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# **SAS<sup>®</sup>** **Clinical Standards Toolkit 1.4** **Installation Qualification**

The correct bibliographic citation for this manual is as follows: SAS Institute Inc. 2011. *SAS® Clinical Standards Toolkit 1.4: Installation Qualification*. Cary, NC: SAS Institute Inc.

### **SAS® Clinical Standards Toolkit 1.4: Installation Qualification**

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1st electronic book, November 2011

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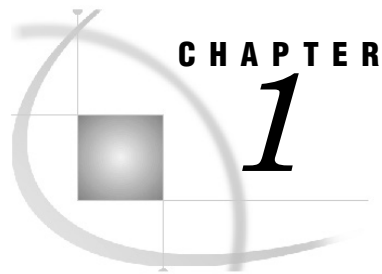
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## CHAPTER

## 1

# Installation Qualification

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## Purpose

This document explains how to verify that SAS Clinical Standards Toolkit 1.4 has been installed correctly and is functioning properly. The installation is tested by running a series of SAS programs. These tests must be run in the sequence presented.

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## Notes and Assumptions

- ❑ SAS 9.3 has been installed and is functioning correctly; it is not being tested.
- ❑ The SAS Clinical Standards Toolkit 1.4 has been installed.
- ❑ The person running these tests is familiar with running SAS programs. This includes being able to submit SAS programs via the Program Editor, review the SAS log, and review the contents of SAS data sets.
- ❑ This document is used for both the UNIX and Microsoft Windows environments. The forward slash character (/) is used in file paths as the separator between path components, which works in both operating system environments.

- Within this document:
  - **SASINSTALL** is used to denote the SAS Installation Folder. This is the folder into which all SAS products are installed.
    - The default value for SAS 9.3 on Microsoft Windows is C:/Program Files/SASHome.
    - The default value varies on UNIX machines, please consult your system administrator.
  - **SASROOT** is used to denote the root folder for the SAS System installation.
    - The default value for SAS 9.3 is **SASINSTALL/SASFoundation/9.3**.
- The tests refer to the following variables, which are defined relative to **SASINSTALL**. When running the tests, substitute the variables with the following associated paths.
  - **CST\_SDTM\_311**  
**SASINSTALL/SASClinicalStandardsToolkitSDTM311/1.4/sample/cdisc-sdtm-3.1.1/sascstdemodata**
  - **CST\_SDTM\_312**  
**SASINSTALL/SASClinicalStandardsToolkitSDTM312/1.4/sample/cdisc-sdtm-3.1.2/sascstdemodata**
  - **CST\_ODM**  
**SASINSTALL/SASClinicalStandardsToolkitODM130/1.4/sample/cdisc-odm-1.3.0**
  - **CST\_CRTDDS**  
**SASINSTALL/SASClinicalStandardsToolkitCRTDDS10/1.4/sample/cdisc-crtdds-1.0**
  - **CST\_ADAM**  
**SASINSTALL/SASClinicalStandardsToolkitADam21/1.4/sample/cdisc-adam-2.1/sascstdemodata**
- Tests 2, 7, and 21 generate PDF files. On Microsoft Windows, when the PDF is generated, a browser window should automatically appear containing the PDF for viewing. On UNIX, if you have not set up the SAS configuration variable SAS.helpBrowser, you get a popup message: “The requested information could not be displayed because the connection to the remote browser server failed”. Click OK to continue. Configure your UNIX SAS environment to support a browser that can display PDF files or copy the PDF file to an environment where you can examine it.

---

## Test 1: SDTM 3.1.1 Validation

---

### Introduction

This test runs the sample program that ships as part of the SDTM 3.1.1 standard. If this program runs successfully and produces the expected results, then the SDTM 3.1.1 standard is correctly installed and functioning properly.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program and select CST\_SD<sub>TM</sub>\_311/programs/validate\_data.sas.
- 3 Select Run- → Submit.  
It outputs to the SAS Log and generates two SAS data sets: Validation\_results and Validation\_metrics. These data sets can be found in the Results library within the SAS Explorer window.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set Validation\_results for errors.  
It should be consistent with the following table. It contains additional columns, but checking these is sufficient. Bolded values are dynamic and subject to change at time the code is submitted.

Row	Result Identifier	Validation Check Identifier	Unique Invocation of resultid	Seq # within resultseq	Source data
1	CST0108		1	1	CST_SETPROPERTIES
2	CST0102		1	1	CST_CREATEDS
3	CST0200		1	1	CSTUTIL_PROCESSETUP
4	CST0108		1	1	CST_SETPROPERTIES
5	CST0108		1	1	CST_SETPROPERTIES
6	CST0200		1	1	SDTM_VALIDATE
7	CST0200		1	2	SDTM_VALIDATE
8	CST0200		1	3	SDTM_VALIDATE
9	CST0200		1	4	SDTM_VALIDATE
10	CST0200		1	5	SDTM_VALIDATE
11	CST0200		1	6	SDTM_VALIDATE
12	CST0200		1	7	SDTM_VALIDATE
13	CST0200		1	8	SDTM_VALIDATE
14	CST0200		1	9	SDTM_VALIDATE
15	CST00200		1	10	SDTM_VALIDATE
16	CST0025	SDTM0011	1	1	SRCDATA.SUPPAE
17	CST0025	SDTM0011	2	1	SRCDATA.SUPPAE
18	CST0025	SDTM0012	1	1	SRCDATA.SUPPAE
<b>19–133</b>	Many additional similar rows are reported.				
N = 133					

Additional columns for rows 1–18 are as follows:

Row	Resolved message text from message file	Result Severity	resultflag	_cst_rc
1	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-framework-1.4/programs/initialize.properties	Info	0	0
2	work.sasreferences was created as requested	Info	0	0
3	Process setup is using this SASReferences: C:\DOCUME~1\userid\LOCALS~1\Temp\SAS Temporary Files\_TD2932/sasreferences	Info	0	0
4	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-sdtm-3.1.1-1.4/programs/initialize.properties	Info	0	0
5	The properties were processed from the PATH !sasroot/././SASClinicalStandardsToolkitSDTM311/1.4/sample/cdisc-sdtm-3.1.1/sascstdemodata/programs/validation.properties	Info	0	0
6	PROCESS STANDARD: CDISC-SDTM	Info	0	0
7	PROCESS STANDARDVERSION: 3.1.1	Info	0	0
8	PROCESS DRIVER: SDTM_VALIDATE	Info	0	0
9	<b>PROCESS DATE: 2011-08-05T13:59:31</b>	Info	0	0
10	PROCESS TYPE: VALIDATION	Info	0	0
11	PROCESS SASREFERENCES: C:\DOCUME~1\userid\LOCALS~1\Temp\SAS Temporary Files\_TD2932/sasreferences.sas7bdat	Info	0	0
12	PROCESS STUDYROOTPATH: !sasroot/././SASClinicalStandardsToolkitSDTM311/1.4/sample/cdisc-sdtm-3.1.1/sascstdemodata	Info	0	0
13	PROCESS GLOBALLIBRARY: c:\cstGlobalLibrary	Info	0	0
14	PROCESS CSTVERSION: 1.4	Info	0	0
15	PROCESS CONTROLLED TERMINOLOGY SOURCE: c:/cstGlobalLibrary/standards/cdisc-terminology-1.4/cdisc-sdtm/200810/formats/cterms (Controlled Terminology released by NCI on 2011-04-08)	Info	0	0
16	Data set not found in reference standard - compliance not assessed	Warning: Check incomplete	1	0
17	Data set not found in reference standard - compliance not assessed	Warning: Check incomplete	1	0
18	Data set not found in reference standard - compliance not assessed	Warning: Check incomplete	1	0
19-133	Many additional similar rows are reported.			
N = 133				

6 Close the SAS session.

---

## Sign-Off

<i>Test 1:SDTM 3.1.1 Validation</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 2: SDTM 3.1.1 Report Process Results

### Introduction

This test produces a sample report based on SDTM 3.1.1 process results.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_SD TM\_311/programs/cst\_report.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and generates a PDF file. No result data set is created.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the PDF file; it is named cstreport.pdf and is located in the folder CST\_SD TM\_311/results.

As noted in the Notes and Assumptions section, this PDF file should be displayed automatically on Microsoft Windows. If you are on UNIX, refer back to this section for instructions for approaches for viewing the PDF.

- a) All five of the following report panels should be generated.
  - i. Report Summary
  - ii. Process Inputs/Outputs
  - iii. Process Metrics
  - iv. General Process Reporting
  - v. Process Results (contains many bookmarks)
- b) All titles, paths, dates, etc., should appear correct.

SAS Clinical Standards Toolkit 1.4 CDISC-SDTM 3.1.1 VALIDATION	
Process Inputs/Outputs	
Type	Path
Autocall Libraries	(sdmcode sasautos)
	sdmcode: c:/cstGlobalLibrary/standards/cdisc-sdtm-3.1.1-1.4/macros
Format Search Path Libraries	(cstfmt srcfmt)
	cstfmt:
	srcfmt: !sasroot/.../SASClinicalStandardsToolkitSDTM311/1.4/sample/cdisc-sdtm-3.1.1/sascstdemodata/terminology/formats
Reference Metadata	c:/cstGlobalLibrary/standards/cdisc-sdtm-3.1.1-1.4/metadata
Source Data	!sasroot/.../SASClinicalStandardsToolkitSDTM311/1.4/sample/cdisc-sdtm-3.1.1/sascstdemodata/data
Source Metadata	!sasroot/.../SASClinicalStandardsToolkitSDTM311/1.4/sample/cdisc-sdtm-3.1.1/sascstdemodata/metadata

- 6 Close the SAS session.

---

## Sign-Off

<i>Test 2: SDTM 3.1.1 Report Process Results</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 3: SDTM 3.1.2 Validation

---

### Introduction

Now, run tests for SDTM 3.1.2. The tests are located in a different base directory than those for SDTM 3.1.1. This test verifies that the files required to validate a set of SDTM 3.1.2 domains are properly defined.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program. Select CST\_SD TM\_312/programs/validate\_data.sas.
- 3 Select Run → Submit.

This program outputs to the log and creates the data sets Validation\_results and Validation\_metrics. These data sets can be found in the Results library within the SAS Explorer window.

- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set Validation\_results.

It is located in the Results library in the Explorer.

- a) For the records where the column labeled “Validation check identifier” (named checkid) is blank, examine the message column and check for correct paths and process metadata.
  - b) The column labeled “Process status” (named \_cst\_rc) should be 0 for all records and there should not be any checks with result severity = ‘Warning: Check not run’.
  - c) The data set should contain 100 records.
- 6 Review the data set Validation\_metrics.

It should contain the following in the last few rows:

Metric parameter	Count of records
# of distinct check invocations	13
# check invocations not run	0
Errors (severity=High) reported	0
Warnings (severity=Medium) reported	10
Notes (severity=Low) reported	0
Structural errors, warnings and notes	85
Content errors, warnings and notes	0

- 7 End the current SAS session.

---

## Sign-Off

<i>Test 3: SDTM 3.1.2 Validation</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 4: SDTM 3.1.2 Build Source Data

### Introduction

This test references derived data from a CRT-DDS (define.xml) file to build a library of SDTM 3.1.2 domains.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select *CST\_SDTM\_312/programs/create\_sasdatafromxpt.sas*.
- 3 Select Run → Submit.

The code outputs to the SAS log and creates a data set *xpt\_results* under *CST\_SDTM\_312/results* and 33 data sets under *CST\_SDTM\_312/derived/data*. For this program, the library information was cleaned up, so these files are not immediately accessible under Libraries in the SAS Explorer. On Microsoft Windows, you can access these files through the SAS Explorer by navigating from within the SAS Explorer starting at the node labeled “My Computer”. On UNIX, it is necessary for you to copy these data sets into a folder that is viewable by the SAS Explorer (e.g., your Home Directory listed under Favorite Folders).

- 4 Review the log to see if there are any errors or warnings; there should not be any errors.

You might sporadically see warnings in the SAS log such as “WARNING: Libname <libref> is not assigned.” These occur with redundant requests to clear SAS librefs and/or filerefs and do not indicate a problem with the SAS Clinical Standards Toolkit installation.

- 5 Review the data set *xpt\_results*.
  - a) Examine the “Resolved message text from message file” column (named message) and check for correct paths and process metadata.
  - b) The column labeled “Process status” (named *\_cst\_rc*) should be 0 for all records and there should not be any checks with *resultseverity=’Warning: Check not*

	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)
1	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-frame	Info
2	CST0102		1	1	CST_CREATEDS	work.sasreferences was created as requested	Info
3	CST0200		1	1	CSTUTIL_PROCESSSETUP	Process setup is using this SASReferences: C:\DOCUME~1\geligh\LOCALS~1\Temporary Files\TD4104_WILLIS2_/sasreference	Info
4	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-sdtm	Info
5	CST0200		1	1	SDTMUTIL_CREATESASDATAFROMX	PROCESS STANDARD: CDISC-SDTM	Info
6	CST0200		1	2	SDTMUTIL_CREATESASDATAFROMX	PROCESS STANDARDVERSION: 3.1.2	Info
7	CST0200		1	3	SDTMUTIL_CREATESASDATAFROMX	PROCESS DRIVER: CREATE_SASDATAFROMXPT	Info
8	CST0200		1	4	SDTMUTIL_CREATESASDATAFROMX	PROCESS DATE: 2011-08-05T14:37:05	Info
9	CST0200		1	5	SDTMUTIL_CREATESASDATAFROMX	PROCESS TYPE: DATA DERIVATION	Info
10	CST0200		1	6	SDTMUTIL_CREATESASDATAFROMX	PROCESS SASREFERENCES: work._cstsasrefs	Info
11	CST0200		1	7	SDTMUTIL_CREATESASDATAFROMX	PROCESS STUDYROOTPATH: %sasroot/./../SASClinicalStandardsToolkit	Info
12	CST0200		1	8	SDTMUTIL_CREATESASDATAFROMX	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info
13	CST0200		1	9	SDTMUTIL_CREATESASDATAFROMX	PROCESS CSTVERSION: 1.4	Info
14	CST0200		1	10	SDTMUTIL_CREATESASDATAFROMX	Process completed successfully	Info

- run’.
- c) The data set should contain 14 records, and the last record should report “Process completed successfully”. See the sample output in screenshot above; values that refer to temporary folders/files or PROCESS DATE: vary.
- 6** Review the folder CST\_SD TM\_312/derived/data.
- a) There should be 33 new SAS data sets.
  - b) The data set dm should have 70 records and 20 columns.
- 7** End the current SAS session.

## Sign-Off

<i>Test 4: SDTM 3.1.2 Build Source Data</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 5: SDTM 3.1.2 Build Source Metadata

---

### Introduction

This test references derived data from a CRT-DDS (define.xml) file to build a set of SDTM 3.1.2 metadata in a structure required by SAS Clinical Standards Toolkit.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select `CST_SDTM_312/programs/create_sourcemetadata.sas`.
- 3 Select Run → Submit.

This code outputs to the SAS log and create data sets in both the results and derived/metadata subfolders under `CST_SDTM_312`. As in Test 4, the library information was cleaned up by the program so these files are not immediately accessible under Libraries in the SAS Explorer. On Microsoft Windows, you can access these files through the SAS Explorer by navigating from within the SAS Explorer starting at the node labeled “My Computer”. On UNIX, you need to copy these data sets into a folder that is viewable by the SAS Explorer.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set `srcmeta_results` under `CST_SDTM_312/results`.
  - a) Examine the “Resolved message text from message file” column (named `message`) and check for correct paths and process metadata.
  - b) The column labeled “Process status” (named `_cst_rc`) should be 0 for all records.

	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
1	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-frame	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:\DOCUME~1\geligh\LOCALS~1\Temporary Files\TD4524_WILLIS2_/sasreference	Info	0	0	
4	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-sdm	Info	0	0	
5	CST0200		1	1	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS STANDARD: CDISC-SDTM	Info	0	0	
6	CST0200		1	2	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS STANDARDVERSION: 3.1.2	Info	0	0	
7	CST0200		1	3	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS DRIVER: CREATE_SOURCEMETADATA	Info	0	0	
8	CST0200		1	4	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS DATE: 2011-08-05T14:58:39	Info	0	0	
9	CST0200		1	5	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS TYPE: METADATA DERIVATION	Info	0	0	
10	CST0200		1	6	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS SASREFERENCES: work_cstasrefs	Info	0	0	
11	CST0200		1	7	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS STUDYROOTPATH: !sasroot/././SASClinicalStandardsToolki	Info	0	0	
12	CST0200		1	8	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0	
13	CST0200		1	9	SDTMUTIL_CREATESRCMETAFROMCRTDDS	PROCESS CSTVERSION: 1.4	Info	0	0	
14	CST0074		1	10	SDTMUTIL_CREATESRCMETAFROMCRTDDS	Study reference data created in C:\Program Files\SASHome\SASClinicalStandardsTo	Info	0	0	source_tables
15	CST0074		1	11	SDTMUTIL_CREATESRCMETAFROMCRTDDS	Study reference data created in C:\Program Files\SASHome\SASClinicalStandardsTo	Info	0	0	source_columns
16	CST0074		1	12	SDTMUTIL_CREATESRCMETAFROMCRTDDS	Study reference data created in C:\Program Files\SASHome\SASClinicalStandardsTo	Info	0	0	source_study

c) The data set should contain 16 records. The last 3 records should report that study reference data was created in folder *CST\_SDTM\_312/derived/metadata*. See the sample output in screenshot above; values that refer to temporary folders/files or PROCESS DATE: vary.

6 Review the folder *CST\_SDTM\_312/derived/metadata*.

a) There should be three new data sets: *source\_columns*, *source\_study*, and *source\_tables*.

b) The data set *source\_tables* should have 33 records and 15 columns.

7 End the SAS session.

## Sign-Off

<i>Test 5: SDTM 3.1.2 Build Source Metadata</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 6: SDTM 3.1.2 Build SAS Formats

---

### Introduction

This test references derived data from a CRT-DDS (define.xml) file to build a SAS format catalog representing the codelists in the CRT-DDS file.

---

### Steps

- 1 Start a new SAS session
- 2 In the SAS Program Editor, select File → Open Program and select `CST_SDTM_312/programs/create_formatsfromcrtds.sas`.
- 3 Select Run → Submit.

The code outputs to the SAS log and creates data set `codelist_results` in `CST_SDTM_312/results` and creates a catalog named `cterms` under `CST_SDTM_312/derived/formats`. As in tests 4 and 5, the library information was cleaned up by the program so these files are not immediately accessible under Libraries in the SAS Explorer. On Microsoft Windows, you can access these files through the SAS Explorer by navigating from within the SAS Explorer starting at the node labeled “My Computer”. On UNIX, it is necessary to copy these data sets into a folder that is viewable by the SAS Explorer. At the end of the run, the FMTLIB output appears.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set `codelist_results` under `CST_SDTM_312/results`.
  - a) Examine the “Resolved message text from message file” column (named `message`) and check for correct paths and process metadata.
  - b) The column labeled “Process status” (named `_cst_rc`) should be 0 for all records and there should not be any checks with `result severity=Warning: Check not run`.

	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)
1	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-frame	Info
2	CST0102		1	1	CST_CREATEDS	work.sasreferences was created as requested	Info
3	CST0200		1	1	CSTUTIL_PROCESSETUP	Process setup is using this SASReferences: C:\DOCUME~1\geligh\LOCALS~1\Tem Temporary Files\TD5248_WILLIS2_/sasreference	Info
4	CST0108		1	1	CST_SETPROPERTIES	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-sdtm	Info
5	CST0200		1	1	SDTMUTIL_CREATEFORMATSFROMC	PROCESS STANDARD: CDISC-SDTM	Info
6	CST0200		1	2	SDTMUTIL_CREATEFORMATSFROMC	PROCESS STANDARDVERSION: 3.1.2	Info
7	CST0200		1	3	SDTMUTIL_CREATEFORMATSFROMC	PROCESS DRIVER: CREATE_CODELISTFROMCRTDDS	Info
8	CST0200		1	4	SDTMUTIL_CREATEFORMATSFROMC	PROCESS DATE: 2011-08-05T15:10:29	Info
9	CST0200		1	5	SDTMUTIL_CREATEFORMATSFROMC	PROCESS TYPE: METADATA DERIVATION	Info
10	CST0200		1	6	SDTMUTIL_CREATEFORMATSFROMC	PROCESS SASREFERENCES: work_cstsasrefs	Info
11	CST0200		1	7	SDTMUTIL_CREATEFORMATSFROMC	PROCESS STUDYROOTPATH: %sasroot%/../SASClinicalStandardsToolki	Info
12	CST0200		1	8	SDTMUTIL_CREATEFORMATSFROMC	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info
13	CST0200		1	9	SDTMUTIL_CREATEFORMATSFROMC	PROCESS CSTVERSION: 1.4	Info
14	CST0200		1	10	SDTMUTIL_CREATEFORMATSFROMC	Process completed successfully	Info

c) The data set should contain 14 records. The last record should report “Process completed successfully”. See the sample output in screenshot above; values that refer to temporary folders/files or PROCESS DATE: vary.

Folder CST\_SDTM\_312/derived/formats should contain a catalog cterms (named cterms.sas7bcat).

6 Open cterms and verify that it has 32 formats.

The data set can show 39 formats if it previously existed; in this case, the 32 formats are appended to the file.

7 End the current SAS session.

## Sign-Off

Test 6 – SDTM 3.1.2 Build SAS Formats	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 7: SDTM 3.1.2 Report Check Metadata

### Introduction

This test verifies that all metadata about SDTM 3.1.2 validation checks is properly installed. A sample report itemizes this metadata.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_SD TM\_312/programs/cst\_metadatareport.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and generates a PDF file named cstcheckmetadatareport.pdf in directory CST\_SD TM\_312/results. No result data set is created.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the PDF file. Sample output from Page 1 below.

SAS Clinical Standards Toolkit 1.4 CDISC-SDTM 3.1.2 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
SDTM0001	***	WebSDM	IR5000	Identifies domain table that has zero rows and therefore contains no data	Warning	_ALL_	
SDTM0002	***	SAS	SAS0017	A load of data into JANUS requires that the DM, DS and EX domains be submitted for each study to be loaded.	Error	DM+DS+EX	
SDTM0003	***	SAS	SAS0018	WebSDM and the SDTM model require only the DM domain be present.	Error	DM	
SDTM0004	***	SAS	SAS0033	Source metadata includes domain data set not found in reference metadata	Note	_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_	
SDTM0012	***	WebSDM	IR5252	Identifies a column listed in the domain description as Required ('Req') but not included in the SAS dataset for that domain	Error	_ALL_	
SDTM0013	***	WebSDM	IR5253	Identifies a column listed in the domain description as Expected ('Exp') but not included in the SAS dataset for that domain	Warning	_ALL_	
SDTM0014	***	SAS	SAS0008	Identifies a column listed in the domain description as Permissible ('Perm') but not included in the SAS dataset for that domain	Note	_ALL_	

- a) All four of the following report sections should be generated.
  - i. The Report Procedure (Check Overview)
  - ii. Additional Check Details
  - iii. Validation Message Details
  - iv. Reference Information
- b) All titles, footnotes, column headers, and cell contents should appear correct.

- c) In the Reference Information section, look for at least one value of “OpenCDISC” in the column named Source of Information (e.g., the row for validation check SDTM0231).
- 6 End the current SAS session.

---

### Sign-Off

<i>Test 7 – SDTM 3.1.2 Report Check Metadata</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 8: CRT-DDS Validate

### Introduction

This test validates a SAS representation of the metadata and data that is defined in the SAS representation of the CRT-DDS model.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_CRTDDS/Programs/validate\_crtds\_data.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and creates a validation\_results data set and a validation\_metrics data set under CST\_CRTDDS/results. This code can fill up the LOG window if running interactively. If so, save the output of the log to a file when prompted to do so.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the validation\_results data set under CST\_CRTDDS/results.  
In the SAS Explorer, you can also view it as Validation\_results in the Results library.
  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The data set should contain 196 records.
  - c) In rows 15 and 16, there should be two records with Warning: Check not run. Both of these records have checkid="CRT0100" and resultid="CST0022".
- 6 Review the data set validation\_metrics under CST\_CRTDDS/results.  
In the SAS Explorer, you can also view it as Validation\_metrics in the Results library.
  - a) The data set should contain 329 records.
  - b) The last record should report that there were 21 records with "Content errors, warnings and notes".
- 7 End the current SAS session.

### Sign-Off

<i>Test 8 – CRT-DDS Validate</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 9: CRT-DDS Create SAS CRT-DDS from SDTM

### Introduction

If this program runs successfully and produces the expected results, then the SAS Clinical Standards Toolkit has derived CRT-DDS metadata from an SDTM study as a prerequisite to building a define.xml file in Test 12.

### Steps

- 1 Start a new SAS session, and submit the CRT-DDS Create sample program `CST_CRTDDS/programs/create_crtds_from_sdtm.sas`.  
The sample program outputs to the SAS Log and creates 39 data sets in folder `CST_CRTDDS/data` and a results data set in the folder `CST_CRTDDS/results` folder.
- 2 Review the log to see if there are any errors or warnings; there should not be any.
- 3 Review the folder `CST_CRTDDS/data`.
  - a) There should be 39 new SAS data sets.
  - b) The data set codelists should have 32 records and 5 columns.
- 4 Close the SAS session.

### Sign-Off

<i>Test 9 – CRT-DDS Create SAS CRT-DDS from SDTM</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 10: CRT-DDS Create SAS CRT-DDS from Define.xml

---

### Introduction

This test creates a CRT-DDS SAS representation files from the define.xml.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_CRTDDS/Programs/create\_sascrtdds\_fromxml.sas.
- 3 Select Run → Submit.

This code outputs to the SAS log and creates the SAS representation of the CRT-DDS data sets under CST\_CRTDDS/deriveddata.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set read\_results under CST\_CRTDDS/results.

In the SAS Explorer, you can also view it as Read\_results in the Results library.

  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The column named resultflag should be 0 for all records.
  - c) The data set should contain 45 records.
  - d) There should be a record, with srcdata="CRTDDS\_READ", reporting that the define.xml file was read successfully.
  - e) There should be a record, with srcdata="JAVA CHECK"; the record should report "No java issues".
- 6 The folder CST\_CRTDDS/deriveddata should contain 39 SAS data sets representing the SAS interpretation of the CRT-DDS format.
- 7 Open the clitemdecodetranslatedtext SAS data set. It should contain 2909 observations. Below is a screen shot of the first 17 observations.

	Human-readable text appropriate for a particular language	Natural language or country-specific language variant	Foreign key: CodeListItems.DID
1	DOSE INCREASED	en	N77984
2	DOSE NOT CHANGED	en	N77995
3	DOSE REDUCED	en	N78006
4	DRUG INTERRUPTED	en	N78017
5	DRUG WITHDRAWN	en	N78028
6	NOT APPLICABLE	en	N78039
7	UNKNOWN	en	N78050
8	MILD	en	N78068
9	MODERATE	en	N78079
10	SEVERE	en	N78090
11	DAYS	en	N78108
12	HOURS	en	N78119
13	MONTHS	en	N78130
14	WEEKS	en	N78141
15	YEARS	en	N78152
16	ABW	en	N78170
17	AFG	en	N78181

8 End the current SAS session.

---

### Sign-Off

Test 10 – CRT-DDS Create SAS CRT-DDS from Define.xml	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 11: CRT-DDS Import from XML Export to XML (Round Trip)

---

### Introduction

This test reads a CRT-DDS define.xml and creates the 39 SAS data sets in the Work library representing the CRTDDS model. It then exports these generated data sets and creates a CRT-DDS define.xml file. This verifies the round tripping from XML to data to XML.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_CRTDDS/Programs/import\_sascrtdds\_fromxml\_export\_toxml.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and creates a define1-0-0.xml and a define\_export.xml under CST\_CRTDDS/sourcexml. It also creates a data set, import\_results, under CST\_CRTDDS/results.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data in the work directory under the SAS Explorer.  
There are 39 data sets representing SAS interpretation of the CRTDDS model. These data sets do not contain any underscores in their names.
- 6 Review the data set import\_results under CST\_CRTDDS/results.  
In the SAS Explorer, you can also view it as Import\_results in the Results library.
  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The column named resultflag should be 0 for all records.
  - c) The data set should contain 43 records.
  - d) There should be a record, with srcdata="CRTDDS\_READ", reporting that the define\_import.xml file was read successfully.
  - e) There should be a record, with srcdata="JAVA CHECK", should report "No java issues".
- 7 Review the data set export\_results under CST\_CRTDDS/results.  
In the SAS Explorer, you can also view it as Export\_results in the Results library.
  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The column named resultflag should be 0 for all records.
  - c) The data set should contain 97 records.
  - d) There should be a record, with srcdata="CRTDDS\_WRITE", reporting that the define\_export.xml file was created (row76).
  - e) There should be a record, with srcdata="JAVA CHECK", should report "No java issues" (row 78).
- 8 Under CST\_CRTDDS/sourcexml, the define\_import.xml and define\_exporet.xml should be the same size of 201 KB.

9 Click the define\_export.xml file to open it and click Vital Signs next to the VS table.

This takes you to the VS table. Click the variable VSTESTCD.

10 In the next screen, click the SIZE variable in the VSTESTCD–FRMSIZE row.

The table should look like the following:

SIZE, Reference Name (SIZE)	
SMALL	SMALL
MEDIUM	MEDIUM
LARGE	LARGE

11 End the current SAS session.

---

### Sign-Off

Test 11 – CRT-DDS Import from XML Export to XML (Round Trip)	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 12: CRT-DDS Create Define.xml

### Introduction

If this program runs successfully and produces the expected results, then the SAS Clinical Standards Toolkit Java and XML-related libraries have been installed correctly. The SAS Clinical Standards Toolkit and libraries can be used to create a CRT-DDS (define.xml) file.

### Steps

- 1 Start a new SAS session and submit the CRT-DDS Create Define.xml sample program `CST_CRTDDS/programs/create_crtds_define.sas`.

It writes to the SAS Log and generates two files in `CST_CRTDDS/sourcexml` and a results data set in the folder `CST_CRTDDS/results` folder.

- 2 Review the log to see if there are any errors or warnings; there should not be any.
- 3 Two files should have been generated in `CST_CRTDDS/sourcexml`: `define.xml` and `define1-0-0.xsl`.
- 4 You need to examine the `define.xml` in a Web browser.

On Microsoft Windows, you can open it by double-clicking it in the SAS Program Editor. This renders the file in your default Web browser or 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 the two files to an environment where you can bring up the `define.xml` in a Web browser. The style sheet information in `define1-0-0.xsl` is not guaranteed to work for all browser types and versions to produce the correct HTML, but it does work for Internet Explorer version 6.0 and higher. In the browser, the `define.xml` contains a number of tables.

The first table should appear similar to the following table (only the first few rows are provided here). Minor variations in appearance are possible and are not a problem. Reviewing these rows is sufficient to confirm that the product is installed and functioning properly.

Datasets for Study study1					
Dataset	Description	Structure	Purpose	Keys	Location
AE	<a href="#">Adverse Events</a>	Events - One record per event per subject	Tabulation	STUDYID USUBJID AETERM AESTDTC	<a href="#">Adverse Events SAS transport file</a>
CM	<a href="#">Concomitant Medications</a>	Interventions - One record per medication intervention episode per subject	Tabulation	STUDYID USUBJID CMTRT CMSTDTC	<a href="#">Concomitant Medications SAS transport file</a>
CO	<a href="#">Comments</a>	Special Purpose - One record per comment per subject	Tabulation	STUDYID USUBJID COSEQ	<a href="#">Comments SAS transport file</a>
DM	<a href="#">Demographics</a>	Special Purpose - One record per subject	Tabulation	STUDYID USUBJID	<a href="#">Demographics SAS transport file</a>
DS	<a href="#">Disposition</a>	Events - One record per disposition status or protocol milestone per subject	Tabulation	STUDYID USUBJID DSSTDTC	<a href="#">Disposition SAS transport file</a>
DV	<a href="#">Protocol Deviations</a>	Events - One record per protocol deviation per subject	Tabulation	STUDYID USUBJID DVSEQ	<a href="#">Protocol Deviations SAS transport file</a>
EG	<a href="#">ECG Test Results</a>	Findings - One record per ECG observation per time point per visit per subject	Tabulation	STUDYID USUBJID EGTESTCD VISITNUM EGTPNUM EGSEQ	<a href="#">ECG Test Results SAS transport file</a>
EX	<a href="#">Exposure</a>	Interventions - One record per constant dosing interval per subject	Tabulation	STUDYID USUBJID EXTRT EXSTDTC	<a href="#">Exposure SAS transport file</a>

- 5 The `define.xml` also contains tables for the following:
  - a) For each domain, a table lists its variables.
  - b) Computational Algorithms Section
  - c) Controlled Terminology

The last table in define.xml contains controlled terminology. The last few items in the file should be values for VSTESTCD, including the values BMI and WEIGHT.

- 6 End the SAS session.

---

## Sign-Off

<i>Test 12 – CRT-DDS Create Define.xml</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 13: ODM 1.3.0 Create SAS ODM from XML

---

### Introduction

This test reads a CDISC ODM 1.3.0 XML file and builds a SAS representation of the metadata that is defined in the XML.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_ODM/Programs/create\_sasodm\_fromxml.sas.
- 3 Select Run → Submit.

This code outputs to the SAS log and creates data sets in the formats, metadata and data subfolders under CST\_ODM/derived and also creates a read\_results data set under CST\_ODM/results.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the read\_results data set under CST\_ODM/results.

In the SAS Explorer, you can also view it as Read\_results in the Results library.

  - a) Examine the message column to verify correct paths and process metadata
  - b) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - c) The data set should contain 49 records.
  - d) The last record should report that the ODM file was read successfully.

The folder CST\_ODM/derived/metadata should contain two data sets: source\_tables and source\_columns.

You can also view these data sets in the SAS Explorer in the library named Srcmeta.

  - a) The data set source\_tables should have 66 rows and 10 columns.
  - b) The data set source\_columns should have 315 rows and 16 columns.
- 6 Review the folder CST\_ODM/derived/data.
  - a) There should be 66 new SAS data sets.
  - b) The data set codelists should have 23 records and 5 columns.
- 7 Review the folder CST\_ODM/derived/formats
  - a) There should be three new data sets and three new format catalogs.
  - b) The odmfmtcat\_en data set should have 957 records and five columns.
- 8 End the current SAS session.

---

## Sign-Off

<i>Test 13 – ODM1.3.0 Create SAS ODM From XML</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 14: ODM 1.3.0 Validate SAS ODM

---

### Introduction

This test validates a SAS representation of the metadata that is defined in the CDISC ODM 1.3.0 XML file.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_ODM/Programs/validate\_odm\_data.sas.
- 3 Select Run → Submit.

This code outputs to the SAS log and creates a validation\_results data set and a validation\_metrics data set under CST\_ODM/results. This code can fill up the LOG window if running interactively. If so, save the output of the log to a file when prompted to do so.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the validation\_results data set under CST\_ODM/results.

In the SAS Explorer, you can also view it as Validation\_results in the Results library.

  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The data set should contain 343 records.
  - c) There should be 2 records with resultflag=1 and resultseverity="Error". Both of these records have checkid="ODM0110" and resultid="ODM0110". The errors messages start with "The foreign key OID does not have a corresponding value in the target data set".
- 6 Review the data set validation\_metrics under CST\_ODM/results.

In the SAS Explorer, you can also view it as Validation\_metrics in the Results library.

  - a) The data set should contain 604 records.
  - b) The last record should report that there were two records with "Content errors, warnings and notes".
- 7 End the current SAS session.

---

## Sign-Off

<i>Test 14 – ODM1.3.0 Validate SAS ODM</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 15: ODM 1.3.0 Create ODM XML from SAS ODM

### Introduction

This test creates a CDISC ODM 1.3.0 XML file from the SAS representation of the metadata.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_ODM/Programs/create\_odmxml.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and creates an XML file odm\_sample\_out.xml in the CST\_ODM/sourcexml folder and also creates a write\_results data set under CST\_ODM/results.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set write\_results under CST\_ODM/results.  
In the SAS Explorer, you can also view it as Write\_results in the Results library.
  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The column named resultflag should be 0 for all records.
  - c) The data set should contain 65 records.
  - d) There should be a record, with srcdata="ODM\_WRITE", reporting that the ODM file was created.
  - e) The last record, with srcdata="ODM\_XMLVALIDATE", should report that no errors were found in the ODM file.
- 6 The folder CST\_ODM/sourcexml should contain a new XML file odm\_sample\_out.xml, which should have the same size in Kb (317 Kb) as the XML file odm\_sample.xml in the same folder.
- 7 End the current SAS session.

### Sign-Off

<i>Test 15 – ODM1.3.0 Create ODM XML from SAS ODM</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 16: ODM 1.3.0 Find Unsupported Tags in ODM XML

### Introduction

This test parses a CDISC ODM 1.3.0 XML file and finds elements and attributes that SAS Clinical Standards Toolkit does not recognize by default. These might be, for example, vendor or customer extensions or new tags implemented in a later version of ODM.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_ODM/Programs/find\_unsupported\_tags.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and creates a readxmltags\_results data set under CST\_ODM/results.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the data set readxmltags\_results under CST\_ODM/results.  
In the SAS Explorer, you can also view it as Readxmltags\_results in the Results library.
  - a) The column labeled Process status (named \_cst\_rc) should be 0 for all records.
  - b) The column named resultflag should be 0 for 4 records, and should be 1 for all other records.
  - c) The data set should contain 24 records.
  - d) There should be four records (with checkid=" ODM0900") where the column named message indicates "Element found in XML file that is not present in CDISC ODM Model".
- 6 End the current SAS session.

### Sign-Off

<i>Test 16 – ODM1.3.0 Find Unsupported Tags in ODM XML</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 17: SDTM Controlled Terminology 201104

---

### Introduction

This test verifies that controlled terminology package 201104 for SDTM is installed and is available to SAS Clinical Standards Toolkit processes.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, enter the following SAS code.

```
%cstutil_setcstgroot;

libname fmts "&_cstGRoot./standards/cdisc-terminology-1.4/cdisc-
sdtm/201104/formats";
options fmtsearch=(fmts.terms);

* Does expected format exist?  *;
data _null_;
    result = put('Albumin/Creatinine', $LBTEST.);
run;

data _null_;
    set fmts.terms (where=(codelist='LBTEST')) end=last;
    attrib result format=$200.;
    retain found 0 result '';
    if n =1 then
        result='Albumin/Creatinine';
    if cdisc_submission_value=result then
    do;
        found=1;
        result=catx(' ', 'Formatted value', result, 'found');
        put result=;
    end;
    if last and found=0 then put result= 'not found';
run;
```

If the format cannot be found (SAS log reports “ERROR 48-59: The format \$LBTEST was not found or could not be loaded.”) or if the specific test value is not found, then there are problems with the installation and/or availability of the controlled terminology package to the SAS Clinical Standards Toolkit processes. You should see the following line at the end of the SAS log:

```
result=Formatted value Albumin/Creatinine found
```

- 3 End the current SAS session.

---

## Sign-Off

<i>Test 17 – SDTM Controlled Terminology 201104</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 18: ADaM Controlled Terminology 201101

---

### Introduction

This test verifies that controlled terminology package 201101 for ADaM has been installed and is available to SAS Clinical Standards Toolkit processes.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, enter the following SAS code.

```
%cstutil_setcstgroot;

libname fmts "&_cstGRoot./standards/cdisc-terminology-1.4/cdisc-
adam/201101/formats";
options fmtsearch=(fmts.terms);

* Does expected format exist?  *;
data _null_;
    result = put('DERIVED', $PARAMTYP.);
run;

data _null_;
    set fmts.terms (where=(codelist='PARAMTYP')) end=last;
    attrib result format=$200.;
    retain found 0 result '';
    if n =1 then
        result='DERIVED';
    if cdisc_submission_value=result then
    do;
        found=1;
        result=catx(' ', 'Formatted value', result, 'found');
        put result=;
    end;
    if last and found=0 then put result= 'not found';
run;
```

If the format cannot be found (SAS log reports “ERROR 48-59: The format \$PARAMTYP was not found or could not be loaded.”) or if the specific test value is not found, then there are problems with the installation and/or availability of the controlled terminology package to the SAS Clinical Standards Toolkit processes. You should see the following line at the end of the SAS log:

```
result=Formatted value DERIVED found
```

- 3 End the current SAS session.

---

## Sign-Off

<i>Test 18 – ADaM Controlled Terminology 201101</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 19: CDASH Controlled Terminology 201104

---

### Introduction

This test verifies that controlled terminology package 201104 for CDASH has been installed and is available to SAS Clinical Standards Toolkit processes.

---

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, enter the following SAS code.

```
%cstutil_setcstgroot;

libname fmts "&_cstGRoot./standards/cdisc-terminology-1.4/cdisc-
cdash/201104/formats";
options fmtsearch=(fmts.cterms);

* Does expected format exist?  *;
data _null_;
    result = put('AEROSOL', $CMDOSFRM.);
run;

data _null_;
    set fmts.cterms (where=(codelist='CMDOSFRM')) end=last;
    attrib result format=$200.;
    retain found 0 result '';
    if n =1 then
        result='AEROSOL';
    if cdisc_submission_value=result then
    do;
        found=1;
        result=catx(' ', 'Formatted value', result, 'found');
        put result=;
    end;
    if last and found=0 then put result= 'not found';
run;
```

If the format cannot be found (SAS log reports “ERROR 48-59: The format \$CMDOSFRM was not found or could not be loaded.”) or if the specific test value is not found, then there are problems with the installation and/or availability of the controlled terminology package to the SAS Clinical Standards Toolkit processes. You should see the following line at the end of the SAS log:

```
result=Formatted value AEROSOL found
```

- 3 End the current SAS session.

---

## Sign-Off

<i>Test 19 – CDASH Controlled Terminology 201104</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

---

## Test 20: ADaM 2.1 Validation

---

### Introduction

This test runs the sample program that ships as part of the ADaM 2.1 standard. If this program runs successfully and produces the expected results, then the ADaM 2.1 standard is correctly installed and functioning properly.

---

### Steps

- 1 Submit the ADaM 2.1 validation sample program  
CST\_ADAM/programs/validate\_data.sas.

It outputs to the SAS Log and generate two SAS data sets: Validation\_results and Validation\_metrics. These data sets can be found in the Results library within the SAS Explorer window.

- 2 Review the log to see if there are any errors or warnings; there should not be any.

3 Review the data set Validation\_results for errors.

It should be consistent with the following table. Values that refer to temporary folders/files, user IDs, or PROCESS DATE: vary (in bold below). It contains additional columns, but checking these is sufficient.

Row	Result Identifier	Validation Check Identifier	Unique Invocation of resultid	Seq # within resultseq	Source data
1	CST0108		1	1	CST_SETPROPERTIES
2	CST0102		1	1	CST_CREATEDS
3	CST0200		1	1	CSTUTIL_PROCESSETUP
4	CST0108		1	1	CST_SETPROPERTIES
5	CST0108		1	1	CST_SETPROPERTIES
6	CST0200		1	1	ADAM_VALIDATE
7	CST0200		1	2	ADAM_VALIDATE
8	CST0200		1	3	ADAM_VALIDATE
9	CST0200		1	4	ADAM_VALIDATE
10	CST0200		1	5	ADAM_VALIDATE
11	CST0200		1	6	ADAM_VALIDATE
12	CST0200		1	7	ADAM_VALIDATE
13	CST0200		1	8	ADAM_VALIDATE
14	CST0200		1	9	ADAM_VALIDATE
15	CST0200		1	10	ADAM_VALIDATE
16	CST0100	ADAM0001	1	1	SRCDATA.ADSL
17	CST0100	ADAM0002	1	1	WORK._CSTCOLUMNMETADATA
18	CST0025	ADAM0003	1	1	WORK._CSTCOLUMNMETADATA
19	CST0025	ADAM0007	1	1	WORK._CSTCOLUMNMETADATA
20-38	Many additional similar rows are reported.				
N = 38					

Additional columns for rows 1–19 are as follows:

Row	Resolved message text from message file	Result Severity	resultflag	_cst_rc
1	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst-framework-1.4/programs/initialize.properties	Info	0	0
2	work.validation_sasrefs was created as requested	Info	0	0
3	Process setup is using this SASReferences: C:\DOCUME~1\userid\LOCALS~1\Temp\SAS Temporary Files\_TD4812/validation_sasrefs	Info	0	0
4	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-adam-2.1-1.4/programs/initialize.properties	Info	0	0
5	The properties were processed from the PATH !sasroot/././SASClinicalStandardsToolkitADaM21/1.4/sample/cdisc-adam-2.1/sascstdemodata/programs/validation.properties	Info	0	0

Row	Resolved message text from message file	Result Severity	resultflag	_cst_rc
6	PROCESS STANDARD: CDISC-ADAM	Info	0	0
7	PROCESS STANDARDVERSION: 2.1	Info	0	0
8	PROCESS DRIVER: ADAM_VALIDATE	Info	0	0
9	PROCESS DATE: 2011-08-10T14:32:59	Info	0	0
10	PROCESS TYPE: VALIDATION	Info	0	0
11	PROCESS SASREFERENCES: C:\DOCUME~1\userid\LOCALS~1\Temp\SAS Temporary Files\_TD4812/validation_sasrefs.sas7bdat	Info	0	0
12	PROCESS STUDYROOTPATH: !sasroot/./SASClinicalStandardsToolkitADaM21/1.4/sample/cdisc-adam-2.1/sascstdemodata	Info	0	0
13	PROCESS GLOBALLIBRARY: c:/cstGlobalLibrary	Info	0	0
14	PROCESS CSTVERSION: 1.4	Info	0	0
15	PROCESS CONTROLLED TERMINOLOGY SOURCE: c:/cstGlobalLibrary/standards/cdisc-terminology-1.4/cdisc-adam/201101/formats/cterm (Controlled Terminology released by NCI on 2011-01-07)	Info	0	0
16	No errors detected in SRCDATA.ADSL	Info	0	0
17	No errors detected in source data	Info	0	0
18	No errors detected in source data	Info	0	0
19	No errors detected in source data	Info	0	0
20-38	Many additional similar rows are reported.			
N = 38				

4 Close the SAS session.

## Sign-Off

Test 20 – ADaM 2.1 Validation	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Test 21: ADaM 2.1 Report Process Results

### Introduction

This test produces a sample report based on ADaM 2.1 process results.

### Steps

- 1 Start a new SAS session.
- 2 In the SAS Program Editor, select File → Open Program, and select CST\_ADAM/programs/cst\_report.sas.
- 3 Select Run → Submit.  
This code outputs to the SAS log and generates a PDF file. No result data set is created.
- 4 Review the log to see if there are any errors or warnings; there should not be any.
- 5 Review the PDF file; it is named cstreport.pdf and is located in the folder CST\_ADAM/results.

As noted in the Notes and Assumptions section, this PDF file should automatically be displayed on Microsoft Windows. If you are on UNIX, refer back to this section for instructions for approaches for viewing the PDF.

- a) All five of the following report panels should be generated.
  - i. Report Summary
  - ii. Process Inputs/Outputs
  - iii. Process Metrics
  - iv. General Process Reporting
  - v. Process Results (will contain many bookmarks)
- b) All titles, paths, dates, etc. should appear correct. Compare to image below.

<b>SAS Clinical Standards Toolkit 1.4</b> <b>CDISC-ADAM 2.1 VALIDATION</b>	
<b>Process Inputs/Outputs</b>	
Type	Path
Autocall Libraries	(adamauto sasautos)
	adamauto: c:/cstGlobalLibrary/standards/cdisc-adam-2.1-1.4/macros
Format Search Path Libraries	(cstfmt)
	cstfmt: c:/cstGlobalLibrary/standards/cdisc-terminology-1.4/cdisc-adam/current/formats
Source Data	Isasroot/././SASClinicalStandardsToolkitADaM21/1.4/sample/cdisc-adam-2.1/sascstdemodata/baddata
Source Metadata	Isasroot/././SASClinicalStandardsToolkitADaM21/1.4/sample/cdisc-adam-2.1/sascstdemodata/badmetadata

- 6 Close the SAS session.

---

## Sign-Off

<i>Test 21 – ADaM 2.1 Report Process Results</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

## Final Sign-Off

In the table below, indicate your final assessment about whether or not SAS Clinical Standards Toolkit 1.4 is installed correctly and is functioning properly.

If any of the IQOQ tests listed above did not pass, then the final IQOQ assessment must not be passed, unless you have provided sufficient documentation to explain otherwise.

<i>Final assessment of all testing.</i>	
Signature	
Date Test Was Executed	
Did the IQOQ pass? (Yes or No)	
Comments	



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