

USING CDISC VALIDATION TOOLS IN A VALIDATED HOSTED ENVIRONMENT



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AGENDA

- Introduction
- Problem Scenario
- Validation Tools Implementation in Hosted Environment
 - OpenCDISC
 - SAS Clinical Standards Toolkit (SAS/CST)
- Validation Report – M&M Report
- Workflow

INTRODUCTION

- **CDISC Validation Tools**

- **OpenCDISC** – Java Based GUI / CLI tool.
 - Execution Mode - PC based UI, Command Line Interface, SAS Program with X Command
- **SAS/CST** - Standards Metadata (SAS datasets) and Framework SAS Macros
 - Execution Mode - SAS Program with CST Macro calls.

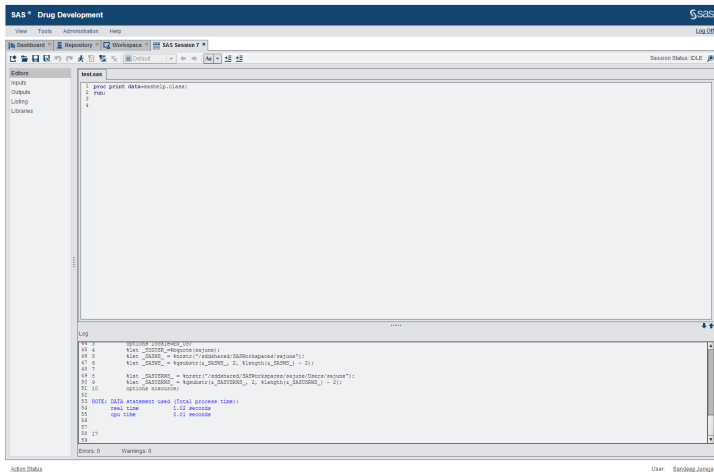
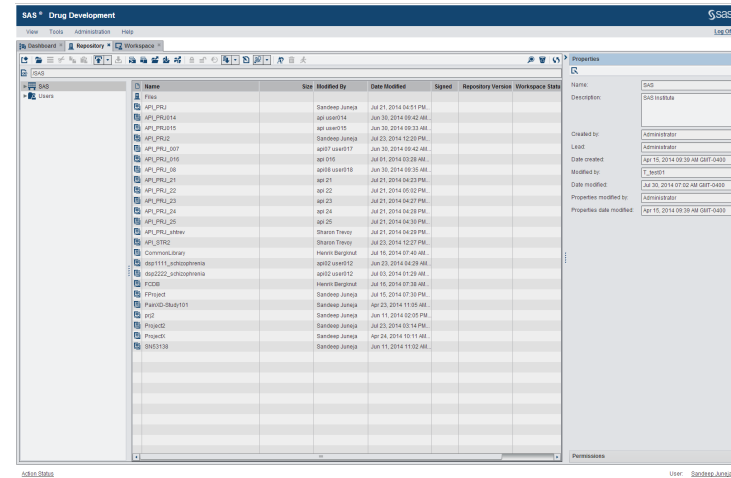
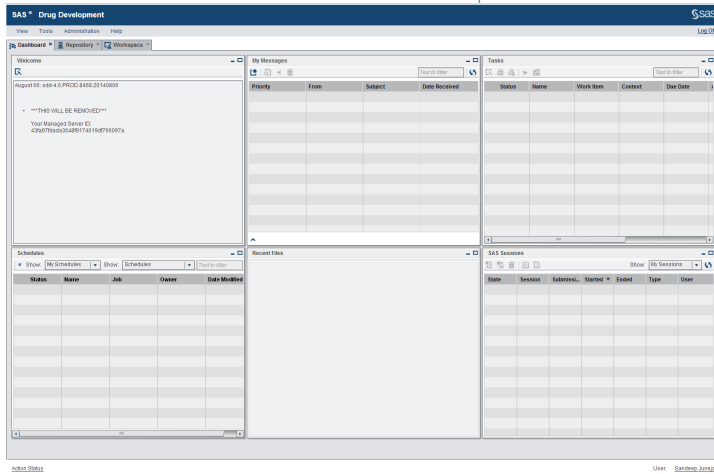
- **Validated Hosted Environment**

- **Validation** – “Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specification and quality attributes.”
- **Hosted Environment** – “A facility in which a third-party holds the data and runs the programs in its own computers”
- **Lock-down environment.**
- **All Updates are controlled updates.**

PROBLEM SCENARIO

- Hosted Environment usually **don't allow**
 - *OS Commands Execution*
 - *No Updates to the software Install Area*
- **How to Execute OpenCDISC checks from inside Hosted Environment?**
 - Develop SAS Macro that can be used to execute OpenCDISC checks *without using X Command – OS Commands*
- **How to Register New Standards to toolkit inside Hosted Environment?**
- **How to Register Customized Domains to existing Standards in toolkit inside Hosted Environment?**
 - *Install Standards Metadata under Regulated Access Area* - a location where it can be controlled, versioned and audited.
 - Tell toolkit to reference Standards Metadata from *Regulated Access Area* and **NOT Install location**.
- **Hosted Environment Used**
 - SAS Product – **SAS Drug Development** a web-based Analytical Platform/ Environment is used as Hosted Environment to address the issue

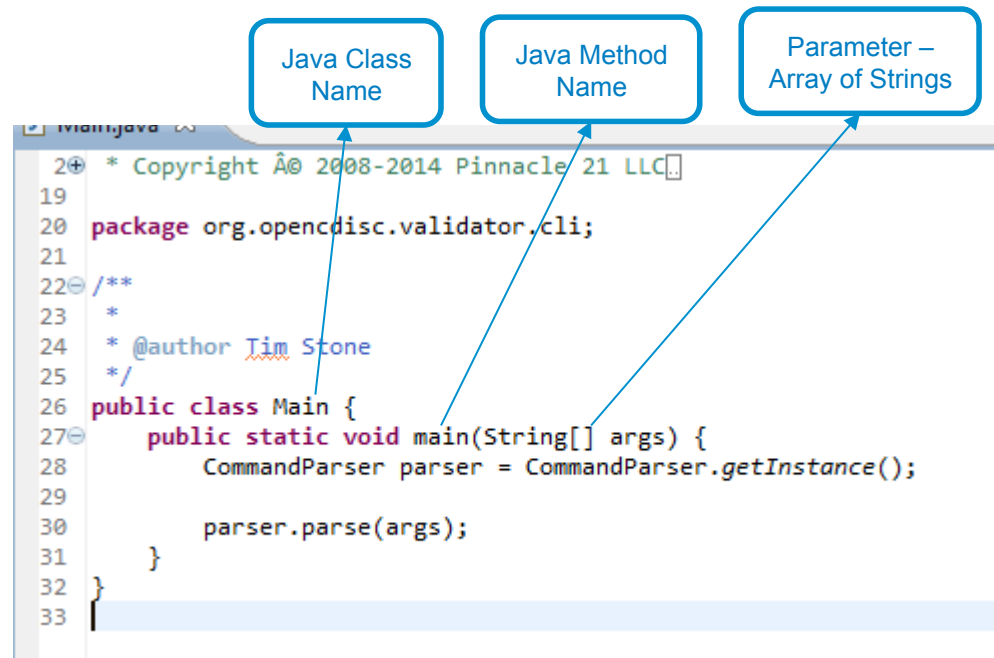
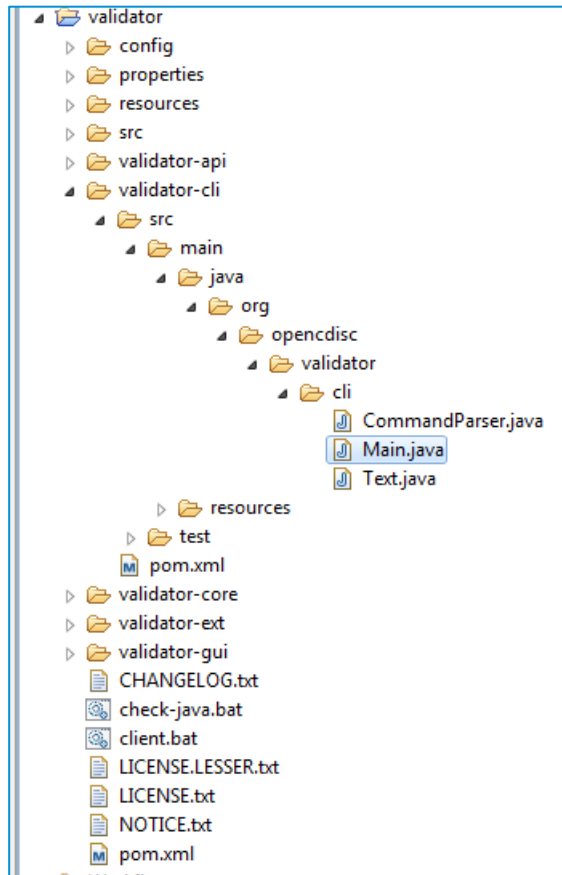
SAS DRUG DEVELOPMENT OVERVIEW



- Web Based Environment
- Dashboard / Repository / Workspace
- Versioning / E-signature / Check-in/ Check-out / Groups / Permissions / Privileges / Audit trail
- SAS Program Development / Execution
- Hosted Environment

OPENCDISC JAVA CODE

- Download and understand OpenCDISC Java Code
 - Download it from <http://svn.opencdisc.org/validator/>
 - Install it in Eclipse – Java IDE



- Known Issue
 - Missing `.trim()`
- Regenerate Jar File

```
private String getCommand(String commandString) {
    if (commandString.startsWith(COMMAND_PREFIX)) {
        commandString = commandString.substring(COMMAND_PREFIX.length());
    }

    if (commandString.contains(COMMAND_SEPARATOR)) {
        commandString = commandString.substring(0, commandString.indexOf(COMMAND_SEPARATOR));
    }

    return commandString;
}

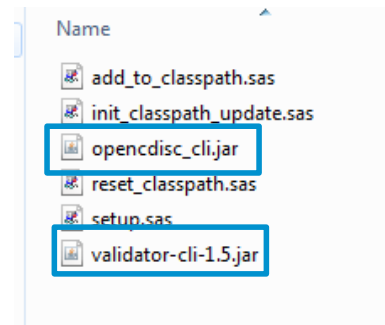
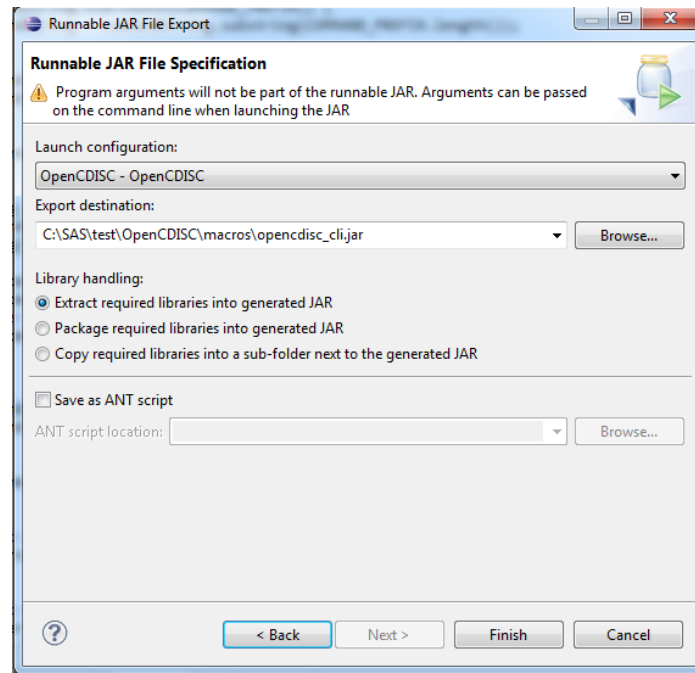
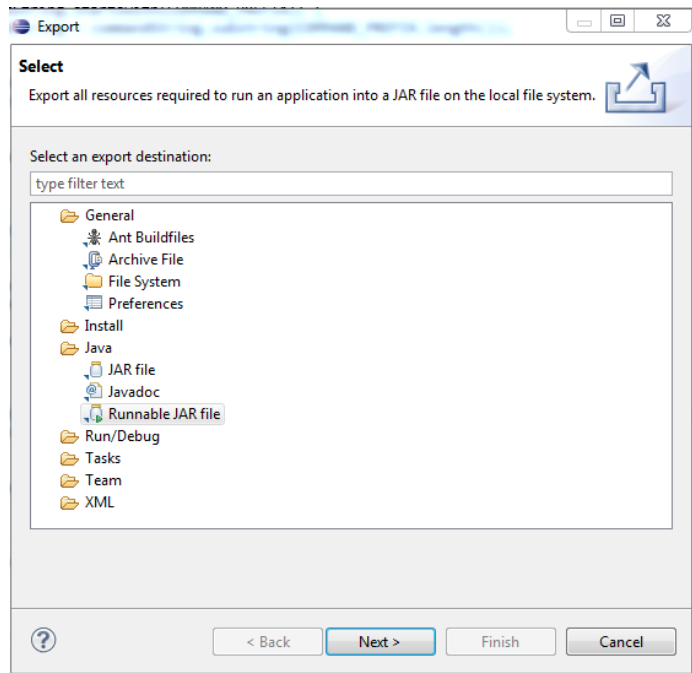
private String getValue(String commandString) {
    if (commandString.contains(COMMAND_SEPARATOR)) {
        String[] components = commandString.split(Pattern.quote(COMMAND_SEPARATOR), 2);

        if (components.length == 2) {
            commandString = components[1];
        } else {
            commandString = "";
        }
    }

    if (commandString.startsWith(COMMAND_ESCAPE) && commandString.endsWith(COMMAND_ESCAPE)) {
        commandString = commandString.substring(1, commandString.length() - 1);
    }

    return commandString;
}
```

OPENCDISC REGENERATE JAR FILE



OPENCDISC SAS CODE – RUN_OPENCDISC.SAS

```
%macro Run_openCDISC(Params=, debug=%str(N));
<PRE-PROCESSING CODE TO GENERATE ARRAY OF NAME=VALUE PAIR>
.....
data _opencdisc_cli;
  dcl javaobj j("org/opencdisc/validator/cli/Main");          class Main
  array s{&i.} $200 (&cmd.);  (String[] args)
  j.callStaticVoidMethod("main",s);  public static void main
run;
%mend Run_openCDISC;

%include "&macloc./setup.sas";
%init_classpath_update;
%*add_to_classpath(&macloc./validator-cli-1.5.jar);
%add_to_classpath(&macloc./opencdisc_cli.jar);
* Validate SDTM datasets;
%Run_openCDISC(Params=%nrquote(
  task=Validate,
  source=&bpath.\xpt\,
  config=&bpath.\opencdisc-validator\config\config-sdtm-3.1.2.xml,
  report=&bpath.\OpenCDISC_Results_%SYSFUNC(translate(%SYSFUNC(datetime()), E8601DT.),'-',':')) .xls,
  report:type=Excel,
  report:cutoff=10,
  report:overwrite=yes),
  debug=N);
%reset_classpath;
```

- OpenCDISC Parameter Reference - <http://www.opencdisc.org/using-opencdisc-validator-cli>
- SAS JavaObj - <http://support.sas.com/rnd/base/datastep/dot/javaobj.html>
- Dynamically setting Classpath - <http://support.sas.com/kb/38/518.html>

OPENCDISC HOSTED ENVIRONMENT – RUN_OPENCDISC.SAS

- Screenshot for hosted environment

The screenshot displays the SAS Workspace browser interface. The left pane shows a hierarchical tree view of the workspace structure. The right pane shows a list of files in the selected directory. Two blue arrows point from the '01_Run_OpenCDISC.sas' file in the right pane to two separate lists of files.

Top List of Files:

Name
add_to_classpath.sas
init_classpath_update.sas
opencdisc_cli.jar
reset_classpath.sas
validator-cli-1.5.jar

Bottom List of Files:

Name
config
lib
reports
CHANGELOG.txt
check-java.bat
client.bat
LICENSE.txt
NOTICE.txt

- Dynamically setting Classpath - <http://support.sas.com/kb/38/518.html>
- OpenCDISC Validator - <http://www.opencdisc.org/download>

OPENCDISC

HOSTED ENVIRONMENT – RUN OPENCDISC.SAS

```

Editors      01_Run_OpenCDISC_2.sas
Inputs
Outputs
Listing
Libraries

77 %if (%super(%sysfunc(strip(task)))=DEFINE) &then &do;
78 * Generate Define.xml;
79 %OpenCDISC(Params=><None>)
80 task=>generate,
81 source=>study_path..Xpt/,
82 config=>%<None>, /opendisc-validator/config/config-stdm-3.1.2.xml,
83 output=>study_path..results/OpenCDISC_define.xml,
84 outputoverwrite=yes,
85 debug=>);
86
87 %end;
88 *Reset to Original ClassPath;
89 %reset_classpath;
90
91 %mend run_opendisc;
92
93 %Run_OpenCDISC(OGRoot=>%str(&s_sasw/SAS/Files/cst_add/programs/Study_Management/opendisc),
94 study_path=>%str(&s_sasw/SAS/Files/cst_add/Study-101),
95 task=>%date());
96
*****

LOG
147          cpu time           0.01 seconds
148
149 *****
150 MAUTOLOCDISPLAY(ADD_TO_CLASSPATH): This macro was compiled from the autocall file /ddshare/SASWorkspaces/sajune/SAS/Files/cst_add/programs/Study_Management/open
151
152 NOTE: DATA statement used (Total process time):
153    real time           0.00 seconds
154    cpu time            0.00 seconds
155
156
157 NOTE: Setting Java classpath to !CLASSPATH;ddshare/SASWorkspaces/sajune/SAS/Files/cst_add/programs/Study_Management/opendisc/macros/opendisc_cll.jar
158
159 Beginning validation, please wait...
160 The Validation has completed.
161 NOTE: The data set WORK_OPENCIDING_CLL has 1 observations and 7 variables.
162 NOTE: DATA statement used (Total process time):
163    real time           6.11 seconds
164    cpu time            0.01 seconds
165
166
167 MAUTOLOCDISPLAY(RESET_CLASSPATH): This macro was compiled from the autocall file /ddshare/SASWorkspaces/sajune/SAS/Files/cst_add/programs/Study_Management/open
168 NOTE: Setting Java classpath back to its original state: !CLASSPATH
169
170
171          *%Run_OpenCDISC(OGRoot=>%str(&s_sasw/SAS/Files/cst_add/programs/Study_Management/opendisc),
172 study_path=>%str(&s_sasw/SAS/Files/cst_add/Study-101),
173 task=>Define);
174
175          * Validate SDTM datasets w.r.t Define.xml;
176 %set

```

The screenshot shows the SAS Studio interface. On the left, the 'Workspace' panel displays a hierarchical tree of the project files. The 'results' folder is highlighted. On the right, the 'Files' panel shows a list of files, including 'cst_mm.xls', 'cstreport.pdf', 'metrics.sas7bdat', 'OpenCDISC_Results_2014-08-01T19:33:27.xls', 'OpenCDISC_Results_2014-08-01T19:33:27.xls', 'validation_metrics.sas7bdat', and 'validation_results.sas7bdat'. The file 'OpenCDISC_Results_2014-08-01T19:33:27.xls' is highlighted with a red box.

OPENCDISC ONE TIME CHANGE

- Update the SAS Config file with path for the Java Jar file and SAS Macro

```
/* define the location of the OpenCDISC Macro */
-insert sasautos "C:\SAS\test\OpenCDISC"

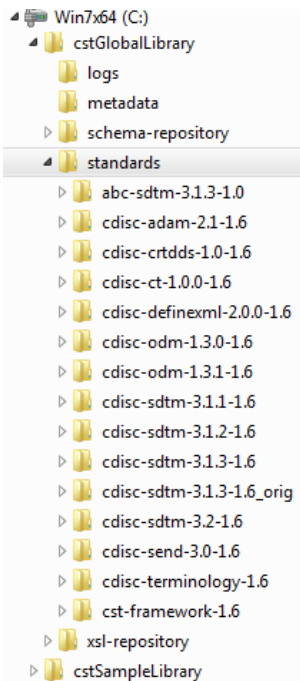
/*put OpenCDISC jar on the classpath*/
-JREOPTIONS (-Dsas.app.class.dirs=C:\SAS\test\OpenCDISC)
```

```
%include "&macloc./setup.sas";
%init_classpath_update;
%*add_to_classpath(&macloc./validator-cli-1.5.jar);
%add_to_classpath(&macloc./opencdisc_cli.jar);
* Validate SDTM datasets;
%Run_openCDISC(Params=%nrquote(
    task=Validate,
    source=&bpath.\xpt\,
    config=&bpath.\opencdisc-validator\config\config-sdtm-3.1.2.xml,
    report=&bpath.\OpenCDISC_Results_%SYSFUNC(translate(%SYSFUNC(datetime()), E8601DT.),'-',':')) .xls,
    report:type=Excel,
    report:cutoff=10,
    report:overwrite=yes));
%reset_classpath;
```

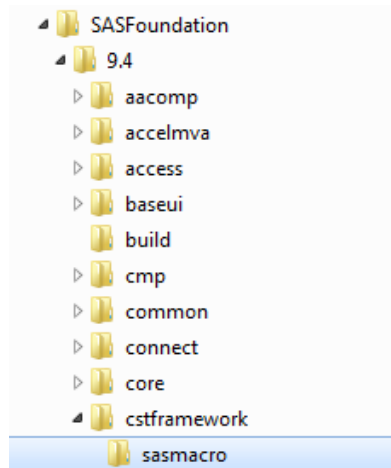
- Write SAS Macro using SAS JavaObj
- PC
 - Include Path for OpenCDISC Jar file and SAS Macro in SAS Configuration file
- Hosted Environment
 - Use Dynamically add jar file to classpath concept - Dynamically setting Classpath - <http://support.sas.com/kb/38/518.html>
 - One Time Request for Change - Update the SAS Configuration file with Jar file location and SAS Macro location.

SAS/CST PC ENVIRONMENT

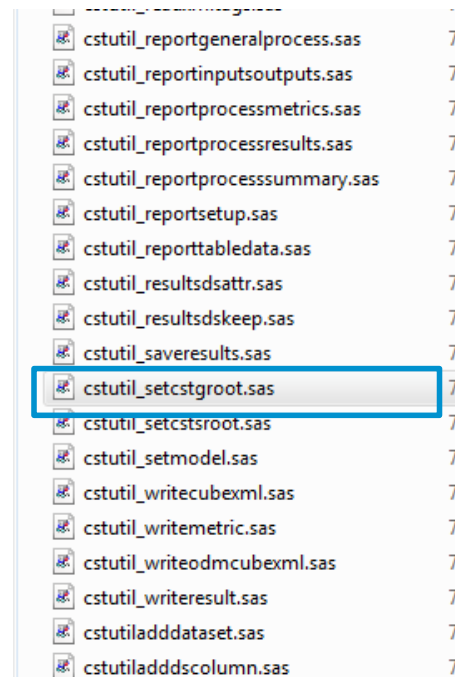
- Standards Metadata – c:/cstGlobalLibrary
- Framework SAS Macros - !SASROOT/cstframework/sasmacro
- %cstutil_setcstgroot – Initialization driver / macro



CST Standards directory structure



CST SAS Macros directory



SAS/CST TOOLKIT INITIALIZATION

- Identify Base path for location of Standards Metadata

```
%macro cstutil_setcstgroot(
    ) / des='CST: Set _cstGRoot macro variable';

    %global _cstGRoot;
    %if &sysver=9.3 %then %cstutilsetcstgroot93;
    %else %let _cstGRoot=%sysfunc(kcompress(%sysfunc(getoption(CSTGLOBALLIB)),%str(%)));

%mend cstutil_setcstgroot;

%* Auto generated by the CST-Framework post installation configuration component;

%macro cstutilsetcstgroot93;
    %let _cstGRoot=c:/cstGlobalLibrary;
%mend;
```

```
7   proc options option= CSTGLOBALIB;
8   run;

SAS (r) Proprietary Software Release 9.4  TS1M0

CSTGLOBALIB="C:\cstGlobalLibrary"
    Specifies the location of the SAS Clinical Standards Toolkit global library.
NOTE: PROCEDURE OPTIONS used (Total process time):
    real time           0.07 seconds
    cpu time            0.00 seconds
```

```
35   proc options option= CSTGLOBALIB;
36   run;

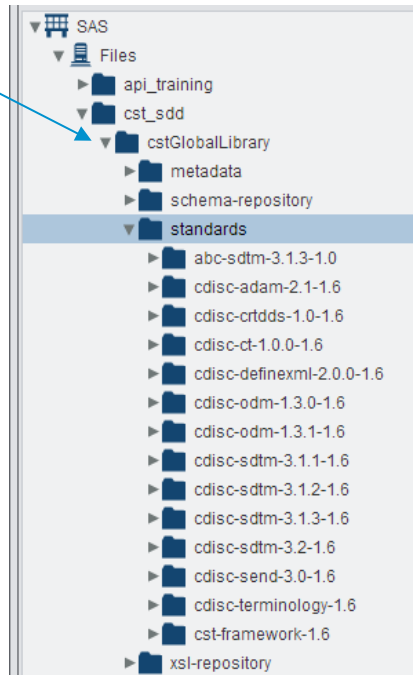
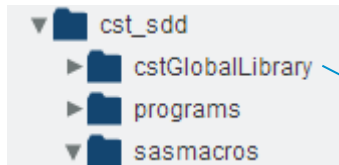
SAS (r) Proprietary Software Release 9.4  TS1M1
NOTE: PROCEDURE OPTIONS used (Total process time):
    real time           0.00 seconds
    cpu time            0.00 seconds
```

```
CSTGLOBALIB="/sfw/cstGlobalLibrary"
```

Specifies the location of the SAS Clinical Standards Toolkit global library.

SAS/CST HOSTED ENVIRONMENT

- cstGlobalLibrary – contains toolkit Metadata & Standards Information
- standards – contains Standards Metadata
- sasmacros – Updated CST framework SAS macros



Name
cstutil_reportgeneralprocess.sas
cstutil_reportinputsoutputs.sas
cstutil_reportprocessmetrics.sas
cstutil_reportprocessresults.sas
cstutil_reportprocesssummary.sas
cstutil_setcstgroot.sas
setup.sas

SAS/CST CUSTOMIZE TOOLKIT SETUP

- Update %cstutil_setcstgroot to support Hosted Environment – SDD
- Add path of updated macro in SASAUTOS.

```
%macro cstutil_setcstgroot(  
  ) / des='CST: Set _cstGRoot macro variable';  
  
  %global _cstGRoot;  
  
  * Check Execution Environment - WINDOWS OR SAS DRUG DEVELOPMENT (SDD);  
  %if %symexist(_sasws_) %then %let env=SDD; %else %let env=WIN;  
  %put env=%env.;  
  
  %if (%env.=WIN) %then %do;  
    %if %sysver=9.3 %then %cstutilsetcstgroot93;  
    %else %let _cstGRoot=%sysfunc(kcompress(%sysfunc(getoption(CSTGLOBALLIB)),%str(%)));  
  %end;  
  %else %do;  
    %let _cstGRoot=%str(&_sasws_/SAS/Files/cst_sdd/cstGlobalLibrary);  
  %end;  
%mend cstutil_setcstgroot;
```

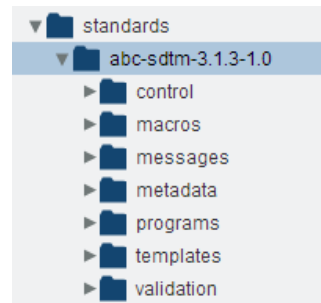
```
cstutil_setcstgroot.sas * setup.sas *  
  
1  
2 %let sdd_sas_api_loc=%sysget(SASROOT)/sddapi/sdd-sas-macro-1.4/sasmacros/;  
3 %put &sdd_sas_api_loc;  
4  
5 %let cst_mac_loc=%str(&_sasws_/SAS/Files/cst_sdd/sasmacros);  
6 %put &cst_mac_loc;  
7  
8 %let opendisc_mac_loc=%str(&_sasws_/SAS/Files/cst_sdd/programs/Study_Management/opendisc/macros);  
9 %put &opendisc_mac_loc;  
10  
11 options SASAUTOS=("&sdd_sas_api_loc" "&cst_mac_loc" "&opendisc_mac_loc" SASAUTOS) MAUTOSOURCE MRECALL MAUTOLOCDISPLAY ;  
12 %put %qsysfunc(getoption(SASAUTOS));
```

SAS/CST REGISTER CUSTOM STANDARD

- Register CUSTOM Standard in toolkit – ABC-SDTM-3.1.3-1.0
- Make copy of Base Standard and update the respective standard metadata
- Update toolkit Global Metadata

```
$RegisterStd(StdName=%str(CDISC-SDTM),
             BaseStd=%str(cdisc-sdtm-3.1.3-1.6),
             NewStd=%str(abc-sdtm-3.1.3-1.0),
             default=%str(Y)
             );
```

Name
abc-sdtm-3.1.3-1.0



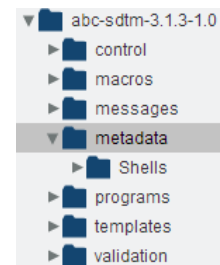
standard	mnemonic	standardversion	groupname	groupversion	comment	rootpath	studylibraryroo...	controlsubfolder	templatesubfol...	isstandarddefa...	iscstframework	is...
ABC-SDTM	SDTM	3.1.3	SDTM	3.1.3	ABC ABC ABC ...	&_cstGRoot/st...	&_cstSRoot/cd...	control	templates	Y	N	Y

standard	standardversion	type	subtype	SASref	reftype	iotype	filetype	allowoverwrite	relpathprefix	path	order
ABC-SDTM	3.1.3	autocall		autocall	fileref	input	folder	N		&_cstGRoot/st...	
ABC-SDTM	3.1.3	classmetadata	column	refmeta	libref	input	dataset	N		&_cstGRoot/st...	
ABC-SDTM	3.1.3	classmetadata	table	refmeta	libref	input	dataset	N		&_cstGRoot/st...	
ABC-SDTM	3.1.3	cstmetadata	lookup	stdmeta	libref	input	dataset	N		&_cstGRoot/st...	
ABC-SDTM	3.1.3	cstmetadata	macrovariable...	stdmeta	libref	input	dataset	N		&_cstGRoot/st...	
ABC-SDTM	3.1.3	cstmetadata	macrovariables	stdmeta	libref	input	dataset	N		&_cstGRoot/st...	

SAS/CST REGISTER CUSTOMIZE DOMAIN

- Register NEW Domain in the standard
- Update the Reference Metadata – Reference_tables & Reference_columns

```
%CreateNewDomain(Standard=%str(ABC-SDTM), StandardVersion=%str(3.1.3),
DomainClass=%str(FINDINGS), DomainName=%str(XP), DomainLabel=%str(Pregnancy),
KeepIDVars=%str("STUDYID" "DOMAIN" "USUBJID" "SEQ"),
KeepTVars="VISITNUM" "VISIT" "VISITDY" "DTC" "STDTC" "ENDTC" "DUR",
DomainKeys=%str(STUDYID USUBJID VISITNUM VISITDY),
XmlTitle=%str(Pregnancy SAS transport file),
StructureDesc=%str(One Record per Subject),
Comment=%nrbquote(It Describes the Pregnancy Results for the trial));
```

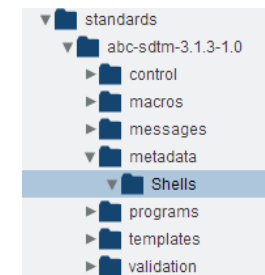


Name
Shells
class_columns.sas7bdat
class_tables.sas7bdat
cported.xpt
reference_columns.sas7bdat
reference_tables.sas7bdat

AS Session 10 ✕ WRKSPC.REFERENCE_TABLES.DATASET ✕ WRKSPC.REFERENCE_COLUMNS.DATASET

STRIP(PUT(Table, \$32.)) = "XP"

SA\$ref	Table	Label	Class	XmlPath	XmlTitle
REFMETA	XP	Pregnancy	Findings	../transport/xp.xpt	Pregnancy SA..



Name
ae.sas7bdat
ce.sas7bdat
cm.sas7bdat
co.sas7bdat
da.sas7bdat
dm.sas7bdat
ds.sas7bdat

sasref	table	column	label	order	type
REFMETA	XP	STUDYID	Study Identifier	1	C
REFMETA	XP	DOMAIN	Domain Abbrev...	2	C
REFMETA	XP	USUBJID	Unique Subject...	3	C
REFMETA	XP	XPSEQ	Sequence Num...	4	N
REFMETA	XP	XPTESTCD	Study Name of	5	C

SAS / CST VALIDATE DATA

- Specify the standards , check types and check list to be executed
- Generates – validation_metrics, validation_results, cstreport.pdf

```
%validate_data(cstStd=%str(ABC-SDTM),
               cstStdVer=%str(3.1.3),
               chklist=%str("METADATA"),chktype=%str("OPENCDISC"),
               study_path=%str(&_sasws_/SAS/Files/cst_sdd/Study-101));
```

SAS Session 9 * WRKSPC.VALIDATION_METRICS.DATASET * WRKSPC.VALIDATION_RES

None

metricparameter	reccount	resultid	srcdata
# of data sets tested	11	SDTM0001	_ALL_
# of observations	12	SDTM0001	LIB6552.AE
# of observations	10	SDTM0001	LIB6552.DM
# of observations	10	SDTM0001	LIB6552.EX
# of observations	38	SDTM0001	LIB6552.SV

S Session 9 * WRKSPC.VALIDATION_METRICS.DATASET * WRKSPC.VALIDATION_RESULTS.DATASET *

None

resultid	checkid	resultseq	seqno	srcdata	message
CST0108		1	1	CST_SETPRO...	The properties were processed from th
CST0200		1	1	CST_CREATE...	The SAS libref cstmplit was allocated to
CST0102		1	2	CST_CREATE...	work.sasreferences was created as rec
CST0200		1	1	CSTUTIL_PRO...	Process setup is using this SASReferer
CST0200		1	1	CST_INSERTS...	SASReferences data set was successf
CST0076		1	2	WORK_CSTSA...	SAS fileref from SASref=sdtauto sasre

Name
cst_mm.xls
cstreport.pdf
metrics.sas7bdat
OpenCDISC_Results_2014-08-01T19-33-27..
OpenCDISC_Results_2014-08-08T13-49-40..
validation_metrics.sas7bdat
validation_results.sas7bdat

SAS Clinical Standards Toolkit 1.6 ABC-SDTM 3.1.3 VALIDATION

Process Metrics

Summary Metrics		Table Metrics				
Metric	#	Table	# Check Invocations	# Recs (if available)	# Errors	# Check Invocations Not Run
# of distinct check invocations	229	AE	80	240	127	15
# check invocations not run	59	DM	81	260	95	15
Errors (severity=High) reported	13	EX	74	141	54	13

SAS Clinical Standards Toolkit 1.6 ABC-SDTM 3.1.3 VALIDATION

Process Results, Table: AE

Check ID	Check Invocation	Seq #	Source Data	Result Identifier	Message	Severity	Problem Detected?	Actual Value	Keys
SDTM0201	1	1	lib6552.AE	SDTM0201	Null value in column	Error	Yes	DOMAIN=	STUDYID= SASCSTDDEMODATA, USUBJID=S001P003, AEDECOD=Abdominal pain, AESTDTC=2008-02-13T12:00
SDTM0201	1	2	lib6552.AE	SDTM0201	Null value in column	Error	Yes	AETERM=	STUDYID= SASCSTDDEMODATA, USUBJID=S001P008, AEDECOD=Rash pruritic, AESTDTC=2008-03-01T16:30

VALIDATION REPORT

METRICS & MATRIX (M&M) REPORT

- Update the Reporting Macros to capture dynamic temporary datasets into known temporary datasets

	cstutil_reportgeneralprocess.sas
	cstutil_reportinputsoutputs.sas
	cstutil_reportprocessmetrics.sas
	cstutil_reportprocessresults.sas
	cstutil_reportprocesssummary.sas

```
data _cstGP;  
  set &_cstResultsDSet;  
run;
```

```
data work._cstIO;  
  set work._cstTemp;  
run;
```

```
data _cstPM;  
  set _cstRptDS;  
run;
```

```
data _cstPS;  
  set _cstRptDS;  
run;
```

```
%cst_MM_report(cstStd=%str(ABC-SDTM),  
  cstStdVer=%nrquote(3.1.3),  
  report_path=%str(&_amp;_sasws_/SAS/Files/cst_sdd/Study-101/results));
```

	Name
	cst_mm.xls
	cstreport.pdf
	metrics.sas7bdat
	OpenCDISC_MM.xls
	OpenCDISC_Results_2014-08-01T19-33-27..
	OpenCDISC_Results_2014-08-08T13-49-40..
	validation_metrics.sas7bdat
	validation_results.sas7bdat

VALIDATION REPORT

SAS/CST METRICS & MATRIX (M&M) REPORT

- Metrics & Matrix Report

```
%cst_MM_report(cstStd=%str(ABC-SDTM),
               cstStdVer=%str(3.1.3),
               report_path=%str(&_amp;_sasws_/SAS/Files/cst_sdd/Study-101/results));
```

Summary Metrics		Table Metrics					
Metric	#	Table	# Check Invocations	# Recs (if available)	# Errors	# Check Invocations Not Run	
# of distinct check invocations	229	AE	80	240	127	15	
# check invocations not run	59	DM	81	260	95	15	
Errors (severity=High) reported	13	EX	74	141	54	13	
Warnings (severity=Medium) reported	473	SV	51	96	44	11	
Notes (severity=Low) reported	599	TA	51	71	13	12	
Structural errors, warnings and notes	4	TE	46	55	1	11	
Content errors, warnings and notes	1130	TI	44	52	1	19	
		TS	61	99	32	14	
		TV	47	59	8	15	
		VS	79	752	660	23	
		XP	94	152	49	35	

Check ID	Check Source	Message	TableScope	ColumnScope	Check Severity	Elapsed Time	CST	AE	DM	EX	SV	TA
SDTM0124	WebSDM	Invalid value for **TEST variable	CLASS.FINDINGS	**TEST	Pass	0:00:01						
SDTM0125	WebSDM	Invalid value for **TESTCD variable	CLASS.FINDINGS	**TESTCD	Pass	0:00:01						
SDTM0128	WebSDM	Invalid value for TSPARM variable	TS	TSPARM	Pass	0:00:01						
SDTM0129	WebSDM	Invalid value for TSPARMCD variable	TS	TSPARMCD	Pass	0:00:01						
SDTM0130	OpenCDISC	Invalid value for ARMCD variable	DM+TA+TV	ARMCD	Pass	0:00:01		✓ (10/ 10)				✓ (6/ 6)
SDTM0130	SAS	Invalid value for ACTARMCD variable	DM	ACTARMCD	Pass	0:00:01		✓ (10/ 10)				
SDTM0131	OpenCDISC	Invalid value for ETCD variable	SE+TA+TE	ETCD	Pass	0:00:01						✓ (6/ 6)
SDTM0190	WebSDM	Date must be less than or equal to latest disposition date	DS+AE+EG+LB+VS+EX		Not Executed	0:00:00	●					
SDTM0191	OpenCDISC	AE start date must be less than or equal to latest disposition date	AE	[AE]SDTC[DS]SDTC	Not Executed	0:00:00	●					
SDTM0192	OpenCDISC	Observation date must be less than or equal to latest disposition date	EG+LB+VS	[**]DT[CD]SDTC[DS]SDTC	Not Executed	0:00:00	●					
SDTM0193	OpenCDISC	Exposure end date must be less than or equal to latest disposition date	EX	[EXEND]CD[DS]SDTC	Not Executed	0:00:00	●					
SDTM0201	WebSDM	Null value in column	_ALL_	_ALL_	Pass	0:00:04			✓ (340/ 9)			✓ (60/ 6)
SDTM0201	WebSDM	Null value in column	_ALL_	_ALL_	Error	0:00:04		X (612/ 10)			X (418/ 10)	
SDTM0202	SAS	Null value in column	_ALL_	_ALL_	Pass	0:00:04			✓ (418/ 10)			
SDTM0202	SAS	Null value in column	_ALL_	_ALL_	Note	0:00:04		■ (512/ 9)	■ (280/ 10)	■ (340/ 9)		■ (60/ 6)

VALIDATION REPORT

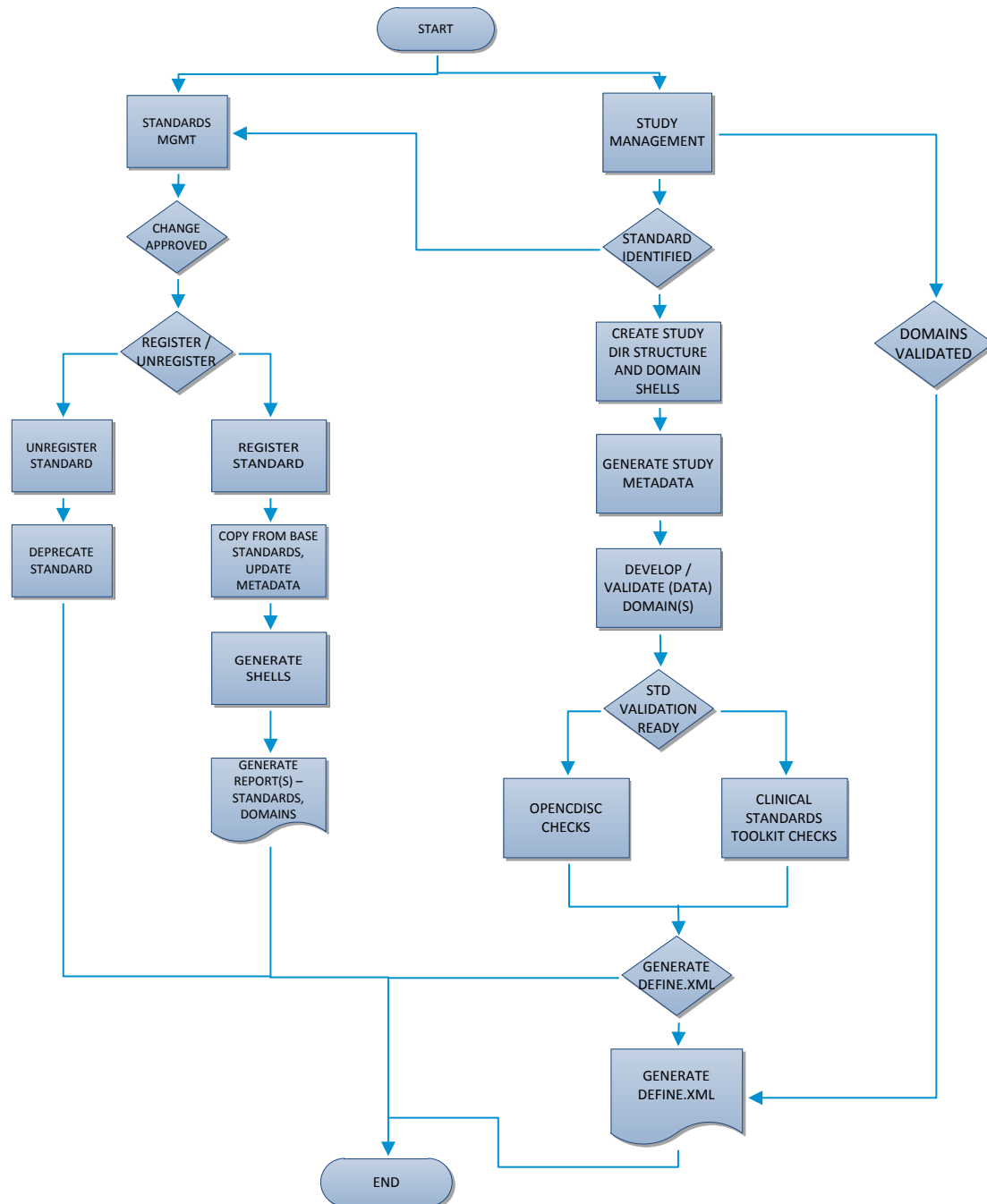
OPENCDISC MATRIX REPORT

```
%let bpath=%nrquote(&_sasws_/SAS/Files/cst_sdd/Study-101/results);
%MatrixReport(infile=%nrquote(&bpath./OpenCDISC_Results_2014-08T13-49-40.xls),
               outfile=%nrquote(&bpath./OpenCDISC_MM.xls));
```

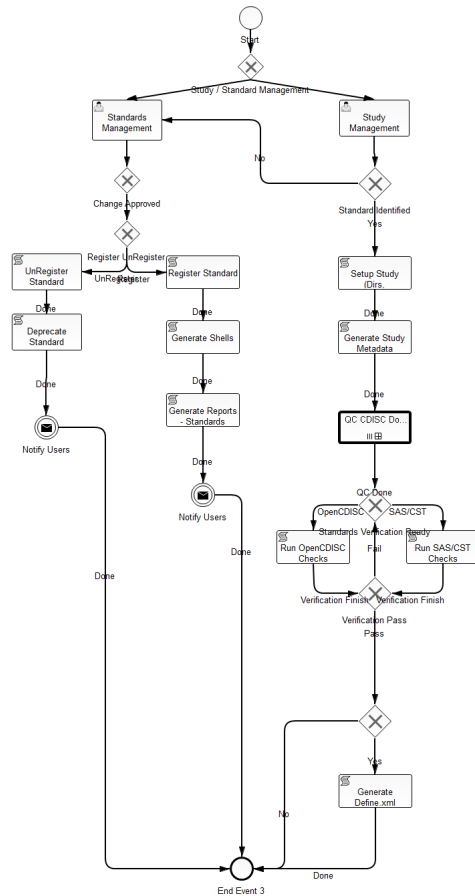
A	B	C	D	E	F	G	H	I	J	K
SDTM Domains 3.1.2										
Rule ID	Message	Description	Category	Severity	GLOBAL	AE	CM	DM	DS	EX
SD1107	Missing LB dataset	Lab Test Results (LB) dataset should be included in every submission	Presence	Warning	▲					
SD1108	Missing VS dataset	Vital Signs (VS) dataset should be included in every submission	Presence	Warning	▲					
SD1111	Missing SE dataset	Subject Elements (SE) dataset should be included in every submission	Presence	Warning	▲					
SD1112	Missing TA dataset	Trial Arms (TA) dataset should be included in every submission	Presence	Warning	▲					
SD1113	Missing TE dataset	Trial Elements (TE) dataset should be included in every submission	Presence	Warning	▲					
SD1115	Missing TS dataset	Trial Summary (TS) dataset should be included in every submission	Presence	Error	✗					
SD0002	NULL value in -- variable marked as Required	Required variables (where Core attribute is 'Req') cannot be NULL for any records	Presence	Error		✗		✗		
SD0003	Invalid ISO 8601 value for -- variable	Value of Dates/Time variables ('DTC') must conform to the ISO 8601 international standard	Format	Error				✗		
SD0004	Inconsistent value for DOMAIN	Domain Abbreviation (DOMAIN) variable should be consistent with the name of the dataset	Consistency	Warning				▲		
SD0005	Duplicate value for --SEQ variable	The value of Sequence Number (--SEQ) variable must be unique for each record within a domain and within of Unique Subject Identifier (USUBJID) or Pool Identifier (POOLID) variables value when they are present in the domain.	Consistency	Error		✗				
SD0009	No qualifiers set to 'Y', when AE is Serious	When Serious Event (AESER) variable value is 'Y', then at least one of seriousness criteria variables is expected to have value 'Y' (Involves Cancer (AESCAN), Congenital Anomaly or Birth Defect (AESCONG), Persist or Signif Disability/Incapacity (AESDISAB), Results in Death (AESDTH), Requires or Prolongs Hospitalization (AESHOSP), Is Life Threatening (AESLIFE), or Other Medically Important Serious Event (AESMIE))	Consistency	Warning		▲				
SD0011	ARM is not 'Screen Failure', when ARMCD equals 'SCRNFALL', or vice versa	Description of Arm (ARM) must equal 'Screen Failure', when Arm Code (ARMCD) is 'SCRNFALL', and vice versa	Consistency	Error				✗		
SD0012	--STDY is after --ENDY	Study Day of Start of Event, Exposure or Observation (--STDY) must be less or equal to Study Day of End of Event, Exposure or Observation (--ENDY)	Limit	Error		✗				
SD0013	--STDTC is after --ENDTC	Start Date/Time of Event, Exposure or Observation (--STDTC) must be less or equal to End Date/Time of Event, Exposure or Observation (--ENDTC)	Limit	Error		✗				

WORKFLOW

STANDARDS & STUDY MANAGEMENT



WORKFLOW BPMN 2.0 STANDARDS & STUDY MANAGEMENT



```

<?xml version="1.0" encoding="UTF-8"?>
<definitions xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="http://www.omg.org/spec/BPMN/20100524/MODEL" xmlns:activiti="http://activiti.org/bpm">
  <itemDefinition id="ItemDefinition_1" structureRef="Test Message"/>
  <message id="Message_1" itemRef="ItemDefinition_1" name="Message 1"/>
  <message id="Message_2" itemRef="ItemDefinition_1" name="Message 2"/>
  <process id="SSProcessFlow" name="Standards & Study Process Flow" isExecutable="true">
    <startEvent id="startevent1" name="Start">
      <outgoing>flow1</outgoing>
    </startEvent>
    <exclusiveGateway id="exclusivgateway1" name="Study / Standard Management" gatewayDirection="Diverging">
      <incoming>flow1</incoming>
      <outgoing>flow3</outgoing>
      <outgoing>flow4</outgoing>
    </exclusiveGateway>
    <sequenceFlow id="flow1" sourceRef="startevent1" targetRef="exclusivgateway1"/>
    <userTask id="usertask2" name="Study Management" implementation="#WebService">
      <incoming>flow3</incoming>
      <outgoing>SequenceFlow_5</outgoing>
    </userTask>
    <sequenceFlow id="flow3" sourceRef="exclusivgateway1" targetRef="usertask2"/>
    <userTask id="usertask3" name="Standards Management">
      <incoming>SequenceFlow_10</incoming>
      <outgoing>flow5</outgoing>
    </userTask>
    <sequenceFlow id="flow5" sourceRef="exclusivgateway1" targetRef="usertask3"/>
    <exclusiveGateway id="exclusivgateway2" name="Change Approved" gatewayDirection="Diverging">
      <incoming>flow5</incoming>
      <outgoing>flow6</outgoing>
    </exclusiveGateway>
    <sequenceFlow id="flow6" sourceRef="usertask3" targetRef="exclusivgateway2"/>
    <exclusiveGateway id="exclusivgateway3" name="Register UnRegister" gatewayDirection="Diverging">
      <documentation id="Documentation_1">Change Approved</documentation>
      <incoming>flow6</incoming>
      <outgoing>SequenceFlow_4</outgoing>
    </exclusiveGateway>
    <sequenceFlow id="flow7" sourceRef="exclusivgateway2" targetRef="exclusivgateway3"/>
    <sequenceFlow id="flow8" name="Done" sourceRef="ScriptTask_2" targetRef="ScriptTask_2"/>
    <scriptTask id="servicetask2" name="Deprecate Standard">
      <incoming>flow8</incoming>
      <outgoing>SequenceFlow_1</outgoing>
    </scriptTask>
    <sequenceFlow id="SequenceFlow_4" name="Register" sourceRef="exclusivgateway3" targetRef="ScriptTask_1"/>
    <scriptTask id="ScriptTask_2" name="UnRegister Standard">
      <incoming>flow7</incoming>
      <outgoing>flow8</outgoing>
    </scriptTask>
  </process>
</definitions>

```

- **Download link for**
 - **Run_OpenCDISC SAS macro**
 - **OpenCDISC M&M Report SAS macro**
 - **SAS/CST M&M Report SAS macro**
- <https://communities.sas.com/docs/DOC-7781>

THANK YOU!

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SAS DRUG DEVELOPMENT FORUM:

[HTTPS://COMMUNITIES.SAS.COM/COMMUNITY/SUPPORT-COMMUNITIES/SAS-DRUG-DEVELOPMENT](https://communities.sas.com/community/support-communities/sas-drug-development)



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