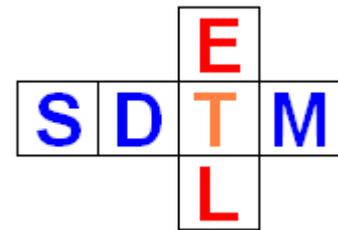# SDTM-ETL 4.0: Transforming define.xml 2.0 to define.xml 2.1

Author: Jozef Aerts, XML4Pharma

Last update: 2020-12-29

Define.xml 2.1

Already since its release in January 2019, the define.xml standard version is supported by and has been implemented in SDTM-ETL. For each of the new SDTM and SEND versions, templates are available and for most of the specific features of version 2.1, SDTM-ETL has ist wizards.
Also the FDA announced to accept define.xml 2.1 as of April 2021.

We also obtained signals from our customers that they want to move older projects that use define.xml 2.0 to define.xml 2.1. Other customers would like to submit to the FDA using define.xml 2.1, but have concerns about validation, as Pinnacle21 does not support define.xml 2.1. With the acquisition by Certara, there is also a fear that the P21 Community version will soon disappear, without ever have had support for define.xml 2.1. We are all waiting for CDISC CORE... These customers want to keep using define.xml 2.0, validate their datasets with P21 Community version as long as that is still possible, and then, at the very end, update the define.xml from v.2.0 to 2.1 for submission.

We therefore added a feature to be able to transform define.xml 2.0 files to 2.1.
This can be run either from SDTM-ETL directly or in stand-alone mode.

Transforming a loaded define.xml 2.0 to 2.1 within SDTM-ETL

After having loaded a define.xml 2.0 (or using the template), use the menu "Transform", followed by "Generate define.xml 2.1 starting from define.xml 2.0":
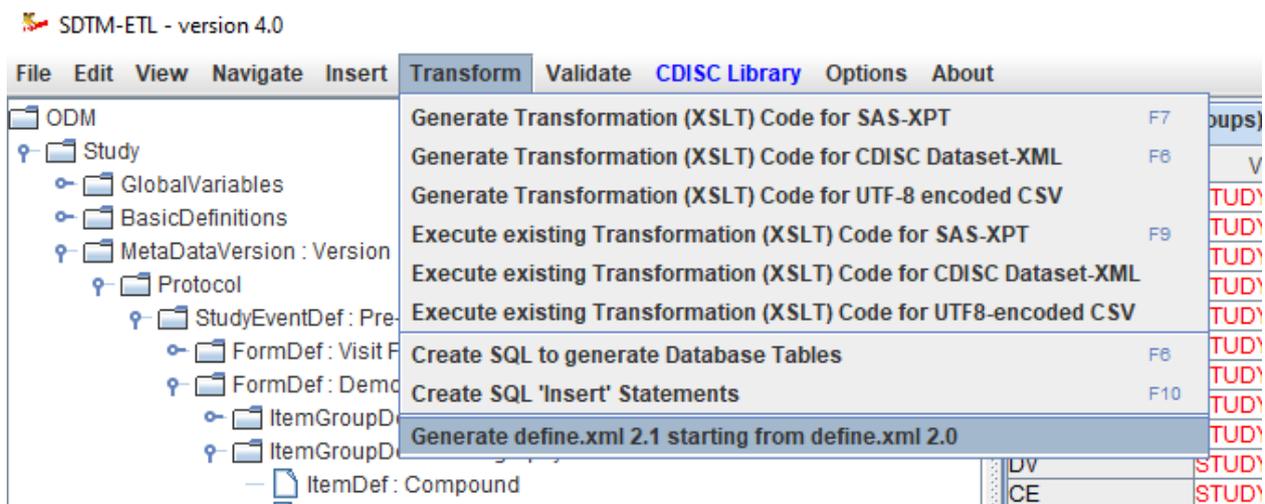
The following window then appears:

The user can choose between using the currently loaded define.xml 2.0 as the input, or another define.xml 2.0 from file. For the latter, select "define.xml 2.0 from file", and then use the upper "Browse" button to select the define.xml 2.0 file.

Then select the location for the define.xml 2.1 file to be created. For example:

Then click the "Transform" button.

The transformation is then executed, and after a few seconds the following message will appear:
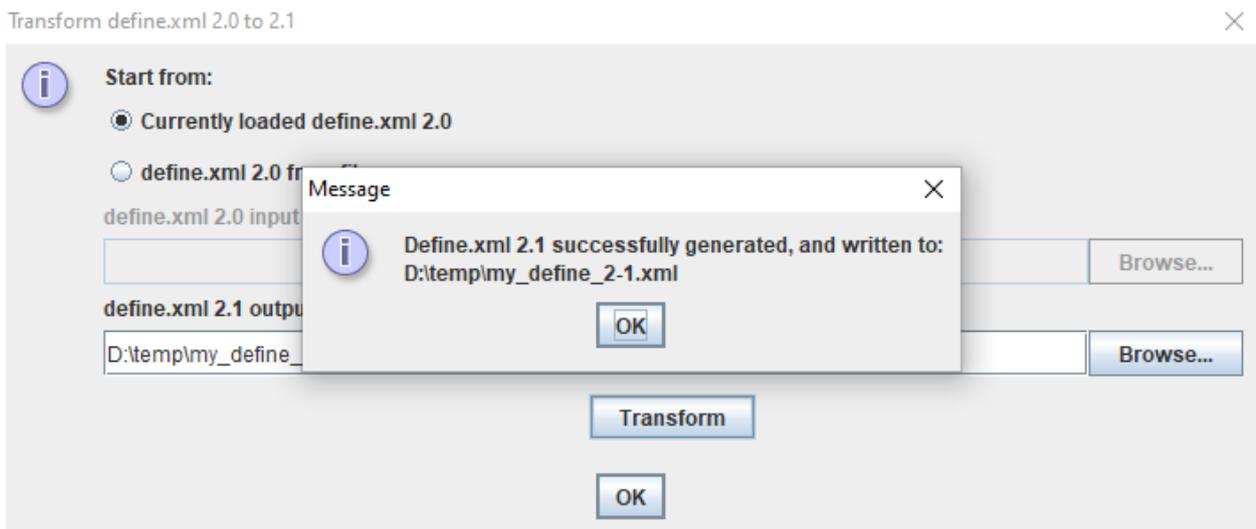
The user can then load the newly created define.xml 2.1 file, work with it, and also e.g. "clean it up" for the generation of a final submission file to the FDA or any other regulatory authority that accepts define.xml 2.1.
The original define.xml 2.0 file is not touched and remains available.

**<u>Transforming a define.xml 2.0 file to 2.1 in "stand alone" mode</u>**

One can also transform a define.xml 2.0 file to 2.1 in stand-alone mode.
For this, look in the folder where you installed the SDTM-ETL software.
For Windows, you will a file "define_2-0_to_2-1.bat":
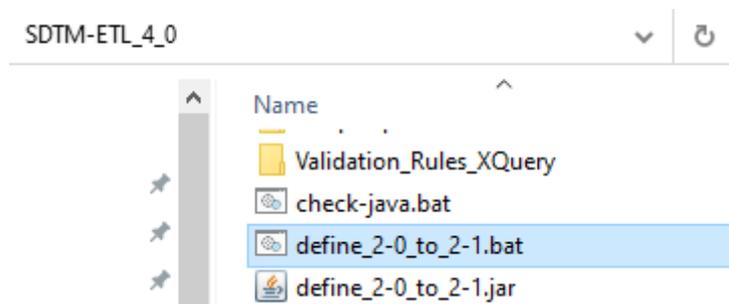
double-click "define_2-0_to_2-1.<u>bat</u>". The following window is then displayed:
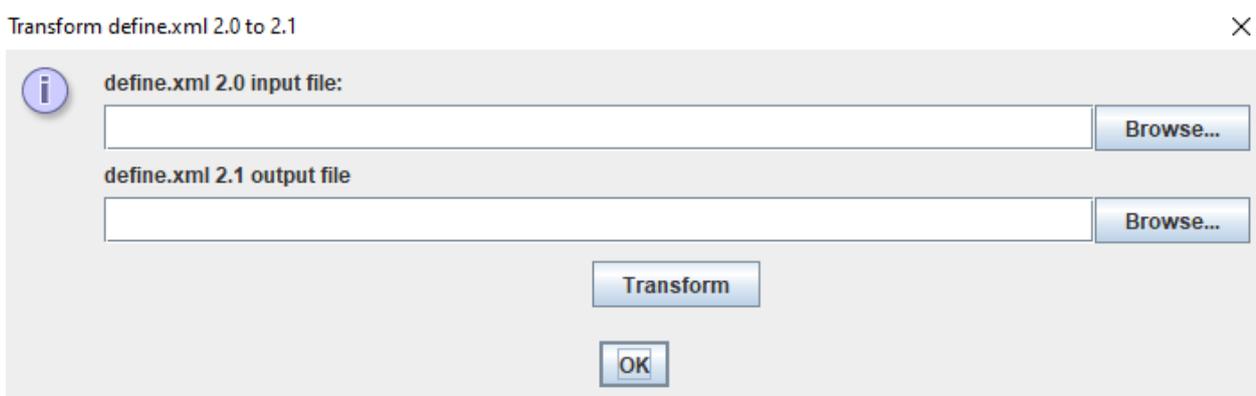
Then, use the "Browse" buttons to select an input define.xml 2.0 file, and the location (including file name) of the output define.xml 2.1 file to be created. For example:
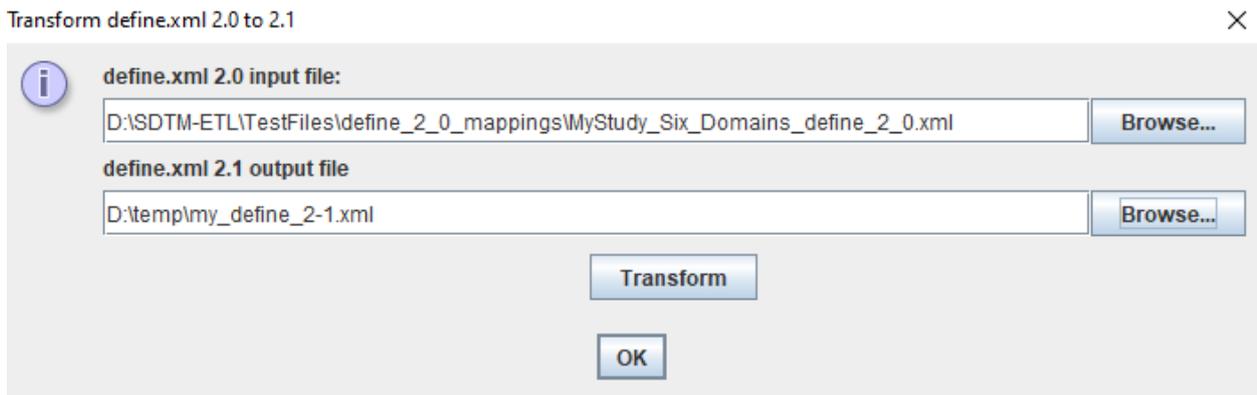
and use the "Transform" button to start the validation.
After a few seconds, a message appears:
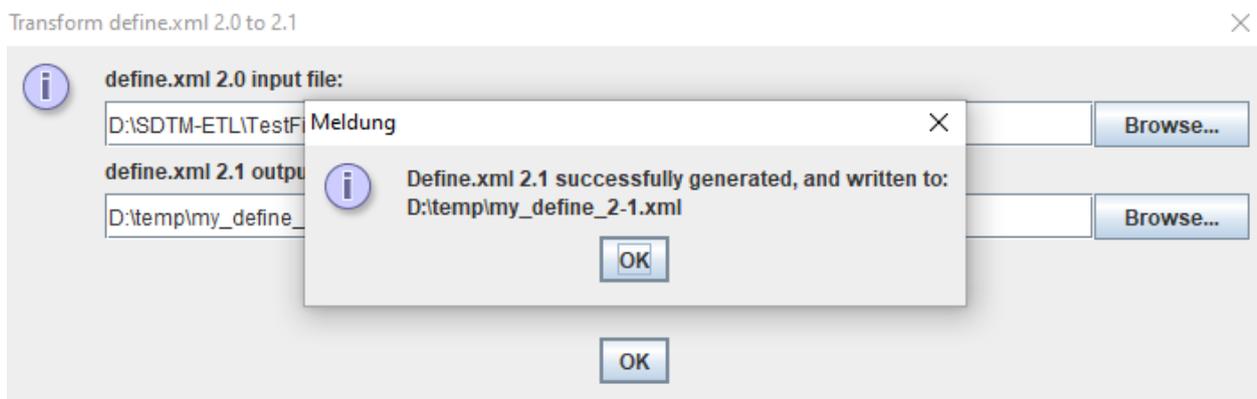
Limitations

A number of new features of version 2.1 of the Define-XML standard have not been implemented (yet) in SDTM-ETL, especially regarding using different versions of the SDTM-IG and SEND-IG depending on the domain (e.g. using SDTM-IG 3.4 for DM, and using SDTM-IG 3.3 for VS), as well as using different versions of controlled terminology for different variables.
This also means that when transforming a define.xml 2.0 to define.xml 2.1, all datasets will be assumed to conform to the same version of the SDTM-IG or SEND-IG, and that all variables will be assumed to use the same version of CDISC controlled terminology.