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/](http://svn.opencdisc.org/validator/)
  - Install it in Eclipse – Java IDE

```java
package org.opencdisc.validator.cli;

public static void main(String[] args) {
    CommandParser parser = CommandParser.GetInstance();
    parser.parse(args);
}
```
OPENCDISC  JAVA CODE – COMMANDPARSER.JAVA

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

```java
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**

- **Export**
  - **Select**
    - Export all resources required to run an application into a JAR file on the local file system.
  
- **Runnable JAR File Export**
  - **Launch configuration**:
    - OpenCDISC - OpenCDISC
  
- **Export destination**:
  
- **Library handling**:
  - Extract required libraries into generated JAR
  - Package required libraries into generated JAR
  - Copy required libraries into a sub-folder next to the generated JAR

- **Save as ANT script**

- **ANT script location**:

- **Browse...**

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

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This information is confidential and covered under the terms of any SAS agreements as executed by customer and SAS Institute Inc.
%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");
  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-sdtn-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;

• Dynamically setting Classpath - [http://support.sas.com/kb/38/518.html](http://support.sas.com/kb/38/518.html)
• Screenshot for hosted environment

• Dynamically setting Classpath - [http://support.sas.com/kb/38/518.html](http://support.sas.com/kb/38/518.html)
• OpenCDISC Validator - [http://www.opencdisc.org/download](http://www.opencdisc.org/download)
OPENCDISC

HOSTED ENVIRONMENT – RUN_OPENCDISC.SAS
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=%nrbquote{
  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;
**OPENCDISC SUMMARY**

- 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](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
TOOLKIT INITIALIZATION

- Identify Base path for location of Standards Metadata

```sas
%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;
```

```sas
proc options option= CSTGLOBALLIB;
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

```sas
proc options option= CSTGLOBALLIB;
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="/srw/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
**SAS/CST** CUSTOMIZE TOOLKIT SETUP

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

```sas
%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;
```

```sas
%let sdd_sas_api_loc=%sysget(SASROOT)/sddapi/sdd-sas-macro-1.4/sasmacros/;
%put sdd_sas_api_loc;

%let cst_mac_loc=%str(&sasws_/SAS/Files/cst_sdd/sasmacros); 
%put cst_mac_loc;

%let opendisc_mac_loc=%str(&sasws_/SAS/Files/cst_sdd/programs/Study_Management/opendisc/macros); 
%put opendisc_mac_loc;

11  options SASAUTOS=(&sdd_sas_api_loc "&cst_mac_loc" "&opendisc_mac_loc" SASAUTOS) MAUTOSOURCE MRECALL MAUTOLOCDISPLAY; 
12  %put %sysfunc(getoption(SASAUTOS));
```
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
SAS/CST REGISTER CUSTOMIZE DOMAIN

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

VALIDATE DATA

- Specify the standards, check types and check list to be executed
- Generates – validation_metrics, validation_results, cstreport.pdf
• Update the Reporting Macros to capture dynamic temporary datasets into known temporary datasets
SAS/CST METRICS & MATRIX (M&M) REPORT

- Metrics & Matrix Report

---

### Summary Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th># Of Distinct Check Invocations</th>
<th># Check Invocations (if available)</th>
<th># Recs</th>
<th># Error</th>
<th># Check Invocations Not Run</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td># of distinct check invocations</td>
<td>220</td>
<td>60</td>
<td>240</td>
<td>127</td>
<td>15</td>
</tr>
<tr>
<td># check invocations net run</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Errors (severity=High) reported</td>
<td>13</td>
<td>74</td>
<td>141</td>
<td>54</td>
<td>13</td>
</tr>
<tr>
<td>Warnings (severity=Medium)</td>
<td>473</td>
<td>51</td>
<td>96</td>
<td>44</td>
<td>11</td>
</tr>
<tr>
<td>Notes (severity=Low) exported</td>
<td>113</td>
<td>46</td>
<td>55</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Structural errors, warnings and notes</td>
<td>1130</td>
<td>44</td>
<td>52</td>
<td>1</td>
<td>19</td>
</tr>
<tr>
<td>Content errors, warnings and notes</td>
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<td></td>
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</tr>
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</table>

### Table Metrics

<table>
<thead>
<tr>
<th>Metric</th>
<th>CST</th>
<th>DM</th>
<th>AE</th>
<th>DV</th>
<th>TA</th>
<th>TE</th>
<th>TI</th>
<th>TV</th>
<th>VS</th>
<th>XP</th>
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<tbody>
<tr>
<td># of check invocations</td>
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<tr>
<td>Errors (severity=High) reported</td>
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<tr>
<td>Warnings (severity=Medium)</td>
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<tr>
<td>Notes (severity=Low) exported</td>
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<tr>
<td>Structural errors, warnings and notes</td>
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<td>Content errors, warnings and notes</td>
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</tr>
</tbody>
</table>

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### Check Check Log

<table>
<thead>
<tr>
<th>ID</th>
<th>Source</th>
<th>Message</th>
<th>Tablescope</th>
<th>ColumnsScope</th>
<th>Severity</th>
<th>Elapsed Time</th>
<th>CST</th>
<th>AE</th>
<th>DM</th>
<th>EX</th>
<th>SV</th>
<th>TA</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>
### Validation Report

#### OpenCDISC Matrix Report

<table>
<thead>
<tr>
<th>Rule ID</th>
<th>Description</th>
<th>Category</th>
<th>Severity</th>
<th>GLQMA</th>
<th>AE</th>
<th>CH</th>
<th>DM</th>
<th>DS</th>
<th>EX</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD1167</td>
<td>Lab Test Results (LR) dataset should be included in every submission</td>
<td>Presence</td>
<td>Warning</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD1168</td>
<td>Vital Signs (VS) dataset should be included in every submission</td>
<td>Presence</td>
<td>Warning</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>SD1111</td>
<td>Subject Elements (SE) dataset should be included in every submission</td>
<td>Presence</td>
<td>Warning</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SD1112</td>
<td>Trial Arms (TA) dataset should be included in every submission</td>
<td>Presence</td>
<td>Warning</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>SD1113</td>
<td>Trial Elements (TE) dataset should be included in every submission</td>
<td>Presence</td>
<td>Warning</td>
<td>⬤</td>
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</tr>
<tr>
<td>SD1115</td>
<td>Trial Summary (TS) dataset should be included in every submission</td>
<td>Presence</td>
<td>Error</td>
<td>⬤</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>SD3002</td>
<td>NULL value in --VALUE-- variable must be unique for each record within a domain and within a Unique Subject Identifier (USID) or Pool identifier (POOLID)</td>
<td>Required</td>
<td>Error</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>SD3003</td>
<td>Value of Date/Time variable (UTC) must conform to the ISO 8601 international standard</td>
<td>Format</td>
<td>Error</td>
<td>⬤</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>SD3004</td>
<td>Domain Abstraction (IOAAb) variable should be consistent with the name of the dataset</td>
<td>Inconsistent Value</td>
<td>Error</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>SD3005</td>
<td>The value of Sequence Number (--SEQ--) variable must be unique for each record within a domain and within a Unique Subject Identifier (USID) or Pool identifier (POOLID)</td>
<td>Consistency</td>
<td>Error</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>SD3006</td>
<td>No qualifiers to test for an AEs between AEs</td>
<td>Consistency</td>
<td>Error</td>
<td>⬤</td>
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<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>SD3011</td>
<td>Description of Arm (ARMA) must equal ‘Screen Failure’ when Arm Code (ARMCD) is ‘SRRGNF’ and vice versa</td>
<td>Consistency</td>
<td>Error</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>SD3012</td>
<td>Start Date/Time of Event, Exposure or Observation (-STDT) must be less or equal to End Date/Time of Event, Exposure or Observation (-ENDT)</td>
<td>Limit</td>
<td>Error</td>
<td>⬤</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

**Matrix** | **GLOBAL** | **AE** | **CH** | **DM** | **DS** | **EX** | **F** | **G** | **H** | **I** | **J** | **K** | **L** | **M** | **N** | **O** | **P** | **Q** | **R** | **S** | **T** | **U** | **V** | **W** | **X** | **Y** | **Z** |
STANDARDS & STUDY MANAGEMENT
WORKFLOW

BPMN 2.0 STANDARDS & STUDY MANAGEMENT
• 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