



SAS® Clinical Data Standards Toolkit, Version 1.2
Installation Qualification
SAS 9.1.3 Windows

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Purpose

This documents how to verify that a SAS Clinical Standards Toolkit 1.2 has been installed correctly and is functioning properly.

The installation will be tested by running a series of SAS programs. These tests must be run in the sequence presented.

This is applicable to installations on both SAS 9.1.3 and SAS 9.2. Any differences will be noted within this document.

Notes and Assumptions

- The SAS System itself is assumed to be installed and functioning correctly. The SAS System is not being tested here.
- The person running these tests is familiar with how to run SAS programs. This includes being able to edit, submit, review the SAS log, review the contents of SAS datasets and non-SAS files.
- All links within this document are to the default Microsoft Windows locations.
- Within this document
 - [!SASINSTALL](#) is used to denote the SAS Installation Folder. This is the folder into which all SAS product are installed. The default value of !SASINSTALL for SAS 9.1.3 and SAS 9.2 for Microsoft Windows is [C:\Program Files\SAS](#).
 - [!SASROOT](#) is used to denote the root folder for the SAS System installation. The default value of !SASROOT for SAS 9.1.3 for Windows is [C:\Program Files\SAS\SAS 9.1](#).
 - The default value of !SASROOT for SAS 9.2 for Windows is [C:\Program Files\SAS\SASFoundation\9.2](#)
 - !SASWORK is used to denote the SAS work folder. Some tests will require you to interactively locate the !SASWORK folder. The full path for the !SASWORK folder can be found by issuing the SAS command: LIBNAME WORK LIST;

Test 1 – SAS hot fix for ISO 8601 Informat has been installed

If you have downloaded SAS Clinical Data Standards Toolkit 1.2 from the SAS hot-fix site, you should verify that the SAS hot fix for the ISO 8601 SAS Informat has installed.

NOTE: This step is not necessary if you are running SAS Version 9.2.

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 Informat has been installed</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 2 –SDTM 3.1.1 Validation is installed and functioning properly.

This test will run 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 for the version of SAS you are using

SAS 9.1.3	!SASINSTALL\SASClinicalStandardsToolkitSDTM311\9.1.3\sample\cdisc-sdtm-3.1.1\sascstdemodata\programs\validate_data.sas
SAS 9.2	!SASINSTALL\SASClinicalStandardsToolkitSDTM311\9.2\sample\cdisc-sdtm-3.1.1\sascstdemodata\programs\validate_data.sas

The sample program will generate a SAS Log and two output SAS datasets.

2. Review the SAS Log for errors.
- The log must not contain any errors.
 - The log may contain some minor warnings such as type conversions.

3. Review the Results Dataset for errors. This dataset is located here

SAS 9.1.3	!SASINSTALL\SASClinicalStandardsToolkitSDTM311\9.1.3\sample\cdisc-sdtm-3.1.1\sascstdemodata\results\validation_results.sas7bdat
SAS 9.2	!SASINSTALL\SASClinicalStandardsToolkitSDTM311\9.2\sample\cdisc-sdtm-3.1.1\sascstdemodata\results\validation_results.sas7bdat

The validation_results dataset should be consistent with the following table. The validation_results dataset will contain additional columns, but checking these is sufficient.

4. **SAS 9.1.3** After reviewing the table below, close the SAS session.

Row	resultid	checkid	resultseq	seqno	srcdata
1	CST0108		1	1	CST_SETPROPERTIES
2	CST0108		1	1	CST_SETPROPERTIES
3	CST0108		1	1	CST_SETPROPERTIES
4	CST0200		1	1	SDTM_VALIDATE
5	CST0200		1	2	SDTM_VALIDATE
6	CST0200		1	3	SDTM_VALIDATE
7	CST0200		1	4	SDTM_VALIDATE
8	CST0200		1	5	SDTM_VALIDATE
9	CST0200		1	6	SDTM_VALIDATE

Row	resultid	checkid	resultseq	seqno	srcdata
10	CST0100	SDTM0011	1	1	WORK._CSTSRCCOLUMNMETADATA
11	CST0100	SDTM0012	1	1	WORK._CSTSRCCOLUMNMETADATA
12	CST0100	SDTM0013	1	1	WORK._CSTSRCCOLUMNMETADATA
13	CST0100	SDTM0014	1	1	WORK._CSTSRCCOLUMNMETADATA
14	SDTM0015	SDTM0015	1	1	SUPPAE
15	SDTM0015	SDTM0015	1	2	SUPPAE
16	SDTM0015	SDTM0015	1	3	SUPPAE
17	SDTM0015	SDTM0015	1	4	SUPPAE
18	SDTM0015	SDTM0015	1	5	SUPPAE
19	SDTM0015	SDTM0015	1	6	SUPPAE
20	SDTM0015	SDTM0015	1	7	SUPPAE
21	SDTM0015	SDTM0015	1	8	SUPPAE
22	SDTM0015	SDTM0015	1	9	SUPPAE
23	SDTM0015	SDTM0015	1	10	SUPPAE
24	CST0100	SDTM0019	1	1	WORK._CSTSRCCOLUMNMETADATA
25	CST0100	SDTM0020	1	1	WORK._CSTSRCCOLUMNMETADATA
26	CST0100	SDTM0022	1	1	WORK._CSTSRCCOLUMNMETADATA
27	CST0100	SDTM0023	1	1	WORK._CSTSRCCOLUMNMETADATA
28	CST0100	SDTM0030	1	1	WORK._CSTSRCCOLUMNMETADATA
29	CST0100	SDTM0031	1	1	WORK._CSTSRCCOLUMNMETADATA
30	CST0100	SDTM0032	1	1	WORK._CSTSRCCOLUMNMETADATA
N = 30					

Row	message	resultseverity	resultflag	_cst_rc
1	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst- framework/programs/initialize.properties	Info	0	0
2	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-sdtm- 3.1.1/programs/initialize.properties	Info	0	0

Row	message	resultseverity	resultflag	_cst_rc
3	The properties were processed from the PATH !sasroot/../../SASClinicalStandardsToolkitSDTM311/9.2/sample/cdisc-sdtm-3.1.1/sascstdemodata\programs/validation.properties	Info	0	0
4	PROCESS STANDARD: CDISC-SDTM	Info	0	0
5	PROCESS STANDARDVERSION: 3.1.1	Info	0	0
6	PROCESS DRIVER: SDTM_VALIDATE	Info	0	0
7	PROCESS DATE: 2009-06-18T21:55:09	Info	0	0
8	PROCESS TYPE: VALIDATION	Info	0	0
9	PROCESS SASREFERENCES: !sasroot/../../SASClinicalStandardsToolkitSDTM311/9.2/sample/cdisc-sdtm-3.1.1/sascstdemodata\control/sasreferences.sas7bdat	Info	0	0
10	No errors detected in source data	Info	0	0
11	No errors detected in source data	Info	0	0
12	No errors detected in source data	Info	0	0
13	No errors detected in source data	Info	0	0
14	Variable IDVAR appears in dataset but is not in SDTM standard	Warning	1	0
15	Variable IDVARVAL appears in dataset but is not in SDTM standard	Warning	1	0
16	Variable QEVAL appears in dataset but is not in SDTM standard	Warning	1	0
17	Variable QLABEL appears in dataset but is not in SDTM standard	Warning	1	0
18	Variable QNAM appears in dataset but is not in SDTM standard	Warning	1	0
19	Variable QORIG appears in dataset but is not in SDTM standard	Warning	1	0
20	Variable QVAL appears in dataset but is not in SDTM standard	Warning	1	0
21	Variable RDOMAIN appears in dataset but is not in SDTM standard	Warning	1	0
22	Variable STUDYID appears in dataset but is not in SDTM standard	Warning	1	0
23	Variable USUBJID appears in dataset but is not in SDTM standard	Warning	1	0
24	No errors detected in source data	Info	0	0
25	No errors detected in source data	Info	0	0
26	No errors detected in source data	Info	0	0
27	No errors detected in source data	Info	0	0
28	No errors detected in source data	Info	0	0
29	No errors detected in source data	Info	0	0

Row	message	resultseverity	resultflag	_cst_rc
30	No errors detected in source data	Info	0	0
N = 30				

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 – CRT-DDS Create is installed and functioning properly.

This test will run the first of the three sample programs that ship as part of the CRT-DDS standard. If this program runs successfully and produces the expected results, then the CRT-DDS Create is correctly installed and functioning properly.

Steps

- 1. Submit the CRT-DDS Create sample program for the version of SAS you are using

SAS 9.1.3	!SASINSTALL\SASClinicalStandardsToolkitCRTDDS10\9.1.3\sample\cdisc-crtds-1.0\Programs\Create_crtds10_from_sdtm311.sas
SAS 9.2	!SASINSTALL\SASClinicalStandardsToolkitCRTDDS10\9.2\sample\cdisc-crtds-1.0\Programs\Create_crtds10_from_sdtm311.sas

The sample program will generate a SAS Log and along with a results dataset. The result dataset is written to !SASWORK; therefore, you will need to run this program interactively in either SAS windowing environment or SAS Enterprise Guide.

- 2. Review the SAS Log for errors.
 - a. The log must not contain any errors.
 - b. The log may contain some minor warnings such as type conversions.
- 3. Review the Results Dataset for errors. This dataset is WORK._cstresults. The WORK._cstresults dataset should be consistent with the following table. The WORK._cstresults dataset will contain additional columns, but checking these is sufficient.
- 4. **SAS 9.1.3** After reviewing the table below, close the SAS session.

Row	resultid	checkid	resultseq	seqno	srcdata
1	CST0108		1	1	CST_SETPROPERTIES
2	CST0108		1	1	CST_SETPROPERTIES
3	CST0108		1	1	CST_SETPROPERTIES
4	CST0102		1	1	CST_CREATEDS
5	CST0200		1	1	CREATE_CRDDDS10_FROM_SDTM311
6	CST0200		1	2	CREATE_CRDDDS10_FROM_SDTM311
7	CST0200		1	3	CREATE_CRDDDS10_FROM_SDTM311
8	CST0200		1	4	CREATE_CRDDDS10_FROM_SDTM311
9	CST0200		1	5	CREATE_CRDDDS10_FROM_SDTM311
10	CST0200		1	6	CREATE_CRDDDS10_FROM_SDTM311

Row	resultid	checkid	resultseq	seqno	srcdata
11	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
12	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
13	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
14	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
15	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
16	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
17	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
18	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
19	CST0102		1	1	CRTDDS_SDTM311TODEFINE10
N = 19					

Row	message	resultseverity	resultflag	_cst_rc
1	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst- framework/programs/initialize.properties	Info	0	0
2	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-crtdds- 1.0/programs/initialize.properties	Info	0	0
3	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-terminology- 200810/programs/initialize.properties	Info	0	0
4	work.sasreferences was created as requested	Info	0	0
5	PROCESS STANDARD: CDISC-CRTDDS	Info	0	0
6	PROCESS STANDARDVERSION: 1.0	Info	0	0
7	PROCESS DRIVER: CREATE_CRTDDS10_FROM_SDTM311	Info	0	0
8	PROCESS DATE: 2009-05-29T15:06:37	Info	0	0
9	PROCESS TYPE: SDTM TO CRTDDS	Info	0	0
10	PROCESS SASREFERENCES: work.sasreferences	Info	0	0
11	work.definodocument was created as requested	Info	0	0
12	work.study was created as requested	Info	0	0
13	work.metadataversion was created as requested	Info	0	0
14	work.itemgroupdefs was created as requested	Info	0	0

Row	message	resultseverity	resultflag	_cst_rc
15	work.codelists was created as requested	Info	0	0
16	work.codelistitems was created as requested	Info	0	0
17	work.clitemdecodetranslatedtext was created as requested	Info	0	0
18	work.itemdefs was created as requested	Info	0	0
19	work.itemgroupdefitemrefs was created as requested	Info	0	0
N = 19				

Sign-Off

<i>Test 3 – CRT-DDS Create is installed and functioning properly.</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 4 – CRT-DDS Validation is installed and functioning properly.

This test will run the second of the three sample programs that ship as part of the CRT-DDS standard. If this program runs successfully and produces the expected results, then the CRT-DDS Validation is correctly installed and functioning properly.

Steps

- 1. Submit the CRT-DDS Create sample program for the version of SAS you are using

SAS 9.1.3	!SASINSTALL\SASClinicalStandardsToolkitCRTDDS10\9.1.3\sample\cdisc-crtdds-1.0\Programs\validate CRTDDS_data.sas
SAS 9.2	!SASINSTALL\SASClinicalStandardsToolkitCRTDDS10\9.2\sample\cdisc-crtdds-1.0\Programs\validate CRTDDS_data.sas

Note: The name in the header comment for this SAS program does not match the name of the file. This does not impact the performance of this program.

The sample program will generate a SAS Log and along with a results dataset. The result dataset is written to !SASWORK; therefore, you will need to run this program interactively in either SAS windowing environment or SAS Enterprise Guide.

- 2. Review the SAS Log for errors.
 - a. The log must not contain any errors.
 - b. The log may contain some minor warnings such as type conversions.
- 3. Review the Results Dataset for errors. This dataset is WORK.validation_results. The WORK.validation_results dataset should be consistent with the following table. The WORK.validation_results dataset will contain additional columns, but checking these is sufficient.
- 4. **SAS 9.1.3** After reviewing the table below, close the SAS session.

Row	resultid	checkid	resultseq	seqno	srcdata
1	CST0108		1	1	CST_SETPROPERTIES
2	CST0108		1	1	CST_SETPROPERTIES
3	CST0102		1	1	CST_CREATEDS
4	CST0200		1	1	VALIDATE_CRTDDS_DATA
5	CST0200		1	2	VALIDATE_CRTDDS_DATA
6	CST0200		1	3	VALIDATE_CRTDDS_DATA
7	CST0200		1	4	VALIDATE_CRTDDS_DATA

Row	resultid	checkid	resultseq	seqno	srcdata
8	CST0200		1	5	VALIDATE_CRTDDS_DATA
9	CST0200		1	6	VALIDATE_CRTDDS_DATA
10	CST0200		1	1	CRTDDS_VALIDATE
11	CST0200		1	2	CRTDDS_VALIDATE
12	CST0200		1	3	CRTDDS_VALIDATE
13	CST0200		1	4	CRTDDS_VALIDATE
14	CST0200		1	5	CRTDDS_VALIDATE
15	CST0200		1	6	CRTDDS_VALIDATE
16	CST0100	CRT0100	1	1	SRCDATA.DefineDocument
17	CST0100	CRT0101	1	1	SRCDATA.DefineDocument
18	CST0004	CRT0106	1	1	CSTCHECK_COLUMN
19	CST0100	CRT0110	1	1	SRCDATA.Study (SRCDATA.DefineDocument)
20	CST0004	CRT0113	1	1	CSTCHECK_RECMMISMATCH
21	CST0029	CRT0114	1	1	CSTCHECK_NOTINCODELIST
22	CST0033	CRT0114	1	2	CSTCHECK_NOTINCODELIST
23	CST0100	CRT0114	1	3	SRCDATA.CodeLists.DataType
24	CST0100	CRT0114	1	4	SRCDATA.DefineDocument.Archival
25	CST0100	CRT0114	1	5	SRCDATA.DefineDocument.FileType
26	CST0100	CRT0114	1	6	SRCDATA.DefineDocument.Granularity
27	CST0100	CRT0114	1	7	SRCDATA.ItemDefs.DataType
28	CST0100	CRT0114	1	8	SRCDATA.ItemGroupDefItemRefs.Mandatory
29	CST0100	CRT0114	1	9	SRCDATA.ItemGroupDefs.Repeating
30	CST0100	CRT0114	1	10	SRCDATA.ItemGroupDefs.IsReferenceData
N = 30					

Row	message	resultseverity	resultflag	_cst_rc
1	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cst- framework/programs/initialize.properties	Info	0	0

Row	message	resultseverity	resultflag	_cst_rc
2	The properties were processed from the PATH c:/cstGlobalLibrary/standards/cdisc-crtdds- 1.0/programs/initialize.properties	Info	0	0
3	work.sasreferences was created as requested	Info	0	0
4	PROCESS STANDARD: CDISC-CRTDDS	Info	0	0
5	PROCESS STANDARDVERSION: 1.0	Info	0	0
6	PROCESS DRIVER: VALIDATE_DATA	Info	0	0
7	PROCESS DATE: 2009-05-29T15:10:24	Info	0	0
8	PROCESS TYPE: VALIDATE CRT-DDS DATA	Info	0	0
9	PROCESS SASREFERENCES: work.sasreferences	Info	0	0
10	PROCESS STANDARD:	Info	0	0
11	PROCESS STANDARDVERSION:	Info	0	0
12	PROCESS DRIVER: CRTDDS_VALIDATE	Info	0	0
13	PROCESS DATE: 2009-05-29T15:10:24	Info	0	0
14	PROCESS TYPE: VALIDATION	Info	0	0
15	PROCESS SASREFERENCES:	Info	0	0
16	No errors detected in SRCDATA.DefineDocument	Info	0	0
17	No errors detected in SRCDATA.DefineDocument	Info	0	0
18	No columns evaluated - check validation_control specification	Warning: Check not run	-1	0
19	No errors detected in source data	Info	0	0
20	No columns evaluated - check validation_control specification	Warning: Check not run	-1	0
21	Format catalog WORK.FORMATS in fmtsearch could not be found	Info	0	0
22	Format search path has been set to WORK.FORMATS CRTFMT.CRTDDSCT	Info	0	0
23	No errors detected in source data	Info	0	0
24	No errors detected in source data	Info	0	0
25	No errors detected in source data	Info	0	0
26	No errors detected in source data	Info	0	0
27	No errors detected in source data	Info	0	0
28	No errors detected in source data	Info	0	0

Row	message	resultseverity	resultflag	_cst_rc
29	No errors detected in source data	Info	0	0
30	No errors detected in source data	Info	0	0
N = 30				

Sign-Off

<i>Test 4 – CRT-DDS Validation is installed and functioning properly.</i>	
Signature	
Date Test Was Executed	
Did the test pass? (Yes or No)	
Comments	

Test 5 – CRT-DDS Create Define.xml is installed and functioning properly.

This test will run the third of the three sample programs that ship as part of the CRT-DDS standard. If this program runs successfully and produces the expected results, then the CRT-DDS Create Define.xml is correctly installed and functioning properly.

Steps

1. Submit the CRT-DDS Create Define.xml sample program for the version of SAS you are using

SAS 9.1.3	!SASINSTALL\SASClinicalStandardsToolkitCRTDDS10\9.1.3\sample\cdisc-crtdds-1.0\Programs\create_crtds_define.sas
SAS 9.2	!SASINSTALL\SASClinicalStandardsToolkitCRTDDS10\9.2\sample\cdisc-crtdds-1.0\Programs\create_crtds_define.sas

Note: The name in the header comment for these SAS programs do not match the names of the files. This does not impact the performance of these programs.

The sample program will generate a SAS Log and along with a results dataset. The result dataset is written to !SASWORK; therefore, you will need to run this program interactively in either SAS windowing environment or SAS Enterprise Guide.

2. Review the SAS Log for errors.
- The log must not contain any errors.
 - The log may contain some minor warnings such as type conversions.
3. Review the Results Dataset for errors. This dataset is WORK.crtds_results.
The WORK.crtds_results dataset should be consistent with the following tables, depending upon the release being installed.. The WORK.crtds_results dataset will contain additional columns, but checking these is sufficient.

Table for SAS 9.1.3

Row	resultid	checkid	resultseq	seqno	srcdata
1	CST0102		1	1	CST_CREATEDS
2	CST0075		1	1	WORK.SASREFERENCES
3	CST0200		1	1	CREATE_CRTRDDS_DEFINE
4	CST0200		1	2	CREATE_CRTRDDS_DEFINE
5	CST0200		1	3	CREATE_CRTRDDS_DEFINE
6	CST0200		1	4	CREATE_CRTRDDS_DEFINE
7	CST0200		1	5	CREATE_CRTRDDS_DEFINE
8	CST0200		1	6	CREATE_CRTRDDS_DEFINE
9	CST0122		1	1	CST_CREATETABLESFORDATASTANDARD
10	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
11	CRT0001	CRT0001	.	.	XML TRANSFORMER
12	CRT0001	CRT0001	.	.	XML TRANSFORMER
13	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER

Row	resultid	checkid	resultseq	seqno	srcdata
14	CRT0001	CRT0001	.	.	XML TRANSFORMER
15	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
16	CRT0001	CRT0001	.	.	XML TRANSFORMER
17	CRT0001	CRT0001	.	.	XML TRANSFORMER
18	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
19	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
20	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
21	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
22	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
23	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
24	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
25	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
26	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
27	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
28	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
29	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
30	CRT0010		1	2	CRTDDS_WRITE
31	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
32	CRT0001	CRT0001	.	.	XML TRANSFORMER
33	CRT0001	CRT0001	.	.	XML TRANSFORMER
34	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
35	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
36	CRT0001	CRT0001	.	.	XML TRANSFORMER
37	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
38	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
39	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
40	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
41	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
42	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
43	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
44	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
45	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
46	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
47	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
48	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
49	CRT0115		1	1	CRTDDS_XMLVALIDATE
N=49					

Row	Message	resultseverity	resultflag	_cst_rc
1	work.sasreferences was created as requested	Info	0	0
2	Unable to allocate fileref for EXTXML	Error	-1	0
3	PROCESS STANDARD: CDISC-CRTDDS	Info	0	0
4	PROCESS STANDARDVERSION: 1.0	Info	0	0
5	PROCESS DRIVER: CREATE_CRTDDS_DEFINE	Info	0	0
6	PROCESS DATE: 2009-07-06T10:41:10	Info	0	0

7	PROCESS TYPE: CREATE CRT-DDS DEFINE.XML	Info	0	0
8	PROCESS SASREFERENCES: work.sasreferences	Info	0	0
9	The tables were created for CDISC-CRTDDS 1.0 in library _cst7583	Info	0	0
10	Import Or Export: EXPORT	Info	0	0
11	Transform starting.	Info	0	0
12	Using JRE: C:\Program Files\SAS\Shared Files\JRE\1.4.2_09	Info	0	0
13	Standards XML Path: C:/DOCUME~1/GENELI~1.IBI/LOCALS~1/Temp/SAS Temporary Files/_TD1052/define.xml	Info	0	0
14	Transform time: 5625 ms.	Info	0	0
15	Creating Output Folders: true	Info	0	0
16	Transform complete.	Info	0	0
17	The document validated successfully	Info	0	0
18	Custom Stylesheet: c:/cstGlobalLibrary/standards/cdisc-crtdds-1.0/stylesheet/define1-0-0.xsl	Info	0	0
19	Is Validating XML: true	Info	0	0
20	Creating Display Stylesheet: true	Info	0	0
21	Custom Stylesheet Output Shortname: define1-0-0.xsl	Info	0	0
22	Log File Location: C:/DOCUME~1/GENELI~1.IBI/LOCALS~1/Temp/SAS Temporary Files/_TD1052/_log4658	Info	0	0
23	XSL Repository Location: c:/cstGlobalLibrary/xsl-repository	Info	0	0
24	Output Encoding: UTF-8	Info	0	0
25	Header Comment Text: Produced from SAS data using the SAS Clinical Toolkit.	Info	0	0
26	Standard Version: 1.0	Info	0	0
27	Fail on Validation Error: false	Info	0	0
28	Standard Name: CDISC-CRTDDS	Info	0	0
29	Schema Repository Location: c:/cstGlobalLibrary/schema-repository	Info	0	0
30	The CRT-DDS file was created at C:\DOCUME~1\GENELI~1.IBI\LOCALS~1\Temp\SAS Temporary Files_TD1052\define.xml	Info	0	0
31	Import Or Export: EXPORT	Info	0	0
32	Transform starting.	Info	0	0
33	Using JRE: C:\Program Files\SAS\Shared Files\JRE\1.4.2_09	Info	0	0
34	Standards XML Path: C:/DOCUME~1/GENELI~1.IBI/LOCALS~1/Temp/SAS Temporary Files/_TD1052/define.xml	Info	0	0
35	Creating Output Folders: true	Info	0	0
36	The document validated successfully	Info	0	0
37	Custom Stylesheet: null	Info	0	0
38	Is Validating XML: true	Info	0	0
39	Creating Display Stylesheet: false	Info	0	0
40	Custom Stylesheet Output Shortname: null	Info	0	0
41	Log File Location: C:\DOCUME~1\GENELI~1.IBI\LOCALS~1\Temp\SAS Temporary Files_TD1052/_log2491	Info	0	0

42	XSL Repository Location: null	Info	0	0
43	Output Encoding: UTF-8	Info	0	0
44	Header Comment Text: Produced from SAS data using the SAS Clinical Toolkit.	Info	0	0
45	Standard Version: 1.0	Info	0	0
46	Fail on Validation Error: false	Info	0	0
47	Standard Name: CDISC-CRTDDS	Info	0	0
48	Schema Repository Location: c:/cstGlobalLibrary/schema-repository	Info	0	0
49	No errors were found in the CRT-DDS file.	Info	0	0
N=49				

Table for SAS 9.2

Row	resultid	checkid	resultseq	seqno	srcdata
1	CST0102		1	1	CST_CREATEDS
2	CST0075		1	1	WORK.SASREFERENCES
3	CST0200		1	1	CREATE_CRTDDS_DEFINE
4	CST0200		1	2	CREATE_CRTDDS_DEFINE
5	CST0200		1	3	CREATE_CRTDDS_DEFINE
6	CST0200		1	4	CREATE_CRTDDS_DEFINE
7	CST0200		1	5	CREATE_CRTDDS_DEFINE
8	CST0200		1	6	CREATE_CRTDDS_DEFINE
9	CST0122		1	1	CST_CREATETABLESFORDATASTANDARD
10	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
11	CRT0001	CRT0001	.	.	XML TRANSFORMER
12	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
13	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
14	CRT0001	CRT0001	.	.	XML TRANSFORMER
15	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
16	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
17	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
18	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
19	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
20	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
21	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER

Row	resultid	checkid	resultseq	seqno	srcdata
22	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
23	CRT0001	CRT0001	.	.	XML TRANSFORMER
24	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
25	CRT0001	CRT0001	.	.	XML TRANSFORMER
26	CRT0001	CRT0001	.	.	XML TRANSFORMER
27	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
28	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
29	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
30	CRT0010		1	2	CRTDDS_WRITE
31	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
32	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
33	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
34	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
35	CRT0001	CRT0001	.	.	XML TRANSFORMER
36	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
37	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
38	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
39	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
40	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
41	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
42	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
43	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
44	CRT0001	CRT0001	.	.	XML TRANSFORMER
45	CRT0001	CRT0001	.	.	XML TRANSFORMER
46	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
47	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
48	CRT0001	CRT0001	.	.	XML TRANSFORMER PARAMETER
49	CRT0115		1	1	CRTDDS_XMLVALIDATE
N = 49					

Row	message	resultseverity	resultflag	_cst_rc
1	work.sasreferences was created as requested	Info	0	0
2	Unable to allocate fileref for EXTXML	Error	-1	0
3	PROCESS STANDARD: CDISC-CRTDDS	Info	0	0
4	PROCESS STANDARDVERSION: 1.0	Info	0	0
5	PROCESS DRIVER: CREATE_CRTDDS_DEFINE	Info	0	0
6	PROCESS DATE: 2009-05-29T15:13:41	Info	0	0
7	PROCESS TYPE: CREATE CRT-DDS DEFINE.XML	Info	0	0
8	PROCESS SASREFERENCES: work.sasreferences	Info	0	0
9	The tables were created for CDISC-CRTDDS 1.0 in library _cst4124	Info	0	0
10	Header Comment Text: Produced from SAS data using the SAS Clinical Toolkit.	Info	0	0
11	The document validated successfully	Info	0	0
12	Standard Name: CDISC-CRTDDS	Info	0	0
13	Creating Display Stylesheet: true	Info	0	0
14	Transform complete.	Info	0	0
15	Output Encoding: UTF-8	Info	0	0
16	Log File Location: C:/Documents and Settings/chuck.reap/Local Settings/Temp/SEG4604/SAS Temporary Files/_TD1532/Prc2/_log0301	Info	0	0
17	Import Or Export: EXPORT	Info	0	0
18	Is Validating XML: true	Info	0	0
19	Standard Version: 1.0	Info	0	0
20	Custom Stylesheet: c:/cstGlobalLibrary/standards/cdisc-crtdds-1.0/stylesheet/define1-0-0.xsl	Info	0	0
21	Creating Output Folders: true	Info	0	0
22	XSL Repository Location: c:/cstGlobalLibrary/xsl-repository	Info	0	0
23	Transform time: 906 ms.	Info	0	0
24	Fail on Validation Error: false	Info	0	0
25	Transform starting.	Info	0	0
26	Using JRE: C:\PROGRA~1\Java\JRE15~1.0_1	Info	0	0
27	Standards XML Path: C:/Documents and Settings/chuck.reap/Local Settings/Temp/SEG4604/SAS Temporary Files/_TD1532/Prc2/define.xml	Info	0	0
28	Schema Repository Location: c:/cstGlobalLibrary/schema-repository	Info	0	0

Row	message	resultseverity	resultflag	_cst_rc
29	Custom Stylesheet Output Shortname: define1-0-0.xsl	Info	0	0
30	The CRT-DDS file was created at C:\Documents and Settings\chuck.reap\Local Settings\Temp\SEG4604\SAS Temporary Files_TD1532\Prc2\define.xml	Info	0	0
31	Header Comment Text: Produced from SAS data using the SAS Clinical Toolkit.	Info	0	0
32	Output Encoding: UTF-8	Info	0	0
33	Standard Name: CDISC-CRTDDS	Info	0	0
34	Creating Display Stylesheet: false	Info	0	0
35	The document validated successfully	Info	0	0
36	Fail on Validation Error: false	Info	0	0
37	Log File Location: C:\Documents and Settings\chuck.reap\Local Settings\Temp\SEG4604\SAS Temporary Files_TD1532\Prc2_log6333	Info	0	0
38	Import Or Export: EXPORT	Info	0	0
39	Is Validating XML: true	Info	0	0
40	Standard Version: 1.0	Info	0	0
41	Custom Stylesheet: null	Info	0	0
42	Creating Output Folders: true	Info	0	0
43	XSL Repository Location: null	Info	0	0
44	Transform starting.	Info	0	0
45	Using JRE: C:\PROGRA~1\Java\JRE15~1.0_1	Info	0	0
46	Standards XML Path: C:/Documents and Settings/chuck.reap/Local Settings/Temp/SEG4604/SAS Temporary Files/_TD1532/Prc2/define.xml	Info	0	0
47	Schema Repository Location: c:/cstGlobalLibrary/schema-repository	Info	0	0
48	Custom Stylesheet Output Shortname: null	Info	0	0
49	No errors were found in the CRT-DDS file.	Info	0	0
N = 49				

- 4. Review the define.xml file that was created. This file will be written to !SASWORK, but since it is not a SAS file, you will need to view it outside of SAS.

Hints for locating the define.xml file

1. Submit the following statement in SAS. It will display the full path to the work folder.

```
LIBNAME WORK LIST;
```

2. In the CRTDDS_RESULTS dataset, locate the following message (the path will be different.). This is found on the 46th row of the dataset.

```
Standards XML Path: C:/some/path/SAS Temporary Files/_TD3540 /define.xml
```

Once you have for located !SASWORK, Use Windows Explorer to navigate to the folder. The folder will contain a file named define.xml. Open define.xml in a web browser. (Hint, most web browsers will enable you to drag and drop the define.xml file.)

The resulting file will look like the following table. Minor variations in appearance are possible and are not a problem. Only the first few lines are shown below. Reviewing these rows is sufficient to confirm 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 AETERM 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 DSSTDTC	

Sign-Off

Test 5 – CRT-DDS Create Define is installed and functioning properly.

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 1.2 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	