



Let SAS handle your CDISC compliance check: automating OpenCDISC Validator in SAS

Edwin J. van Stein, Chiltern International, The Netherlands

THE FINE ART OF CLINICAL RESEARCH

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Introduction

- OpenCDISC Validator: free, open source tool for checking clinical data compliance with CDISC standards
- Written in Java
- Graphical user interface and command line interface
- Input: SAS V5 XPORT files or delimited files
- Output: Excel or CSV



Introduction

OpenCDISC Validator

File Help

What would you like to do? ☒ Validate Data ☐ Generate Define.xml

Standard: SEND

Source Format: SAS® Transport (XPORT)

Source Data:

Browse
Remove
Clear

You can select multiple files or folders as sources

Configuration: config-send-3.0.xml

Define.xml:

Optional

Report Format: CSV [Report Settings](#)

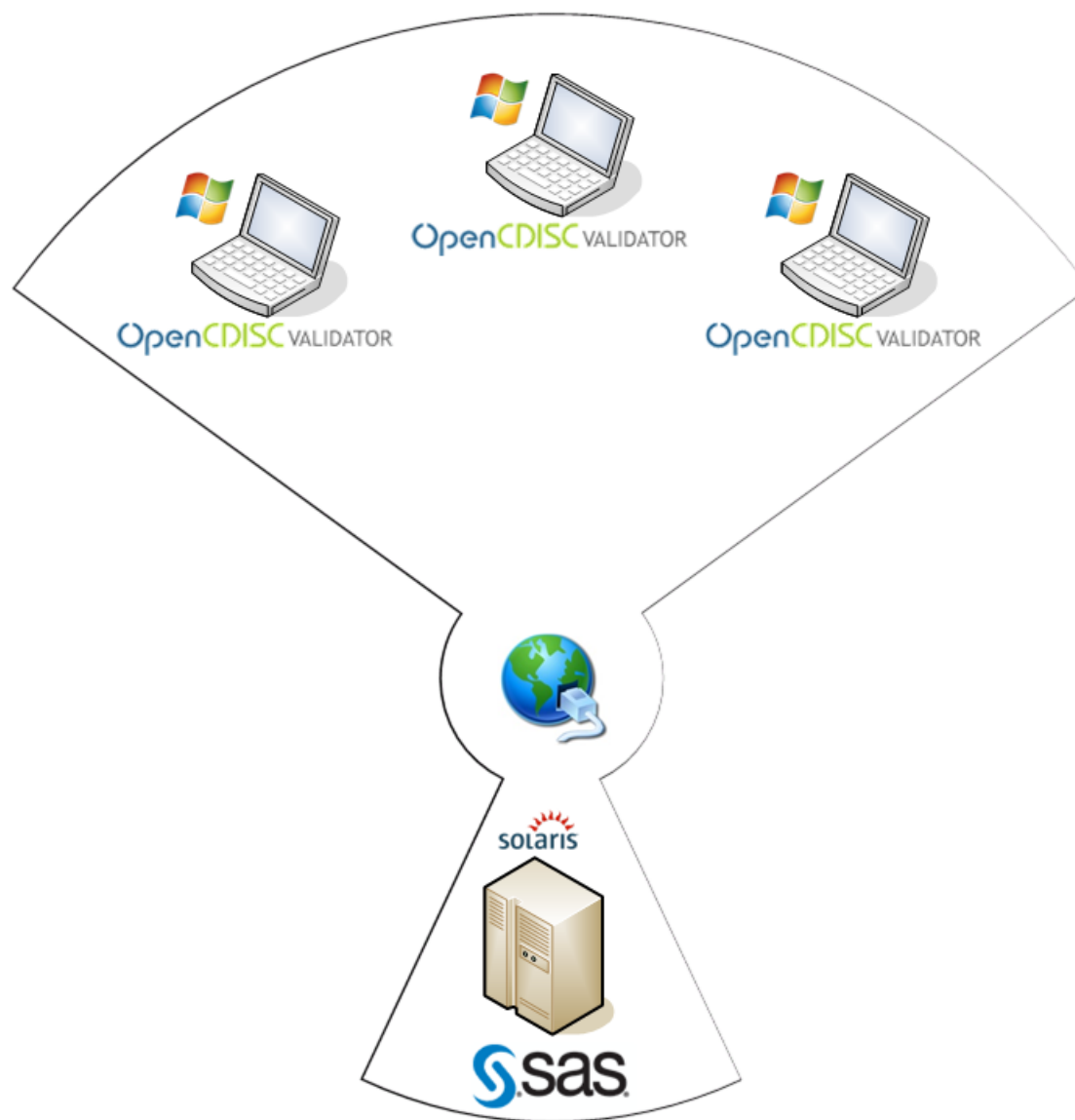
Progress:

Waiting to begin.

Start Stop



Rationale



Running OpenCDISC Validator CLI

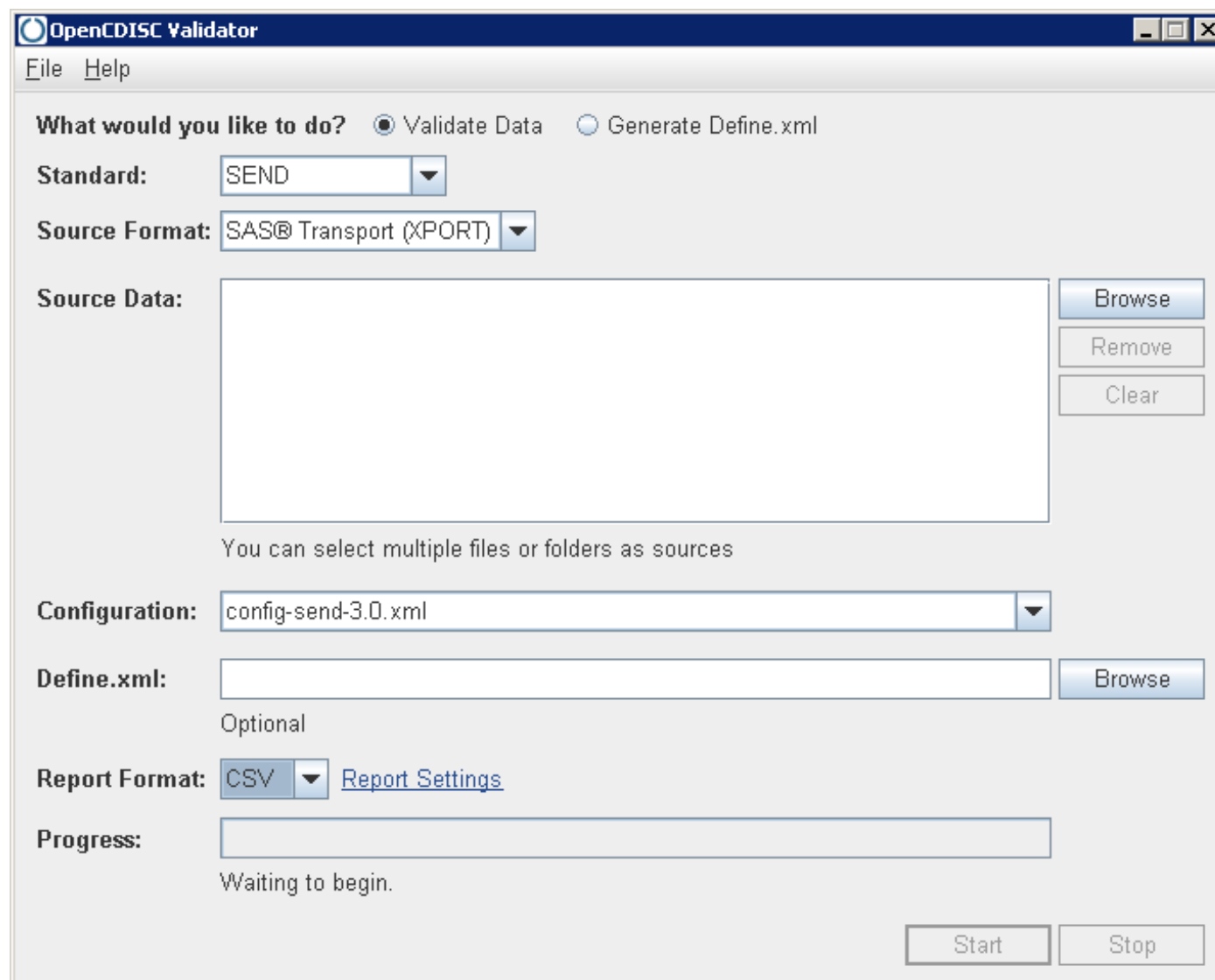
```
cd [location of OpenCDISC]  
[Java application launcher location]\java [options] -jar [OpenCDISC jar]  
[parameters]
```

- Go to OpenCDISC directory
- Launch Java
- Specify validator-cli-1.3.jar for the –jar option
- Add OpenCDISC parameters

```
cd C:\sas\opencdisc  
C:\sas\java\bin\java -jar lib\validator-cli-1.3.jar -source=C:\sas\testdata\*.xpt  
-config=config\config-sdtm-3.1.2.xml
```



Running OpenCDISC Validator CLI

A screenshot of the OpenCDISC Validator application window. The window has a title bar with the text "OpenCDISC Validator" and standard window controls. Below the title bar is a menu bar with "File" and "Help". The main area contains several sections: "What would you like to do?" with radio buttons for "Validate Data" (selected) and "Generate Define.xml"; "Standard:" with a dropdown menu showing "SEND"; "Source Format:" with a dropdown menu showing "SAS® Transport (XPORT)"; "Source Data:" with a large empty text box and three buttons: "Browse", "Remove", and "Clear"; "Configuration:" with a dropdown menu showing "config-send-3.0.xml"; "Define.xml:" with an empty text box and a "Browse" button; "Report Format:" with a dropdown menu showing "CSV" and a link to "Report Settings"; and "Progress:" with an empty progress bar. At the bottom right are "Start" and "Stop" buttons. A status bar at the bottom says "Waiting to begin."

OpenCDISC Validator

File Help

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Source Data:

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You can select multiple files or folders as sources

Configuration: config-send-3.0.xml

Define.xml:

Browse

Optional

Report Format: CSV [Report Settings](#)

Progress:

Waiting to begin.

Start Stop

Running **system commands** in SAS

- Multiple ways:
 - X statements
 - X commands
 - FILENAME PIPE statements
 - CALL SYSTEM routine
 - SYSTASK statements
 - %SYSEXEC calls



Running **system commands** in SAS

Important options:

- XCMD
- XSYNC
- XWAIT

Other things to keep in mind:

- Command separator is operating system dependent
- Directory delimiter is operating system dependent
- Redirection sequence **2>&1**
 - File handle 0: standard input (STDIN)
 - File handle 1: standard output (STDOUT)
 - File handle 2: standard error (STDERR)



Running **system commands** in SAS

```
filename javachk pipe "cd C:\sas\opencdisc  
& C:\sas\java\bin\java -version 2>&1";
```

```
data _javachk;  
  infile javachk;  
  input;  
  length cmd $2000;  
  cmd=_infile_;  
run;
```

VIEWTABLE: Work._javachk	
	cmd
1	java version "1.6.0_31"
2	Java(TM) SE Runtime Environment (build 1.6.0_31-b05)
3	Java HotSpot(TM) Client VM (build 20.6-b01, mixed mode, sharing)

Combining OpenCDISC Validator and SAS

```
filename runoc pipe "cd C:\sas\opencdisc & C:\sas  
  \java\bin\java -jar lib\validator-cli-1.3.jar -  
  source=C:\sas\testdata\*.xpt -config=config  
  \config-sdtm-3.1.2.xml 2>&1";
```

```
data _runoc;  
  infile runoc;  
  input;  
  length cmd $2000;  
  cmd=_infile_;  
run;
```

VIEWTABLE: Work._runoc	
	cmd
1	Beginning validation, please wait...
2	The validation has completed.



Getting the results in SAS

opencdisc-report-2012-07-23T14-00-28.xls [Compatibility Mode] - Microsoft Excel

OpenCDISC Validator Report							
Configuration: C:\sas\opencdisc\config\config-sdtm-3.1.1.xml							
Define.xml: Not provided							
Generated: 2012-07-23T14:00:29							
Processed Sources							
Name	Label	Class	Source	Records	Errors	Warnings	Notices
AE	Adverse Events	Events	ae.xpt	111	0	0	0
CM	Concomitant Medications	Interventions	cm.xpt	36	0	0	0
DM	Demographics	Special Purpose	dm.xpt	153	0	1	1
DS	Disposition	Events	ds.xpt	393	0	3	0
DV	Protocol Deviations	Events	dv.xpt	27	0	0	0
EG	ECG Test Results	Findings	eg.xpt	25783	0	309	0
EX	Exposure	Interventions	ex.xpt	717	0	2	0
LB	Laboratory Tests	Findings	lb.xpt	9974	0	2835	0
MH	Medical History	Events	mh.xpt	25	0	0	0
ML	Interventions	Interventions	ml.xpt	383	0	0	0
PC	Findings	Findings	pc.xpt	2592	0	0	0
PE	Physical Examinations	Findings	pe.xpt	2304	0	2	0
PG	Findings	Findings	pg.xpt	288	0	0	0
PP	Findings	Findings	pp.xpt	1288	0	0	0
SC	Subject Characteristics	Findings	sc.xpt	160	0	0	0
SE	Subject Elements	Study Design	se.xpt	1343	0	2	0
SU	Substance Use	Interventions	su.xpt	240	0	3	0
SUPPAE	Supplemental Qualifiers	Special Purpose	suppae.xpt	1128	0	0	0
SUPPCM	Supplemental Qualifiers	Special Purpose	suppcm.xpt	108	0	0	0
SUPPDM	Supplemental Qualifiers	Special Purpose	suppdm.xpt	299	0	0	0
SUPPDS	Supplemental Qualifiers	Special Purpose	suppds.xpt	49	0	0	0

Ready | Dataset Summary | Issue Summary | Details | Rules | 100%

Getting the results in SAS

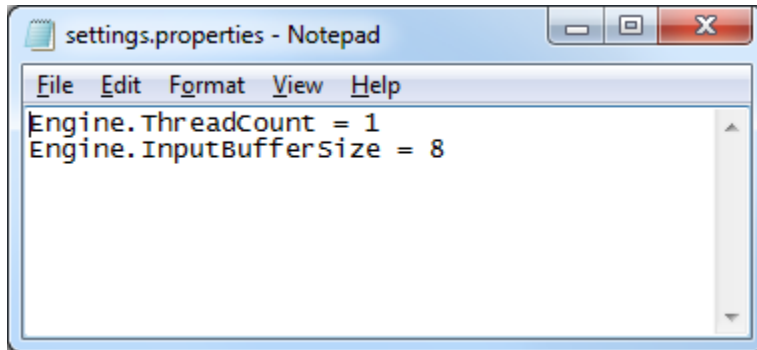
- Excel
 - SAS/ACCESS to PC Files and PC Files Server needed on Unix
- CSV
 - PROC IMPORT
 - DATA step with INFILE statement
- XML
 - LIBNAME XML with XMLMap

```
proc import datafile="C:\sas\opencdisc\reports  
  \report.csv" out=_report dbms=csv replace;  
  datarow=2;  
  getnames=yes;  
  guessingrows=32676;  
run;
```

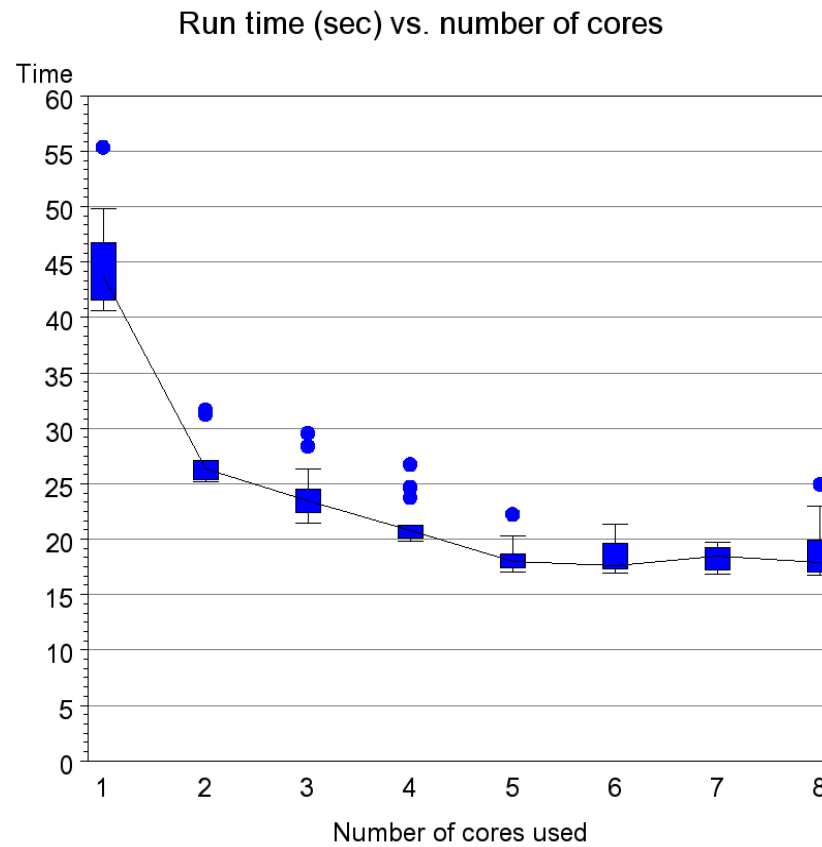


Performance

- lib\properties\settings.properties
 - Engine.ThreadCount



Performance



Troubleshooting

- Directories specified correctly?
- Does it run outside of SAS?
- Exotic Java exceptions > latest Java version?
- Does it run using the GUI?
- Can the OpenCDISC community help?



Other systems

- R-project: `system()` function
- Stata: shell command
- MATLAB: `system()` function or exclamation point character (!)



Conclusion

- Easy
- Safe valuable time
 - No file transfer needed
 - Leverage computing power of server
- Output available for further processing
 - Excel report: complete and looks good
 - CSV report: for further processing in SAS



Contribute

A screenshot of a web browser displaying the PhUSE Wiki page. The browser's address bar shows the URL: [http://www.phusewiki.org/wiki/index.php?title=Let SAS handle your CDISC compliance check: automating OpenCDISC Validator in SAS](http://www.phusewiki.org/wiki/index.php?title=Let_SAS_handle_your_CDISC_compliance_check:_automating_OpenCDISC_Validator_in_SAS). The page features a PhUSE logo on the left sidebar with navigation links like Home, Categories, Recent changes, Projects, FDA Working Groups, Annual Conference, Good Programming Practice, PhUSE Wiki Help, and Toolbox. The main content area has a title "Let SAS handle your CDISC compliance check: automating OpenCDISC Validator in SAS" in a large orange box. Below the title, it says "Edwin J. van Stein, Chiltern International, The Netherlands". A "Contents" box lists 12 sections: 1 ABSTRACT, 2 INTRODUCTION, 3 OPENCDISC COMMAND LINE INTERFACE, 4 CALLING IT FROM SAS, 5 OUTPUT, 6 PERFORMANCE, 7 TROUBLESHOOTING, 8 OTHER STATISTICAL SOFTWARE PACKAGES, 9 CONCLUSION, 10 REFERENCES, 11 CONTACT INFORMATION, and 12 DOWNLOADS. The "ABSTRACT" section is expanded, showing text about the OpenCDISC Validator tool. The "INTRODUCTION" section is also visible at the bottom.

[http://www.phusewiki.org/wiki/index.php?title=Let SAS handle your CDISC compliance check: automating OpenCDISC Validator in SAS](http://www.phusewiki.org/wiki/index.php?title=Let_SAS_handle_your_CDISC_compliance_check:_automating_OpenCDISC_Validator_in_SAS)

Questions?



THE FINE ART OF CLINICAL RESEARCH

Edwin J. van Stein
Chiltern International
Crown Business Center Key-Point
Schipholweg 103
2316 XC Leiden
The Netherlands

Email: edwin.vanstein@chiltern.com
ejvanstein@gmail.com

Web: <http://nl.linkedin.com/in/ejvanstein>

