_cstCrMne on upcase(&_cstStMne..column)=upcase(&_cstCrMne..column) where &_cstCrMne..column ne "" and (&_cstStMne..&_cstAttr ne &_cstCrMne..&_cstAttr);quit;
27	ADAM0603	SAS	cstcheck_crossstdcomparedomains	class:ADAE		%let _cstCRDomName=AE;proc sql noprint;create table _cstcompare as select &_cstStMne..* from (select sasref, table, column from _cstsrccolumnmetadata (where=(table="&_cstDomainOnly"))) &_cstStMne inner join (select tc.table, c.column from (select distinct(column) from _cstrefcrosscolmeta (where=(table in ("&_cstCRDomName" "SUPP&_cstCRDomName") and column =: "&_cstCRDomName")) c left join (select table from _cstrefcrosscolmeta (where=(table in ("&_cstCRDomName" "SUPP&_cstCRDomName") and column =: "&_cstCRDomName")) tc) on c.column=tc.column)) &_cstCrMne on &_cstStMne..column=&_cstCrMne..column;select count(*) into: _cstColCnt from _cstcompare;select column into: _cstColList separated by " " from _cstcompare;quit;proc datasets lib=work nolist;delete _cstcompare;quit;%macro _cstTemp;data _cstProblems;set &_cstDSName;stop;run;%do z=1 %to &_cstColCnt;%let _cstColumn=%SYSFUNC(scan(&_cstColList,&z," "));proc sql noprint;create table _cstappend as select &_cstStMne..*, "&_cstColumn" as _cstBadColumn length=32 format=$32., &_cstCrMne..&_cstColumn as &_cstCrMne._&_cstColumn from &_cstDSName &_cstStMne left join &_cstCrossDataLib..&_cstCRDomName &_cstCrMne on &_cstStMne..studyid=&_cstCrMne..studyid and &_cstStMne..usubjid=&_cstCrMne..usubjid and &_cstStMne..aeseq=&_cstCrMne..aeseq where &_cstStMne..&_cstColumn ne &_cstCrMne..&_cstColumn;quit;%let dsid=%sysfunc(open(_cstappend));%let num=%sysfunc(attrn(&dsid,nobs));%let dsid=%sysfunc(close(&dsid));%if &num>0 %then %do;data _cstProblems; set _cstProblems _cstappend;run;%end;proc datasets lib=work nolist;delete _cstappend;quit;%end;%let dsid=%sysfunc(open(_cstproblems));%let num=%sysfunc(attrn(&dsid,nobs));%let dsid=%sysfunc(close(&dsid));%if &num>0 %then %do;proc sql noprint;select distinct _cstBadColumn into: _cstColList separated by " " from _cstproblems;quit;%end;%mend;%_cstTemp;%let _cstUseBadVar=1;

Sample Data for Validation and Reporting

The SAS Clinical Standards Toolkit implementation of ADaM includes two sets of data and metadata. One set supports the SAS Clinical Standards Toolkit ADaM reporting. In this set, few, if any, data errors and anomalies are included, and this set is considered a clean, analysis-ready set of data. A second set includes illustrative data and metadata errors to demonstrate ADaM validation functionality.

The following figure shows some of the installed SAS files for ADaM, the data and metadata folders that support reporting, and the baddata and badmetadata folders that support validation. The corresponding sample driver programs (analyze_data.sas and validate_data.sas, respectively), which are located in the programs folder (as shown in Figure 10.5 on page 429) point to the correct source data and metadata folders.

Figure 10.5 *Example Folder Hierarchy for a CDISC ADaM Sample Study*



```
cstSampleLibrary
  cdisc-adam-2.1-1.7
    sascstdemodata
      analysis
      baddata
      badmetadata
      control
      data
      metadata
      programs
      results
      terminology
```

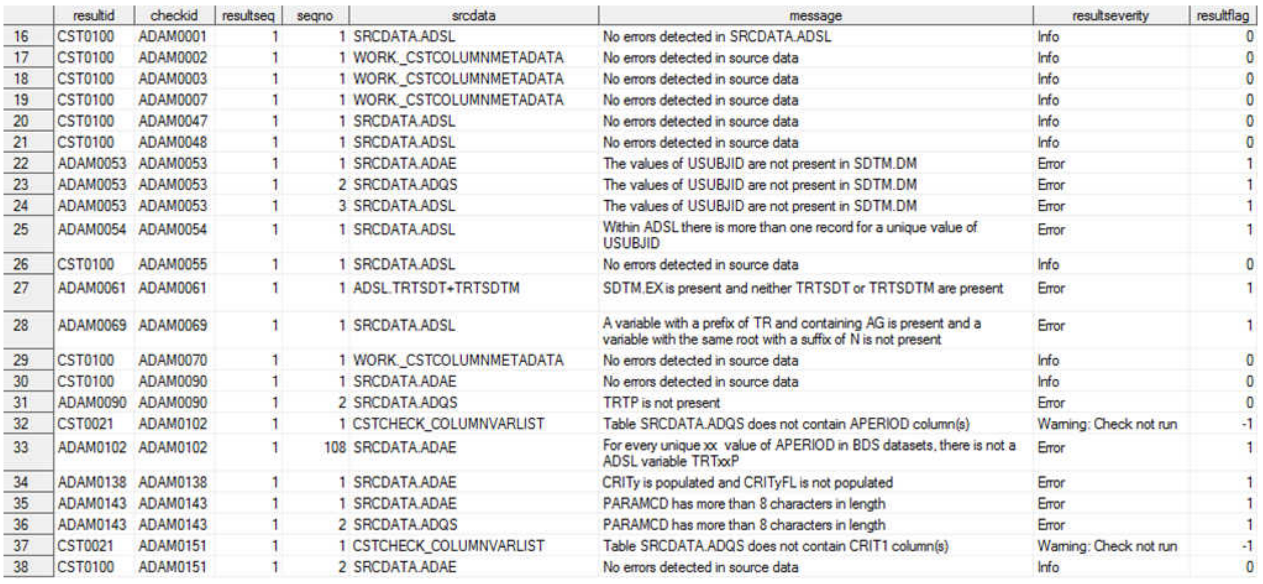
```
Name
cported.xpt
source_columns.sas7bdat
source_study.sas7bdat
source_tables.sas7bdat
source_values.sas7bdat
```

Validation Results

The results of an ADaM validation process, as documented in the validation_results data set, are shown in Figure 10.6 on page 430 and Figure 10.7 on page 431. The first 15 records of the data set shown in Figure 10.6 on page 430 have been excluded from the display because they report generic process setup and metadata information common to all validation processes.

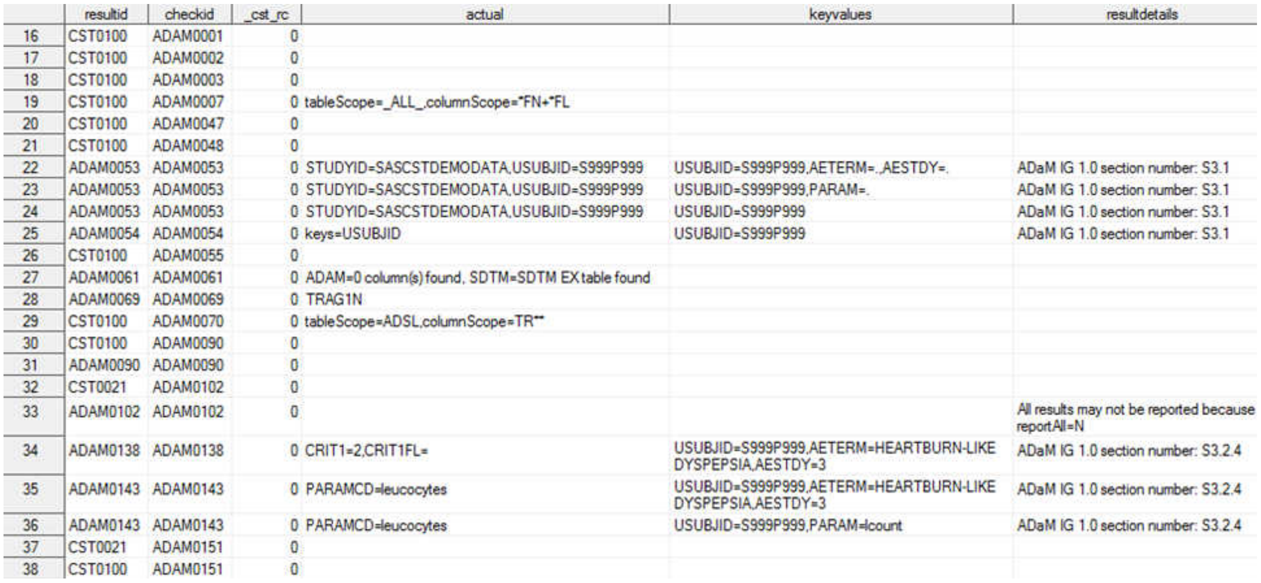
Records 22 through 24 report the results of one of the cross-standard validation checks. This validation check finds a subject (USUBJID) in the ADaM data sets that was not found in the SDTM DM domain.

Figure 10.6 Results from an ADaM Validation Process (Partial Listing)



	resultid	checkid	resultseq	seqno	srcdata	message	resultseverity	resultflag
16	CST0100	ADAM0001	1	1	SRCDATA.ADSL	No errors detected in SRCDATA.ADSL	Info	0
17	CST0100	ADAM0002	1	1	WORK._CSTCOLUMNMETADATA	No errors detected in source data	Info	0
18	CST0100	ADAM0003	1	1	WORK._CSTCOLUMNMETADATA	No errors detected in source data	Info	0
19	CST0100	ADAM0007	1	1	WORK._CSTCOLUMNMETADATA	No errors detected in source data	Info	0
20	CST0100	ADAM0047	1	1	SRCDATA.ADSL	No errors detected in source data	Info	0
21	CST0100	ADAM0048	1	1	SRCDATA.ADSL	No errors detected in source data	Info	0
22	ADAM0053	ADAM0053	1	1	SRCDATA.ADAE	The values of USUBJID are not present in SDTM.DM	Error	1
23	ADAM0053	ADAM0053	1	2	SRCDATA.ADQS	The values of USUBJID are not present in SDTM.DM	Error	1
24	ADAM0053	ADAM0053	1	3	SRCDATA.ADSL	The values of USUBJID are not present in SDTM.DM	Error	1
25	ADAM0054	ADAM0054	1	1	SRCDATA.ADSL	Within ADSL there is more than one record for a unique value of USUBJID	Error	1
26	CST0100	ADAM0055	1	1	SRCDATA.ADSL	No errors detected in source data	Info	0
27	ADAM0061	ADAM0061	1	1	ADSL.TRTSDT+TRTSDTM	SDTM.EX is present and neither TRTSDT or TRTSDTM are present	Error	1
28	ADAM0069	ADAM0069	1	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
29	CST0100	ADAM0070	1	1	WORK._CSTCOLUMNMETADATA	No errors detected in source data	Info	0
30	CST0100	ADAM0090	1	1	SRCDATA.ADAE	No errors detected in source data	Info	0
31	ADAM0090	ADAM0090	1	2	SRCDATA.ADQS	TRTP is not present	Error	0
32	CST0021	ADAM0102	1	1	CSTCHECK_COLUMNVARLIST	Table SRCDATA.ADQS does not contain APERIOD column(s)	Warning: Check not run	-1
33	ADAM0102	ADAM0102	1	108	SRCDATA.ADAE	For every unique xx value of APERIOD in BDS datasets, there is not a ADSL variable TRTxxP	Error	1
34	ADAM0138	ADAM0138	1	1	SRCDATA.ADAE	CRITy is populated and CRITyFL is not populated	Error	1
35	ADAM0143	ADAM0143	1	1	SRCDATA.ADAE	PARAMCD has more than 8 characters in length	Error	1
36	ADAM0143	ADAM0143	1	2	SRCDATA.ADQS	PARAMCD has more than 8 characters in length	Error	1
37	CST0021	ADAM0151	1	1	CSTCHECK_COLUMNVARLIST	Table SRCDATA.ADQS does not contain CRIT1 column(s)	Warning: Check not run	-1
38	CST0100	ADAM0151	1	2	SRCDATA.ADAE	No errors detected in source data	Info	0

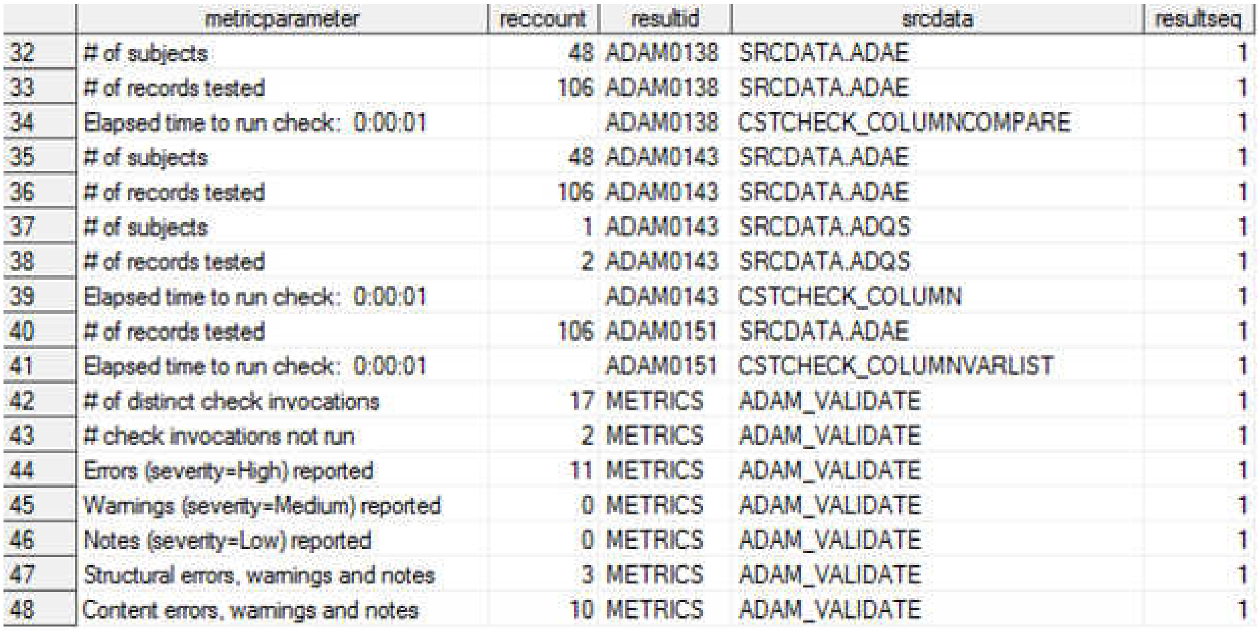
Figure 10.7 Results from an ADaM Validation Process (Partial Listing—Continued)



	resultid	checkid	_cst_rc	actual	keyvalues	resultdetails
16	CST0100	ADAM0001	0			
17	CST0100	ADAM0002	0			
18	CST0100	ADAM0003	0			
19	CST0100	ADAM0007	0	tableScope=_ALL_,columnScope=*FN+*FL		
20	CST0100	ADAM0047	0			
21	CST0100	ADAM0048	0			
22	ADAM0053	ADAM0053	0	STUDYID=SASCSTDEMODATA,USUBJID=S999P999	USUBJID=S999P999,AETERM=.,AESTDY=.	ADaM IG 1.0 section number: S3.1
23	ADAM0053	ADAM0053	0	STUDYID=SASCSTDEMODATA,USUBJID=S999P999	USUBJID=S999P999,PARAM=.	ADaM IG 1.0 section number: S3.1
24	ADAM0053	ADAM0053	0	STUDYID=SASCSTDEMODATA,USUBJID=S999P999	USUBJID=S999P999	ADaM IG 1.0 section number: S3.1
25	ADAM0054	ADAM0054	0	keys=USUBJID	USUBJID=S999P999	ADaM IG 1.0 section number: S3.1
26	CST0100	ADAM0055	0			
27	ADAM0061	ADAM0061	0	ADAM=0 column(s) found, SDTM=SDTM EX table found		
28	ADAM0069	ADAM0069	0	TRAG1N		
29	CST0100	ADAM0070	0	tableScope=ADSL,columnScope=TR**		
30	CST0100	ADAM0090	0			
31	ADAM0090	ADAM0090	0			
32	CST0021	ADAM0102	0			
33	ADAM0102	ADAM0102	0			All results may not be reported because reportAll=N
34	ADAM0138	ADAM0138	0	CRIT1=2,CRIT1FL=	USUBJID=S999P999,AETERM=HEARTBURN-LIKE DYSPEPSIA,AESTDY=3	ADaM IG 1.0 section number: S3.2.4
35	ADAM0143	ADAM0143	0	PARAMCD=leucocytes	USUBJID=S999P999,AETERM=HEARTBURN-LIKE DYSPEPSIA,AESTDY=3	ADaM IG 1.0 section number: S3.2.4
36	ADAM0143	ADAM0143	0	PARAMCD=leucocytes	USUBJID=S999P999,PARAM=lcount	ADaM IG 1.0 section number: S3.2.4
37	CST0021	ADAM0151	0			
38	CST0100	ADAM0151	0			

A partial report of the validation_metrics data set (including a process summary noting that 17 checks were attempted, two could not be run, and 11 errors were detected) is shown in Figure 10.8 on page 432. The two checks that could not be run referenced columns in the check metadata that could not be found or assessed in the source data sets.

Figure 10.8 *Metrics from an ADaM Validation Process (Partial Listing)*



	metricparameter	reccount	resultid	srcdata	resultseq
32	# of subjects	48	ADAM0138	SRCDATA.ADAE	1
33	# of records tested	106	ADAM0138	SRCDATA.ADAE	1
34	Elapsed time to run check: 0:00:01		ADAM0138	CSTCHECK_COLUMNCOMPARE	1
35	# of subjects	48	ADAM0143	SRCDATA.ADAE	1
36	# of records tested	106	ADAM0143	SRCDATA.ADAE	1
37	# of subjects	1	ADAM0143	SRCDATA.ADQS	1
38	# of records tested	2	ADAM0143	SRCDATA.ADQS	1
39	Elapsed time to run check: 0:00:01		ADAM0143	CSTCHECK_COLUMN	1
40	# of records tested	106	ADAM0151	SRCDATA.ADAE	1
41	Elapsed time to run check: 0:00:01		ADAM0151	CSTCHECK_COLUMNVARLIST	1
42	# of distinct check invocations	17	METRICS	ADAM_VALIDATE	1
43	# check invocations not run	2	METRICS	ADAM_VALIDATE	1
44	Errors (severity=High) reported	11	METRICS	ADAM_VALIDATE	1
45	Warnings (severity=Medium) reported	0	METRICS	ADAM_VALIDATE	1
46	Notes (severity=Low) reported	0	METRICS	ADAM_VALIDATE	1
47	Structural errors, warnings and notes	3	METRICS	ADAM_VALIDATE	1
48	Content errors, warnings and notes	10	METRICS	ADAM_VALIDATE	1

Sample Reporting Methodology

Overview

The primary purpose of the CDISC ADaM standard is to build analysis data sets that support analysis and reporting of clinical research. This purpose, in turn, supports the greater goal of submitting clinical research results to regulatory authorities. These regulatory authorities determine the efficacy and safety of a medical device or product.

The *Analysis Data Model (ADaM), Version 2.1* document provides specifications for the structure and content of analysis data sets, and a suggested metadata format for documenting the analysis results generated. Analysis results metadata describe the major attributes of a specified analysis result found in a clinical study report or submission. Analysis results metadata support traceability from an analysis result used in a statistical display to the data in the analysis data sets.

The SAS Clinical Standards Toolkit representation of the ADaM standard includes a sample implementation of an analysis reporting methodology.

Note: This methodology is for illustrative purposes only. Each organization has its own set of processes and workflows that support the generation of a clinical study report or submission. The sample reporting methodology provided with the SAS Clinical Standards Toolkit is intended to be representative of similar industry reporting methodologies. The intent is not to provide a definitive reporting methodology, but to illustrate the interaction of reporting components through the adoption of the ADaM standard. The format for the analysis results metadata in the SAS Clinical Standards Toolkit has been updated for the processes that create a Define-XML 2.0 file that include analysis results metadata according to the Analysis Results Metadata 1.0 for Define-XML 2.0 specification.

Key clinical trial reporting components are shown in the following table:

Table 10.5 *Key Clinical Trial Reporting Components*

Reporting Component	Comments
Clinical Protocol, Statistical Analysis Plan	Used to identify and define data to be collected, analysis methods and algorithms to be used, and efficacy endpoints and safety measures that determine report output.
Source Data	Source data for analysis data sets, often SDTM. Traceability back to source data is a key ADaM requirement.
Source Metadata	Metadata about the source data.
Controlled Terminology	Set of allowable terms used in any source or analysis data set. For CDISC, NCI EVS serves as the primary source of terms.
Analysis Data Sets	ADaM data sets, typically including the ADSL data set and any number of BDS data sets (for example, ADAE and ADLB) required to support analyses.
Analysis Data Set Metadata	Metadata about the analysis data sets.

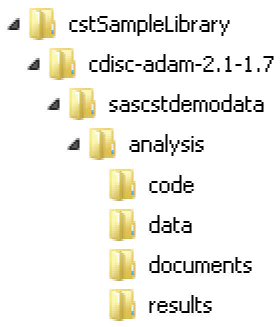
Reporting Component	Comments
Analysis Results (tables, listings, and figures) For more information, see "Analysis Results (Tables, Listings, and Figures)" on page 441.	The set of statistical displays (for example, text, tabular, or graphical presentation of results) or inferential statements (such as p-values or estimates of treatment effect).
TLF Metadata (to include table shells) For more information, see "TLF Metadata" on page 435.	Commonly provided as table shells. Can also include display-specific metadata (often as Microsoft Excel files) used by the analysis programs to generate the displays.
Analysis Results Metadata For more information, see "Analysis Results Metadata" on page 442.	Defined by the *Analysis Data Model (ADaM), Version 2.1* document, Section 5.3. For more information, see Table 10.4 on page 422.
Analysis Programs For more information, see "Analysis Programs" on page 438.	Programming code that uses the analysis data sets (and, optionally, TLF metadata) to create the analysis results.
Submission Package (for example, eCTD)	The structured submission used to package data, metadata, code, and results in a standard form to facilitate review.
Define.xml	A metadata format that documents each tabulation (SDTM) or analysis (ADaM) data set, ancillary documents, and controlled terminology for a study or submission.
CSR/ISS/ISE	The focus of each ADaM implementation. Most commonly a Clinical Study Report (CSR) for a single clinical study. Can be an Integrated Summary of Safety (ISS) or Integrated Summary of Efficacy (ISE) across multiple clinical studies.

The majority of the files supporting the ADaM sample reporting methodology provided with the SAS Clinical Standards Toolkit are located in the ADaM analysis folder:

***sample study library directory*/cdisc-adam-2.1/sascstdemodata/analysis**

Here is an illustration of the ADaM analysis folder hierarchy:

Figure 10.9 SAS Clinical Standards Toolkit ADaM Analysis Folder Hierarchy



Here are noteworthy folders:

- The code folder contains the code to create each statistical display. This corresponds to the Analysis Results component described in Table 10.5 on page 433.
- The data folder contains the display-specific metadata noted in the TLF Metadata component of Table 10.5 on page 433.
- The documents folder contains table shells for the TLF Metadata component. For more information about table shells, see “TLF Metadata” on page 435.
- The results folder contains several sample statistical displays, which correspond to the Analysis Results component.

TLF Metadata

A common industry reporting strategy is to create *table shells* (templates) that specify the output for each statistical display. The SAS Clinical Standards Toolkit provides sample table shells in this file:

***sample study library directory*/cdisc-adam-2.1-1.7/sascstdemodata/analysis/documents/Mock_tables_shells.pdf**.

One of these displays, a table reporting patient demographics (Table 14.2.01), follows:

Figure 10.10 *SAS Clinical Standards Toolkit Sample Table Shell*

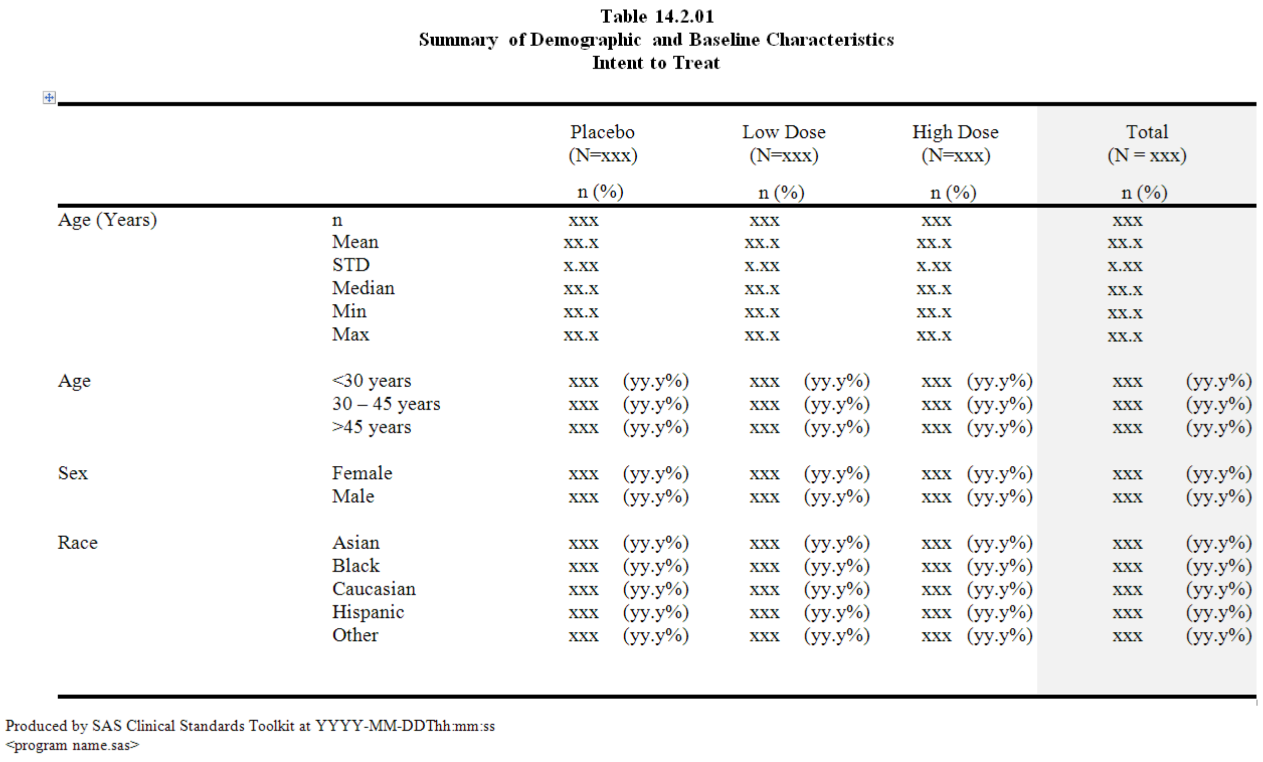


Table 14.2.01
Summary of Demographic and Baseline Characteristics
Intent to Treat

		Placebo (N=xxx)		Low Dose (N=xxx)		High Dose (N=xxx)		Total (N = xxx)	
		n (%)		n (%)		n (%)		n (%)	
Age (Years)	n	xxx		xxx		xxx		xxx	
	Mean	xx.x		xx.x		xx.x		xx.x	
	STD	x.xx		x.xx		x.xx		x.xx	
	Median	xx.x		xx.x		xx.x		xx.x	
	Min	xx.x		xx.x		xx.x		xx.x	
	Max	xx.x		xx.x		xx.x		xx.x	
Age	<30 years	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	30 – 45 years	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	>45 years	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Sex	Female	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Male	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
Race	Asian	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Black	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Caucasian	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Hispanic	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)
	Other	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)	xxx	(yy.y%)

Produced by SAS Clinical Standards Toolkit at YYYY-MM-DDThh:mm:ss
<program name.sas>

The elements of each table shell (for example, titles, footnotes, headings, column and row labels, cell formatting, and so on) are sometimes captured in a metadata format, often in Microsoft Excel files. The usual intent is to create reporting macros that can generate analysis reports based on this metadata, so that changes in metadata are all that is required to modify and rerun any report.

For the SAS Clinical Standards Toolkit, sample metadata is included that demonstrates the use of such metadata within the ADaM reporting environment.

Note: The sample metadata provided does not represent a full implementation. All metadata fields used in the report examples are not provided.

Supplemental metadata is provided in this file:

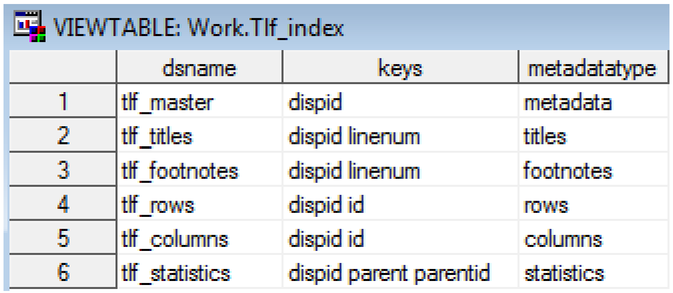
`sample study library directory`**`/cdisc-adam-2.1-1.7/sascstdemodata/metadata/tlfddt.xml`**

To interpret this metadata, a sample SAS XML map file (tlfddt.map) is provided in the same folder. SAS data sets, representing this XML metadata, are provided in the library of SAS files located here:

***sample study library directory*/cdisc-adam-2.1-1.7/sascstdemodata/analysis/data**

The following figures provide examples of some of the metadata available in the source XML file. This metadata has been extracted into SAS data sets.

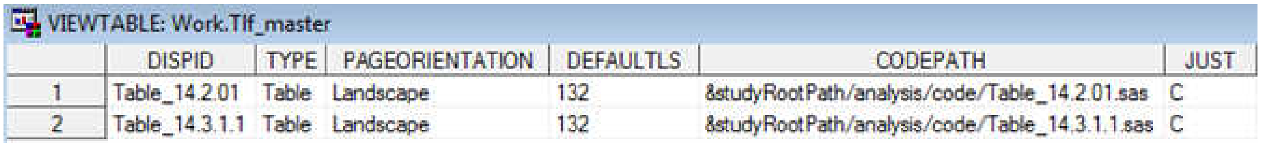
Figure 10.11 *Sample TLF Metadata: Tlf_index*



VIEWTABLE: Work.Tlf_index

	dsname	keys	metadatatype
1	tlf_master	dispid	metadata
2	tlf_titles	dispid linenum	titles
3	tlf_footnotes	dispid linenum	footnotes
4	tlf_rows	dispid id	rows
5	tlf_columns	dispid id	columns
6	tlf_statistics	dispid parent parentid	statistics

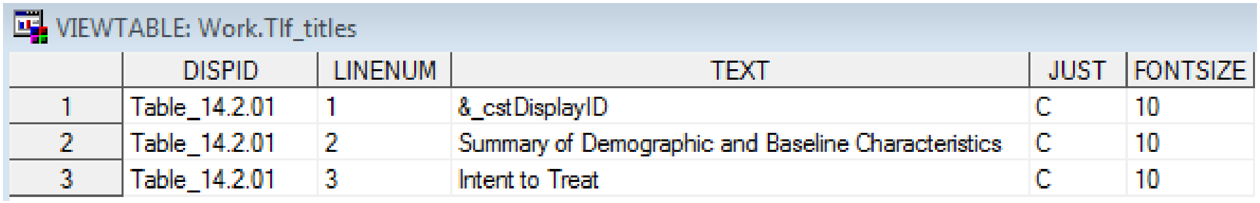
Figure 10.12 *Sample TLF Metadata: Tlf_master*



VIEWTABLE: Work.Tlf_master

	DISPID	TYPE	PAGEORIENTATION	DEFAULTLS	CODEPATH	JUST
1	Table_14.2.01	Table	Landscape	132	&studyRootPath/analysis/code/Table_14.2.01.sas	C
2	Table_14.3.1.1	Table	Landscape	132	&studyRootPath/analysis/code/Table_14.3.1.1.sas	C

Figure 10.13 *Sample TLF Metadata: Tlf_titles*



VIEWTABLE: Work.Tlf_titles

	DISPID	LINENUM	TEXT	JUST	FONTSIZE
1	Table_14.2.01	1	&_cstDisplayID	C	10
2	Table_14.2.01	2	Summary of Demographic and Baseline Characteristics	C	10
3	Table_14.2.01	3	Intent to Treat	C	10

Row 1 of the Tlf_master data set describes a centered landscape table and shows where the generating code can be found. The title for that table is provided in the Tlf_titles file. These tables correspond to the table shell titles specified in Figure 10.10 on page 436.

Analysis Programs

The analysis program to generate sample Table 14.2.01 is located here:

***sample study library directory*/cdisc-adam-2.1-1.7/sascstdemodata/analysis/code**

Two versions are provided:

- Table_14.2.01.sas uses the TLF metadata described previously.
- Table_14.2.01_nomd.sas does not rely on TLF metadata to generate the report output.

As noted above, these sample analysis programs do not fully use the sample TLF metadata provided with the SAS Clinical Standards Toolkit. The basic coding strategy adopted with each SAS Clinical Standards Toolkit sample analysis program is to build each section (one or more row combinations) and to concatenate these sections into a single input file used by PROC REPORT.

A sample driver program is provided to perform the process setup, to define (or reference) the SASReferences data set, to perform any required report setup, and to call the generic ADaM reporting macro %ADAM_CREATEDISPLAY. This sample driver program is located here:

***sample study library directory*/cdisc-adam-2.1-1.7/sascstdemodata/programs/analyze_data.sas**

In the sample driver program, a call is made to %ADAM_CREATEDISPLAY for each analysis report to be produced:

```
%adam_createdisplay (displaysrc=Metadata,useanalysisresults=N,usetlfddt=Y,
displayid=%str(Table_14.2.01));
```

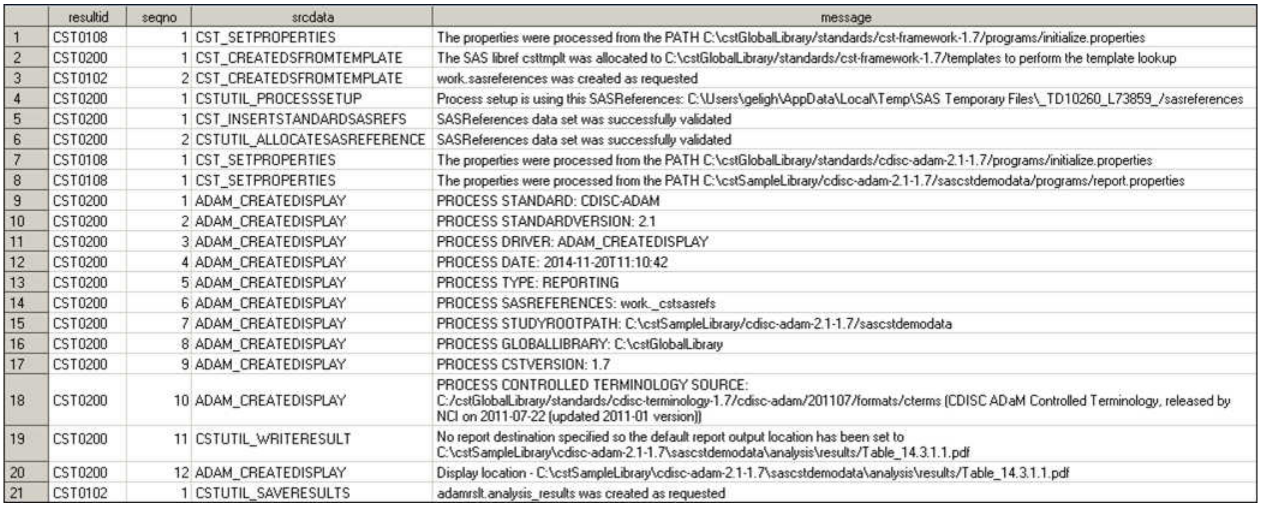
To automate this process of creating all analysis reports for a study, it would be necessary to cycle through any available metadata (such as that described in Figure 10.12 on page 437) to construct multiple calls to the %ADAM_CREATEDISPLAY macro. The %ADAM_CREATEDISPLAY macro header provides an overview of the macro functionality and a summary of the defined macro parameters:

```
adam_createdisplay
```

```
Creates an analysis result display from ADaM analysis data sets.

The path to the code to create the display is provided either directly in the
macro parameters or is derived from a metadata source. Examples of metadata
sources are analysis results metadata or Tables, Listings, and Figures data
definition metadata (TLFDDT) that you maintain and reference in the
SASReferences data set.

Two primary paths (parameter settings) are supported:
   1. A code source is specified. A fully qualified path is required. The
      expectation is that this module is %included below to generate an
      analysis result (display).
   2. Metadata provides the information necessary to generate an analysis
      result (display). This metadata is in the form of the CDISC ADaM
      analysis results metadata, supplemental Tables, Listings, and Figures
      data definition metadata (TLFDDT), or both.

@macvar studyRootPath Root path to the sample source study
@macvar _cstCTDescription Description of controlled terminology packet
@macvar _cstDebug Turns debugging on or off for the session
@macvar cstDefaultReportFormat Specifies the SAS ODS report destination
@macvar _cstGRoot Root path of the Toolkit Global Library
@macvar _cstResultsDS Results data set
@macvar _cstResultSeq Results: Unique invocation of check
@macvar _cstSASRefs Run-time SASReferences data set derived in process setup
@macvar _cstSeqCnt Results: Sequence number within _cstResultSeq
@macvar _cstSrcData Results: Source entity being evaluated
@macvar _cstStandard Name of a standard registered to Toolkit
@macvar _cstStandardVersion Version of the standard referenced in _cstStandard
@macvar _cst_rc Task error status
@macvar _cstVersion Version of the SAS Clinical Standards Toolkit
@macvar _CSTTLF_MASTERCODEPATH Dynamically derived code segment path from
           TLF metadata.
@macvar workpath Path to the SAS session work library

@param _cstDisplaySrc - required - Where information comes from to generate
           the result.
           Values:  Code | Metadata
           Default: Metadata
@param _cstDisplayCode - conditional - Either a valid filename or the fully
           qualified path to code that produces an analysis result. If
           _cstDisplaySrc=Code, this parameter is used and is required. All of
           the remaining parameters are ignored.
@param _cstUseAnalysisResults - conditional - The study-specific analysis
           results metadata are used to provide report metadata.
           If _cstDisplaySrc=Metadata, either this parameter or _cstUseTLFddt
           must be set to Y. If both _cstUseAnalysisResults and _cstUseTLFddt
           are set to Y, _cstUseAnalysisResults takes precedence.
           Values:  N | Y
           Default: Y
@param _cstUseTLFddt - conditional - The study-specific mock table shell
           metadata (known as Tables, Listings, and Figures data definition
           metadata (TLFDDT)) are used to provide report metadata.
           If _cstDisplaySrc=Metadata, either this parameter or
           _cstUseAnalysisResults must be set to Y. If both
           _cstUseAnalysisResults and _cstUseTLFddt are set to Y,
           _cstUseAnalysisResults takes precedence.
           Values:  N | Y
           Default: Y
@param _cstDisplayID - conditional - The ID of the display from the designated
           metadata source. If _cstDisplaySrc=Metadata, this parameter is
           required.
@param _cstDisplayPath - optional - A valid filename or the fully qualified
           path to the generated display. If not provided, the code looks in
           SASReferences for type=report.
```

The SAS Clinical Standards Toolkit ADaM reporting methodology uses a report.properties file to specify the default report format. By default, the property (and global macro variable) _cstDefaultReportFormat is set to PDF. Submitting the analyze_data.sas driver program produces the specified statistical displays and generates a process results data set. Here is a sample results data set:

Figure 10.14 *Sample Results Data Set Generated by the analyze_data.sas Driver Program*



	resultid	seqno	srcdata	message
1	CST0108	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cst-framework-1.7/programs/initialize.properties
2	CST0200	1	CST_CREATEDSFROMTEMPLATE	The SAS libref csttmplt was allocated to C:\cstGlobalLibrary/standards/cst-framework-1.7/templates to perform the template lookup
3	CST0102	2	CST_CREATEDSFROMTEMPLATE	work.sasreferences was created as requested
4	CST0200	1	CSTUTIL_PROCESSSETUP	Process setup is using this SASReferences: C:\Users\geligh\AppData\Local\Temp\SAS Temporary Files_TD10260_L73859_/sasreferences
5	CST0200	1	CST_INSERTSTANDARDSASREFS	SASReferences data set was successfully validated
6	CST0200	2	CSTUTIL_ALLOCATESASREFERENCE	SASReferences data set was successfully validated
7	CST0108	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cdisc-adam-2.1-1.7/programs/initialize.properties
8	CST0108	1	CST_SETPROPERTIES	The properties were processed from the PATH C:\cstSampleLibrary/cdisc-adam-2.1-1.7/sascstdemodata/programs/report.properties
9	CST0200	1	ADAM_CREATEDISPLAY	PROCESS STANDARD: CDISC-ADAM
10	CST0200	2	ADAM_CREATEDISPLAY	PROCESS STANDARDVERSION: 2.1
11	CST0200	3	ADAM_CREATEDISPLAY	PROCESS DRIVER: ADAM_CREATEDISPLAY
12	CST0200	4	ADAM_CREATEDISPLAY	PROCESS DATE: 2014-11-20T11:10:42
13	CST0200	5	ADAM_CREATEDISPLAY	PROCESS TYPE: REPORTING
14	CST0200	6	ADAM_CREATEDISPLAY	PROCESS SASREFERENCES: work._cstsasrefs
15	CST0200	7	ADAM_CREATEDISPLAY	PROCESS STUDYROOTPATH: C:\cstSampleLibrary/cdisc-adam-2.1-1.7/sascstdemodata
16	CST0200	8	ADAM_CREATEDISPLAY	PROCESS GLOBALLIBRARY: C:\cstGlobalLibrary
17	CST0200	9	ADAM_CREATEDISPLAY	PROCESS CSTVERSION: 1.7
18	CST0200	10	ADAM_CREATEDISPLAY	PROCESS CONTROLLED TERMINOLOGY SOURCE: C:/cstGlobalLibrary/standards/cdisc-terminology-1.7/cdisc-adam/201107/formats/cterms (CDISC ADaM Controlled Terminology, released by NCI on 2011-07-22 (updated 2011-01 version))
19	CST0200	11	CSTUTIL_WRITERESULT	No report destination specified so the default report output location has been set to C:\cstSampleLibrary\cdisc-adam-2.1-1.7\sascstdemodata\analysis\results/Table_14.3.1.1.pdf
20	CST0200	12	ADAM_CREATEDISPLAY	Display location - C:\cstSampleLibrary\cdisc-adam-2.1-1.7\sascstdemodata\analysis\results/Table_14.3.1.1.pdf
21	CST0102	1	CSTUTIL_SAVERESULTS	adamrslt.analysis_results was created as requested

Analysis Results (Tables, Listings, and Figures)

Each generated statistical display should correspond to a table shell, as described in the TLF Metadata section. (See Figure 10.10 on page 436.)

For example, the Summary of Demographic and Baseline Characteristics provided in Table 14.2.01 is shown in this figure.

Figure 10.15 *Sample Analysis Report: Table 14.2.01*

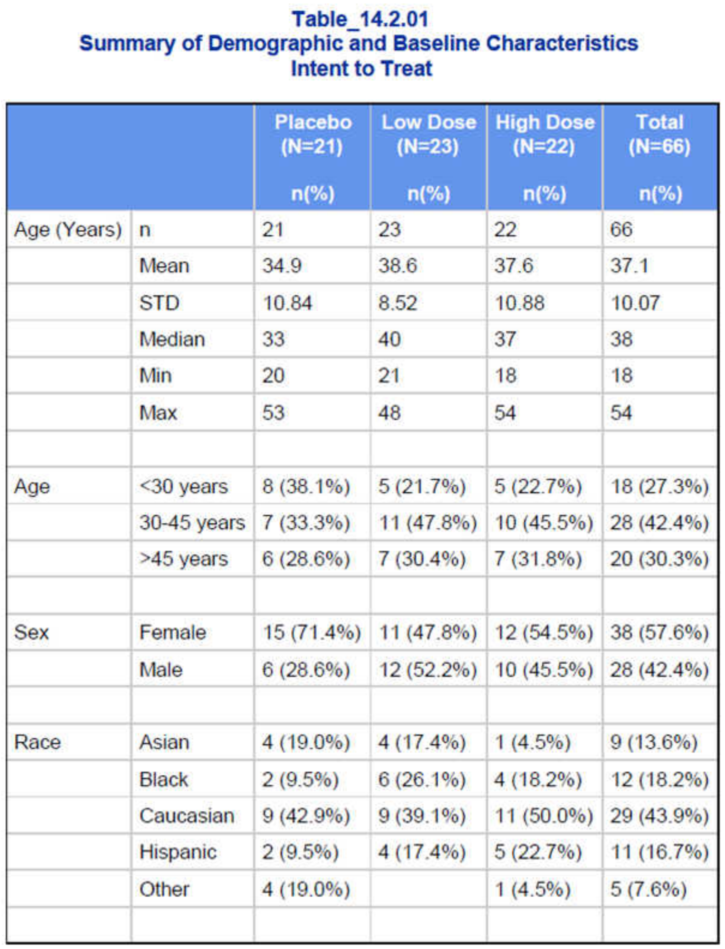


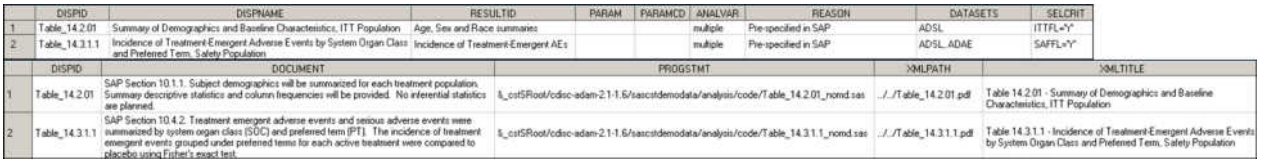
Table_14.2.01
Summary of Demographic and Baseline Characteristics
Intent to Treat

		Placebo (N=21) n(%)	Low Dose (N=23) n(%)	High Dose (N=22) n(%)	Total (N=66) n(%)
Age (Years)	n	21	23	22	66
	Mean	34.9	38.6	37.6	37.1
	STD	10.84	8.52	10.88	10.07
	Median	33	40	37	38
	Min	20	21	18	18
	Max	53	48	54	54
Age	<30 years	8 (38.1%)	5 (21.7%)	5 (22.7%)	18 (27.3%)
	30-45 years	7 (33.3%)	11 (47.8%)	10 (45.5%)	28 (42.4%)
	>45 years	6 (28.6%)	7 (30.4%)	7 (31.8%)	20 (30.3%)
Sex	Female	15 (71.4%)	11 (47.8%)	12 (54.5%)	38 (57.6%)
	Male	6 (28.6%)	12 (52.2%)	10 (45.5%)	28 (42.4%)
Race	Asian	4 (19.0%)	4 (17.4%)	1 (4.5%)	9 (13.6%)
	Black	2 (9.5%)	6 (26.1%)	4 (18.2%)	12 (18.2%)
	Caucasian	9 (42.9%)	9 (39.1%)	11 (50.0%)	29 (43.9%)
	Hispanic	2 (9.5%)	4 (17.4%)	5 (22.7%)	11 (16.7%)
	Other	4 (19.0%)		1 (4.5%)	5 (7.6%)

Analysis Results Metadata

The *Analysis Data Model (ADaM), Version 2.1* document provides specifications for capturing analysis results. As a result, traceability back to the contributing source data is possible. Table 10.4 on page 422 identifies the columns to be included in the analysis results data set. All analysis results metadata for the two statistical displays provided with the SAS Clinical Standards Toolkit is shown in this figure:

Figure 10.16 *Analysis Results Metadata*



	DISPID	DISPNAME	RESULTID	PARAM	PARAMCD	ANALVAR	REASON	DATASETS	SELCRIT
1	Table_14.2.01	Summary of Demographics and Baseline Characteristics, ITT Population	Age, Sex and Race summaries			multiple	Pre-specified in SAP	ADSL	ITTFL="Y"
2	Table_14.3.1.1	Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term, Safety Population	Incidence of Treatment-Emergent AEs			multiple	Pre-specified in SAP	ADSL ADAE	SAFFL="Y"

	DISPID	DOCUMENT	PROGSTMT	XMLPATH	XMLTITLE
1	Table_14.2.01	SAP Section 10.1.1. Subject demographics will be summarized for each treatment population. Summary descriptive statistics and column frequencies will be provided. No inferential statistics are planned.	&_cstSRoot/cdisc-adam-2.1-1.6/sascstdemodata/analysis/code/Table_14.2.01_nomd.sas	../../Table_14.2.01.pdf	Table 14.2.01 - Summary of Demographics and Baseline Characteristics, ITT Population
2	Table_14.3.1.1	SAP Section 10.4.2. Treatment emergent adverse events and serious adverse events were summarized by system organ class (SOC) and preferred term (PT). The incidence of treatment emergent events grouped under preferred terms for each active treatment were compared to placebo using Fisher's exact test.	&_cstSRoot/cdisc-adam-2.1-1.6/sascstdemodata/analysis/code/Table_14.3.1.1_nomd.sas	../../Table_14.3.1.1.pdf	Table 14.3.1.1 - Incidence of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term, Safety Population

The analysis results data set is located here:

***sample study library directory*/cdisc-adam-2.1-1.7/sascstdemodata/metadata/analysis_results.sas7bdat**

11 Reporting

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Sample Reports

Overview

To show how the SAS Clinical Standards Toolkit metadata and results can be summarized in a report format, several sample reports are available with the SAS Clinical Standards Toolkit. These reports are offered as templates that can be modified to facilitate data review. The report templates are PROC REPORT implementations that use ODS to generate report output in a variety of formats supported by ODS. Three sample reports are provided:

- Report 1: This report is applicable to most SAS Clinical Standards Toolkit processes. It itemizes records that are written to the Results data by the process. In the case of validation processes, this report itemizes Results data set records by validation check.

- Report 2: This report is specific to the SAS Clinical Standards Toolkit validation processes for standards that have the concept of source data domains (for example, CDISC SDTM and CDISC ADaM). Results are summarized by domain.
- Report 3: This report is specific to the SAS Clinical Standards Toolkit validation functionality that summarizes all available metadata about validation checks for a supported standard. This report offers a multi-panel or one-page-per-check presentation format.

Process Results Reporting

Reports 1 and 2 have multiple sections or panels. Each section can be generated, if you choose to do so. Here are the sections that are common to each report:

- a report summary
- a listing of key process inputs and outputs as defined in the SASReferences data set
- a summary of validation metrics
- a general process messaging panel

A sample driver program is provided to define the SAS Clinical Standards Toolkit environment and to call the primary task framework macro (%CSTUTIL_CREATEREPORT). This excerpt from the driver program header provides a brief overview:

```
cst_report.sas

Sample driver program to perform a primary Toolkit action, in this case,
reporting of process results. This code performs any needed set-up and data
management tasks, followed by one or more calls to the %cstutil_createreport()
macro to generate report output.

Two options for invoking this routine are addressed in these scenarios:
  (1) This code is run as a natural continuation of a CST process, within
       the same SAS session, with all required files available.  The working
       assumption is that the SASReferences data set (referenced by the
       _cstSASRefs macro) exists and contains information on all input files
       required for reporting.
```

```
     (2) This code is being run in another SAS session with no CST setup
         established, but the user has a CST results data set and therefore can
         derive the location of the SASReferences file that can provide the full
         CST setup needed to run the reports.

  Assumptions:
    To generate all panels for both types of reports, the following metadata
    is expected:
          - the SASReferences file must exist, and must be identified in the
            call to cstutil_processsetup if it is not work.sasreferences.
          - a Results data set.
          - a (validation-specific) Metrics data set.
          - the (validation-specific) run-time Control data set itemizing the
            validation checks requested.
          - access to the (validation-specific) check messages data set.
```

The reporting as implemented in the SAS Clinical Standards Toolkit attempts to address these two scenarios described in the driver program header above:

1 Some SAS Clinical Standards Toolkit task (such as validation against a reference standard) has been completed. The Results data set has been created. And, in the same SAS session (or batch job stream), you want to generate one or both reports. In this scenario, the reporting process uses the SASReferences data set defined by the global macro variable _cstSASRefs that was used by the previous process. The Results data set to be summarized in the report is the data set that was previously created and perhaps persisted to a location other than the SAS Work library. (Whether the data set was persisted was specified in the SASReferences data set.) Other files required by the report are identified in Table 11.1 on page 447.

> **TIP** Best Practice Recommendation: Do not call the cleanup macro %CSTUTIL_CLEANUPCSTSESSION between primary tasks in a SAS Clinical Standards Toolkit SAS session (such as between validation and reporting). This keeps required files, macro variables, autocall paths, and so on, available for the reporting code.

2 The Results data set that was created in some prior SAS Clinical Standards Toolkit session is available. You want to generate one or both reports. The SAS Clinical Standards Toolkit processes add informational records to the Results data set, documenting the process itself. For example, a SAS Clinical Standards Toolkit

CDISC SDTM validation process writes records to the Results data set that contains this sample message text:

```
Message
PROCESS STANDARD: CDISC-SDTM
PROCESS STANDARDVERSION: 3.1.3
PROCESS DRIVER: SDTM_VALIDATE
PROCESS DATE: 2012-10-01T09:57:14
PROCESS TYPE: VALIDATION
PROCESS SASREFERENCES:
      &_cstSRoot./cdisc-sdtm-3.1.3-1.7/sascstdemodata/control/
      sasreferences.sas7bdat
```

From this information, a reporting process can attempt to find and open the referenced SASReferences data set to derive information for some or all of the report sections.

CAUTION! There are obvious limits to how useful any SAS Clinical Standards Toolkit Results data set can be in rebuilding a session for reporting purposes. For example, if the SASReferences data set was built in the Work library in a previous session, then it is not available and the report process fails. Similarly, if the SASReferences data set references library and file paths using a macro variable prefix (for example, &_cstGRoot or &studyRootPath), and those macro variables are not set or point to a different root path than the original process, then the report process might fail or yield unpredictable results. In the example above, the referenced SASReferences data set points to the sample library folder hierarchy that was used for a SAS Clinical Standards Toolkit 1.5 process. This folder hierarchy still exists in the SAS Clinical Standards Toolkit 1.7, so the results data set would more likely be found. This scenario or technique is most appropriate for sites that adopt a consistent means of building and populating SASReferences data sets.

Table 11.1 *Metadata Sources for Reporting*

Data or Metadata Source	Scenario 1: Continuation of an Active SAS Session	Scenario 2: Using a Results Data Set from a Previous SAS Session
SASReferences	&_cstSASRefs used by the prior task that generated the Results data set.	The Results data set record containing the message PROCESS SASREFERENCES attempts to use the referenced file. &_cstSASRefs is set to this file.
Results	Precedence: 1 The data set referenced in &_cstSASRefs with type=results and subtype is either results or validationresults. 2 The data set referenced by &_cstResultsDS.	As provided in the cst_report.sas driver program _cstRptResultsDS macro variable.
Metrics	Precedence: 1 The data set referenced in &_cstSASRefs with type=results and subtype is either metrics or validationmetrics. 2 The data set referenced by &_cstMetricsDS.	The data set referenced in &_cstSASRefs with type=results and subtype is either metrics or validationmetrics.
Validation_Control	The data set referenced in &_cstSASRefs with type=control and subtype=validation.	The data set referenced in &_cstSASRefs with type=control and subtype=validation.
Messages	&_cstMessages used by the prior task.	&_cstMessages built by a call to %CSTUTIL_ ALLOCATESASREFERENCES.

Note: In the SAS Clinical Standards Toolkit, you are able to define report output locations in the SASReferences data set. These locations can be defined with type=report in SASReferences. They can be further specified in the framework

Standardlookup data set. For more information, see Chapter 2, “Framework,” on page 7.

This code is excerpted from the cst_report.sas driver program and performs the setup tasks that are specific to reporting:

```
* Initialize macro variables used for this task *;
%let _cstRptControl=;
%let _cstRptLib=;
%let _cstRptMetricsDS=;
%let _cstRptOutputFile=&studyOutputPath/results/cstreport.pdf;
%let _cstRptResultsDS=;
%let _cstSetupSrc=SASREFERENCES;
%let _cstStandard=CDISC-SDTM;
%let _cstStandardVersion=3.1.2;

%cstutil_processsetup(_cstSASReferencesLocation=&studyrootpath/control);
%cstutil_reportsetup(_cstRptType=Results);
```

In this piece of code:

- The report output is specified in the _cstRptOutputFile variable and is in **`&studyOutputPath/results/cstreport.pdf`**. The studyOutputPath variable was previously defined to point to a folder with Write permissions.
- The _cstSetupSrc=SASREFERENCES statement tells the process that a SASReferences data set is available and should be used to complete setup tasks.
- The call to the %CSTUTIL_PROCESSSETUP macro provides the location of the SASReferences data set using the previously defined &studyRootPath variable.
- The call to the %CSTUTIL_REPORTSETUP macro completes the setup steps that are required to generate report 1, itemizing results data set records by validation check.

An alternative setup to support Scenario 2, as described on page 445, would include these code excerpts:

```
%let _cstSetupSrc=RESULTS;
%cstutil_processsetup();
%let _cstRptResultsDS=work.validation_results;
%cstutil_reportsetup(_cstRptType=Results);
```

In this piece of code:

- The _cstSetupSrc=RESULTS statement tells the process that a SAS Clinical Standards Toolkit process results data set should be used as the initial metadata source to complete the setup tasks.
- The call to the %CSTUTIL_PROCESSSETUP macro without parameters, and with _cstSetupSrc=RESULTS, defers the remaining setup steps to the cstutil_reportsetup macro.
- The call to the %CSTUTIL_REPORTSETUP macro completes the setup steps required to generate report 1, itemizing work.validation_results records.

As the final step, the reporting driver program makes one or more calls to the utility reporting macro. At a minimum (using default parameter values), a macro call to create report 2 might include this code:

```
%cstutil_createreport(_cstsasreferencesdset=&_cstSASRefs,_cstreportbydomain=Y,
_cstreportoutput=&studyrootpath/results/cstchecktablereport.pdf);
```

Note: For more information about the %CSTUTIL_CREATEREPORT macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

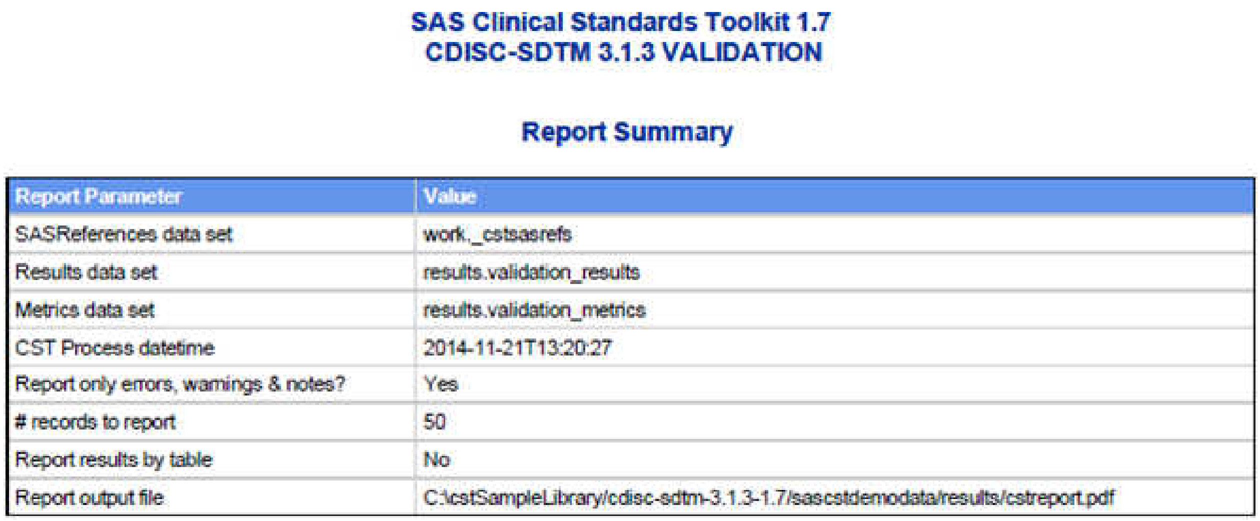
A more complete example of the %CSTUTIL_CREATEREPORT reporting macro includes this macro call:

```
%cstutil_createreport(
   _cstsasreferencesdset=&_cstSASRefs,
   _cstresultsdset=&_cstRptResultsDS,
   _cstmetricsdset=&_cstRptMetricsDS,
   _cstreportbytable=N,
   _cstreporterrorsonly=Y,
   _cstreportobs=50,
   _cstreportoutput=%nrbquote(&_cstRptOutputFile),
   _cstsummaryReport=Y,
   _cstioReport=Y,
   _cstmetricsReport=Y,
   _cstgeneralResultsReport=Y,
   _cstcheckIdResultsReport=Y);
```

Interpretation of this request produces a (validation) results listing that contains all five report panels and includes only the first 50 errors that are reported for each validation check.

The following displays show report content. The displays apply to report 1 (by checkid) unless otherwise indicated.

Figure 11.1 Example of Report Summary

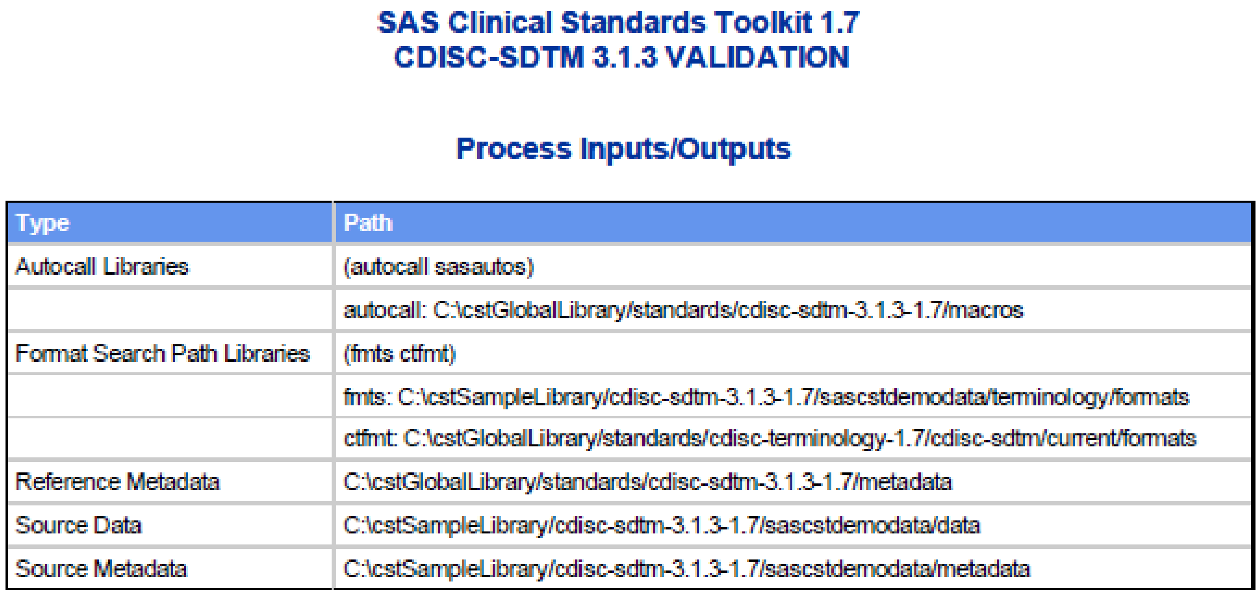


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

Report Summary

Report Parameter	Value
SASReferences data set	work._cstsasrefs
Results data set	results.validation_results
Metrics data set	results.validation_metrics
CST Process datetime	2014-11-21T13:20:27
Report only errors, warnings & notes?	Yes
# records to report	50
Report results by table	No
Report output file	C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata/results/cstreport.pdf

Figure 11.2 Example of Process Inputs and Outputs

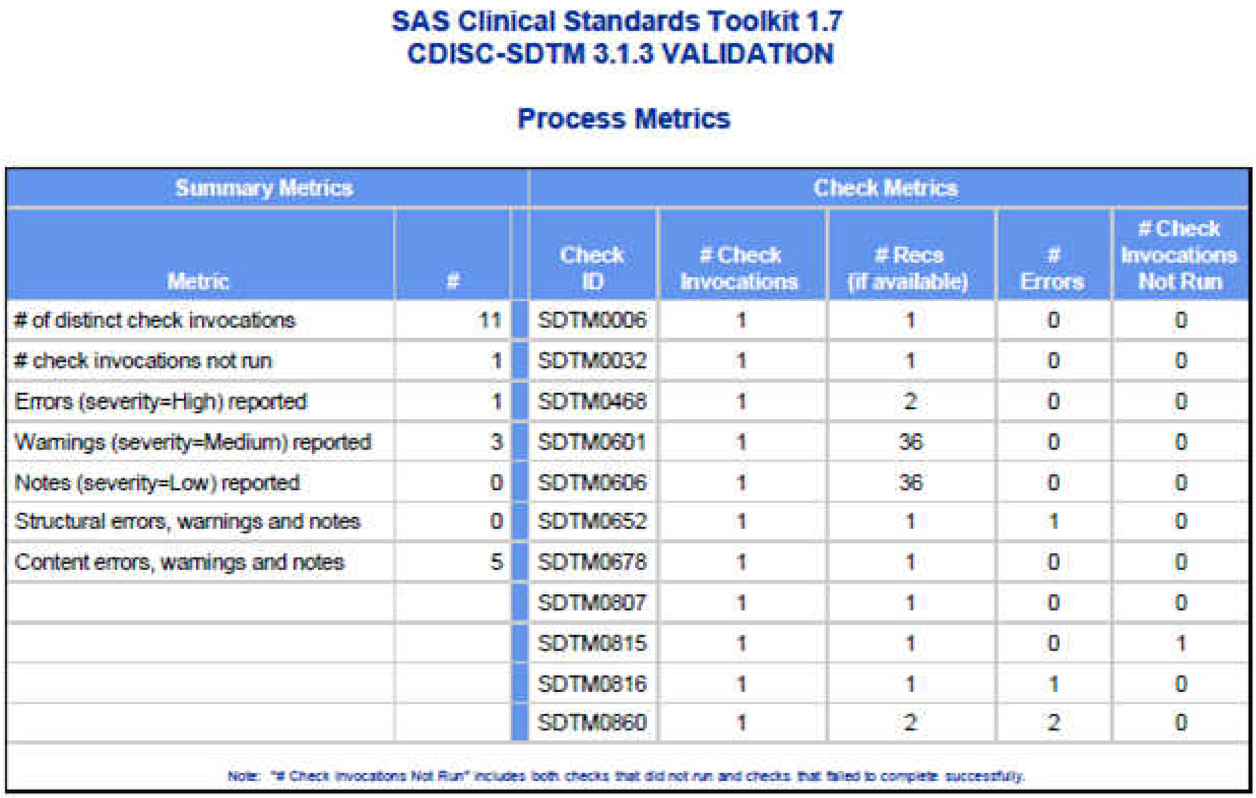


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

Process Inputs/Outputs

Type	Path
Autocall Libraries	(autocall sasautos)
	autocall: C:\cstGlobalLibrary/standards/cdisc-sdtm-3.1.3-1.7/macros
Format Search Path Libraries	(fmts ctfmt)
	fmts: C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata/terminology/formats
	ctfmt: C:\cstGlobalLibrary/standards/cdisc-terminology-1.7/cdisc-sdtm/current/formats
Reference Metadata	C:\cstGlobalLibrary/standards/cdisc-sdtm-3.1.3-1.7/metadata
Source Data	C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata/data
Source Metadata	C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata/metadata

Figure 11.3 Example of Process Metrics (Report 1)



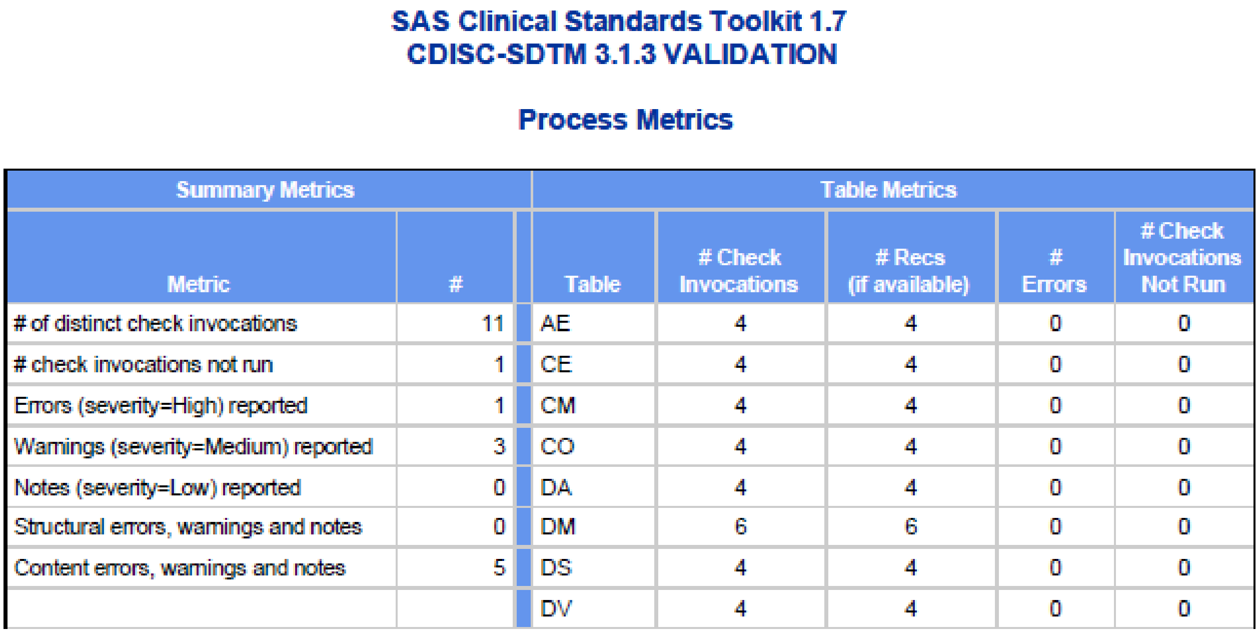
SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

Process Metrics

Summary Metrics		Check Metrics				
Metric	#	Check ID	# Check Invocations	# Recs (if available)	# Errors	# Check Invocations Not Run
# of distinct check invocations	11	SDTM0006	1	1	0	0
# check invocations not run	1	SDTM0032	1	1	0	0
Errors (severity=High) reported	1	SDTM0468	1	2	0	0
Warnings (severity=Medium) reported	3	SDTM0601	1	36	0	0
Notes (severity=Low) reported	0	SDTM0606	1	36	0	0
Structural errors, warnings and notes	0	SDTM0652	1	1	1	0
Content errors, warnings and notes	5	SDTM0678	1	1	0	0
		SDTM0807	1	1	0	0
		SDTM0815	1	1	0	1
		SDTM0816	1	1	1	0
		SDTM0860	1	2	2	0

Note: "# Check Invocations Not Run" includes both checks that did not run and checks that failed to complete successfully.

Figure 11.4 Example of Process Metrics by Domain (Report 2)

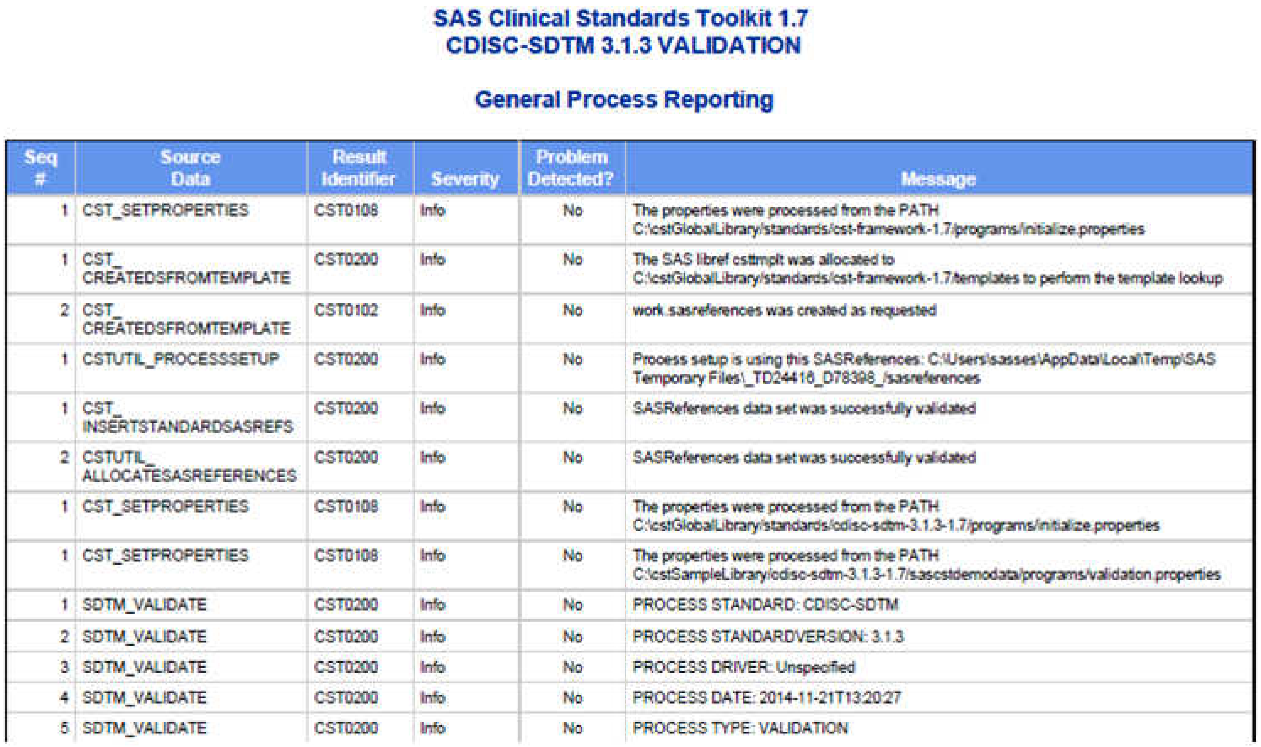


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

Process Metrics

Summary Metrics			Table Metrics				
Metric	#		Table	# Check Invocations	# Recs (if available)	# Errors	# Check Invocations Not Run
# of distinct check invocations	11		AE	4	4	0	0
# check invocations not run	1		CE	4	4	0	0
Errors (severity=High) reported	1		CM	4	4	0	0
Warnings (severity=Medium) reported	3		CO	4	4	0	0
Notes (severity=Low) reported	0		DA	4	4	0	0
Structural errors, warnings and notes	0		DM	6	6	0	0
Content errors, warnings and notes	5		DS	4	4	0	0
			DV	4	4	0	0

Figure 11.5 Example of General Process Reporting

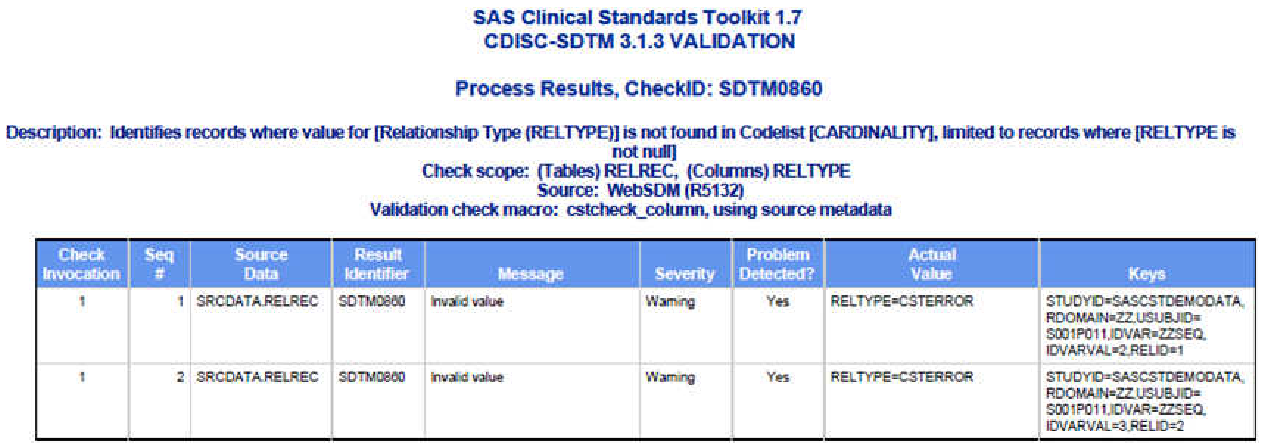


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

General Process Reporting

Seq #	Source Data	Result Identifier	Severity	Problem Detected?	Message
1	CST_SETPROPERTIES	CST0108	Info	No	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cst-framework-1.7/programs/initialize.properties
1	CST_ CREATEDSFROMTEMPLATE	CST0200	Info	No	The SAS libref csttmplt was allocated to C:\cstGlobalLibrary/standards/cst-framework-1.7/templates to perform the template lookup
2	CST_ CREATEDSFROMTEMPLATE	CST0102	Info	No	work.sasreferences was created as requested
1	CSTUTIL_PROCESSSETUP	CST0200	Info	No	Process setup is using this SASReferences: C:\Users\sasses\AppData\Local\Temp\SAS Temporary Files_TD24416_D78398_/sasreferences
1	CST_ INSERTSTANDARDSASREFS	CST0200	Info	No	SASReferences data set was successfully validated
2	CSTUTIL_ ALLOCATESASREFERENCES	CST0200	Info	No	SASReferences data set was successfully validated
1	CST_SETPROPERTIES	CST0108	Info	No	The properties were processed from the PATH C:\cstGlobalLibrary/standards/cdisc-sdtm-3.1.3-1.7/programs/initialize.properties
1	CST_SETPROPERTIES	CST0108	Info	No	The properties were processed from the PATH C:\cstSampleLibrary/cdisc-sdtm-3.1.3-1.7/sascstdemodata/programs/validation.properties
1	SDTM_VALIDATE	CST0200	Info	No	PROCESS STANDARD: CDISC-SDTM
2	SDTM_VALIDATE	CST0200	Info	No	PROCESS STANDARDVERSION: 3.1.3
3	SDTM_VALIDATE	CST0200	Info	No	PROCESS DRIVER: Unspecified
4	SDTM_VALIDATE	CST0200	Info	No	PROCESS DATE: 2014-11-21T13:20:27
5	SDTM_VALIDATE	CST0200	Info	No	PROCESS TYPE: VALIDATION

Figure 11.6 Example of Validation Results by CheckID (Report 1)



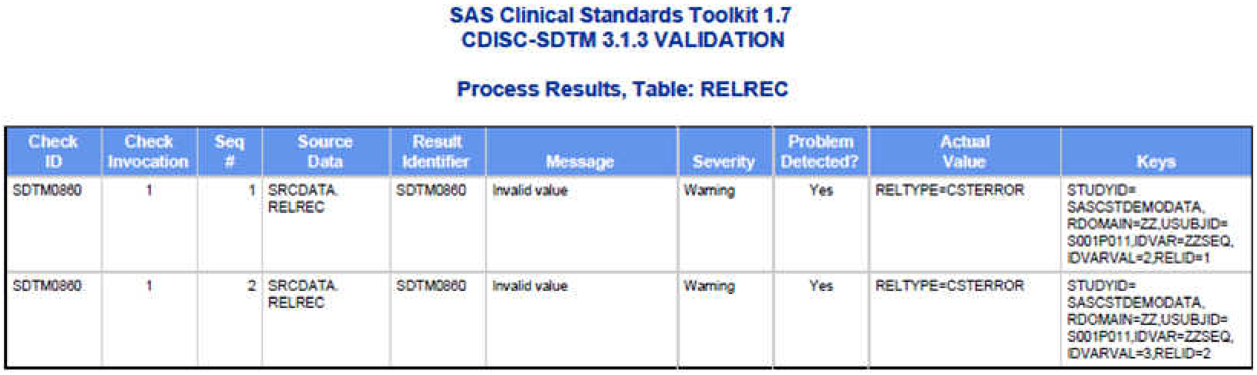
SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

Process Results, CheckID: SDTM0860

Description: Identifies records where value for [Relationship Type (RELTYPE)] is not found in Codelist [CARDINALITY], limited to records where [RELTYPE is not null]
Check scope: (Tables) RELREC, (Columns) RELTYPE
Source: WebSDM (R5132)
Validation check macro: cstcheck_column, using source metadata

Check Invocation	Seq #	Source Data	Result Identifier	Message	Severity	Problem Detected?	Actual Value	Keys
1	1	SRCDATA.RELREC	SDTM0860	Invalid value	Warning	Yes	RELTYPE=CSTERROR	STUDYID=SASCSTDEMODATA, RDOMAIN=ZZ,USUBJID= S001P011,IDVAR=ZZSEQ, IDVARVAL=2,RELID=1
1	2	SRCDATA.RELREC	SDTM0860	Invalid value	Warning	Yes	RELTYPE=CSTERROR	STUDYID=SASCSTDEMODATA, RDOMAIN=ZZ,USUBJID= S001P011,IDVAR=ZZSEQ, IDVARVAL=3,RELID=2

Figure 11.7 *Example of Validation Results by Domain (Report 2)*



SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 VALIDATION

Process Results, Table: RELREC

Check ID	Check Invocation	Seq #	Source Data	Result Identifier	Message	Severity	Problem Detected?	Actual Value	Keys
SDTM0860	1	1	SRCDATA. RELREC	SDTM0860	Invalid value	Warning	Yes	RELTYPE=CSTERROR	STUDYID= SASCSTDEMODATA, RDOMAIN=ZZ,USUBJID= S001P011,IDVAR=ZZSEQ, IDVARVAL=2,RELID=1
SDTM0860	1	2	SRCDATA. RELREC	SDTM0860	Invalid value	Warning	Yes	RELTYPE=CSTERROR	STUDYID= SASCSTDEMODATA, RDOMAIN=ZZ,USUBJID= S001P011,IDVAR=ZZSEQ, IDVARVAL=3,RELID=2

Validation Check Metadata Reporting

Report 3 offers the complete set of metadata about each validation check that is available in the SAS Clinical Standards Toolkit. The report can be printed in a multi-panel or one-page-per-check presentation format.

A sample driver program is provided to define the SAS Clinical Standards Toolkit environment and to call the primary task framework macro (%CSTUTIL_CREATEMETADATAREPORT). This excerpt from the driver program header provides a brief overview:

```
cst_metadatareport.sas

Sample driver program to perform reporting of validation check metadata.
This code performs any needed set-up and data management tasks, followed by
one or more calls to the %cstutil_createmetadatareport() macro to generate
report output.

Two scenarios for invoking this routine are addressed in this driver module:
  (1) This code is run as a natural continuation of a CST process, within
      the same SAS session, with all required files available.  The working
      assumption is that the SASReferences data set (&_cstSASRefs) exists and
      contains information on all files required for reporting.
  (2) This code is being run in another SAS session with no CST setup
      established.  In this case, the user assumes responsibility for
      defining all librefs and macro variables needed to run the reports,
      although defaults are set.
```

```
Assumptions:
(1) SASReferences is not required for this task.  If found, it will be used.
    If not found, default libraries and macro variables are set and may be
    overridden by the user.
(2) The user of this code may override any cstutil_createmetadatareport
    parameter values.
(3) Only the cstutil_createmetadatareport &_cstRptControl and &_cstMessages
    parameters are REQUIRED.
(4) If the _cststdrefds parameter is not set, the associated panel cannot be
    generated.
(5) By default, a PDF report format is assumed. This may be overridden.
(6) Report output will be written to cstcheckmetadatareport.pdf in the SAS
    WORK library unless another location is specified in SASReferences or
    in the set-up code below.
(7) The report macro cstutil_createmetadatareport will only produce panel 1
    (Check Overview) unless any of the last 3 parameters are set to Y.
```

Report setup is similar to reporting on process results. The only key difference is that the call to the %CSTUTIL_REPORTSETUP macro passes a different parameter value to request check metadata reporting:

```
%cstutil_reportsetup(_cstRptType=Metadata);
```

To generate the metadata report, the reporting driver program makes one or more calls to the utility reporting macro. At a minimum (using default parameter values), a macro call to create report 3 might include this code:

```
%cstutil_createmetadatareport(
                 _cstValidationDS=&_cstRptControl
                ,_cstMessagesDS=&_cstMessages
                ,_cstReportOutput=%bquote(&_cstRptOutput)
                );
```

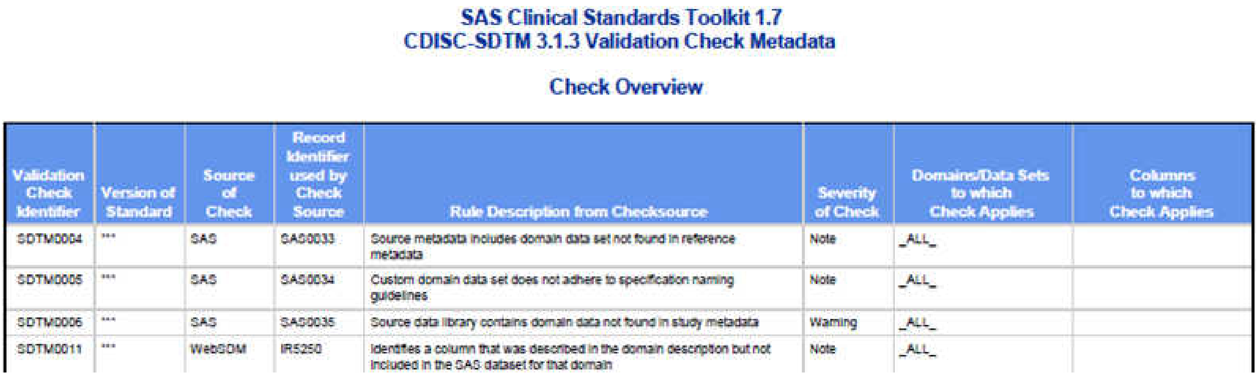
Note: For more information about the %CSTUTIL_CREATEMETADATAREPORT macro, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

A more complete example of the %CSTUTIL_CREATEMETADATAREPORT reporting macro includes this macro call:

```
%cstutil_createmetadatareport(
   _cststandardtitle=%str(CDISC-SDTM 3.1.3 Validation Check Metadata),
   _cstvalidationds=refcntl.validation_master,
   _cstvalidationdswhclause=,
   _cstmessagesds=&_cstMessages,
   _cststdrefds=refcntl.validation_stdref,
   _cstreportoutput=%nrbquote(&studyOutputPath/results/cstcheckmetadatareport.pdf),
   _cstcheckmdreport=Y,
   _cstmessagereport=Y,
   _cststdrefreport=Y,
   _cstrecordview=N);
```

Interpretation of this request produces a validation check metadata report (cstcheckmetadatareport.pdf) that contains all four report sections for the CDISC SDTM 3.1.3 validation checks.

Figure 11.8 *Example of Check Overview*

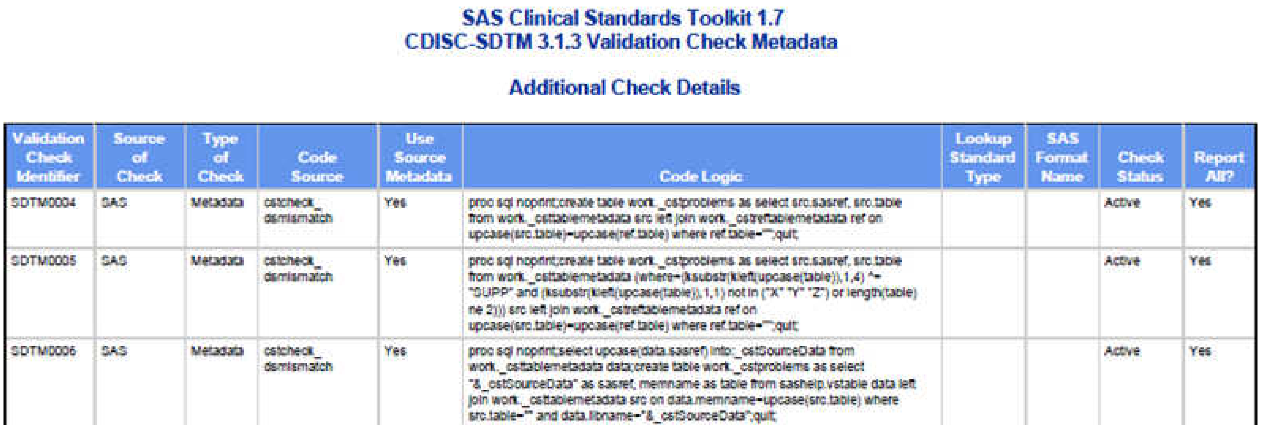


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 Validation Check Metadata

Check Overview

Validation Check Identifier	Version of Standard	Source of Check	Record Identifier used by Check Source	Rule Description from Checksource	Severity of Check	Domains/Data Sets to which Check Applies	Columns to which Check Applies
SDTM0004	***	SAS	SAS0033	Source metadata includes domain data set not found in reference metadata	Note	_ALL_	
SDTM0005	***	SAS	SAS0034	Custom domain data set does not adhere to specification naming guidelines	Note	_ALL_	
SDTM0006	***	SAS	SAS0035	Source data library contains domain data not found in study metadata	Warning	_ALL_	
SDTM0011	***	WebSDM	IR5250	Identifies a column that was described in the domain description but not included in the SAS dataset for that domain	Note	_ALL_	

Figure 11.9 *Example of Additional Check Details (Panel 2) [_cstCheckMDReport=Y]*

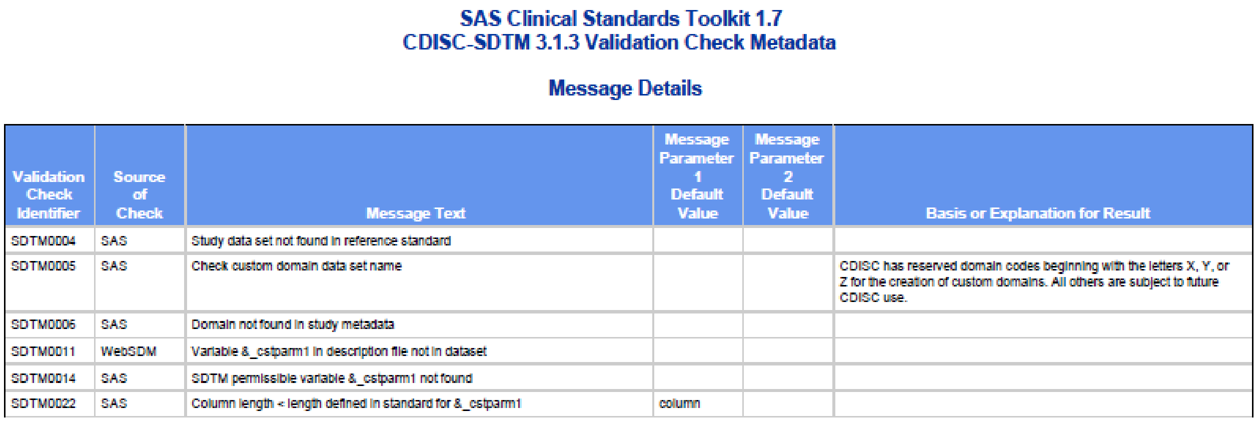


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 Validation Check Metadata

Additional Check Details

Validation Check Identifier	Source of Check	Type of Check	Code Source	Use Source Metadata	Code Logic	Lookup Standard Type	SAS Format Name	Check Status	Report All?
SDTM0004	SAS	Metadata	cstcheck_dsmismatch	Yes	proc sql noprint;create table work._cstproblems as select src.sasref, src.table from work._csttablemetadata src left join work._cstreftablemetadata ref on upcase(src.table)=upcase(ref.table) where ref.table="";quit;			Active	Yes
SDTM0005	SAS	Metadata	cstcheck_dsmismatch	Yes	proc sql noprint;create table work._cstproblems as select src.sasref, src.table from work._csttablemetadata (where=(ksubstr(kleft(upcase(table)),1,4) ^= "SUPP" and (ksubstr(kleft(upcase(table)),1,1) not in ("X" "Y" "Z") or length(table) ne 2))) src left join work._cstreftablemetadata ref on upcase(src.table)=upcase(ref.table) where ref.table="";quit;			Active	Yes
SDTM0006	SAS	Metadata	cstcheck_dsmismatch	Yes	proc sql noprint;select upcase(data.sasref) into:_cstSourceData from work._csttablemetadata data;create table work._cstproblems as select "&_cstSourceData" as sasref, memname as table from sashelp.vstable data left join work._csttablemetadata src on data.memname=upcase(src.table) where src.table="" and data.libname="&_cstSourceData";quit;			Active	Yes

***Figure 11.10** Example of Message Details (Panel 3) [_cstMessageReport=Y]*

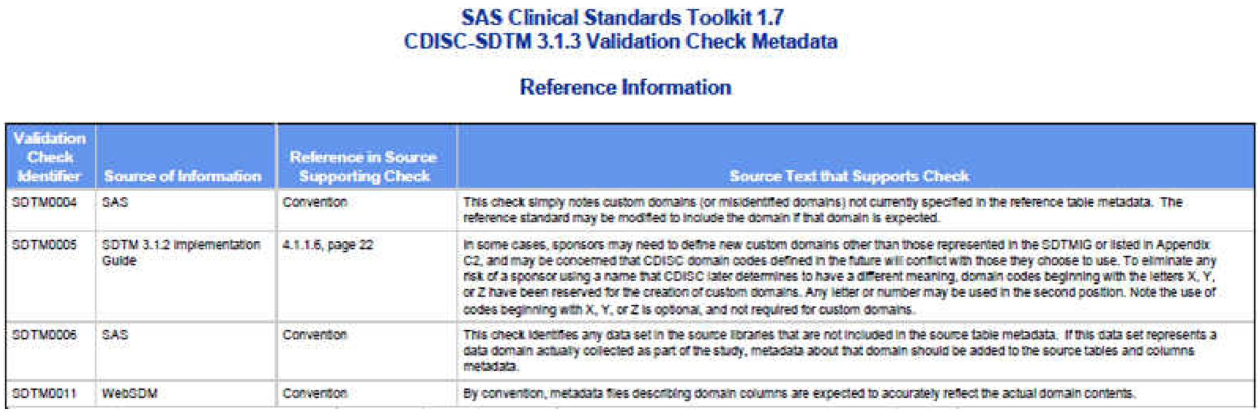


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 Validation Check Metadata

Message Details

Validation Check Identifier	Source of Check	Message Text	Message Parameter 1 Default Value	Message Parameter 2 Default Value	Basis or Explanation for Result
SDTM0004	SAS	Study data set not found in reference standard			
SDTM0005	SAS	Check custom domain data set name			CDISC has reserved domain codes beginning with the letters X, Y, or Z for the creation of custom domains. All others are subject to future CDISC use.
SDTM0006	SAS	Domain not found in study metadata			
SDTM0011	WebSDM	Variable &_cstparm1 in description file not in dataset			
SDTM0014	SAS	SDTM permissible variable &_cstparm1 not found			
SDTM0022	SAS	Column length < length defined in standard for &_cstparm1	column		

***Figure 11.11** Example of Reference Information (Panel 4) [_cstSTDRefReport=Y]*

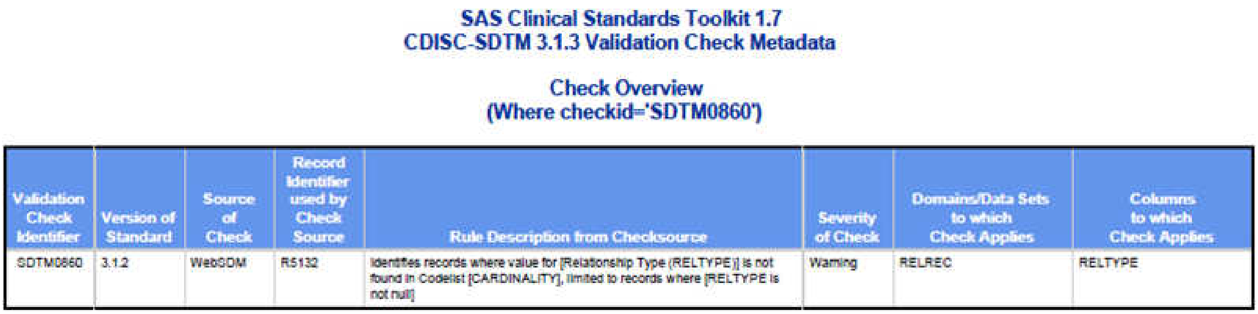


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 Validation Check Metadata

Reference Information

Validation Check Identifier	Source of Information	Reference in Source Supporting Check	Source Text that Supports Check
SDTM0004	SAS	Convention	This check simply notes custom domains (or misidentified domains) not currently specified in the reference table metadata. The reference standard may be modified to include the domain if that domain is expected.
SDTM0005	SDTM 3.1.2 Implementation Guide	4.1.1.6, page 22	In some cases, sponsors may need to define new custom domains other than those represented in the SDTMIG or listed in Appendix C2, and may be concerned that CDISC domain codes defined in the future will conflict with those they choose to use. To eliminate any risk of a sponsor using a name that CDISC later determines to have a different meaning, domain codes beginning with the letters X, Y, or Z have been reserved for the creation of custom domains. Any letter or number may be used in the second position. Note the use of codes beginning with X, Y, or Z is optional, and not required for custom domains.
SDTM0006	SAS	Convention	This check identifies any data set in the source libraries that are not included in the source table metadata. If this data set represents a data domain actually collected as part of the study, metadata about that domain should be added to the source tables and columns metadata.
SDTM0011	WebSDM	Convention	By convention, metadata files describing domain columns are expected to accurately reflect the actual domain contents.

***Figure 11.12** Example of Using WHERE Clause [_cstValidationDSWhClause=checkid='SDTM0801']*

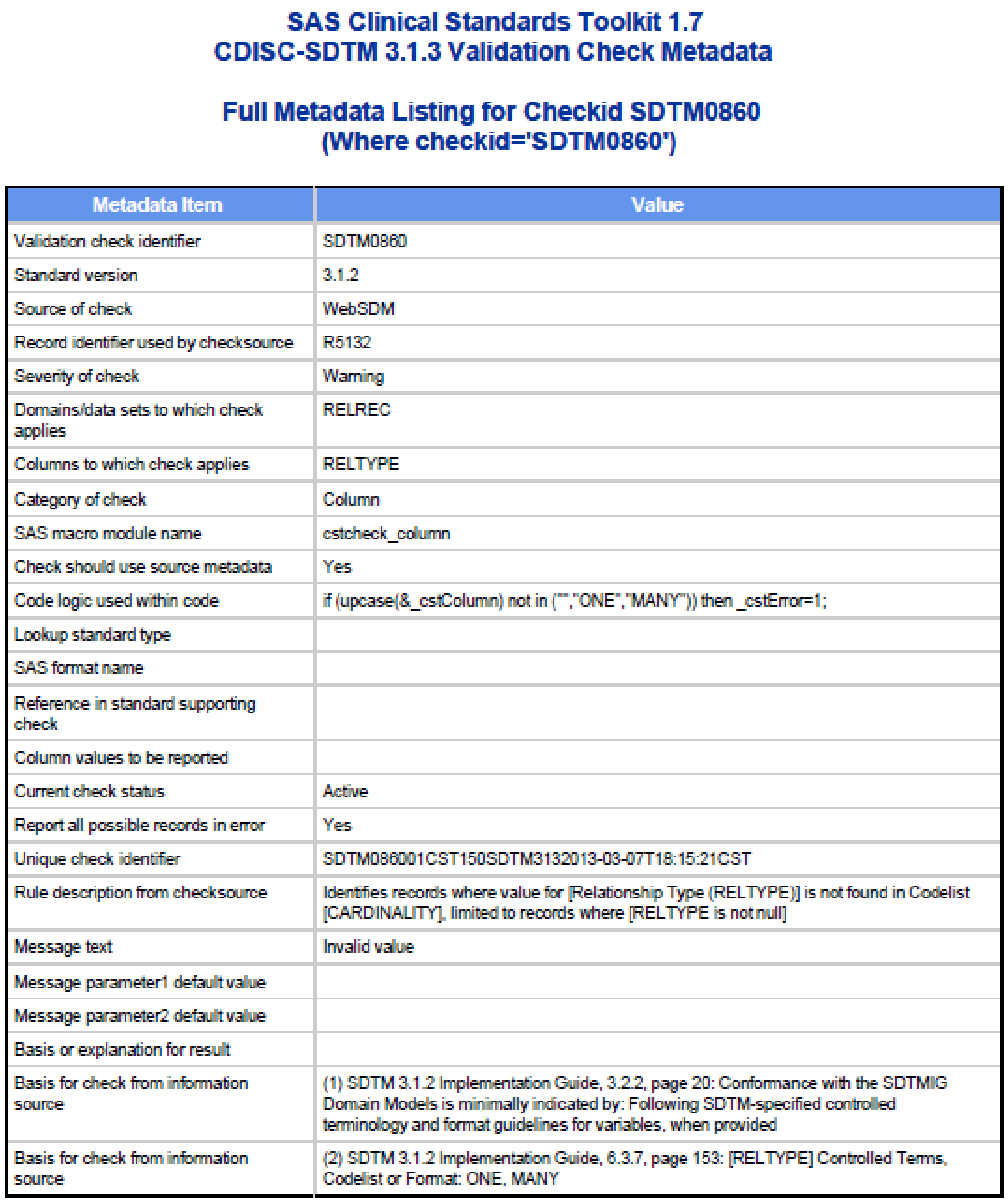


SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 Validation Check Metadata

Check Overview
(Where checkid='SDTM0860')

Validation Check Identifier	Version of Standard	Source of Check	Record Identifier used by Check Source	Rule Description from Checksource	Severity of Check	Domains/Data Sets to which Check Applies	Columns to which Check Applies
SDTM0860	3.1.2	WebSDM	R5132	Identifies records where value for [Relationship Type (RELTYPE)] is not found in Codelist [CARDINALITY], limited to records where [RELTYPE is not null]	Warning	RELREC	RELTYPE

Figure 11.13 Example of by Record View [_cstRecordView=Y]



SAS Clinical Standards Toolkit 1.7
CDISC-SDTM 3.1.3 Validation Check Metadata

Full Metadata Listing for Checkid SDTM0860
(Where checkid='SDTM0860')

Metadata Item	Value
Validation check identifier	SDTM0860
Standard version	3.1.2
Source of check	WebSDM
Record identifier used by checksource	R5132
Severity of check	Warning
Domains/data sets to which check applies	RELREC
Columns to which check applies	RELTYPE
Category of check	Column
SAS macro module name	cstcheck_column
Check should use source metadata	Yes
Code logic used within code	if (upcase(&_cstColumn) not in ("","ONE","MANY")) then _cstError=1;
Lookup standard type	
SAS format name	
Reference in standard supporting check	
Column values to be reported	
Current check status	Active
Report all possible records in error	Yes
Unique check identifier	SDTM086001CST150SDTM3132013-03-07T18:15:21CST
Rule description from checksource	Identifies records where value for [Relationship Type (RELTYPE)] is not found in Codelist [CARDINALITY], limited to records where [RELTYPE is not null]
Message text	Invalid value
Message parameter1 default value	
Message parameter2 default value	
Basis or explanation for result	
Basis for check from information source	(1) SDTM 3.1.2 Implementation Guide, 3.2.2, page 20: Conformance with the SDTMIG Domain Models is minimally indicated by: Following SDTM-specified controlled terminology and format guidelines for variables, when provided
Basis for check from information source	(2) SDTM 3.1.2 Implementation Guide, 6.3.7, page 153: [RELTYPE] Controlled Terms, Codelist or Format: ONE, MANY

Appendix 1

Global Macro Variables

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Global Macro Variables and Their Associated Metadata 460

Overview

Most of the SAS Clinical Standards Toolkit global macro variables that are provided by SAS are defined in properties files in the form of name and value pairs. Here is an example:

```
_cstDebug=0
```

Each registered standard, including CST-Framework, has an initialize.properties file. This file specifies global macro variables that are required by the standard and are available for use in any SAS Clinical Standards Toolkit process that references the standard. Each registered standard might have an action-related properties file that specifies global macro variables that are needed for processes that perform the action. An example of this type of action-related properties file is validation.properties.

A properties file is processed in one of two ways:

1 A direct call is made to the SAS Clinical Standards Toolkit utility macro %CST_SETSTANDARDPROPERTIES in a code module, such as a driver program like validate_data.sas. The %CST_SETSTANDARDPROPERTIES macro calls cst_setproperties.

2 The file is included in the SASReferences data set (with type=properties), in which the %CSTUTIL_ALLOCATESASREFERENCES macro calls the %CST_SETPROPERTIES macro.

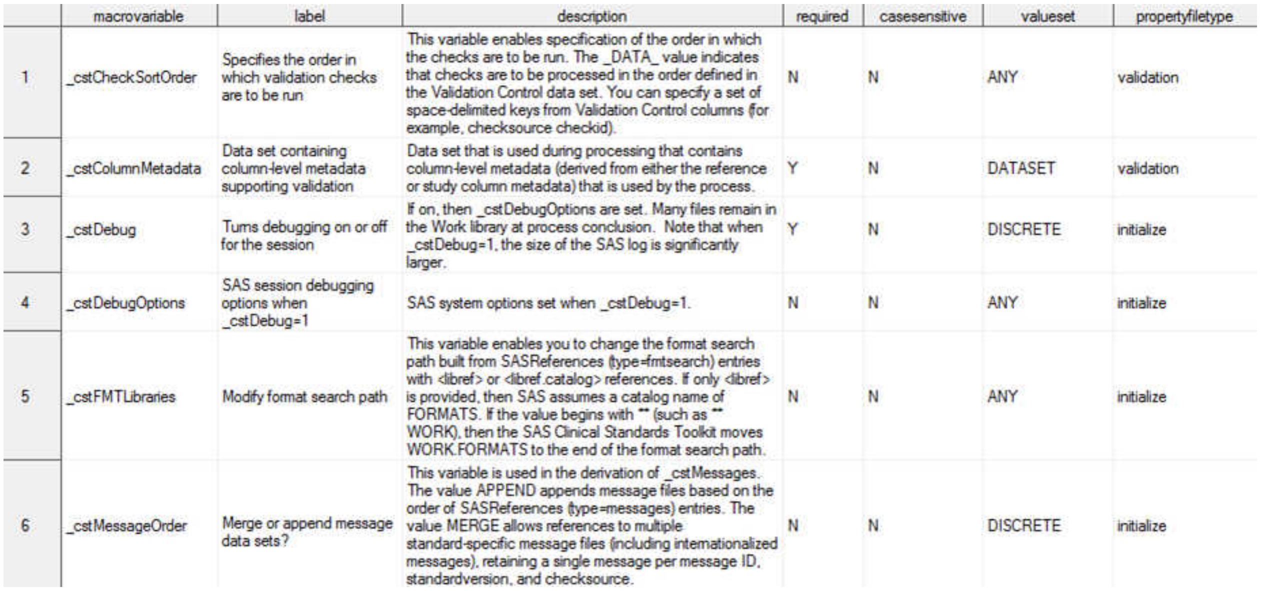
Global macro variables can be deleted at the end of a process if the SAS Clinical Standards Toolkit utility macro %CSTUTIL_CLEANUPCSTSESSION is called with the _cstDeleteGlobalMacroVars parameter set to 1.

Global Macro Variables and Their Associated Metadata

Global macro variables and their associated metadata can be found in the standardmacrovariables and standardmacrovariabledetails data sets in the standard control folder.

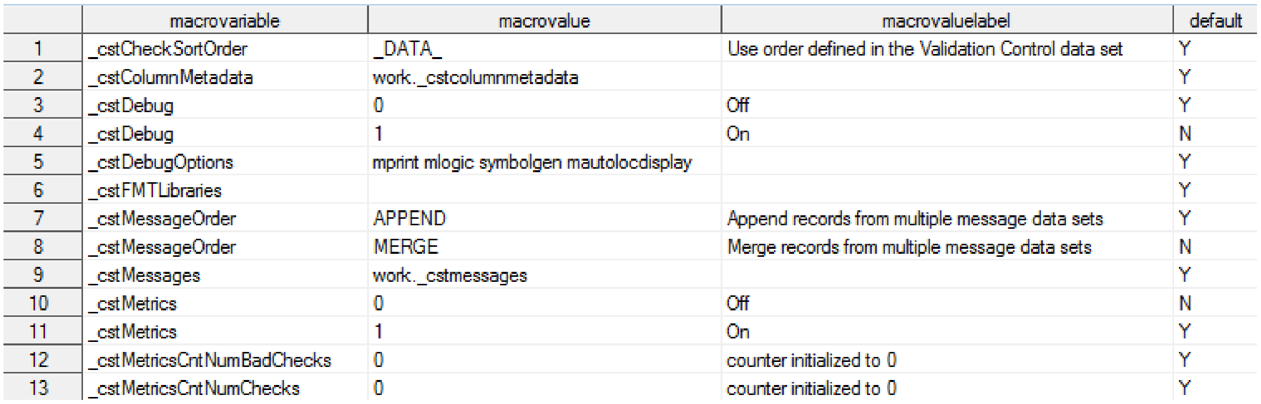
The following displays show examples of the standardmacrovariables data set and the standardmacrovariabledetails data set.

Figure A1.1 *Example of the standardmacrovariables Data Set*



	macrovariable	label	description	required	casesensitive	valueset	propertyfiletype
1	_cstCheckSortOrder	Specifies the order in which validation checks are to be run	This variable enables specification of the order in which the checks are to be run. The _DATA_ value indicates that checks are to be processed in the order defined in the Validation Control data set. You can specify a set of space-delimited keys from Validation Control columns (for example, checksource checkid).	N	N	ANY	validation
2	_cstColumnMetadata	Data set containing column-level metadata supporting validation	Data set that is used during processing that contains column-level metadata (derived from either the reference or study column metadata) that is used by the process.	Y	N	DATASET	validation
3	_cstDebug	Turns debugging on or off for the session	If on, then _cstDebugOptions are set. Many files remain in the Work library at process conclusion. Note that when _cstDebug=1, the size of the SAS log is significantly larger.	Y	N	DISCRETE	initialize
4	_cstDebugOptions	SAS session debugging options when _cstDebug=1	SAS system options set when _cstDebug=1.	N	N	ANY	initialize
5	_cstFMTLibraries	Modify format search path	This variable enables you to change the format search path built from SASReferences (type=fmtsearch) entries with <libref> or <libref.catalog> references. If only <libref> is provided, then SAS assumes a catalog name of FORMATS. If the value begins with "*" (such as "* WORK), then the SAS Clinical Standards Toolkit moves WORK.FORMATS to the end of the format search path.	N	N	ANY	initialize
6	_cstMessageOrder	Merge or append message data sets?	This variable is used in the derivation of _cstMessages. The value APPEND appends message files based on the order of SASReferences (type=messages) entries. The value MERGE allows references to multiple standard-specific message files (including internationalized messages), retaining a single message per message ID, standardversion, and checksource.	N	N	DISCRETE	initialize

Figure A1.2 *Example of the standardmacrovariabledetails Data Set*



	macrovariable	macrovalue	macrovaluelabel	default
1	_cstCheckSortOrder	_DATA_	Use order defined in the Validation Control data set	Y
2	_cstColumnMetadata	work._cstcolumnmetadata		Y
3	_cstDebug	0	Off	Y
4	_cstDebug	1	On	N
5	_cstDebugOptions	mprint mlogic symbolgen mautolocdisplay		Y
6	_cstFMTLibraries			Y
7	_cstMessageOrder	APPEND	Append records from multiple message data sets	Y
8	_cstMessageOrder	MERGE	Merge records from multiple message data sets	N
9	_cstMessages	work._cstmessages		Y
10	_cstMetrics	0	Off	N
11	_cstMetrics	1	On	Y
12	_cstMetricsCntNumBadChecks	0	counter initialized to 0	Y
13	_cstMetricsCntNumChecks	0	counter initialized to 0	Y

The standardmacrovariables and standardmacrovariabledetails data sets can be easily merged with the following SAS code:

```
proc sql;
  select smv.*, smvd.macrovalue, smvd.macrovaluelabel, smvd.default
  from control.standardmacrovariables smv,
       control.standardmacrovariabledetails smvd
  where smv.macrovariable = smvd.macrovariable;
quit;
```

Here are several commonly used global macro variables that are not defined in the properties files previously described:

Global Macro Variable	Example	Comments
_cstGRoot	C:\cstGlobalLibrary	This variable is required. It defines the location of _cstGlobalLibrary. It is set with the autocall macro %CSTUTIL_SETCSTGROOT, which is called in most framework macros. It is used most often in SASReferences paths to enable relative path mobility.

Global Macro Variable	Example	Comments
_cstSRoot	C:\cstSampleLibrary	This variable is optional. It defines the location of _cstSampleLibrary. It is set with the autocall macro %CSTUTIL_SETCSTSROOT, which is called in most sample driver programs to derive the studyRootPath and studyOutputPath global macro variables.
studyRootPath	C:\Study1	This variable is optional. It defines the location of study data and metadata. It is often set in user-defined driver programs (for example, validate_data.sas). It is used in SASReferences paths to limit the changes that are required when changing input data sources, which facilitates portability.
studyOutputPath	C:\Study1\output	This variable is optional. It defines the location of generated output. It is often set in user-defined driver programs (for example, validate_data.sas). It is used in SASReferences paths to limit the changes that are required when changing output locations, which facilitates portability.

Appendix 2

Additional Utility Macros

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The %CSTUTILSQLCOLUMNDEFINITION Macro 464

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Replacing Extended ASCII Characters in a SAS Data Set 473

The %CSTUTILFINDFIXEXTDASCIICHARS Macro 473

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Example: Using an External SAS Format 488

Overview

To help you develop content for a new standard or study, SAS provides these macros:

- %CSTUTILSQLCOLUMNDEFINITION
- %CSTUTILSQLGENERATETABLE
- %CSTUTILFINDFIXEXTDASCIICHARS

The %CSTUTILSQLCOLUMNDEFINITION and %CSTUTILSQLGENERATETABLE macros deconstruct a SAS data set and create code for SAS SQL, ANSI SQL, or Oracle SQL. You then modify the resulting code to fit your needs and submit it as needed.

The %CSTUTILFINDFIXEXTDASCIICHARS macro scans a SAS data set and replaces extended ASCII characters with characters that are acceptable to SAS.

For more detailed information about these macros, see the *SAS Clinical Standards Toolkit: Macro API Documentation*.

Generating PROC SQL Code to Create and Populate Data Sets

The %CSTUTILSQLCOLUMNDEFINITION Macro

The %CSTUTILSQLCOLUMNDEFINITION macro generates the SQL equivalent of the SAS ATTRIB statement in a SAS data set. The structure and content of the returned code differs based on what type of SQL code you choose to generate: SAS, ANSI, or Oracle.

The macro checks each column name in the SAS data set against a list of reserved words for both ANSI SQL and Oracle SQL. If a reserved word is found in the SAS data set, a message appears in the SAS log file, and the macro appends __SQL1 (single underline, single underline, SQL1) to the column name in the SAS data set. In the generated code, you must decide whether to modify the column name in the generated code or rename the column in the SAS data set before submitting the macro.

The results of the macro are intended to be used by the %CSTUTILSQLGENERATETABLE macro. However, you can use the results with other macros as needed. The %CSTUTILSQLCOLUMNDEFINITION macro can be run stand-alone.

Example: Generating SAS SQL

The following example demonstrates generating SAS PROC SQL code for the CDISC SDTM AE domain:

```
libname sdtm32 'c:\cstSampleLibrary\cdisc-sdtm-3.2-1.7\sascstdemodata\data';
%let _cstColumnDef=;
%cstutilsqlcolumndefinition(_cstSourceDS=sdtm32.ae,_cstSQLColDef=_cstColumnDef,
                            _cstSQLType=SAS);
%put &=_cstColumnDef;
```

The %CSTUTILSQLGENERATETABLE macro populates the &_cstColumnDef macro variable with the following SAS PROC SQL column description values:

```
_CSTCOLUMNDEF=(
STUDYID char(40) label="Study Identifier",
DOMAIN char(8) label="Domain Abbreviation",
USUBJID char(40) label="Unique Subject Identifier",
AESEQ numeric label="Sequence Number",
AEGRPID char(40) label="Group ID",
AEREFID char(40) label="Reference ID",
AESPID char(40) label="Sponsor-Defined Identifier",
AETERM char(200) label="Reported Term for the Adverse Event",
AEMODIFY char(200) label="Modified Reported Term",
AELLT char(100) label="Lowest Level Term",
AELLTCD numeric label="Lowest Level Term Code",
AEDECOD char(200) label="Dictionary-Derived Term",
AEPTCD numeric label="Preferred Term Code",
AEHLT char(100) label="High Level Term",
AEHLTCD numeric label="High Level Term Code",
AEHLGT char(100) label="High Level Group Term",
AEHLGTCD numeric label="High Level Group Term Code",
AECAT char(40) label="Category for Adverse Event",
AESCAT char(40) label="Subcategory for Adverse Event",
AEPRESP char(2) label="Pre-Specified Adverse Event",
AEBODSYS char(80) label="Body System or Organ Class",
AEBDSYCD numeric label="Body System or Organ Class Code",
AESOC char(80) label="Primary System Organ Class",
AESOCCD numeric label="Primary System Organ Class Code",
AELOC char(40) label="Location of Event",
AESEV char(20) label="Severity/Intensity",
AESER char(2) label="Serious Event",
AEACN char(40) label="Action Taken with Study Treatment",
AEACNOTH char(200) label="Other Action Taken",
AEREL char(40) label="Causality",
AERELNST char(40) label="Relationship to Non-Study Treatment",
AEPATT char(20) label="Pattern of Adverse Event",
AEOUT char(40) label="Outcome of Adverse Event",
AESCAN char(2) label="Involves Cancer",
AESCONG char(2) label="Congenital Anomaly or Birth Defect",
AESDISAB char(2) label="Persist or Signif Disability/Incapacity",
AESDTH char(2) label="Results in Death",
AESHOSP char(2) label="Requires or Prolongs Hospitalization",
AESLIFE char(2) label="Is Life Threatening",
AESOD char(2) label="Occurred with Overdose",
AESMIE char(2) label="Other Medically Important Serious Event",
AECONTRT char(2) label="Concomitant or Additional Trtmnt Given",
AETOXGR char(20) label="Standard Toxicity Grade",
AESTDTC char(64) label="Start Date/Time of Adverse Event",
AEENDTC char(64) label="End Date/Time of Adverse Event",
AESTDY numeric label="Study Day of Start of Adverse Event",
AEENDY numeric label="Study Day of End of Adverse Event",
AEDUR char(64) label="Duration of Adverse Event",
AEENRF char(20) label="End Relative to Reference Period",
AEENRTPT char(40) label="End Relative to Reference Time Point",
AEENTPT char(40) label="End Reference Time Point" )
```

Example: Generating ANSI SQL

The following example demonstrates generating ANSI SQL code for the SDTM AE domain:

```
%cstutilsqlcolumndefinition(_cstSourceDS=sdtm32.ae,_cstSQLColDef=_cstColumnDef,
                            _cstSQLType=ANSI);
%put &=_cstColumnDef;
```

The %CSTUTILSQLGENERATETABLE macro populates the &_cstColumnDef macro variable with the following ANSI SQL column description values:

```
_CSTCOLUMNDEF=(
STUDYID varchar(40),
DOMAIN varchar(8),
USUBJID varchar(40),
AESEQ numeric,
AEGRPID varchar(40),
AEREFID varchar(40),
AESPID varchar(40),
AETERM varchar(200),
AEMODIFY varchar(200),
AELLT varchar(100),
AELLTCD numeric,
AEDECOD varchar(200),
AEPTCD numeric,
AEHLT varchar(100),
AEHLTCD numeric,
AEHLGT varchar(100),
AEHLGTCD numeric,
AECAT varchar(40),
AESCAT varchar(40),
AEPRESP varchar(2),
AEBODSYS varchar(80),
AEBDSYCD numeric,
AESOC varchar(80),
AESOCCD numeric,
AELOC varchar(40),
AESEV varchar(20),
AESER varchar(2),
AEACN varchar(40),
AEACNOTH varchar(200),
AEREL varchar(40),
AERELNST varchar(40),
AEPATT varchar(20),
AEOUT varchar(40),
AESCAN varchar(2),
AESCONG varchar(2),
AESDISAB varchar(2),
AESDTH varchar(2),
AESHOSP varchar(2),
AESLIFE varchar(2),
AESOD varchar(2),
AESMIE varchar(2),
AECONTRT varchar(2),
AETOXGR varchar(20),
AESTDTC varchar(64),
AEENDTC varchar(64),
AESTDY numeric,
AEENDY numeric,
AEDUR varchar(64),
AEENRF varchar(20),
AEENRTPT varchar(40),
AEENTPT varchar(40) )
```

Example: Generating Oracle SQL

The following example demonstrates generating Oracle SQL code for the CDISC SDTM AE domain:

```
%cstutilsqlcolumndefinition(_cstSourceDS=sdtm32.ae,_cstSQLColDef=_cstColumnDef,
                            _cstSQLType=ORACLE);
%put &=_cstColumnDef;
```

The %CSTUTILSQLGENERATETABLE macro populates the &_cstColumnDef macro variable with the following Oracle SQL column description values:

```
_CSTCOLUMNDEF=(
STUDYID varchar2(40),
DOMAIN__SQL1 varchar2(8),
USUBJID varchar2(40),
AESEQ numeric,
AEGRPID varchar2(40),
AEREFID varchar2(40),
AESPID varchar2(40),
AETERM varchar2(200),
AEMODIFY varchar2(200),
AELLT varchar2(100),
AELLTCD numeric,
AEDECOD varchar2(200),
AEPTCD numeric,
AEHLT varchar2(100),
AEHLTCD numeric,
AEHLGT varchar2(100),
AEHLGTCD numeric,
AECAT varchar2(40),
AESCAT varchar2(40),
AEPRESP varchar2(2),
AEBODSYS varchar2(80),
AEBDSYCD numeric,
AESOC varchar2(80),
AESOCCD numeric,
AELOC varchar2(40),
AESEV varchar2(20),
AESER varchar2(2),
AEACN varchar2(40),
AEACNOTH varchar2(200),
AEREL varchar2(40),
AERELNST varchar2(40),
AEPATT varchar2(20),
AEOUT varchar2(40),
AESCAN varchar2(2),
AESCONG varchar2(2),
AESDISAB varchar2(2),
AESDTH varchar2(2),
AESHOSP varchar2(2),
AESLIFE varchar2(2),
AESOD varchar2(2),
AESMIE varchar2(2),
AECONTRT varchar2(2),
AETOXGR varchar2(20),
AESTDTC varchar2(64),
AEENDTC varchar2(64),
AESTDY numeric,
AEENDY numeric,
AEDUR varchar2(64),
AEENRF varchar2(20),
AEENRTPT varchar2(40),
AEENTPT varchar2(40) )
```

Generating PROC SQL Code to Create a Table from a SAS Data Set

The %CSTUTILSQLGENERATETABLE Macro

The %CSTUTILSQLGENERATETABLE macro creates code that enables you to create a table from a SAS data set. The type of code to create is specified by the _cstSQLType parameter: SAS PROC SQL, ANSI SQL, or Oracle SQL. The SAS data set is specified by the _cstSourceDS parameter.

The code created by the %CSTUTILSQLGENERATETABLE macro serves as a template that you can modify. The template code handles more than 90% of the SAS data sets that are passed to it. You might need to perform these tasks:

- Modify the template code for certain conditions that could pose a problem, such as nested quotation marks in the data.

- For ANSI SQL and Oracle SQL, review modified reserved words. The macro identifies reserved words and appends a reserved word with __SQL1 (single underline, single underline, SQL1).
- For ANSI SQL and Oracle SQL, review and modify the SQL code as needed.

Example: Generating SAS PROC SQL Code

The following example demonstrates generating SAS PROC SQL code for the CDISC SDTM AE data set:

```
libname test 'c:\test\data';
%cstutilsqlgeneratetable(_cstDSName=AE,_cstDSLibraryIn=SDTM32,_cstDSLibraryOut=test,
                         _cstSQLFile=c:\test\create_sasSQL.sas,_cstSQLType=SAS);
```

The resulting SAS PROC SQL code is written to the create_sasSQL.sas file, which is specified by the _cstSQLFile parameter. The resulting table generated by the SQL code is written to the test library, which is specified by the _cstDSLibraryOut parameter.

The following is an excerpt of the generated code in the create_sasSQL.sas file:

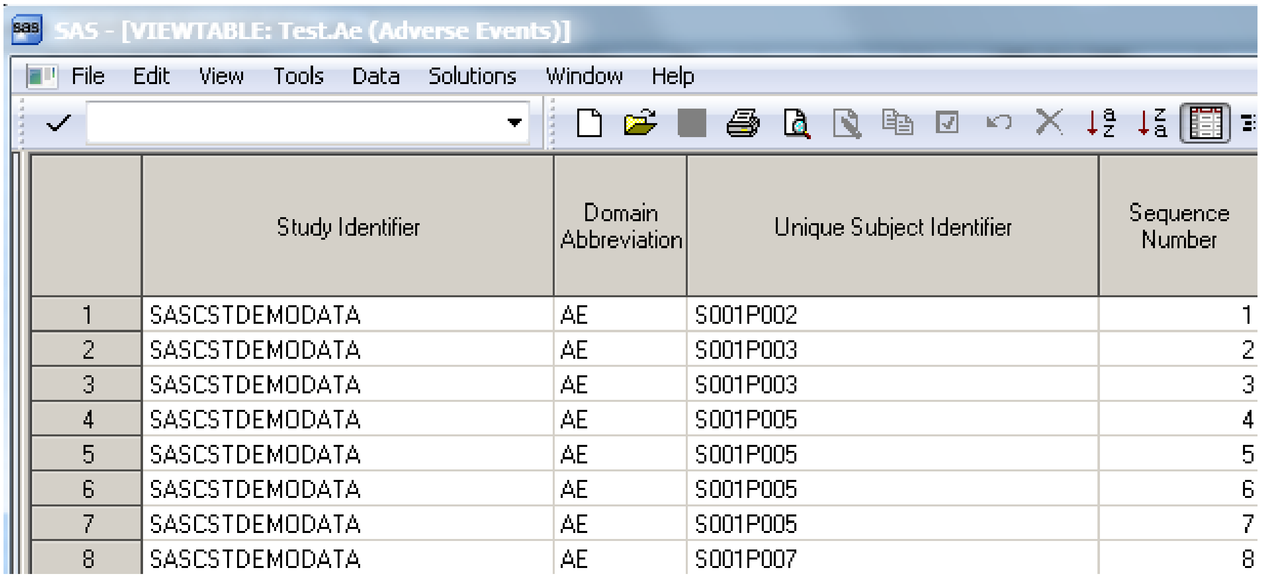
```
proc sql;
   create table work.cst7495 (label="Adverse Events")
   (STUDYID char(40) label="Study Identifier", DOMAIN char(8) label="Domain Abbreviation",...);
   insert into work.cst7495
   values ('SASCSTDEMODATA' , 'AE' , 'S001P002' , 1, '' , '' , '' , 'ABDOMINAL PAIN' , '' , '' ,...)
   values ('SASCSTDEMODATA' , 'AE' , 'S001P003' , 2, '' , '' , '' , 'ABDOMINAL CRAMP' , '' , 'Abdominal...)
   values ('SASCSTDEMODATA' , 'AE' , 'S001P003' , 3, '' , '' , '' , 'RASH' , '' , 'Rash' , 10037844,...)
.
.
.
   ;
   create table test.AE (label="Adverse Events")
   as select * from work.cst7495 order by STUDYID, USUBJID, AEDECOD, AESTDTC
   ;
   drop table work.cst7495
   ;
quit;
```

Note: The line `(STUDYID char(40) label="Study Identifier", DOMAIN char(8) label="Domain Abbreviation",...)` came from the call to %CSTUTILSQLCOLUMNDEFINITION.

After you submit the create_sasSQL.sas file in a SAS session, the AE data set is created in the test library.

The following display shows the AE data set.

Figure A2.1 *AE Data Set*

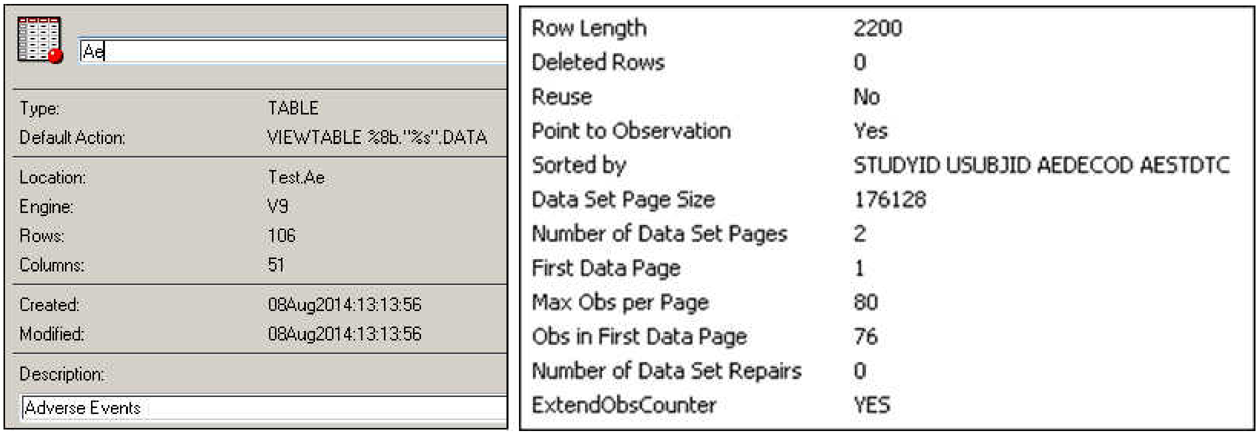


SAS - [VIEWTABLE: Test.Ae (Adverse Events)]

	Study Identifier	Domain Abbreviation	Unique Subject Identifier	Sequence Number
1	SASCSTDEMODATA	AE	S001P002	1
2	SASCSTDEMODATA	AE	S001P003	2
3	SASCSTDEMODATA	AE	S001P003	3
4	SASCSTDEMODATA	AE	S001P005	4
5	SASCSTDEMODATA	AE	S001P005	5
6	SASCSTDEMODATA	AE	S001P005	6
7	SASCSTDEMODATA	AE	S001P005	7
8	SASCSTDEMODATA	AE	S001P007	8

The following display shows that, in addition to the data, metadata (such as the label and the sort order) of the AE data set is retained.

Figure A2.2 *AE Data Set Metadata*



Ae

Type:	TABLE
Default Action:	VIEWTABLE %8b."%s".DATA
Location:	Test.Ae
Engine:	V9
Rows:	106
Columns:	51
Created:	08Aug2014:13:13:56
Modified:	08Aug2014:13:13:56
Description:	

Adverse Events

Row Length	2200
Deleted Rows	0
Reuse	No
Point to Observation	Yes
Sorted by	STUDYID USUBJID AEDECOD AESTDTC
Data Set Page Size	176128
Number of Data Set Pages	2
First Data Page	1
Max Obs per Page	80
Obs in First Data Page	76
Number of Data Set Repairs	0
ExtendObsCounter	YES

Example: Generating ANSI SQL Code

The following example demonstrates generating ANSI SQL code for the CDISC SDTM AE data set:

```
%cstutilsqlgeneratetable(_cstDSName=AE,_cstDSLibraryIn=SDTM32,_cstDSLibraryOut=test,
                         _cstSQLFile=c:\test\create_ansiSQL.sas,_cstSQLType=ANSI);
```

The following is an excerpt of the generated code in the create_ansiSQL.sas file:

```
create table AE
(STUDYID varchar(40), DOMAIN varchar(8), USUBJID varchar(40), AESEQ numeric, AEGRPID varchar(40),...);
insert into AE
   values ('SASCSTDEMODATA' , 'AE' , 'S001P002' , 1, '' , '' , '' , 'ABDOMINAL PAIN' , '' , '' , NULL,...)
   values ('SASCSTDEMODATA' , 'AE' , 'S001P003' , 2, '' , '' , '' , 'ABDOMINAL CRAMP' , '' , ...)
   values ('SASCSTDEMODATA' , 'AE' , 'S001P003' , 3, '' , '' , '' , 'RASH' , '' , 'Rash' , 10037844 ...)
   values ('SASCSTDEMODATA' , 'AE' , 'S001P005' , 4, '' , '' , '' , 'ABDOMINAL CRAMP' , '' ...)
   .
   .
   .
   values ('SASCSTDEMODATA' , 'AE' , 'S003P019' , 106, '' , '' , '' , 'HEARTBURN-LIKE DYSPEPSIA'...)
;
```

Note: The line `(STUDYID varchar(40), DOMAIN varchar(8), USUBJID varchar(40), AESEQ numeric, AEGRPID varchar(40),...)` came from the call to %CSTUTILSQLCOLUMNDEFINITION.

Example: Generating Oracle SQL Code

The following example demonstrates generating Oracle SQL code for the CDISC SDTM AE data set:

```
%cstutilsqlgeneratetable(_cstDSName=AE,_cstDSLibraryIn=SDTM32,_cstDSLibraryOut=test,
                         _cstSQLFile=c:\test\create_oracleSQL.sas,_cstSQLType=ORACLE);
```

The following is an excerpt of the generated code in the create_oracleSQL.sas file:

```
create table AE
(STUDYID varchar2(40), DOMAIN__SQL1 varchar2(8), USUBJID varchar2(40), AESEQ numeric, AEGRPID...);
insert into AE (STUDYID, DOMAIN__SQL1, USUBJID, AESEQ, AEGRPID, AEREFID, AESPID, AETERM, AEMODIFY...)
values ('SASCSTDEMODATA' , 'AE' , 'S001P002' , 1, '' , '' , '' , 'ABDOMINAL PAIN' , '' , '' , NULL,...)
insert into AE (STUDYID, DOMAIN__SQL1, USUBJID, AESEQ, AEGRPID, AEREFID, AESPID, AETERM, AEMODIFY,...)
values ('SASCSTDEMODATA' , 'AE' , 'S001P003' , 2, '' , '' , '' , 'ABDOMINAL CRAMP' , '' ,...)
```

```
insert into AE (STUDYID, DOMAIN__SQL1, USUBJID, AESEQ, AEGRPID, AEREFID, AESPID, AETERM, AEMODIFY,...)
values ('SASCSTDEMODATA' , 'AE' , 'S001P003' , 3, '' , '' , '' , 'RASH' , '' , 'Rash' , 10037844,...)
.
.
.
insert into AE (STUDYID, DOMAIN__SQL1, USUBJID, AESEQ, AEGRPID, AEREFID, AESPID, AETERM, AEMODIFY,...)
values ('SASCSTDEMODATA' , 'AE' , 'S003P019' , 106, '' , '' , '' , 'HEARTBURN-LIKE DYSPEPSIA' , '' ,...);
;
```

Note: The line `(STUDYID varchar2(40), DOMAIN__SQL1 varchar2(8), USUBJID varchar2(40), AESEQ numeric, AEGRPID...);` came from the call to %CSTUTILSQLCOLUMNDEFINITION.

Notice the DOMAIN column from the AE data set has been renamed in the generated Oracle SQL code as DOMAIN__SQL1. The word “domain” is a reserved word in Oracle SQL. Therefore, the macro appends __SQL1. You must decide where to change this column name: In the data set before submitting the macro or in the generated Oracle SQL code (to rename the column in the generated table).

After submitting the macro, the SAS log file contains the following warning message:

```
[CSTLOGMESSAGE.CSTUTILSQLCOLUMNDEFINITION] WARNING: Column [DOMAIN ] is an ORACLE SQL
          RESERVED WORD - This column may need to be changed in the contributing SAS data set.
[CSTLOGMESSAGE.CSTUTILSQLCOLUMNDEFINITION] WARNING: Column [DOMAIN ] is being renamed to
          DOMAIN__SQL1 .
```

Replacing Extended ASCII Characters in a SAS Data Set

The %CSTUTILFINDFIXEXTDASCIICHARS Macro

The %CSTUTILFINDFIXEXTDASCIICHARS macro performs these tasks:

- identify extended ASCII characters in column values in a SAS data set
- create a SAS data set that contains the extended ASCII characters and their replacement characters
- generate code to replace the extended ASCII characters with acceptable characters

Extended ASCII characters occur most often when a SAS data set is populated by reading a Microsoft Excel spreadsheet or Word document that contains characters such as curly quotation marks and double quotation marks.

You can modify the generated code or submit it as is.

Note: The code generated by this macro replaces the extended ASCII characters in the SAS data set, not the macro itself.

This macro uses a SAS format in the macro code to map replacement characters to the extended ASCII characters. SAS provides a default format for mapping to common extended ASCII characters. You should review the mappings, change them, or create new mappings.

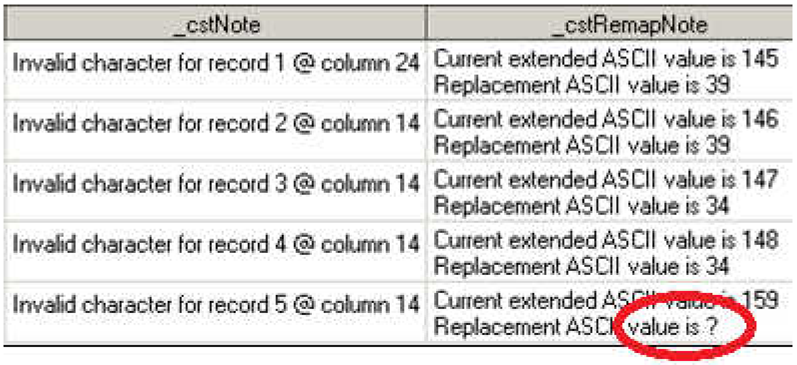
Note: This macro does not handle double-byte character set (DBCS) data.

In addition to the SAS format in the macro code, this macro accepts an external SAS format that you create. This external SAS format enables you to create different ASCII mappings for different studies or standards without having to change the global mappings in the macro code. For more information, see “Example: Using an External SAS Format” on page 488.

This macro creates a SAS data set (specified by the _cstOutputDS parameter) that contains the extended ASCII characters and the characters with which to replace them. An extended ASCII character that does not have a replacement character is indicated by a question mark (?) (or the value specified by the _cstExtFmtOtherValue parameter) in the _cstRemapNote column. The ? provides a visual cue that a valid value is needed to replace an extended ASCII character.

The following display shows an example of the visual cue:

Figure A2.3 Visual Cue That a Valid Value Is Needed



_cstNote	_cstRemapNote
Invalid character for record 1 @ column 24	Current extended ASCII value is 145 Replacement ASCII value is 39
Invalid character for record 2 @ column 14	Current extended ASCII value is 146 Replacement ASCII value is 39
Invalid character for record 3 @ column 14	Current extended ASCII value is 147 Replacement ASCII value is 34
Invalid character for record 4 @ column 14	Current extended ASCII value is 148 Replacement ASCII value is 34
Invalid character for record 5 @ column 14	Current extended ASCII value is 159 Replacement ASCII value is ?

Note: You must map replacement characters in either the SAS format in the macro code or in an external SAS format, and then resubmit the macro to ensure that all extended ASCII characters are replaced.

Data sets that are created by generated code are written to the output directory specified by the _cstWriteToLib parameter. The default output directory is WORK. Data set labels and the sort order of the original data sets are maintained.

Note: You must manage the output directory because files can be overwritten by subsequent submissions of the generated code.

Example: Mapped Extended ASCII Characters

The following example demonstrates identifying the extended ASCII characters in the stringchars column of the data set testdata.ext_ascii. The replacement characters are part of the default format mapping provided by SAS.

```
%cstutilfindfixextdasciichars(
   _cstDSName=testdata.ext_ascii,
   _cstColumnName=stringchars,
   _cstGeneratedCodeFile=c:/fixascii/findextendedascii.sas);
```

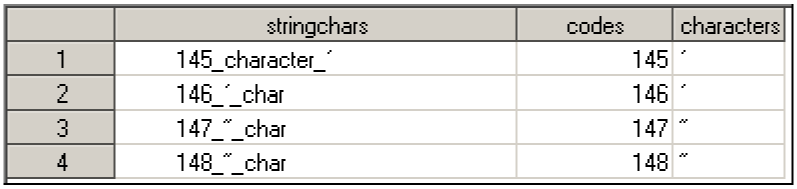
Here are the meanings of the parameters:

- _cstDSName is the data set to examine.

- _cstColumnName is the column to examine.
- _cstGeneratedCodeFile is the SAS code file to generate.

The following display shows the data set before the extended ASCII characters ` , ' , " , and " (ASCII values 145 through 148) are replaced:

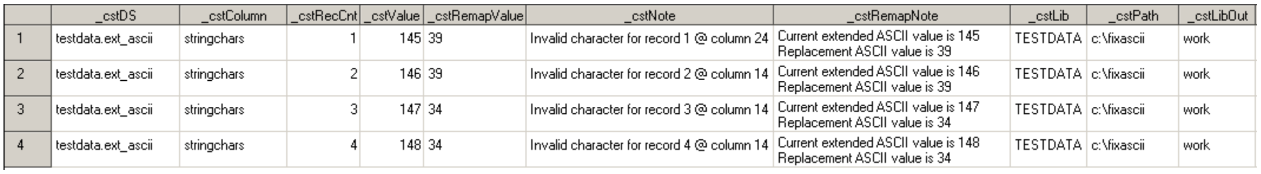
Figure A2.4 testdata.ext_ascii Data Set Before Replacing the Extended ASCII Characters



	stringchars	codes	characters
1	145_character_´	145	´
2	146_´_char	146	´
3	147_˝_char	147	˝
4	148_˝_char	148	˝

The %CSTUTILFINDFIXEXTDASCIICHARS macro creates the work._cstProblems data set (the default) that contains the extended ASCII characters and their replacement characters. The following display shows selected columns that illustrate the content of the work._cstProblems data set:

Figure A2.5 work._cstProblems Data Set



	_cstDS	_cstColumn	_cstRecCnt	_cstValue	_cstRemapValue	_cstNote	_cstRemapNote	_cstLib	_cstPath	_cstLibOut
1	testdata.ext_ascii	stringchars	1	145	39	Invalid character for record 1 @ column 24	Current extended ASCII value is 145 Replacement ASCII value is 39	TESTDATA	c:\fixascii	work
2	testdata.ext_ascii	stringchars	2	146	39	Invalid character for record 2 @ column 14	Current extended ASCII value is 146 Replacement ASCII value is 39	TESTDATA	c:\fixascii	work
3	testdata.ext_ascii	stringchars	3	147	34	Invalid character for record 3 @ column 14	Current extended ASCII value is 147 Replacement ASCII value is 34	TESTDATA	c:\fixascii	work
4	testdata.ext_ascii	stringchars	4	148	34	Invalid character for record 4 @ column 14	Current extended ASCII value is 148 Replacement ASCII value is 34	TESTDATA	c:\fixascii	work

The _cstNote column identifies the record number and the column position of the record value of the extended ASCII character. The _cstRemapNote column specifies the extended ASCII character and its replacement value.

All of the records in testdata.ext_ascii that contain extended ASCII characters have replacement values. As a result, the macro is submitted and the following SAS code is generated in the findextendedascii.sas file:

```
%macro _cstFixASCII;
********************************************;
**********  Initialize libraries  **********;
********************************************;


libname TESTDATA "c:\fixascii";
```

```
*********************************************************************************;
**********  Updating data set testdata.ext_ascii                       **********;
*********************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=testdata.ext_ascii,
                                      _cstAttribute=LABEL);
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=testdata.ext_ascii,
                                         _cstAttribute=SORTEDBY);


data work.ext_ascii %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set testdata.ext_ascii ;
    if _n_= 1 then do;
      stringchars=tranwrd(stringchars,byte(145),byte(39));
    end;
    if _n_= 2 then do;
      stringchars=tranwrd(stringchars,byte(146),byte(39));
    end;
    if _n_= 3 then do;
      stringchars=tranwrd(stringchars,byte(147),byte(34));
    end;
    if _n_= 4 then do;
      stringchars=tranwrd(stringchars,byte(148),byte(34));
    end;
run;

%if %length(&_cstDSSortVars)>0 %then
%do;
  proc sort data=work.ext_ascii;
    by &_cstDSSortVars
  run;
%end;

%mend;

%_cstFixASCII;
```

All four extended ASCII characters are included in this generated code. A combination of the BYTE and TRANWRD functions is used to convert the extended ASCII characters to replacement characters. The %CSTUTILGETATTRIBUTE macro retrieves the sort order and the label of the original data set. If they exist, these values are used when the output data set is created to maintain the original metadata associated with the original files. Otherwise, the original label and sort order are lost.

The following display shows the data set after replacing the extended ASCII characters:

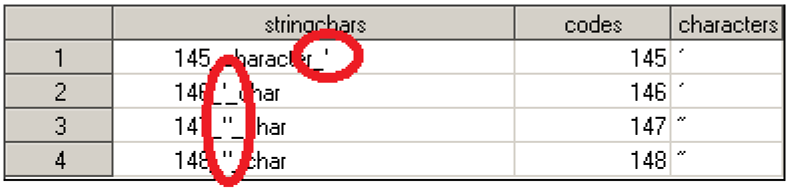


Figure A2.6 *work.ext_ascii Data Set After Replacing the Extended ASCII Characters*

	stringchars	codes	characters
1	145_character_'	145	´
2	146_'_char	146	´
3	147_"_char	147	˝
4	148_"_char	148	˝

Example: Unmapped Extended ASCII Characters

The following example demonstrates identifying the extended ASCII characters in the stringchars column of the testdata.ext_ascii2 data set. In addition to the extended ASCII characters in the previous example (` ,' , “ , and ”), the data set includes Ÿ (ASCII value 159).

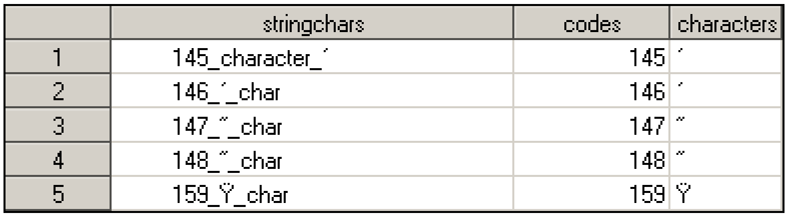


Figure A2.7 *testdata.ext_ascii2 Data Set*

	stringchars	codes	characters
1	145_character_´	145	´
2	146_´_char	146	´
3	147_˝_char	147	˝
4	148_˝_char	148	˝
5	159_Ÿ_char	159	Ÿ

To identify the extended ASCII characters that must be replaced, the following parameters are specified in the %CSTUTILFINDFIXEXTDASCIICHARS macro:

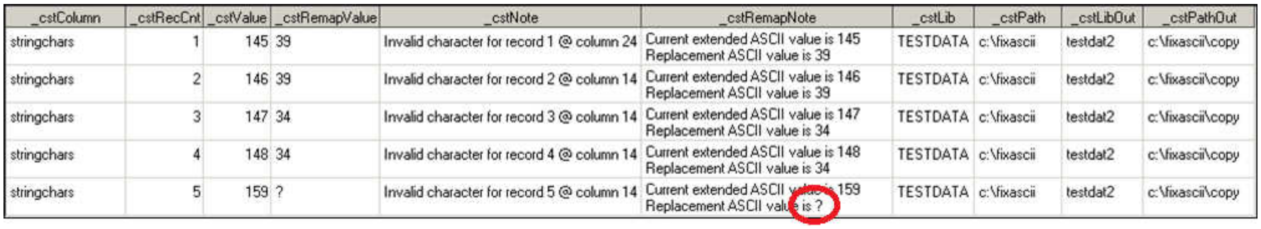
```
%cstutilfindfixextdasciichars(
   _cstDSName=testdata.ext_ascii2,
   _cstColumnName=stringchars,
   _cstGeneratedCodeFile=c:/fixascii/findextendedascii2.sas,
   _cstOutputDS=work._cstProblems2,
   _cstWriteToLib=testdat2);
```

Here are the meanings of the two parameters not specified in the previous example:

- _cstOuputDS is the data set to record the references to extended ASCII characters in _cstDSName. The value is specified as work._cstProblems2. (The default is work._cstProblems, which was used by default in the previous example.)
- The _cstWriteToLib parameter is the library in which to write the data sets created by the generated code. This is specified as testdat2.

The following display shows the content of the work._cstProblems2 data set:

Figure A2.8 *Content of the work._cstProblems2 Data Set*



_cstColumn	_cstRecCnt	_cstValue	_cstRemapValue	_cstNote	_cstRemapNote	_cstLib	_cstPath	_cstLibOut	_cstPathOut
stringchars	1	145	39	Invalid character for record 1 @ column 24	Current extended ASCII value is 145 Replacement ASCII value is 39	TESTDATA	c:\fixascii	testdat2	c:\fixascii\copy
stringchars	2	146	39	Invalid character for record 2 @ column 14	Current extended ASCII value is 146 Replacement ASCII value is 39	TESTDATA	c:\fixascii	testdat2	c:\fixascii\copy
stringchars	3	147	34	Invalid character for record 3 @ column 14	Current extended ASCII value is 147 Replacement ASCII value is 34	TESTDATA	c:\fixascii	testdat2	c:\fixascii\copy
stringchars	4	148	34	Invalid character for record 4 @ column 14	Current extended ASCII value is 148 Replacement ASCII value is 34	TESTDATA	c:\fixascii	testdat2	c:\fixascii\copy
stringchars	5	159	?	Invalid character for record 5 @ column 14	Current extended ASCII value is 159 Replacement ASCII value is ?	TESTDATA	c:\fixascii	testdat2	c:\fixascii\copy

The _cstNote column identifies the record number and the column position of the record value of the extended ASCII character. The _cstRemapNote column specifies the extended ASCII character and its replacement value.

Notice that the fifth record has a ? as the replacement ASCII character. This is the visual cue shown in Figure A2.3 on page 475.

Note: All extended ASCII characters must be mapped before submitting the generated code.

Although one of the extended ASCII characters is not mapped, the SAS code is still generated in the **`c:/fixascii/findextendedascii2.sas`** file, which is specified by the _cstGeneratedCodeFile parameter.

Here is the generated code:

```
%macro _cstFixASCII;
********************************************;
**********  Initialize libraries  **********;
********************************************;

libname TESTDATA "c:\fixascii";
libname testdat2 "c:\fixascii\copy";
```

```
*********************************************************************************;
**********  Updating data set testdata.ext_ascii2                      **********;
*********************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=testdata.ext_ascii2,
                                      _cstAttribute=LABEL);
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=testdata.ext_ascii2,
                                         _cstAttribute=SORTEDBY);


data testdat2.ext_ascii2 %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set testdata.ext_ascii2 ;
    if _n_= 1 then do;
      stringchars=tranwrd(stringchars,byte(145),byte(39));
    end;
    if _n_= 2 then do;
      stringchars=tranwrd(stringchars,byte(146),byte(39));
    end;
    if _n_= 3 then do;
      stringchars=tranwrd(stringchars,byte(147),byte(34));
    end;
    if _n_= 4 then do;
      stringchars=tranwrd(stringchars,byte(148),byte(34));
    end;
    if _n_= 5 then do;
      stringchars=tranwrd(stringchars,byte(159),byte(?));
    end;
run;

%if %length(&_cstDSSortVars)>0 %then
%do;
  proc sort data=testdat2.ext_ascii2;
    by &_cstDSSortVars
  run;
%end;

%mend;

%_cstFixASCII;
```

Notice the differences between this SAS code and the SAS code for the previous example. This SAS code includes an additional LIBNAME statement for the output library reference specified by the _cstWriteToLib parameter (testdat2).

The line

```
stringchars=tranwrd(stringchars,byte(159),byte(?))
```

contains the unmapped extended ASCII character. In addition to the ? as a visual cue that a replacement value is needed, a message is written to the SAS log file after the %CSTUTILFINDFIXEXTDASCIICHARS macro is submitted.

```
****************************************************************************************
[CSTLOGMESSAGE.CSTUTILFINDFIXEXTDASCIICHARS] WARNING: Unresolved extended ASCII characters are
 present in the data. Refer to work._cstProblems2 for more information.
[CSTLOGMESSAGE.CSTUTILFINDFIXEXTDASCIICHARS] WARNING: These unresolved values need to be
updated in the PROC FORMAT statement of this macro.
****************************************************************************************
```

You can handle an unmapped extended ASCII character in these ways:

- Temporary solution

  To create a complete data set for a single submission of the generated code, edit the generated code to specify a valid ASCII replacement value for the extended ASCII character. (The extended ASCII character is the ? in the line

  ```
  stringchars=tranwrd(stringchars,byte(159),byte(?))
  ```

  .)

  Note: This mapping is lost the next time the %CSTUTILFINDFIXEXTDASCIICHARS macro is run.

- Permanent solution

  To create a complete data set every time the %CSTUTILFINDFIXEXTDASCIICHARS macro is run, add the valid ASCII replacement value to the SAS format in the SAS code that is generated by the %CSTUTILFINDFIXEXTDASCIICHARS macro. Or, add the valid ASCII replacement value to an external SAS format that is used by the macro. In these ways, the extended ASCII character is always mapped in the generated code.

Regardless of the way that you choose, you must submit the generated code after making the changes.

Example: Running Against All Data Sets in a Library

The previous examples operated on one data set and one column. This situation occurs when you are familiar with the data and know in which data set extended ASCII characters might be located.

When you are unfamiliar with the data and there are many data sets, the %CSTUTILFINDFIXEXTDASCIICHARS macro enables you to examine all data sets in a specific library for extended ASCII characters.

The following example demonstrates identifying the extended ASCII characters in all of the data sets and in all of the columns in the testdata library:

```
%cstutilfindfixextdasciichars(
   _cstDSName=testdata._ALL_,
   _cstGeneratedCodeFile=c:/fixascii/findfixextendedascii3.sas);
```

The _cstDSName parameter includes the LIBNAME reference and the keyword _ALL_.

Note: The _cstColumnName parameter is omitted and cannot be used with the _ALL_ keyword.

The following messages are written to the SAS log file:

```
>>>>>
>>>>> Starting test for: TESTDATA.EXT_ASCII
>>>>>

>>>>> Variable List 1='stringchars' 'characters'
>>>>> Variable List 2=stringchars characters
>>>>> Variable Count=       2
>>>>>


>>>>>
>>>>> Starting test for: TESTDATA.EXT_ASCII2
>>>>>

>>>>> Variable List 1='stringchars' 'characters'
>>>>> Variable List 2=stringchars characters
>>>>> Variable Count=       2
>>>>>
```

As each data set is examined, a starting message (`Starting test for`) and a list of variables (`Variable List` to `Variable Count`) are written to the SAS log file.

The following warning message is written to the SAS log file to inform you that unresolved extended ASCII characters are present in the data set:

```
************************************************************************************************
[CSTLOGMESSAGE.CSTUTILFINDFIXEXTDASCIICHARS] WARNING: Unresolved extended ASCII characters are
present in the data. Refer to work._cstProblems for more information.
[CSTLOGMESSAGE.CSTUTILFINDFIXEXTDASCIICHARS] WARNING: These unresolved values need to be
updated in the PROC FORMAT statement of this macro.
************************************************************************************************
```

The generated code is written to the findfixextendedascii3.sas file. No value was specified for the _cstWriteToLib parameter, so no output library is generated and the output data sets are written to the Work directory, which is the default directory.

Here is the generated code:

```
%macro _cstFixASCII;
********************************************;
**********  Initialize libraries  **********;
********************************************;

libname TESTDATA "c:\fixascii";

*******************************************************************************;
**********  Updating data set TESTDATA.EXT_ASCII                     **********;
*******************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=TESTDATA.EXT_ASCII,
                                      _cstAttribute=LABEL);
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=TESTDATA.EXT_ASCII,
                                         _cstAttribute=SORTEDBY);

data work.EXT_ASCII %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set TESTDATA.EXT_ASCII ;
    if _n_= 1 then do;
      characters=tranwrd(characters,byte(145),byte(39));
      stringchars=tranwrd(stringchars,byte(145),byte(39));
    end;
    if _n_= 2 then do;
      characters=tranwrd(characters,byte(146),byte(39));
      stringchars=tranwrd(stringchars,byte(146),byte(39));
    end;
    if _n_= 3 then do;
      characters=tranwrd(characters,byte(147),byte(34));
      stringchars=tranwrd(stringchars,byte(147),byte(34));
    end;
    if _n_= 4 then do;
      characters=tranwrd(characters,byte(148),byte(34));
      stringchars=tranwrd(stringchars,byte(148),byte(34));
    end;
run;

%if %length(&_cstDSSortVars)>0 %then
%do;
  proc sort data=work.EXT_ASCII;
    by &_cstDSSortVars
  run;
%end;

*************************************************************************************;
**********  Updating data set TESTDATA.EXT_ASCII2                        **********;
*************************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=TESTDATA.EXT_ASCII2,
                                      _cstAttribute=LABEL);
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=TESTDATA.EXT_ASCII2,
                                         _cstAttribute=SORTEDBY);

data work.EXT_ASCII2 %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set TESTDATA.EXT_ASCII2 ;
    if _n_= 1 then do;
      characters=tranwrd(characters,byte(145),byte(39));
      stringchars=tranwrd(stringchars,byte(145),byte(39));
    end;
    if _n_= 2 then do;
      characters=tranwrd(characters,byte(146),byte(39));
      stringchars=tranwrd(stringchars,byte(146),byte(39));
    end;
    if _n_= 3 then do;
      characters=tranwrd(characters,byte(147),byte(34));
      stringchars=tranwrd(stringchars,byte(147),byte(34));
    end;
    if _n_= 4 then do;
      characters=tranwrd(characters,byte(148),byte(34));
      stringchars=tranwrd(stringchars,byte(148),byte(34));
    end;
    if _n_= 5 then do;
      characters=tranwrd(characters,byte(159),byte(?));
      stringchars=tranwrd(stringchars,byte(159),byte(?));
    end;
run;

%if %length(&_cstDSSortVars)>0 %then
```

```
%do;
  proc sort data=work.EXT_ASCII2;
    by &_cstDSSortVars
  run;
%end;

%mend;
```

Before any updates can be made to the ext_ascii2 data set, the following lines of code must be resolved by mapping a value to the extended ASCII character 159:

```
characters=tranwrd(characters,byte(159),byte(?));
      stringchars=tranwrd(stringchars,byte(159),byte(?));
```

Example: Running Across Multiple Libraries

To save time, you can examine multiple libraries, data sets, and columns. You do this by specifying the _cstRetainOutputDS parameter as Y, which causes the output data set specified by the _cstOutputDS parameter to be retained between submissions of the %CSTUTILFINDFIXEXTDASCIICHARS macro.

By retaining the _cstOutputDS output data set, the data from each submission of the macro is appended to the data set. After the last submission of the macro, the generated code contains all of the changes found for each submission of the macro.

Note: For each submission of the macro, the _cstRetainOutputDS parameter must be specified as **Y** and the _cstGeneratedCodeFile parameter must specify the same file.

This example examines all columns in testdata.ext_ascii. The output data set is specified as work.all_asciiProblems.

For the first submission, the _cstRetainOutputDS parameter is specified as **N**. This clears the existing data set specified by the _cstOutputDS parameter.

```
%(
   _cstDSName=testdata.ext_ascii,
   _cstGeneratedCodeFile=c:/fixascii/findfixextendedascii4.sas,
   _cstOutputDS=work.all_asciiProblems,
   _cstRetainOutputDS=N,
   _cstFindFix=Find);
```

For the second submission, the _cstRetainOutputDS parameter is specified as **Y**. The output data set remains specified as work.all_asciiProblems.

```
%cstutilfindfixextdasciichars(
   _cstDSName=testdat2.all_ascii,
   _cstGeneratedCodeFile=c:/fixascii/findfixextendedascii4.sas,
   _cstOutputDS=work.all_asciiProblems,
   _cstRetainOutputDS=Y,
   _cstFindFix=Find);
```

When the SAS code is generated, there are two

```
   Initialize libraries
```

blocks in the code: one for TESTDATA and another for TESTDAT2 (with corresponding output libraries OUT1 and OUT2).

Here is an excerpt of the generated code in the findfixextendedascii4.sas file:

```
%macro _cstFixASCII;
*******************************************;
**********  Initialize libraries  **********;
*******************************************;

libname TESTDAT2 "c:\fixascii\copy";
libname out2 "c:\fixascii\output_two";

*********************************************************************************;
**********  Updating data set testdat2.all_ascii                      **********;
*********************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=testdat2.all_ascii,
                                      _cstAttribute=LABEL);
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=testdat2.all_ascii,
                                         _cstAttribute=SORTEDBY);


data out1.all_ascii %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set testdat2.all_ascii ;
    if _n_= 1 then do;
      test_characters=tranwrd(test_characters,byte(9),byte(32));
      test_stringchars=tranwrd(test_stringchars,byte(9),byte(32));
    end;
…
…
    if _n_= 16 then do;
      test_characters=tranwrd(test_characters,byte(155),byte(62));
      test_stringchars=tranwrd(test_stringchars,byte(155),byte(62));
    end;
```

```
run;

%if %length(&_cstDSSortVars)>0 %then
%do;
  proc sort data=out1.all_ascii;
    by &_cstDSSortVars
  run;
%end;

********************************************;
**********  Initialize libraries  **********;
********************************************;

libname TESTDATA "c:\fixascii";
libname out1 "c:\fixascii\output_one";

***********************************************************************************;
**********  Updating data set testdata.ext_ascii                         **********;
***********************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=testdata.ext_ascii,
                                      _cstAttribute=LABEL);
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=testdata.ext_ascii,
                                         _cstAttribute=SORTEDBY);


data out1.ext_ascii %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set testdata.ext_ascii ;
    if _n_= 1 then do;
      characters=tranwrd(characters,byte(145),byte(39));
      stringchars=tranwrd(stringchars,byte(145),byte(39));
    end;
…
…
    if _n_= 4 then do;
      characters=tranwrd(characters,byte(148),byte(34));
      stringchars=tranwrd(stringchars,byte(148),byte(34));
    end;
run;

%if %length(&_cstDSSortVars)>0 %then
%do;
  proc sort data=out1.ext_ascii;
    by &_cstDSSortVars
  run;
%end;

%mend;
```

```
%_cstFixASCII;
```

Example: Using an External SAS Format

An external SAS format can be used to map extended ASCII characters to replacement characters. This external SAS format can be provided in a file that is specified by the _cstExternalFmt parameter. This external SAS format enables you to create different ASCII mappings for different studies or standards without having to change the global mappings in the macro code. If no external SAS format is specified, the %CSTUTILFINDFIXEXTDASCIICHARS macro defaults to a SAS format that is included in the generated code. You can modify the external SAS format.

When you use an external SAS format, you must specify the value in the external SAS format that indicates a missing value. You specify this missing value in the _cstExtFmtOtherValue parameter. For example, if the external SAS format specifies `other=MISSING`, the value of the _cstExtFmtOtherValue parameter must be **`MISSING`**. The %CSTUTILFINDFIXEXTDASCIICHARS macro can then act on the missing value.

Note: If the _cstExtFmtOtherValue parameter is not specified exactly as the `other=` statement in the external SAS format, the macro does not detect the missing value.

If the external SAS format does not contain a `other=` statement, the default value is `**`.

Here is an example of an external SAS format and the macro submission:

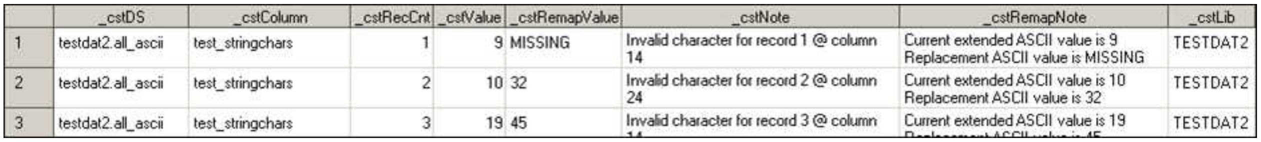
```
proc format library=work.myformats;
  value asciifmt
  10=32
  19=45
  20=45
  24=39
  25=39
  28=34
  29=34
  139=60
  145=39
  146=39
  147=34
  148=34
  150=45
```

```
      151=45
      155=62
      other=MISSING;
   run;

   options fmtsearch=(work.myformats);

   %cstutilfindfixextdasciichars(
      _cstDSName=testdat2.all_ascii,
      _cstColumnName=stringchars,
      _cstExternalFmt=asciifmt,
      _cstExtFmtOtherValue=MISSING,
      _cstGeneratedCodeFile=c:/fixascii/findfixextendedascii5.sas,
      _cstOutputDS=all_cstProblems,
      _cstRetainOutputDS=N,
      _cstWriteToLib=work,
      _cstFindFix=Find
      );
```

Note: Best practices recommend that an external SAS format be stored in a managed permanent format catalog.

The following display shows the _cstOutputDS data set. The _cstRemapValue for other is MISSING, which alerts you to a problem:

Figure A2.9 _cstOutputDS Data Set



	_cstDS	_cstColumn	_cstRecCnt	_cstValue	_cstRemapValue	_cstNote	_cstRemapNote	_cstLib
1	testdat2.all_ascii	test_stringchars	1	9	MISSING	Invalid character for record 1 @ column 14	Current extended ASCII value is 9 Replacement ASCII value is MISSING	TESTDAT2
2	testdat2.all_ascii	test_stringchars	2	10	32	Invalid character for record 2 @ column 24	Current extended ASCII value is 10 Replacement ASCII value is 32	TESTDAT2
3	testdat2.all_ascii	test_stringchars	3	19	45	Invalid character for record 3 @ column	Current extended ASCII value is 19	TESTDAT2

Here is an excerpt of the generated code:

```
%macro _cstFixASCII;
********************************************;
**********  Initialize libraries  **********;
********************************************;

libname TESTDAT2 "c:\fixascii\copy";

**********************************************************************************;
**********  Updating data set testdat2.all_ascii                         **********;
**********************************************************************************;
%let _cstDSLabel=%cstutilgetattribute(_cstDataSetName=testdat2.all_ascii,
                                      _cstAttribute=LABEL);
```

```
%let _cstDSSortVars=%cstutilgetattribute(_cstDataSetName=testdat2.all_ascii,
                                         _cstAttribute=SORTEDBY);


data work.all_ascii %if %length(&_cstDSLabel)>0 %then (label="&_cstDSLabel"); %else;;
  set testdat2.all_ascii ;
    if _n_= 1 then do;
      test_stringchars=tranwrd(test_stringchars,byte(9),byte(MISSING));
    end;
    if _n_= 2 then do;
      test_stringchars=tranwrd(test_stringchars,byte(10),byte(32));
    end;
    if _n_= 3 then do;
...
...
...
```

The line `test_stringchars=tranwrd(test_stringchars,byte(9),byte(MISSING));` is the visual cue that an additional mapping is required. This represents the `other=` value specified in the external SAS format.

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