PharmaSUG 2013 – AD05

Running OpenCDISC in SAS

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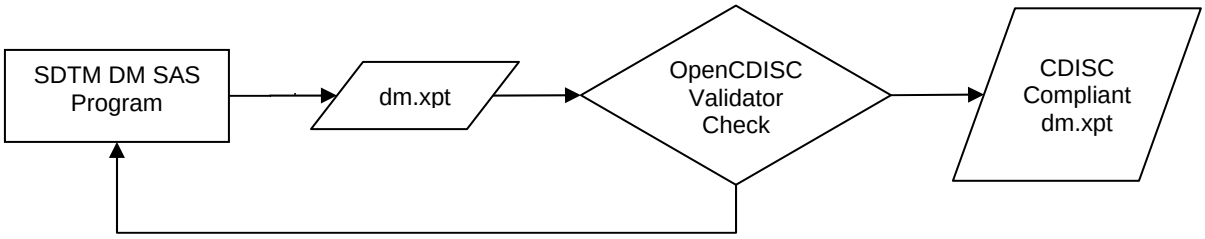
ABSTRACT

OpenCDISC provides great compliance checks against CDISC outputs like SDTM, ADaM, SEND and Define.xml. OpenCDISC is an easy point-and-click software package for CDISC compliance checks. SAS programmers usually run OpenCDISC as an independent executable file after creating CDISC datasets, but there is a way to execute OpenCDISC from within a SAS program. This means that SAS programmers will be able to create SDTM or ADaM datasets and check for CDISC compliance by running OpenCDISC in the same SAS program.

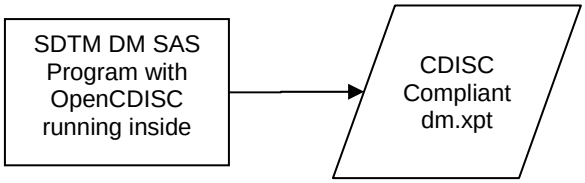
This paper will show how to run OpenCDISC from within a SAS program. It will also show how to call the OpenCDISC compliance check software within a SAS ® program and how to assign the parameters such as SDTM, SAS Transport file, the location of the source data, the version of compliance checks, the output type, and the location of OpenCDISC compliance check reports.

THE CURRENT PROCESS OF CDISC COMPLIANCE CHECK



THE NEW PROCESS OF CDISC COMPLIANCE CHECK

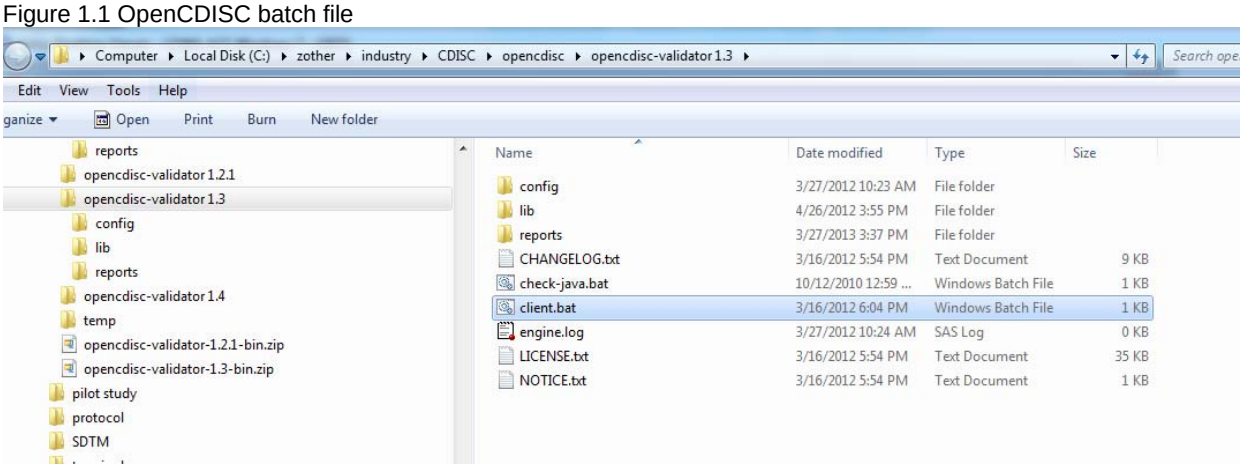
If we run OpenCDISC in SAS, we can create SDTM Compliant DM transport file in one step like below.



INTRODUCTION OF OPENCDISC

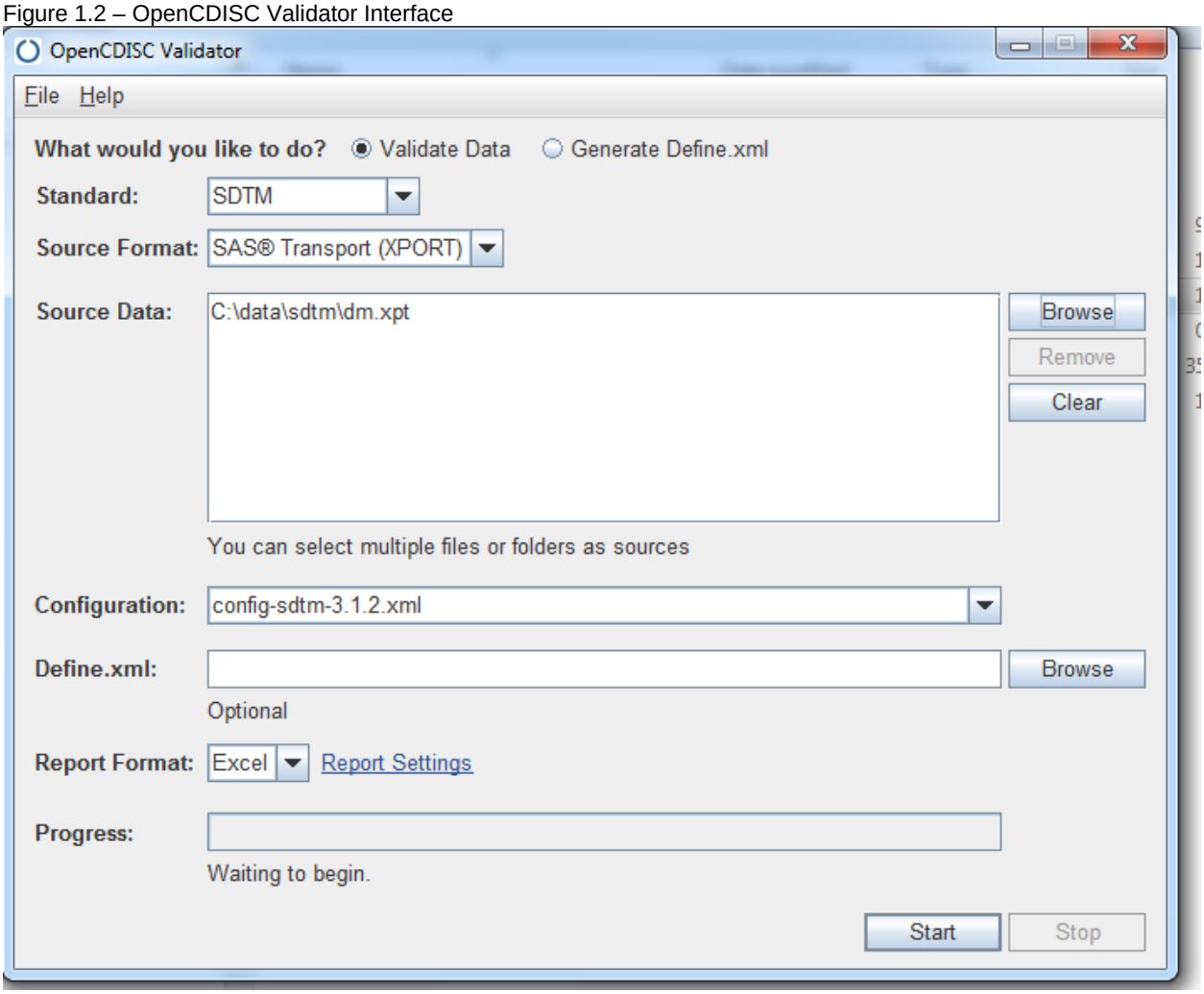
OpenCDISC is a CDISC compliance check software. It is open-source software. The most recent version is 1.4 and released in March 14th, 2013 . This paper is based on the version 1.3, but it will also show how to run 1.4 version.

Figure 1.1 OpenCDISC batch file



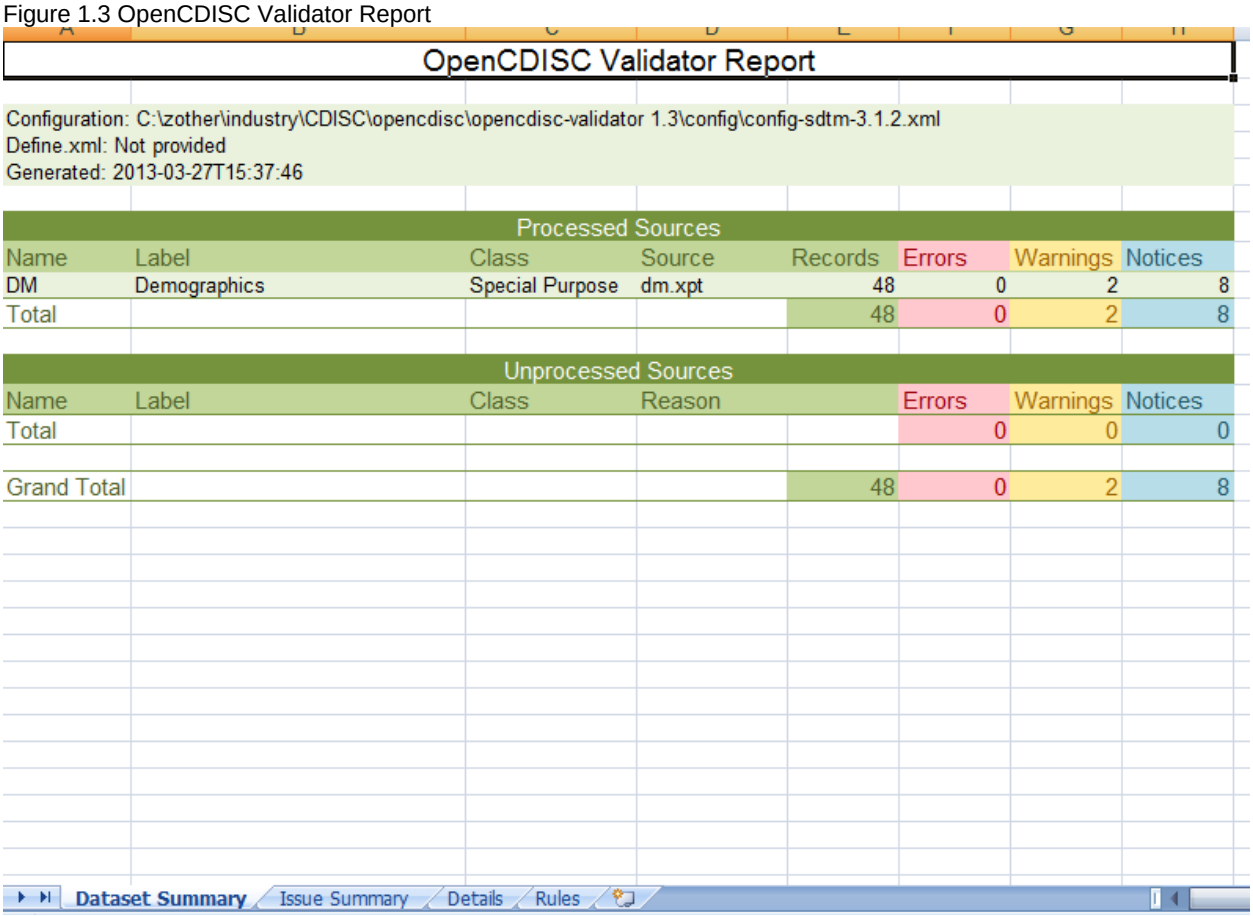
When double-clicking client.bat as shown in Figure 1.1, OpenCDISC validation will start. But, please note that OpenCDISC requires the Java runtime Environment(JRE) 1.5 or higher.
The Figure 1.2 shows OpenCIDSC Validation interface.

Figure 1.2 – OpenCDISC Validator Interface



As we see Figure 1.2, we select “Validate Data”, ”SDTM”, “SAS Transport(XPORT)”, “dm.xpt”, “config-sdtm-3.1.2.xml” and “Excel”. This will produce the OpenCDISC Validator Report as shown in Figure 1.3.

Figure 1.3 OpenCDISC Validator Report



OpenCDISC Validator Report

Configuration: C:\zother\industry\CDISC\opencdisc\opencdisc-validator 1.3\config\config-sdtm-3.1.2.xml
Define.xml: Not provided
Generated: 2013-03-27T15:37:46

Processed Sources

Name	Label	Class	Source	Records	Errors	Warnings	Notices
DM	Demographics	Special Purpose	dm.xpt	48	0	2	8
Total				48	0	2	8

Unprocessed Sources

Name	Label	Class	Reason	Errors	Warnings	Notices
Total				0	0	0
Grand Total				48	0	2	8

Dataset Summary | Issue Summary | Details | Rules

The functionality of OpenCDISC is as follows:

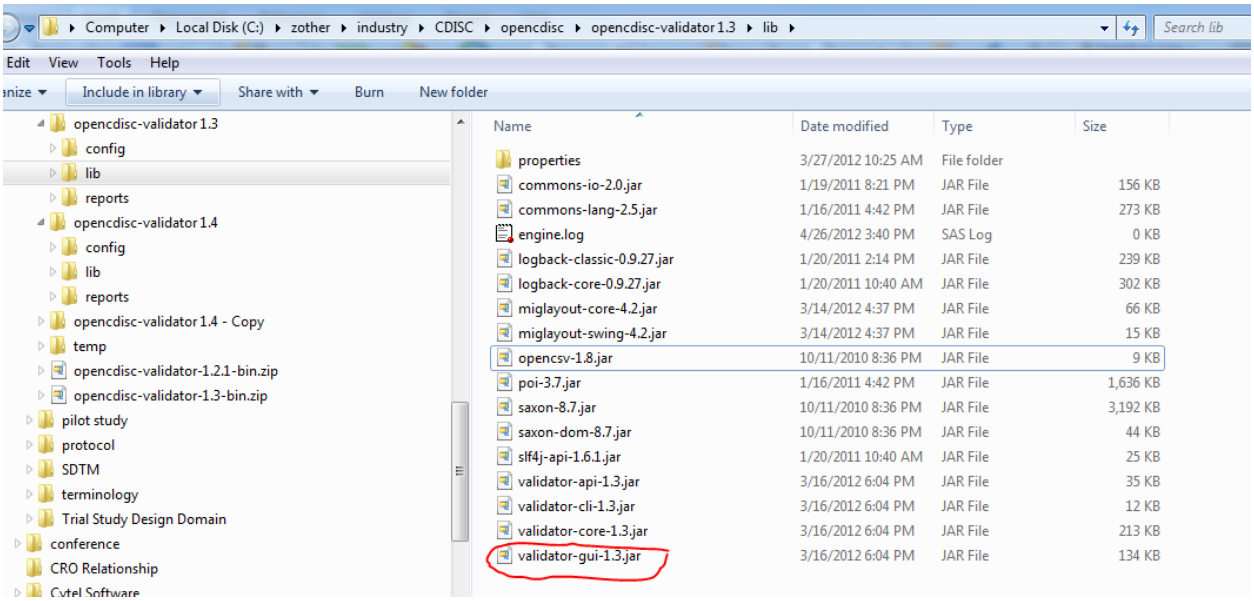
- Validation of Data
  - SDTM
  - ADaM
  - Send
  - Define.xml
  - Tabular data
- Creation of Define.xml

The client.bat file in Figure 1.1 contains the following command:

```
START /B javaw -Xms256m -Xmx1024m -jar lib/validator-gui-1.3.jar
```

The client.bat file indicates that it will starts validator-gui-1.3.jar program shown in Figure 1.4.

FIGURE 1.4 the location of Validator-gui-1.3.jar



HOW TO RUN OPENCDISC IN SAS

The first option is to call the Java program in SAS using the "x" command.

The command statement will call the main Java program within the Validator GUI JAR file, and will start the OpenCDISC Validator Interface seen in Figure 1.2.

```
****opening OpenCDISC Validator Interface;
x java -jar " C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.3\lib\validator-gui-
1.3.jar";
```

In addition to the GUI interface, OpenCDISC also provides a command line utility.

The second option is to pass the parameters (e.g. "Validate Data", "SDTM") directly to the Command Line Interpreter (CLI) Java program. Appendix A shows the possible parameters that can be passed to the CLI Java program from SAS.

The following are a few of the useful parameters that we are able to pass to the Java program.

- Type of works – Compliance check on data or generate Define.xml
- Location and format of source data
- Name of location of configuration file
- Location of Define.xml
- Report format
- Name and location of OpenCDISC Validator Report

Below is a sample command that we can run using the same inputs as in Figure 1.2, and its output is the exactly same as OpenCDISC Validator Report in Figure 1.3.

```
**** running OpenCDISC by assigning command lines;
x java -jar "C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.3\lib\validator-cli-
1.3.jar" -task="validate" -type="sdtm" -source:type="sas" -source="C:\data\sdtm\dm.xpt"
-config="C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.3\config\config-sdtm-3.1.2.xml"
-report:type="excel" -report="C:\data\openCDISC_v1.3_DM.xls" –report:overwrite="yes";
```

The detailed parameters descriptions are as follow

- `-jar ""C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.3\lib\validator-cli-1.3.jar " : The path of OpenCDISC Java program`
- `-task="validate" : we can choose either "validate" or "generate"`
- `-type="sdtm" : we can choose "sdtm", "adam" or "send"`
- `-source="C:\data\sdtm\dm.xpt" : the path of source SDTM dm.xpt file`
- `-source:type="sas" : SAS transport file`
- `-config="C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.3\config\config-sdtm-3.1.2.xml : the path and name of configuration`

- `-report="C:\data\openCDISC_v1.3_DM.xls"'` : the saved location of OpenCDISC Validator Report
- `-report:type="excel"` : output type as Excel
- `–report:overwrite=”yes”` : overwrite the previous OpenCDISC Validator Report.

HOW TO RUN OPENCDISC VALIDATOR 1.4

Below is a sample command that we can run using the same inputs as in Figure 1.2 using version 1.4. Appendix B shows the possible parameters that can be passed to the CLI Java program from SAS for OpenCDISC Validator 1.4.

```
**** running OpenCDISC by assigning command lines;
x java -jar “C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.4\lib\validator-cli-
1.4.jar" -task="validate" -type="sdtm" -source:type="sas" -source="C:\data\sdtm\dm.xpt"
-config="C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.4\config\config-sdtm-3.1.3.xml
\config-sdtm-3.1.2.xml" –config:cdisc=”2012-12-21” -report="C:\data\openCDISC_v1.4_DM.xls" -
report:type="excel"  –report:overwrite=”yes”;
```

The detailed parameters descriptions are as follow

- `-jar ""C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.4\lib\validator-cli-1.4.jar "` : The path of OpenCDISC Java program
- `-task="validate"` : we can choose either “validate” or “generate”
- `-type="sdtm"` : we can choose “sdtm”, “adam” or “send”
- `-source="C:\data\sdtm\dm.xpt"` : the path of source SDTM dm.xpt file
- `-source:type="sas"` : SAS transport file
- `-config="C:\zother\industry\CDISC\opencdiec\opencdisc-validator 1.4\config\config-sdtm-3.1.3.xml”` : the path and name of configuration
- `–config:cdisc=”2012-12-21”` : the version of CDISC terminology
- `-report="C:\data\openCDISC_v1.4_DM.xls"'` : the saved location of OpenCDISC Validator Report
- `-report:type="excel"` : output type as Excel
- `–report:overwrite=”yes”` : overwrite the previous OpenCDISC Validator Report.

The output is a little bit different because we are using SDTM 3.1.3 validation configuration.

BENEFITS OF RUNNING OPENCDISC IN SAS

1. One process.
2. We will be able to create a dataset and perform a compliance check in a single action.
3. We have a control on the name and saving location of the OpenCDISC Validator Report.

CONCLUSION

Running OpenCDISC in SAS can save time and effort. It will consolidate two processes into a single process. SAS programmers not only create CDISC datasets, but they also perform CDISC compliance checks running OpenCDISC in SAS.

REFERENCES

www.opencdisc.org

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I would like to acknowledge and extend my heartfelt gratitude to Eric Silver for sharing his expertise on Java Programs.
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CONTACT INFORMATION

Your comments and questions are valued and welcomed. Please contact the author at

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TRADEMARKS

APPENDIX A – OPENCDISC CLI JAVA PROGRAM PARAMETERS FOR VERSION 1.3

The list below contains the parameters that can be passed to the OpenCDISC Command Line Interpreter program. This list can be produced by running the following command:

```
C:\zother\industry\CDISC\opencdisc\opencdisc-validator 1.3\lib>java -jar validator-cli-1.3.jar -
help
```

- Values in parentheses ( ) are the default values if the parameter is not specified
- Values in brackets <> are descriptions and should be replaced by user
- Values separated by a pipe | indicate the only acceptable values

```
--------------------------------------------------------------------------
                 OpenCDISC Validator Command Line Client
--------------------------------------------------------------------------

The following parameters may be passed to the Validator. Note that
certain parameters may be required.

For additional help, or to submit suggestions, please visit our community
at http://www.opencdisc.org/

General Parameters
   -task               Validate|Generate (Validate)
   -type               SDTM|Define|Custom (SDTM)

Source Data Parameters
   -source              <path>
   -source:type         SAS|Delimited (SAS)
   -source:delimiter    <delimiter> (,)
   -source:qualifier    <qualifier> (")

Configuration Parameters
   -config              <path>
   -config:define       <path>
   -config:codelists    <path>

Report Parameters
   -report              <path>
   -report:type         Excel|HTML|CSV|XML (Excel)
   -report:cutoff       <#> (1000)
   -report:overwrite    yes|no

Generation Parameters
   -output              <path>
   -output:overwrite    yes|no
```

APPENDIX B – OPENCDISC CLI JAVA PROGRAM PARAMETERS FOR VERSION 1.4

The list below contains the parameters that can be passed to the OpenCDISC Command Line Interpreter program. This list can be produced by running the following command:

```
java -jar validator-cli-1.4.jar –help
```

- Values in parentheses ( ) are the default values if the parameter is not specified
- Values in brackets <> are descriptions and should be replaced by user
- Values separated by a pipe | indicate the only acceptable values

```
------------------------------------------------------------------------
                  OpenCDISC Validator Command Line Client
------------------------------------------------------------------------

The following parameters may be passed to the Validator. Note that certain parameters may be
required.

For additional help, or to submit suggestions, please visit our community at
http://www.opencdisc.org/

General Parameters
    -task               Validate|Generate (Validate)
    -type               SDTM|ADaM|SEND|Define|Custom (SDTM)

Source Data Parameters
    -source             <path>
    -source:type        SAS|Delimited (SAS)
    -source:delimiter   <delimiter> (,)
    -source:qualifier   <qualifier> (")

Configuration Parameters
    -config             <path>
    -config:define      <path>
    -config:codelists   <path>
    -config:cdisc       <version>
    -config:meddra      <version>

Report Parameters
    -report             <path>
    -report:type        Excel|CSV|XML (Excel)
    -report:cutoff      <#> (1000)
    -report:overwrite   yes|no

Generation Parameters
    -output             <path>
  -output:overwrite   yes|no
```