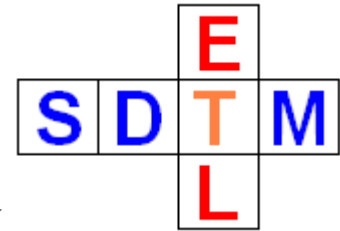# SDTM-ETL 3.2/4.x User Manual and Tutorial
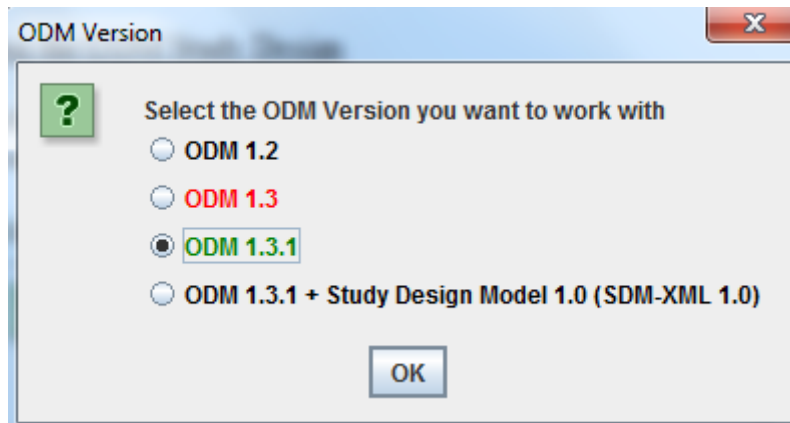
Author: Jozef Aerts, XML4Pharma

Last update: 2022-06-19

## 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, and ODM 1.3.1.
In case you have 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:
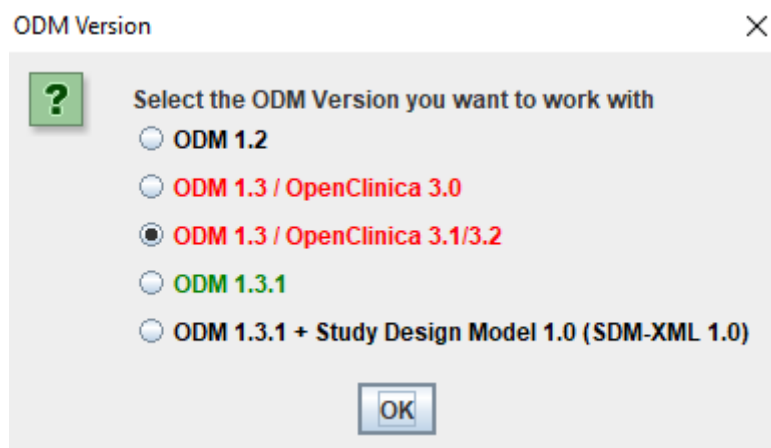
In our case, our study design has been written in ODM version 1.3.1.
Click OK to continue.

If your ODM file contains unsupported vendor extensions[1], you will see another dialog, allowing to

---

[1]SDTM-ETL currently supports OpenClinica and Clinovo ClinCapture vendor extensions – the latter is a branching off of OpenClinica

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):
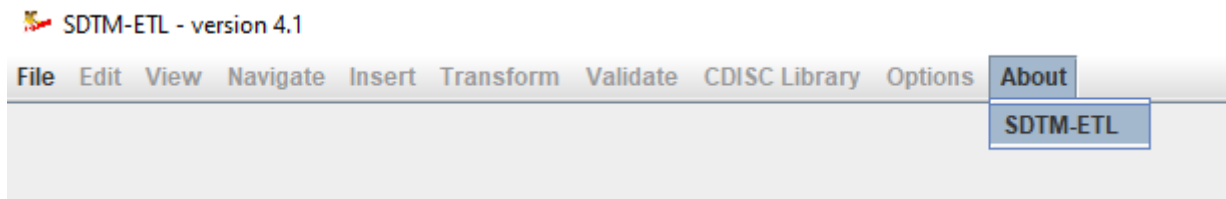
The "About" menu gives you some basic information about the software, and allows you to read the license conditions.
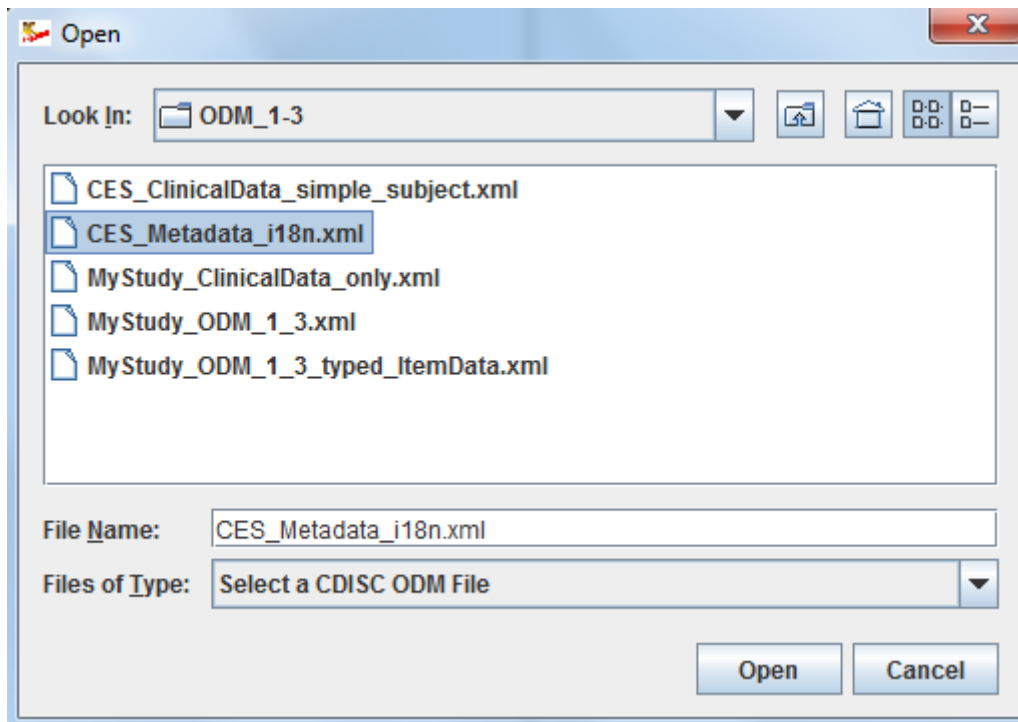
We can now start loading the ODM file. To do so, use the menu "File – Load ODM file":
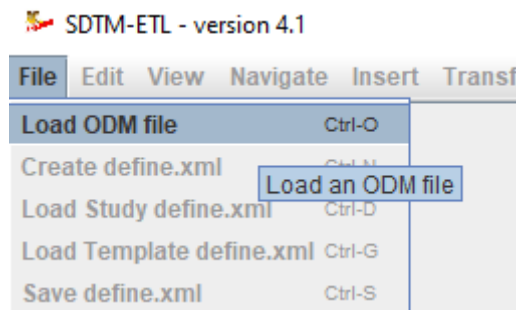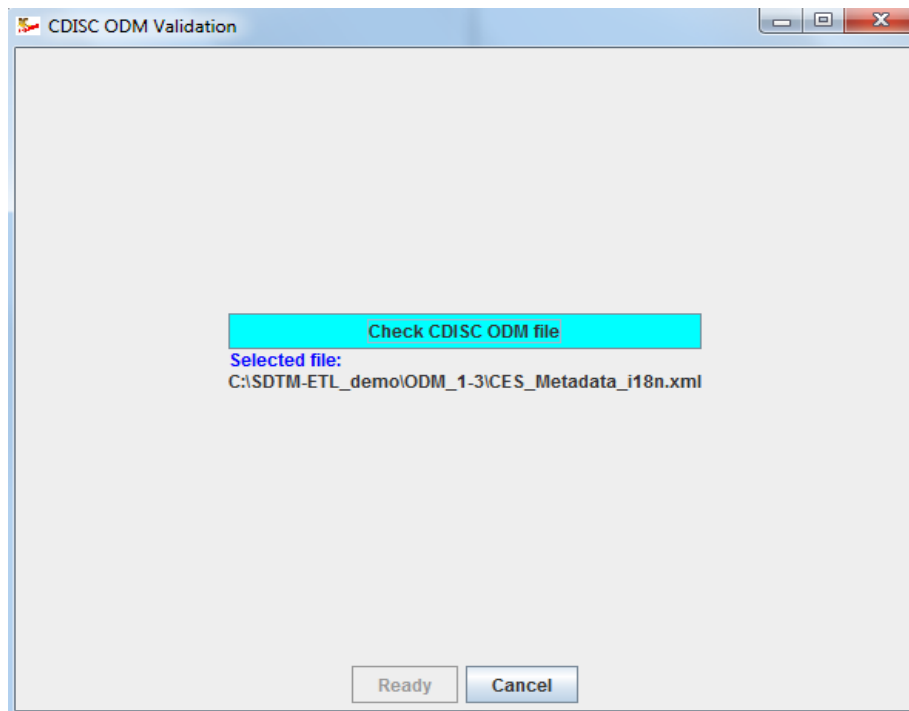

or just use CTRL-O.

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 design[2]:


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:
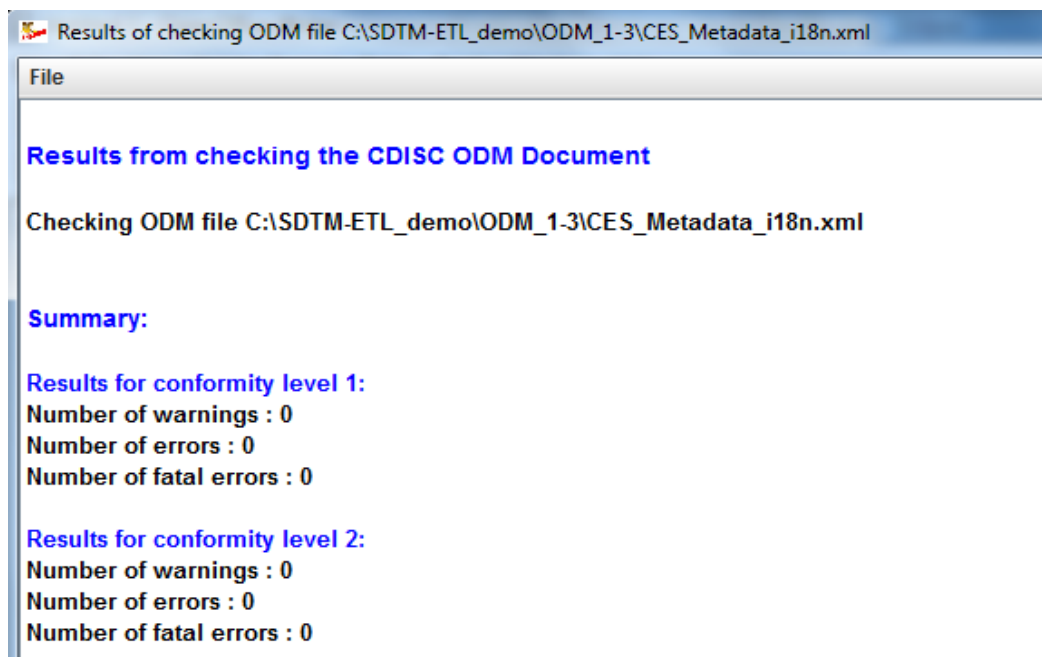
Everything went fine.

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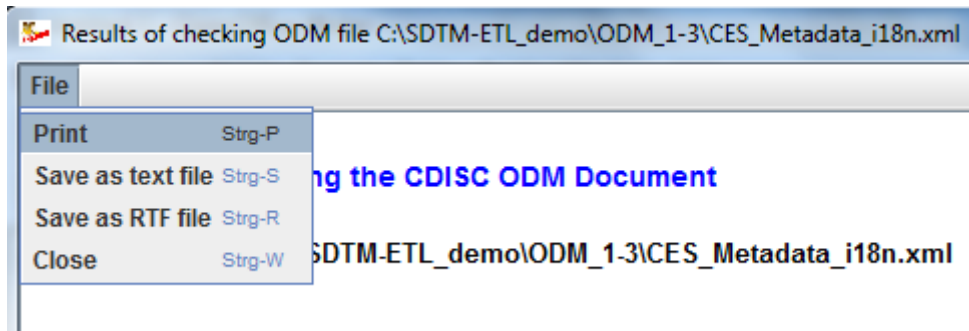
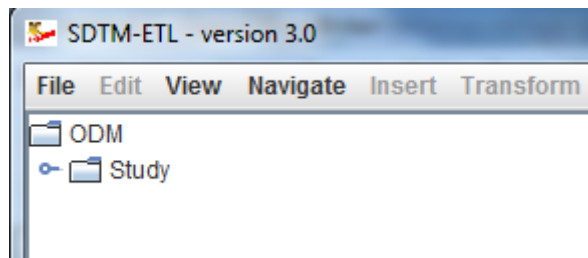As everything went fine in our case, you can now close the window, and click "Ready" in the "ODM Validation" dialog. The ODM file is loaded, and on the left side of the main screen, a tree view of our study design is displayed. Also some more menus have become available:

You can expand the tree by clicking on the symbol left of the "Study":
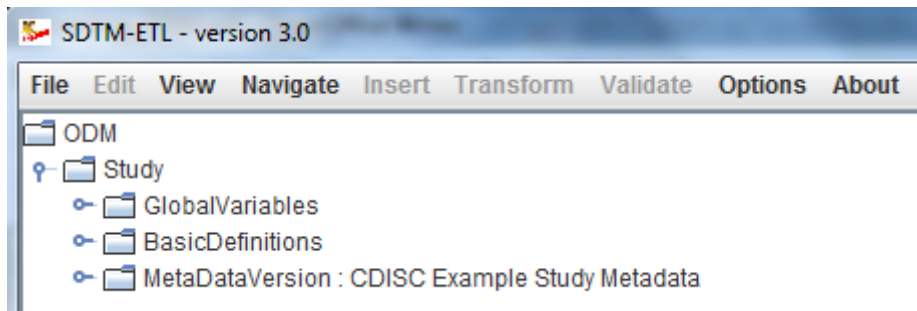
and e.g. then expand the branch for "MetaDataVersion". By expanding and collapsing tree nodes, you can then always navigate to those parts of the study design that is of interest to you. For example:
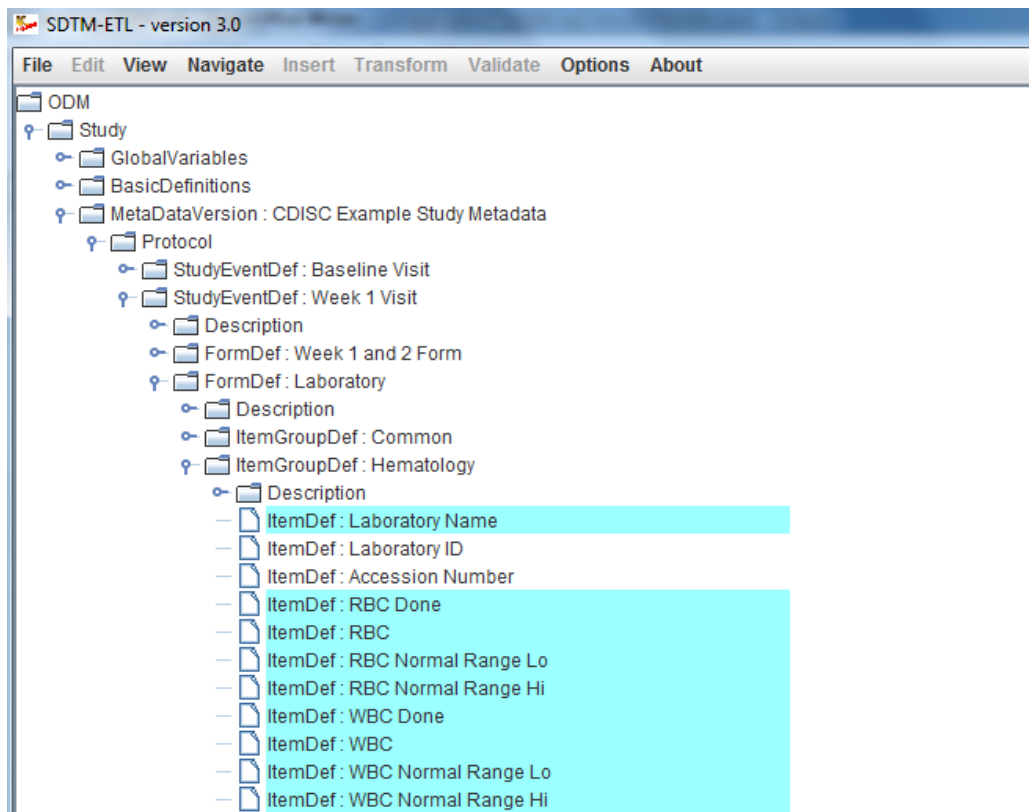
One sees that some of the "ItemDefs" have a cyan-colored background. These are items that have been annotated in the ODM Study Design as being of importance to SDTM, using the "Alias" mechanism, or using "SDSVarName" as an attribute on ItemDef. For those knowing ODM not very well, these are two mechanisms for annotation ODM study design with SDTM information[3]. If you hold the mouse over such an item, you obtain additional information about how the item can or should be mapped to the SDTM. For example:
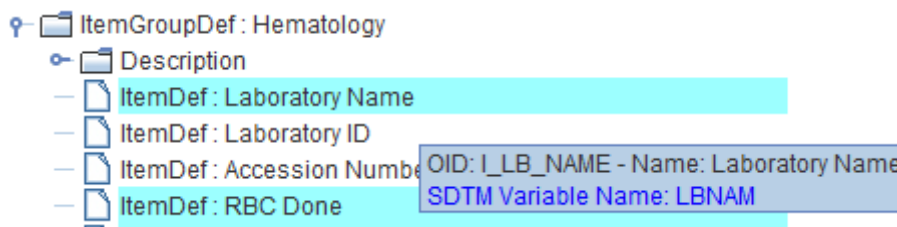
Or in the case of "systolic blood pressure":

---
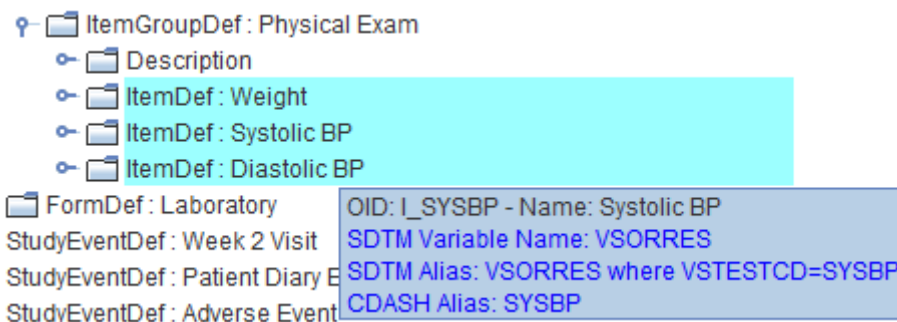
[3]Of course the same applies to „SEND" information

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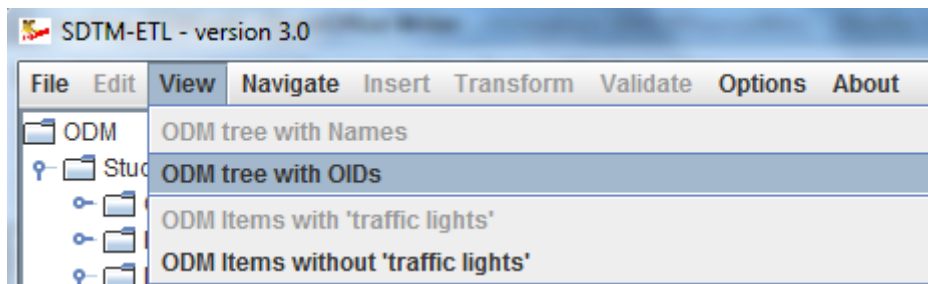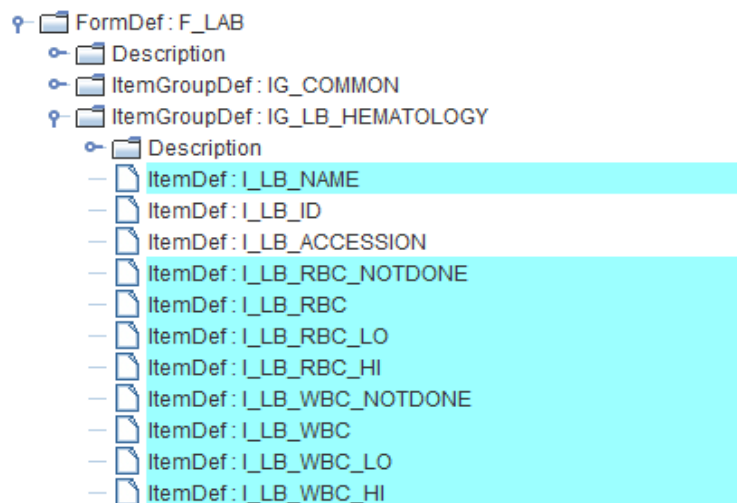
As you might have noticed, each tree node is shown with the value of the "Name" attribute of the corresponding ODM node. In some cases however, it can be very useful to see the tree node with its identifier (which is the "OID" in ODM). To do so, use the menu "View – ODM tree with OIDs":

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.

When navigating through the tree view of our study design we will usually use the mouse, but some people prefer using the keyboard. In this case, one can use arrow up and arrow down, page up and page down to navigate to the top or to the bottom, arrow right and arrow left to expand / collapse a tree node. One can also use one of the menu items from the "Navigate" menu to do the same.

A good number of items usually are reused many times in the study design. For example, the item "Site Number" (OID I_SITE) is used in almost every form. If we want to find out in which ones an item is used, use the menus "Navigate – Next Instance" and "Navigate – Previous Instance":
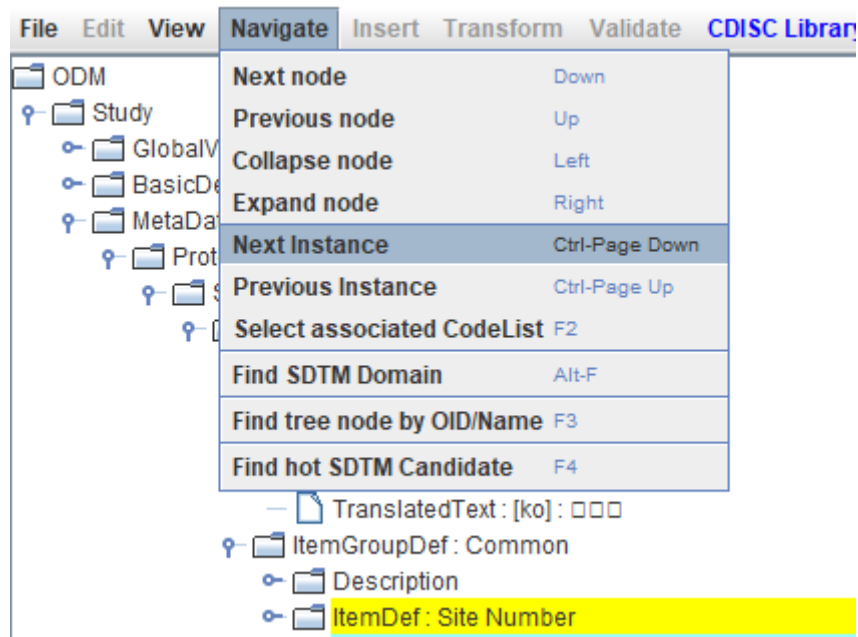
If applied on the first instance of "Site Number", this will jump to the next occurrence of this item, and when necessary, expand the full branch of the tree to make it visible. For example:
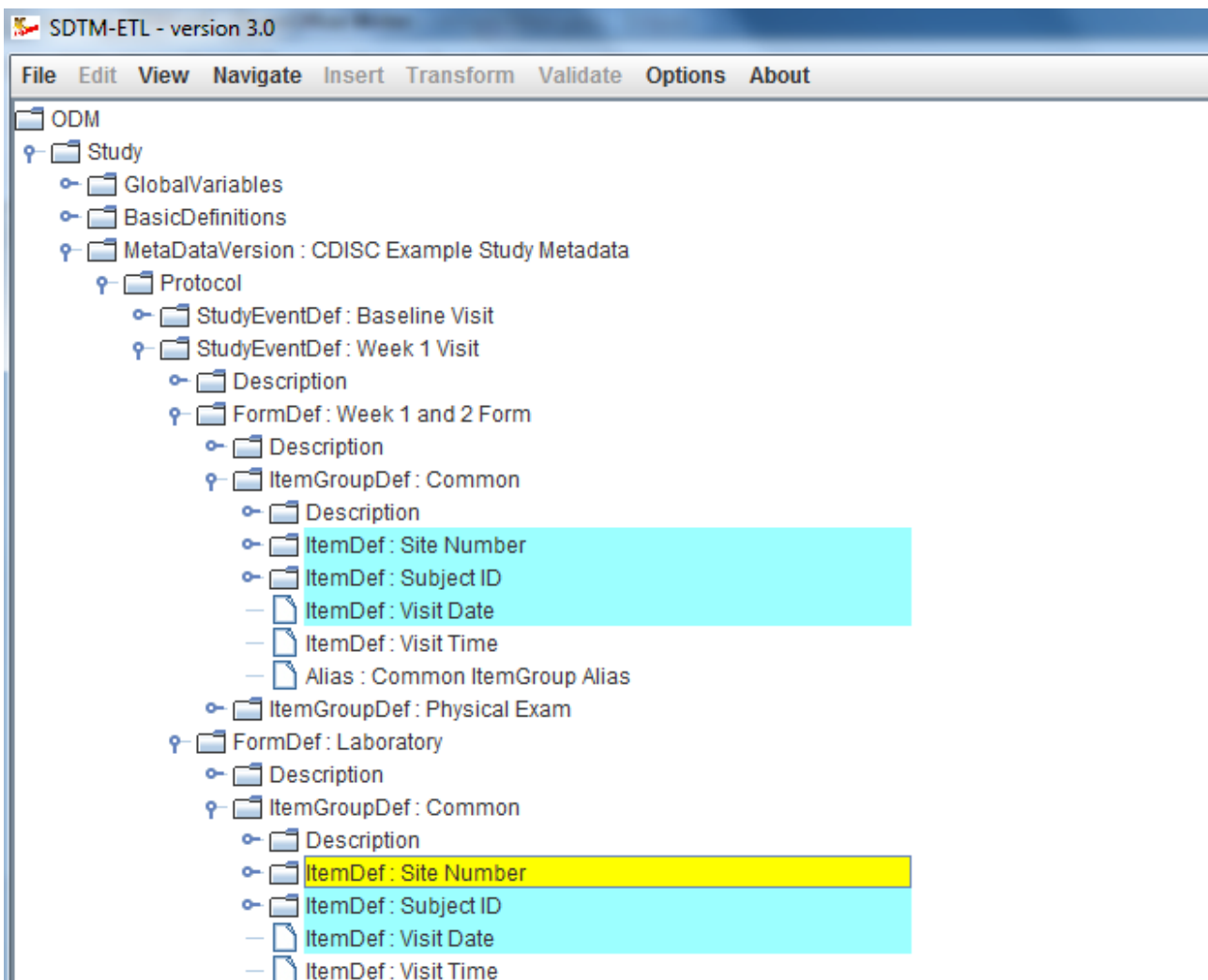
which can also be achieved using the keyboard combination "CTRL – page down". Similarly, one

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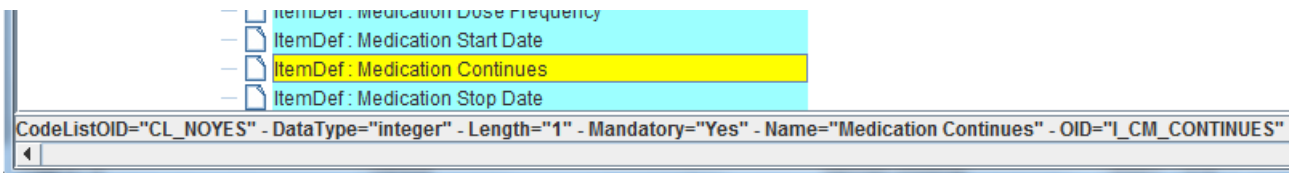
stating CodeListOID="CL_NOYES", but also displaying information like the data type of the item, the length, whether it is a mandatory question in the form, and of course the OID.

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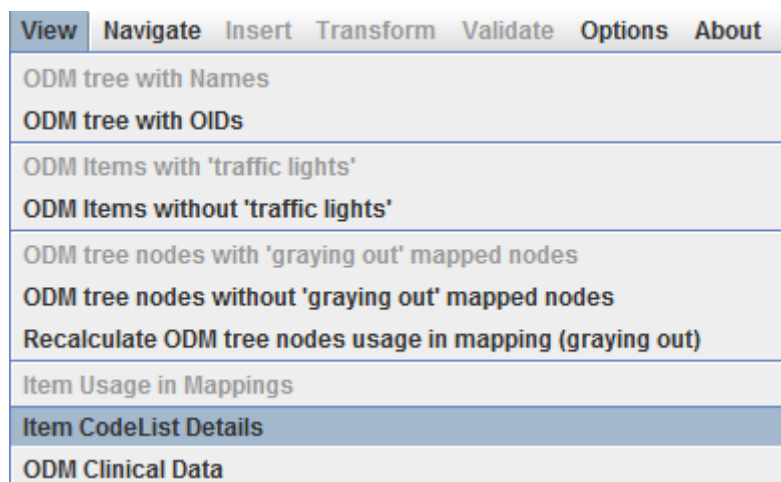
The system will then expand the tree node for the associated node, and select and jump to it (even if it was not visible before). In our case:

```
o—[] CodeList : Diary Day
o—[] CodeList : No Yes
      o—[] CodeListItem
            o—[] Decode
                  —[] TranslatedText : No
                  —[] TranslatedText : Non
                  —[] TranslatedText : Nein
                  —[] TranslatedText
      o—[] CodeListItem
            o—[] Decode
                  —[] TranslatedText : Yes
                  —[] TranslatedText : Oui
                  —[] TranslatedText : Ja
                  —[] TranslatedText
```
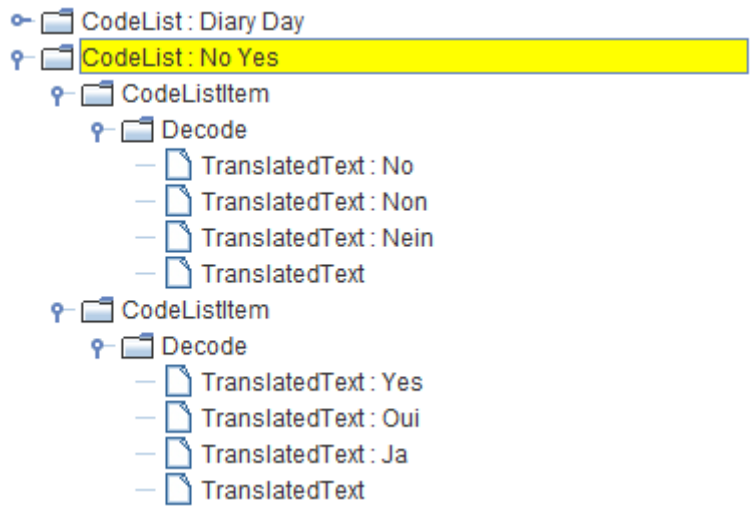
Similarly, if one want to find all details about a specific item in the tree, one can use the menu "View - All Item Details". This will generate a set of tables which is then displayed in a new window. For example, for "Visit Date":

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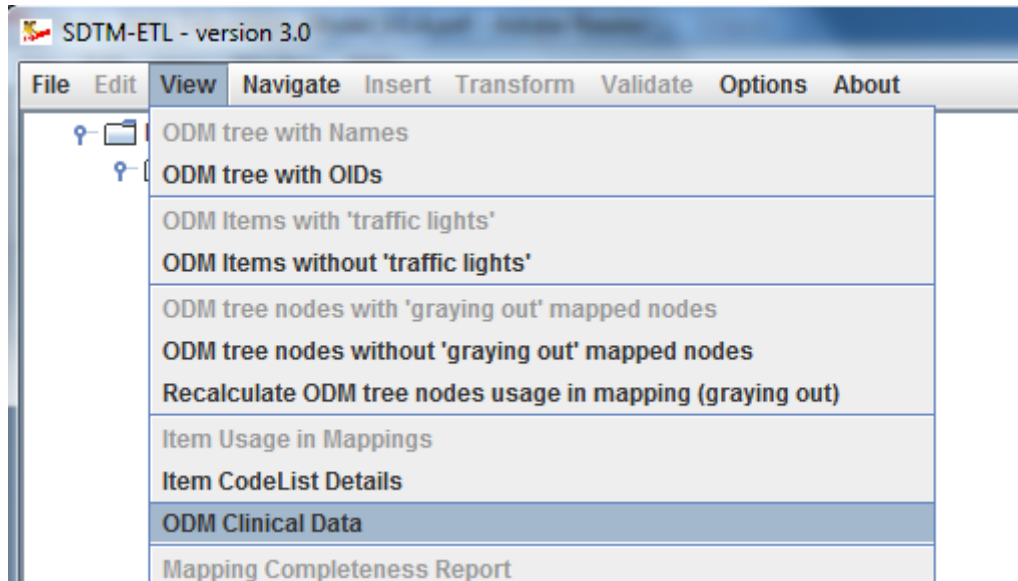
A dialog is then displayed allowing the user to select a file with ODM clinical data, and to set the scope for the search. For example, for "Visit Number", at least one occurrence per visit is expected, so the checkbox "Generalize for all StudyEvents" is checked. Using the checkbox "also display RepeatKeys",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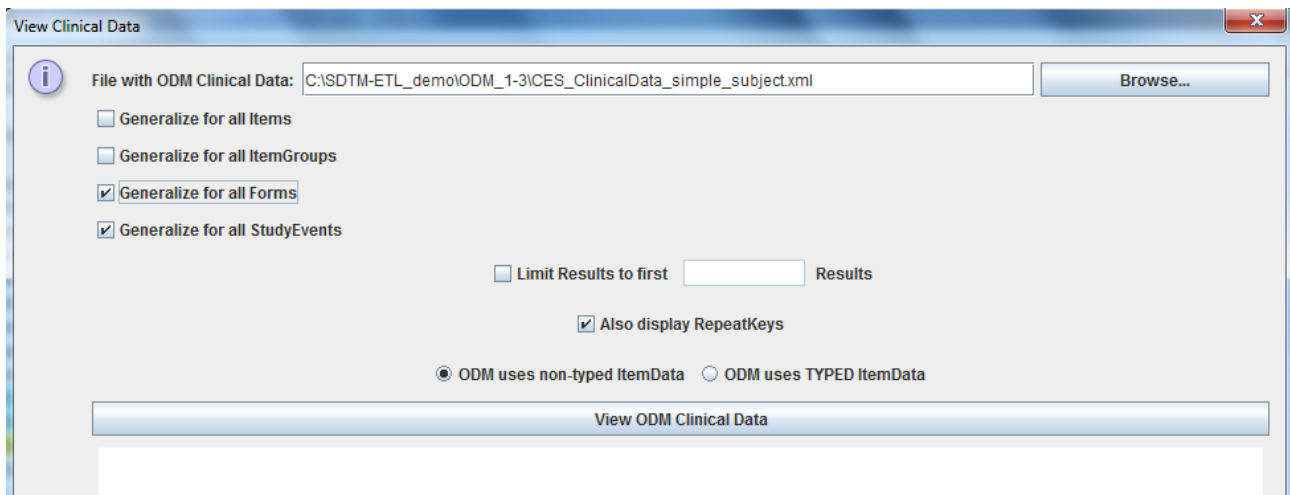

For example, for the item "visit date" (OID I_VISIT), the following table is then obtained:

Subject	StudyEvent	RepeatKey	Form	RepeatKey	ItemGroup	RepeatKey	Item	Value
001	BASELINE		F_BASELINE		IG_COMMON		I_VISIT	2010-02-27
001	BASELINE		F_CM	1	IG_COMMON		I_VISIT	2010-02-27
001	BASELINE		F_LAB		IG_COMMON		I_VISIT	2010-02-27
001	WEEK_1		F_WEEK_1_2		IG_COMMON		I_VISIT	2010-03-06
001	WEEK_1		F_LAB		IG_COMMON		I_VISIT	2010-03-06
001	WEEK_2		F_WEEK_1_2		IG_COMMON		I_VISIT	2010-03-13
001	WEEK_2		F_LAB		IG_COMMON		I_VISIT	2010-03-13
001	DIARY	1	F_DIARY		IG_COMMON		I_VISIT	2010-03-13
001	AE		F_AE	1	IG_COMMON		I_VISIT	2010-03-13
001	AE		F_CM	1	IG_COMMON		I_VISIT	2010-03-13

showing all visit dates that were registered using this item in any visit on any form.

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":
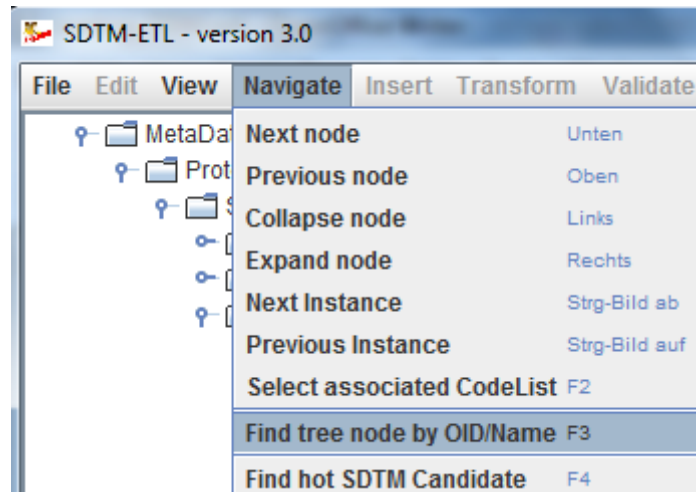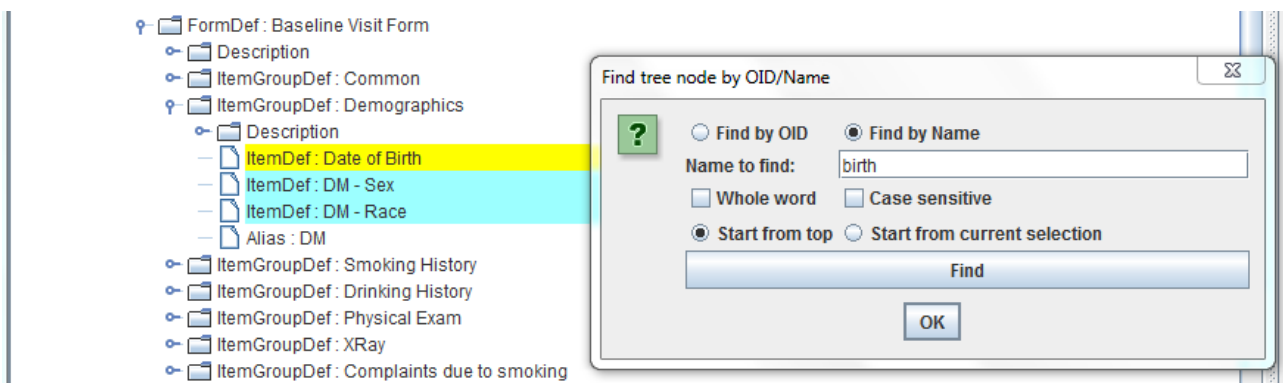

A dialog is then displayed:
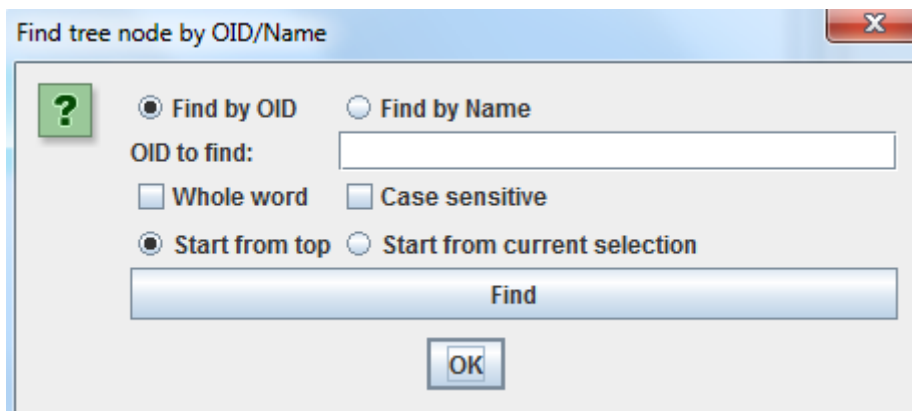
In our case, we guess that an Item about the birth date of will have the word "birth" in the Item name, so we use:
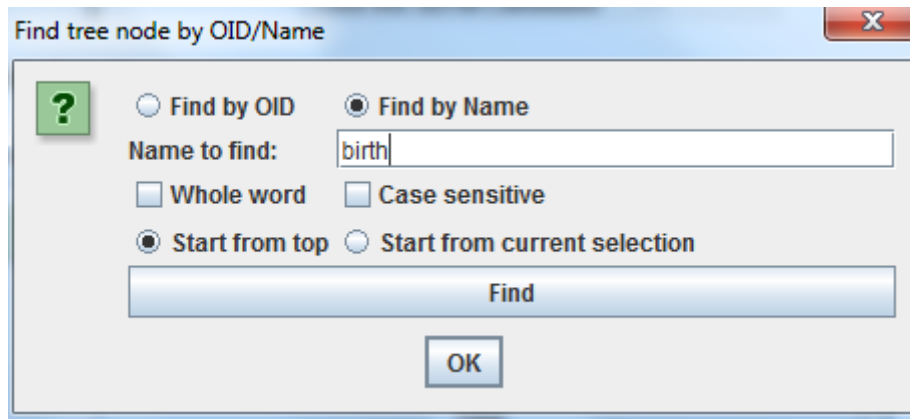
and using the "Find" button, we immediately find:

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 are developed.