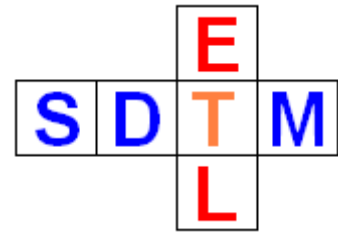


SDTM-ETL 4.5 User Manual and Tutorial

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Working with Viedoc ODM files

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Introduction

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 between sites.

[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.

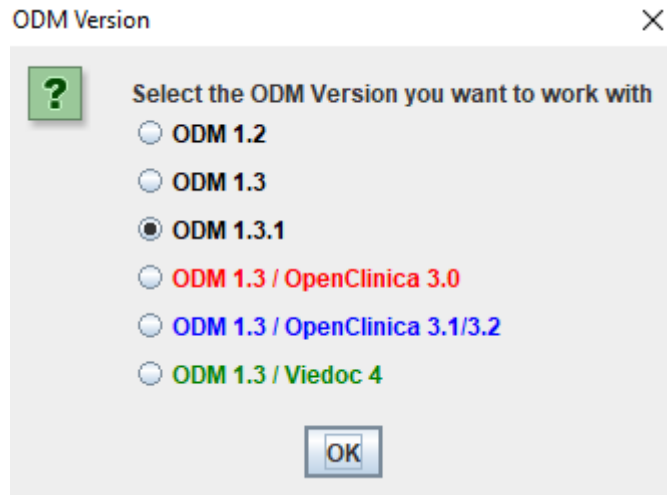
This tutorial explains how this is done in SDTM-ETL v.4.5.

Working with ODM Viedoc files using the "Viedoc" version 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.

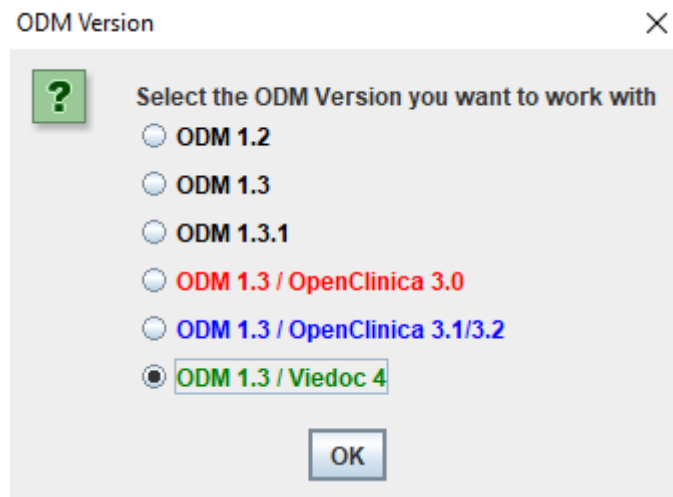
In the following example, we demonstrate the use of Viedoc-ODM for a customer who wanted to have support for as well OpenClinica 3.0 and 3.1, as for Viedoc v.4.

With this special version, one of the first dialogs that is displayed is:



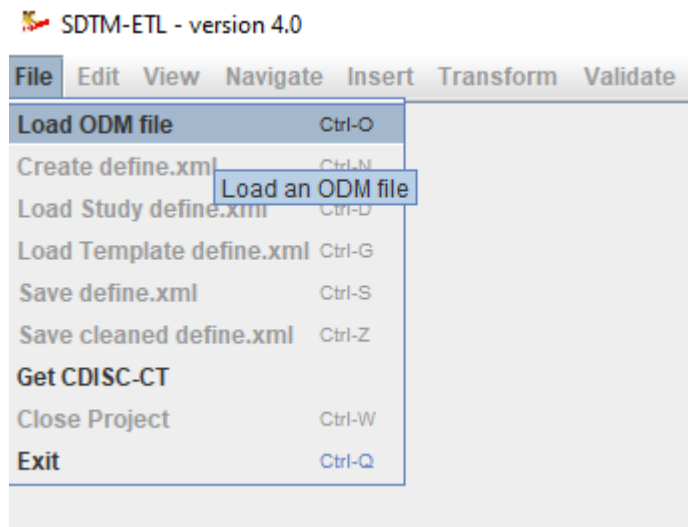
allowing you to choose with which ODM version you want to work. The OpenClinica ODM exports that are supported here are ODM 1.3 from OpenClinica 3.0, and ODM 1.3 from OpenClinica 3.1, as well as Viedoc version 4 ODM exports.

In our case, we select "ODM 1.3 / Viedoc 4".

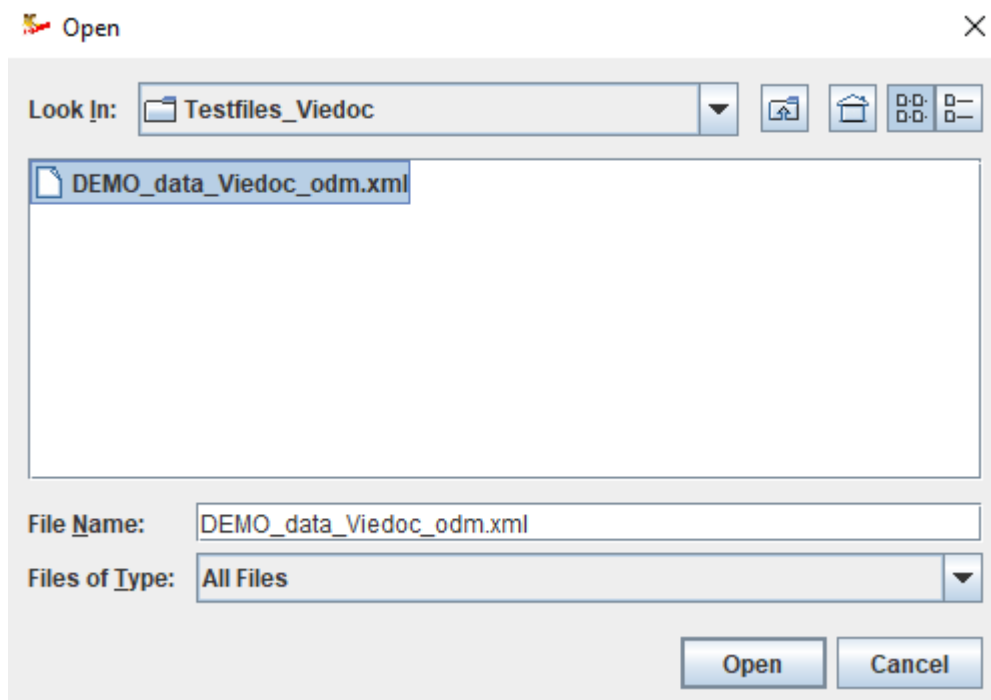


This will then allow to load the ODM file that was generated by Viedoc v.4 with extensions.

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

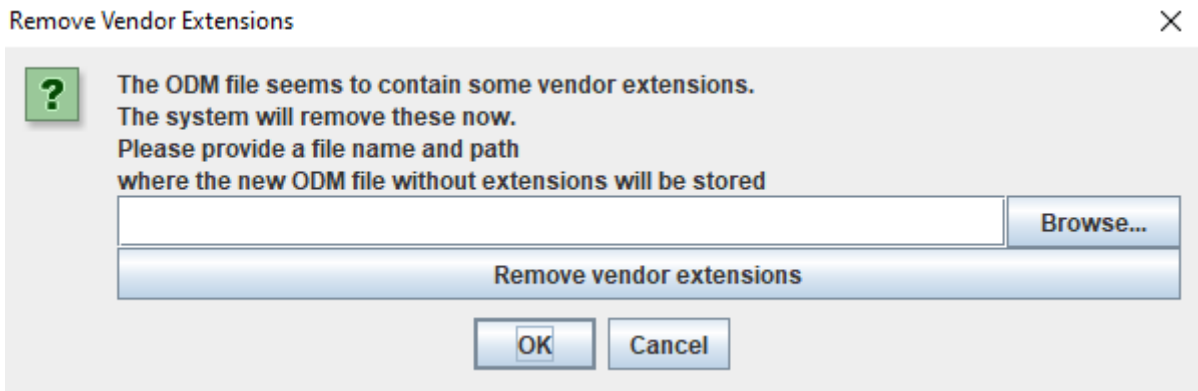


for example:

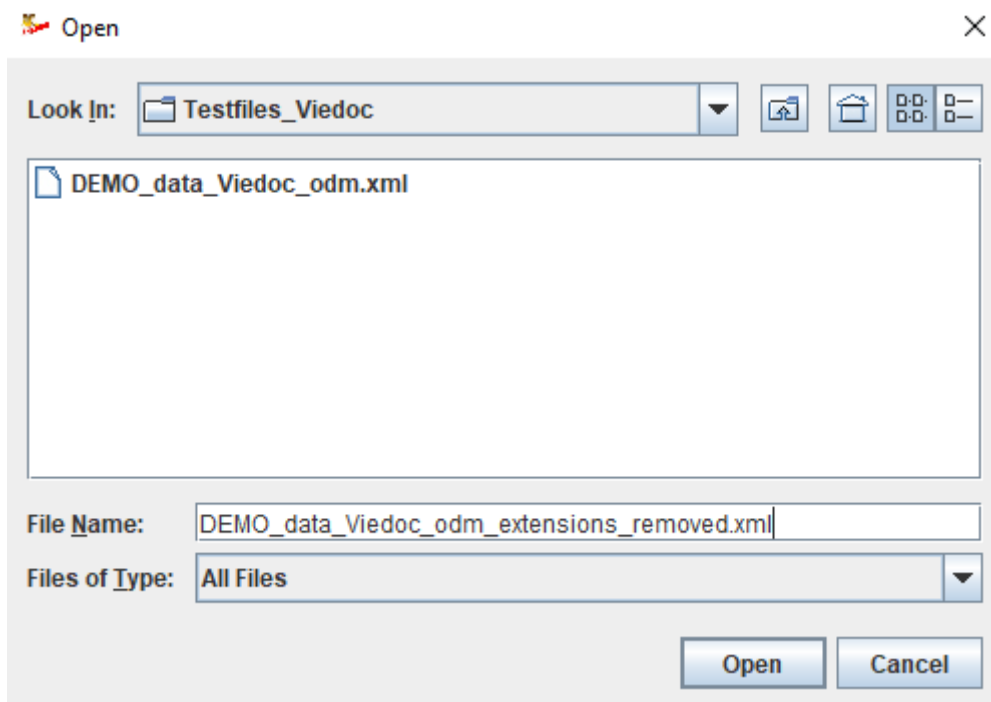


A. Removing Viedoc-specific "vendor extensions"

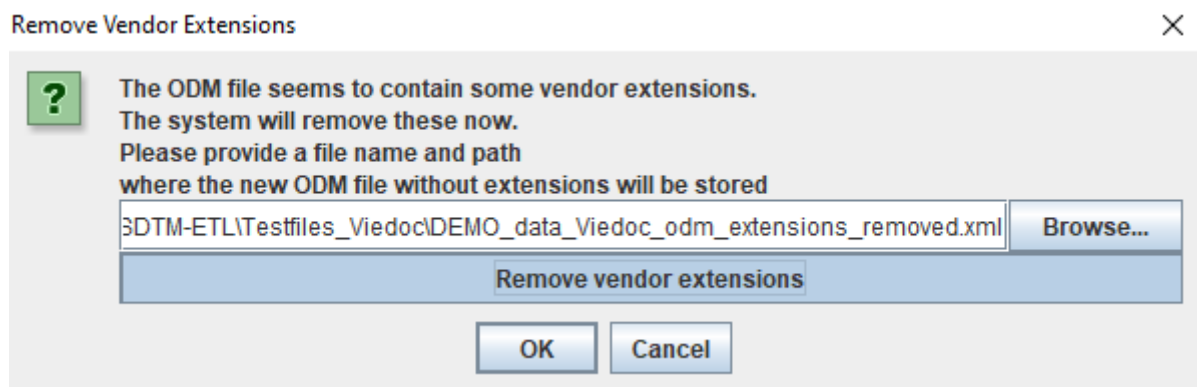
After clicking "Open", the following dialog appears:



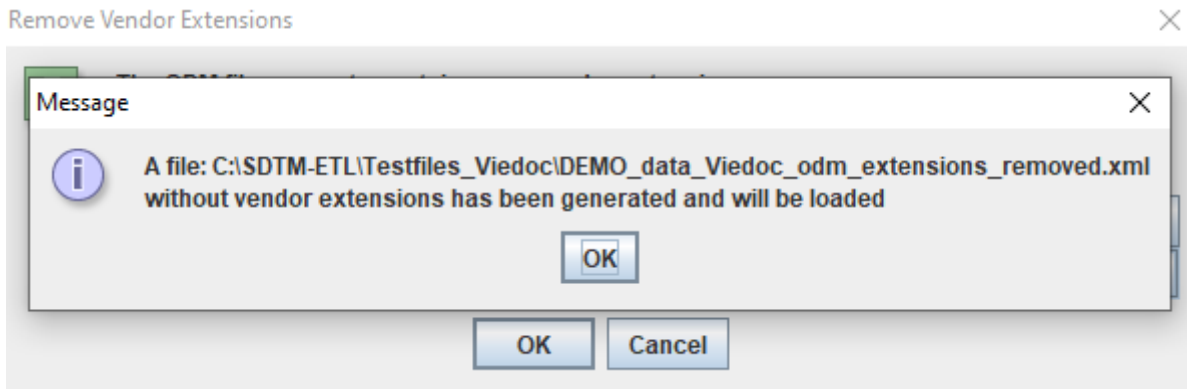
The Viedoc ODM file contains a Viedoc-specific vendor extensions, which all are administrative, and that we cannot use for the mapping, so these will be removed. We then need to provide a file name for the ODM file that will be generated. For example:



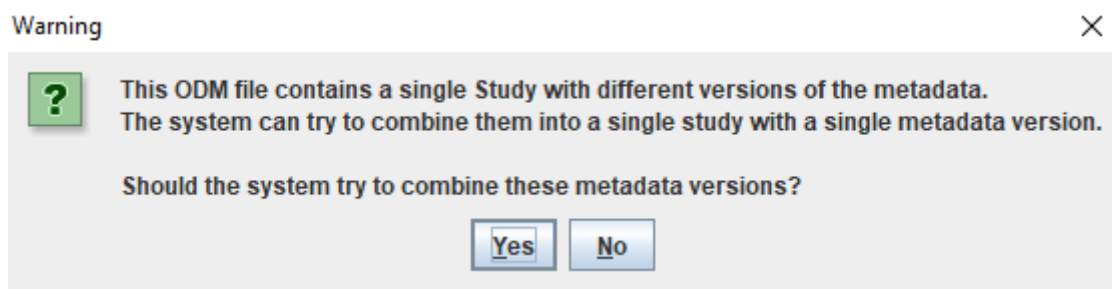
When one want to later continue with developing the mappings to SDTM, one can then start from the file without the Viedoc-specific extensions. After clicking "Open", one starts the removal of the extensions by clicking "Removing vendor extensions":



leading to, after about one minute:

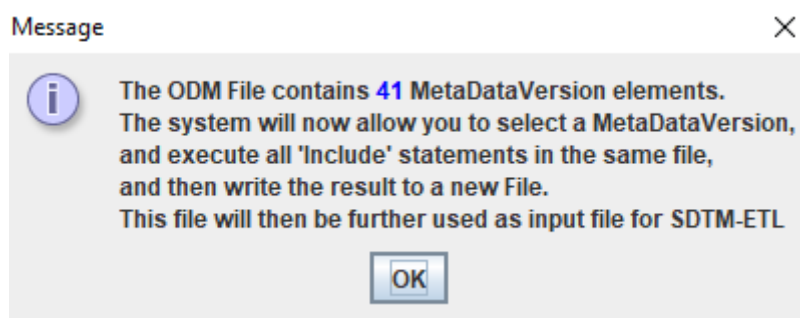


Clicking "OK" twice then leads to the following dialog:

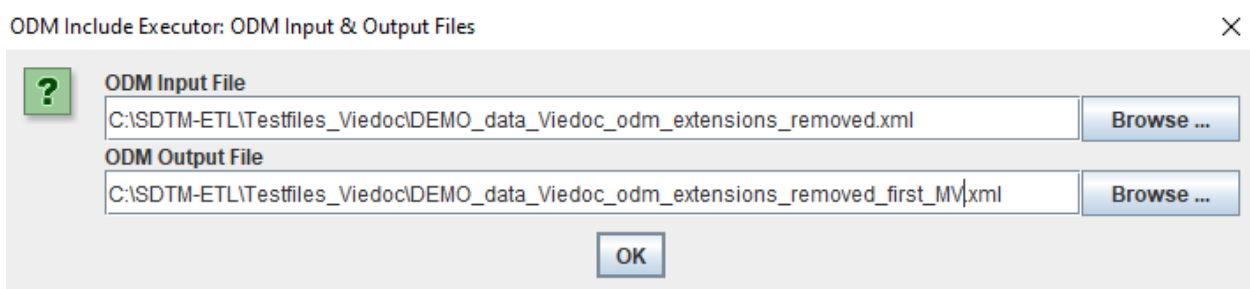


B. Working with a single "MetaDataVersion"

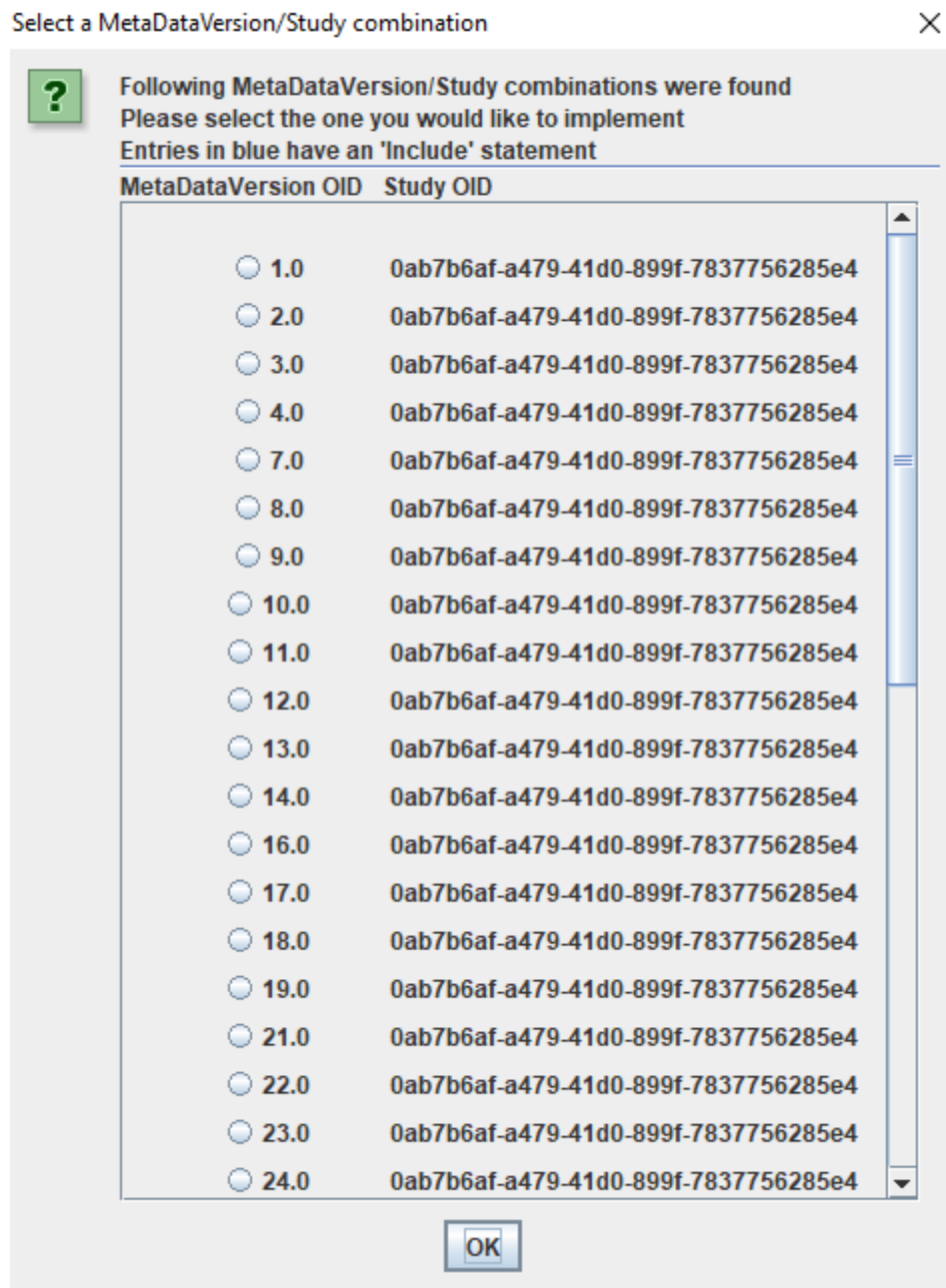
It might be that we only want to work with a single version of the metadata from the ODM file (this will normally be the exception). In that case, "No" must be clicked, after which the system asks us which version of the metadata must be used:



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:



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

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

MetaDataVersion	Study OID
<input checked="" type="radio"/> 1.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 2.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 3.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 4.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 7.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 8.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 9.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 10.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 11.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 12.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 13.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 14.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 16.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 17.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 18.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 19.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 21.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 22.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 23.0	0ab7b6af-a479-41d0-899f-7837756285e4
<input type="radio"/> 24.0	0ab7b6af-a479-41d0-899f-7837756285e4

OK

Remark that verion "GEN_CODELISTS" only contains codelists, so is not of use for us at this moment.

After clicking "OK", we get:

Message

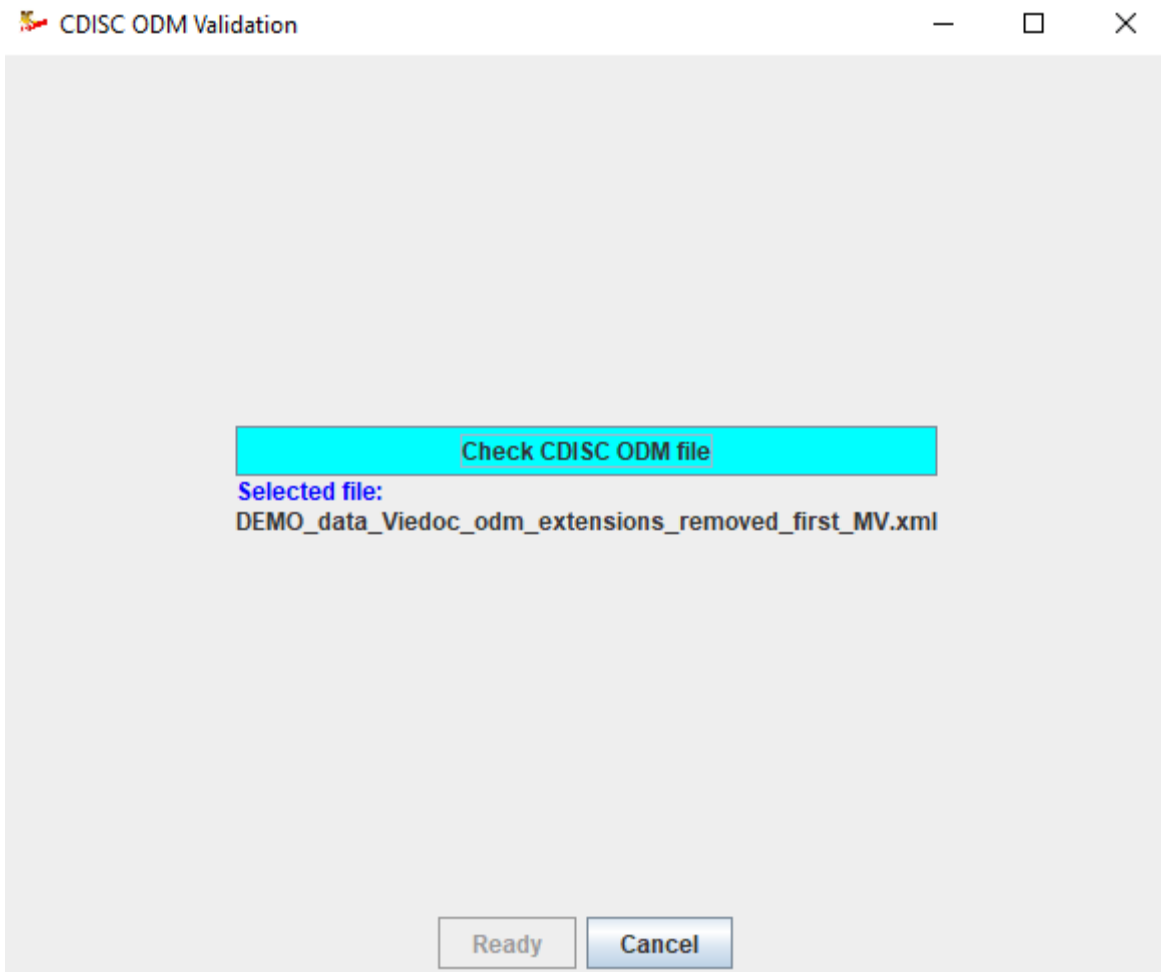


Result of 'Include' Execution written to file:

C:\SDTM-ETL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed_first_MV.xml

OK

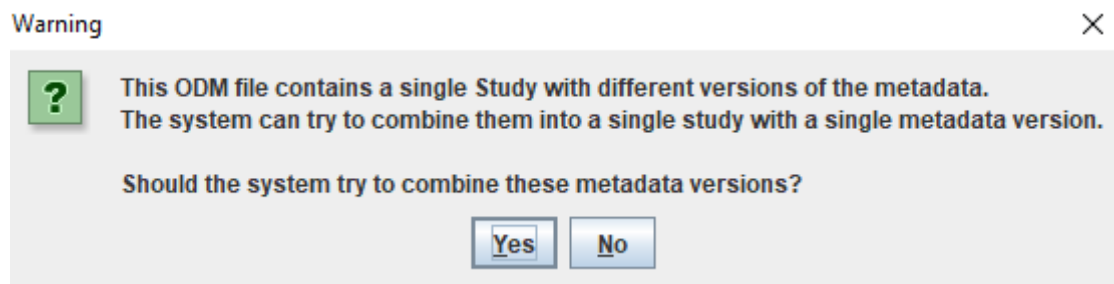
followed by the usual "Validation" dialog:



C. Merging "MetaDataVersions"

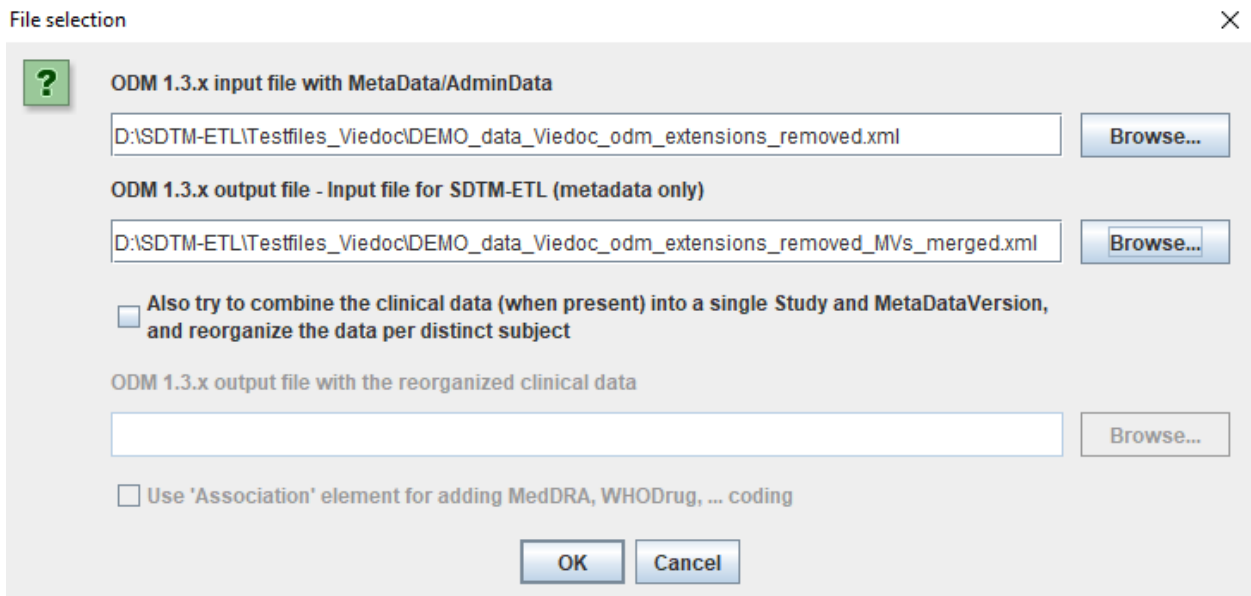
Viedoc has a rather "special" way of using "MetaDataVersion" of ODM, resulting in that the clinical data of the study is spread over different "MetaDataVersion"-s¹.

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:



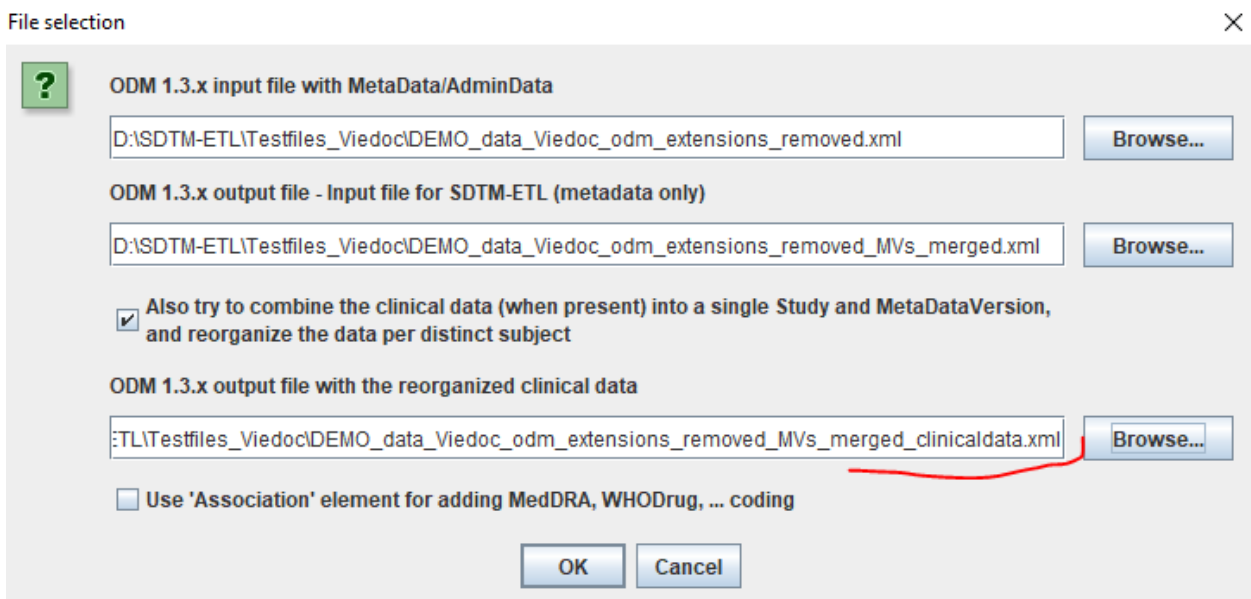
After clicking "Yes", we get:

¹ This probably is related with the way how studies are developed in Viedoc.



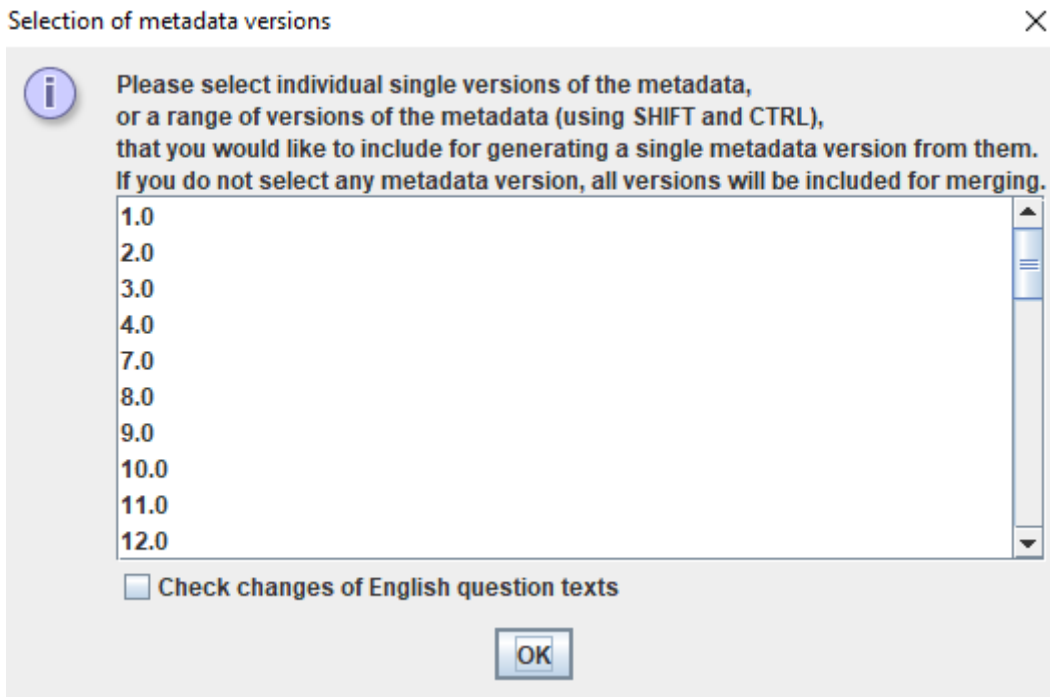
where we provide a file name and path under "ODM 1.3.x output file" for the file with a single, merged version of the metadata.

We usually however also want to merge the "ClinicalData" into a single "MetaDataVersion", and take care that all the subject data is reorganized in such a way that there is only one "SubjectData" element per distinct subject. We then also check "Also try to combine clinical data ..." and provide a file where the reorganized clinical data will be written to:



We will explain the use of the "Use 'Association' element ..." in a separate section.

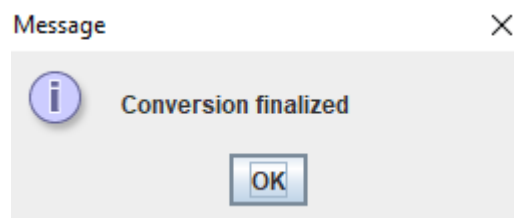
We then need to click "Start conversion", a new dialog is displayed:



Asking us which "MetaDataVersion"s should be included. If we do not select anything, the system will merge all MetaDataVersions.

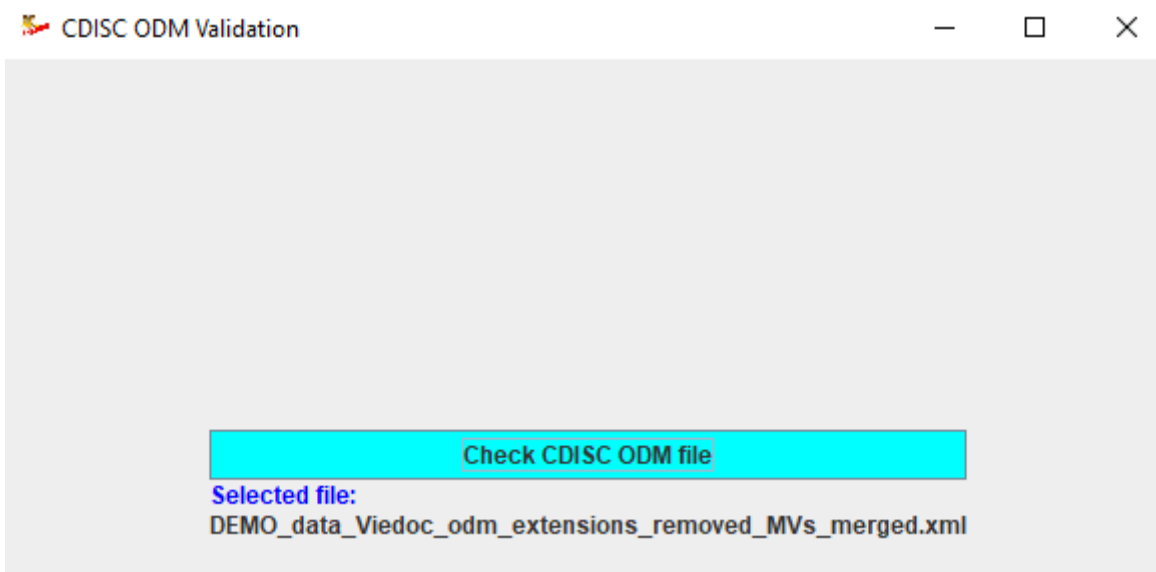
If you don't trust that the question texts on the eCRF items have been the same between the metadata-versions, also check the checkbox "Check changes of English question texts". This will then compare all datapoint definitions ("ItemDef" in ODM) with the same OID identifier, and compare the values of the text of the "Question/TranslatedText" content. If it find any differences between them, it will report on them².

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:

² If the question text has changed between "MetaDataVersion"s, this means that it is potentially dangerous to merge these, as the meaning of a data point may be different, depending on the "MetaDataVersion".



In this case, the result of the validation is:

Results of checking ODM file C:\SDTM-ETL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed_MVs_merged.xml

File

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

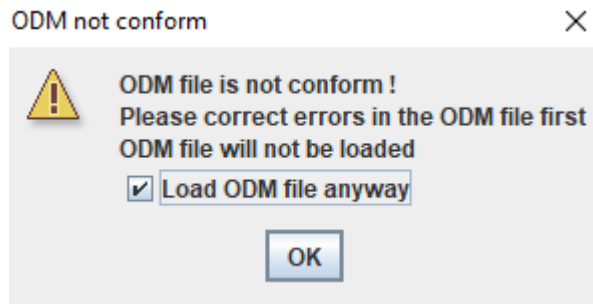
Level 1 ERROR The content of element 'Question' is not complete.
At least one of the following is expected:
- TranslatedText

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

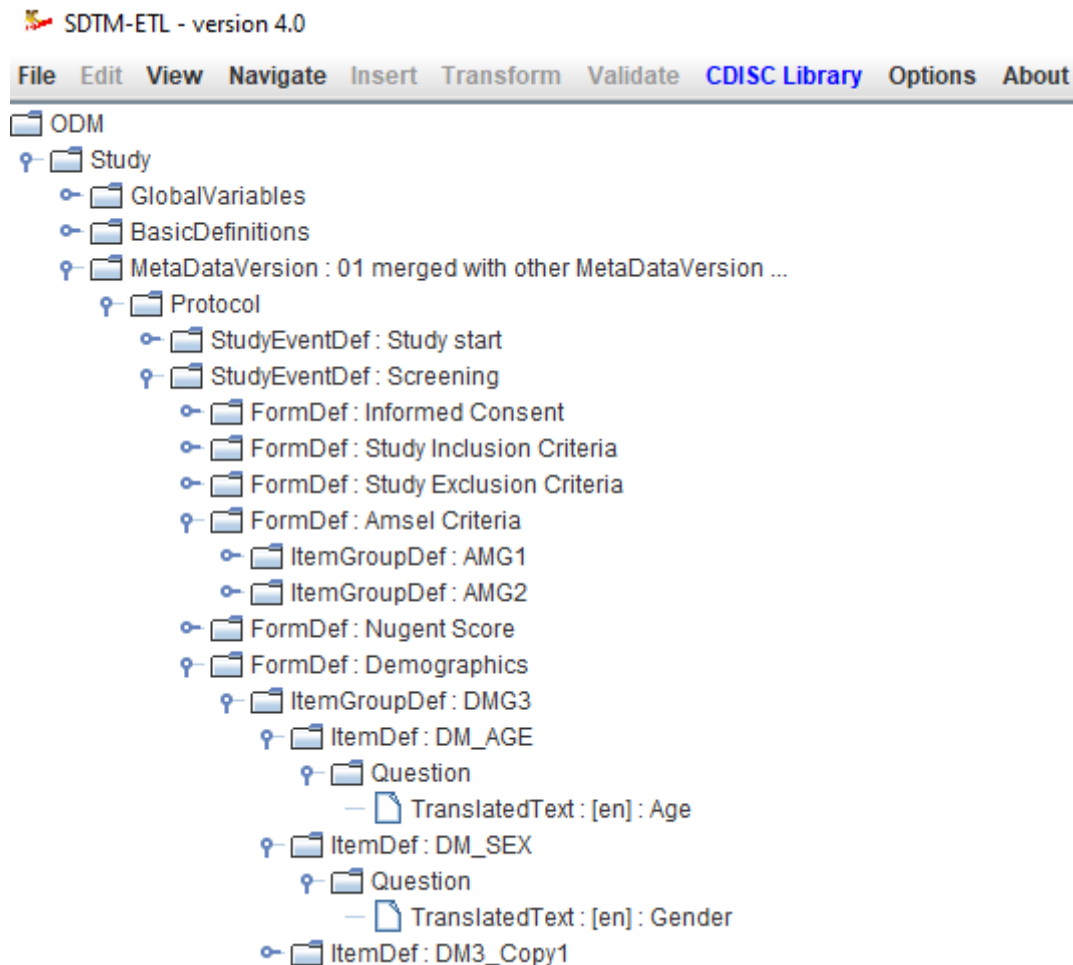
Level 1 ERROR The content of element 'Question' is not complete.
At least one of the following is expected:
- TranslatedText

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 (Viedoc non-compliance) 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 real need to merge clinical data for different subjects having had different versions of the metadata into a single one. It may however lead to SDTM datasets in which the data is not grouped per subject. So, using the file with the (also) merged "ClinicalData" usually has advantages.

D. MedDRA and WHODrug coding

Viedoc has, in its ODM export, a somewhat special way of providing MedDRA and WHODrug coding for collected data points.

Most EDC vendors, when having support for such coding anyway, treat the codings as just normal data points (ItemDef - ItemData) which can however only be added by people with a specific role ("coders"). Viedoc however uses the "Association" elements of ODM to add the codings (MedDRA or WHODrug) to individual data points. This is very well explained in the Viedoc document "[Medical coding in ODM export](#)".

For example:


```
<Association StudyOID=[REDACTED] MetadataVersionOID="GEN_CODELISTS">
  <KeySet StudyOID=[REDACTED] SubjectKey="01-057" StudyEventOID="CM" StudyEventRepeatKey="3"
    FormOID="CM" FormRepeatKey="1$CM" ItemGroupOID="CMG1" ItemOID="CMTRT" v4:SubjectFormSeqNo="3" v4:OriginSubjectFormSeqNo="" />
  <KeySet StudyOID=[REDACTED] SubjectKey="01-057" StudyEventOID="CM" StudyEventRepeatKey="3"
    FormOID="CM" FormRepeatKey="1$CM" ItemGroupOID="CMG1" ItemOID="CMTRT" v4:SubjectFormSeqNo="3" v4:OriginSubjectFormSeqNo="" />
  <Annotation SegNum="1">
    <Comment>Vitamin B complex</Comment>
    <Flag>
      <FlagValue CodeListOID="CL_ANNOTATION_TYPE">MedicalCoding</FlagValue>
    </Flag>
    <Flag>
      <FlagValue CodeListOID="CL_DICT_TYPE">WHODrug</FlagValue>
    </Flag>
    <Flag>
      <FlagValue CodeListOID="CL_CODING_SCOPE">5016</FlagValue>
    </Flag>
    <Flag>
      <FlagValue CodeListOID="CL_CODE_SEQ_NO">1</FlagValue>
    </Flag>
    <FlagValue CodeListOID="CL_WHODRUG_WHODRUG_GLOBAL_C3_SEPTEMBER_1_2021">90003601001</FlagValue>
    <FlagType CodeListOID="CL_WHODRUG_PROP">DrugCode</FlagType>
    </Flag>
    <FlagValue CodeListOID="CL_WHODRUG_WHODRUG_GLOBAL_C3_SEPTEMBER_1_2021">Vitamins</FlagValue>
    <FlagType CodeListOID="CL_WHODRUG_PROP">DrugName</FlagType>
    </Flag>
    <FlagValue CodeListOID="CL_WHODRUG_WHODRUG_GLOBAL_C3_SEPTEMBER_1_2021"></FlagValue>
    <FlagType CodeListOID="CL_WHODRUG_PROP">NameSpecifier</FlagType>
    </Flag>
    <Flag>
      <FlagValue CodeListOID="CL_WHODRUG_WHODRUG_GLOBAL_C3_SEPTEMBER_1_2021">N</FlagValue>
    <FlagType CodeListOID="CL_WHODRUG_PROP">OldForm</FlagType>
    </Flag>
    <Flag>
      <FlagValue CodeListOID="CL_WHODRUG_WHODRUG_GLOBAL_C3_SEPTEMBER_1_2021" />
    <FlagType CodeListOID="CL_WHODRUG_PROP">Ingredients</FlagType>
    </Flag>
    <Flag>
      <FlagValue CodeListOID="CL_WHODRUG_WHODRUG_GLOBAL_C3_SEPTEMBER_1_2021">A11 VITAMINS</FlagValue>
    <FlagType CodeListOID="CL_WHODRUG_PROP">ATCCodes</FlagType>
    </Flag>
  </Annotation>
</Association>
```

Stating the WHODrug coding for the datapoint of subject "01-057" with StudyEventOID "CM" and StudyEventRepeatKey "3", FormOID "CM", FormRepeatKey "1\$CM", ItemGroup "CMG1" and Item "CMTRT" (i.e. uniquely defining the datapoint), with the WHODrug code "90003601001" and name "Vitamins" for which the ATC code is "A11".

This mechanism is, as it is Viedoc-specific, however not supported by SDTM-ETL. There is however the possibility to automatically add the coding values to the ItemGroup that also contains the reference datapoint in the clinical data during the step that generates a single MetadataVersion:

File selection



 ODM 1.3.x input file with MetaData/AdminData

D:\SDTM-ETL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed.xml

ODM 1.3.x output file - Input file for SDTM-ETL (metadata only)

D:\SDTM-ETL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed_MVs_merged.xml

Also try to combine the clinical data (when present) into a single Study and MetaDataVersion, and reorganize the data per distinct subject

ODM 1.3.x output file with the reorganized clinical data


:TL\Testfiles_Viedoc\DEMO_data_Viedoc_odm_extensions_removed_MVs_merged_clinicaldata.xml

Use 'Association' element for adding MedDRA, WHODrug, ... coding

When checking the checkbox "Use 'Association' element for adding MedDRA, WHODrug ... coding", an additional instruction is displayed:

Message



 In the next step, do not forget to also select the **GEN_CODELISTS** metadata versions, as this is necessary to generate the metadata for the coding items to be added.

When one then continues, and ensures the MetaDataVersion "GEN_CODELISTS" is included (this is always the case when one selects none of the MetaDataVersions", as that means "include all", the final result in the ODM file will e.g. be:

```

<StudyEventData StudyEventOID="CM" StudyEventRepeatKey="3">
  <AuditRecord UserRef UserOID="USR.7766"></UserRef>
  <LocationRef LocationOID="LOC.14117"></LocationRef>
  <DateTimeStamp>2023-01-05T08:06:23.895Z</DateTimeStamp>
  <ReasonForChange>Revision applied</ReasonForChange>
</AuditRecord>
<FormData FormOID="CM" FormRepeatKey="1$CM">
  <AuditRecord UserRef UserOID="USR.2256"></UserRef>
  <LocationRef LocationOID="LOC.14117"></LocationRef>
  <DateTimeStamp>2022-10-11T11:32:42.753Z</DateTimeStamp>
</AuditRecord>
<ItemGroupData ItemGroupOID="CMG1"><ItemDataDouble ItemOID="CMSPID" AuditRecordID="AR.64332074">3</ItemDataDouble>
  <ItemDataString ItemOID="CMVRT" AuditRecordID="AR.64685722">Vitamin B complex</ItemDataString>
  <ItemDataString ItemOID="DrugCode">90003601001</ItemDataString>
  <ItemDataString ItemOID="CountryName">Not Applicable</ItemDataString>
  <ItemDataString ItemOID="DrugName">Vitamins</ItemDataString>
  <ItemDataString ItemOID="ATCCodes">All VITAMINS</ItemDataString>
  <ItemDataString ItemOID="Generic">N</ItemDataString>
  <ItemDataString ItemOID="Ingredients">null</ItemDataString>
  <ItemDataString ItemOID="MedProdId">49763</ItemDataString>
  <ItemDataString ItemOID="PharmForm">Unspecified</ItemDataString>
  <ItemDataString ItemOID="OldForm">N</ItemDataString>
  <ItemDataString ItemOID="MAH">None</ItemDataString>
  <ItemDataString ItemOID="NameSpecifier">null</ItemDataString>
  <ItemDataString ItemOID="PreferredName">Vitamins</ItemDataString>
  <ItemDataString ItemOID="CountryCode">N/A</ItemDataString>
  <ItemDataString ItemOID="PreferredCode">90003601001</ItemDataString>
  <ItemDataString ItemOID="Strength">Unspecified</ItemDataString>
</ItemGroupData>
<ItemGroupData ItemGroupOID="CMG3"><ItemDataInteger ItemOID="CMONGO" AuditRecordID="AR.64332073">1</ItemDataInteger>
  <ItemDataPartialDate ItemOID="CMSTDAT" AuditRecordID="AR.64332073">2022-05</ItemDataPartialDate>
</ItemGroupData>
<ItemGroupData ItemGroupOID="CMG4"><ItemDataInteger ItemOID="CMDOSFRQ" AuditRecordID="AR.64332073">9</ItemDataInteger>
  <ItemDataInteger ItemOID="CMDOSU" AuditRecordID="AR.64685724">17</ItemDataInteger>
  <ItemDataDouble ItemOID="CMDSTX" AuditRecordID="AR.64685723">1</ItemDataDouble>
  <ItemDataInteger ItemOID="CMROUTE" AuditRecordID="AR.64332073">12</ItemDataInteger>
</ItemGroupData>
<ItemGroupData ItemGroupOID="CMG5"><ItemDataInteger ItemOID="CMINDC" AuditRecordID="AR.64332073">4</ItemDataInteger>
  <ItemDataString ItemOID="CMOTH" AuditRecordID="AR.64332073">by own choice. Not on doctors prescription.</ItemDataString>
</ItemGroupData>
</FormData>
</StudyEventData>

```

or for an adverse event:

```

<ItemGroupData ItemGroupOID="AEG1">
  <ItemDataInteger ItemOID="AESI" AuditRecordID="AR.56110903">2</ItemDataInteger>
  <ItemDataDouble ItemOID="AESPID" AuditRecordID="AR.56110904">3</ItemDataDouble>
  <ItemDataString ItemOID="AETERM" AuditRecordID="AR.56110903">Increased transaminases</ItemDataString>
  <ItemDataString ItemOID="hlt_name">Liver function analyses</ItemDataString>
  <ItemDataString ItemOID="llt_code">10054889</ItemDataString>
  <ItemDataString ItemOID="hlt_code">10024689</ItemDataString>
  <ItemDataString ItemOID="pt_soc_code">10022891</ItemDataString>
  <ItemDataString ItemOID="soc_code">10022891</ItemDataString>
  <ItemDataString ItemOID="hlgt_code">10019809</ItemDataString>
  <ItemDataString ItemOID="llt_name">Transaminases increased</ItemDataString>
  <ItemDataString ItemOID="hlgt_name">Hepatobiliary investigations</ItemDataString>
  <ItemDataString ItemOID="llt_currency">Y</ItemDataString>
  <ItemDataString ItemOID="soc_name">Investigations</ItemDataString>
  <ItemDataString ItemOID="pt_name">Transaminases increased</ItemDataString>
  <ItemDataString ItemOID="soc_abbrev">Inv</ItemDataString>
  <ItemDataString ItemOID="pt_code">10054889</ItemDataString>
</ItemGroupData>

```

Use of Viedoc Extensions

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.