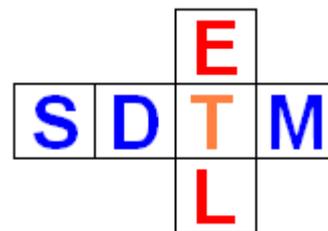


SDTM-ETL 3.0 User Manual and Tutorial

Author: Jozef Aerts, XML4Pharma

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Working with OpenClinica ODM files

OpenClinica© and Clinovo Clincapture© are two open source EDC systems that allow export of ODM files, however with extension elements and attributes. ClinCapture is a „branching off“ or a „fork“, meaning that Clinivo copied the OpenClinica source (which they are entitled to as it is Open Source code under a LGPL license), changed some things, and started distributing the modified software.

One of the parts that was not changed by Clinovo is the export of ODM files with OpenClinica extension attributes and elements. So, an OpenClinica export to ODM has exactly the same structure as a ClinCapture ODM export. In the following we will then also not make a distinction anymore, and speak about „OpenClinica ODM“, as OpenClinica is the real originator.

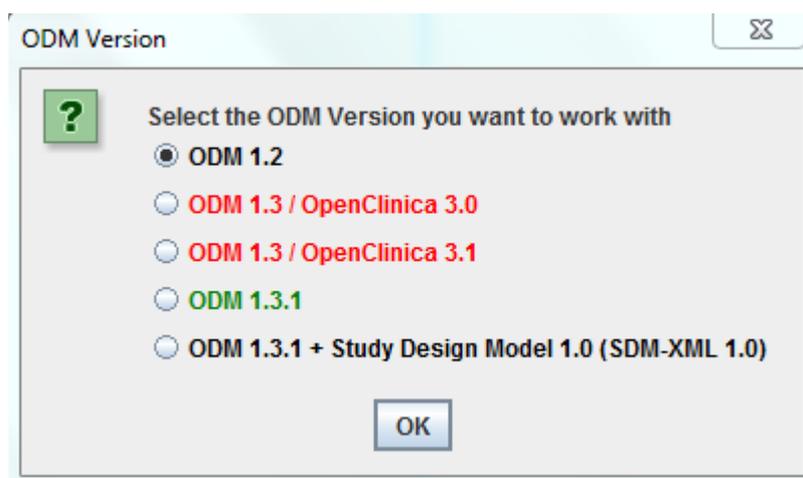
SDTM-ETL users can obtain the software in two „flavors“: the normal favor which does not support the OpenClinica extensions, but still has some special features for working with OpenClinica ODM files (explained later) and an „OpenClinica flavor“, which fully supports most of the OpenClinica to the ODM standard.

Working with ODM OpenClinica files using the „OpenClinica flavor“ of SDTM-ETL

Working with this special version of the software only makes sense if you really want to use some of the OpenClinica extension attributes and elements, requiring you to understand what these extensions to ODM are meant for and how they work.

If you don't need these extension (in most cases you don't), use the standard version of SDTM-ETL.

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

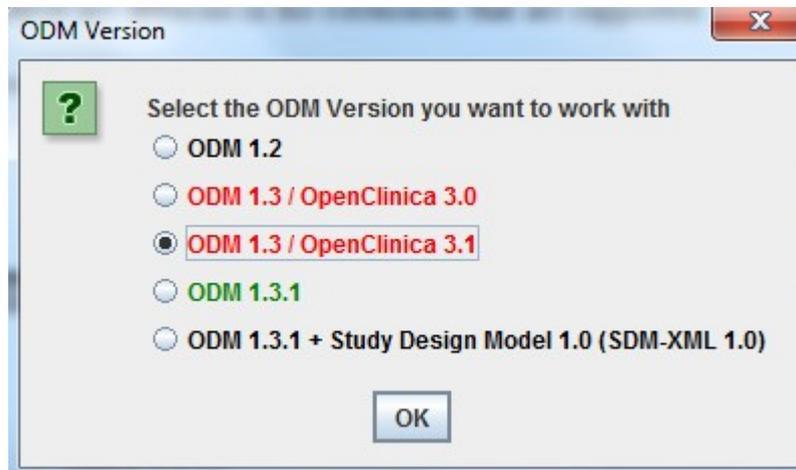


allowing you to choose with which ODM version you want to work. The OpenClinica ODM exports that are supported are ODM 1.3 from OpenClinica 3.0, and ODM 1.3 from OpenClinica 3.1. Please note that these are different in the extensions that are supported.

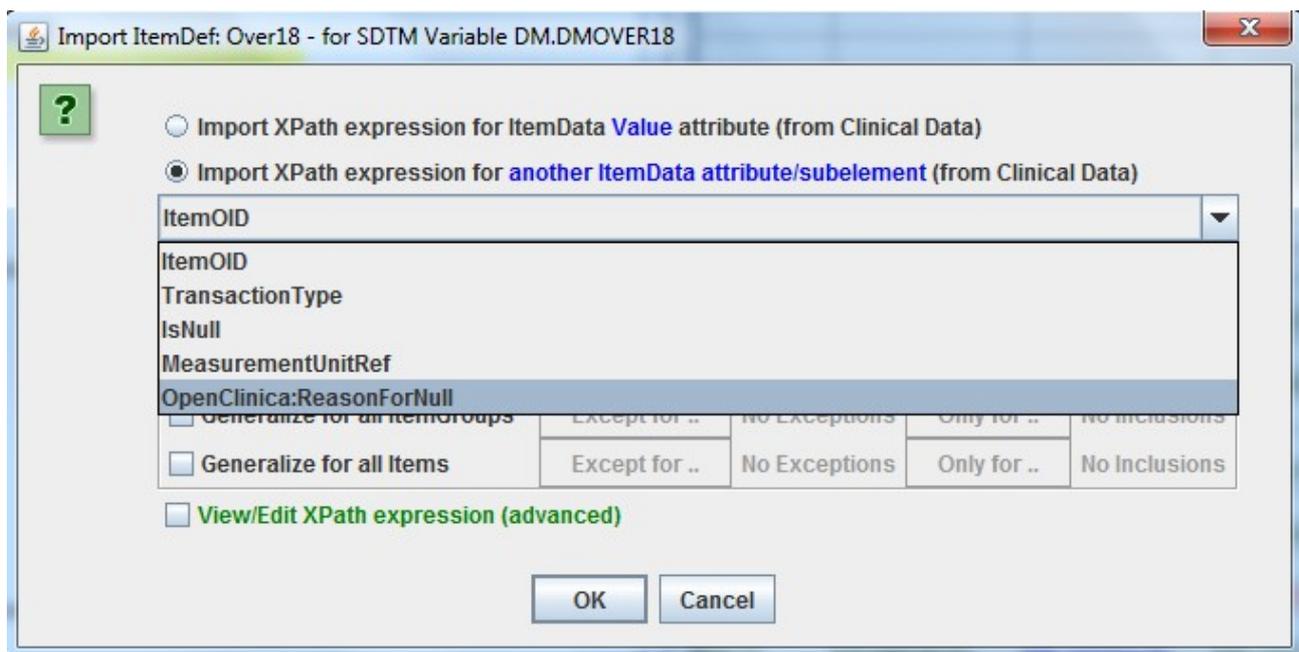
If you would like to work with an OpenClinica ODM export but do wish not to work with the

extensions, than choose „ODM 1.3.1“.

Suppose that you want to work with an OpenClinica 3.1 ODM file, than you select the third radiobutton:



This will then load the ODM file that was generated by OpenClinica 3.1 with extensions. For example, if you do a drag-and-drop from an ODM ItemDef to an SDTM table cell, you do have some extra options for what exactly you want to use from the ItemDef in the mapping:

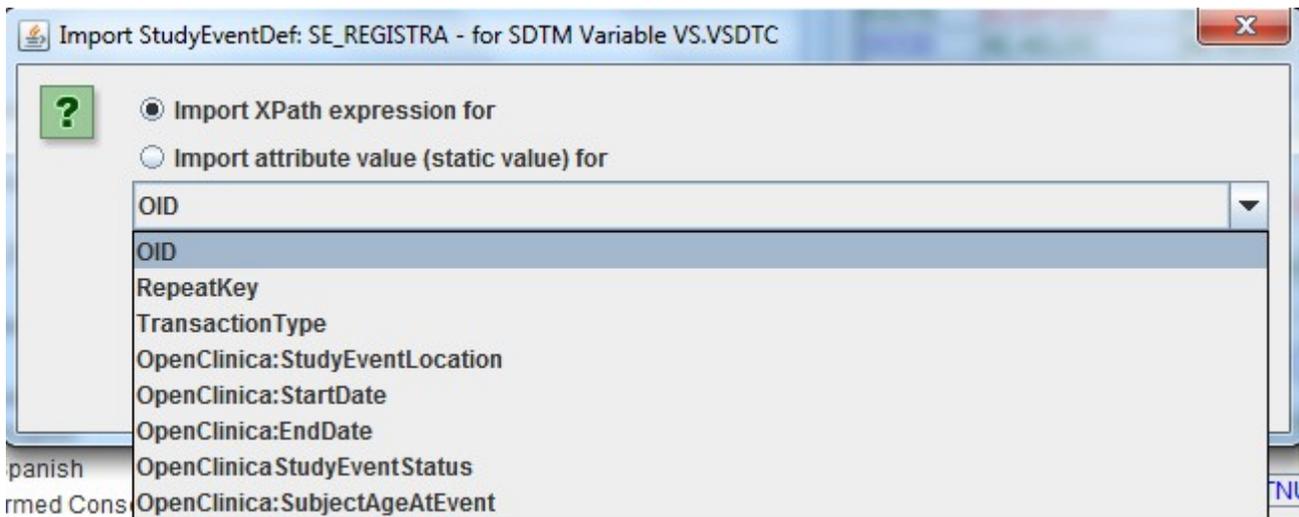


If you inspect an OpenClinica ODM file, you might see some data points that have a null value, and an additional attribute „living“ in the OpenClinica namespace „OpenClinica:ReasonForNull“.

For example:

```
<ItemData ItemOID="Over18" IsNull="Yes" OpenClinica:ReasonForNull="forgotten" />
```

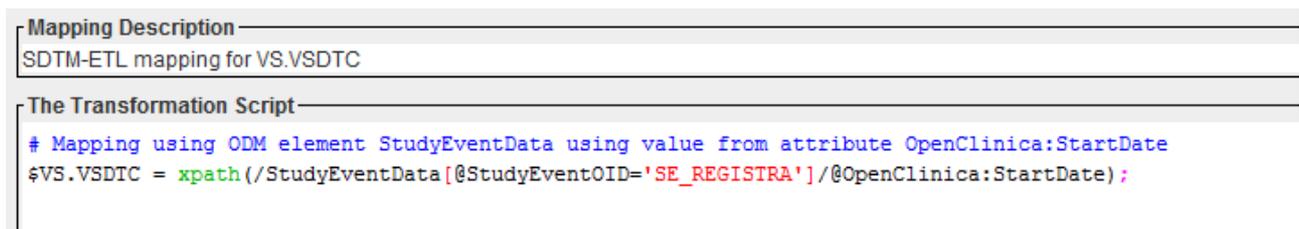
If you did a drag-and-drop from a „StudyEvent“ to a cell, you even have more available selections, e.g.:



as OpenClinica does store information from visits as attributes to „StudyEventData“, and not as CRF data points as is usual with ODM.

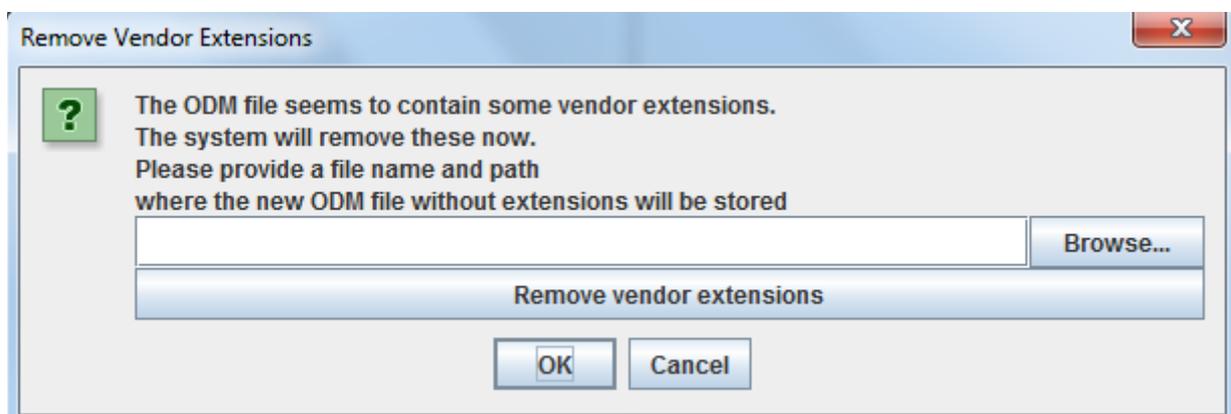
Especially the „StartDate“, „EndDate“ and „StudyEventLocation“ attributes will often be used in mappings to SDTM, e.g. for --STDTC, --ENDTC and „SITE“ (in DM).

If e.g. „StartDate“ was chosen, the mapping may look like:

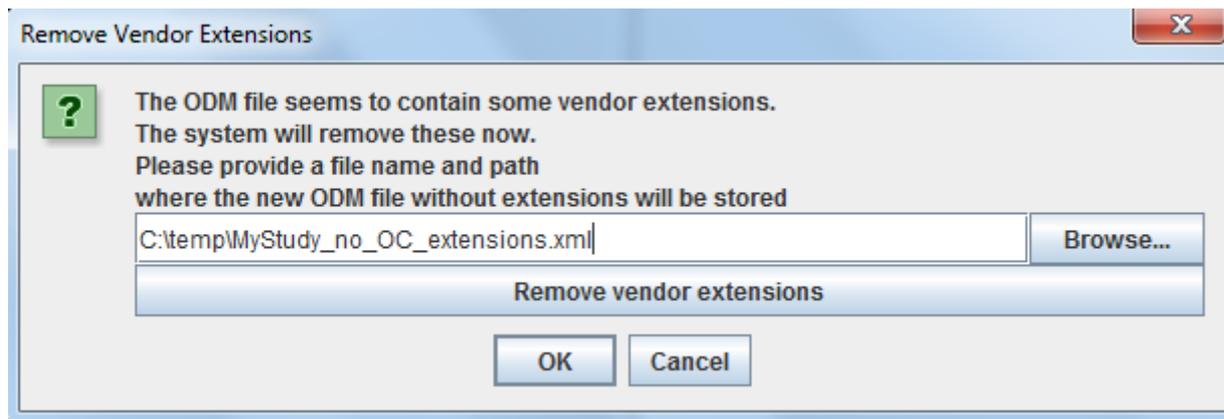


Working with ODM OpenClinica files using the normal version of SDTM-ETL

If you work with the normal version of SDTM-ETL, and load an ODM file that contains OpenClinica extensions, the program will first try to remove the extensions, and you will get the following dialog:



You are asked to provide a file name and path where the ODM file that is freed of OpenClinica extensions. This has the advantage that you can later pick that file, and do not need to remove the extensions again. For example:



A file „MyStudy_no_OC_extensions.xml“ will be created in the directory „C:\temp“. If you now click the „Remove vendor extensions“, that file will be created and also loaded into SDTM-ETL (you do not need to do an extra loading step).

The result is now the normal ODM tree, and when doing a drag-and-drop, you will not see anything about the OpenClinica extensions anymore.

OpenClinica and multiple studies / multiple sites

In OpenClinica ODM exports, one often finds different „Study“ elements, e.g. one for each site. Having different „versions“ of the same study depending on the site is questionable for electronic submissions to regulatory authorities (subject can not really be compared as they were subject to different versions of the protocol), but it is a reality.

In case there are different „Study“ elements, and they are independent from each other (i.e. they do not include each other like a russian matryoshka doll – see further), then the software will try to combine these into a single one. You should however validate the result of the combination yourself, as this is not „bullet proof“.

For example, consider the following OpenClinica ODM file:

```
<?xml version="1.0" encoding="UTF-8"?>
<ODM FileOID="SDRUG_Plus_Non_CRF_Data_-_All_AvailableD20100203130736-0500" Description="SDRUG Plus Non CRF Data"
  <Study OID="S_R0112345">
    <GlobalVariables>
      <StudyName>Docetaxel in Patients With Completely Resected NSCLC</StudyName>
      <StudyDescription>
        This is a demo study
      </StudyDescription>
      <ProtocolName>R01-123456-1</ProtocolName>
    </GlobalVariables>
    <BasicDefinitions>
      <MeasurementUnit OID="MU_F" Name="F">
        <Symbol>
          <TranslatedText>F</TranslatedText>
        </Symbol>
      </MeasurementUnit>
    </BasicDefinitions>
    <MetaDataVersion OID="v1.0.0" Name="MetaDataVersion_v1.0.0">
      <Protocol>
        <StudyEventRef StudyEventOID="SE_REGISTRA" OrderNumber="1" Mandatory="Yes"/>
        <StudyEventRef StudyEventOID="SE_INITIALT" OrderNumber="2" Mandatory="Yes"/>
        <StudyEventRef StudyEventOID="SE_FOLLOWUP" OrderNumber="3" Mandatory="Yes"/>
        <StudyEventRef StudyEventOID="SE_ADVERSEEE" OrderNumber="4" Mandatory="Yes"/>
        <StudyEventRef StudyEventOID="SE_DOSINGVI" OrderNumber="5" Mandatory="Yes"/>
      </Protocol>
    </MetaDataVersion>
  </Study>
</ODM>
```

defining 5 visits, and their forms, groups of items and codelists. For example:

```
<StudyEventDef OID="SE_REGISTRA" Name="Registration Visit" Repeating="No" Type="Scheduled">
  <FormRef FormOID="F_ELIG_V10" Mandatory="Yes" />
  <FormRef FormOID="F_PHYS_ENGL" Mandatory="Yes" />
  <FormRef FormOID="F_PHYS_SPAN" Mandatory="Yes" />
  <FormRef FormOID="F_VERI_V30" Mandatory="Yes" />
</StudyEventDef>
```

stating the 4 forms need to be used in the „registration visit“.

In the same file, one finds a second study definition:

```
<Study OID="S_R0112345_3192">
  <GlobalVariables>
  </GlobalVariables>
  <BasicDefinitions>
  </BasicDefinitions>
  <MetaDataVersion OID="v1.0.0-S_R0112345_3192" Name="MetaDataVersion_v1.0.0-S_R0112345_3192">
    <Include StudyOID ="S_R0112345" MetaDataVersionOID="v1.0.0" />
  </MetaDataVersion>
  <Protocol>
    <StudyEventRef StudyEventOID="SE_REGISTRA" OrderNumber="1" Mandatory="Yes" />
    <StudyEventRef StudyEventOID="SE_INITIALT" OrderNumber="2" Mandatory="Yes" />
    <StudyEventRef StudyEventOID="SE_FOLLOWUP" OrderNumber="3" Mandatory="Yes" />
  </Protocol>
  <StudyEventDef OID="SE_REGISTRA" Name="Registration Visit" Repeating="No" Type="Scheduled">
    <FormRef FormOID="F_PHYS_ENGL" Mandatory="Yes" />
    <FormRef FormOID="F_PHYS_SPAN" Mandatory="Yes" />
  </StudyEventDef>
```

Notice the „Include“ statement, stating that all information of the „S_R0112345“ study with MetaDataVersion „v1.0.0“ (i.e. the previous study design“) must be included in the current study definition. This usually works like a russian matryoshka doll, but it is a bit more complicated. For a good explanation, see e.g.: http://xml4pharmaserver.com/XML4PharmaWiki/doku.php?id=the_include_mechanism_in_cdisc_odm_study_descriptions



Essentially, this would mean that after executing the „Include“ in this second study definition one would have two instances of the definition of the content of StudyEvent „SE_REGISTRA“, but only the second the new one is applicable, as the „Include“ mechanism has been defined so that when a new definition is provided it overrides the previous one.

There even is a third study definition in the file:

```

<Study OID="$S_R0112345_9477">
  <GlobalVariables>
  </GlobalVariables>
  <BasicDefinitions>
  </BasicDefinitions>
  <MetaDataVersion OID="v1.0.0-$S_R0112345_9477" Name="MetaDataVersion_v1.0.0-$S_R0112345_9477">
    <Include StudyOID="$S_R0112345" MetaDataVersionOID="v1.0.0"/>
    <Protocol>
      <StudyEventRef StudyEventOID="SE_REGISTRA" OrderNumber="1" Mandatory="Yes"/>
      <StudyEventRef StudyEventOID="SE_INITIALT" OrderNumber="2" Mandatory="Yes"/>
      <StudyEventRef StudyEventOID="SE_FOLLOWUP" OrderNumber="3" Mandatory="Yes"/>
      <StudyEventRef StudyEventOID="SE_ADVERSEEE" OrderNumber="4" Mandatory="Yes"/>
    </Protocol>
    <StudyEventDef OID="SE_REGISTRA" Name="Registration Visit" Repeating="No" Type="Scheduled">
      <FormRef FormOID="F_ELIG_V10" Mandatory="Yes"/>
      <FormRef FormOID="F_PHYS_ENGL" Mandatory="Yes"/>
      <FormRef FormOID="F_PHYS_SPAN" Mandatory="Yes"/>
    </StudyEventDef>
  </MetaDataVersion>
</Study>

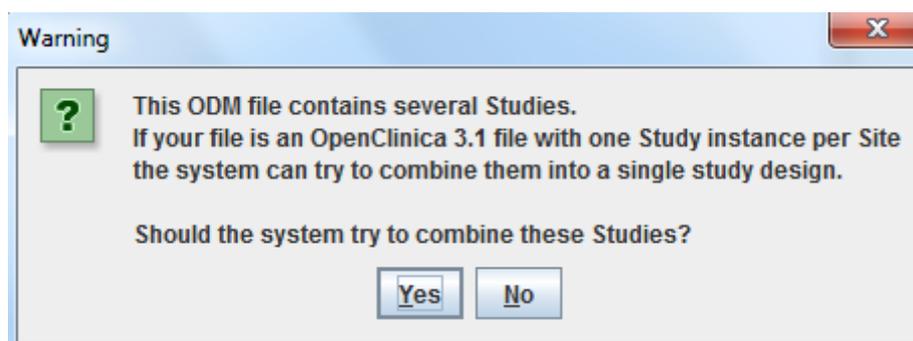
```

Also here, there is an „Include“ statement stating to first include all definitions of the first study, with all following definitions (the new ones) either overriding the old ones (if one with the same OID is present), or adding a new definition (if no such one was present yet). This applies as well to StudyEvents (visits), Forms, ItemGroups, Items, CodeLists, etc..

If one looks into the details, essentially what this study design is saying is:

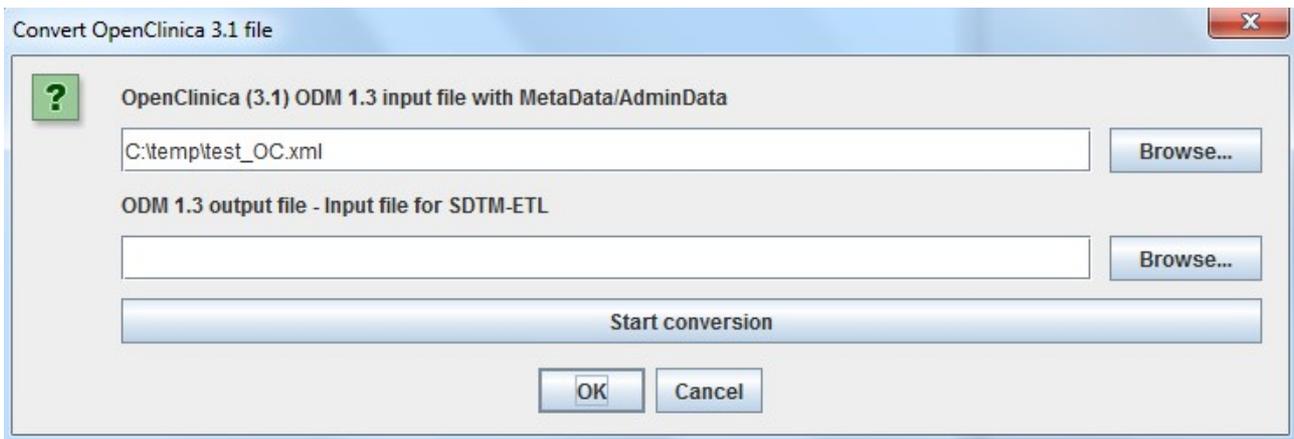
- there are 5 visits defined
- the registration visit („SE_REGISTRA“) uses 4 forms by default, if nothing else is defined for a single site
- site 3192 (Study OID = S_R0112345_3192) uses only 2 forms („F_PHYS_ENGL“ and „F_PHYS_SPAN“) in the registration visit, the new definition for SE_REGISTRA overrides the old one.
- site 9477 (Study OID = S_R0112345_9477) uses 3 forms in the registration visit (F_ELIG_V10, F_PHYS_ENGL and F_PHYS_SPAN).

When trying to load this file (independent on whether you have the „OpenClinica flavor“ of the software or the normal version), you will get the following dialog:

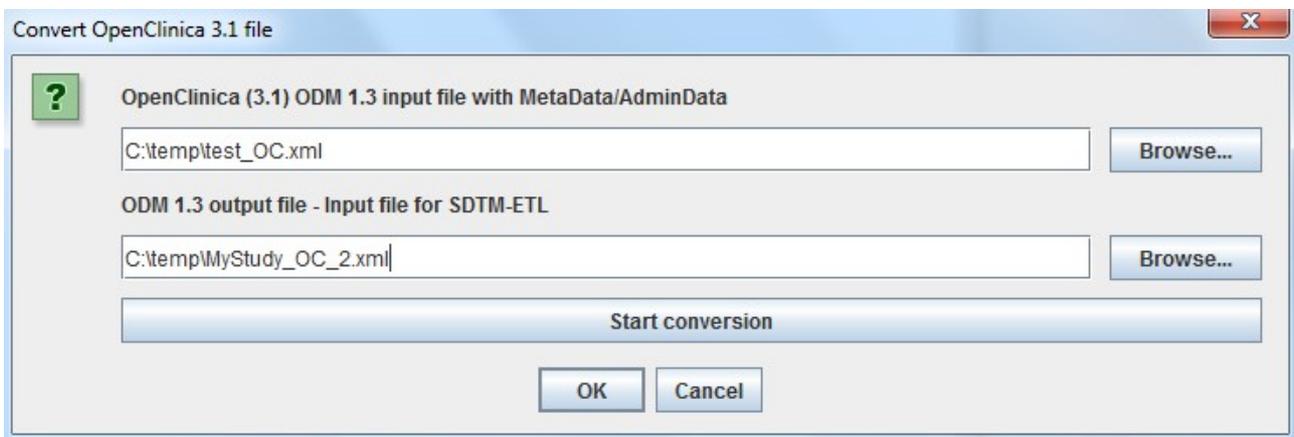


If you say „No“, the system will stop loading file and ask you to provide an ODM file containing a single „Study-MetaDataVersion“ combination.

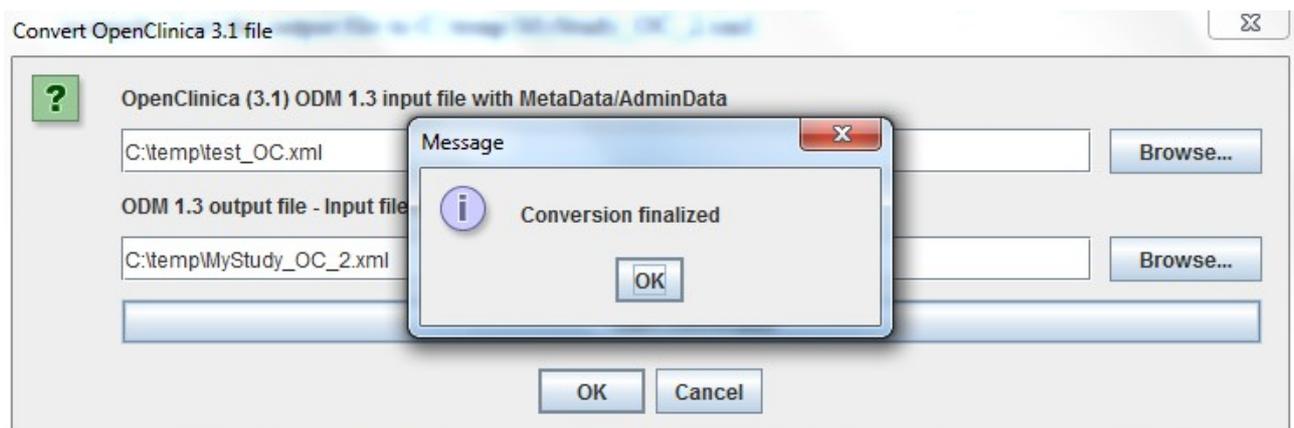
If you click „Yes“, the following dialog is displayed:



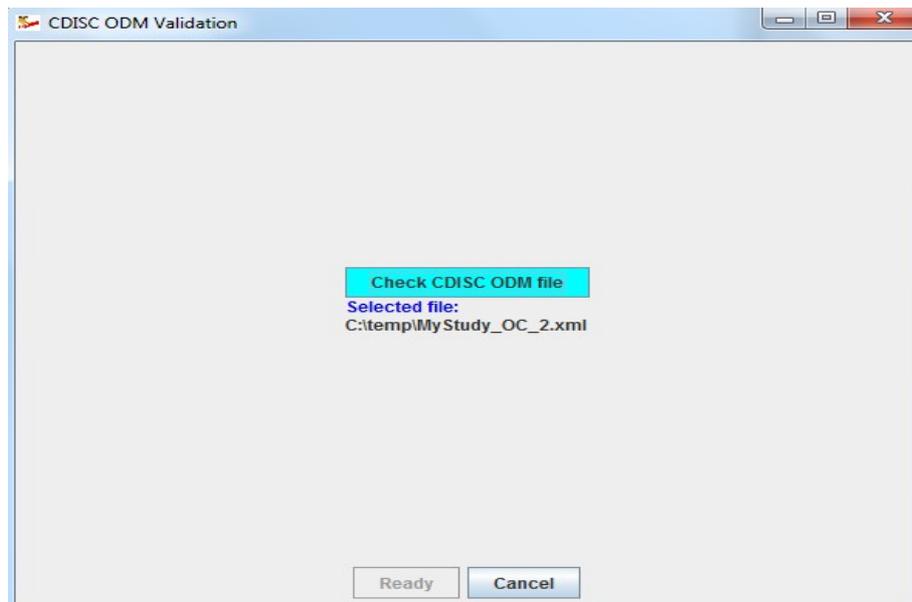
asking for a file path where the system can write the combined studies (i.e. into a single one). You can then later pick that particular file instead of having to go through the whole process again. For example, I set the output file to C:\temp\MyStudy_OC_2.xml:



When then clicking „Start conversion“, such a file containing a single Study is generated and stored into the file MyStudy_OC_2.xml in directory C:\temp:



When then clicking OK, the file MyStudy_OC_2.xml is loaded and validation can start (as usual):



The result file MyStudy_OC_2.xml looks like:

```
<MetaDataVersion Name="MetaDataVersion_v1.0.0" OID="v1.0.0">
  <Protocol>
    <StudyEventRef Mandatory="Yes" OrderNumber="1" StudyEventOID="SE_REGISTRA"/>
    <StudyEventRef Mandatory="Yes" OrderNumber="2" StudyEventOID="SE_INITIALT"/>
    <StudyEventRef Mandatory="Yes" OrderNumber="3" StudyEventOID="SE_FOLLOWUP"/>
    <StudyEventRef Mandatory="Yes" OrderNumber="4" StudyEventOID="SE_ADVERSEE"/>
    <StudyEventRef Mandatory="Yes" OrderNumber="5" StudyEventOID="SE_DOSINGVI"/>
  </Protocol>
  <StudyEventDef Name="Registration Visit" OID="SE_REGISTRA" Repeating="No" Type="Scheduled">
    <FormRef FormOID="F_ELIG_V10" Mandatory="Yes" OrderNumber="1"/>
    <FormRef FormOID="F_PHYS_ENGL" Mandatory="Yes" OrderNumber="2"/>
    <FormRef FormOID="F_PHYS_SPAN" Mandatory="Yes" OrderNumber="3"/>
    <FormRef FormOID="F_VERI_V30" Mandatory="Yes" OrderNumber="4"/>
  </StudyEventDef>
</MetaDataVersion>
```

Listing all 5 visits and all 4 forms for the registration visit.

Note that it will not always be so easy to combine the different „studies“/“sites“ into a single file. Therefore it is very important that you inspect the result file and validate its contents.