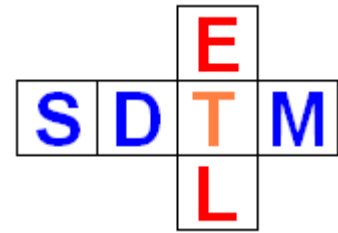SDTM-ETL 4.0 User Manual and Tutorial

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Working with Viedoc ODM files

Different vendors developed not only different vendor extensions to the CDISC ODM standard, but also use the ODM standard in different ways. For example, OpenClinica uses "one study per site" with one version of the metadata for each "study", encompassing for (slight) differences of the metadata per site.
Viedoc however sets up different "MetaDataVersion" instances within a single "Study" element in the ODM in some cases, e.g. for covering protocol updates.

SDTM-ETL however only accepts a single study and version of the metadata for developing and executing the mappings. This means that in the case of Viedoc-ODM with different versions of the metadata, these need to be merged into a single version, i.e. one single "MetaDataVersion" element within the ODM file with metadata.
This tutorial explains how this is done in SDTM-ETL v.4.0.

Working with ODM Viedoc files using the „Viedoc" of SDTM-ETL

Different customers have different EDC systems or different ODM exports available from different EDC systems. Therefore, we developed extensions to SDTM-ETL covering peculiarities for Medidata Rave, OpenClinica/ClinCapture and Viedoc. Each customer can then choose which of these must be supported in his/her instance of the software.

In the following example, we demonstrate the use of Viedoc-ODM for a customer who wanted to have support for as well OpenClinica 3.0 and 3.1, as for Viedoc v.4.
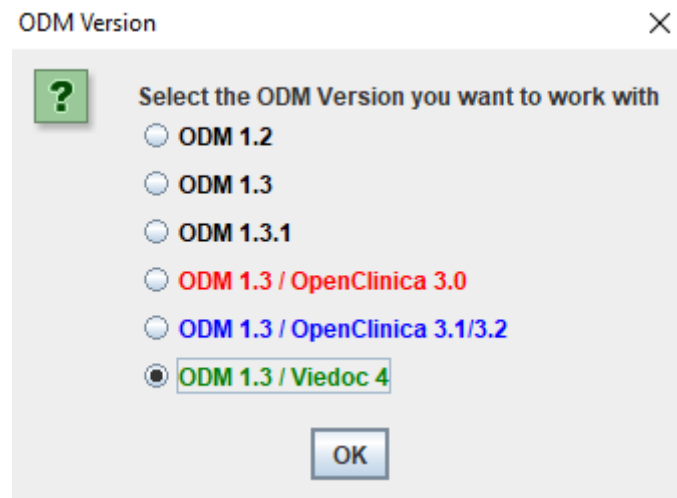
With this special version, one of the first dialogs that is displayed is:
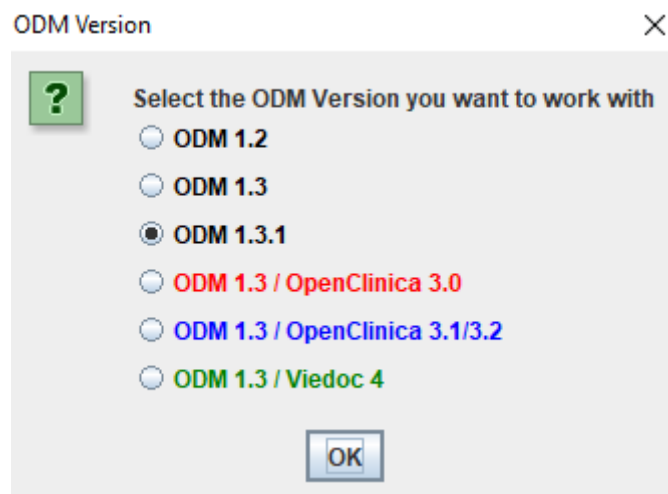
allowing you to choose with which ODM version you want to work. The OpenClinica ODM exports that are supported here are ODM 1.3 from OpenClinica 3.0, and ODM 1.3 from
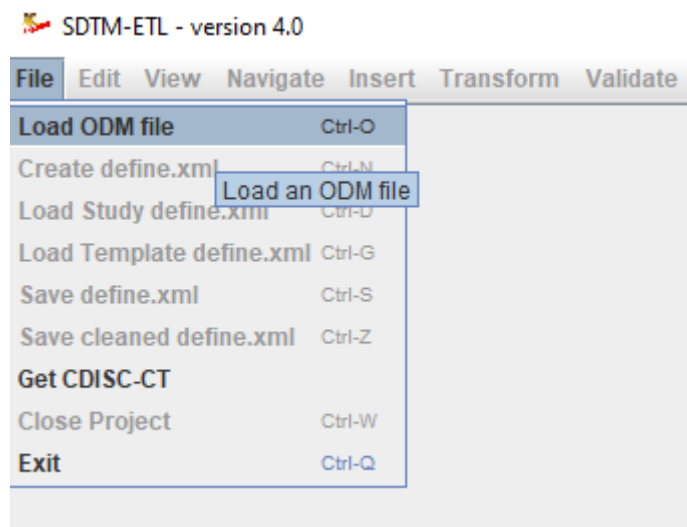
OpenClinica 3.1, as well as Viedoc version 4 ODM exports.
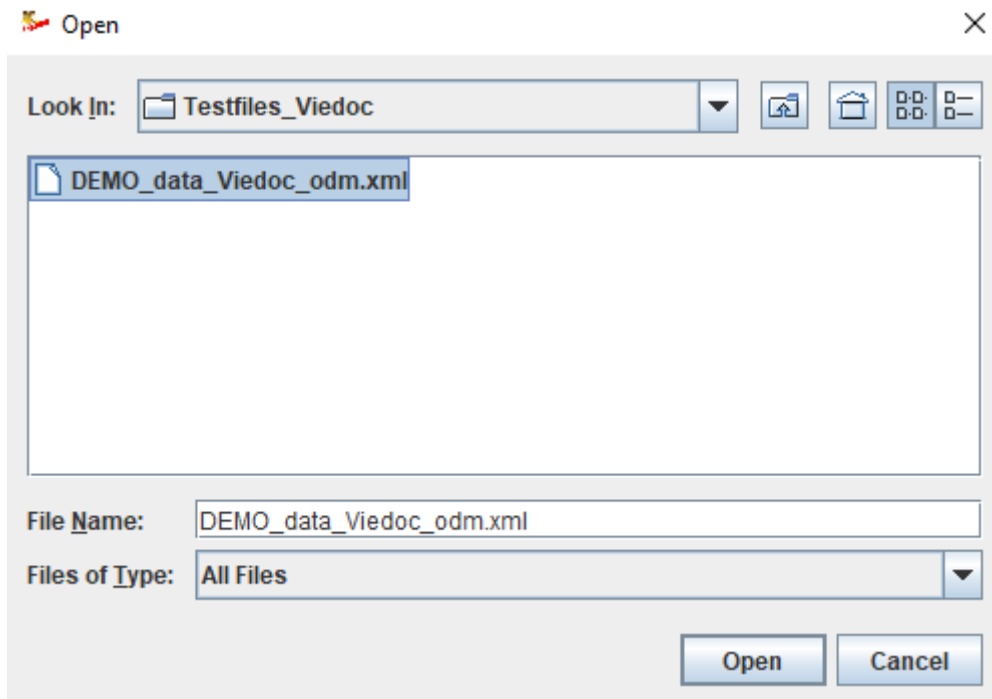
In our case, we select "ODM 1.3 / Viedoc 4".

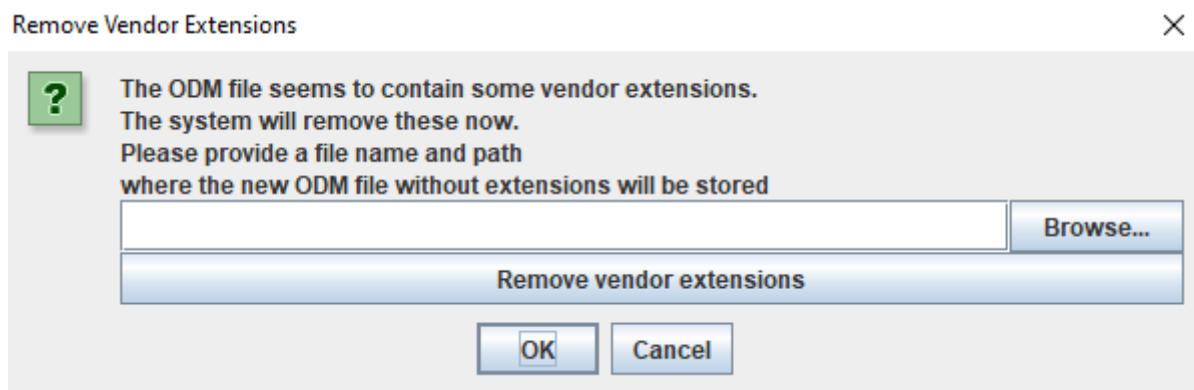This will then load the ODM file that was generated by Viedoc v.4 with extensions.

We can then start opening ODM files, in this case a Viedoc ODM file:


for example:

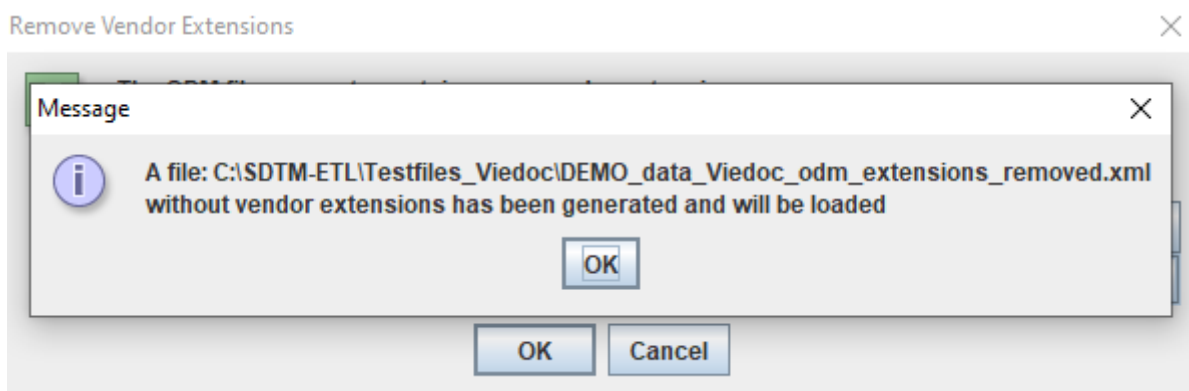After clicking "Open", the following dialog appears:

The Viedoc ODM file contains a Viedoc-specific vendor extensions, which all are administrative, and that we cannot use for the mapping, so these will be removed. We then need to provide a file name for the ODM file that will be generated. For example:
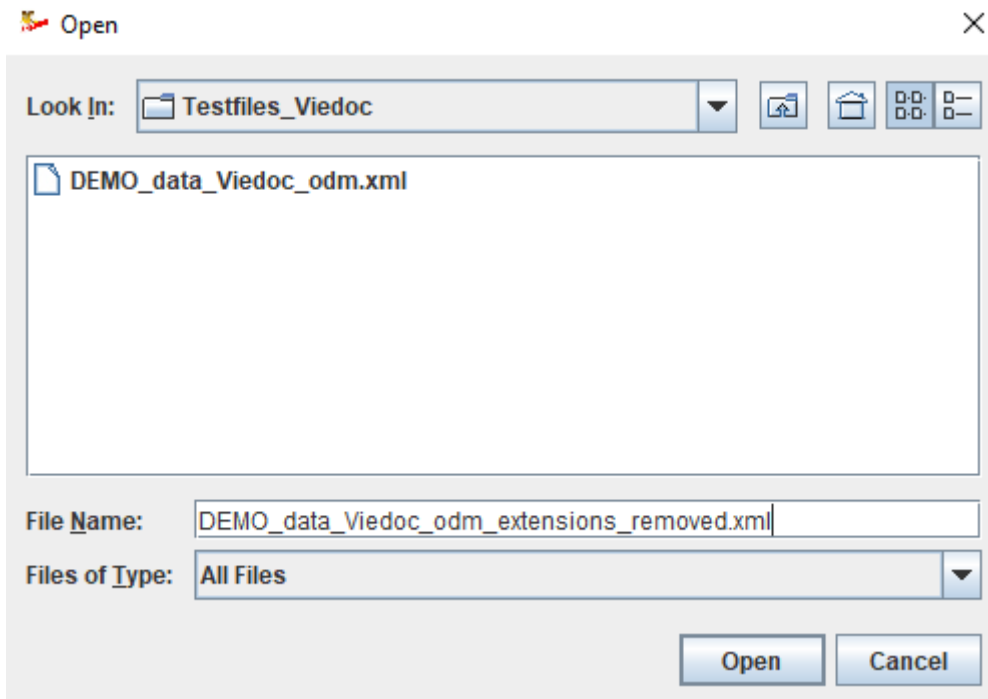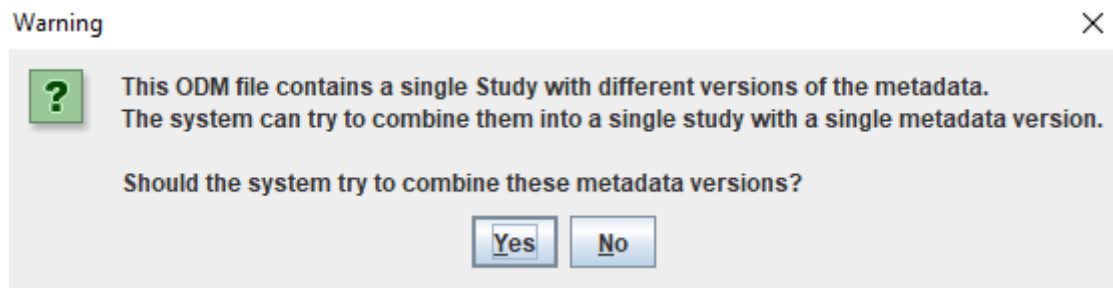
When one want to later continue with developing the mappings to SDTM, one can then start from the file without the Viedoc-specific extensions.

After clicking "Open", one can then start the removal of the extensions by clicking "Removing vendor extensions":
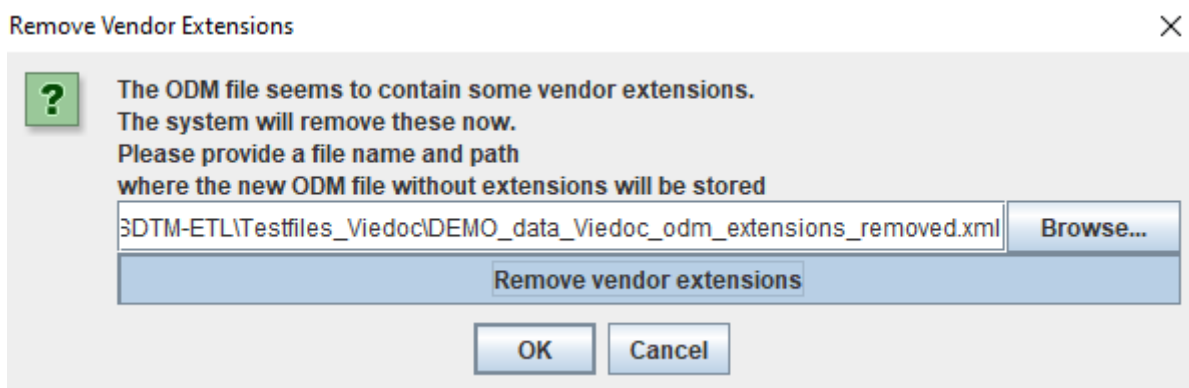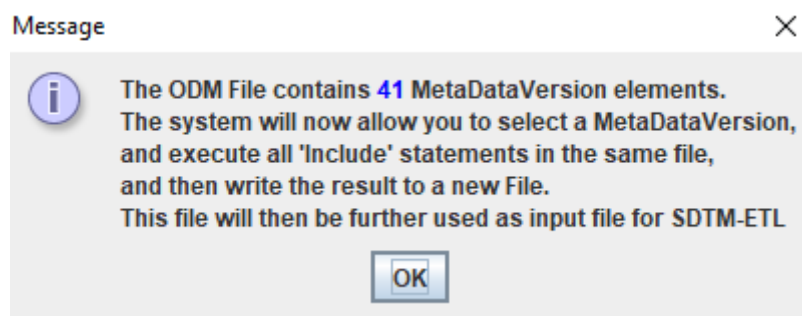

leading to, after about one minute:

Clicking "OK" twice then leads to the following dialog:

It might be that we only want to work with a single version of the metadata from the ODM file. In that case, "No" must be clicked, after which the system asks us which version of the metadata must be used:

followed by:
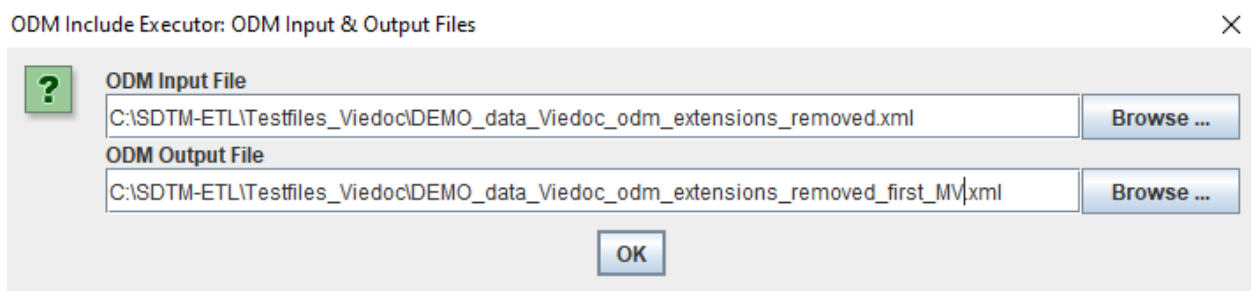
where we provide a file name and path for the ODM Output File, where we want to store the ODM file only containing our selected version of the metadata. After clicking "OK", the following dialog appears:

Select a MetaDataVersion/Study combination   ✕

? Following MetaDataVersion/Study combinations were found
  Please select the one you would like to implement
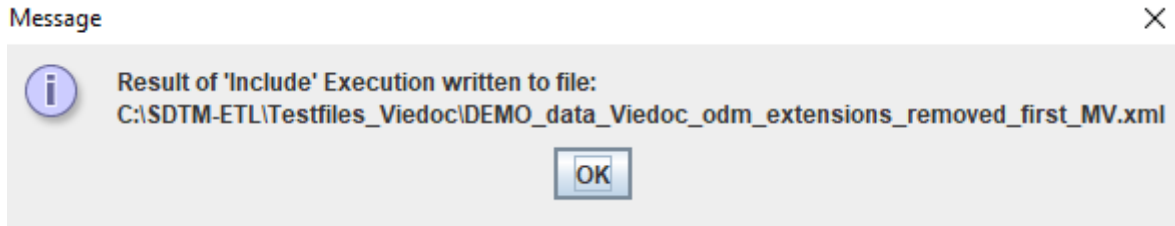 Entries in blue have an 'Include' statement
  MetaDataVersion OID   Study OID

○ 1.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 2.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 3.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 4.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 7.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 8.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 9.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 10.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 11.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 12.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 13.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 14.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 16.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 17.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 18.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 19.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 21.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 22.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 23.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ 24.0	0ab7b6af-a479-41d0-899f-7837756285e4

OK

Listing all the versions of the metadata found in this file. If we e.g. only want to use the last (latest) one, we select it and then click "OK":

○ 41.1	0ab7b6af-a479-41d0-899f-7837756285e4
○ 42.1	0ab7b6af-a479-41d0-899f-7837756285e4
○ 43.0	0ab7b6af-a479-41d0-899f-7837756285e4
● 44.0	0ab7b6af-a479-41d0-899f-7837756285e4
○ GEN_CODELISTS	0ab7b6af-a479-41d0-899f-7837756285e4

OK

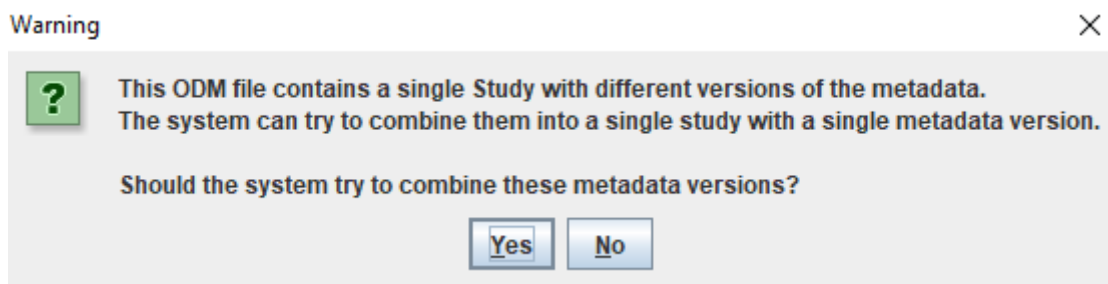Remark that verion "GEN_CODELISTS" only contains codelists, so is not of use for us.
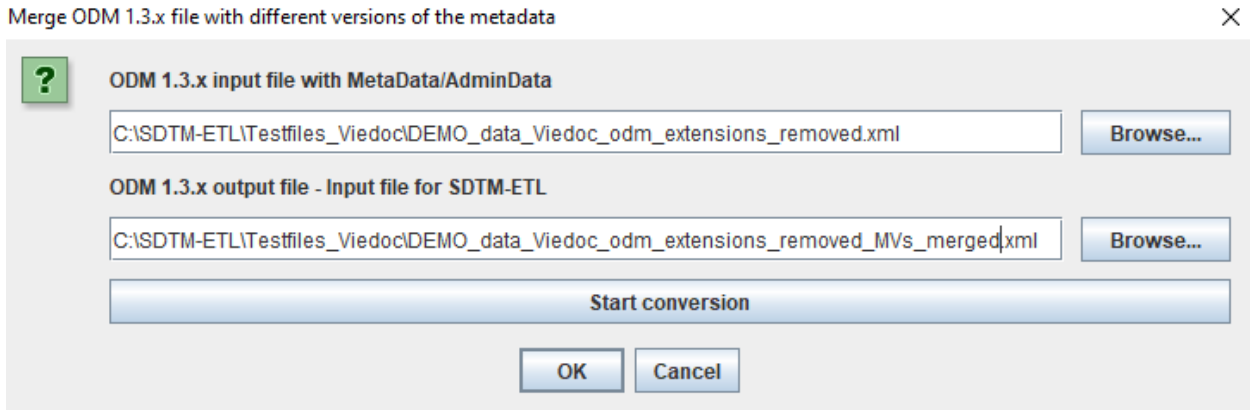
After clicking "OK", we get:

Message ✕

ⓘ **Result of 'Include' Execution written to file:**
C:\SDTM-ETL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed_first_MV.xml

OK

followed by the usual "Validation" dialog:

CDISC ODM Validation — ☐ ✕

Check CDISC ODM file
Selected file:
**DEMO_data_Viedoc_odm_extensions_removed_first_MV.xml**

Ready Cancel
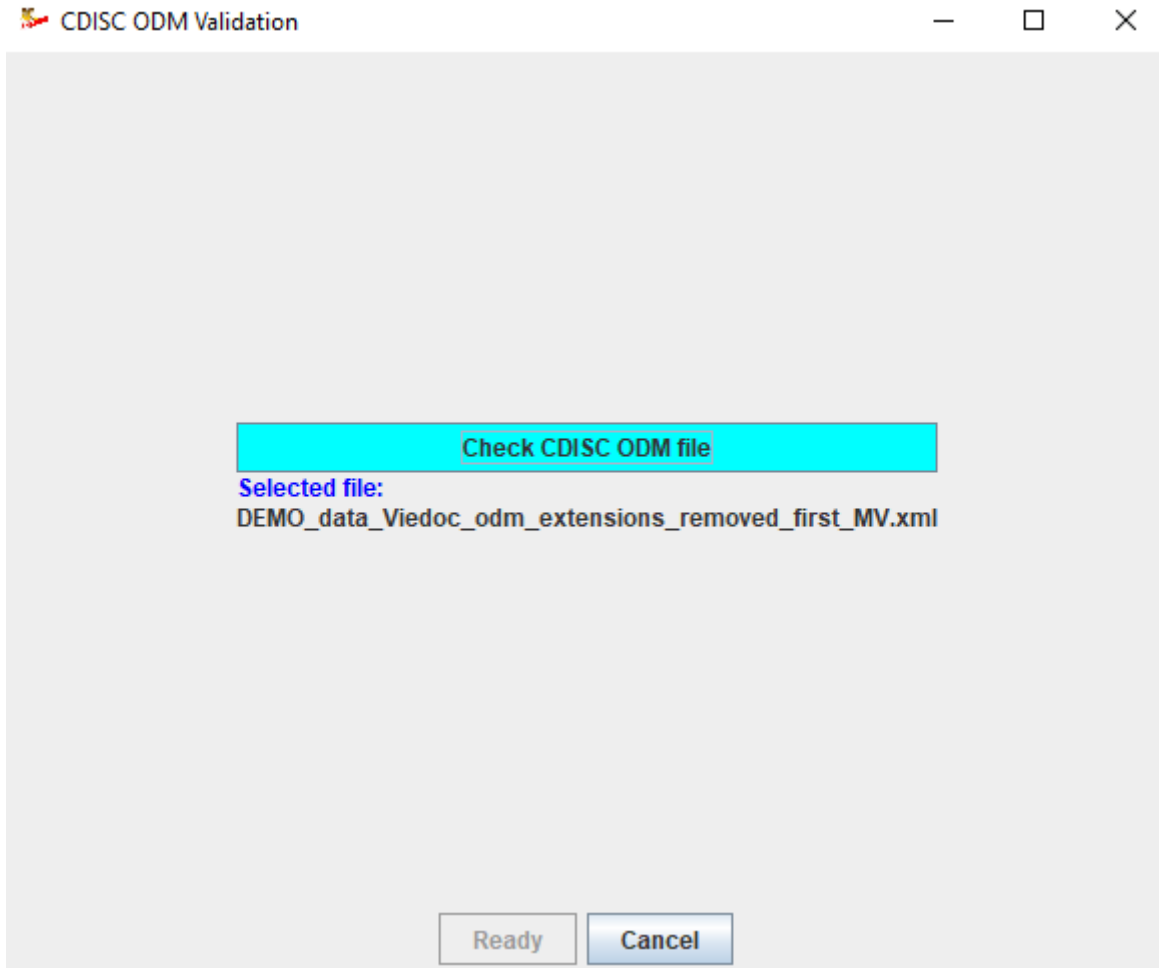
In case however we do NOT want to use a single version of the metadata from the many, but want to merge all versions of the metadata into a single one, we need to click "Yes" in the dialog asking us whether to select one version of the metadata or to merge them all into a single one:

Warning ✕

? **This ODM file contains a single Study with different versions of the metadata.**
The system can try to combine them into a single study with a single metadata version.

Should the system try to combine these metadata versions?
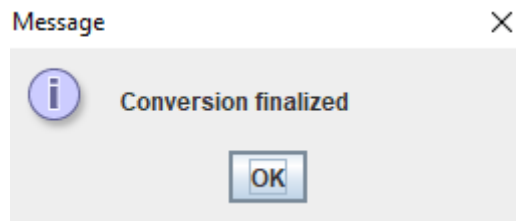
Yes No

After clicking "Yes", we get:

where we provide a file name and path under "ODM 1.3.x output file" for the file with a single, merged version of the metadata. We then need to click "Start conversion":
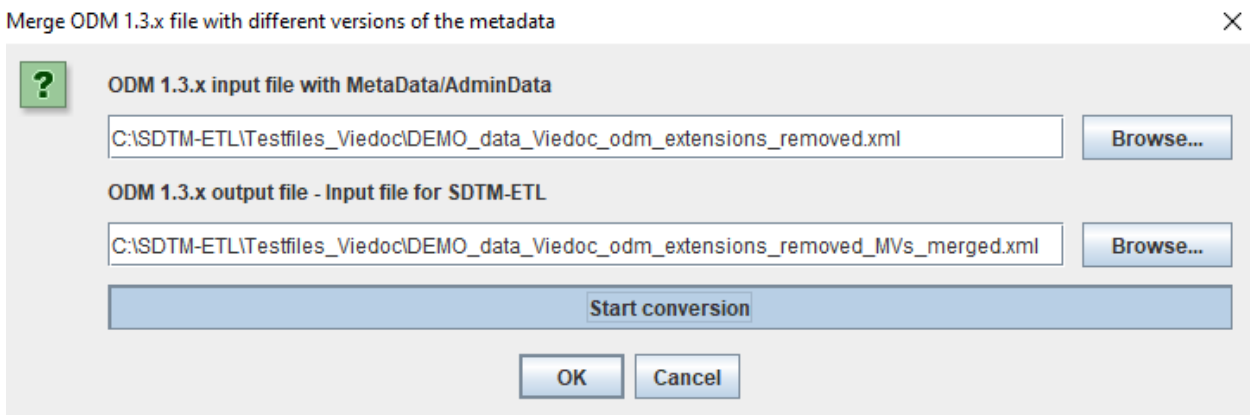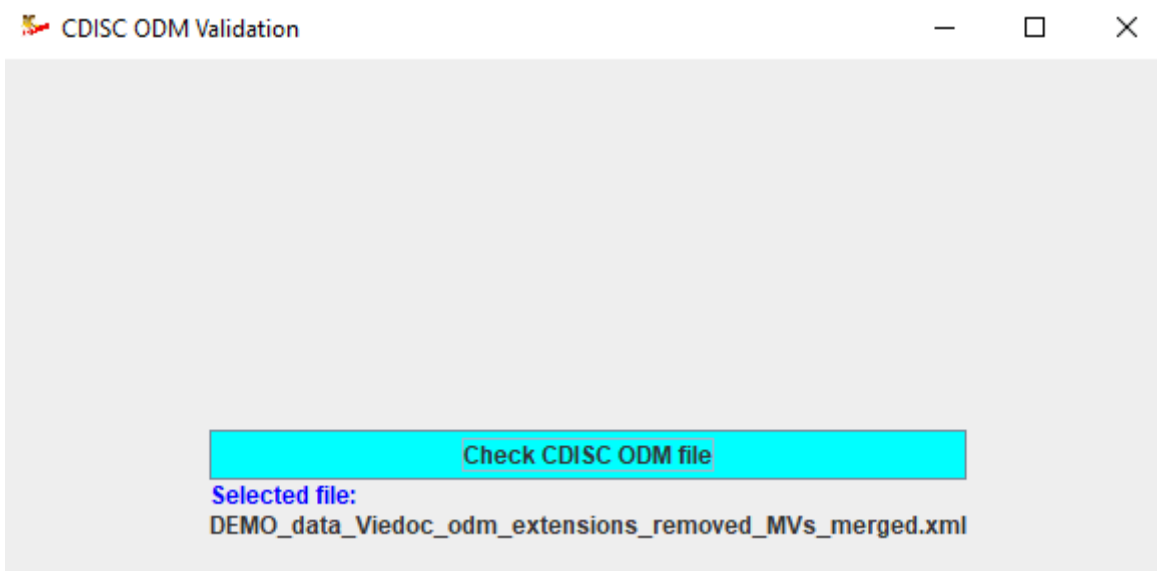

Depending on the size and number of metadata versions, the conversion can take up to a minute. When finished, a message is displayed:

Clicking "OK" twice then leads to the usual "Validation" dialog:

In this case, the result of the validation is:

Results from checking the CDISC ODM Document

Checking ODM file C:\SDTM-ETL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed_MVs_merged.xml

Level 1 ERROR The content of element 'Question' is not complete.
At least one of the following is expected:
- TranslatedText

Level 1 ERROR The content of element 'Question' is not complete.
At least one of the following is expected:
- TranslatedText

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Level 1 ERROR The content of element 'Question' is not complete.
At least one of the following is expected:
- TranslatedText

stating that for some "Question" (under "ItemDef") elements, the mandatory "TranslatedText" element is missing. This is however a minor discrepancy with the CDISC ODM standard, so we decide to continue loading anyway:

The ODM tree is then generated, e.g. looking like:
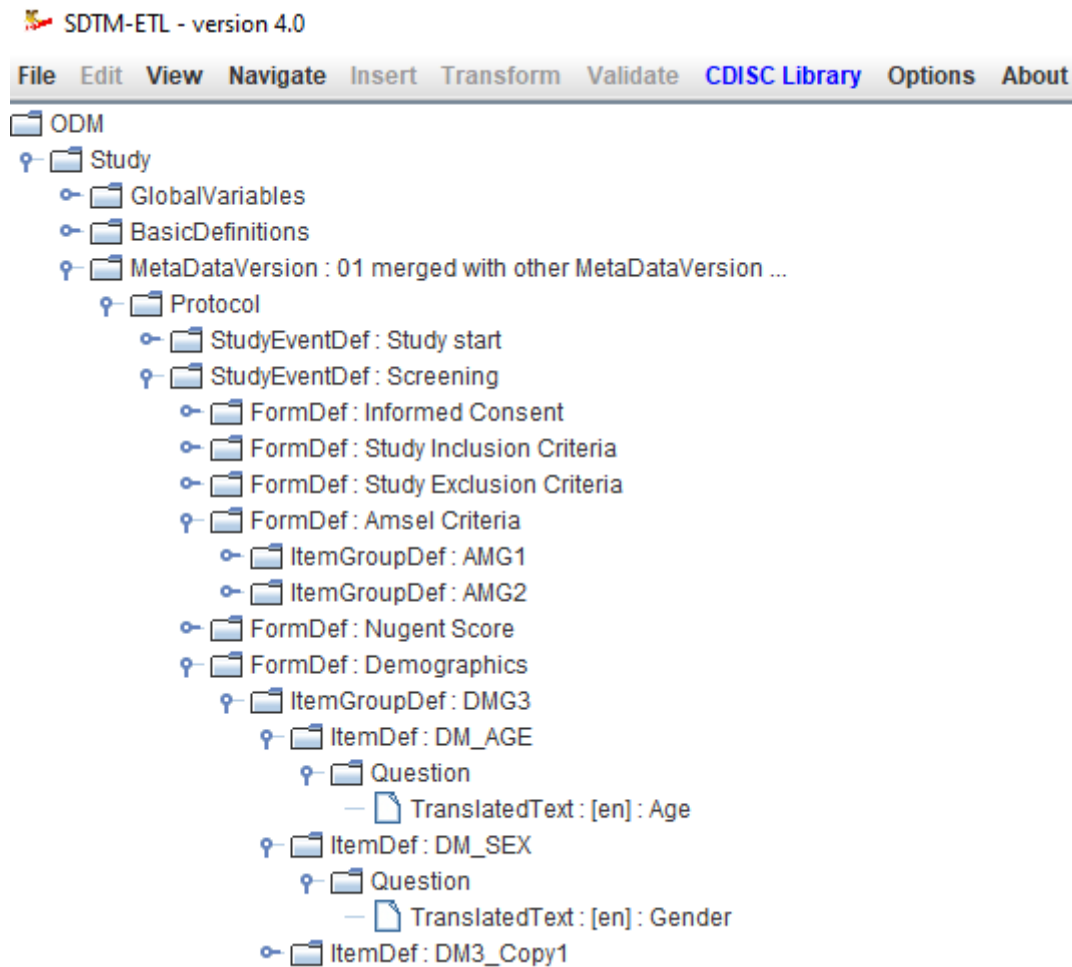
And one can start developing the mappings after selection of an SDTM-IG or SEND-IG version.

The next time, we do not need to repeat the whole procedure, we can just start from the file "DEMO_data_Viedoc_odm_extensions_removed_MVs_merged.xml".

When then later executing the mappings on real clinical data, the system will not check for the version of the metadata in the "ClinicalData" section of the ODM file with the captured clinical data, so there is no need to merge clinical data for different subjects having had different versions of the metadata into a single one.

Remark that the Viedoc vendor extensions were not used in this tutorial. If you would like to use them, please let us now, and we will be happy to extend the software for that use case.