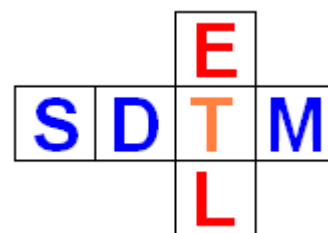


# SDTM-ETL 5.0 User Manual and Tutorial: Using the "ODMSubjectRetriever"

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Last update: 2025-06-17



## Introduction

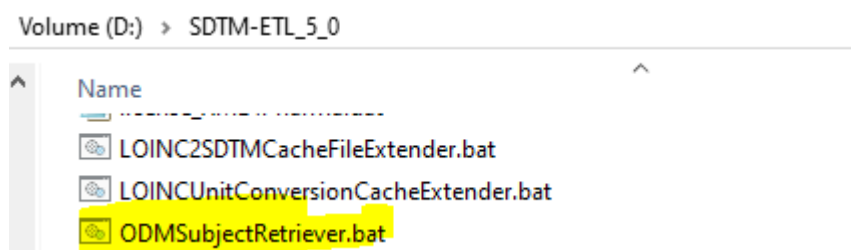
The "ODMSubjectRetriever" is a small utility program introduced in SDTM-ETL 5.0 and very recently extended, to allow users to create a subset of clinical data in ODM format for a small number of subjects, or to exclude subjects from an existing ODM file with clinical data.

It was developed on request of one of our users who had very large ODM files with many or very many subjects, which meant that, during initial development and testing of the mappings, it could take considerable time to execute the developed mappings on the original ODM file with clinical data. They just wanted to be able to test the mappings on clinical data of a single subject or a few subjects only.

Essentially, the "ODMSubjectRetriever" allows to generate an ODM file with a subset of subjects by the ODM "SubjectKey"

## Starting the "ODMSubjectRetriever"

In the distribution for Windows, one will find a file "ODMSubjectRetriever.bat"



To start the software, double-click "ODMSubjectRetriever.bat".

This will open a new window:

ODM Subject Retriever

Input ODM file with Clinical Data:

☒ Include Subjects  
☐ Exclude Subjects

List of SubjectKey values (space-separated) of subjects to be **included** in the output ODM

Output ODM file with Clinical Data of the selected subjects:

Remark that in the original (old) version, you will not have the radiobutton "Exclude Subjects". This has recently been added to be able to select subjects (by the ODM "SubjectKey") to be removed.

## Using the "ODMSubjectRetriever" to select subjects to be included or excluded

One will first select an ODM input file, usually using the upper "Browse" button, which opens a "file chooser" and e.g. leads to:

ODM Subject Retriever

Input ODM file with Clinical Data:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_more\_subjects.xml

☒ Include Subjects  
☐ Exclude Subjects

List of SubjectKey values (space-separated) of subjects to be **included** in the output ODM

Output ODM file with Clinical Data of the selected subjects:

In the next step, one can choose between providing a list of subjects (by the "SubjectKey") to be included ("Include Subjects" radiobutton) or providing a list of subjects to be excluded ("Exclude Subjects" radiobutton). If the "Exclude Subjects" radiobutton is selected, the label in the next line will change into:

ODM Subject Retriever

Input ODM file with Clinical Data:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_more\_subjects.xml Browse

☐ Include Subjects

☒ Exclude Subjects

List of SubjectKey values (space-separated) of subjects to be **excluded** from the output ODM List Subjects

Output ODM file with Clinical Data of the selected subjects:

Browse

Execute subject data retrieval

By clicking the "List Subjects" button, a list of the subjects (by "SubjectKey") to be either included or excluded is displayed. For example for "Include Subject":

ODM Subject Retriever

Input ODM file with Clinical Data:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_more\_subjects.xml Browse

☒ Include Subjects

☐ Exclude Subjects

List of SubjectKey values (space-separated) of subjects to be **included** in the output ODM List Subjects

Output ODM file with Clinical Data of the selected subjects:

Browse

Execute subject data retrieval

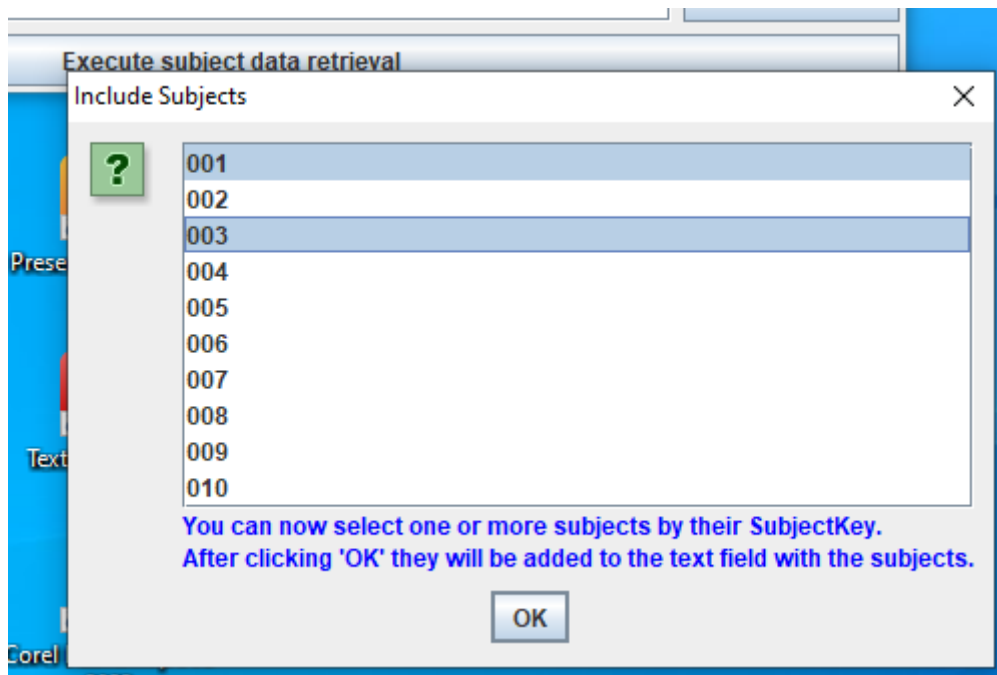
**Include Subjects**

001  
002  
003  
004  
005  
006  
007  
008  
009  
010

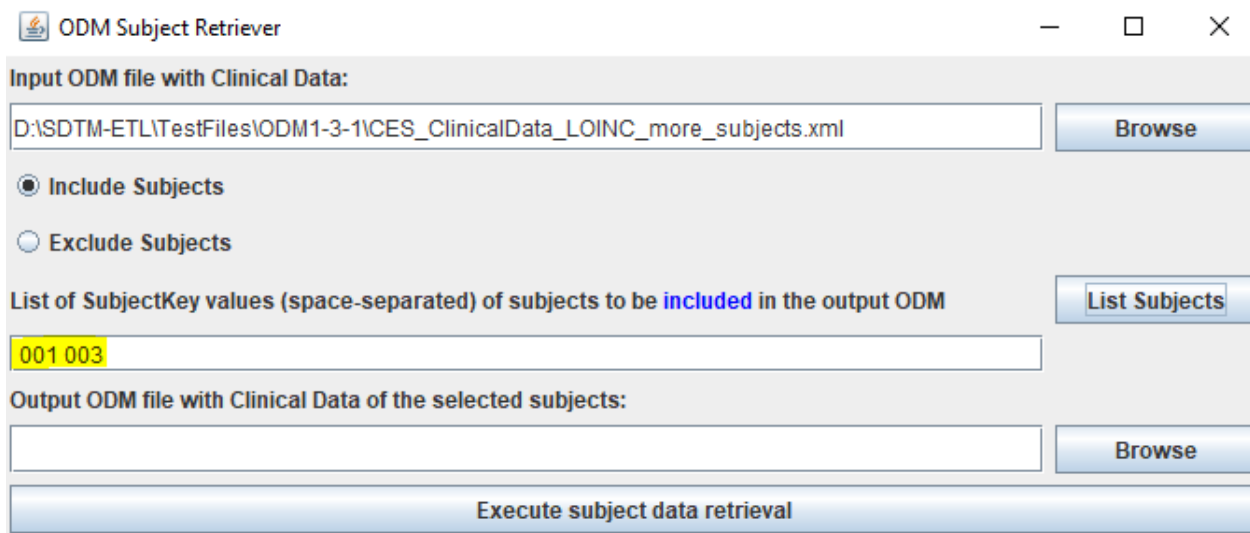
You can now select one or more subjects by their SubjectKey.  
After clicking 'OK' they will be added to the text field with the subjects.

OK

If we only want to retain the subjects "001" and "003" in the ODM output file, we just select these using the mouse (use "Ctrl" for multiple selection), e.g.:



leading to have the field below "List of SubjectKey ..." to be filled with:



One can of course also type the values ...

We then need to select an ODM file to be created, which, at least for the "ClinicalData" part will mostly be a copy of the input ODM file, but with only the subjects from the list included (when "Include Subjects" is selected), or without the subjects from the list (when "Exclude Subjects" is selected). For example:

ODM Subject Retriever

Input ODM file with Clinical Data:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_more\_subjects.xml Browse

☒ Include Subjects  
☐ Exclude Subjects

List of SubjectKey values (space-separated) of subjects to be **included** in the output ODM List Subjects

001 003

Output ODM file with Clinical Data of the selected subjects:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_Subjects\_001\_003.xml Browse

Execute subject data retrieval

and then clicking "Execute subject data retrieval", will, after a few seconds (depending on the file size of the input file), lead to the message:

ODM Subject Retriever

Input ODM file with Clinical Data:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_more\_subjects.xml Browse

☒ Include Subjects  
☐ Exclude Subjects

List of SubjectKey values (space-separated) of subjects to be **included** in the output ODM List Subjects

001 003

Output ODM file with Clinical Data of the selected subjects:

D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_Subjects\_001\_003.xml Browse

Execute subject data retrieval

**Done**

File with clinical data for selected subjects written to:  
D:\SDTM-ETL\TestFiles\ODM1-3-1\CES\_ClinicalData\_LOINC\_Subjects\_001\_003.xml  
File size is: 0.046 MB

OK

When one now opens the generated ODM file, e.g. using NotePad++ (or an XML editor), and collapses the "SubjectData" elements, one will see that the generated ODM file only contains data for two subjects:

```

1  <?xml version="1.0" encoding="UTF-8"?>
2  <ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
3      xmlns:ds="http://www.w3.org/2000/09/xmldsig#"
4      xmlns:xs="http://www.w3.org/2001/XMLSchema"
5      xmlns:xlink="http://www.w3.org/1999/xlink"
6      CreationDateTime="2010-09-17T14:15:23+01:00"
7      Description="A simple trial to demonstrate the end-to-end application of the CDISC Standards"
8      FileOID="CES_001"
9      FileType="Snapshot"
10     Granularity="SingleSubject"
11     ODMVersion="1.3.1"
12     SourceSystem="XML4Pharma CDISC ODM ClinicalData Collection"
13     SourceSystemVersion="2008R2">
14     <ClinicalData StudyOID="CES" MetaDataVersionOID="CES_MDV_V1">
15         <SubjectData SubjectKey="001">
16         <SubjectData SubjectKey="003">
17     </ClinicalData>
18 </ODM>

```

If one had selected "Exclude Subjects", the newly created file will contain the data of all the subjects, except from subjects with SubjectKey "001" and "003".

## Conclusions

The "ODMSubjectRetriever" utility program can be used to generate an ODM file with only one or a few subjects. Using such a generated file can help speeding up testing the developed mappings. Of course, for generating the final SDTM/SEND datasets, one will need to use an ODM file with the clinical data for all the subjects.

A new feature is to be able to exclude subjects, which can e.g. be "screening failures" for which one does not want to have data in the SDTM datasets. This can normally however also be done by ODM export settings in the EDC system.