CLI and Batch / SDTM-ETL Light execution of SDTM-ETL v.4.3

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This document describes how to run the transformations for generating SDTM from the command line using the CLI (Command Line Interface) or in batch, and how to use the "SDTM-ETL Light" version of the software, for executing mappings and generate SDTM files, but without working on the mappings themselves.

Running SDTM-ETL execution in batch mode / CLI mode

It is also possible to execute the mappings, and generate SDTM datasets from existing mappings, in line command or batch mode, e.g. on a server, using commands or scripts that are executed using the CLI (Command Line Interface).

Although it is easily possible to execute the software for generating SDTM/SEND datasets by typing the command from the command line, one will usually store the commend in a file (".bat" file on Windows, ".sh" file on Linux/Unix) and run that file. Such files are usually designated as "batch file".

The contents of such a batch file for will be very similar to the SDTM-ETL.bat file, but there are also a good number of differences, as the execution command has a good number of additional parameters.

First of all, the batch file should set the libraries for executing the software, for example:

The base for executing in batch mode is given by:

```
java -Xms256M -Xmx1024M -jar SDTM-ETL_Executor.jar
com.xml4pharma.sdtmetl.light.SDTMETLExecutor ...
```

The -Xms256M and -Xmx1024M parameters indicate the amount of memory the java VM is allowed to claim, the first being the amount at start, and the latter being the maximum allowed at all. 1024MB will be sufficient in most cases, but the user may decide to either a lower value or increase the amount of memory claimed by the Java Virtual Machine (VM), depending on the amount of mappings and the sizes of the files to be transformed.
It is advised never to allow more than about 50% of the available physical memory, as the operating system usually also uses a lot of memory.

The command is followed by the set of keywords and parameters. For example, in the case SAS-XPT must be generated:

```
java -Xms256M -Xmx1024M -jar  SDTM-ETL_Executor.jar
com.xml4pharma.sdtmetl.light.SDTMETLExecutor -DEFINEVERSION 2.0
-GENERATECOMMENTSDOMAIN
-DEFINEFILELOCATION C:\SDTM-ETL\TestFiles\MyStudy_Six_Domains_define_2_0.xml
-CLINICALDATAFILELOCATION C:\SDTM-ETL\TestFiles\ODM1-3\MyStudy_ODM_1_3.xml
-STUDYID MyStudy
-ODMVERSION 1.3
-METADATAFILELOCATION C:\SDTM-ETL\TestFiles\ODM1-3\MyStudy_ODM_1_3.xml
-GENERATESASXPT
-SASXPTDIRECTORYLOCATION C:\SASXPTSamples\
-GENERATERELRECDOMAIN
-GENERATECOMMENTSDOMAIN
-GENERATESUPPQUALDOMAINS
```

All these should be in a single line (no carriage return).

Or when Dataset-XML must be generated:

```
java -Xms256M -Xmx1024M -jar  SDTM-ETL_Executor.jar
com.xml4pharma.sdtmetl.light.SDTMETLExecutor
-DEFINEVERSION 2.0 -GENERATECOMMENTSDOMAIN
-DEFINEFILELOCATION C:\SDTM-ETL\TestFiles\MyStudy_Six_Domains_define_2_0.xml
-CLINICALDATAFILELOCATION C:\SDTM-ETL\TestFiles\ODM1-3\MyStudy_ODM_1_3.xml
-STUDYID MyStudy -ODMVERSION 1.3
-METADATAFILELOCATION C:\SDTM-ETL\TestFiles\ODM1-3\MyStudyNew_ODM_1_3.xml
-GENERATEDATASETXML
-DATASETXMLDIRECTORYLOCATION C:\temp\ -GENERATERELRECDOMAIN
-GENERATECOMMENTSDOMAIN
-GENERATESUPPQUALDOMAINS
```

I.e. each keyword starts with a dash ("-") and is, depending on the keyword itself, followed by a parameter value.
The list of keywords and parameters is given in the following table. Those given in bold-italic are ***mandatory***. If one of these is absent, the program will issue a warning and stop.

All parameters/keywords may be given either in lower case or mixed case or uppercase.
They will however be translated to uppercase before interpretation by the program.

Parameter / keyword	**Parameter value**	**Explanation**
-DEFINEFILELOCATION	file path	absolute or relative path of the define.xml file containing the mappings. See also remark on file paths.
-CLINICALDATAFILELOCATION	file path	absolute or relative path of the file containing the clinical data. See also remark on file paths.
-METADATAFILELOCATION	file path	absolute or relative path of the file containing the metadata (i.e. study design). This can be identical to the path for the clinical data when the file contains both metadata and clinical data.
-ADMINDATAFILELOCATION	file path	only necessary when the mappings use data from the administrative data section of the study, and this section is not included in the file with clinical data. The former is essentially the case when the SDTM-ETL functions "sitename()" is used in one or more mappings. See also remark on file paths.
-XMLOUTPUTFILELOCATION	file path	absolute or relative path of the file where the SDTM/SEND data in XML format will be written to. Required when the output is in Dataset-XML format. See also remark on file paths.
-STUDYID	OID of the study	The OID of the study, as given in the Study/@OID attribute of the file with metadata (or ClinicalData/@StudyOID in the file with clinical data).

Parameter / keyword	Parameter value	Explanation
-ODMVERSION	version of the ODM standard used for the study metadata and clinical data	Default is "1.2". Can be either "1.2", "1.3" or "1.3.1".
-DEFINEVERSION	Version of the define.xml file containing the mappings	Can be "1.0" or "2.0" or "2.1" Remark that Define-XML v.1.0 is outdated and has limited support in SDTM-ETL 4.0.
-GENERATESUPPQUALDOMAINS	none	keyword to indicate that supplemental qualifier datasets should be generated for: a) automated splitting of records with more than 200 characters (usually necessary when also SAS XPT datasets need to be generated) b) non-standard SDTM variables (NSVs) that need to be moved to the corresponding SUPP--domain. Remark that when this keyword is omitted, no splitting is done, which may be problematic when output is in SAS XPT format.
-GENERATERELRECDOMAIN	none	keyword to indicate that a RELREC domain needs to be automatically created for "RELREC" variables (see user manual for further details).
-GENERATE_1_N_RELREC	none	keyword to indicate that the software should attempt to generate 1:n relationships in the automatically generated RELREC domain. Only to be used in combination with the -GENERATERELRECDOMAIN keyword.
-GENERATECOMMENTSDOMAIN	none	keyword to indicate that a Comments (CO) domain needs to be automatically generated from "Comment" variables (see user manual for further details).
-GENERATESASXPT	none	keyword to indicate that SAS XPT SDTM/SEND datasets should be generated. It is recommended to then also use the keyword "-GENERATESUPPQUALDOMAINS" as otherwise records of more than 200 characters will be cut after the 200th character.
-SASXPTDIRECTORYLOCATION	file path	absolute or relative path of the directory where the SAS XPT files need to be written to. Only to be used in combination with the "-GENERATESASXPT" keyword

Parameter / keyword	Parameter value	Explanation
-GENERATEDATASETJSON	none	
-DATASETJSONDIRECTORYLOCATION	file path	
-GENERATEDATASETXML	none	keyword to indicate that modern CDISC Dataset-XML datasets should be generated. Either "-GENERATESASXPT" or "-GENERATEDATASETXML" or "-GENERATEUTF8CSV" must be provided
-DATASETXMLDIRECTORYLOCATION	file path	absolute or relative path of the directory where the Dataset-XML files need to be written to. Only to be used in combination with the "-GENERATEDATASETXML" keyword
-GENERATEUTF8CSV	none	keyword to indicate that UTF-8 encoded CSV should be generated. Either "-GENERATESASXPT" or "-GENERATEDATASETXML" or "-GENERATEUTF8CSV" must be provided
-UTF8CSVDIRECTORYLOCATION	file path	absolute or relative path of the directory where the UTF-8 encoded files need to be written to. Only to be used in combination with the "-GENERATEUTF8CSV " keyword
-UTF8CSVADDHEADERLINES	none	add 2 header lines to the UTF-8 encoded CSV file, one with the variable names, and one with the variable labels
-USETYPEDITEMDATA	none	keyword to indicate that the clinical data use "typed ItemData" elements (e.g. ItemDataInteger". May only be used when ODMVERSION is either 1.3 or 1.3.1 (so not for ODM version 1.2)
-ISOPENCLINICAVERSION	none	keyword to indicate that support needs to be provided for the OpenClinica 3.x extensions to the ODM standard. Can only be used with the "OpenClinica version" of the software.
-POSTPROCESSINGFORLOBXFL	none	keyword to indicate that --LOBXFL values must be generated using postprocessing for Findings datasets. Requires that the corresponding --LOBXFL variable is define in the define.xml that drives the dataset generation.
-GENERATEMERGEDDATASETSSPLITDOMAINS	none	keyword to indicate that in case that there are "split domain" datasets to be generated (e.g. LBUR, LBCH, LBHE), also a "merged" dataset (and possible the corresponding merged SUPP-- dataset) needs to be generated. This dataset than gets the name of the domain, extended by "_merg" (e.g. LB_merg.xpt)

Using "batch" execution in production

When having a process in place for doing the batch execution in production mode, it may be wise to use a define.xml file with the template removed, i.e. only keeping the study-specific domain/dataset definitions, this as loading the template takes considerable time.
One can generate such a "template-free" define.xml in SDTM-ETL using the menu "File - Save cleaned define.xml", but taking care that all mappings ("MethodDef" elements in the define.xml) are retained.

Of course, one should always test the batch execution carefully before taking it into production.

Example batch files

Example batch files can be found in the distribution. These can be used as start for your own files, but need to be adapted for your own use case, especially for the file paths. Following files are available:

Batch_example_SDTM-ETL_SASXPT.bat	Example file for generation of SDTM files in SAS XPT files
Batch_example_SDTM-ETL_DatasetJSON.bat	Example file for generation of SDTM files in modern Dataset-JSON format.
Batch_example_SDTM-ETL_DatasetXML.bat	Example file for generation of SDTM files in modern Dataset-XML format
Batch_example_SDTM-ETL_SASXPT_define_2-1.bat	Example file for generation of SDTM files in SAS XPT files from a Define-XML 2.1 file with mappings
Batch_example_SDTM-ETL_SASXPT_RWS.bat	Test example file using mappings that use RESTful web services for generating SDTM records

These example batch files use example ODM and Define-XML files from the "TestFiles" folder that is included in the distribution.

Remark concerning file paths

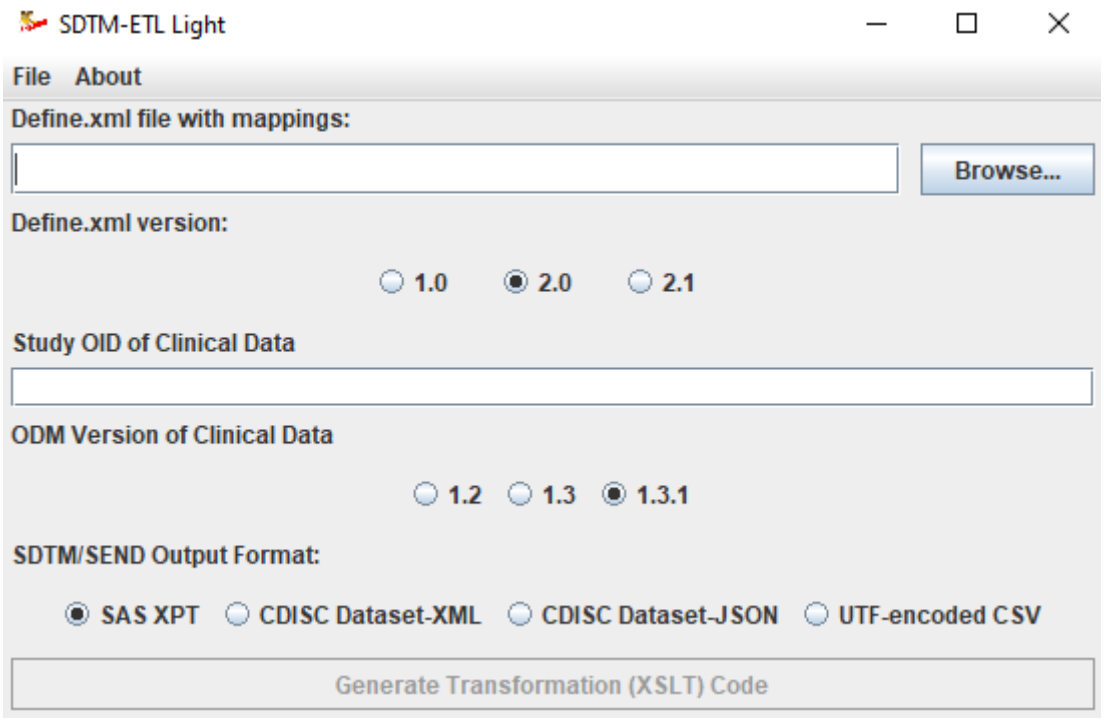
File paths can be absolute or relative with respect to the directory from which the batch execution is run.
In case the file path contains one or more blanks, the whole path should be embedded in double quotes. For example:

... -DEFINEFILELOCATION "C:\Documents and Settings\My Define Files\MyStudyDefine.xml"

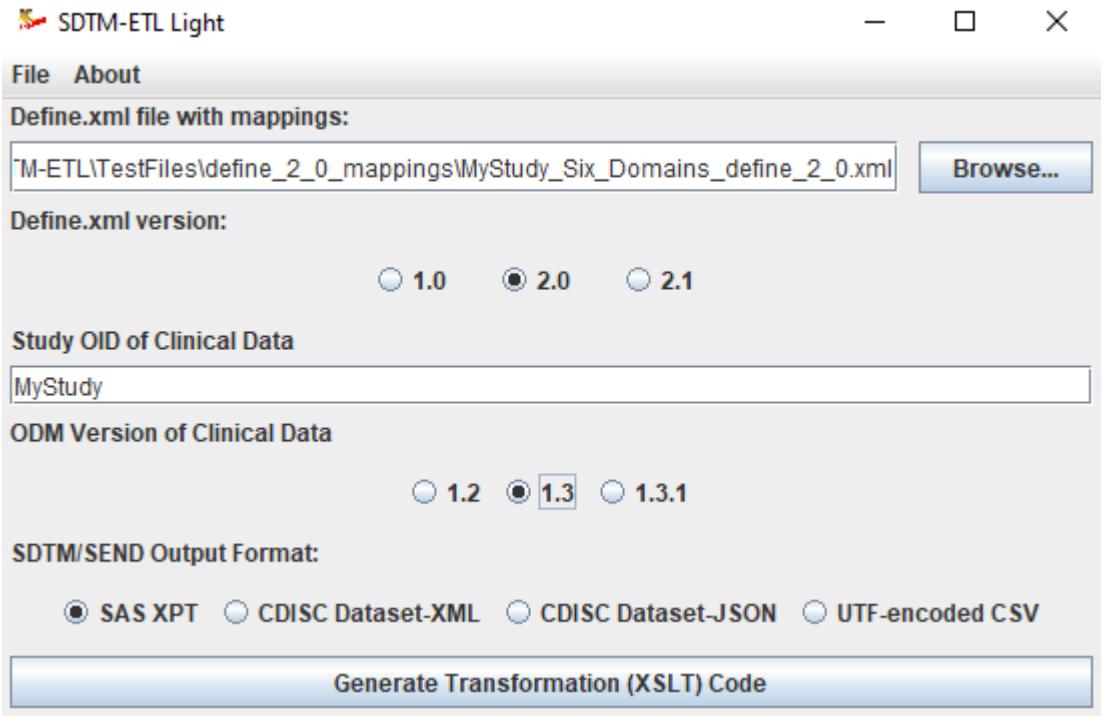
Starting transformation-execution-only from a simple graphical user interface ("SDTM-ETL Light")

Whereas the instructions provided above are ideal for executing the transformations on a server, e.g. at regular times using a cron job scheduler, some people may also want to execute the mappings on a normal PC or workstation, but without working on the mappings themselves, i.e. just executing them. For this use case, we developed a simple graphical interface. This "light" version can be started using the file "***SDTM-ETL_execution_only_GUI.bat***".

When started, the following graphical user interface is shown:

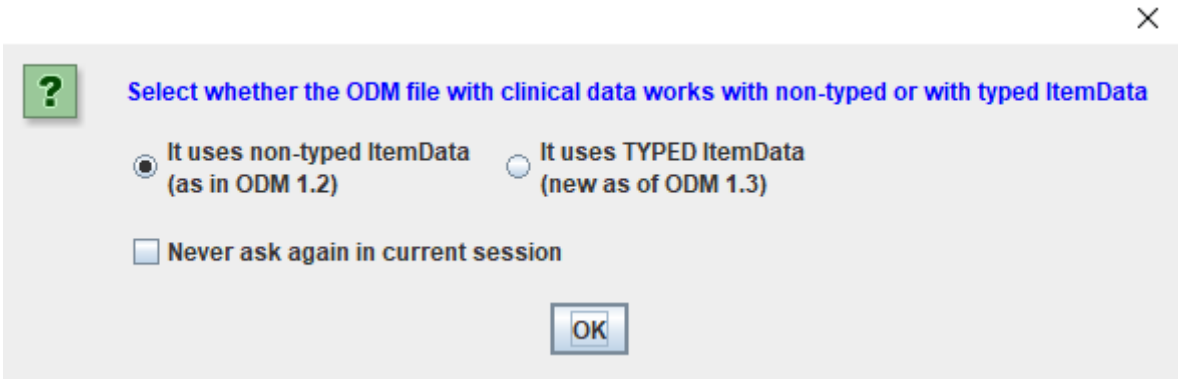


One should then fill in all fields and select the appropriate checkboxes, e.g.:

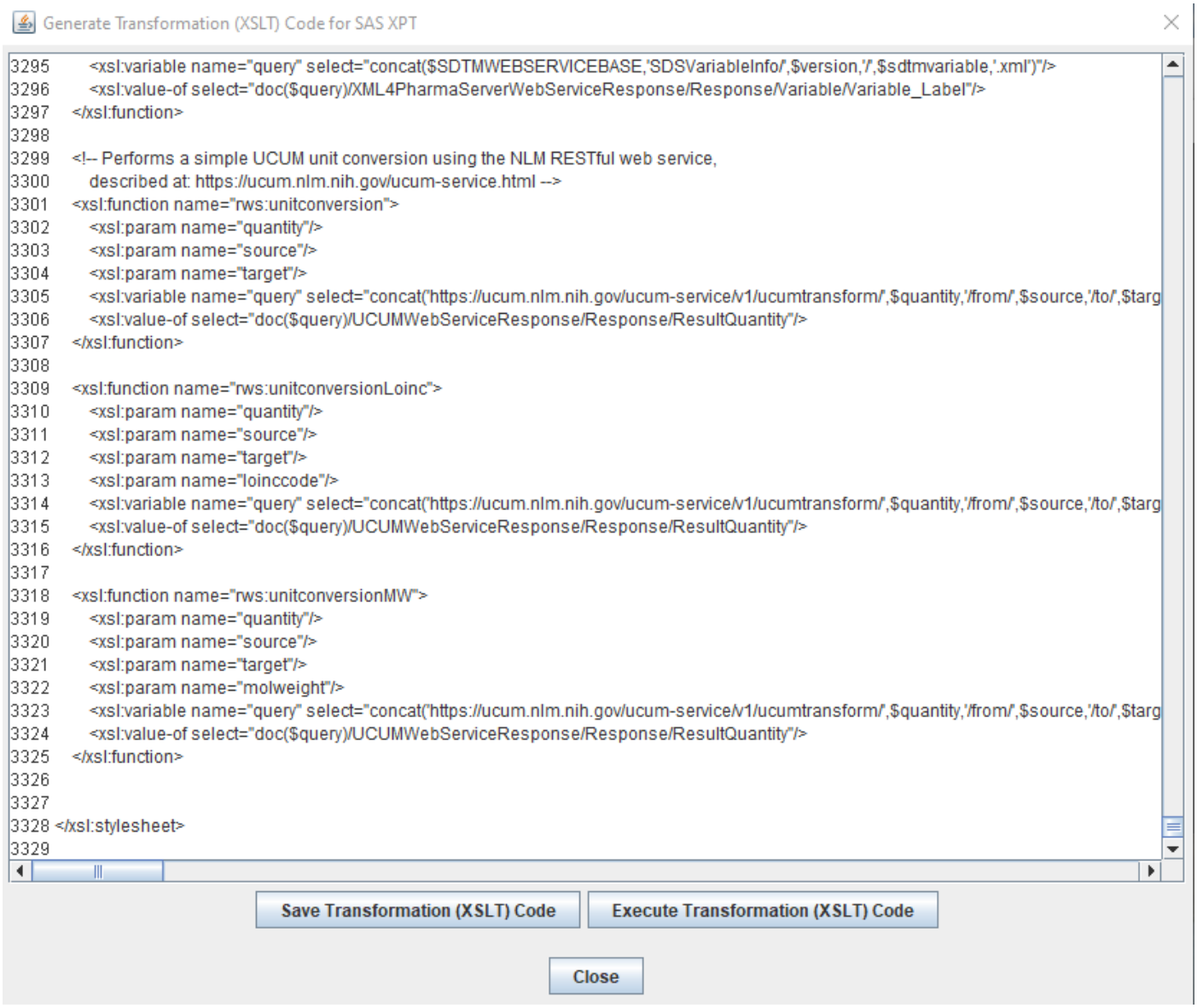


And can then choose between "SAS XPT" (SAS Transport 5), CDISC's own Dataset-XML or Dataset-JSON format, and UTF-8 encoded CSV for the output format.

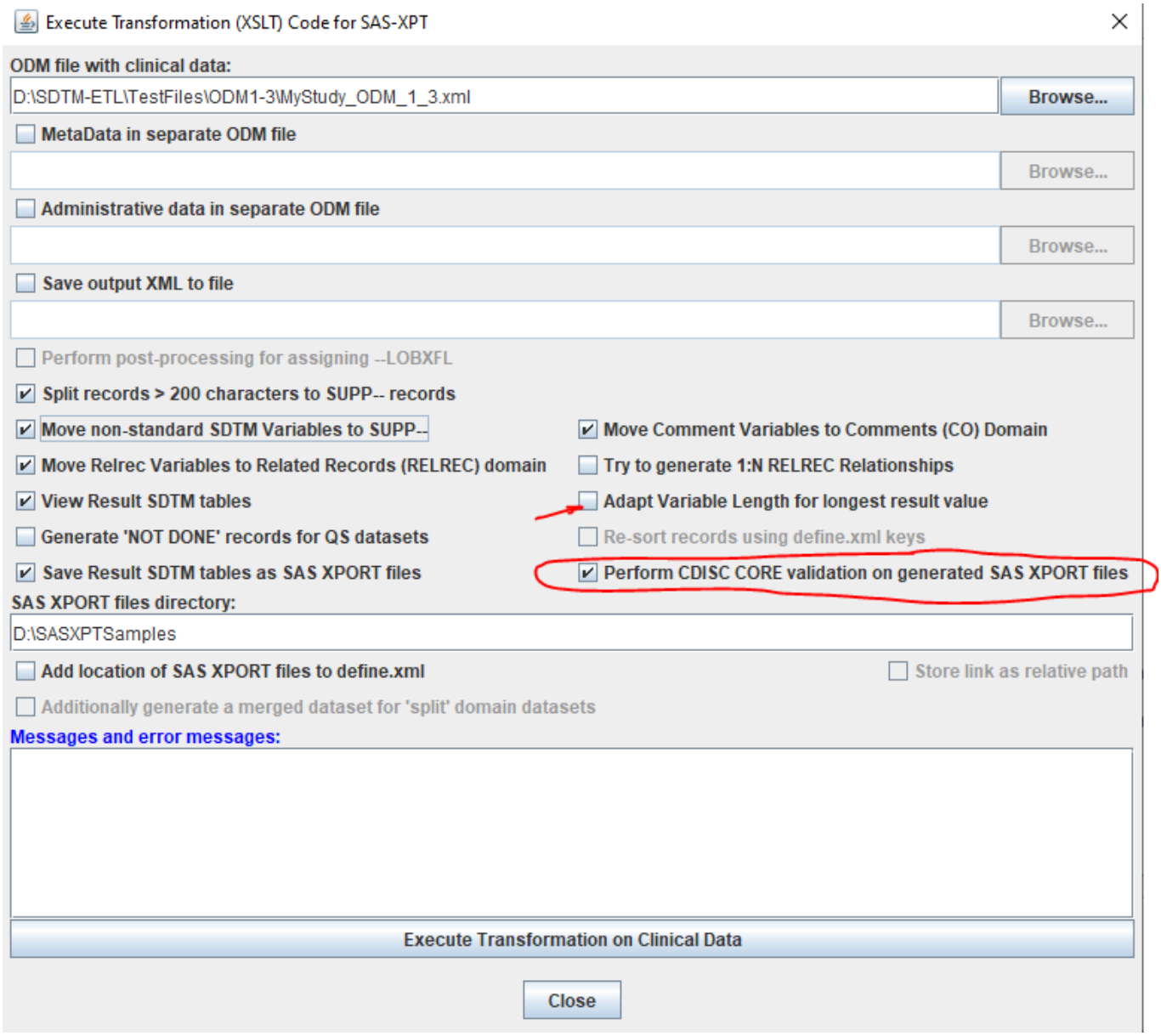
When the clicking the "Generate Transformation (XSLT) Code, the dialogs that we already know from the full version pop up:



followed by:



Upon clicking the "Execute Transformation (XSLT) Code" button, the classic dialog for entering source and target and the different options is displayed:



As usual, one can select several "special" options, such as optimizing the XPT files for file size[1], using the checkbox "Adapt Variable Length for longest value", generation of "NOT DONE" records in the case of QS datasets, and generation of "1:N" RELREC relationships".

New in SDTM-ETL 4.2 is that one can ask the system to re-sort the records according to the "keys" ("KeySequence" attributes) in the define.xml, which should only be necessary when the data in the source ODM is not in chronological order). The checkbox for this option will only be made visible when the system detects such keys in the define.xml file from which the mapping execution is started.
Another new feature in SDTM-ETL is to perform CDISC CORE validation on the generated datasets, essentially replacing the "crappy" Pinnacle21 validation engine.
See the separate documents "SDTM-ETL 4.2 new features overview" and "Validating SDTM/SEND datasets using CDISC-CORE" on the SDTM-ETL website.

The final step is then to click the button "Execute Transformation on Clinical Data" which starts the transformation execution.

For further details about the last steps, see the tutorials on the SDTM-ETL website.

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[1] This is due to that the outdated SAS-XPT is a highly inefficient format, where values, shorter than the variable length, are padded with blanks until the given length is reached.