



THE
POWER
TO KNOW.

SAS[®] Clinical Data Standards Toolkit 1.3 Installation Qualification



The correct bibliographic citation for this manual is as follows: SAS Institute Inc. 2010. *SAS® Clinical Data Standards Toolkit 1.3: Installation Qualification*. Cary, NC: SAS Institute Inc.

SAS® Clinical Data Standards Toolkit 1.3: Installation Qualification

Copyright © 2010, SAS Institute Inc., Cary, NC, USA

All rights reserved. Produced in the United States of America.

For a hard-copy book: No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without the prior written permission of the publisher, SAS Institute Inc.

For a Web download or e-book: Your use of this publication shall be governed by the terms established by the vendor at the time you acquire this publication.

U.S. Government Restricted Rights Notice. Use, duplication, or disclosure of this software and related documentation by the U.S. government is subject to the Agreement with SAS Institute and the restrictions set forth in FAR 52.227-19 Commercial Computer Software-Restricted Rights (June 1987).

SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27513.

1st electronic book, November 2010

2nd electronic book, December 2010

SAS® Publishing provides a complete selection of books and electronic products to help customers use SAS software to its fullest potential. For more information about our e-books, e-learning products, CDs, and hard-copy books, visit the SAS Publishing Web site at support.sas.com/publishing or call 1-800-727-3228.

SAS® and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. ® indicates USA registration.

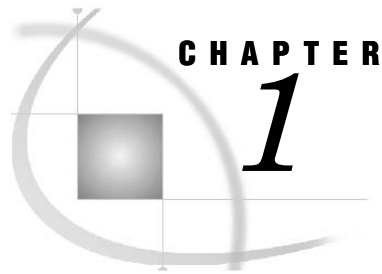
Other brand and product names are registered trademarks or trademarks of their respective companies.

Contents

Chapter 1 Installation Qualification 1

Purpose	1
Notes and Assumptions	2
Test 1 – SAS Hot Fix for ISO 8601 Informats Has Been Installed	3
Steps	3
Sign-off	3
Test 2 –SDTM 3.1.1 Validation	3
Steps	3
Sign-off	5
Test 3 – SDTM 3.1.1 Report Process Results	5
Steps	6
Sign-off	6
Test 4 – SDTM 3.1.2 Validation	6
Steps	6
Sign-off	7
Test 5 – SDTM 3.1.2 Build Source Data	7
Steps	7
Sign-off	8
Test 6 – SDTM 3.1.2 Build Source Metadata	8
Steps	8
Sign-off	9
Test 7 – SDTM 3.1.2 Build SAS Formats	9
Steps	9
Sign-off	10
Test 8 – SDTM 3.1.2 Report Check Metadata	10
Steps	10
Sign-off	11
Test 9 – CRT-DDS Create	11
Steps	11
Sign-off	11
Test 10 – CRT-DDS Create Define.xml	11
Steps	12
Sign-off	13
Test 11 – ODM 1.3.0 Create SAS ODM from XML	13
Steps	13
Sign-off	14
Test 12 – Controlled Terminology 200810	14

Steps	14
Sign-off	15
Test 13 – Controlled Terminology 201003	15
Steps	15
Sign-off	16
Final Sign-off	16



Installation Qualification

Installation Qualification 1

Purpose 1

Notes and Assumptions 2

Test 1 – SAS Hot Fix for ISO 8601 Informats Has Been Installed 3

Steps 3

Sign-off 3

Test 2 – SDTM 3.1.1 Validation 3

Steps 3

Sign-off 5

Test 3 – SDTM 3.1.1 Report Process Results 5

Steps 6

Sign-off 6

Test 4 – SDTM 3.1.2 Validation 6

Steps 6

Sign-off 7

Test 5 – SDTM 3.1.2 Build Source Data 7

Steps 7

Sign-off 8

Test 6 – SDTM 3.1.2 Build Source Metadata 8

Steps 8

Sign-off 9

Test 7 – SDTM 3.1.2 Build SAS Formats 9

Steps 9

Sign-off 10

Test 8 – SDTM 3.1.2 Report Check Metadata 10

Steps 10

Sign-off 11

Test 9 – CRT-DDS Create 11

Steps 11

Sign-off 11

Test 10 – CRT-DDS Create Define.xml 11

Steps 12

Sign-off 13

Test 11 – ODM 1.3.0 Create SAS ODM from XML 13

Steps 13

Sign-off 14

Test 12 – Controlled Terminology 200810 14

Steps 14

Sign-off 15

Test 13 – Controlled Terminology 201003 15

Steps 15

Sign-off 16

Final Sign-off 16

Purpose

- This document explains how to verify that SAS Clinical Standards Toolkit 1.3 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 that is presented.

Notes and Assumptions

- ❑ The SAS System itself is assumed to be installed and functioning correctly. It is not being tested.
- ❑ SAS Clinical Standards Toolkit 1.3 has been installed.
- ❑ The following code should be run to confirm that the post-installation step to update the CDISC-SDTM 3.1.2 data set validation_master has been completed.

```
%cstutil_setcstgroot;
libname refcntl "&cstGRoot./standards/cdisc-sdtm-3.1.2-
1.3/validation/control";
```

```
data _null_;
  set refcntl.validation_master (where=(checkid='SDTM0602'));
  if columnscope='' then
    put "Post-installation step verified.";
  else
  do;
    put "Warning: It appears that the post-installation step has not been
completed.";
    put "Warning: Review the installation instructions to ensure Toolkit
functions properly.";
  end;
run;
```

- ❑ The person running these tests is familiar with running SAS programs. This includes being able to submit SAS programs using the Program Editor, review the SAS log, and review the contents of SAS data sets.
- ❑ This document is used for both the UNIX and Windows environments. The forward slash character (/) is used in file paths as the separator between path components, which works on both OS environments. There is one table that contains SAS output from a Windows environment that has a backslash in the file paths.
- ❑ Within this document
 - ❑ **SASINSTALL** is used to denote the SAS installation folder. This is the folder into which all SAS products are installed.
 - ❑ **SASROOT** is used to denote the root folder for the SAS system installation.
 - ❑ The default value for SAS 9.1.3 is **SASINSTALL/SAS 9.1**.
 - ❑ The default value for SAS 9.2 is **SASINSTALL/SASFoundation/9.2**.
- ❑ The tests refer to the following variables, which are defined relative to **SASINSTALL**. When running the tests, you need to substitute the variable with the following associated paths.
 - ❑ **CST_SDTM_311**
SASINSTALL/SASClinicalStandardsToolkitSDTM311/1.3/sample/cdisc-sdtm-3.1.1/sascstdemodata
 - ❑ **CST_SDTM_312**
SASINSTALL/SASClinicalStandardsToolkitSDTM312/1.3/sample/cdisc-sdtm-3.1.2/sascstdemodata
 - ❑ **CST_ODM**
SASINSTALL/SASClinicalStandardsToolkitODM130/1.3/sample/cdisc-odm-1.3.0
 - ❑ **CST_CRTDDS**
SASINSTALL/SASClinicalStandardsToolkitCRTDDS10/1.3/sample/cdisc-crtdds-1.0

- ❑ Some of the tests (Tests 3 and 8) generate a PDF file. In Windows, when the PDF is generated, a browser window should automatically appear that contains the PDF for viewing. On UNIX, if you have not set up the SAS configuration variable SAS.helpBrowser, then you get a dialog box that states “The requested information could not be displayed because the connection to the remote browser server failed.” Click **OK** to continue. You should either configure your UNIX SAS environment to support a browser that can display PDF files or you need to copy the PDF file to an environment where you can examine it.

Test 1 – SAS Hot Fix for ISO 8601 InformatS Has Been Installed

This test only needs to be run if you are running SAS Version 9.1.3. If you have downloaded SAS Clinical Data Standards Toolkit 1.3 from the SAS hot-fix site, then you should verify that the SAS hot fix for the ISO 8601 SAS InformatS has installed.

The identifier for this hot fix is E9BD36 and the URL for downloading the Windows version is http://ftp.sas.com/techsup/download/hotfix/e9_win_sbcs.html#E9BD36. For other platforms, go to http://ftp.sas.com/techsup/download/hotfix/e9_sbcs_prod_list.html and search on that page for E9BD36.

Steps

- 1 Verify that this hot fix has been installed following the standard SAS System hot fix installation practices. Refer to the product documentation to identify which hot fix is required. Additional information about hot fixes can be located at <http://ftp.sas.com/techsup/download/hotfix/hotfix.html>

Sign-off

<i>Test 1 – SAS Hot fix for ISO 8601 InformatS has been installed</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 2 –SDTM 3.1.1 Validation

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 Submit the SDTM 3.1.1 validation sample program `CST_SD TM_311/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 whether there are any errors or warnings. There should not be any.
- 3 Review the data set named Validation_results for errors. It should be consistent with the following table. 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	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	CST0025	SDTM0011	1	1	SRCDATA.SUPPAE
16	CST0025	SDTM0011	2	1	SRCDATA.SUPPAE
17	CST0025	SDTM0012	1	1	SRCDATA.SUPPAE
18	CST0025	SDTM0012	2	1	SRCDATA.SUPPAE
19-132	Many additional similar rows are reported.				
N = 132					

The following are the additional columns for rows 1 – 18.

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-1.3/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\2\SAS Temporary Files_TD2932/sasreferences	Info	0	0
4	The properties were processed from the PATH c:\cstGlobalLibrary/standards/cdisc-sdtm-3.1.1-1.3/programs/initialize.properties	Info	0	0

Row	Resolved message text from message file	Result Severity	resultflag	_cst_rc
5	The properties were processed from the PATH !sasroot/././SASClinicalStandardsToolkitSDTM311/1.3/sample/c disc-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	PROCESS DATE: 2010-08-24T20:17:44	Info	0	0
10	PROCESS TYPE: VALIDATION	Info	0	0
11	PROCESS SASREFERENCES: C:\DOCUME~1\userid\LOCALS~1\Temp\2\SAS Temporary Files_TD2932\sasreferences.sas7bdat	Info	0	0
12	PROCESS STUDYROOTPATH: !sasroot/././SASClinicalStandardsToolkitSDTM311/1.3/sample/c disc-sdtm-3.1.1/sascstdemodata	Info	0	0
13	PROCESS GLOBALLIBRARY: c:\cstGlobalLibrary	Info	0	0
14	PROCESS CSTVERSION: 1.3	Info	0	0
15	Data set not found in reference standard - compliance not assessed	Warning: Check incomplete	1	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 - 132	Many additional similar rows are reported.			
N = 132				

4 Close the SAS session.

Sign-off

<i>Test 2 –SDTM 3.1.1 Validation is installed and functioning properly.</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 3 – SDTM 3.1.1 Report Process Results

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

Steps

- 1 Start a new SAS session. In the SAS Program Editor, select File->Open and select ***CST_SDTM_311/*** programs/cst_report.sas.
- 2 Select Run->Submit. This code outputs to the SAS log and generates a PDF file. No result data set is created.
- 3 Review the log to see whether there are any errors or warnings. There should not be any.
- 4 Review the PDF file. It is named cstreport.pdf and is located in the folder ***CST_SDTM_311/results***. As noted in the Notes and Assumptions section, this PDF file should automatically be displayed in Windows. If you are on UNIX, then refer back to this section for instructions for approaches for viewing the PDF.
 - All five of the following report panels should be generated.
 - Report Summary
 - Process Inputs/Outputs
 - Process Metrics
 - General Process Reporting
 - Process Results
 - All titles, paths, dates, and so on, should appear correct.
- 5 Close the SAS session.

Sign-off

<i>Test 4 – SDTM 3.1.1 Report Process Results</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 4 – SDTM 3.1.2 Validation

Now we will run some tests for SDTM 3.1.2, which 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. In the SAS Program Editor, select File->Open and select ***CST_SDTM_312/***programs/validate_data.sas.
- 2 Select Run->Submit. This program outputs to the log and creates the data sets named Validation_results and Validation_metrics. These data sets can be found in the Results library within the SAS Explorer window.
- 3 Review the log to see whether there are any errors or warnings. There should not be any.

- 4 Review the data set named Validation_results.
 - ❑ 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.
 - ❑ 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’.
 - ❑ The data set should contain 99 records.
- 5 Review the data set named 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

- 6 End the current SAS session.

Sign-off

Test 5 – SDTM 3.1.2 Validation	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 5 – SDTM 3.1.2 Build Source Data

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. In the SAS Program Editor, select File->Open and select **CST_SD TM_312/programs/create_sasdatafromxpt.sas**.
- 2 Select Run->Submit. The code outputs to the SAS log and creates a data set named xpt_results under **CST_SD TM_312/results** and 33 data sets under **CST_SD TM_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. In 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 (for example, your Home Directory listed under Favorite Folders).

- 3 Review the log to see whether 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 warnings occur with redundant requests to clear SAS librefs, filerefs, or both and do not indicate a problem with the SAS Clinical Standards Toolkit installation.
- 4 Review the data set named `xpt_results`.
 - 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.
 - 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 run’`.
 - The data set should contain 14 records and the last record should report “Process completed successfully.”
- 5 Review the folder `CST_SD TM_312/derived/data`.
 - There should be 33 new SAS data sets.
 - The data set `dm` should have 70 records and 20 columns.
- 6 End the current SAS session.

Sign-off

<i>Test 6 – SDTM 3.1.2 Build Source Data</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 6 – SDTM 3.1.2 Build Source Metadata

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. In the SAS Program Editor, select File->Open and select `CST_SD TM_312/programs/create_sourcemetadata.sas`.
- 2 Select Run->Submit. This code outputs to the SAS log and creates data sets in both the results and derived/metadata subfolders under `CST_SD TM_312`. As in Test 5, the library information was cleaned up by the program, so these files are not immediately accessible under Libraries in the SAS Explorer. In 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.

- 3 Review the log to see whether there are any errors or warnings. There should not be any.
- 4 Review the data set named srcmeta_results under **CST_SDTM_312/results**.
 - ❑ 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.
 - ❑ The column labeled “process status” (named _cst_rc) should be 0 for all records.
 - ❑ The data set should contain 16 records. The last three records should report that study reference data was created in folder **CST_SDTM_312/derived/metadata**.
- 5 Review the folder **CST_SDTM_312/derived/metadata**.
 - ❑ There should be three new data sets: source_columns, source_study, source_tables.
 - ❑ The data set named source_tables should have 33 records.
- 6 End the SAS session.

Sign-off

<i>Test 3 – SDTM 3.1.1 Build Source Metadata</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 7 – SDTM 3.1.2 Build SAS Formats

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

Steps

- 1 Start a new SAS session. In the SAS Program Editor, select File->Open and select **CST_SDTM_312/programs/create_formatsfromcrtdds.sas**.
- 2 Select Run->Submit. The code outputs to the SAS log and creates a data set named codelist_results in **CST_SDTM_312/results** and creates a catalog named cterms under **CST_SDTM_312/derived/formats**. As in Tests 5 and 6, the library information was cleaned up by the program so these files are not immediately accessible under Libraries in the SAS Explorer. In 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.
- 3 Review the log to see whether there are any errors or warnings. There should not be any.
- 4 Review the data set named codelist_results under **CST_SDTM_312/results**.

- ❑ 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.
 - ❑ 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’.
 - ❑ The data set should contain 14 records. The last record should report “Process completed successfully.”
- 5 Folder *CST_SDTM_312*/derived/formats should contain a catalog cterms (named cterms.sas7bcat). Open cterms and verify that it has 48 formats.
 - 6 End the current SAS session.

Sign-off

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

Test 8 – SDTM 3.1.2 Report Check Metadata

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

Steps

- 1 Start a new SAS session. In the SAS Program Editor, select File->Open and select *CST_SDTM_312*/programs/cst_metadatareport.sas.
- 2 Select Run->Submit. This code outputs to the SAS log and generates a PDF file named cstcheckmetadatareport.pdf in the *CST_SDTM_312*/results directory. No result data set is created.
- 3 Review the log to see whether there are any errors or warnings. There should not be any.
- 4 Review the PDF file.
 - ❑ All four of the following report sections should be generated.
 - ❑ The Report Procedure (Check Overview)
 - ❑ Additional Check Details
 - ❑ Validation Message Details
 - ❑ Reference Information
 - ❑ All titles, footnotes, column headings, and cell contents should appear correct.
 - ❑ In the Reference Information section, look for at least one value of “OpenCDISC” in the column named Source of Information (for example, the row for validation check SDTM0231).
- 5 End the current SAS session.

Sign-off

<i>Test 8 – SDTM 3.1.2 Report Check Metadata</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 9 – CRT-DDS Create

If this program runs successfully and produces the expected results, then SAS Clinical Standards Toolkit has derived CRT-DDS metadata from an SDTM study as a prerequisite to building a define.xml file in Test 10.

Steps

- 1 Start a new SAS session and submit the CRT-DDS create sample program ***CST_CRTDDS***/programs/create_crtds10_from_sdtm311.sas. The sample program outputs to the SAS log and creates 39 data sets in the ***CST_CRTDDS***/data folder.
- 2 Review the log to see whether there are any errors or warnings. There should not be any.
- 3 Review the folder ***CST_CRTDDS***/data.
 - There should be 39 new SAS data sets.
 - The data set codelists should have 32 records and five columns.
- 4 Close the SAS session.

Sign-off

<i>Test 9 – CRT-DDS Create is installed and functioning properly.</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 10 – CRT-DDS Create Define.xml

If this program runs successfully and produces the expected results, then SAS Clinical Standards Toolkit Java and XML-related libraries have been installed correctly and 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 data sets in *CST_CRTDDS/sourcexml*.
- 2 Review the log to see whether there are any errors or warnings; there should not be any. You might see one warning that states, “The JAVAOBJ is an experimental feature in this release and is not intended for use in the development of production applications.”
- 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 file in a Web browser. In Windows, you can open it by double-clicking on it in the SAS Program Editor. This renders the file in your default Web browser. On UNIX, if you have not set up your browser configuration in SAS, then 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 have been 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	Adverse Events	Events - One record per event per subject	Tabulation	STUDYID USUBJID AEDECOD AESTDTC	
CM	Concomitant Medications	Interventions - One record per medication intervention episode per subject	Tabulation	STUDYID USUBJID CMTRT CMSTDTC	
CO	Comments	Special Purpose - One record per comment per subject	Tabulation	STUDYID USUBJID COSEQ	
DM	Demographics	Special Purpose - One record per subject	Tabulation	STUDYID USUBJID	
DS	Disposition	Events - One record per disposition status or protocol milestone per subject	Tabulation	STUDYID USUBJID DSDECOD DSSTDTC	
DV	Protocol Deviations	Events - One record per protocol deviation per subject	Tabulation	STUDYID USUBJID DVTERM DSSTDTC	

EG	ECG Test Results	Findings - One record per ECG observation per time point per visit per subject	Tabulation	STUDYID USUBJID EGTESTCD VISITNUM EGTPTREF EGTPTNUM
EX	Exposure	Interventions - One record per constant dosing interval per subject	Tabulation	STUDYID USUBJID EXTRT EXSTDTC
IE	Inclusion/Exclusion Exceptions	Findings - One record per Inclusion/Exclusion criteria exception per subject	Tabulation	STUDYID USUBJID IETESTCD

- 5 The define.xml also contains tables for the following:
 - For each domain, a table lists its variables.
 - Value Level Metadata
 - Computational Algorithms Section
 - Controlled Terminology
- 6 The last table in the define.xml file contains Controlled Terminology. The last few items in the file should be values for VSTESTCD, including the values BMI and WEIGHT.
- 7 End the SAS session.

Sign-off

<i>Test 10 – CRT-DDS Create Define.xml is installed and functioning properly</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 11 – ODM 1.3.0 Create SAS ODM from XML

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. In the SAS Program Editor, select File->Open and select **CST_ODM/Programs/create_sasodm_fromxml.sas**.
- 2 Select Run->Submit. This code outputs to the SAS log and creates data sets in the results, metadata, and data subfolders under **CST_ODM**.
- 3 Review the log to see whether there are any errors or warnings. There should not be any. You might see one warning that states, “The JAVAOBJ is an experimental

feature in this release and is not intended for use in the development of production applications.”

- 4 Review the data set `read_results` under ***CST_ODM***/results. In the SAS Explorer, you can also view it as `Read_results` in the Results library.
 - Examine the message column to verify correct paths and process metadata.
 - The column labeled Process status (named `_cst_rc`) should be 0 for all records.
 - The data set should contain 15 records.
 - The last record should report that the ODM file was read successfully.
- 5 The folder ***CST_ODM***/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`.
 - The data set `source_tables` should have 52 rows and 10 columns.
 - The data set `source_columns` should have 241 rows and 15 columns.
- 6 Review the folder ***CST_ODM***/data.
 - There should be 52 new SAS data sets.
 - The data set `codelists` should have six records and five columns.
- 7 End the current SAS session.

Sign-off

<i>Test 11 – ODM1.3.0 Create SAS ODM From XML</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 12 – Controlled Terminology 200810

This test verifies that the controlled terminology package 200810 has been installed and is available to SAS Clinical Standards Toolkit processes.

Steps

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

```
%cstutil_setcstgroot;

libname fmts "&_cstGroot./standards/cdisc-terminology-200810-1.3/formats";
options fmtsearch=(fmts.terms);

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

data _null_;
```

```

set fmts.cterms (where=(codelist='LBTEST')) end=last;
attrib result format=$200.;
retain found 0 result '';
if _n_=1 then
    result='Albumin/Creatinine Ratio';
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, availability of the Controlled Terminology package to SAS Clinical Standards Toolkit processes, or both. You should see the following line at the end of the SAS log:

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

- 3 End the current SAS session.

Sign-off

Test 12 – Controlled Terminology 200810	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 13 – Controlled Terminology 201003

This test verifies that the controlled terminology package 201003 has been installed and is available to SAS Clinical Standards Toolkit processes.

Steps

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

```

%cstutil_setcstgroot;

libname fmts "&_cstGRoot./standards/cdisc-terminology-201003-1.3/formats";
options fmtsearch=(fmts.cterms);

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

data _null_;
    set fmts.cterms (where=(codelist='COUNTRY')) end=last;
    attrib result format=$200.;
    retain found 0 result '';

```

```

if _n_=1 then
  result='BLM';
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 \$COUNTRY was not found or could not be loaded.”) or if the specific test value is not found then there are problems with the installation, availability of the Controlled Terminology package to SAS Clinical Standards Toolkit processes, or both. You should see the following line at the end of the SAS log:

```
result=Formatted value BLM found
```

- 3 End the current SAS session.

Sign-off

<i>Test 13 – Controlled Terminology 201003</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Final Sign-off

In the following table, indicate your final assessment about whether SAS Clinical Standards Toolkit 1.3 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.

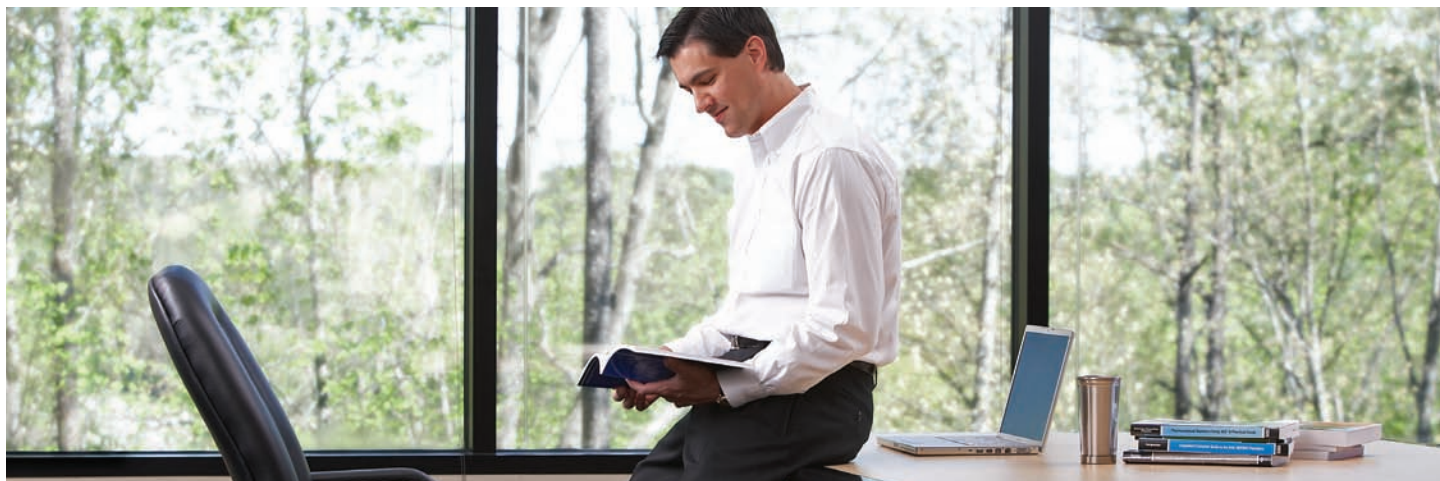
<i>Final assessment of all testing.</i>	
Signature	
Date Test Was Executed	
Did the IQOQ pass? (Yes or No)	
Comments	

Your Turn

We welcome your feedback.

- If you have comments about this book, please send them to **yourturn@sas.com**. Include the full title and page numbers (if applicable).
- If you have comments about the software, please send them to **suggest@sas.com**.

SAS® Publishing Delivers!



SAS Publishing provides you with a wide range of resources to help you develop your SAS software expertise. Visit us online at support.sas.com/bookstore.

SAS® PRESS

SAS Press titles deliver expert advice from SAS® users worldwide. Written by experienced SAS professionals, SAS Press books deliver real-world insights on a broad range of topics for all skill levels.

support.sas.com/saspress

SAS® DOCUMENTATION

We produce a full range of primary documentation:

- Online help built into the software
- Tutorials integrated into the product
- Reference documentation delivered in HTML and PDF formats—free on the Web
- Hard-copy books

support.sas.com/documentation

SAS® PUBLISHING NEWS

Subscribe to SAS Publishing News to receive up-to-date information via e-mail about all new SAS titles, product news, special offers and promotions, and Web site features.

support.sas.com/spn

SOCIAL MEDIA: JOIN THE CONVERSATION!

Connect with SAS Publishing through social media. Visit our Web site for links to our pages on Facebook, Twitter, and LinkedIn. Learn about our blogs, author podcasts, and RSS feeds, too.

support.sas.com/socialmedia



**THE
POWER
TO KNOW®**