

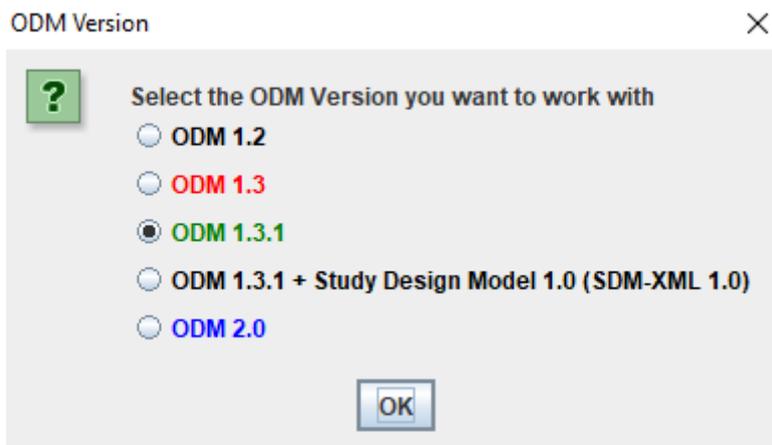
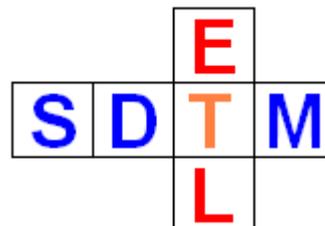
SDTM-ETL 5.0 User Manual and Tutorial

Author: Jozef Aerts, XML4Pharma

Last update: 2025-02-03

Loading and inspecting the ODM Study Design

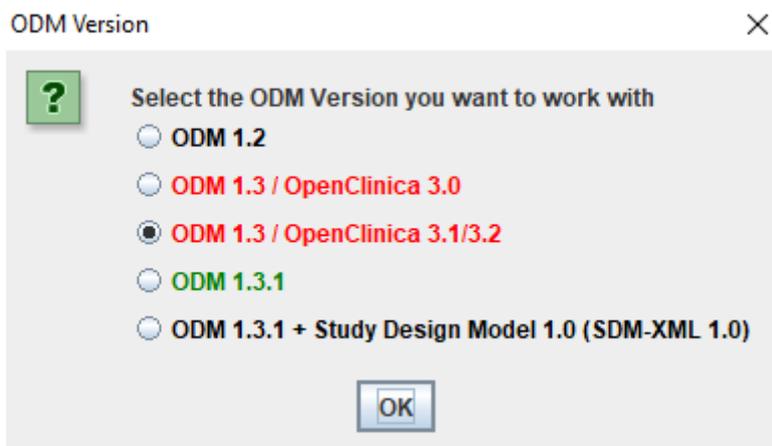
After you have started the SDTM-ETL software, you will be prompted for the version of the CDISC ODM standard that your study design is in:



You can choose between ODM 1.2, ODM 1.3, ODM 1.3.1, and ODM 2.0.

In case you have also implemented the "Study Design Model in XML" extension in your study design, choose the "ODM 1.3.1 + Study Design Model 1.0"

Users who have obtained the "OpenClinica version" will also see a choice between OpenClinica version 3.0 and 3.1:



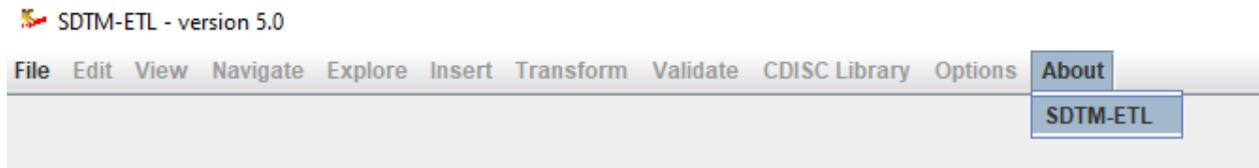
In our case, our study design has been written in ODM version 1.3.1. Click OK to continue.

If your ODM file contains unsupported vendor extensions¹, you will see another dialog, allowing to

¹SDTM-ETL currently supports OpenClinica and Clinovo ClinCapture vendor extensions – the latter is a branching off of OpenClinica, as well as Medidata and Viedoc extensions.

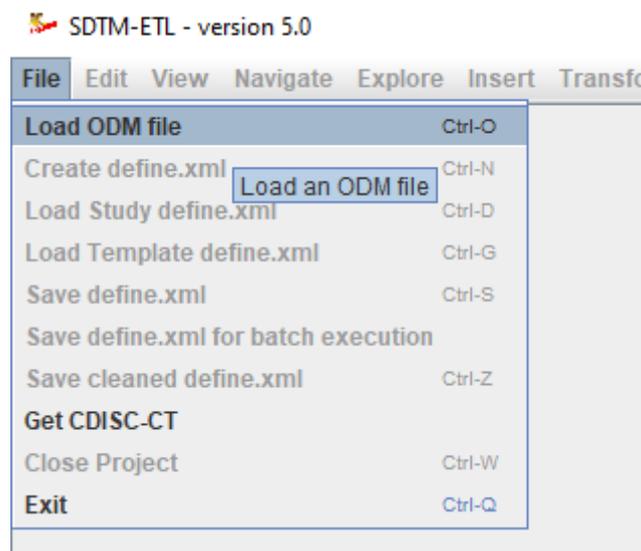
remove the unsupported vendor extension elements and attributes from the ODM file. For details, please see the tutorial "Removing Vendor Extensions".

The following screen is now displayed (partial view):



The "About" menu gives you some basic information about the software, and allows you to read the license conditions.

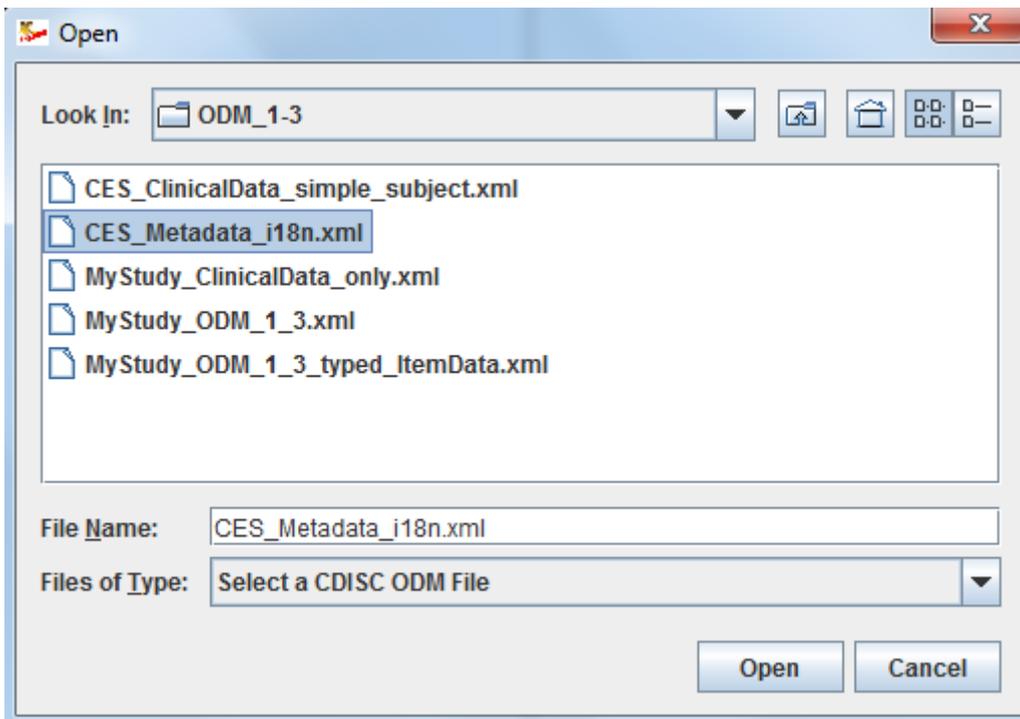
We can now start loading the ODM file. To do so, use the menu "File – Load ODM file":



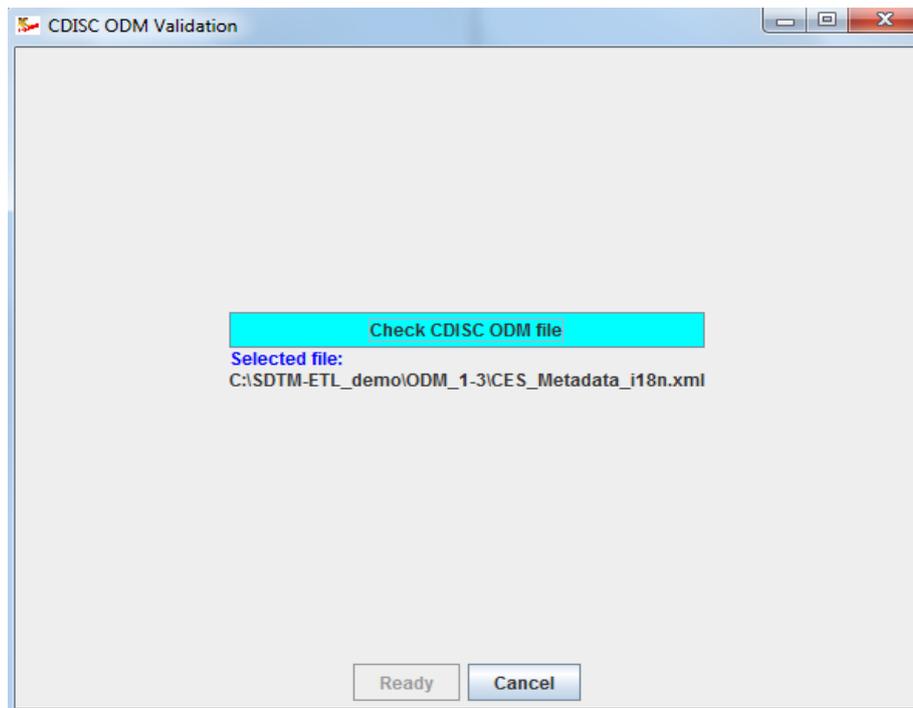
or just use CTRL-O.

A filechooser dialog is displayed, allowing to select the ODM file of your choice. In our case, we select an ODM file with the internationalized "CES" study design²:

²This is a study design originally developed by Dave Ibersen-Hurst for demo purposes, and later extended by others.

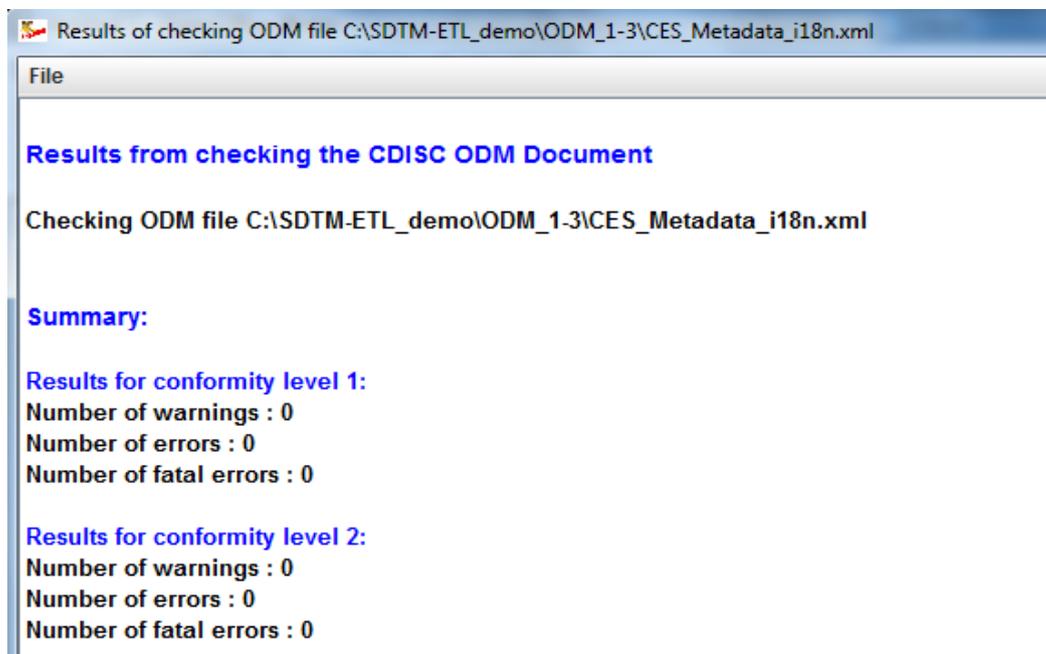


As the file needs to be a valid ODM file, a validation step now follows. The following dialog is displayed:



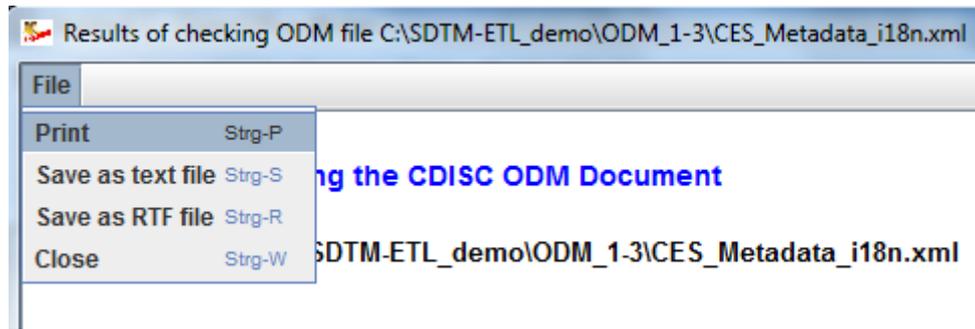
Click the "Check CDISC ODM file" to start validation.

During validation, you will be able to see the progress and interim error and warning messages (if it's too bad, you can still interrupt the process). After a few seconds, a window with the results of the validation is shown:

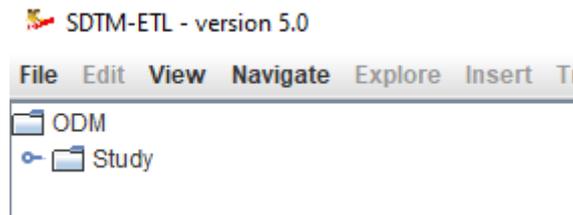


Everything went fine.

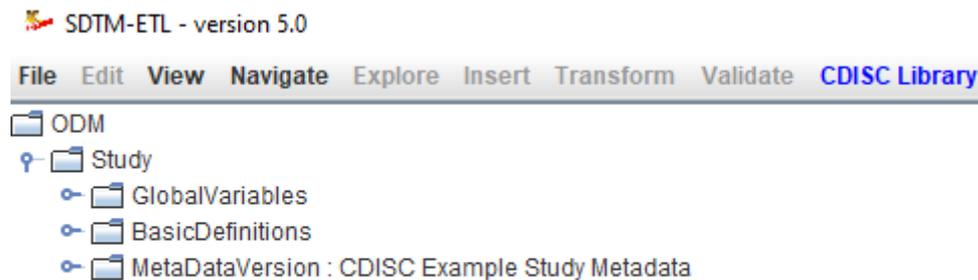
In case you have errors, you can save the report that is displayed on the screen to a text or to an RTF file, or print the report. To do so, use the menu "File" followed by the action of what you want to do:



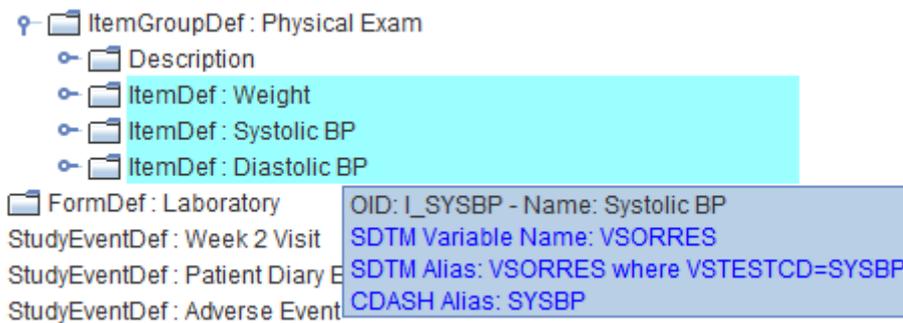
As everything went fine in our case, you can now close the window, and click "Ready" in the "ODM Validation" dialog. The ODM file is loaded, and on the left side of the main screen, a tree view of our study design is displayed. Also some more menus have become available:



You can expand the tree by clicking on the symbol left of the "Study":



and e.g. then expand the branch for "MetaDataVersion". By expanding and collapsing tree nodes, you can then always navigate to those parts of the study design that is of interest to you. For example:



where one sees that there is also a CDASH annotation.

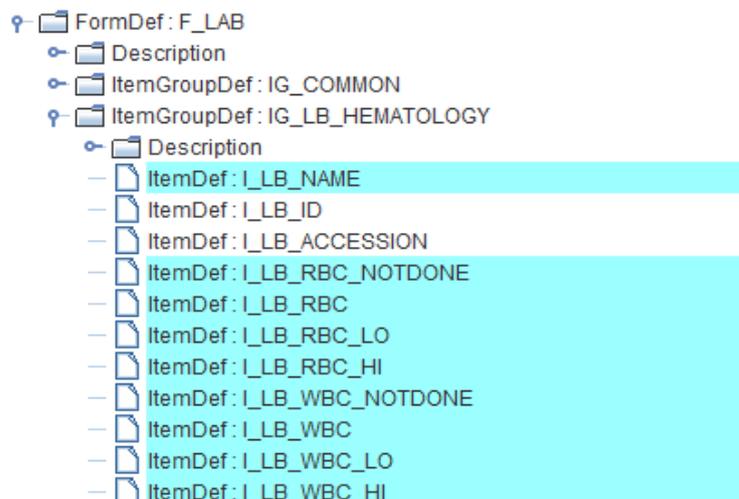
Later, we will see that this can help the mapping process enormously.

Once the study design displayed as a tree, there is a lot of things we can already do.

As you might have noticed, each tree node is shown with the value of the "Name" attribute of the corresponding ODM node. In some cases however, it can be very useful to see the tree node with its identifier (which is the "OID" in ODM). To do so, use the menu "View – ODM tree with OIDs":

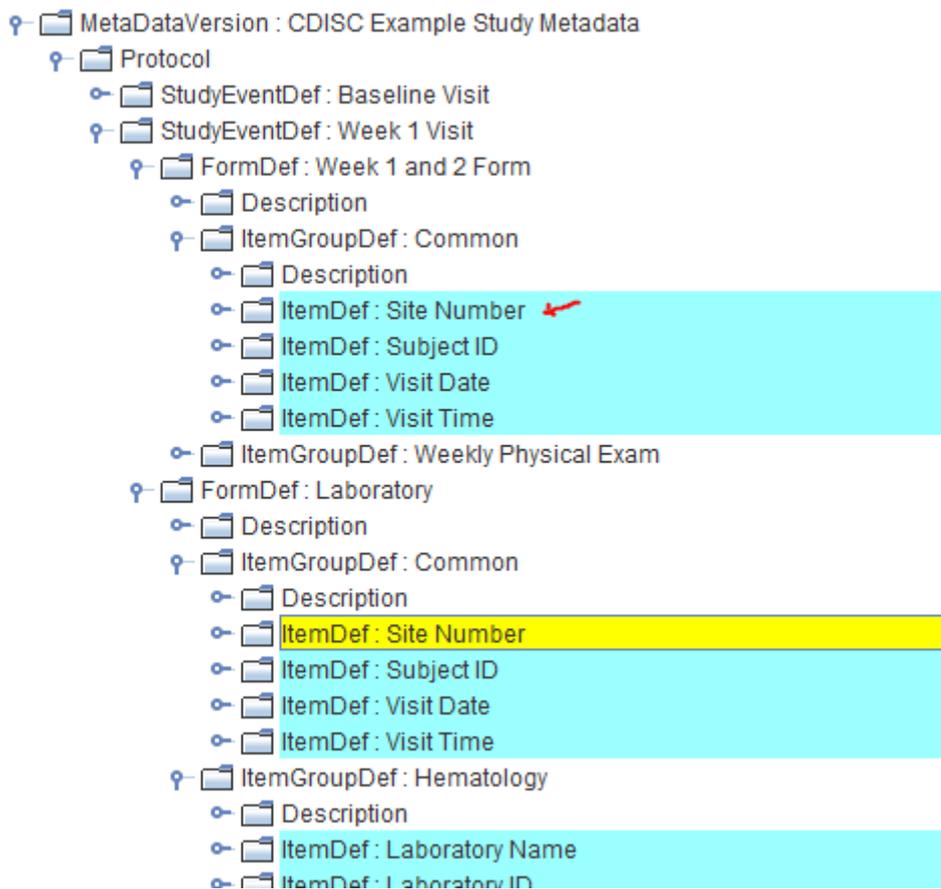


which in our case leads to:



One can then always go back to a tree view with the names of the nodes, by using the menu "View - ODM tree with Names"

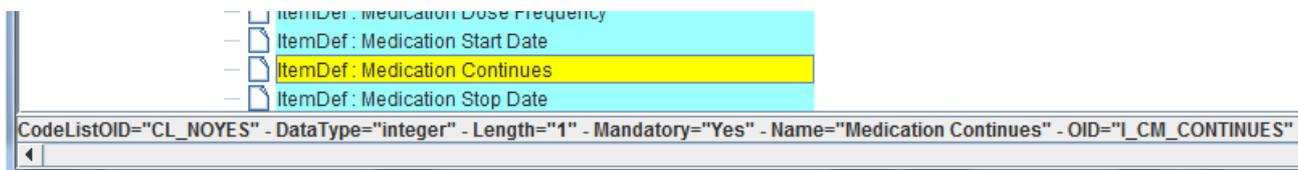
We can still ignore the menu "View – ODM tree without 'traffic lights'", this will be of importance once we have loaded an SDTM template.



which can also be achieved using the keyboard combination "CTRL – page down". Similarly, one can navigate to the previous occurrence by using the menu "Navigate – Previous Instance", or use "CTRL – Page up".

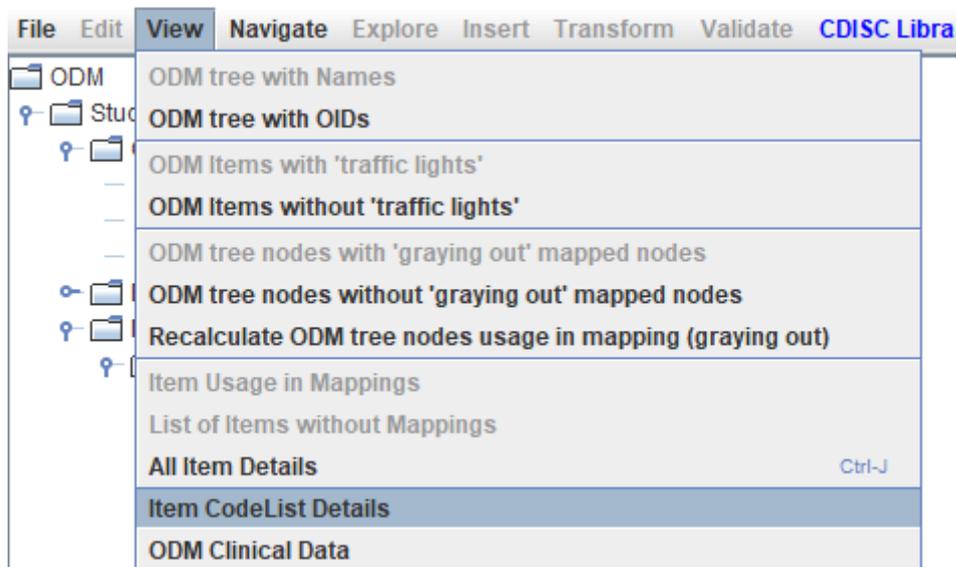
In many cases, this will be very useful, as in SDTM there are many occasions where there is a structure "one record per ... per visit per subject", so we need to find out for which visits there may be a record for the specific variable.

Some items in our study design have an associated codelist. This can easily be seen by selecting the item, and then look into the „information bar“ near the bottom of the screen. For example:

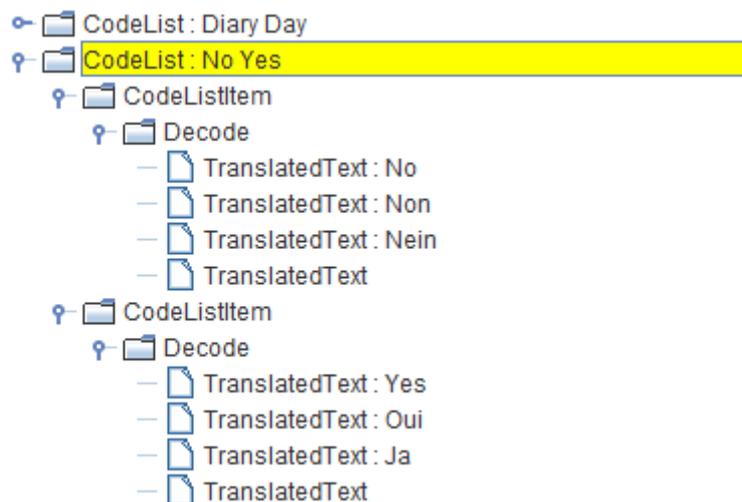


stating CodeListOID="CL_NOYES", but also displaying information like the data type of the item, the length, whether it is a mandatory question in the form, and of course the OID.

In many cases, one will want to know the details of the associated codelist. This can be achieved by using the menu "View – Item CodeList Details":



The system will then expand the tree node for the associated node, and select and jump to it (even if it was not visible before). In our case:



Similarly, if one want to find all details about a specific item in the tree, one can use the menu "View - All Item Details". This will generate a set of tables which is then displayed in a new window. For example, for "Visit Date":



**Details for ItemDef with OID I_VISIT
with Name 'Visit Date'**

Data type	Mandatory?	Max. Length	Max. Characters after decimal point	SASFieldName	Mapping to SDTM variable
date	Yes			VISITDAT	RFSTDTC

Question

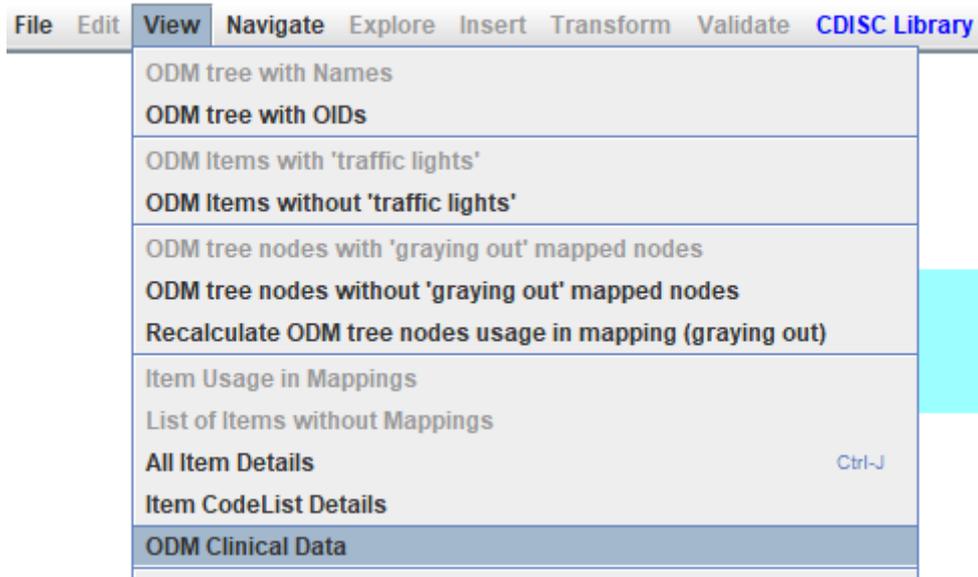
Language	Description
en	Visit Date
fr	Date de Visite
de	Besuchsdatum
ko	□□□□

Alias: Synonyms in another context

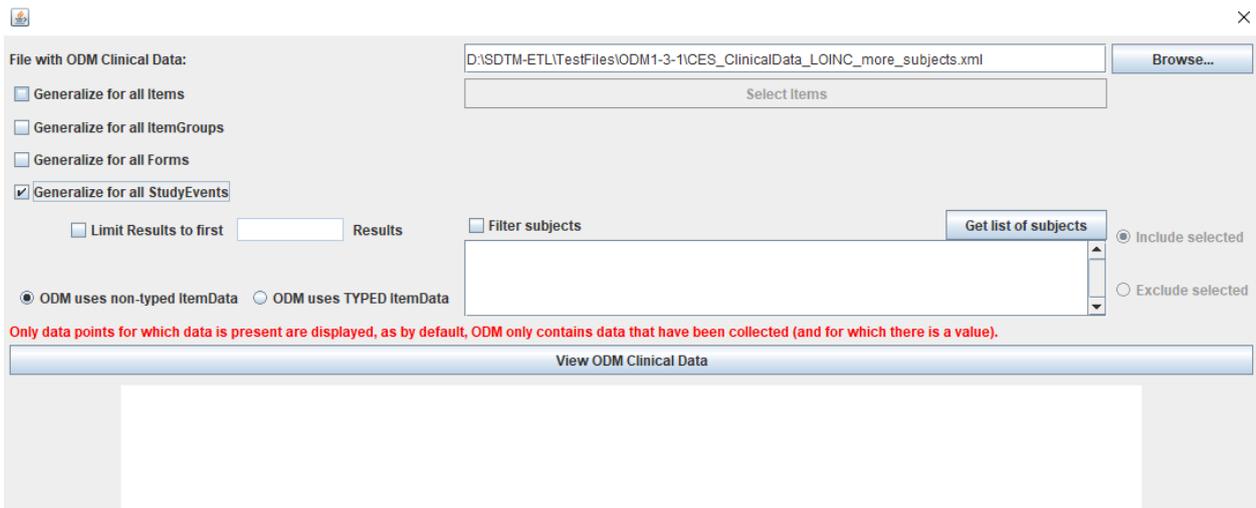
Context	Synonym (name)
CDASH	VISDAT
SDTM	VSDTC

A very important feature of the software is that one can inspect (already) collected clinical data for that item. This will also often give insight in how the item can be mapped to SDTM, especially in the case the data is free text, and when the ODM study design was not annotated with SDTM information.

In order to find collected clinical data for a specific item, select that item first, and then use the menu "View – ODM Clinical Data":



A dialog is then displayed allowing the user to select a file with ODM clinical data, and to set the scope for the search. For example, for "Erythrocytes", at least one occurrence per visit is expected, so the checkbox "Generalize for all StudyEvents" is checked:



For example, for the item "Erythrocytes" (I_LB_RBC), the following table is then obtained:

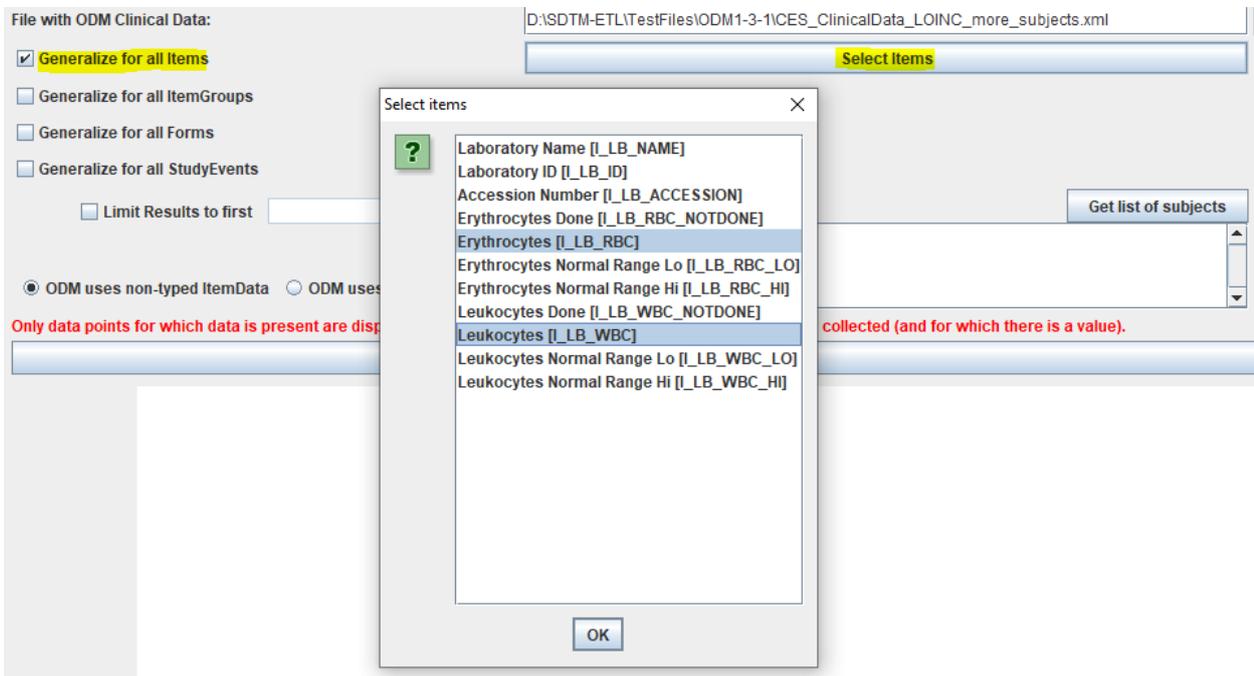
The table displays the following data points for Erythrocytes:

Subject	StudyEvent	Form	ItemGroup	Item	Name	Value
001	BASELINE	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	4.9
001	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.1
001	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.1
001	WEEK_2	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.4
002	BASELINE	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.0
002	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.2
002	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.1
002	WEEK_2	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.5
003	BASELINE	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	4.9
003	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.2
003	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.2
003	WEEK_2	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.3
004	BASELINE	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	4.88
004	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.2
004	WEEK_1	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.0
004	WEEK_2	F_LAB	IG_LB_HEMATOLO...	I_LB_RBC	Erythrocytes	5.5

Max.Length expected: 8 - Max.Length encountered: 4

showing all erythrocyte values that were captured using this item in any visit.

If one also wants to have the "Leukocytes" values display, then use "Generalize for all Items", then click "Select Items", and select both "Erythrocytes" and "Leukocytes":



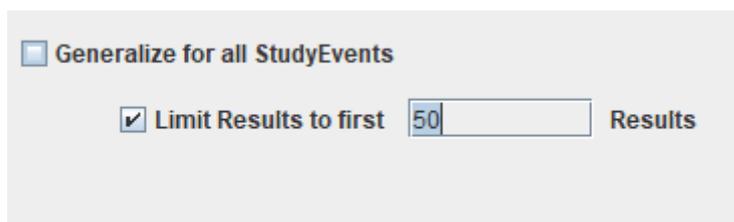
and then click "View ODM Clinical Data" again, leading to the result:

The screenshot shows the 'View ODM Clinical Data' table. The table has columns for Subject, StudyEvent, Form, ItemGroup, Item, Name, and Value. The data points are as follows:

Subject	StudyEvent	Form	ItemGroup	Item	Name	Value
001	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.1
001	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.4
001	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.1
001	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.5
002	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.2
002	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.3
002	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.1
002	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.6
003	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.2
003	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.7
003	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.2
003	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.4
004	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.2
004	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	6.24
004	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_RBC	Erythrocytes	5.0
004	WEEK_1	F_LAB	IG_LB_HEMATOLOGY	I_LB_WBC	Leukocytes	7.1

Max.Length expected: 8 - Max.Length encountered: 4

In case one just wants to have a first impression what the values look like, and one has a lot of such data, one can use the checkbox and field "Limit Results to first ... Results"

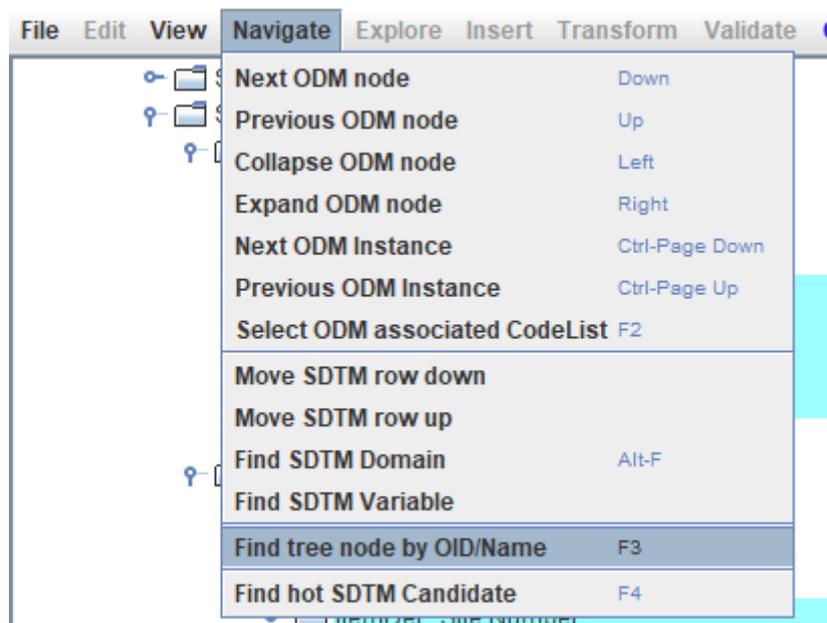


One can also limit the selection to results for specific subjects. In order to do so, first use the checkbox "Filter subjects" and then (if there is no list yet) click "Get list of subjects".

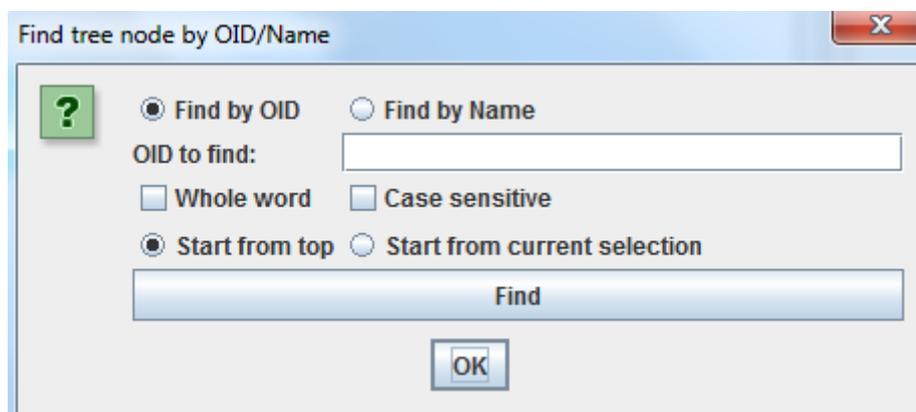


One can then select one or more subjects from the list, and either include them to have the results for them displayed, or exclude them, the latter using the radiobutton "Exclude selected".

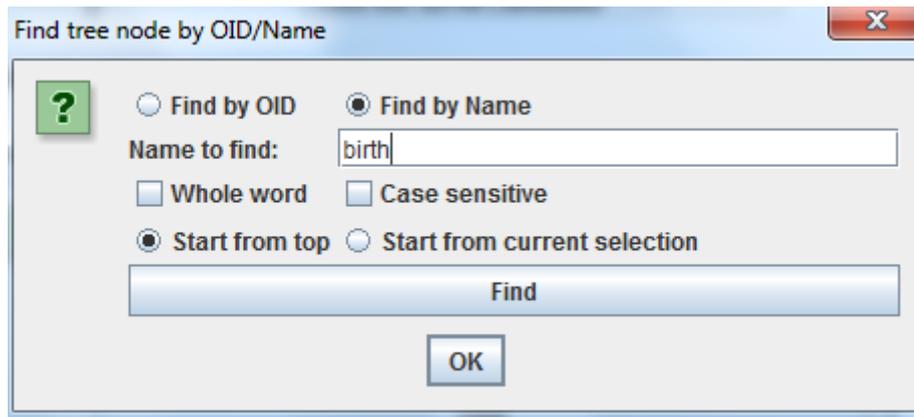
Last but not least let us have a look at another feature for finding particular items in the study design tree. For example, we need to retrieve the birth date of the subject for populating the SDTM variable "BRTHDTC" in the demographics domain. However, we do not know where the corresponding item occurs in the study design tree. We can start expanding and collapsing tree nodes, but this is of course very inefficient. We can however do a textual search in the tree using the menu "Navigate – Find tree node by OID/Name":



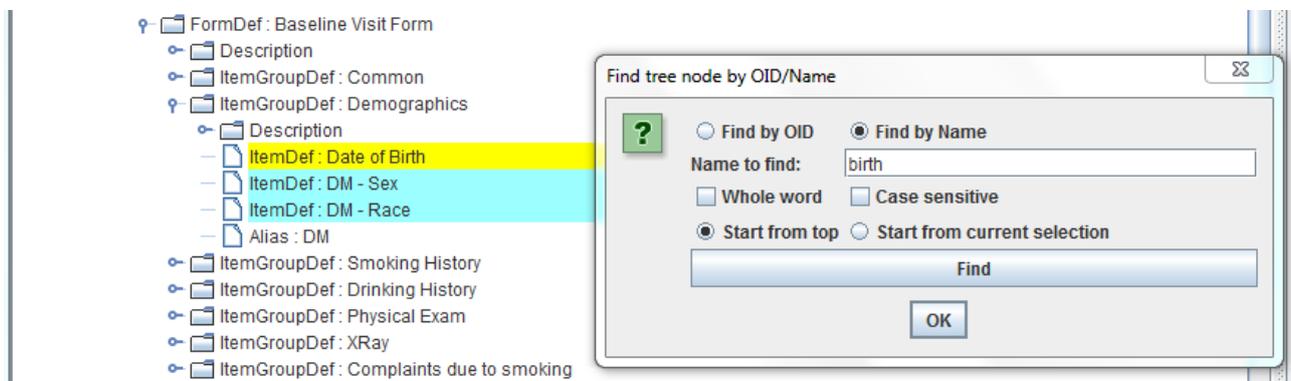
A dialog is then displayed:



In our case, we guess that an Item about the birth date of will have the word "birth" in the Item name, so we use:



and using the "Find" button, we immediately find:



even when that tree node was not visible before.

The menu "Navigate – Find hot SDTM Candidate" will be explained later when the first mappings to SDTM or SEND are developed.