

Smart Submission Dataset Viewer

User Manual

By XML4Pharma

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This user manual and also other manuals and tutorials can always be found on our website:

http://www.xml4pharma.com/Smart_Submission_Dataset_Viewer/

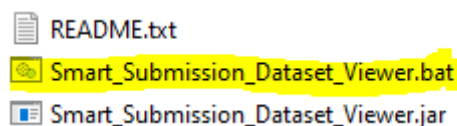
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Starting the application

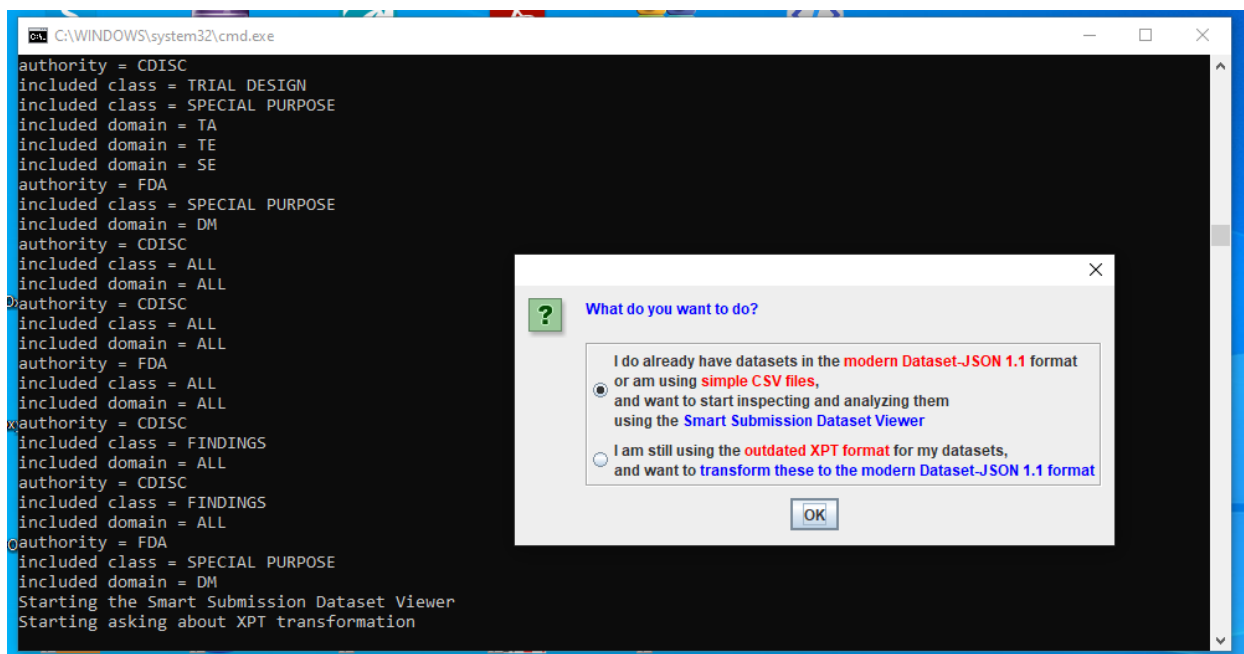
The software comes as a Java application. For installation instructions, please find them [here](#). The document also contains information about setting up a desktop shortcut for the software.

Essentially, one starts the software by a double-click on "Smart_Submission_Dataset_Viewer.bat" (Windows) or "Smart_Submission_Dataset_Viewer.sh" (Linux and Mac) in the folder where you installed the "Smart Submission Dataset Viewer". For example:



or on the corresponding shortcut item on the desktop.

This will start with the opening screen:



At the same time, a "console window" (the "black" window) is opened, that will display all information messages produced by the software, and which are also stored in a log file, which can be found in the folder "logs".

The opening screen asks whether one already has modern CDISC Dataset-JSON 1.1 files available, or that one wants to convert existing SAS-XPT files to Dataset-JSON. For the latter, see the separate tutorial "Generating Dataset-JSON from SAS-XPT".

If one already uses Dataset-JSON, and one does not want to be asked again about conversion from SAS-XPT, this opening screen can be skipped by setting a parameter in the "properties.dat" file. See the section "The 'properties.dat' file".

Selecting data standard, define.xml and to-be-loaded files

In case no conversion from SAS-XPT file is needed as one already has files in Dataset-JSON format, clicking "OK" leads to the main screen:

Standard: **SDTM** [Options]

Dataset source type: ☒ Dataset-JSON 1.1 ☐ Dataset-NDJSON ☐ CSV Files

Dataset-JSON metadata: ☒ Use define.xml for metadata ☐ Use Dataset-JSON internal metadata

Define.xml: [Browse] [Get from API]

Define.xml version: ☒ 2.1 ☐ 2.0 ☐ 1.0 [View]

Dataset-JSON data files:

For adding files, you can use drag-and-drop, or use the 'Add' button

[Add] [Add from API]

[Remove]

[Clear]

☐ Show record number in first column

☐ Bring SUPPQUAL data back to original dataset

Progress:

0%

 0/0 files read

0%

 % validation done

0%

 CDISC Library

☐ Perform CORE validation on datasets
☐ Create HTML report from extended JSON report
☐ Only perform CORE validation DO NOT display datasets themselves

☐ Create and show Validation report table
☐ Also generate Excel report

Validation Rules Selections

MedDRA Files Directory

WHODrug Files Directory

CORE validation progress:

0%

[Start] [Interrupt]

First, one will want to select the standard for which the viewer will be used. Current choices are: "SDTM", "SEND", "ADaM" and "Other tabular". In this manual, we will use an SDTM example. These choices are there in order to optimize display and additional features. For example, CDISC ADaM does not have the concept of "Supplemental Qualifier datasets" (SUPPQUAL), so when ADaM is selected, the checkbox "Bring SUPPQUAL data back to original dataset" will be disabled. Also, when one selects "ADaM, some new choices appear, such as:

Standard: **ADaM**

☒ Display ADaM dates/datetimes as ISO-8601
☐ Display ADaM dates/datetimes as integer

We will explain the "Options" button on the right top later.

After having selected the standard, one must select in which format the data will delivered to the viewer. The choices are:

- Dataset-JSON 1.1: This is the "regular" CDISC Dataset-JSON 1.1 format, for which the specification can be found at: <https://cdisc-org.github.io/DataExchange-DatasetJson/doc/dataset-json1-1.html>. You will probably want to have your submission data files in this format in 90% of the cases. Information about software packages and tools to develop the mappings for, and generate submission files in Dataset-JSON can be found at: <https://wiki.cdisc.org/display/DSJSONHACK/Hackathon+I+Projects>. Some SDTM/SEND mapping tools, such as the "[SDTM-ETL](#)" software, also allow to generate submission datasets in Dataset-JSON format.

- Dataset-NDJSON

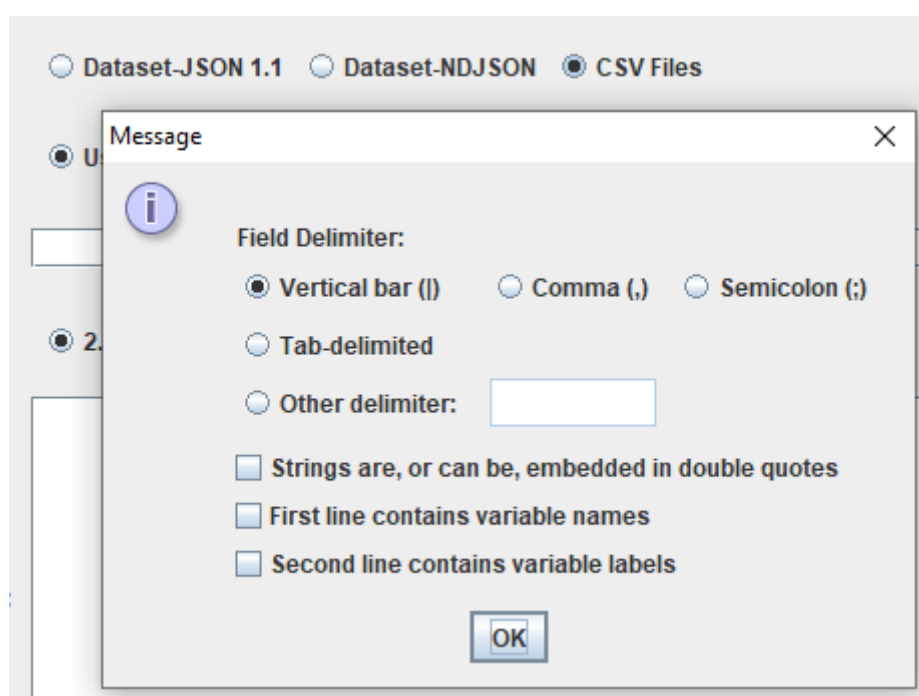
This is a special form of Dataset-JSON 1.1 in which each record is on a separate line in the file, each line containing a separate JSON object (ND stands for "newline delimited"). It can be advantageous to be able to process for very large datasets in software tools that store the JSON in memory.

The specification can also be found on the [CDISC Wiki](#).

The Smart Submission Dataset Viewer however uses "streaming" when reading the contents of the files, so that, at least for our software, there is no difference in performance between Dataset-JSON and Dataset-NDJSON. But as people might want to generate Dataset-NDJSON for other reasons, we of course need to support it.

- CSV (Comma-separated Values).

When selecting "CSV", the following dialog is shown:



allowing the user to select or assign the delimiter between fields to be used and further details how the data is organized.

Using CSV can be useful when e.g. obtaining SDTM/SEND/ADaM files as Excel or any other spreadsheet format.

Suppose we selected "SDTM" and "Dataset-JSON", then we need to select whether we want to use a define.xml file for loading the metadata for the files, or that we just want to use the metadata that is already present in the Dataset-JSON files themselves.

Dataset source type: ☒ Dataset-JSON 1.1 ☐ Dataset-NDJSON ☐ CSV Files

Dataset-JSON metadata: ☒ Use define.xml for metadata ☐ Use Dataset-JSON internal metadata

As the amount of metadata in the Dataset-JSON files themselves is very limited, it is always best to use the define.xml for loading the metadata. This however requires to have a good quality define.xml. Generating such a define.xml starting from an Excel file (as a "specification") is not always a good idea, as it often produces low-quality define.xml files. There are however different mapping tools on the market that generate a quality define.xml "synchronously" with the mappings themselves. There is also a good number of software tools for developing, generating and updating/extending define.xml on the market that come with a user-friendly graphical user interface.

Depending on whether one selects "Use define.xml for metadata" or "Use Dataset-JSON internal metadata", some features will become available or disabled. For example, the feature "Bring SUPPQUAL data back to original dataset" requires information from the define.xml. As such, this checkbox will be disabled when one selected "Use Dataset-JSON internal metadata". Also many data validation features, such as checking values against their variable codelist, are only possible when using the define.xml for loading the metadata (see later).

When having selected "Use define.xml for metadata", one should now first select the define.xml, by using the "Browse" button, and then select the define.xml that is applicable to the datasets to be loaded.

Dataset-JSON metadata: ☒ Use define.xml for metadata ☐ Use Dataset-JSON internal metadata

Define.xml:

Define.xml version: ☒ 2.1 ☐ 2.0 ☐ 1.0

In the current version of the software, one also sees a "Get from API" button. This is currently for demonstration purposes only, and is explained in the section "Using APIs".

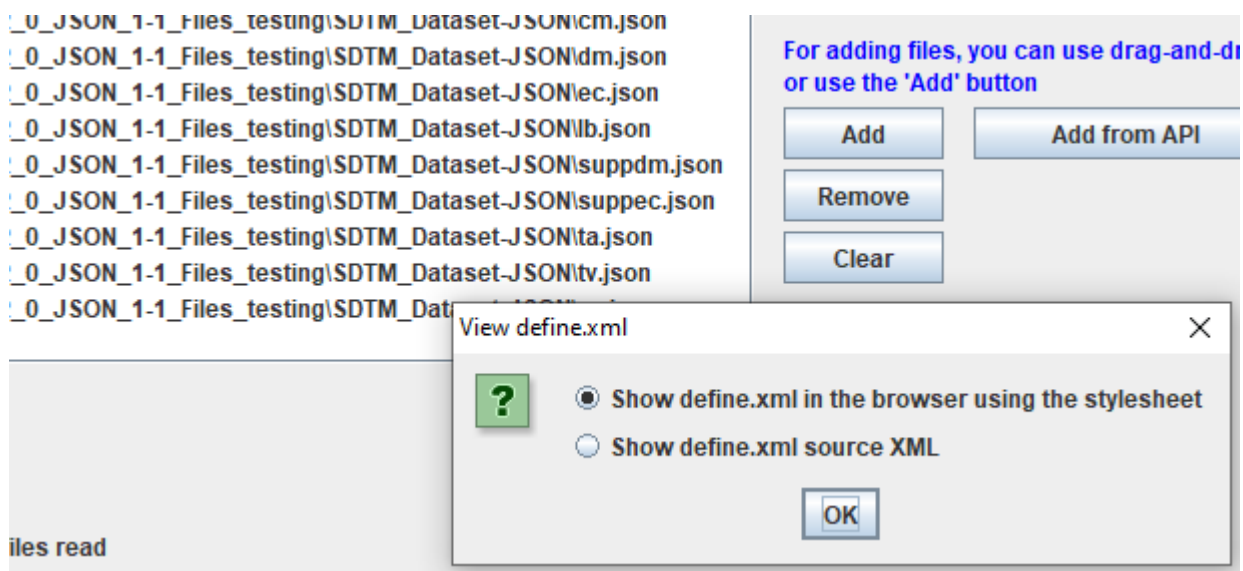
In this manual, we will explain many of the features using the Dataset-JSON 1.1 files from the ["SDTM Metadata Submission Guidelines v2.0"](#) published by CDISC. So we select its define.xml e.g.:

Define.xml:

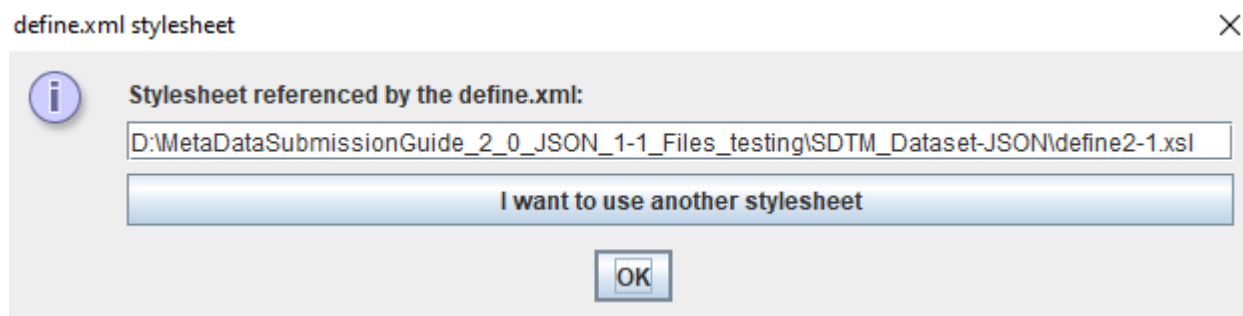
Define.xml version: ☒ 2.1 ☐ 2.0 ☐ 1.0

Normally, the software will recognize which version of Define-XML the define.xml file implements, and in this case automatically select "2.1" for "Define.xml" version, but it is always a good idea to check this.

One can now also inspect the contents of the define.xml by clicking the "View" button. The following dialog is then displayed:



If one chooses "Show define.xml in the browser ...", the system proposes to use a stylesheet it found in the same folder as the define.xml itself, but also allows the user to select another stylesheet:



Remark that the "Smart Submission Dataset Viewer" does not come with Define-XML stylesheets, as the stylesheet is the responsibility of the user's organization. The stylesheet will then be applied and then display the define.xml as HTML in your default browser, e.g.

CDISCPIL01

[Annotated CRF](#)

- Supplemental Documents
- Standards
- Datasets
- Controlled Terminology
- Methods

Expand all VLM

Collapse all VLM

Date/Time of Define-XML document generation: 2021-01-24T16:59:33

Define-XML version: 2.1.0

Define-XML Context: Submission

Stylesheet version: 2019-02-11

Study Name CDISCPIL01

Study Description Study Data Tabulation Model Metadata Submission Guidelines Sample Study

Protocol Name CDISCPIL01

Metadata Name Data Definitions for MSGv2.0 SDTM datasets.

Metadata Description This metadata version contains only a subset of SDTM domains available in the SDTMIG 3.3. The data contained do not represent the data which would appear together in an actual regulatory submission.

Standard's Conformance Notes: 1) The SDTM v1.7/SDTMIG v3.3 datasets were evaluated manually and programmatically by the CDISC SDS MSG Team. At the completion of the SDTM-MSG v2.0, the CDISC SDTM v1.7/SDTMIG v3.3 conformance rules were recently published, but not available by any validation tools to validate. 2) The Define-XML document was evaluated manually and programmatically by the CDISC SDS MSG Team. At the completion of the SDTM-MSG v2.0, the CDISC Define-XML v2.1 conformance rules were not published, nor available by any validation tools to validate. Please ensure that any official regulatory submission of an Define-XML v2.1 document and accompanying data is done in accordance to the respective regulatory health authorities requirements/guidance.

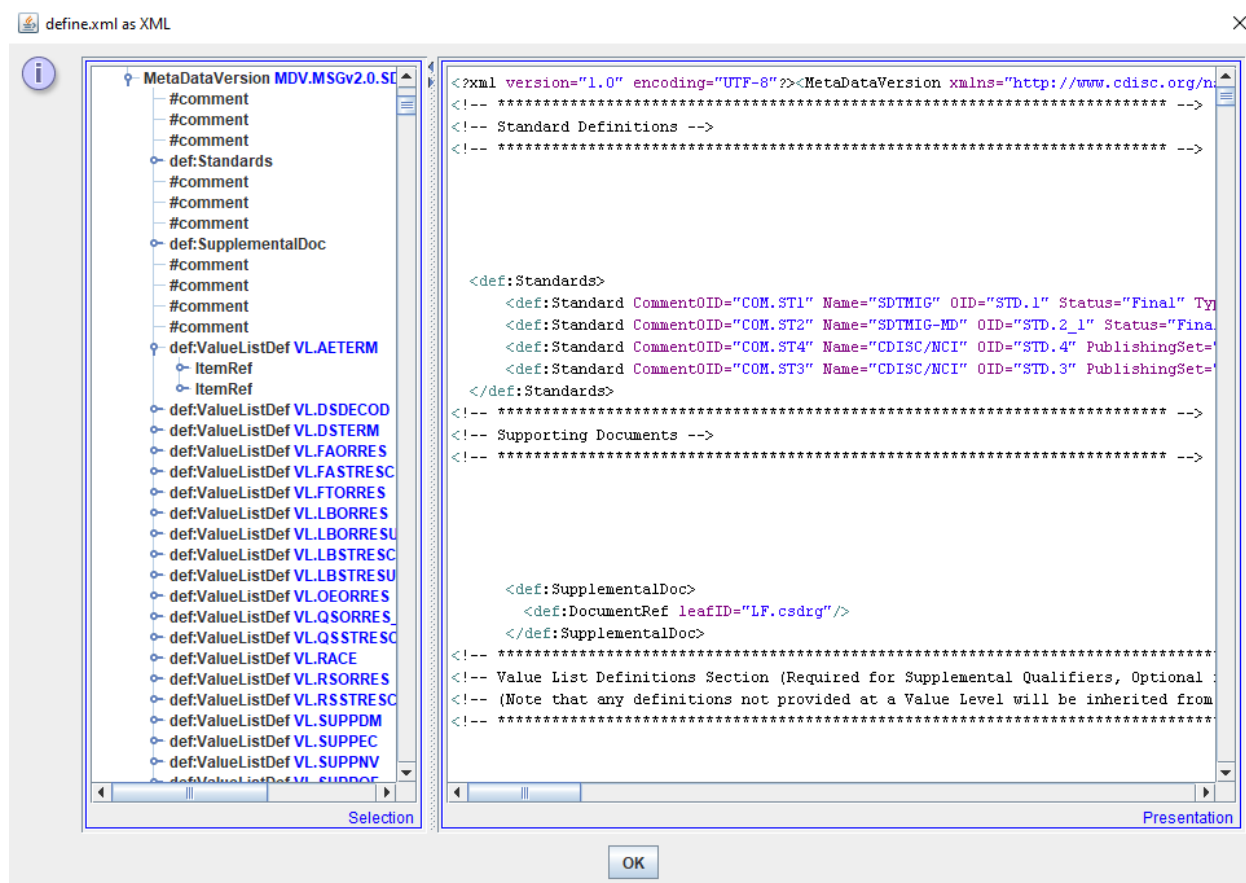
Standards for Study CDISCPIL01

Standard	Type	Status	Documentation
SDTMIG 3.3	IG	Final	
SDTMIG-MD 1.1	IG	Final	
CDISC/NCI DEFINE-XML 2020-12-18	CT	Final	
CDISC/NCI SDTM 2020-12-18	CT	Final	

Datasets

Dataset	Description	Class	Structure	Purpose	Keys	Documentation	Location
TA [SDTMIG 3.3]	Trial Arms	TRIAL DESIGN	One record per planned Element per Arm	Tabulation	STUDYID, ARMCD, TAETORD		ta.json
TE [SDTMIG 3.3]	Trial Elements	TRIAL DESIGN	One record per	Tabulation	STUDYID,		te.json

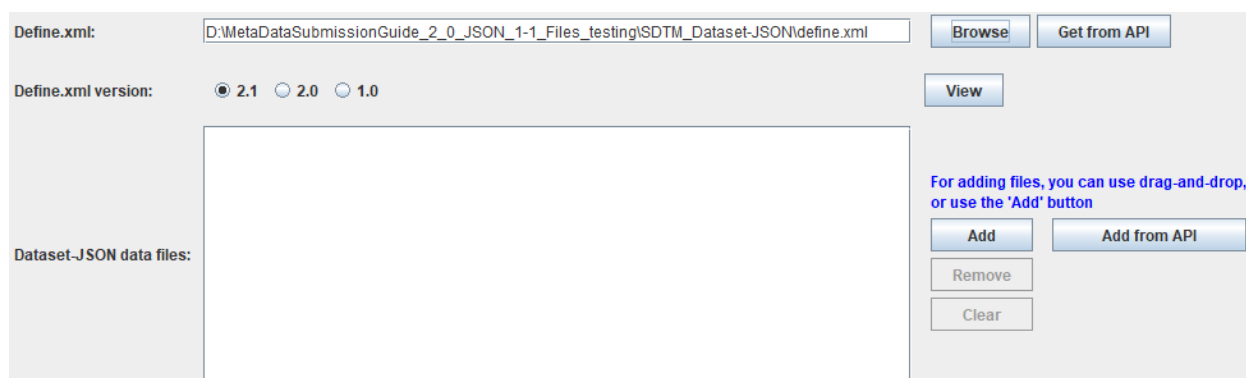
The second choice "show define.xml source XML" allows to display the define.xml as XML itself in a separate window, e.g.:



where one can quickly navigate to specific sections by clicking on one of the tree nodes in the left part of the window.

This feature is of course only of interest to people who understand the XML structure of Define-XML.

We will then want to load our Dataset-JSON files that we want to inspect.



One can either use drag-and-drop, or use the "Add" button, and then use the file chooser that is displayed. Once one or more files have been selected, also the "Remove" and "Clear" buttons become available. The "Remove" button is used to remove some files from the list after having selected them, and the "Clear" button to remove all files from the list.

Also here, the "Add from API" button is for demonstration purposes only and will be explained in the section "Using APIs".

When loading submission files, it is always a good idea to load the DM (Demographics) dataset in the case of SDTM and SEND, or the ADSL (ADaM Subject-level Analysis) in the case of ADaM, as this will not only to validate some of the data against DM/ADSL, but also to "toggle" between a record in any dataset and the "basic" subject data in the DM/ADSL dataset.

Let us first add a few datasets already, e.g.:

Define.xml version: ☒ 2.1 ☐ 2.0 ☐ 1.0 View

Dataset-JSON data files:

- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\ae.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\cm.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\dm.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\ec.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\lb.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\suppdm.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\suppec.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\ta.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\tv.json
- D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\vs.json

For adding files, or use the 'Add'

Add Remove Clear

Don't mind about the order of the datasets in the list, the system will itself set up a more natural order.

Depending on which standard was selected, and whether one will use the define.xml for the metadata or not, a number of features become available. We explain them here for the case that one wants to use the define.xml for the metadata, as this should always be the preferred way.

D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\ta.json
D:\MetaDataSubmissionGuide_2_0_JSON_1-1_Files_testing\SDTM_Dataset-JSON\vs.json

☐ Show record number in first column

☐ Bring SUPPQUAL data back to original dataset

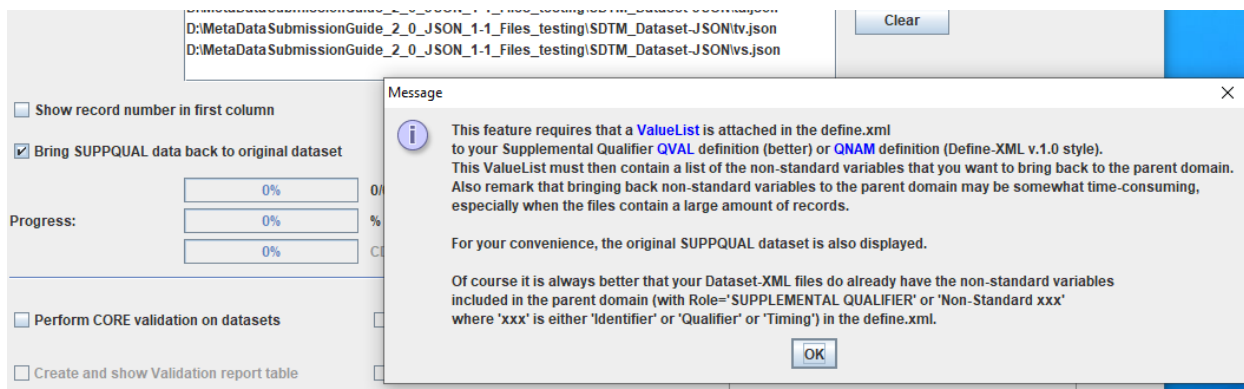
Progress:

0%	0/0 files read
0%	% validation done
0%	CDISC Library

☐ Perform CORE validation on datasets ☐ Create HTML report from extended JSON report ☐ Only DO N

First of all, when the checkbox "Show record number in first column" is checked, the system will add an extra column as the first column, and assign a record number to each record, which is fixed to that record. This also means that when later applying sorting, filtering, or any action that rearranges the order of the records, the record number will remain the same. Such a "pinned" record number can then enormously help when referring to a specific record later. Also see the section "sorting and filtering".

The second checkbox "Bring SUPPQUAL data back to original dataset" will only be enabled when the define.xml is to be used for the metadata. When one selects, some additional information is shown:

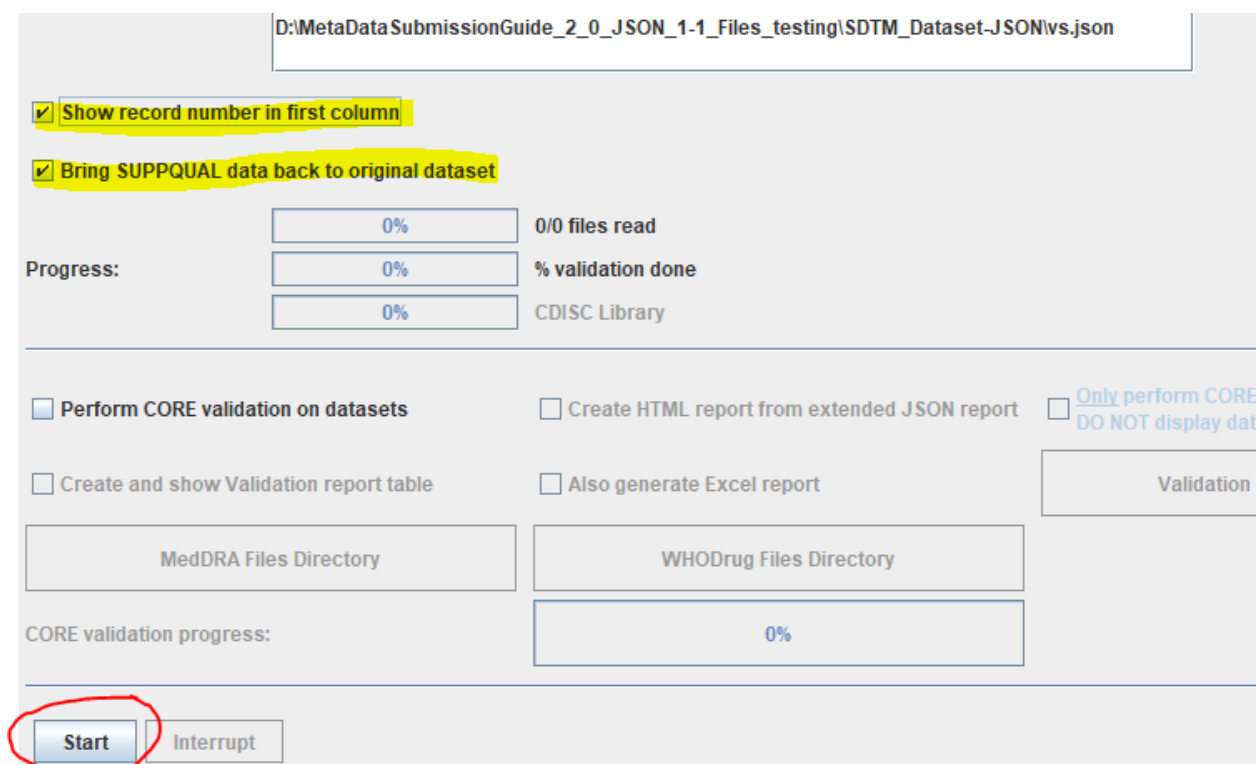


Essentially, it states that this feature will only work when the define.xml has "ValueLists" attached to QVAL for the variable definitions in the SUPPxx datasets.

As we have DM and SUPPDM, and EC and SUPPEC in our list, we check the checkbox. We will discuss the results a bit later.

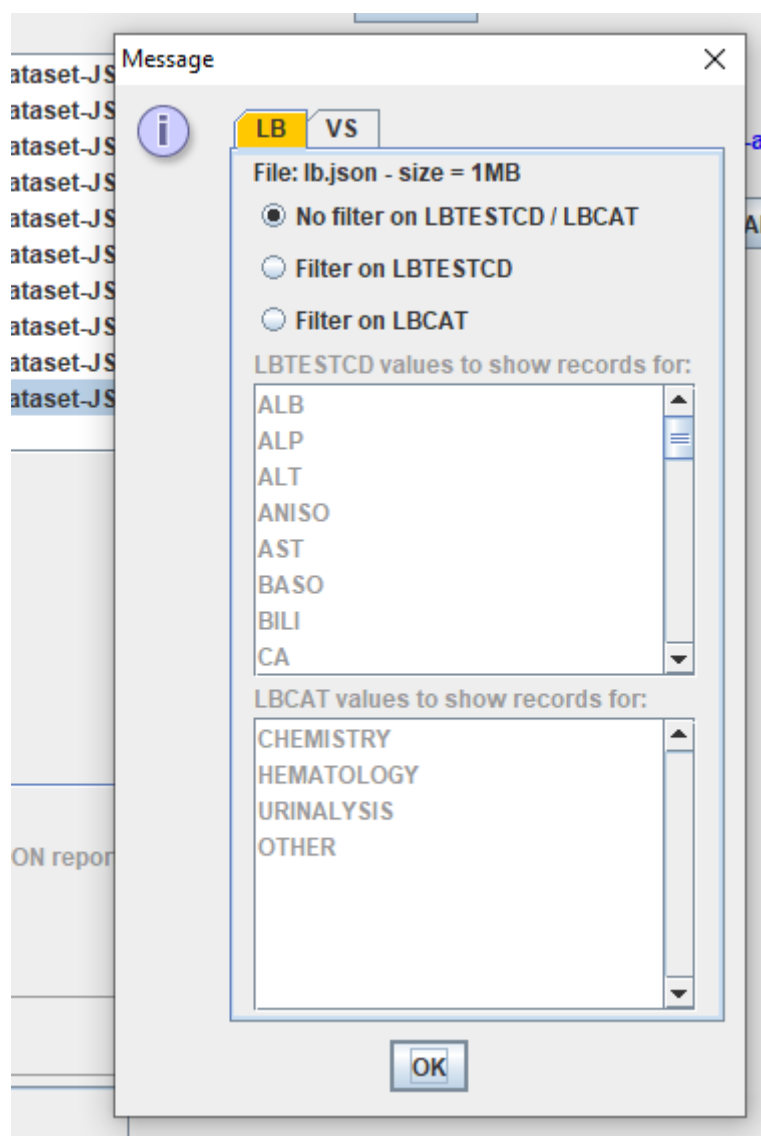
At this moment, we do not set any special options, using the "Options" button yet, so that only essential validation will be performed. We will later explain some of these in a separate section.

With the current settings:



we now click the "Start" button to start the viewing process.

First, the system loads the define.xml , which can take some time, depending on the complexity of the contents of the define.xml (progress bar), in most cases followed by the following dialog:



This dialog is only displayed when some of the to-be-loaded files have a file size that exceeds a certain threshold (see later when treating all the options) and the define.xml has codelists attached to variables such as "--TESTCD", "--CAT" allowing to load subsets of data, such as only "hematology" data for LB. This feature is expected to facilitate the reviewing process considerably¹.

As this dialog is based on information about codelists in the define.xml, it is skipped when the user has decided to use the metadata from the Dataset-JSON files themselves.

We will first not do any "pre-loading filtering".

After clicking "OK", the loading process proceeds and after a few seconds (or more, depending on the number of records to be loaded), the window with all the tables is displayed:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC										
Rec#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL												
1	CDISCPIL0T01	EC	CDISC009	ECSEQ	122	ECREASOC	Reason for Occur Value												
2	CDISCPIL0T01	EC	CDISC009	ECSEQ	123	ECREASOC	Reason for Occur Value												
3	CDISCPIL0T01	EC	CDISC009	ECSEQ	124	ECREASOC	Reason for Occur Value												
4	CDISCPIL0T01	EC	CDISC009	ECSEQ	125	ECREASOC	Reason for Occur Value												
5	CDISCPIL0T01	EC	CDISC009	ECSEQ	126	ECREASOC	Reason for Occur Value												
6	CDISCPIL0T01	EC	CDISC009	ECSEQ	127	ECREASOC	Reason for Occur Value												
7	CDISCPIL0T01	EC	CDISC009	ECSEQ	128	ECREASOC	Reason for Occur Value												

¹ When using the classic "SAS Universal Viewer", the user has no other choice than loading all the records, often leading to "pagination". When then doing additional filtering, the filter only applies to the current "page". As such, using the "SAS Universal Viewer" can easily lead to review problems.

with one tab for each dataset.

As one sees, the system has reordered the datasets into a more natural order, with the "Trial Design" datasets coming first, followed by DM (Demographics) and with the "Supplemental Qualifier" datasets coming at the end

Viewing the results - basic features

Let us first inspect the results for the DM dataset, by clicking on the DM tab:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC			
Rec.#	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	RFXSTDTC	RFXENDTC	RFICDTC	RFPENDTC	DTHDTC	DTH
1	CDISCPIL...	DM	CDISC001	1115	2012-11-30	2013-01-23	2012-11-30	2013-01-23	2012-11-23	2013-05-20		
2	CDISCPIL...	DM	CDISC002	1211	2012-11-15	2013-01-14	2012-11-15	2013-01-12	2012-10-30	2013-01-14	2013-01-14	Y
3	CDISCPIL...	DM	CDISC003	1302	2013-08-29	2013-11-05	2013-08-29	2013-11-05	2013-08-20	2014-02-13		
4	CDISCPIL...	DM	CDISC004	1345	2013-10-08	2014-03-18	2013-10-08	2014-03-18	2013-10-01	2014-03-18		
5	CDISCPIL...	DM	CDISC005	1383	2013-02-04	2013-08-06	2013-02-04	2013-08-06	2013-01-22	2013-08-06		
6	CDISCPIL...	DM	CDISC006	1429	2013-03-19	2013-04-30	2013-03-19	2013-04-30	2013-02-25	2013-04-30		
7	CDISCPIL...	DM	CDISC007	1444	2013-01-05	2013-02-13	2013-01-05	2013-02-12	2012-12-31	2013-06-20		
8	CDISCPIL...	DM	CDISC008	1445	2014-05-11	2014-11-01	2014-05-11	2014-11-01	2014-05-01	2014-11-01	2014-11-01	Y
9	CDISCPIL...	DM	CDISC009	1087	2012-10-22	2013-04-28	2012-10-22	2013-04-28	2012-10-06	2013-04-28		
10	CDISCPIL...	DM	CDISC010	1236	2013-09-21	2013-09-26	2013-09-21	2013-09-21	2013-09-08	2013-09-26		
11	CDISCPIL...	DM	CDISC011	1336	2012-12-07	2013-06-05	2012-12-07	2013-06-05	2012-11-21	2013-07-05		
12	CDISCPIL...	DM	CDISC012	1378	2013-09-03	2014-01-28	2013-09-03	2014-01-28	2013-08-24	2014-01-28		
13	CDISCPIL...	DM	CDISC013	1083	2013-07-22	2013-08-03	2013-07-22	2013-08-01	2013-07-09	2013-08-03	2013-08-03	Y
14	CDISCPIL...	DM	CDISC014	1012	2013-04-03	2013-05-02	2013-04-03	2013-04-29	2013-03-20	2013-09-18		
15	CDISCPIL...	DM	CDISC015	1022					2014-03-17	2014-03-17		
16	CDISCPIL...	DM	CDISC016	1143	2013-04-03	2013-06-01	2013-04-03	2013-05-30	2013-03-30	2013-09-22		
17	CDISCPIL...	DM	CDISC017	1250	2013-09-21	2014-02-08	2013-09-21	2014-01-31	2013-08-21	2014-03-08		
18	CDISCPIL...	DM	CDISC018	1427	2012-12-17	2013-02-18	2012-12-17	2013-02-11	2012-12-13	2013-06-03		

As one sees, an extra column with the (generated) record number has been added

One can now resize columns with the mouse, or even move columns from one place to another (i.e. changing the order of the columns) which is always very useful, as one can then put the columns of interest together. For example, when one is mainly interested in age, sex, and assigned arm of the subjects, one can drag the columns in the following order:

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC
Rec.#	STUDYID	DOMAIN	USUBJID	SUBJID	AGE	AGEU	SEX	ARMCD	RF
1	CDISCPIL0T01	DM	CDISC001	1115	84	YEARS	M	ZAN_LOW	2012
2	CDISCPIL0T01	DM	CDISC002	1211	76	YEARS	F	ZAN_LOW	2012
3	CDISCPIL0T01	DM	CDISC003	1302	61	YEARS	M	ZAN_HIGH	2013
4	CDISCPIL0T01	DM	CDISC004	1345	63	YEARS	F	PLACEBO	2013
5	CDISCPIL0T01	DM	CDISC005	1383	72	YEARS	F	ZAN_HIGH	2013
6	CDISCPIL0T01	DM	CDISC006	1429	84	YEARS	F	ZAN_LOW	2013
7	CDISCPIL0T01	DM	CDISC007	1444	63	YEARS	M	ZAN_HIGH	2013
8	CDISCPIL0T01	DM	CDISC008	1445	75	YEARS	M	PLACEBO	2014
9	CDISCPIL0T01	DM	CDISC009	1087	74	YEARS	F	PLACEBO	2012
10	CDISCPIL0T01	DM	CDISC010	1236	86	YEARS	F	ZAN_HIGH	2013
11	CDISCPIL0T01	DM	CDISC011	1336	73	YEARS	M	ZAN_HIGH	2012
12	CDISCPIL0T01	DM	CDISC012	1378	67	YEARS	M	PLACEBO	2013
13	CDISCPIL0T01	DM	CDISC013	1083	89	YEARS	F	PLACEBO	2013
14	CDISCPIL0T01	DM	CDISC014	1012	67	YEARS	F	ZAN_HIGH	2013
15	CDISCPIL0T01	DM	CDISC015	1022	86	YEARS	F		
16	CDISCPIL0T01	DM	CDISC016	1143	76	YEARS	F	ZAN_LOW	2013
17	CDISCPIL0T01	DM	CDISC017	1250	82	YEARS	F	ZAN_LOW	2013
18	CDISCPIL0T01	DM	CDISC018	1427	74	YEARS	F	ZAN_HIGH	2012

Viewing values for Supplemental Qualifiers

As we checked the checkbox "Bring SUPPQUAL data back to original dataset", we should now also see the values of the "non-standard variables", which were "banned" to SUPPDM, in the DM dataset itself. Remark again that this will only work when a "ValueList" was assigned to the QVAL variable in the define.xml.

When scrolling to the right, we find:

BRTHDTC	RACE	ETHNIC	ARM	ACTARMCD	ACTARM	ARMNRS	ACTARMUD	COUNTRY	RACE1	RACE2	RACE3	RA
1928	WHITE	NOT HISPANIC	Zanomalin...	ZAN_LOW	Zanomalin...			USA				
1936	WHITE	NOT HISPANIC	Zanomalin...	ZAN_LOW	Zanomalin...			USA				
1951	WHITE	NOT HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				
1950	WHITE	NOT HISPANIC	Placebo	PLACEBO	Placebo			USA				
1941	WHITE	NOT HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				
1929	WHITE	NOT HISPANIC	Zanomalin...	ZAN_LOW	Zanomalin...			USA				
1949	WHITE	HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				
1939	MULTIPLE	NOT HISPANIC	Placebo	PLACEBO	Placebo			USA	ASIAN	BLACK OR AFRICAN AMERICAN	WHITE	
1938	WHITE	NOT HISPANIC	Placebo	PLACEBO	Placebo			USA				
1927	WHITE	NOT HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				
1939	WHITE	NOT HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				
1946	BLACK OR ...	NOT HISPANIC	Placebo	PLACEBO	Placebo			USA				
1924	WHITE	NOT HISPANIC	Placebo	PLACEBO	Placebo			USA				
1945	WHITE	NOT HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				
1928	WHITE	NOT HISPANIC				SCREEN F...		USA				
1936	WHITE	NOT HISPANIC	Zanomalin...	ZAN_LOW	Zanomalin...			USA				
1931	WHITE	HISPANIC	Zanomalin...	ZAN_LOW	Zanomalin...			USA				
1938	BLACK OR ...	NOT HISPANIC	Zanomalin...	ZAN_HIGH	Zanomalin...			USA				

that there is one record having "MULTIPLE" for "RACE", and the individual races being depicted in "RACE1", "RACE2", and "RACE3". Also here, we can drag columns so that we get a better oversight of what we are really interested in:

SUBJID	AGE	AGEU	SEX	ARMCD	RACE	RACE1	RACE2	RACE3
1115	84	YEARS	M	ZAN_LOW	WHITE			
1211	76	YEARS	F	ZAN_LOW	WHITE			
1302	61	YEARS	M	ZAN_HIGH	WHITE			
1345	63	YEARS	F	PLACEBO	WHITE			
1383	72	YEARS	F	ZAN_HIGH	WHITE			
1429	84	YEARS	F	ZAN_LOW	WHITE			
1444	63	YEARS	M	ZAN_HIGH	WHITE			
1445	75	YEARS	M	PLACEBO	MULTIPLE	ASIAN	BLACK OR AFRICAN AMERICAN	WHITE
1087	74	YEARS	F	PLACEBO	WHITE			
1236	86	YEARS	F	ZAN_HIGH	WHITE			
1336	73	YEARS	M	ZAN_HIGH	WHITE			
1378	67	YEARS	M	PLACEBO	BLACK OR ...			
1083	89	YEARS	F	PLACEBO	WHITE			
1012	67	YEARS	F	ZAN_HIGH	WHITE			
1022	86	YEARS	F		WHITE			
1143	76	YEARS	F	ZAN_LOW	WHITE			
1250	82	YEARS	F	ZAN_LOW	WHITE			

so that we now see that this subject is male, 75 years old, and received placebo.

Of course, we can still inspect the SUPPDM dataset itself by clicking the SUPPDM tab:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18										
File Tools View Search Options										
TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC	
Rec.#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL		QOR
1	CDISCPLOT01	DM	CDISC008			RACE1	Race 1	ASIAN		CRF
2	CDISCPLOT01	DM	CDISC008			RACE2	Race 2	BLACK OR AFRICAN AM...		CRF
3	CDISCPLOT01	DM	CDISC008			RACE3	Race 3	WHITE		CRF

Showing the reviewer the same information, but in a much less user-friendly way.

Let us know at EC (Exposure as Collected) and SUPPEC. For EC we find:

One sees that when hovering the mouse over a column header, one gets the metadata information as a tooltip.

ECSTDY	ECE...	ECREASOC
112	112	
113	113	Define-XML metadata:
114	114	Name: ECREASOC
115	115	Label: Reason for Occur Value
116	116	Mandatory: Yes
117	117	Datatype: text
118	118	Length: 200
119	119	Non-Standard Variable (NSV)
120	120	
121	121	
122	122	INVESTIGATOR DECISION
123	123	INVESTIGATOR DECISION
124	124	INVESTIGATOR DECISION
125	125	INVESTIGATOR DECISION
126	126	INVESTIGATOR DECISION
127	127	INVESTIGATOR DECISION
128	128	INVESTIGATOR DECISION
129	129	

Smart Submission Dataset Viewer Manual

CTRT	ECPRESP	ECOCUR	ECREASOC	ECDOSE	ECDOSU	ECDOSE
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	N	INVESTIGATOR DECISION			INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT
BO	Y	Y		5	mL	INJECT

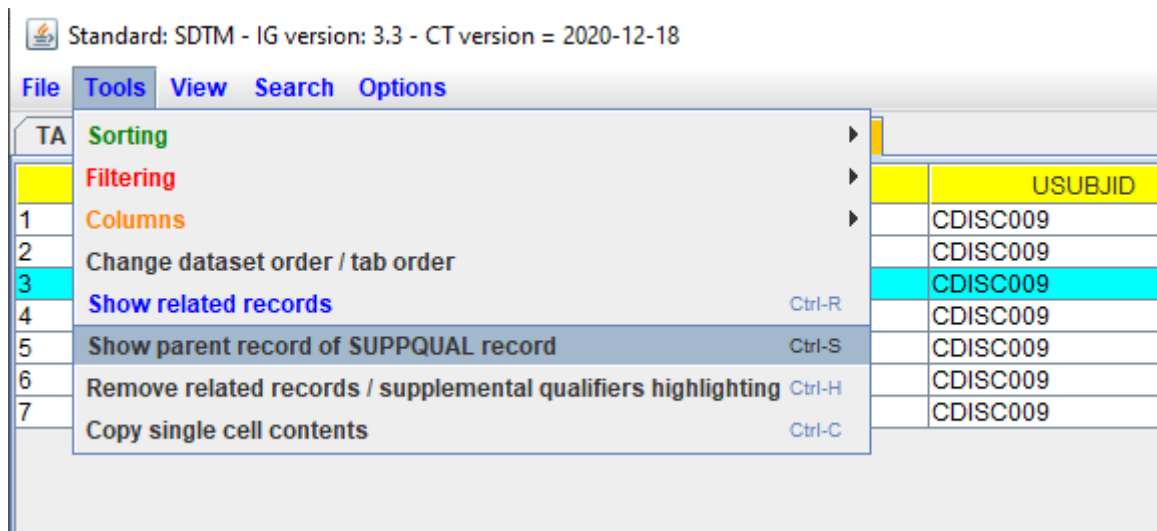
And the SUPPEC dataset:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18										
File Tools View Search Options										
TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC	
Rec#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL		
1	CDISCPIL01	EC	CDISC009	ECSEQ	122	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	
2	CDISCPIL01	EC	CDISC009	ECSEQ	123	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	
3	CDISCPIL01	EC	CDISC009	ECSEQ	124	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	
4	CDISCPIL01	EC	CDISC009	ECSEQ	125	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	
5	CDISCPIL01	EC	CDISC009	ECSEQ	126	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	
6	CDISCPIL01	EC	CDISC009	ECSEQ	127	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	
7	CDISCPIL01	EC	CDISC009	ECSEQ	128	ECREASOC	Reason for Occur Value	INVESTIGATOR DECISION	CC	

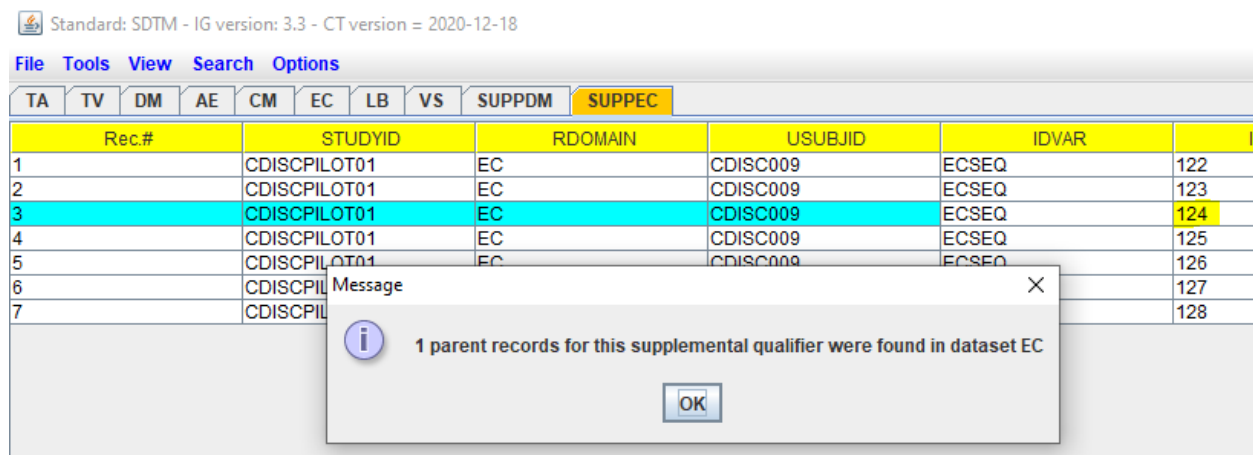
Even when one has not checked the checkbox "Bring SUPPQUAL data back to original dataset", one can easily find the parent record of a SUPPQUAL record. This can be done by selecting a row in the SUPPQUAL table (here SUPPEC):

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18										
File Tools View Search Options										
TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC	
Rec#	STUDYID	RDOMAIN	USUBJID	IDVAR						
1	CDISCPIL01	EC	CDISC009	ECSEQ	122					
2	CDISCPIL01	EC	CDISC009	ECSEQ	123					
3	CDISCPIL01	EC	CDISC009	ECSEQ	124					
4	CDISCPIL01	EC	CDISC009	ECSEQ	125					
5	CDISCPIL01	EC	CDISC009	ECSEQ	126					
6	CDISCPIL01	EC	CDISC009	ECSEQ	127					
7	CDISCPIL01	EC	CDISC009	ECSEQ	128					

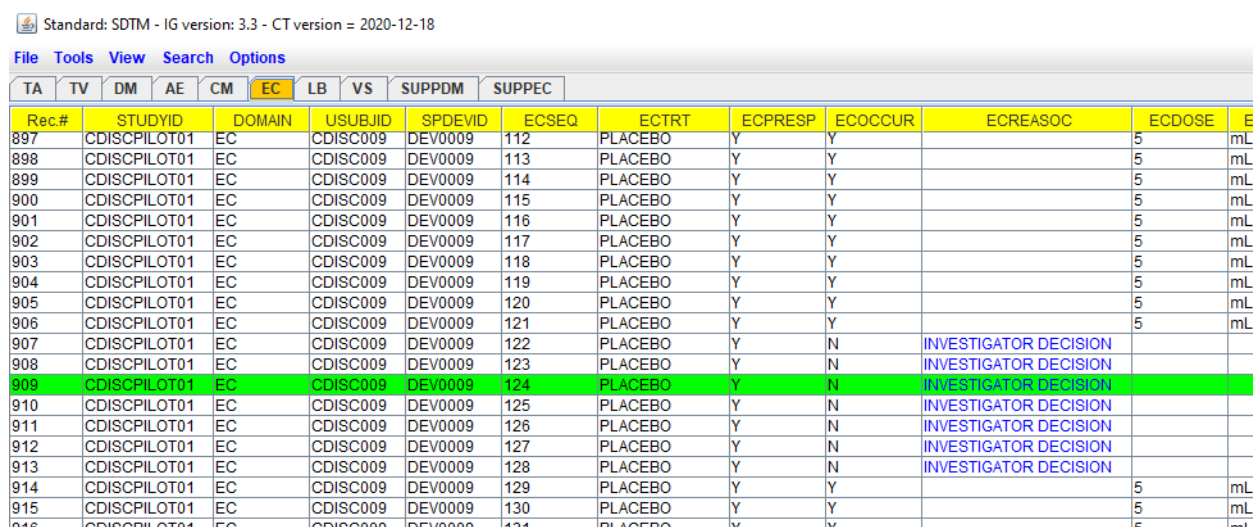
and then using the menu "Tools - Show parent record of SUPPQUAL record" (or just using Ctrl-S on the keyboard)



leading to:



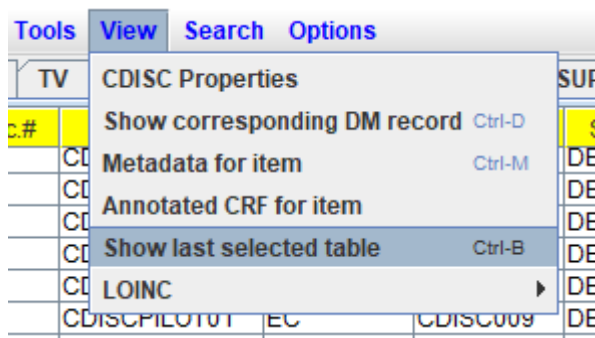
and after clicking "OK", the row for subject CDISC009 and ECSEQ=124 is selected (also the tab for EC is automatically selected) and highlighted:



Remark that when the "identifying variable" (IDVAR) is e.g. a --CAT variable, this will usually lead to more than 1 parent record, and all these will then be highlighted.

One can now "toggle" between the record in EC and the record in SUPPEC (also when the checkbox "Bring

SUPPQUAL data back to original dataset" was not checked) by using the menu "View - Show last selected table", or easier and much faster by just using Ctrl-B on the keyboard:



showing SUPPEC again with the selected record:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC
Rec.#	STUDYID	RDOMAIN	USUBJID	IDVAR					
1	CDISCPILLOT01	EC	CDISC009	ECSEQ					
2	CDISCPILLOT01	EC	CDISC009	ECSEQ					
3	CDISCPILLOT01	EC	CDISC009	ECSEQ					
4	CDISCPILLOT01	EC	CDISC009	ECSEQ					
5	CDISCPILLOT01	EC	CDISC009	ECSEQ					
6	CDISCPILLOT01	EC	CDISC009	ECSEQ					
7	CDISCPILLOT01	EC	CDISC009	ECSEQ					

Looking up basic subject information in DM or ADSL

When inspecting a record in any of the datasets, one can always quickly "jump" to the corresponding record in DM (for SDTM and SEND) or ADSL (for ADaM). For example, when having selected a record in LB:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC									
Rec#	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL	LBORNRLH	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRL	LBSTNRLH	LBINRIND	LB
2757	CDISC014	LB	CDISC014	44	CA	Calcium	CHEMISTRY	8.3	mg/dL	8.4	10.3	2.32035	2.32035	mmol/L	2.1	2.57	NORMAL	
2758	CDISC014	LB	CDISC014	45	CHOL	Cholesterol	CHEMISTRY	210	mg/dL	156	300	5.4306	5.4306	mmol/L	4.03	7.76	NORMAL	
2759	CDISC014	LB	CDISC014	46	CK	Creatine Ki	CHEMISTRY	76	U/L	21	169	76	76	U/L	21	169	NORMAL	
2760	CDISC014	LB	CDISC014	47	CL	Chloride	CHEMISTRY	91	mEq/L	94	112	91	91	mmol/L	94	112	LOW	
2761	CDISC014	LB	CDISC014	48	CREAT	Creatinine	CHEMISTRY	1.2	mg/dL	0.7	1.4	106.08	106.08	umol/L	62	124	NORMAL	
2762	CDISC014	LB	CDISC014	49	GGT	Gamma Gl	CHEMISTRY	31	U/L	5	50	31	31	U/L	5	50	NORMAL	
2763	CDISC014	LB	CDISC014	50	GLUC	Glucose	CHEMISTRY	75	mg/dL	50	250	4.16325	4.16325	mmol/L	2.8	13.9	NORMAL	
2764	CDISC014	LB	CDISC014	51	K	Potassium	CHEMISTRY	4.0	mEq/L	3.4	5.4	4	4	mmol/L	3.4	5.4	NORMAL	
2765	CDISC014	LB	CDISC014	52	SODIUM	Sodium	CHEMISTRY	133	mEq/L	135	145	133	133	mmol/L	135	145	LOW	
2766	CDISC014	LB	CDISC014	53	PHOS	Phosphate	CHEMISTRY	3.6	mg/dL	2.2	5.1	1.16244	1.16244	mmol/L	0.71	1.55	NORMAL	
2767	CDISC014	LB	CDISC014	54	PROT	Protein	CHEMISTRY	7.1	g/dL	6	8	71	71	g/L	60	80	NORMAL	

for subject CDISCPIL014 with a low Chloride value, we can "jump" to the DM record for that subject by using the menu "View - Show corresponding DM record"², or much faster, just using Ctrl-D on the keyboard, leading to:

² In the case of ADaM, the menu item will show "Show corresponding ADSL record"

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC	
Rec.#	STUDYID	DOMAIN	USUBJID	SUBJID	AGE	AGEU	SEX	ARMCD	RACE	RACE1
1	CDISCPLOT01	DM	CDISC001	1115	84	YEARS	M	ZAN_LOW	WHITE	
2	CDISCPLOT01	DM	CDISC002	1211	76	YEARS	F	ZAN_LOW	WHITE	
3	CDISCPLOT01	DM	CDISC003	1302	61	YEARS	M	ZAN_HIGH	WHITE	
4	CDISCPLOT01	DM	CDISC004	1345	63	YEARS	F	PLACEBO	WHITE	
5	CDISCPLOT01	DM	CDISC005	1383	72	YEARS	F	ZAN_HIGH	WHITE	
6	CDISCPLOT01	DM	CDISC006	1429	84	YEARS	F	ZAN_LOW	WHITE	
7	CDISCPLOT01	DM	CDISC007	1444	63	YEARS	M	ZAN_HIGH	WHITE	
8	CDISCPLOT01	DM	CDISC008	1445	75	YEARS	M	PLACEBO	MULTIPLE	ASIAN
9	CDISCPLOT01	DM	CDISC009	1087	74	YEARS	F	PLACEBO	WHITE	
10	CDISCPLOT01	DM	CDISC010	1236	86	YEARS	F	ZAN_HIGH	WHITE	
11	CDISCPLOT01	DM	CDISC011	1336	73	YEARS	M	ZAN_HIGH	WHITE	
12	CDISCPLOT01	DM	CDISC012	1378	67	YEARS	M	PLACEBO	BLACK OR ...	
13	CDISCPLOT01	DM	CDISC013	1083	89	YEARS	F	PLACEBO	WHITE	
14	CDISCPLOT01	DM	CDISC014	1012	67	YEARS	F	ZAN_HIGH	WHITE	
15	CDISCPLOT01	DM	CDISC015	1022	86	YEARS	F		WHITE	
16	CDISCPLOT01	DM	CDISC016	1143	76	YEARS	F	ZAN_LOW	WHITE	
17	CDISCPLOT01	DM	CDISC017	1250	82	YEARS	F	ZAN_LOW	WHITE	
18	CDISCPLOT01	DM	CDISC018	1427	74	YEARS	F	ZAN_HIGH	BLACK OR ...	

showing us that the subject was in the "high xanomeline" arm.

Also here, one can then use Ctrl-B to "toggle" between the two datasets and records.

Sorting and filtering

The result tables can easily be sorted and filtered,

One can sort within a column by clicking on the column header. For example, in LB by clicking on the LBTESTCD column header, the rows will be ordered in alphabetic order for the value of LBTESTCD:

CM	EC	LB	VS	SUPPDM	SUPPEC		
DOMAIN	USUBJID	LBSEQ	LBTESTCD ▲	LBTEST	LBCAT	LBORRES	LBOR
.B	CDISC001	1	ALB	Albumin	CHEMISTRY	3.9	g/dL
.B	CDISC001	38	ALB	Albumin	CHEMISTRY	3.6	g/dL
.B	CDISC001	73	ALB	Albumin	CHEMISTRY	3.5	g/dL
.B	CDISC001	103	ALB	Albumin	CHEMISTRY	3.7	g/dL
.B	CDISC001	118	ALB	Albumin	CHEMISTRY	3.7	g/dL
.B	CDISC001	148	ALB	Albumin	CHEMISTRY	3.9	g/dL
.B	CDISC002	1	ALB	Albumin	CHEMISTRY	4.2	g/dL
.B	CDISC002	38	ALB	Albumin	CHEMISTRY	3.4	g/dL
.B	CDISC002	73	ALB	Albumin	CHEMISTRY	3.6	g/dL
.B	CDISC002	103	ALB	Albumin	CHEMISTRY	3.3	g/dL
.B	CDISC002	133	ALB	Albumin	CHEMISTRY	3.3	g/dL

The next click on the column header then sorts the rows in the reverse order:

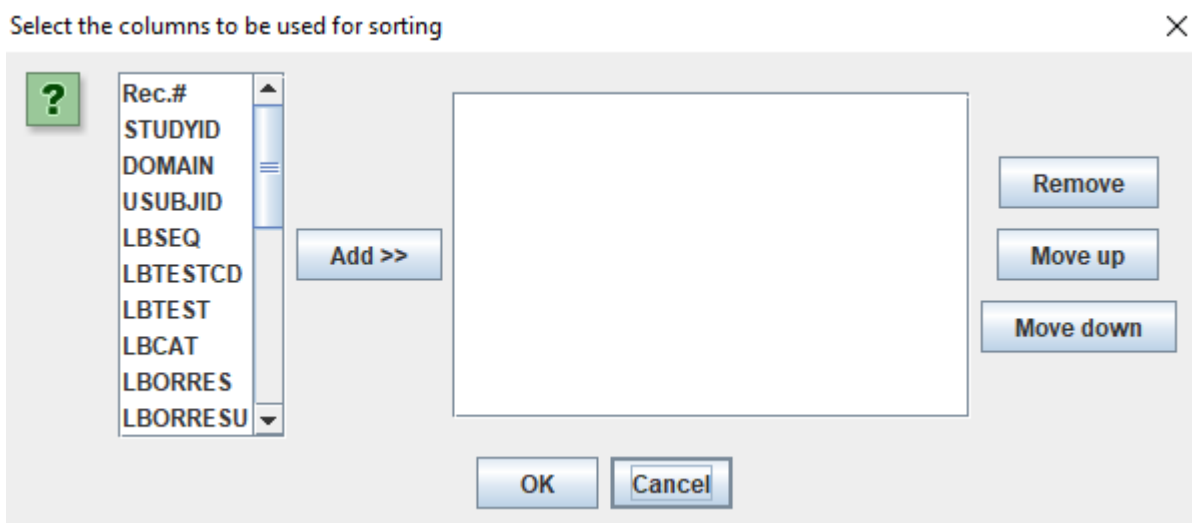
C	LB	VS	SUPPDM	SUPPEC	
N	USUBJID	LBSEQ	LBTESTCD ▼	LBTEST	LBCAT
	CDISC001	37	WBC	Leukocytes	HEMATOL...
	CDISC001	72	WBC	Leukocytes	HEMATOL...
	CDISC001	102	WBC	Leukocytes	HEMATOL...
	CDISC001	147	WBC	Leukocytes	HEMATOL...
	CDISC001	182	WBC	Leukocytes	HEMATOL...

Remark that for numeric variables ("integer" or "float" in the metadata) the rows will be sorted numerically for the variable value.

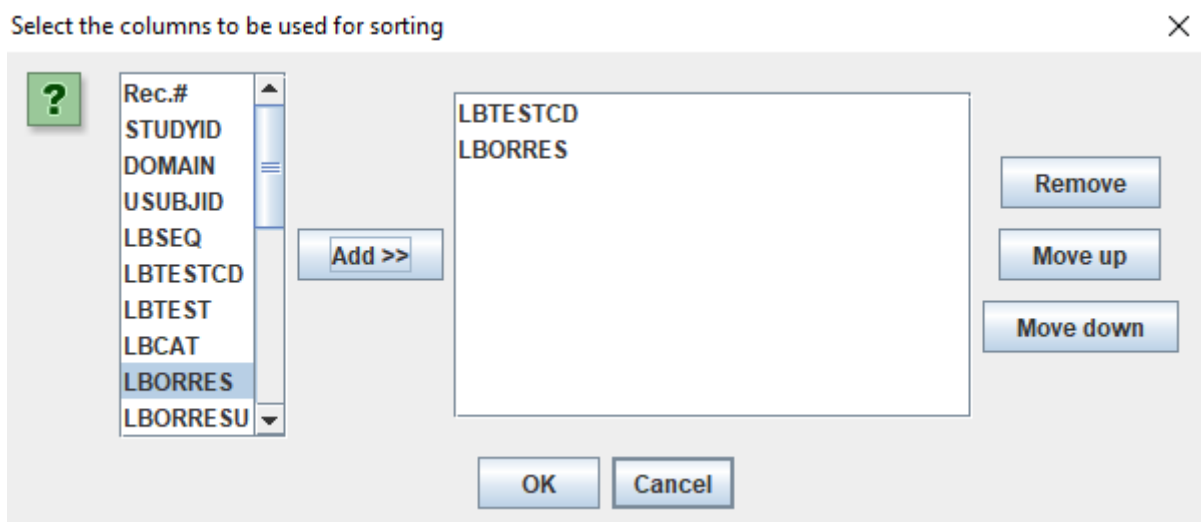
Sorting can also be accomplished using the menu "Tools - Sorting":



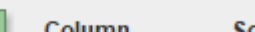
with keyboard shortcuts Ctrl-T (for sorting) Ctrl-U (for unsorting). When using "Sorting", this leads to:



where one can add and remove columns to be sorted on. For example, for sorting on LBTESTCD and LBORRES:



This leads to a new dialog:



Column	Sort ascending	Sort descending
LBTESTCD	☒	☐
LBORRES	☒	☐

OK Cancel

LBTESTCD ▲	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRII	LBSTR
ALB	Albumin	CHEMISTRY	3.3	g/dL	3.5	4.6	33
ALB	Albumin	CHEMISTRY	3.3	g/dL	3.5	4.6	33
ALB	Albumin	CHEMISTRY	3.3	g/dL	3.5	4.6	33
ALB	Albumin	CHEMISTRY	3.4	g/dL	3.5	4.6	34
ALB	Albumin	CHEMISTRY	3.5	g/dL	3.5	4.6	35
ALB	Albumin	CHEMISTRY	3.5	g/dL	3.5	4.6	35
ALB	Albumin	CHEMISTRY	3.6	g/dL	3.5	4.6	36
ALB	Albumin	CHEMISTRY	3.6	g/dL	3.5	4.6	36
ALB	Albumin	CHEMISTRY	3.6	g/dL	3.3	4.9	36
ALB	Albumin	CHEMISTRY	3.6	g/dL	3.3	4.9	36
ALB	Albumin	CHEMISTRY	3.6	g/dL	3.5	4.6	36
ALB	Albumin	CHEMISTRY	3.6	g/dL	3.5	4.6	36
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.3	4.9	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.7	g/dL	3.5	4.6	37
ALB	Albumin	CHEMISTRY	3.8	g/dL	3.5	4.6	38

Also filtering is easily possible, using the menu "Tools - Filtering":

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA Sorting

Filtering

Columns

Change dataset order / tab order

Show related records Ctrl-R

Remove related records / supplemental qualifiers highlighting Ctrl-H

Copy single cell contents Ctrl-C

Filter on USUBJID

Filter on topic variable

Filter on category

Filter on subject demographics

Filter on variable value

Filter on record numbers

Undo last applied filter

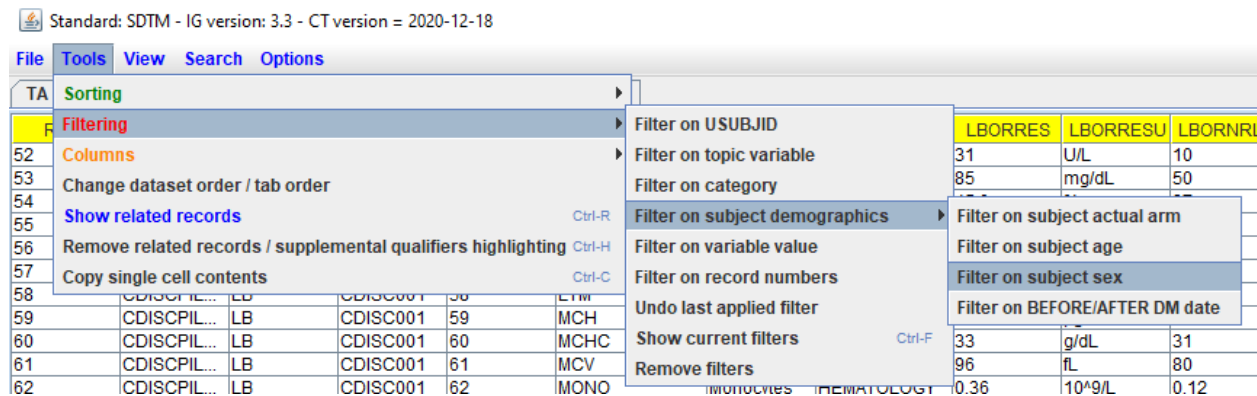
Show current filters Ctrl-F

Remove filters

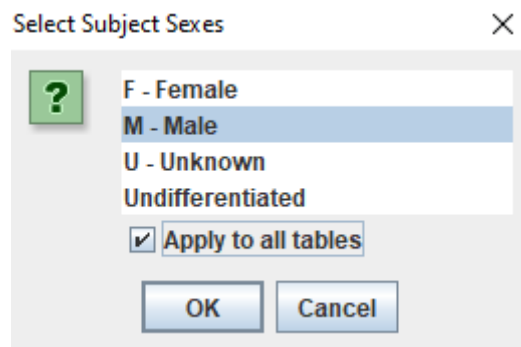
	CDISCIL...	LB	CDISC...		ALB		LBORRES	LBORP
285	CDISCIL...	LB	CDISC001	38	ALB		3.3	g/dL
315	CDISCIL...	LB	CDISC002	73	ALB		3.3	g/dL
1741	CDISCIL...	LB	CDISC003	38	ALB		3.3	g/dL
220	CDISCIL...	LB	CDISC007	38	ALB		3.4	g/dL
73	CDISCIL...	LB	CDISC008	88	ALB	Albumin	3.5	g/dL
1836	CDISCIL...	LB	CDISC009	229	ALB	Albumin	3.5	g/dL
38	CDISCIL...	LB	CDISC001	38	ALB		3.6	g/dL
255	CDISCIL...	LB	CDISC002	73	ALB		3.6	g/dL
382	CDISCIL...	LB	CDISC003	38	ALB		3.6	g/dL
1330	CDISCIL...	LB	CDISC007	38	ALB		3.6	g/dL
1517	CDISCIL...	LB	CDISC008	88	ALB	Albumin	3.6	g/dL
1932	CDISCIL...	LB	CDISC009	229	ALB	Albumin	3.6	g/dL

One can filter on the subject, one the topic variable (--TESTCD for "Findings", --TERM for "Events", --TRT for "Interventions", on category (--CAT variable), on subject demographics (e.g. SEX, RACE, AGE, ...), but also on variable values (ranges) and of course on record numbers. One can apply "filters on filters", so making combination of filters, display them, and remove all the filters.

For example, if we want to filter on the "ketone" lab values for the male subjects, we start by applying a filter on "subject demographics", using the corresponding dialog:



followed by:



and ensure that the checkbox "Apply to all tables" is checked. For DM, we will then see:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC
Rec.#	STUDYID	DOMAIN	USUBJID	SUBJID	SEX	AGE	AGEU		
1	CDISCILOT01	DM	CDISC001	1115	M	84	YEARS		
3	CDISCILOT01	DM	CDISC003	1302	M	61	YEARS		
7	CDISCILOT01	DM	CDISC007	1444	M	63	YEARS		
8	CDISCILOT01	DM	CDISC008	1445	M	75	YEARS		
11	CDISCILOT01	DM	CDISC011	1336	M	73	YEARS		
12	CDISCILOT01	DM	CDISC012	1378	M	67	YEARS		

Only showing the male subjects: CDISC001, CDISC003, CDISC007, CDISC008, CDISC011 and CDISC012. In the LB table we then find:

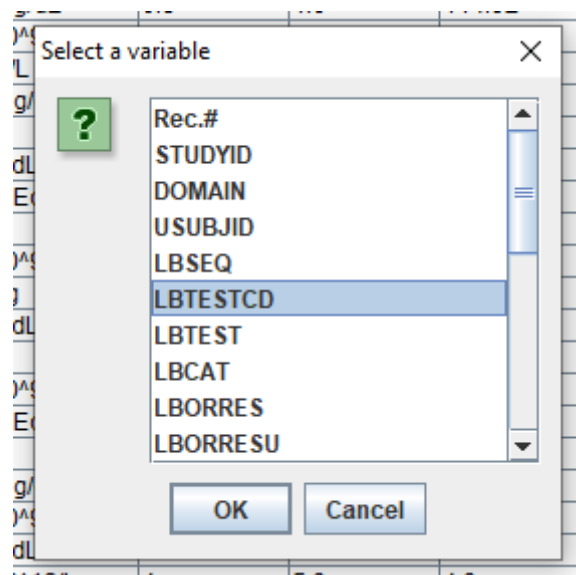
File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC			
Rec.#	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRLH	
178	CDISCPIL...	LB	CDISC001	178	RBC	Erythrocytes	HEMATOL...	4.80	10 ¹² /L	4	5.8	
179	CDISCPIL...	LB	CDISC001	179	SPGRAV	Specific Gr...	URINALYSIS	1.023		1.006	1.03	
180	CDISCPIL...	LB	CDISC001	180	URATE	Urate	CHEMISTRY	4.5	mg/dL	2.5	7.5	
181	CDISCPIL...	LB	CDISC001	181	UROBIL	Urobilinogen	URINALYSIS	0				
182	CDISCPIL...	LB	CDISC001	182	WBC	Leukocytes	HEMATOL...	4.98	10 ⁹ /L	3.8	10.7	
345	CDISCPIL...	LB	CDISC003	1	ALB	Albumin	CHEMISTRY	4.3	g/dL	3.3	4.9	
346	CDISCPIL...	LB	CDISC003	2	ALP	Alkaline Ph...	CHEMISTRY	67	U/L	35	115	
347	CDISCPIL...	LB	CDISC003	3	ALT	Alanine Am...	CHEMISTRY	62	U/L	6	43	
348	CDISCPIL...	LB	CDISC003	4	AST	Aspartate A...	CHEMISTRY	52	U/L	11	36	
349	CDISCPIL...	LB	CDISC003	5	BASO	Basophils	HEMATOL...	0.07	10 ⁹ /L	0	0.2	
350	CDISCPIL...	LB	CDISC003	6	BILI	Bilirubin	CHEMISTRY	0.6	mg/dL	0.2	1.2	
351	CDISCPIL...	LB	CDISC003	7	UREAN	Urea Nitrog...	CHEMISTRY	13	mg/dL	4	24	
352	CDISCPIL...	LB	CDISC003	8	CA	Calcium	CHEMISTRY	9.6	mg/dL	8.4	10.3	
353	CDISCPIL...	LB	CDISC003	9	CHOL	Cholesterol	CHEMISTRY	255	mg/dL	149	286	
354	CDISCPIL...	LB	CDISC003	10	CK	Creatine Ki...	CHEMISTRY	444	U/L	22	198	

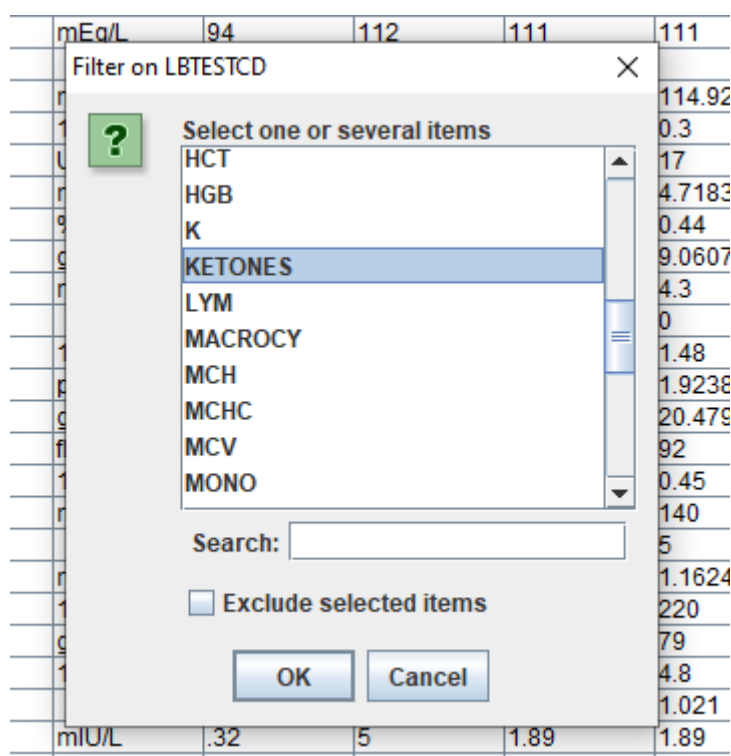
only containing records for male subjects.

On top of this, we want to apply a filter for LBTESTCD = KETONES.

We can do this by filtering on the "topic variable", as for LB, LBTESTCD is the "topic variable", or we can use "Filter on variable value", select LBTESTCD:



and then select "KETONES":



Remark that If one wants to select all values except for a few ones, one can also use the checkbox "Exclude the selected items".

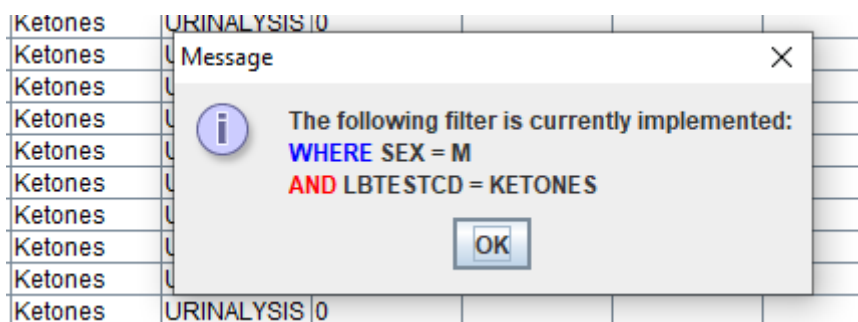
The result after clicking "OK" then is:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

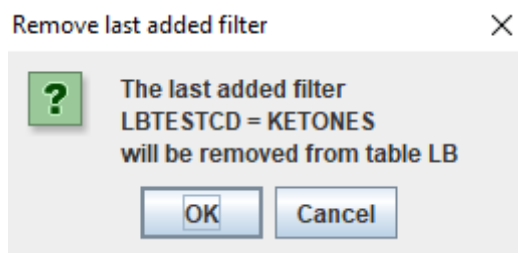
File Tools View Search Options									
TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC
Rec.#	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBOR
20	CDISCPIL01	LB	CDISC001	20	KETONES	Ketones	URINALYSIS	0	
57	CDISCPIL01	LB	CDISC001	57	KETONES	Ketones	URINALYSIS	0	
167	CDISCPIL01	LB	CDISC001	167	KETONES	Ketones	URINALYSIS	0	
364	CDISCPIL01	LB	CDISC003	20	KETONES	Ketones	URINALYSIS	0	
401	CDISCPIL01	LB	CDISC003	57	KETONES	Ketones	URINALYSIS	0	
526	CDISCPIL01	LB	CDISC003	182	KETONES	Ketones	URINALYSIS	0	
1312	CDISCPIL01	LB	CDISC007	20	KETONES	Ketones	URINALYSIS	0	
1349	CDISCPIL01	LB	CDISC007	57	KETONES	Ketones	URINALYSIS	0	
1414	CDISCPIL01	LB	CDISC007	122	KETONES	Ketones	URINALYSIS	0	
1449	CDISCPIL01	LB	CDISC008	20	KETONES	Ketones	URINALYSIS	0	
1500	CDISCPIL01	LB	CDISC008	71	KETONES	Ketones	URINALYSIS	0	
1626	CDISCPIL01	LB	CDISC008	197	KETONES	Ketones	URINALYSIS	0	
1689	CDISCPIL01	LB	CDISC008	260	KETONES	Ketones	URINALYSIS	0	
2111	CDISCPIL01	LB	CDISC011	20	KETONES	Ketones	URINALYSIS	0	
2148	CDISCPIL01	LB	CDISC011	57	KETONES	Ketones	URINALYSIS	0	
2272	CDISCPIL01	LB	CDISC011	181	KETONES	Ketones	URINALYSIS	0	
2368	CDISCPIL01	LB	CDISC011	277	KETONES	Ketones	URINALYSIS	0	
2434	CDISCPIL01	LB	CDISC012	20	KETONES	Ketones	URINALYSIS	0	
2471	CDISCPIL01	LB	CDISC012	57	KETONES	Ketones	URINALYSIS	0	
2596	CDISCPIL01	LB	CDISC012	182	KETONES	Ketones	URINALYSIS	0	
2661	CDISCPIL01	LB	CDISC012	247	KETONES	Ketones	URINALYSIS	0	

only showing the lab records for "ketones" for male subjects CDISC001, CDISC003, CDISC007 etc..

One can always check which filters are on, by using the menu "Tools - Filtering - Show current filters", in our case leading to:



One can also remove the last applied filter using the menu "Tools - Filtering - Undo last applied filter". A message is then displayed:



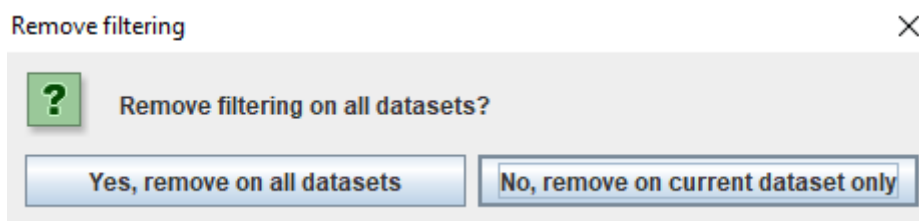
If we do so, and then add a new filter on LBCAT = HEMATOLOGY, the result is:

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File Tools View Search Options

TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC	
Rec.#	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORRESN
165	CDISCPIL0T01	LB	CDISC001	165	HGB	Hemoglobin	HEMATOLOGY	15.2	g/dL	12.5
168	CDISCPIL0T01	LB	CDISC001	168	LYM	Lymphocytes	HEMATOLOGY	1.13	10 ⁹ /L	0.8
169	CDISCPIL0T01	LB	CDISC001	169	MCH	Ery. Mean Corpuscular Hemoglobin	HEMATOLOGY	32	pg	26
170	CDISCPIL0T01	LB	CDISC001	170	MCHC	Ery. Mean Corpuscular HGB Concentration	HEMATOLOGY	34	g/dL	31
171	CDISCPIL0T01	LB	CDISC001	171	MCV	Ery. Mean Corpuscular Volume	HEMATOLOGY	94	fL	80
172	CDISCPIL0T01	LB	CDISC001	172	MONO	Monocytes	HEMATOLOGY	0.41	10 ⁹ /L	0.12
176	CDISCPIL0T01	LB	CDISC001	176	PLAT	Platelets	HEMATOLOGY	174	10 ⁹ /L	130
178	CDISCPIL0T01	LB	CDISC001	178	RBC	Erythrocytes	HEMATOLOGY	4.80	10 ¹² /L	4
182	CDISCPIL0T01	LB	CDISC001	182	WBC	Leukocytes	HEMATOLOGY	4.98	10 ⁹ /L	3.8
349	CDISCPIL0T01	LB	CDISC003	5	BASO	Basophils	HEMATOLOGY	0.07	10 ⁹ /L	0
358	CDISCPIL0T01	LB	CDISC003	14	EOS	Eosinophils	HEMATOLOGY	0.30	10 ⁹ /L	0
361	CDISCPIL0T01	LB	CDISC003	17	HCT	Hematocrit	HEMATOLOGY	44.0	%	37
362	CDISCPIL0T01	LB	CDISC003	18	HGB	Hemoglobin	HEMATOLOGY	14.6	g/dL	12.5
365	CDISCPIL0T01	LB	CDISC003	21	LYM	Lymphocytes	HEMATOLOGY	1.48	10 ⁹ /L	0.8
366	CDISCPIL0T01	LB	CDISC003	22	MCH	Ery. Mean Corpuscular Hemoglobin	HEMATOLOGY	31	pg	26
367	CDISCPIL0T01	LB	CDISC003	23	MCHC	Ery. Mean Corpuscular HGB Concentration	HEMATOLOGY	33	g/dL	31
368	CDISCPIL0T01	LB	CDISC003	24	MCV	Ery. Mean Corpuscular Volume	HEMATOLOGY	92	fL	80
369	CDISCPIL0T01	LB	CDISC003	25	MONO	Monocytes	HEMATOLOGY	0.45	10 ⁹ /L	0.12
373	CDISCPIL0T01	LB	CDISC003	29	PLAT	Platelets	HEMATOLOGY	220	10 ⁹ /L	130

To remove all filters, use the menu "Tools - Filtering - Remove filters", leading to:



Usually, one will want to remove the filters on all the loaded datasets, otherwise things can get a bit messy. When then using "Yes, remove on all datasets", all the tables will be shown in their original state.

One can also always filter on specific subjects, by USUBJID, using the menu "Tools - Filtering - Filter on USUBJID". The system will then present a list of subjects by USUBJID, from which one can select the ones of interest, e.g.:

Select USUBJID

×

?

☒ All Subjects
 ☐ Subjects from current view
 ☐ Type or copy/past subject IDs
 ☐ All currently selected Subjects (0 Subjects)

CDISC001

CDISC002

CDISC003

CDISC004

CDISC005

CDISC006

CDISC007

CDISC008

CDISC009

CDISC010

CDISC011

CDISC012

CDISC013

CDISC014

CDISC015

CDISC016

CDISC017

CDISC018

☐ Exclude selected subjects
 ☐ Apply to all datasets

OK

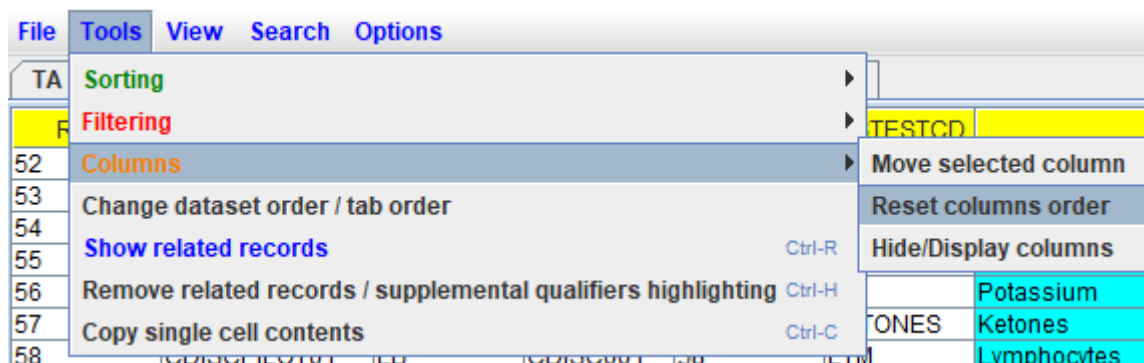
Cancel

Also here, one can filter by exclusion, and apply the filter on either the current loaded datasets on all loaded datasets.

Remark that it is often to do "pre-loading filtering" as explains in the section "Filtering before loading".

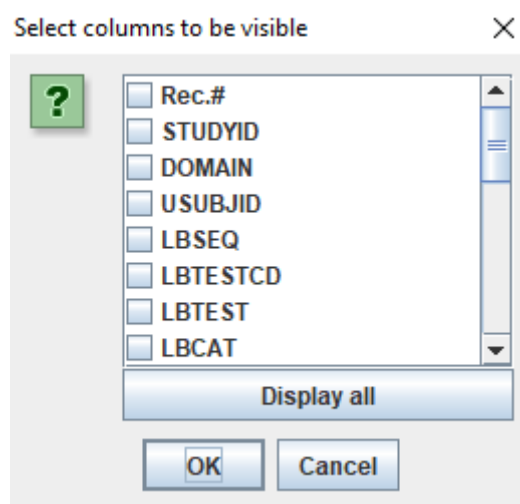
Moving columns around and hiding columns

We already showed how columns can be moved from one place to another, simply by dragging the column header. As in SDTM and SEND, the column order is in principal fixed, one can reset to the original order by using the menu "Tools - Columns - Reset column order":

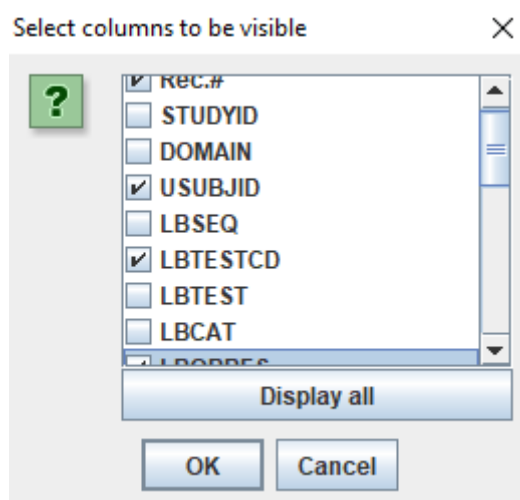


The menu "Tools - Columns - Move selected column" can also be used to move a column to another place (right-click on the column header first to select it), but usually just dragging the column will be the easier way.

One can also hide (and later re-display) columns by using the menu "Tools - Columns - Hide/Display columns". This brings the following dialog up:



When we e.g. want to have "Rec.#", USUBJID, LBTESTCD, LBORRES and LBORRESU displayed, we select these:



leading to:

File Tools View Search Options														
TA	TV	DM	AE	CM	EC	LB	VS	SUPPDM	SUPPEC					
Rec.#	USUBJID	LBTESTCD	LBORRES											
166	..CDISC001	K	.4.7											
167	..CDISC001	KETONES	.0											
168	..CDISC001	LYM	.1.13											
169	..CDISC001	MCH	.32											
170	..CDISC001	MCHC	.34											
171	..CDISC001	MCV	.94											
172	..CDISC001	MONO	.0.41											
173	..CDISC001	SODIUM	.141											
174	..CDISC001	PH	.5											
175	..CDISC001	PHOS	.3.4											
176	..CDISC001	PLAT	.174											
177	..CDISC001	PROT	.7.1											
178	..CDISC001	RBC	.4.80											
179	..CDISC001	SPGRAV	.1.023											
180	..CDISC001	URATE	.4.5											
181	..CDISC001	UROBIL	.0											
182	..CDISC001	WBC	.4.98											
183	..CDISC002	ALB	.4.2											

Remark that the columns to be hidden are not completely hidden, but just "minimized", so that dragging on the edge can make individual columns visible again.

We might want to change this behavior in future depending on the user responses.

Making all the columns visible again, i.e. giving them their original width, can then be done using the same menu, and clicking "Display all".

Connecting Related records (RELREC)

We did already show how one can establish the relationship between rows in the SUPPQUAL (supplemental qualifier) datasets and the "parent" records in the "parent" table, either by "bringing back" the "non-standard variables" to the parent dataset as additional columns (which however requires a quality define.xml) or by "toggling" between the related rows in both the datasets.

There is however another important mechanism of having relationships between records and tables, by the use of the "RELREC" (Related Records) datasets. It is often used to establish the relationship between the AE (adverse events) dataset and the CM (concomitant medications) datasets. Unfortunately, the sample dataset from the "Metadata Submission Guidelines" does not have a good example, so we need to take another example. We find this in the files from the original LZTZ pilot 2013 which we converted from XPT to Dataset-JSON 1.1, and which contain records for describing the relation between AE (adverse events) and DS (disposition). Loading these, together with DM (always a good idea) into the software:

Smart Submission Dataset Viewer

Standard: **SDTM** Options

Dataset source type: ☒ Dataset-JSON 1.1 ☐ Dataset-NDJSON ☐ CSV Files

Dataset-JSON metadata: ☒ Use define.xml for metadata ☐ Use Dataset-JSON internal metadata

Define.xml: Browse Get from API

Define.xml version: ☐ 2.1 ☒ 2.0 ☐ 1.0 View

Dataset-JSON data files:

ion_Dataset_Viewer_Demo_Files\Files_from_LZZT_Pilot_2013_Dataset-JSON_1-1\ae.json

ion_Dataset_Viewer_Demo_Files\Files_from_LZZT_Pilot_2013_Dataset-JSON_1-1\dm.json

ion_Dataset_Viewer_Demo_Files\Files_from_LZZT_Pilot_2013_Dataset-JSON_1-1\ds.json

ion_Dataset_Viewer_Demo_Files\Files_from_LZZT_Pilot_2013_Dataset-JSON_1-1\relrec.json

For adding files, you can use drag-and-drop, or use the 'Add' button

Add Add from API

Remove

Clear

and start loading by clicking the "Start" button, this then leads to:

Standard: SDTM - IG version: 3.1.2 - CT version = null

File Tools View Search Options

DM

RELREC

AE

DS

Rec.#	STUDYID	DOMAIN	USUBJID	AESQ	AESPID	AETERM	AELLT	AELLTCD	AEDECOD	AEPTCD	A
1	CDISCPIL0T01	AE	01-701-1015	1	E07	APPLICATI...	APPLICATI...		APPLICATI...		HLT
2	CDISCPIL0T01	AE	01-701-1015	2	E08	APPLICATI...	APPLICATI...		APPLICATI...		HLT
3	CDISCPIL0T01	AE	01-701-1015	3	E06	DIARRHOEA	DIARRHEA		DIARRHOEA		HLT
4	CDISCPIL0T01	AE	01-701-1023	3	E10	ATRIOVEN...	AV BLOCK ...		ATRIOVEN...		HLT
5	CDISCPIL0T01	AE	01-701-1023	1	E08	ERYTHEMA	ERYTHEMA		ERYTHEMA		HLT
6	CDISCPIL0T01	AE	01-701-1023	2	E09	ERYTHEMA	LOCALIZE...		ERYTHEMA		HLT
7	CDISCPIL0T01	AE	01-701-1023	4	E08	ERYTHEMA	ERYTHEMA		ERYTHEMA		HLT
8	CDISCPIL0T01	AE	01-701-1028	1	E04	APPLICATI...	APPLICATI...		APPLICATI...		HLT
9	CDISCPIL0T01	AE	01-701-1028	2	E05	APPLICATI...	APPLICATI...		APPLICATI...		HLT
10	CDISCPIL0T01	AE	01-701-1034	1	E08	APPLICATI...	APPLICATI...		APPLICATI...		HLT
11	CDISCPIL0T01	AE	01-701-1034	2	E07	FATIGUE	FATIGUE		FATIGUE		HLT
12	CDISCPIL0T01	AE	01-701-1047	4	E09	BUNDLE B...	LEFT BUN...		BUNDLE B...		HLT
13	CDISCPIL0T01	AE	01-701-1047	1	E06	HIATUS HE...	HERNIA HI...		HIATUS HE...		HLT
14	CDISCPIL0T01	AE	01-701-1047	2	E06	HIATUS HE...	HERNIA HI...		HIATUS HE...		HLT
15	CDISCPIL0T01	AE	01-701-1047	3	E08	UPPER RE...	UPPER RE...		UPPER RE...		HLT
16	CDISCPIL0T01	AE	01-701-1097	4	E06	APPLICATI...	APPLICATI...		APPLICATI...		HLT
17	CDISCPIL0T01	AE	01-701-1097	10	E06	APPLICATI...	APPLICATI...		APPLICATI...		HLT
18	CDISCPIL0T01	AE	01-701-1097	3	E07	APPLICATI...	APPLICATI...		APPLICATI...		HLT
19	CDISCPIL0T01	AE	01-701-1097	1	E04	ERYTHEMA	ERYTHEMA		ERYTHEMA		HLT

and for the RELREC table:

Standard SDTM - IG version: 3.1.2 - CT version = null

File Tools View Search Options

DM

RELREC

AE

DS

Rec.#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID
118	CDISCPIL0T01	AE	01-715-1107	AESQ	1		01-715-1107-E01
119	CDISCPIL0T01	AE	01-715-1107	AESQ	3		01-715-1107-E01
120	CDISCPIL0T01	AE	01-715-1321	AESQ	3		01-715-1321-E03
121	CDISCPIL0T01	AE	01-715-1405	AESQ	1		01-715-1405-E02
122	CDISCPIL0T01	AE	01-716-1063	AESQ	6		01-716-1063-E10
123	CDISCPIL0T01	AE	01-716-1071	AESQ	3		01-716-1071-E08
124	CDISCPIL0T01	AE	01-716-1094	AESQ	1		01-716-1094-E07
125	CDISCPIL0T01	AE	01-716-1151	AESQ	2		01-716-1151-E06
126	CDISCPIL0T01	AE	01-716-1189	AESQ	4		01-716-1189-E07
127	CDISCPIL0T01	AE	01-716-1229	AESQ	1		01-716-1229-E01
128	CDISCPIL0T01	AE	01-716-1298	AESQ	3		01-716-1298-E07
129	CDISCPIL0T01	AE	01-716-1298	AESQ	6		01-716-1298-E07
130	CDISCPIL0T01	AE	01-716-1373	AESQ	2		01-716-1373-E04
131	CDISCPIL0T01	AE	01-718-1066	AESQ	3		01-718-1066-E08
132	CDISCPIL0T01	AE	01-718-1079	AESQ	2		01-718-1079-E03
133	CDISCPIL0T01	AE	01-718-1079	AESQ	3		01-718-1079-E03
134	CDISCPIL0T01	AE	01-718-1170	AESQ	5		01-718-1170-E03
135	CDISCPIL0T01	AE	01-718-1250	AESQ	9		01-718-1250-E06
136	CDISCPIL0T01	AE	01-718-1250	AESQ	10		01-718-1250-E06
137	CDISCPIL0T01	AE	01-718-1250	AESQ	11		01-718-1250-E06
138	CDISCPIL0T01	AE	01-718-1371	AESQ	3		01-718-1371-E08
139	CDISCPIL0T01	AE	01-718-1371	AESQ	6		01-718-1371-E08
140	CDISCPIL0T01	DS	01-701-1023	DSSEQ	1		01-701-1023-E09
141	CDISCPIL0T01	DS	01-701-1047	DSSEQ	1		01-701-1047-E09
142	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1		01-701-1111-E16
143	CDISCPIL0T01	DS	01-701-1115	DSSEQ	1		01-701-1115-E13
144	CDISCPIL0T01	DS	01-701-1146	DSSEQ	1		01-701-1146-E13
145	CDISCPIL0T01	DS	01-701-1180	DSSEQ	1		01-701-1180-E07
146	CDISCPIL0T01	DS	01-701-1181	DSSEQ	1		01-701-1181-E16
147	CDISCPIL0T01	DS	01-701-1188	DSSEQ	1		01-701-1188-E09

When sorting by RELID, we better see which AE and DS records are related:

File Tools View Search Options

DM RELREC AE DS

Rec.#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTY...	RELID ▲
1	CDISCPIL0T01	AE	01-701-1023	AESEQ	2		01-701-1023-E09
140	CDISCPIL0T01	DS	01-701-1023	DSSEQ	1		01-701-1023-E09
2	CDISCPIL0T01	AE	01-701-1047	AESEQ	4		01-701-1047-E09
141	CDISCPIL0T01	DS	01-701-1047	DSSEQ	1		01-701-1047-E09
3	CDISCPIL0T01	AE	01-701-1111	AESEQ	7		01-701-1111-E16
142	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1		01-701-1111-E16

showing that for subject 01-701-1023, the AE record with AESEQ=2 is related to the DS record with DSSEQ=1,
and that for subject 01-701-1047, the AE record with AESEQ=4 is related to the DS record with DSSEQ=1.

If we select the latter (record # 141):

File Tools View Search Options

DM RELREC AE DS

Rec.#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTY...	RELID ▲
1	CDISCPIL0T01	AE	01-701-1023	AESEQ	2		01-701-1023-E09
140	CDISCPIL0T01	DS	01-701-1023	DSSEQ	1		01-701-1023-E09
2	CDISCPIL0T01	AE	01-701-1047	AESEQ	4		01-701-1047-E09
141	CDISCPIL0T01	DS	01-701-1047	DSSEQ	1		01-701-1047-E09
3	CDISCPIL0T01	AE	01-701-1111	AESEQ	7		01-701-1111-E16
142	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1		01-701-1111-E16

and then use the menu "Tools - Show related records" (or simply use Ctrl-R on the keyboard), this leads to a message:

File Tools View Search Options

DM RELREC AE DS

Rec.#	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTY...
1	CDISCPIL0T01	AE	01-701-1023	AESEQ	2	
140	CDISCPIL0T01	DS	01-701-1023	DSSEQ	1	
2	CDISCPIL0T01	AE	01-701-1047	AESEQ	4	
141	CDISCPIL0T01	DS	01-701-1047	DSSEQ	1	
3	CDISCPIL0T01	AE	01-701-1111	AESEQ	7	
142	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1	
4	CDISCPIL0T01	AE	01-701-1111	AESEQ	7	
143	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1	
5	CDISCPIL0T01	AE	01-701-1111	AESEQ	7	
6	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1	
144	CDISCPIL0T01	AE	01-701-1111	AESEQ	7	
7	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1	
145	CDISCPIL0T01	AE	01-701-1111	AESEQ	7	
8	CDISCPIL0T01	DS	01-701-1111	DSSEQ	1	

Message



There can be up to **2** related records with RELID '01-701-1047-E09':
Domain = AE - USUBJID = 01-701-1047 - AESEQ = 4
Domain = DS - USUBJID = 01-701-1047 - DSSEQ = 1

OK

and after clicking "OK", additional information is displayed in a separate window:

Related Records core properties and values

RELID: 01-701-1047-E09

Study ID	Dataset	Subject ID	AESEQ	AETERM	VISITNUM/ VISIT	AEDTC	AESTDTC	AEENDTC
CDISCILOT01	AE	01-701-1047	4	BUNDLE BRANCH BLOCK LEFT		2013-03-10	2013-03-10	
Study ID	Dataset	Subject ID	DSSEQ	DSTERM	VISITNUM/ VISIT	DSDTC	DSSTDTC	DSENDTC
CDISCILOT01	DS	01-701-1047	1	ADVERSE EVENT	6 (AMBUL ECG REMOVAL)	2013-03-29	2013-03-29	

showing the details of the relation.

If we then select the AE tab, the specific record is already highlighted:

Standard: SDTM - IG version: 3.1.2 - CT version = null

File Tools View Search Options

DM RELREC AE DS

Rec#	STUDYID	DOMAIN	USUBJID	AESEQ	AESPID	AETERM	AELLT	AELLTCD	AEDECD	AECTCD	AELHT	AELHTCD	AELHGT	AELHGTCD	AEBODSYS	AEBODSYCD	AESOC
1	CDISCILOT01	AE	01-701-1015	1	E07	APPLICATION SITE ERYTHEMA	APPLICATION SITE REDNESS		APPLICATI...		HLT_0517		HLGT_0152		GENERAL		GENERAL
2	CDISCILOT01	AE	01-701-1015	2	E08	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING		APPLICATI...		HLT_0317		HLGT_0338		GENERAL		GENERAL
3	CDISCILOT01	AE	01-701-1015	3	E06	DIARRHOEA	DIARRHOEA		DIARRHOEA		HLT_0148		HLGT_0588		GASTROIN...		GASTROIN...
4	CDISCILOT01	AE	01-701-1023	3	E10	ATRIOVENTRICULAR BLOCK SE	AV BLOCK SECOND DEGREE		ATRIOVEN...		HLT_0415		HLGT_0088		CARDIAC		CARDIAC
5	CDISCILOT01	AE	01-701-1023	1	E08	ERYTHEMA	ERYTHEMA		ERYTHEMA		HLT_0284		HLGT_0192		SKIN AND		SKIN AND
6	CDISCILOT01	AE	01-701-1023	2	E09	ERYTHEMA	LOCALIZED ERYTHEMA		ERYTHEMA		HLT_0284		HLGT_0192		SKIN AND		SKIN AND
7	CDISCILOT01	AE	01-701-1023	4	E08	ERYTHEMA	ERYTHEMA		ERYTHEMA		HLT_0284		HLGT_0192		SKIN AND		SKIN AND
8	CDISCILOT01	AE	01-701-1028	1	E04	APPLICATION SITE ERYTHEMA	APPLICATION SITE ERYTHEMA		APPLICATI...		HLT_0617		HLGT_0152		GENERAL		GENERAL
9	CDISCILOT01	AE	01-701-1028	2	E05	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING		APPLICATI...		HLT_0317		HLGT_0338		GENERAL		GENERAL
10	CDISCILOT01	AE	01-701-1034	1	E08	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING		APPLICATI...		HLT_0317		HLGT_0338		GENERAL		GENERAL
11	CDISCILOT01	AE	01-701-1034	2	E07	FATIGUE	FATIGUE		FATIGUE		HLT_0043		HLGT_0181		GENERAL		GENERAL
12	CDISCILOT01	AE	01-701-1047	4	E06	BUNDLE BRANCH BLOCK LEFT	LEFT BUNDLE BRANCH BLOCK		BUNDLE BR...		HLT_0171		HLGT_0773		GENERAL		GENERAL
13	CDISCILOT01	AE	01-701-1047	1	E06	HIATUS HERNIA	HERNIA HIATAL		HIATUS HE...		HLT_0159		HLGT_0109		GASTROIN...		GASTROIN...
14	CDISCILOT01	AE	01-701-1047	2	E06	HIATUS HERNIA	HERNIA HIATAL		HIATUS HE...		HLT_0159		HLGT_0109		GASTROIN...		GASTROIN...
15	CDISCILOT01	AE	01-701-1047	3	E08	UPPER RESPIRATORY TRACT IN	UPPER RESPIRATORY INFECTI...		UPPER RE...		HLT_0520		HLGT_0489		INFECTIO...		INFECTIO...
16	CDISCILOT01	AE	01-701-1097	4	E06	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING		APPLICATI...		HLT_0317		HLGT_0338		GENERAL		GENERAL
17	CDISCILOT01	AE	01-701-1097	10	E06	APPLICATION SITE PRURITUS	APPLICATION SITE ITCHING		APPLICATI...		HLT_0317		HLGT_0338		GENERAL		GENERAL
18	CDISCILOT01	AE	01-701-1097	3	E07	APPLICATION SITE VESICLES	APPLICATION SITE BLISTER		APPLICATI...		HLT_0180		HLGT_0576		GENERAL		GENERAL
19	CDISCILOT01	AE	01-701-1097	1	E04	ERYTHEMA	ERYTHEMA		ERYTHEMA		HLT_0284		HLGT_0192		SKIN AND		SKIN AND
20	CDISCILOT01	AE	01-701-1097	9	E11	NASAL CONGESTION	NASAL CONGESTION		NASAL CO...		HLT_0118		HLGT_0549		RESPIRAT		RESPIRAT
21	CDISCILOT01	AE	01-701-1097	8	E10	PHARYNGOALGIA	SORE THROAT		PHARYNGO...		HLT_0130		HLGT_0402		RESPIRAT		RESPIRAT

and when selecting the DS tab, also there, the specific record is already highlighted:

Standard: SDTM - IG version: 3.1.2 - CT version = null

File Tools View Search Options

DM RELREC AE DS

Rec#	STUDYID	DOMAIN	USUBJID	DSSEQ	DSSPID	DSTERM	DSDECD	DSCAT	VISITNUM	VISIT	DSDTC	DSSTDTC	DS
1	CDISCILOT01	DS	01-701-1015	1		PROTOCOL COMP	COMPLETED	DISPOSITION EVE...	13	WEEK 26	2014-07-02	2014-07-02	182
2	CDISCILOT01	DS	01-701-1015	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	13	WEEK 26	2014-07-02T11:45	2014-07-02	182
3	CDISCILOT01	DS	01-701-1023	1	24	ADVERSE EVENT	ADVERSE EVENT	DISPOSITION EVE...	5	WEEK 4	2012-09-02	2012-09-02	29
4	CDISCILOT01	DS	01-701-1023	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	5	WEEK 4	2012-09-02T10:15	2012-09-02	29
5	CDISCILOT01	DS	01-701-1023	3		FINAL LAB VISIT	FINAL RETRIEVAL	OTHER EVENT	201	RETRIEVAL	2013-02-18	2013-02-18	198
6	CDISCILOT01	DS	01-701-1028	1		PROTOCOL COMP	COMPLETED	DISPOSITION EVE...	13	WEEK 26	2014-01-14	2014-01-14	180
7	CDISCILOT01	DS	01-701-1028	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	13	WEEK 26	2014-01-14T11:10	2014-01-14	180
8	CDISCILOT01	DS	01-701-1033	1		SPONSOR DECISI	STUDY TERMINAT	DISPOSITION EVE...	5	WEEK 4	2014-04-14	2014-04-14	28
9	CDISCILOT01	DS	01-701-1033	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	5	WEEK 4	2014-04-14T10:38	2014-04-14	28
10	CDISCILOT01	DS	01-701-1033	3		FINAL LAB VISIT	FINAL RETRIEVAL	OTHER EVENT	201	RETRIEVAL	2014-09-15	2014-09-15	182
11	CDISCILOT01	DS	01-701-1034	1		PROTOCOL COMP	COMPLETED	DISPOSITION EVE...	13	WEEK 26	2014-12-30	2014-12-30	183
12	CDISCILOT01	DS	01-701-1034	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	13	WEEK 26	2014-12-30T09:50	2014-12-30	183
13	CDISCILOT01	DS	01-701-1047	1	17	ADVERSE EVENT	ADVERSE EVENT	DISPOSITION EVE...	5	WEEK 4	2012-09-02	2012-09-02	29
14	CDISCILOT01	DS	01-701-1047	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	6.1	UNSCHEDULED 6.1	2013-04-07T11:20	2013-04-07	55
15	CDISCILOT01	DS	01-701-1047	3		FINAL LAB VISIT	FINAL RETRIEVAL	OTHER EVENT	201	RETRIEVAL	2013-07-28	2013-07-28	167
16	CDISCILOT01	DS	01-701-1057	1		SCREEN FAILURE	SCREEN FAILURE	DISPOSITION EVE...	1	SCREENING 1	2013-12-20	2013-12-20	190
17	CDISCILOT01	DS	01-701-1097	1		PROTOCOL COMP	COMPLETED	DISPOSITION EVE...	13	WEEK 26	2014-07-09	2014-07-09	190
18	CDISCILOT01	DS	01-701-1097	2		FINAL LAB VISIT	FINAL LAB VISIT	OTHER EVENT	13	WEEK 26	2014-07-09T09:39	2014-07-09	190
19	CDISCILOT01	DS	01-701-1111	1	32	ADVERSE EVENT	ADVERSE EVENT	DISPOSITION EVE...	4	WEEK 2	2012-09-17	2012-09-17	11

one can then "toggle" between the DS, AE, and RELREC datasets using Ctrl-B on the keyboard, and using Ctrl-B (or the menu "View - Show corresponding DM record"):

Standard: SDTM - IG version: 3.1.2 - CT version = null

File Tools View Search Options

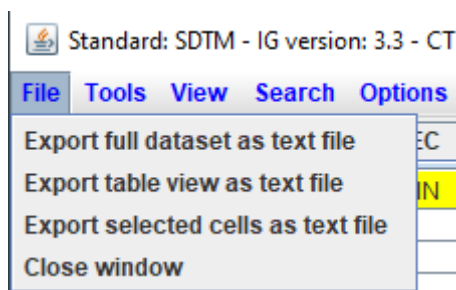
Rec.#	STUDYID	DOMAIN	USUBJID	SUBJID	AGE	AGEU	SEX	RACE	ARMCD	ARM	ACTARMCD	ACTARM	RF
1	CDISCIPIL...	DM	01-701-1015	1015	63	YEARS	F	WHITE	Pbo	Placebo	Pbo	Placebo	2014
2	CDISCIPIL...	DM	01-701-1023	1023	64	YEARS	M	WHITE	Pbo	Placebo	Pbo	Placebo	2012
3	CDISCIPIL...	DM	01-701-1028	1028	71	YEARS	M	WHITE	Xan_Hi	Xanomelin...	Xan_Hi	Xanomelin...	2013
4	CDISCIPIL...	DM	01-701-1033	1033	74	YEARS	M	WHITE	Xan_Lo	Xanomelin...	Xan_Lo	Xanomelin...	2014
5	CDISCIPIL...	DM	01-701-1034	1034	77	YEARS	F	WHITE	Xan_Hi	Xanomelin...	Xan_Hi	Xanomelin...	2014
6	CDISCIPIL...	DM	01-701-1047	1047	85	YEARS	F	WHITE	Pbo	Placebo	Pbo	Placebo	2013
7	CDISCIPIL...	DM	01-701-1057	1057	59	YEARS	F	WHITE	Scrnfail	Screen Fail...	Scrnfail	Screen Fail...	
8	CDISCIPIL...	DM	01-701-1097	1097	68	YEARS	M	WHITE	Xan_Lo	Xanomelin...	Xan_Lo	Xanomelin...	2014
9	CDISCIPIL...	DM	01-701-1111	1111	81	YEARS	F	WHITE	Xan_Lo	Xanomelin...	Xan_Lo	Xanomelin...	2012
10	CDISCIPIL...	DM	01-701-1115	1115	84	YEARS	M	WHITE	Xan_Lo	Xanomelin...	Xan_Lo	Xanomelin...	2012
11	CDISCIPIL...	DM	01-701-1118	1118	52	YEARS	M	WHITE	Pbo	Placebo	Pbo	Placebo	2014
12	CDISCIPIL...	DM	01-701-1130	1130	84	YEARS	M	WHITE	Pbo	Placebo	Pbo	Placebo	2014
13	CDISCIPIL...	DM	01-701-1133	1133	81	YEARS	F	WHITE	Xan_Hi	Xanomelin...	Xan_Hi	Xanomelin...	2012
14	CDISCIPIL...	DM	01-701-1145	1145	57	YEARS	F	WHITE	Scrnfail	Screen Fail...	Scrnfail	Screen Fail...	
15	CDISCIPIL...	DM	01-701-1146	1146	75	YEARS	F	WHITE	Xan_Hi	Xanomelin...	Xan_Hi	Xanomelin...	2013
16	CDISCIPIL...	DM	01-701-1148	1148	57	YEARS	M	WHITE	Xan_Hi	Xanomelin...	Xan_Hi	Xanomelin...	2013

easily find out that this relation is about a 85 year old female who was in the placebo arm.

Exporting the table

In some cases, one want to export the table contents, of parts of it, as simple text or CSV files for use in other applications. Essentially, this should not be necessary, as we do already have the data in modern Dataset-JSON format, but as long as tools like Excel are used in clinical research (they shouldn't except for bookkeeping, that's what they were developed for), people will want to be able to import data from dedicated applications into such applications.

The "Smart Submission Dataset Viewer" provides several possibilities though the menu items "File - Export ...":



One can either export the full dataset of the selected table as a text file, or only the rows and columns that are currently visible, or only the set of currently selected cells. In each of these three cases, the system will ask how to export the data, by the following dialog:

Text file Export

☐ Add line with variable names at top

☐ Add line with variable labels at top

Field delimiter:

☐ put single quotes around strings with spaces or the delimiter

☐ put double quotes around strings with spaces or the delimiter

Text File:

The first two checkboxes allow to add a line with the variable names, and a line with the variable labels, which can serve as a header in receiving applications. The system then asks what the delimited between the fields should be:

giving the choice between the comma, the semicolon and the vertical bar ("pipe" character).

The next two checkboxes allow to set whether either single or double quotes need to be added around the strings values of the variables. This can be important when e.g. the comma is selected as the field delimiter, but the string values themselves can contain the comma character³.

The text field and "Browse" button then allow to define where the text (or CSV) file needs to be written to. Remark that the file will be written using UTF-8 encoding, essentially representing Unicode.

An example of such an export is:

```
1 Rec.#,STUDYID,DOMAIN,USUBID,LBSEQ,LBTESTCD,LBTEST,LBCAT,LBORRES,LBORRESU,LBORNRLO,LBORNRHI,LBTRSC,LBSTRSN,LBSTRSU,LBSTRLO,LBSTRHI,LBNRND,LBLOXFL,VISITNUM,VISIT,EPOCH,LBOTO,LBDY
2 , "Study Identifier", "Domain Abbreviation", "Unique Subject Identifier", "Sequence Number", "Lab Test or Examination Short Name", "Lab Test or Examination Name", "Category for Lab Test", "Result
3 or Finding in Original Units", "Reference Range Lower Limit in Orig Unit", "Reference Range Upper Limit in Orig Unit", "Character Result/Finding in Std Format", "Numeric
4 Result/Finding in Standard Units", "Standard Units", "Reference Range Lower Limit-Std Units", "Reference Range Upper Limit-Std Units", "Reference Range Indicator", "Last Observation Before
5 Exposure Flag", "Visit Number", "Visit Name", "Epoch", "Date/Time of Specimen Collection", "Study Day of Specimen Collection"
6 1,CDISCPIL01,LB,CDISCO01,1,ALB,Albumin,CHEMISTRY,3.9,g/dL,3.5,4.6,39,39,g/L,35,46,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
7 2,CDISCPIL01,LB,CDISCO01,2,ALP,"Alkaline Phosphatase",CHEMISTRY,93,U/L,35,115,93,93,U/L,35,115,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
8 3,CDISCPIL01,LB,CDISCO01,3,ALT,"Alanine Aminotransferase",CHEMISTRY,18,U/L,6,35,18,18,U/L,6,35,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
9 4,CDISCPIL01,LB,CDISCO01,4,AST,"Aspartate Aminotransferase",CHEMISTRY,26,U/L,11,36,26,26,U/L,11,36,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
10 5,CDISCPIL01,LB,CDISCO01,5,Ca,Calcium,CHEMISTRY,9.1,mg/dL,8.4,10.3,9.2,27045,2.27045,mmol/L,2.1,2.57,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
11 6,CDISCPIL01,LB,CDISCO01,6,BIL,Bilirubin,CHEMISTRY,0.5,mg/dL,0.2,1.2,0.55,0.55,umol/L,3.21,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
12 7,CDISCPIL01,LB,CDISCO01,7,UREAN,"Urea Nitrogen",CHEMISTRY,21,mg/dL,4,24,7.457,7.457,mmol/L,1.4,8.6,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
13 8,CDISCPIL01,LB,CDISCO01,8,CHOL,"Cholesterol",CHEMISTRY,254,mg/dL,149,286,4.56844,4.56844,mmol/L,3.85,7.4,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
14 9,CDISCPIL01,LB,CDISCO01,9,CK,"Creatine Kinase",CHEMISTRY,79,U/L,22,198,79,79,U/L,22,198,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
15 10,CDISCPIL01,LB,CDISCO01,10,CL,Chloride,CHEMISTRY,102,mEq/L,94,112,102,102,mmol/L,94,112,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
16 11,CDISCPIL01,LB,CDISCO01,11,COLOR,Color,URINALYSIS,NORMAL,,,,,NORMAL,,,,,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
17 12,CDISCPIL01,LB,CDISCO01,12,COLOR,Color,URINALYSIS,NORMAL,,,,,NORMAL,,,,,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
18 13,CDISCPIL01,LB,CDISCO01,13,CREAT,Creatinine,CHEMISTRY,1.3,mg/dL,0.8,1.6,1.14,92,1.14,92,umol/L,7.1,14.1,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
19 14,CDISCPIL01,LB,CDISCO01,14,EOS,Eosinophils,HMATOLOGY,0.08,10^9/L,0,0.57,0.08,0.08,10^9/L,0,0.57,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
20 15,CDISCPIL01,LB,CDISCO01,15,GOT,"Gamma Glutamyl Transferase",CHEMISTRY,31,U/L,10,50,31,31,U/L,10,50,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
21 16,CDISCPIL01,LB,CDISCO01,16,GLUC,Glucose,CHEMISTRY,74,mg/dL,50,250,4.10774,4.10774,mmol/L,2.8,13.9,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
22 17,CDISCPIL01,LB,CDISCO01,17,HCT,Hematocrit,HMATOLOGY,46.0,%,37,51,0.46,0.46,0.37,0.51,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
23 18,CDISCPIL01,LB,CDISCO01,18,HGB,Hemoglobin,HMATOLOGY,14.9,g/dL,12.5,17.9,24694,9.24694,mmol/L,7.76,10.55,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
24 19,CDISCPIL01,LB,CDISCO01,19,K,Potassium,CHEMISTRY,4.3,mEq/L,3.4,5.4,4.3,4.3,mmol/L,3.4,5.4,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
25 20,CDISCPIL01,LB,CDISCO01,20,KETONES,Ketones,URINALYSIS,0,,,,,0,0,,,,,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
26 21,CDISCPIL01,LB,CDISCO01,21,LYM,Lymphocytes,HMATOLOGY,1.20,10^9/L,0.8,3,1.2,1.2,10^9/L,0.8,3,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
27 22,CDISCPIL01,LB,CDISCO01,22,MCH,"Ery. Mean Corpuscular Hemoglobin",HEMATOLOGY,30,pg,26,34,1.8618,1.8618,fmol,1.6,2.1,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
28 23,CDISCPIL01,LB,CDISCO01,23,MCHC,"Ery. Mean Corpuscular HGB Concentration",HEMATOLOGY,33,g/dL,31,38,20.4798,20.4798,mmol/L,19.24,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
29 24,CDISCPIL01,LB,CDISCO01,24,MCV,"Ery. Mean Corpuscular Volume",HEMATOLOGY,92,fL,80,100,92,92,fL,80,100,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
30 25,CDISCPIL01,LB,CDISCO01,25,MONO,Monocytes,HMATOLOGY,0.38,10^9/L,0.12,0.52,0.38,0.38,10^9/L,0.12,0.52,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
31 26,CDISCPIL01,LB,CDISCO01,26,SODIUM,Sodium,CHEMISTRY,139,mEq/L,135,145,139,139,mmol/L,135,145,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
32 27,CDISCPIL01,LB,CDISCO01,27,PH,pH,URINALYSIS,5.5,5.8,5.5,5.8,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
33 28,CDISCPIL01,LB,CDISCO01,28,PHOS,Phosphate,CHEMISTRY,3.4,mg/dL,2.2,5.1,1.09786,1.09786,mmol/L,0.71,1.65,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
34 29,CDISCPIL01,LB,CDISCO01,29,PLAT,Platelets,HMATOLOGY,150,10^9/L,130,394,150,150,10^9/L,130,394,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
35 30,CDISCPIL01,LB,CDISCO01,30,PROT,Protein,CHEMISTRY,6.7,g/dL,6.8,67,67,g/L,60,80,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
36 31,CDISCPIL01,LB,CDISCO01,31,RBC,Erythrocytes,HMATOLOGY,5.00,10^12/L,4.5,5.5,10^12/L,4.5,5.5,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
37 32,CDISCPIL01,LB,CDISCO01,32,SGRAV,"Specific Gravity",URINALYSIS,1.017,1.006,1.03,1.017,1.017,1.006,1.03,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
38 33,CDISCPIL01,LB,CDISCO01,33,TSH,Thyrotropin,OTHER,2.63,mIU/L,0.32,5.2,2.63,2.63,mIU/L,0.32,5.2,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
39 34,CDISCPIL01,LB,CDISCO01,34,URATE,Urate,CHEMISTRY,4.9,mg/dL,2.5,7.5,291.452,291.452,umol/L,149,446,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
40 35,CDISCPIL01,LB,CDISCO01,35,UROBL,Urobilinogen,URINALYSIS,0,,,,,0,0,,,,,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
41 36,CDISCPIL01,LB,CDISCO01,36,VITB12,"Vitamin B12",OTHER,641,ng/L,200,900,472.9298,472.9298,pmol/L,148,664,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
42 37,CDISCPIL01,LB,CDISCO01,37,WBC,Leukocytes,HMATOLOGY,4.99,10^9/L,3.8,10.7,4.99,4.99,10^9/L,3.8,10.7,NORMAL,Y,1,"SCREENING 1",SCREENING,2012-11-23T11:20,-7
43 38,CDISCPIL01,LB,CDISCO01,38,ALB,Albumin,CHEMISTRY,3.6,g/dL,3.5,4.6,36,36,g/L,35,46,NORMAL,,4,"WEEK 2",TREATMENT,2012-12-13T14:05,14
```

Basic validation

During loading, one will have noticed two "progress bars", one showing the progress of the loading of the data, and the other one showing the progress of the basic validation that is always performed. This primary validation of the data is really very basic, e.g. checking whether "required" variables are populated. For example, when the column AEDECOD (Dictionary-Derived Term for the adverse event), which is a "required" variable, is not populated, the cells are colored red, and a tooltip is provided displaying the cause of the

³ The safest is always to use the vertical bar ("pipe" character) as the field delimiter, as it is a character that seldomly appears in the table values, but it might be that the receiving application, e.g. a worksheet, is not capable to accept that.

issue:

	AELLT	AELLTCD	AEDECOD	AEPTCD	AEHLT	AEHLTCD	AEHLGT

Further validation can be done by setting some options, by clicking the "Options" button in the main window, and by using the CDISC CORE (CDISC Open Rules Engine) features⁴ of the Smart Submission Dataset Viewer.

Search and View

In the "tables view", there are two other menus that we did not explain so far, but are easy to understand. When using the menu "View", one can choose between:

- CDISC properties:
- Show corresponding DM record (Ctrl-D): this was already explained before
- Metadata for item
- Annotated CRF for item
- Show last selected table (Ctrl-B): allows to "toggle" between tables
- LOINC => ... : this will be explained separately later

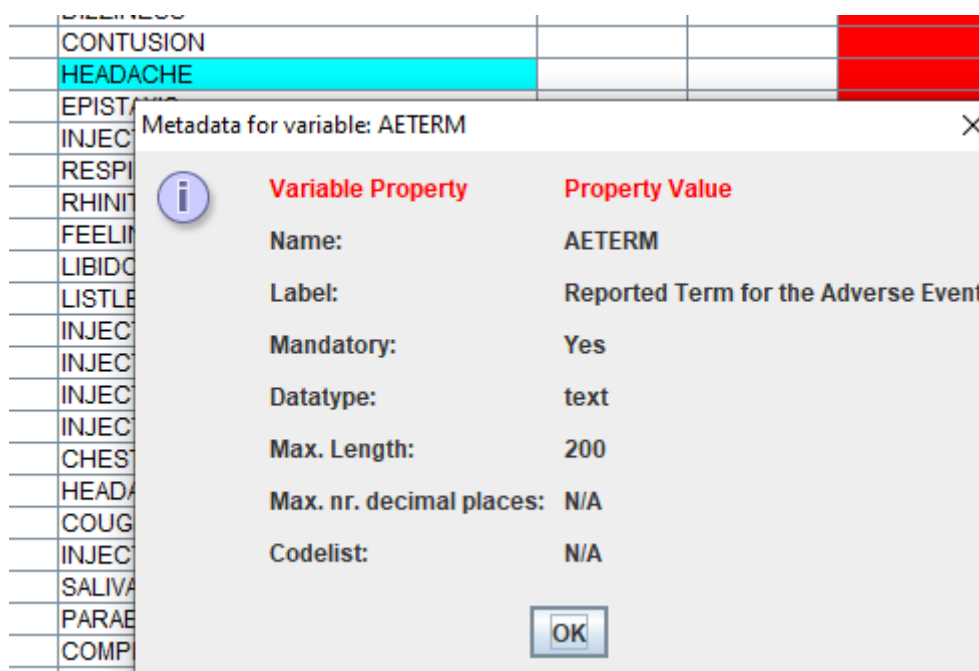
Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18

File	Tools	View	Search	Options
TA	TV	CDISC Properties	SUPPDM	SUPPEC
Rec.#		Show corresponding DM record Ctrl-D	SUBJID	AESEQ
1		Metadata for item Ctrl-M	BC001	1
2		Annotated CRF for item	BC001	2
3		Show last selected table Ctrl-B	BC002	1
4		LOINC	BC002	2
5			BC002	3
6			CDISCPLOT01	AE
			CDISC002	4

View - CDISC properties: displays which IG was used and which version(s), and which version(s) of the CDISC controlled terminology were used. This information is retrieved from the define.xml file.

View - Metadata for item: when a single cell has been selected, and this menu is used, a dialog with metadata information is displayed. For example when "headache" in the AETERM was selected, the resulting information is:

⁴ At the moment of writing (December 2024), the CORE engine is being adapted to accept Dataset-JSON 1.1 as being the input format. CORE was already able to work with Dataset-JSON 1.0, but as we are now moving to Dataset-JSON, some adaptations are necessary.



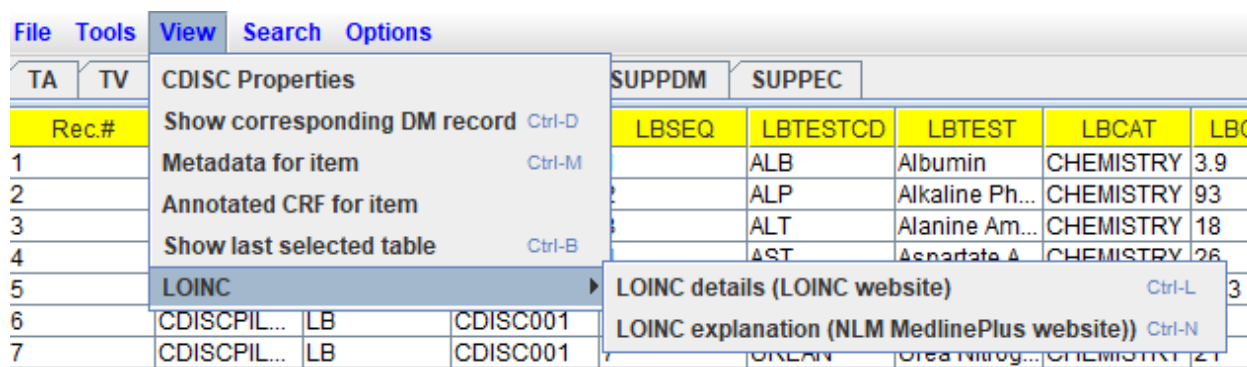
Also this information is retrieved from the define.xml

View - Annotated CRF for item: The goal of this feature is that when a single cell is selected, and the the link to the annotated CRF is present in the define.xml, the annotated CRF is opened in the default PDF viewer on the correct page, or, when there are several pages for the variable, on the first of these.

This feature has not been implemented yet - it is planned for 2025.

The next one "View - LOINC" is a bit special, but important due to the growing importance of LOINC as the only real identifier of the test, not only for lab tests, but also for vital signs, microbiology, virology, questionnaires, ECG, etc.⁵.

When selecting the menu "View - LOINC", we get additional possibilities:



For example, when having selected the code "2093-3" in the LBLOINC column:

⁵ CDISC controlled terminology, as a "post-coordinated" system is not capable to uniquely identify tests, also not when combining values from variables such as LBTESTCD, LBSPEC, LBMETHOD, ... LOINC, as a "pre-coordinated" system makes this "uniqueness" possible. This is also the reason why LOINC is heavily used in healthcare, and is mandated by law in many countries (the number growing) for ordering lab tests and reporting lab results.

File Tools View Search Options												
DM	AE	LBBL	LBCH	SU	VS	SUPPSU						
Rec.#	STUD...	DOMA...	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBLOINC	LBORRESU	LBORNRL0	LBOR
1	CES	LB	001	9	ALB	Albumin	CHEMISTRY	3.9	1751-7	g/dL		
2	CES	LB	001	10	CHOL	Cholesterol	CHEMISTRY	254	2093-3	mg/dL		
3	CES	LB	001	11	BILI	Bilirubin	CHEMISTRY	0.5	1975-2	mg/dL		
4	CES	LB	001	12	BASO	Basophils	CHEMISTRY	0.03	704-7	10 ⁹ /L		
5	CES	LB	001	13	ALB	Albumin	CHEMISTRY	4.2	1751-7	g/dL		
6	CES	LB	001	14	CHOL	Cholesterol	CHEMISTRY	239	2093-3	mg/dL		
7	CES	LB	001	15	BILI	Bilirubin	CHEMISTRY	0.4	1975-2	mg/dL		

and using the menu "View - LOINC - LOINC details", this will trigger a process that opens the LOINC website page for this specific LOINC code in the user's default browser, i.e.:

← → ↺

https://loinc.org/2093-3/

110%

VERSION 2.78

LOINC CODE

2093-3

LONG COMMON NAME

Cholesterol [Mass/volume] in Serum or Plasma

LOINC STATUS

Active

Part Description

LP15493-7 Cholesterol

Cholesterol is a lipidic, waxy alcohol found in the cell membranes and transported in the blood plasma of all animals. It is an essential component of mammalian cell membranes where it establishes proper membrane permeability and fluidity. Cholesterol is the principal sterol synthesized by animals, but small quantities are synthesized in other eukaryotes, such as plants and fungi. It is almost completely absent among prokaryotes, which include bacteria. Cholesterol is classified as a sterol.

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Source: Wikipedia, [Cholesterol](#)

Fully-Specified Name

Component	Cholesterol
Property	MCnc
Time	Pt
System	Ser/Plas
Scale	Qn
Method	

Additional Names

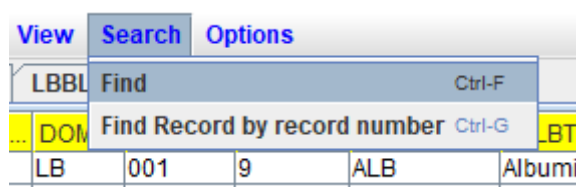
Short Name	Cholest SerPl-mCnc
Display Name	Cholesterol [Mass/Vol]
Source Name	Cholesterol Blood

similarly, when the menu "View - LOINC - LOINC explanation" is used, the page for that code from the NLM (National Library of Medicine) is opened in the user's default browser, i.e.:

The screenshot shows the MedlinePlus website for Cholesterol. The header includes the MedlinePlus logo, a search bar, and navigation links. The main content area has a breadcrumb trail: Home → Health Topics → Cholesterol. The title is "Cholesterol" with a subtitle "Also called: Hypercholesterolemia, Hyperlipidemia, Hyperlipoproteinemia". Below this is a "On this page" section with links to Basics, Learn More, and See, Play and Learn. The Basics section includes links to Summary, Start Here, Diagnosis and Tests, and Treatments and Therapies. The Learn More section includes links to Related Issues, Specifics, and Genetics. The See, Play and Learn section includes links to Videos and Tutorials and Test Your Knowledge. The Research section includes links to Statistics and Research, Clinical Trials, and Journal Articles. The Resources section includes a link to Find an Expert. The For You section includes links to Children and Patient Handouts. To the right of the main content is an illustration of a blood vessel with cholesterol plaques. Below the illustration is a "MEDICAL ENCYCLOPEDIA" sidebar with links to Apolipoprotein B100, Apolipoprotein CII, Bile acid sequestrants for cholesterol, Cholesterol - drug treatment, Cholesterol - what to ask your doctor, Cholesterol and lifestyle, and Cholesterol testing and results.

IMPORTANT REMARK: Essentially, this is an implementation of RWS (RESTful Web Services). The potential for such features is enormous! Using the mechanism, just by selecting the LOINC code, it would become possible to perform things such as literature searches, connect to specialist technical literature and other documentation, and also connect directly connect to specialist (in medicine or in clinical research) AI systems. Implementing this in the Smart Submission Dataset Viewer will often only require to add a few lines in the source code ... the only limitation being ... lack of creativity.

Another menu is "Search", allowing to quickly find a word, part of a word or value in the table, or to quickly jump to a specific record (by record number) in the selected table:



For the former (Search - Find), a separate dialog is then popping up:

The screenshot shows the 'Search' dialog box in the Smart Submission Dataset Viewer. The background is a data table with columns: Rec.#, STUD., DOMA., USUBJID, LBSEQ, LBTESTCD, LBTEST, LBCAT, LBORRES, LBLOINC, LBORRESU, LBORNRL, LBORNRI, and LBSTRESC. The first row of data shows: 1, CES, LB, 001, 9, ALB, Albumin, CHEMISTRY, 3.9, 1751-7, g/dL, and 14160.68. The search dialog box has a search bar with 'basophil' entered, and buttons for 'Search', 'Find Next', 'Match case', 'Whole words only', and 'OK'.

Rec.#	STUD.	DOMA.	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBLOINC	LBORRESU	LBORNRL	LBORNRI	LBSTRESC
1	CES	LB	001	9	ALB	Albumin	CHEMISTRY	3.9	1751-7	g/dL			14160.68

which is pretty self-explaining.

Filtering before loading

When one has large datasets (thousand or even millions of records), it is very hard for reviewers to keep oversight. Of course one can filter after the dataset has been loaded, but in such cases, classic viewers such as the "SAS Universal Viewer" need to do "paging" in order to save memory. With "paging", any filters are only applied to a single page, which can easily lead to information loss. For example, when a reviewer only wants see the Albumin lab test results of a very large dataset, with the "SAS Universal Viewer" he/she can apply the filter on the first loaded page, and needs to repeat the whole process when wanting to see the Albumin values for subjects on other pages.

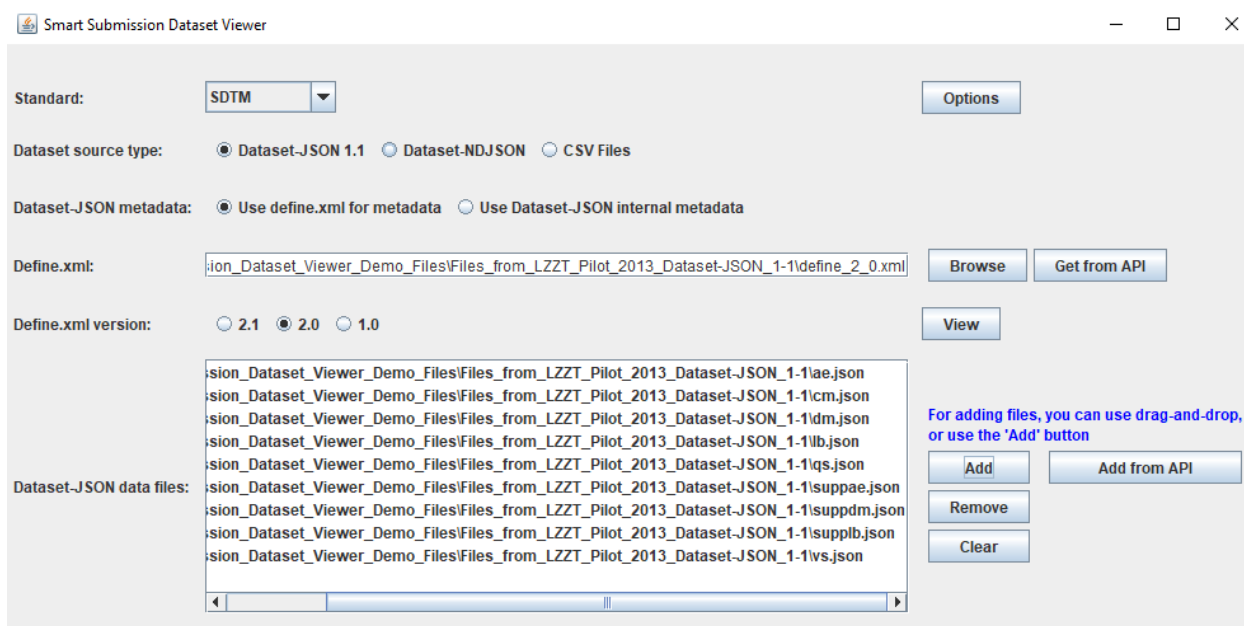
The Smart Submission Dataset Viewer uses a smarter method. Before loading, one can already apply a filter, and only those records that pass the filter are really loaded. This not only saves a lot of memory, but also ensures that all the records that pass the filter will be displayed.

In the Smart Submission Dataset Viewer, filtering is usually based on the --TESTCD or --CAT ("test code" and "category") variables for "Findings" datasets. In the future, we also want to apply the same principle for "Events" datasets (e.g. based on --DECOD), and for "Intervention" datasets, e.g. based on --TRT or --CAT or --INDC. We need input from the users about which variables are the most useful ones to do pre-filtering for these classes.

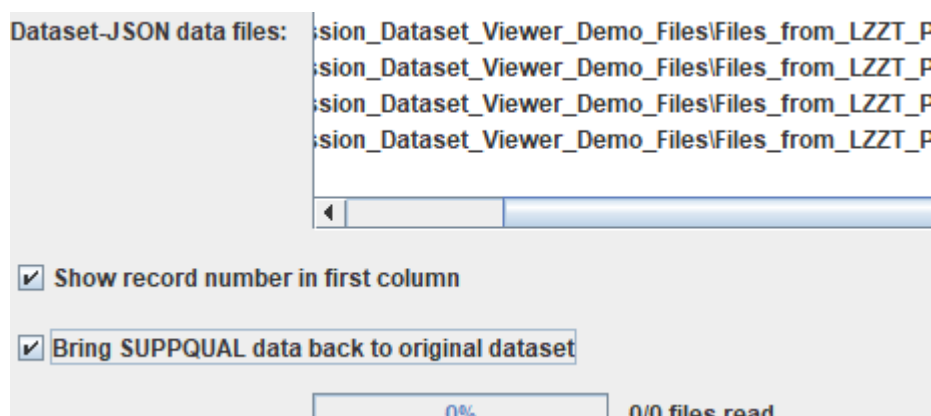
To find out which e.g. test codes or categories are available, a define.xml must be present and a codelist must be attached to the given variable. This is usually already the case for the "Findings" datasets.

The system always offer the user to do pre-filtering on specific datasets, when there is a codelist available from the define.xml, and urge the user to do pre-filtering based on the file sizes, the default being 20MB (this threshold can be changed by the user, see later). For example, in our case, the LB.json dataset has a size of 0.7MB (which is much less than for the SAS-XPT corresponding dataset, which has 2.7MB), but still has almost 3500 records. The LB dataset from the LZTZ-pilot is 10.4MB in size (the corresponding LB.xpt is 66MB), and has almost 60,000 records, which means that in such a case, pre-filtering may very well make sense, as one cannot imagine how a reviewer can handle such an amount of records just by visual inspection.

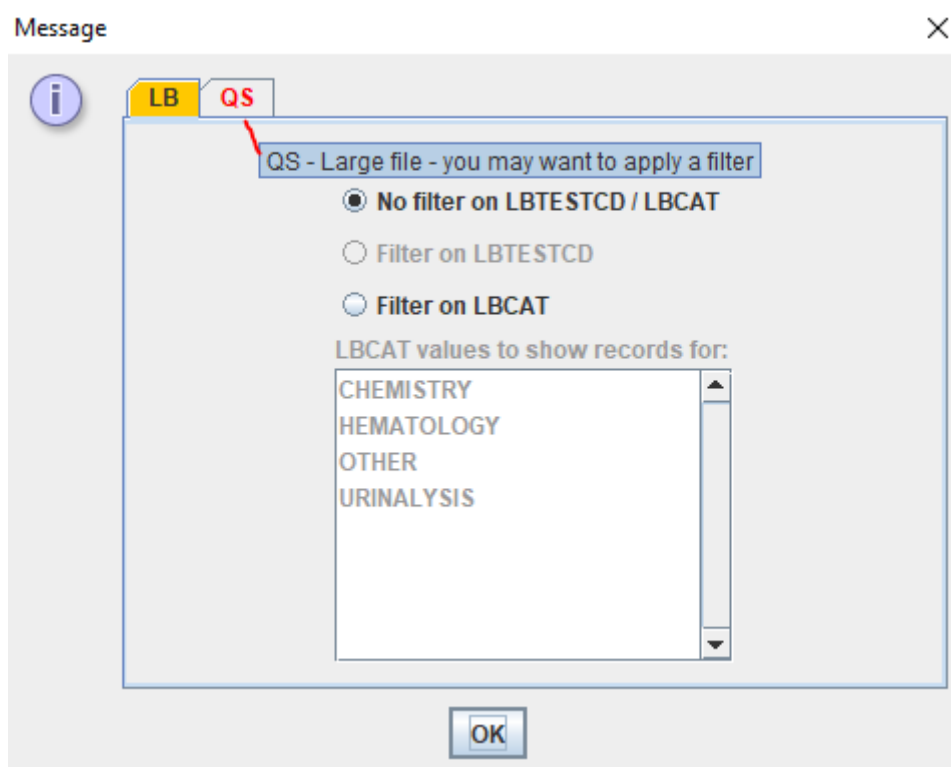
For demonstrating the pre-filtering, we take the SDTM Dataset-JSON files of the LZTZ pilot, and e.g. select:



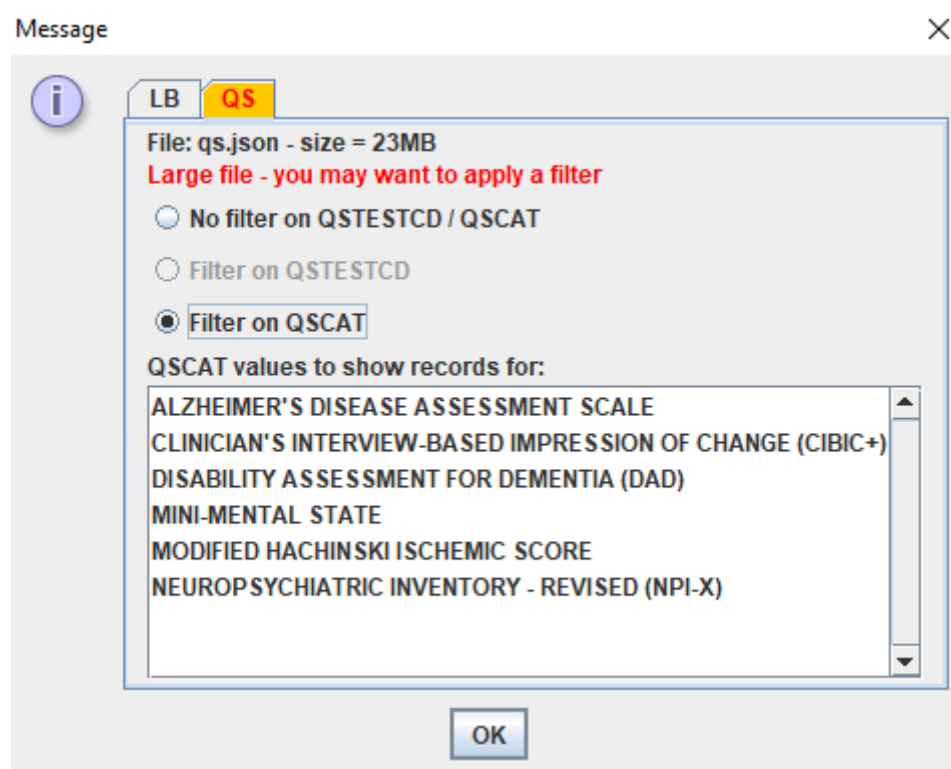
the QS dataset having the largest file size (23MB) followed by the LB dataset (10MB). We also load the SUPPLB dataset (8MB) and the SUPPAE and SUPPDM datasets, and ask the system to "Bring SUPPQUAL data back":



When then clicking "Start", first the define.xml is loaded, and then the system shows us the following dialog:



The system found codelists for LBCAT in the define.xml, so offers to filter on it, and strongly suggests to do pre-filtering for QS, for which it presents:



as it found a codelist for QSCAT, but none for QSTESTCD.

When we leave everything "as is", i.e. do not any pre-filtering, it takes 18 minutes to load, especially "recombining" SUPPLB with LB taking a lot of time.

Anyway, visually inspecting 60,000 LB records doesn't make sense anyway isn't it?

For LB, we pre-filter on "hematology" only, and for QS on "Mini-mental state":

and start loading again. Loading the selection now takes 7 minutes, with the result for LB being:

31	REC#	STUDYID	DOMAIN	USURIO	LRSEQ	LRTESTCD	LRTEST	LEACAT	LBORRES	LBORRE	LB	LB1	LB2	LBST	LBST1	LBST2	LBST3	LBST4	LBST5	LBST6	LBST7	LBST8	LBST9	LBST10	LBST11	LBST12	LBST13	LBST14	LBST15	LBST16	LBST17	LBST18	LBST19	LBST20	LBST21	LBST22	LBST23	LBST24	LBST25	LBST26	LBST27	LBST28	LBST29	LBST30	LBST31	LBST32	LBST33	LBST34	LBST35	LBST36	LBST37	LBST38	LBST39	LBST40	LBST41	LBST42	LBST43	LBST44	LBST45	LBST46	LBST47	LBST48	LBST49	LBST50	LBST51	LBST52	LBST53	LBST54	LBST55	LBST56	LBST57	LBST58	LBST59	LBST60	LBST61	LBST62	LBST63	LBST64	LBST65	LBST66	LBST67	LBST68	LBST69	LBST70	LBST71	LBST72	LBST73	LBST74	LBST75	LBST76	LBST77	LBST78	LBST79	LBST80	LBST81	LBST82	LBST83	LBST84	LBST85	LBST86	LBST87	LBST88	LBST89	LBST90	LBST91	LBST92	LBST93	LBST94	LBST95	LBST96	LBST97	LBST98	LBST99	LBST100	LBST101	LBST102	LBST103	LBST104	LBST105	LBST106	LBST107	LBST108	LBST109	LBST110	LBST111	LBST112	LBST113	LBST114	LBST115	LBST116	LBST117	LBST118	LBST119	LBST120	LBST121	LBST122	LBST123	LBST124	LBST125	LBST126	LBST127	LBST128	LBST129	LBST130	LBST131	LBST132	LBST133	LBST134	LBST135	LBST136	LBST137	LBST138	LBST139	LBST140	LBST141	LBST142	LBST143	LBST144	LBST145	LBST146	LBST147	LBST148	LBST149	LBST150	LBST151	LBST152	LBST153	LBST154	LBST155	LBST156	LBST157	LBST158	LBST159	LBST160	LBST161	LBST162	LBST163	LBST164	LBST165	LBST166	LBST167	LBST168	LBST169	LBST170	LBST171	LBST172	LBST173	LBST174	LBST175	LBST176	LBST177	LBST178	LBST179	LBST180	LBST181	LBST182	LBST183	LBST184	LBST185	LBST186	LBST187	LBST188	LBST189	LBST190	LBST191	LBST192	LBST193	LBST194	LBST195	LBST196	LBST197	LBST198	LBST199	LBST200	LBST201	LBST202	LBST203	LBST204	LBST205	LBST206	LBST207	LBST208	LBST209	LBST210	LBST211	LBST212	LBST213	LBST214	LBST215	LBST216	LBST217	LBST218	LBST219	LBST220	LBST221	LBST222	LBST223	LBST224	LBST225	LBST226	LBST227	LBST228	LBST229	LBST230	LBST231	LBST232	LBST233	LBST234	LBST235	LBST236	LBST237	LBST238	LBST239	LBST240	LBST241	LBST242	LBST243	LBST244	LBST245	LBST246	LBST247	LBST248	LBST249	LBST250	LBST251	LBST252	LBST253	LBST254	LBST255	LBST256	LBST257	LBST258	LBST259	LBST260	LBST261	LBST262	LBST263	LBST264	LBST265	LBST266	LBST267	LBST268	LBST269	LBST270	LBST271	LBST272	LBST273	LBST274	LBST275	LBST276	LBST277	LBST278	LBST279	LBST280	LBST281	LBST282	LBST283	LBST284	LBST285	LBST286	LBST287	LBST288	LBST289	LBST290	LBST291	LBST292	LBST293	LBST294	LBST295	LBST296	LBST297	LBST298	LBST299	LBST300	LBST301	LBST302	LBST303	LBST304	LBST305	LBST306	LBST307	LBST308	LBST309	LBST310	LBST311	LBST312	LBST313	LBST314	LBST315	LBST316	LBST317	LBST318	LBST319	LBST320	LBST321	LBST322	LBST323	LBST324	LBST325	LBST326	LBST327	LBST328	LBST329	LBST330	LBST331	LBST332	LBST333	LBST334	LBST335	LBST336	LBST337	LBST338	LBST339	LBST340	LBST341	LBST342	LBST343	LBST344	LBST345	LBST346	LBST347	LBST348	LBST349	LBST350	LBST351	LBST352	LBST353	LBST354	LBST355	LBST356	LBST357	LBST358	LBST359	LBST360	LBST361	LBST362	LBST363	LBST364	LBST365	LBST366	LBST367	LBST368	LBST369	LBST370	LBST371	LBST372	LBST373	LBST374	LBST375	LBST376	LBST377	LBST378	LBST379	LBST380	LBST381	LBST382	LBST383	LBST384	LBST385	LBST386	LBST387	LBST388	LBST389	LBST390	LBST391	LBST392	LBST393	LBST394	LBST395	LBST396	LBST397	LBST398	LBST399	LBST400	LBST401	LBST402	LBST403	LBST404	LBST405	LBST406	LBST407	LBST408	LBST409	LBST410	LBST411	LBST412	LBST413	LBST414	LBST415	LBST416	LBST417	LBST418	LBST419	LBST420	LBST421	LBST422	LBST423	LBST424	LBST425	LBST426	LBST427	LBST428	LBST429	LBST430	LBST431	LBST432	LBST433	LBST434	LBST435	LBST436	LBST437	LBST438	LBST439	LBST440	LBST441	LBST442	LBST443	LBST444	LBST445	LBST446	LBST447	LBST448	LBST449	LBST450	LBST451	LBST452	LBST453	LBST454	LBST455	LBST456	LBST457	LBST458	LBST459	LBST460	LBST461	LBST462	LBST463	LBST464	LBST465	LBST466	LBST467	LBST468	LBST469	LBST470	LBST471	LBST472	LBST473	LBST474	LBST475	LBST476	LBST477	LBST478	LBST479	LBST480	LBST481	LBST482	LBST483	LBST484	LBST485	LBST486	LBST487	LBST488	LBST489	LBST490	LBST491	LBST492	LBST493	LBST494	LBST495	LBST496	LBST497	LBST498	LBST499	LBST500	LBST501	LBST502	LBST503	LBST504	LBST505	LBST506	LBST507	LBST508	LBST509	LBST510	LBST511	LBST512	LBST513	LBST514	LBST515	LBST516	LBST517	LBST518	LBST519	LBST520	LBST521	LBST522	LBST523	LBST524	LBST525	LBST526	LBST527	LBST528	LBST529	LBST530	LBST531	LBST532	LBST533	LBST534	LBST535	LBST536	LBST537	LBST538	LBST539	LBST540	LBST541	LBST542	LBST543	LBST544	LBST545	LBST546	LBST547	LBST548	LBST549	LBST550	LBST551	LBST552	LBST553	LBST554	LBST555	LBST556	LBST557	LBST558	LBST559	LBST560	LBST561	LBST562	LBST563	LBST564	LBST565	LBST566	LBST567	LBST568	LBST569	LBST570	LBST571	LBST572	LBST573	LBST574	LBST575	LBST576	LBST577	LBST578	LBST579	LBST580	LBST581	LBST582	LBST583	LBST584	LBST585	LBST586	LBST587	LBST588	LBST589	LBST590	LBST591	LBST592	LBST593	LBST594	LBST595	LBST596	LBST597	LBST598	LBST599	LBST600	LBST601	LBST602	LBST603	LBST604	LBST605	LBST606	LBST607	LBST608	LBST609	LBST610	LBST611	LBST612	LBST613	LBST614	LBST615	LBST616	LBST617	LBST618	LBST619	LBST620	LBST621	LBST622	LBST623	LBST624	LBST625	LBST626	LBST627	LB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31	CDISCPL001	LB	01-701-10514	ANISO	Anisocaps	HEMATOLOGY	1		NO UNITS			1	1																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								</																																																																																																																																																																																																																																																																																																																																																																																																																																																	

For QS, we find:

Rec#	STUDYID	DOMAIN	USUBJID	OSSEQ	OSTESTCD	OSTEST	OSCAT	OSSCAT	OSOR	OSORR	OSSTRESO	OSSTRESN	VISITNUM	VISIT	VISITD	OSSTRESU	OSBLFL	OSDR
116395	CDISCIPL01	QS	01-718-1139	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
116396	CDISCIPL01	QS	01-718-1139	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	6	6	6	6	1	SCREENIN	-7			
117040	CDISCIPL01	QS	01-718-1150	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	3	3	3	3	1	SCREENIN	-7			
117041	CDISCIPL01	QS	01-718-1150	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	5	5	5	5	1	SCREENIN	-7			
117042	CDISCIPL01	QS	01-718-1150	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	3	3	3	3	1	SCREENIN	-7			
117043	CDISCIPL01	QS	01-718-1150	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	4	4	4	4	1	SCREENIN	-7			
117044	CDISCIPL01	QS	01-718-1150	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
117045	CDISCIPL01	QS	01-718-1150	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	7	7	7	7	1	SCREENIN	-7			
117573	CDISCIPL01	QS	01-718-1170	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	1	1	1	1	1	SCREENIN	-7			
117574	CDISCIPL01	QS	01-718-1170	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	3	3	3	3	1	SCREENIN	-7			
117575	CDISCIPL01	QS	01-718-1170	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	3	3	3	3	1	SCREENIN	-7			
117576	CDISCIPL01	QS	01-718-1170	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	5	5	5	5	1	SCREENIN	-7			
117577	CDISCIPL01	QS	01-718-1170	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
117578	CDISCIPL01	QS	01-718-1170	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	7	7	7	7	1	SCREENIN	-7			
117957	CDISCIPL01	QS	01-718-1172	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
117958	CDISCIPL01	QS	01-718-1172	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
117959	CDISCIPL01	QS	01-718-1172	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	0	0	0	0	1	SCREENIN	-7			
117960	CDISCIPL01	QS	01-718-1172	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	1	1	1	1	1	SCREENIN	-7			
117961	CDISCIPL01	QS	01-718-1172	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	3	3	3	3	1	SCREENIN	-7			
117962	CDISCIPL01	QS	01-718-1172	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	6	6	6	6	1	SCREENIN	-7			
118470	CDISCIPL01	QS	01-718-1250	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	5	5	5	5	1	SCREENIN	-7			
118471	CDISCIPL01	QS	01-718-1250	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	1	1	1	1	1	SCREENIN	-7			
118472	CDISCIPL01	QS	01-718-1250	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	3	3	3	3	1	SCREENIN	-7			
118473	CDISCIPL01	QS	01-718-1250	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	5	5	5	5	1	SCREENIN	-7			
118474	CDISCIPL01	QS	01-718-1250	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
118475	CDISCIPL01	QS	01-718-1250	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	4	4	4	4	1	SCREENIN	-7			
119058	CDISCIPL01	QS	01-718-1254	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	1	1	1	1	1	SCREENIN	-7			
119059	CDISCIPL01	QS	01-718-1254	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	2	2	2	2	1	SCREENIN	-7			
119060	CDISCIPL01	QS	01-718-1254	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	2	2	2	2	1	SCREENIN	-7			
119061	CDISCIPL01	QS	01-718-1254	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	5	5	5	5	1	SCREENIN	-7			
119062	CDISCIPL01	QS	01-718-1254	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
119063	CDISCIPL01	QS	01-718-1254	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	6	6	6	6	1	SCREENIN	-7			
119755	CDISCIPL01	QS	01-718-1328	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
119756	CDISCIPL01	QS	01-718-1328	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
119757	CDISCIPL01	QS	01-718-1328	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	1	1	1	1	1	SCREENIN	-7			
119758	CDISCIPL01	QS	01-718-1328	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	4	4	4	4	1	SCREENIN	-7			
119759	CDISCIPL01	QS	01-718-1328	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
119770	CDISCIPL01	QS	01-718-1328	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	8	8	8	8	1	SCREENIN	-7			
120269	CDISCIPL01	QS	01-718-1355	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
120270	CDISCIPL01	QS	01-718-1355	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	1	1	1	1	1	SCREENIN	-7			
120271	CDISCIPL01	QS	01-718-1355	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	3	3	3	3	1	SCREENIN	-7			
120272	CDISCIPL01	QS	01-718-1355	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	4	4	4	4	1	SCREENIN	-7			
120273	CDISCIPL01	QS	01-718-1355	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
120274	CDISCIPL01	QS	01-718-1355	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	8	8	8	8	1	SCREENIN	-7			
121053	CDISCIPL01	QS	01-718-1371	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	3	3	3	3	1	SCREENIN	-7			
121054	CDISCIPL01	QS	01-718-1371	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
121055	CDISCIPL01	QS	01-718-1371	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	3	3	3	3	1	SCREENIN	-7			
121056	CDISCIPL01	QS	01-718-1371	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	3	3	3	3	1	SCREENIN	-7			
121057	CDISCIPL01	QS	01-718-1371	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
121058	CDISCIPL01	QS	01-718-1371	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	7	7	7	7	1	SCREENIN	-7			
121508	CDISCIPL01	QS	01-718-1427	2001	MMITM01	WHAT IS THE (YEAR) (SEASON)	MIN-MENTAL STATE	ORIENTATI	0	0	0	0	1	SCREENIN	-7			
121509	CDISCIPL01	QS	01-718-1427	2002	MMITM02	WHERE ARE WE (STATE) (COU	MIN-MENTAL STATE	ORIENTATI	2	2	2	2	1	SCREENIN	-7			
121510	CDISCIPL01	QS	01-718-1427	2003	MMITM03	NAME 3 OBJECTS: 1 SECOND T	MIN-MENTAL STATE	REGISTRAT	3	3	3	3	1	SCREENIN	-7			
121511	CDISCIPL01	QS	01-718-1427	2004	MMITM04	SERIAL 7S: 1 POINT FOR EACH	MIN-MENTAL STATE	ATTENTION	5	5	5	5	1	SCREENIN	-7			
121512	CDISCIPL01	QS	01-718-1427	2005	MMITM05	ASK FOR THE 3 OBJECTS REP	MIN-MENTAL STATE	RECALL	0	0	0	0	1	SCREENIN	-7			
121513	CDISCIPL01	QS	01-718-1427	2006	MMITM06	NAME A PENCIL AND WATCH	MIN-MENTAL STATE	LANGUAGE	9	9	9	9	1	SCREENIN	-7			

Setting Viewer Options

In the main window, one also sees an "Options" button on the right-top side:

Smart Submission Dataset Viewer

Standard:

SDTM

Options

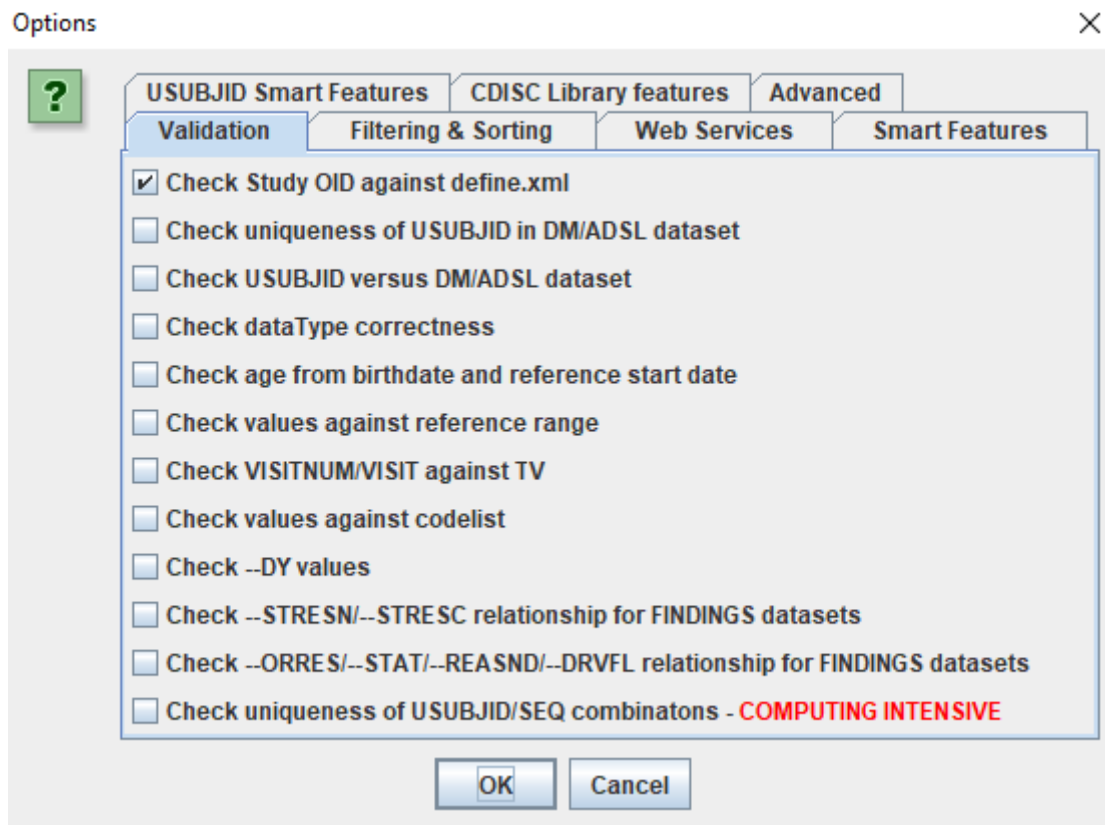
Dataset source type:
☒ Dataset-JSON 1.1
 ☐ Dataset-NDJSON
 ☐ CSV Files

Dataset-JSON metadata:
☒ Use define.xml for metadata
 ☐ Use Dataset-JSON internal metadata

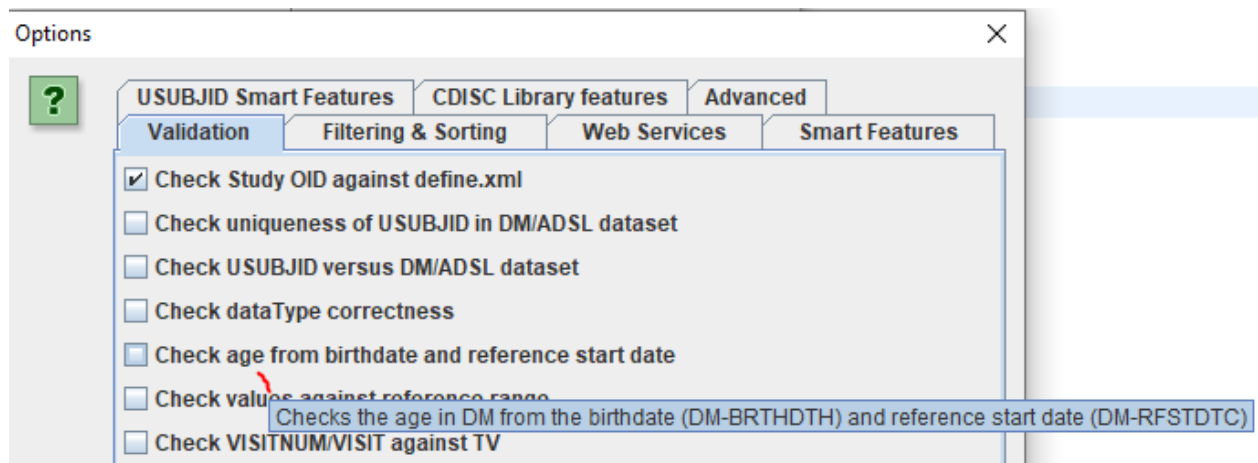
Define.xml:

Browse

When clicked, the following window with different tabs is shown:

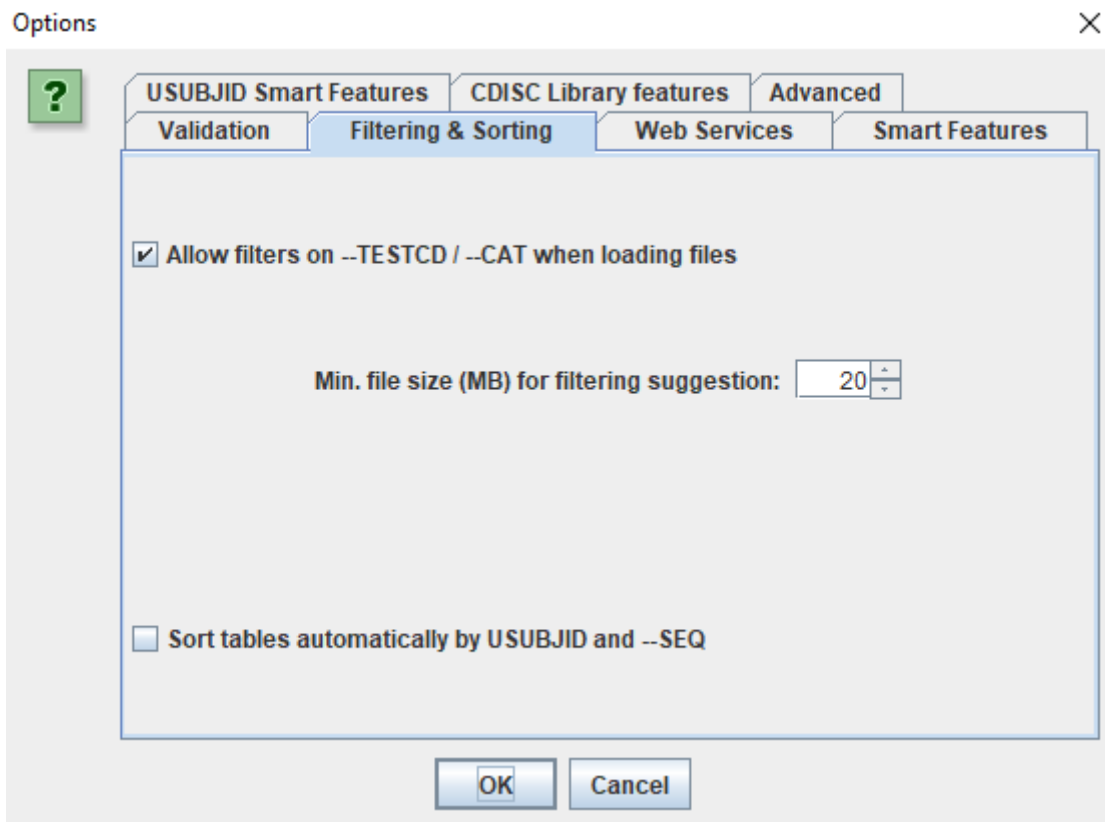


The options for the first tab "Validation" allows to switch on/off certain basic validation options. Most of them are obvious, but one can always hold the mouse over each of them to get more information. For example:



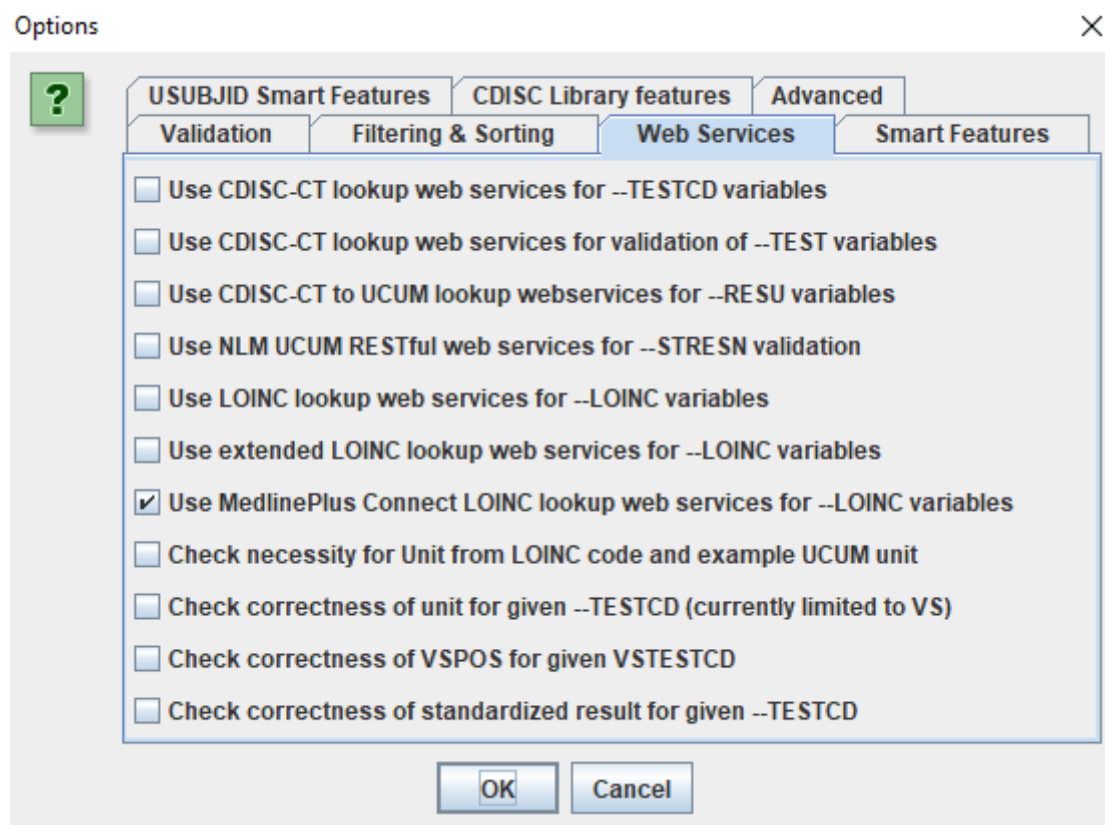
We will later, in the section "Validation" show how these can be used.

A second important tab is the "Filtering and Sorting" tab:

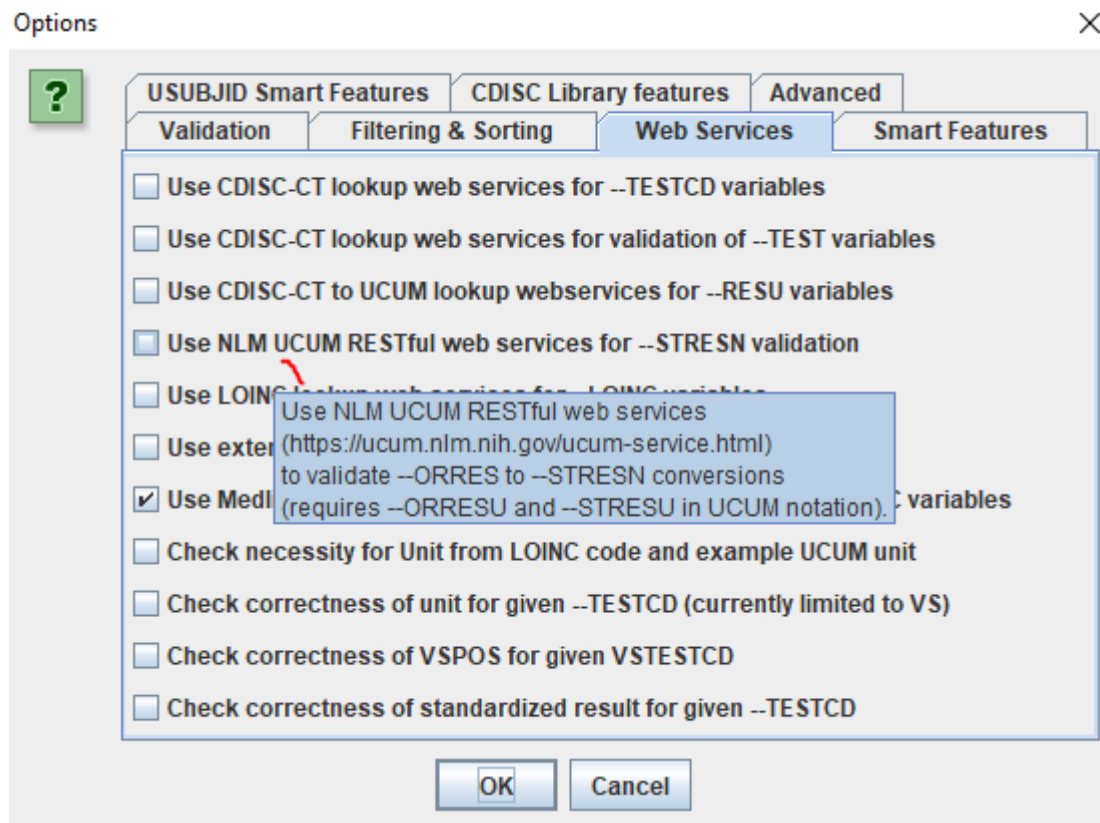


It allows the user to specify whether the system will propose to add "pre-loading filters" and if so, from what dataset size, the system will urge the user to apply a filter - see the section "Filtering before loading".

The next tab is about "Web Services":



The Smart Submission Dataset Viewer is unique in the ability to use (RESTful) web services to aid in validation. Also here, hovering the mouse over an item shows more details about the feature, e.g.:

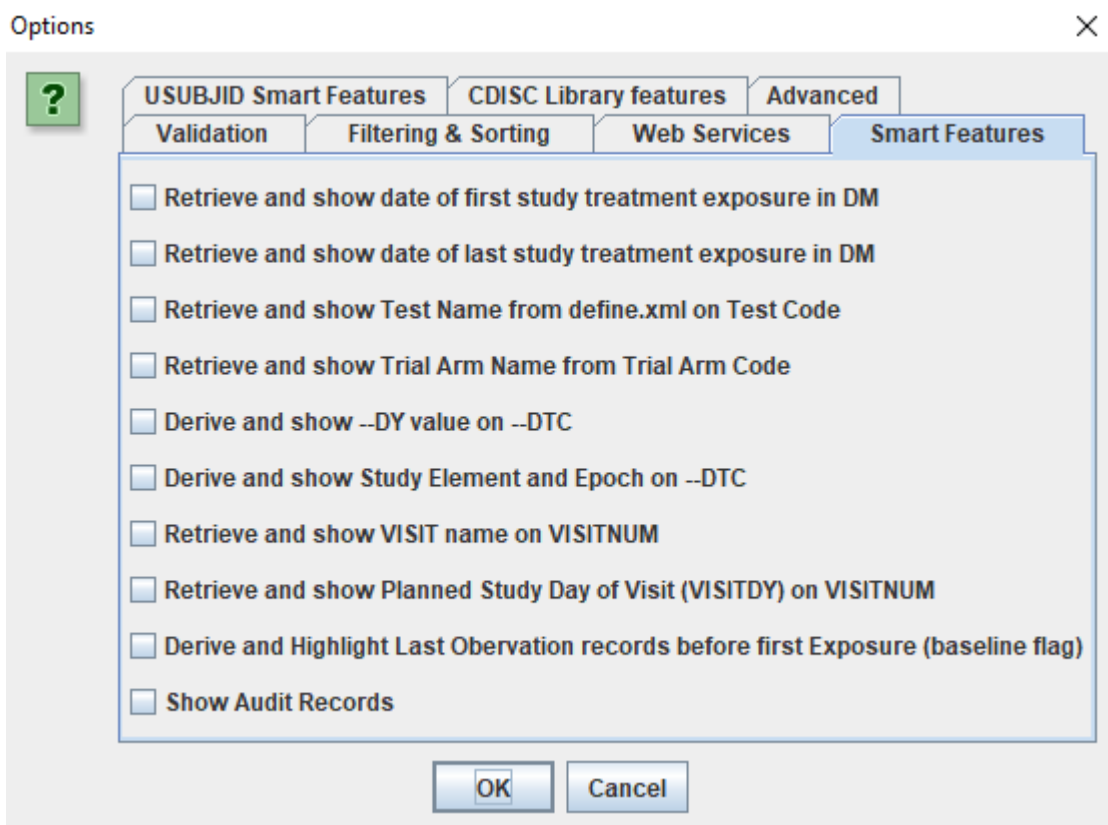


This feature allowing to use the NLM (National Library of Medicine) RESTful web services for automated validation whether the conversion the --ORRES values to the --STRESN values have been done correctly.

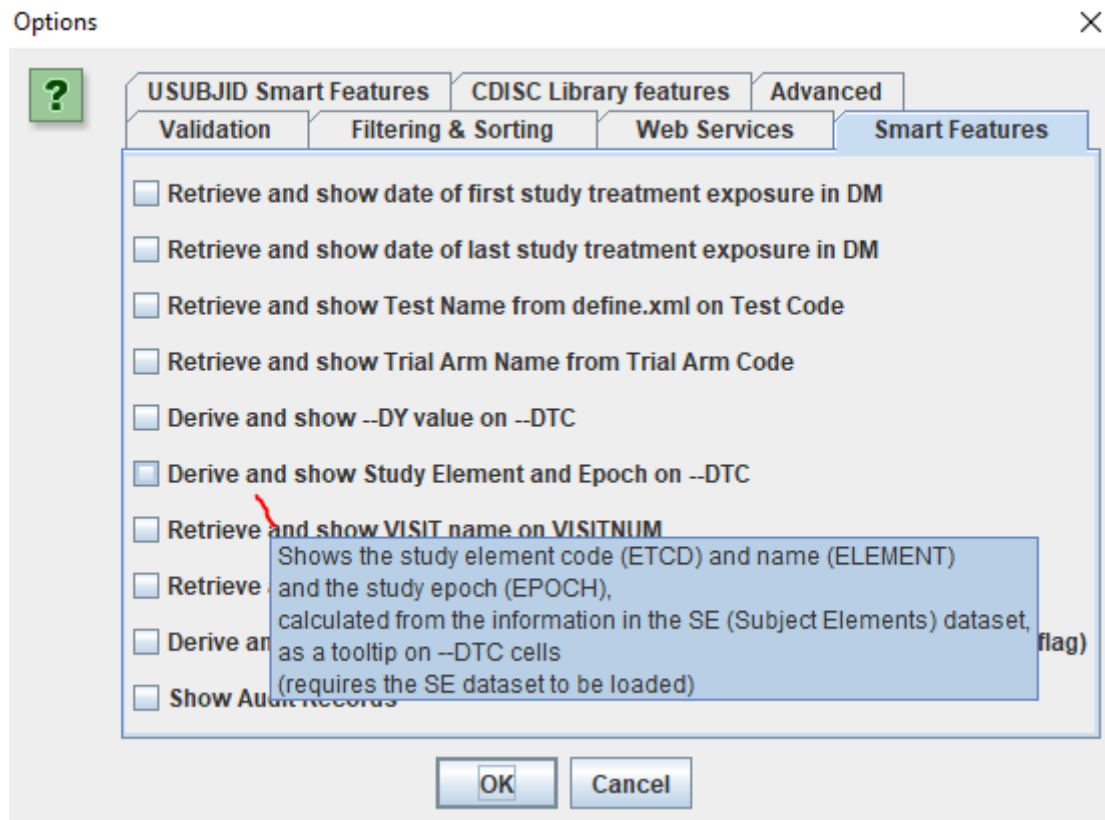
Some of these web service validation features even go far beyond what is available in CDISC CORE (see later) and especially what is offered by Pinnacle21 validation.

More explanation can be found in the separate document "[Using RESTful web services \(NLM, FDA, XML4Pharma\)](#)". Also this document will be updated in the near future.

The next tab is "Smart Features":



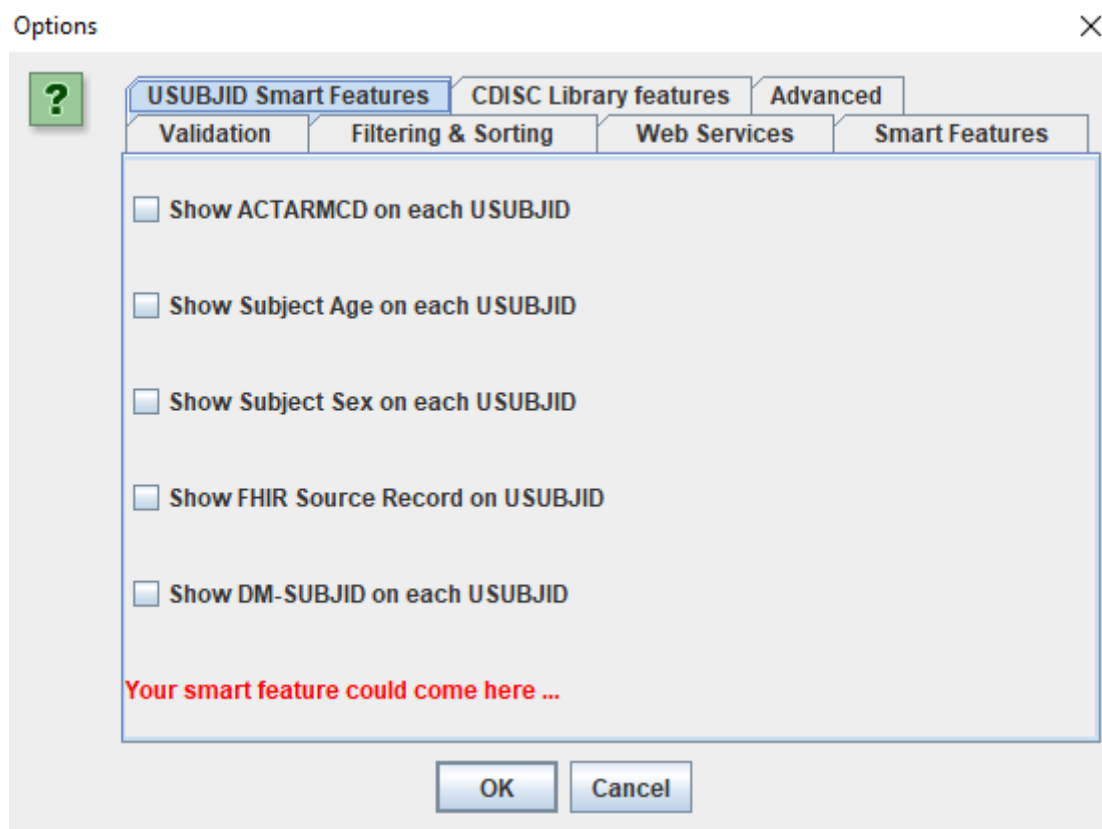
Also these are pretty self-explaining, with the possibility of obtaining additional information by hovering the mouse over an item, for example:



which, when checked, will show the value of EDTC and ELEMENT (study element code and name) as a

tooltip on each --DTC cell in each table, which can be very useful⁶. As one can expect, this requires the SE (Subject Elements) to have been loaded.

Furthermore, there is the tab "USUBJID Smart Features", which is mostly about getting information from the DM dataset (when loaded) in the tables for other datasets:



For example, when the checkboxes "Show Subject Sex on each USUBJID" and "Show ACTARMCD on each USUBJID" are checked, and one hovers the mouse over a "USUBJID" cell e.g. in the LB dataset, one obtains the information about sex and actual arm of that subject in the study. For example:

LB	01-716-1103	46	CHOL	Chole
LB	01-716-1103	81	CHOL	Chole
LB	01-716-1103	111	CHOL	Chole
LB	01-716-1103	01-716-1103 (USUBJID) ACTARMCD: Xan_Lo SEX: Male		Chole
LB	01-716-1103			Chole
LB	01-716-1103			Chole
LB	01-716-1103	236	CHOL	Chole

immediately showing that the subject is a male person and the actual arm was "Xanomelin low".

The same can of course be obtained by "toggling" between the current table and the DM table (using Ctrl-D and Ctrl-B), but just using hovering is of course faster.

As the Smart Submission Dataset Viewer is Open Source software (member of [COSA](#) - CDISC Open Source Alliance), additional "smart features" can always be added⁷ by users, the only limitation being lack of

⁶ This shows again that many "derived" variables in SDTM should not be in SDTM at all. They are only there as the reviewers at the regulatory authorities do not have access to modern viewers that understand CDISC submission standards. So they asked CDISC to add them in SDTM itself.

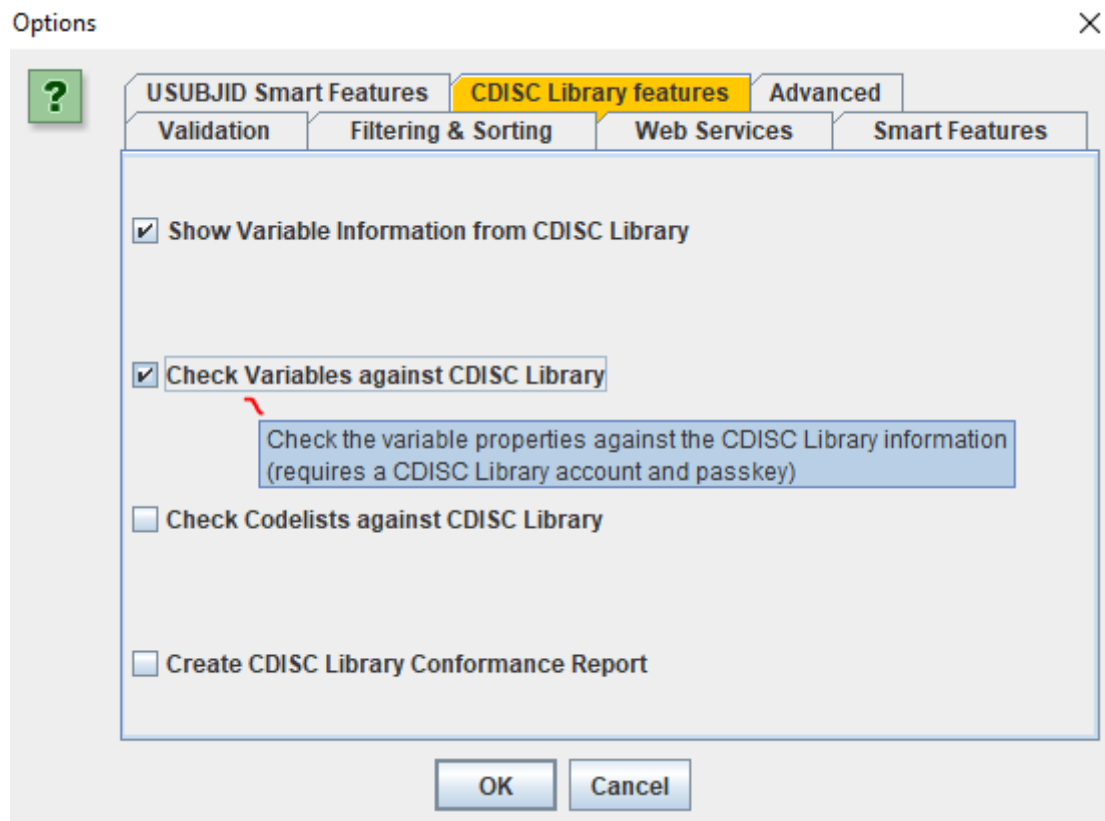
The main reason for this is the mandated use of SAS-XPT, and the use of primitive tools such as the "SAS Universal Viewer". Essentially, the Smart Submission Dataset Viewer lifts these limitations, so that in future, many of the "derived" variables could be removed from the SDTM standard again.

⁷ Of course, suggestions for new "smart features" are always welcome.

imagination ...

Very special is the the option "Show FHIR Source Record on USUBJID". This is an experimental feature showing how SDTM in Dataset-JSON format can include source records as e.g. from Electronic Health Records", and can then be visualized by a viewer. Currently, this has only be implemented for FHIR records. See the document "[Support for embedded EHRs \(FHIR\)" for more details](#). The document still describes this feature for Dataset-XML as the transport format, but the same is of course true for JSON, as the FHIR standard has full support for JSON as the transport format. Remark that embedding source records in SDTM records is impossible when using SAS-XPT. Another reason to get rid of it as soon as possible.

Also the "[CDISC Library](#)" and its [API](#) have been implemented, tab "CDISC Library Features":



allowing to do validation by checking variable and codelist properties (from the define.xml) against the CDISC Library. This feature of course not only requires an internet connect. but also a CDISC Library account and API key. The latter must be stored in the "properties.dat" file - see section "The 'properties.dat' file".

The last tab is "Advanced":

Options

USUBJID Smart Features CDISC Library features **Advanced**

Validation Filtering & Sorting Web Services Smart Features

Tooltips display time (seconds)

10

☐ Use data caching for very large tables

OK Cancel

For example, normally tooltips on cells or other items show up for 10 seconds by default, but the user can set this to another time duration.

The option "Use data caching for very large tables" is currently still in development.

Extended validation

When none of the options in the "Validation" tab has been selected, only very basic validation will be performed (e.g. on "required" variables in the case of SDTM and SEND).

By switching on checkboxes in the "Validation" tab, additional validation checks are performed. This of course comes at the cost of loading time.

For example, when the checkbox "Check values against reference range" is checked, values that fall outside the --STNRLO / --STNRHI range (in any of the SDTM/SEND dataset) are highlighted. For example:

Standard: SDTM - IG version: 3.1.2 - CT version = 2020-12-18

File Tools View Search Options

Rec#	STUDYID	DOMAIN	USUBJID	LBS	LBTEST	LBTEST	LBORRES	LBORRESU	LBORNRL0	LBORNRLHI	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	LBNRIND
28	CDISCPIL0T01	LB	01-701-1015 231	ALT	Alanine Am...	21	U/L	6	34	21	21	U/L	6	34	NORMAL
29	CDISCPIL0T01	LB	01-701-1015 261	ALT	Alanine Am...	23	U/L	6	34	23	23	U/L	6	34	NORMAL
30	CDISCPIL0T01	LB	01-701-1015 296	ALT	Alanine Am...	23	U/L	6	34	23	23	U/L	6	34	NORMAL
31	CDISCPIL0T01	LB	01-701-1015 4	ANISO	Anisocytes	1	NO UNITS			1	1				ABNORMAL Y
32	CDISCPIL0T01	LB	01-701-1015 5	AST	Aspartate A...	40	U/L	9	34	40	40	U/L	9	34	HIGH Y
33	CDISCPIL0T01	LB	01-701-1015 42	AST	Aspartate A...	33	U/L	9	34	33	33	U/L	9	34	NORMAL
34	CDISCPIL0T01	LB	01-701-1015 77	AST	Aspartate A...	21	U/L	9	34	21	21	U/L	9	34	NORMAL
35	CDISCPIL0T01	LB	01-701-1015 107	AST	Aspartate A...	26	U/L	9	34	26	26	U/L	9	34	NORMAL
36	CDISCPIL0T01	LB	01-701-1015 137	AST	Aspartate A...	21	U/L	9	34	21	21	U/L	9	34	NORMAL
37	CDISCPIL0T01	LB	01-701-1015 167	AST	Aspartate A...	22	U/L	9	34	22	22	U/L	9	34	NORMAL
38	CDISCPIL0T01	LB	01-701-1015 202	AST	Aspartate A...	23	U/L	9	34	23	23	U/L	9	34	NORMAL
39	CDISCPIL0T01	LB	01-701-1015 232	AST	Aspartate A...	19	U/L	9	34	19	19	U/L	9	34	NORMAL

where the value of LBSTRESN for record 32, being 40 falls outside the range 9-34 U/L.

This feature can be used by reviewers to quickly find "out-of-range" values without needing to rely on the -NRIND (Reference Range Indicator), provided by the sponsor, and which can have been incorrectly

assigned⁸. This means that the reviewer is now easily able to have an independent assignment, independent of what is provided by the sponsor. Many of the validation features of the viewer do allow the same independency.

The same e.g. applies to the feature "Check --DY values" (--DY = "Study day"). It is one of this variables where we see that very often errors are made, which pass unseen when e.g. using the "SAS Universal Viewer".

Another example is the use of the "CDISC Library". When in that tab, the checkbox "Check Variables against CDISC Library" is checked, and when hovers the mouse over a column header, additional information is provided, such as:

LBORRES	LBORRESU	LBORNRL0	LBORNRLHI	LBSTRESC	LBSTRES
21	U/L	6	34	21	21
23	U/L	Define-XML metadata: Name: LBORRESU Label: Original Units Mandatory: No Datatype: text Length: 8 CDISC Library information: Name: LBORRESU Label: Original Units Core: Exp XPT simple data type: Char CodeList NCLCode: C71620 Discrepancies with CDISC Library: - No CDISC/NCI codelist assigned Expected: C71620			23
23	U/L				23
1	NO UNITS				1
40	U/L				40
33	U/L				33
21	U/L				21
26	U/L				26
21	U/L				21
22	U/L				22
23	U/L				23
19	U/L				19
23	U/L				23
19	U/L				19
0.05	THOU/uL				0.05
0.03	THOU/uL				0.03
0.02	THOU/uL	0	0.2	0.02	0.02

also stating that it was expected that the CDISC codelist C71620 is assigned to variable LBORRESU, which isn't in this case.

We will not explain every validation feature further here as there are a lot of them, and new ones are regularly added. Important to know is that, except for the very basic ones, the default is that they are switched off.

Validation using CDISC CORE

Also CDISC CORE (CDISC Open Rules Engine) have been implemented in the "Smart Submission Dataset Viewer". At the moment of writing (December 2024), the feature has been disabled, as CORE is currently being updated for Dataset-JSON 1.1 (version 1.0 is now deprecated and should not be used anymore). As soon as v.1.1 of Dataset-JSON is implemented in CORE, we will re-add the features to use CDISC CORE validation.

A separate document explaining all the features of validation using CDISC CORE, as implemented in the Smart Submission Dataset Viewer, is currently in development.

⁸ This shows again that such variables such as --NRIND (Reference Range Indicator) should not be part of SDTM (as they are derived). Such variables have only be added on request by regulatory authorities, as the tools of the reviewers are not "smart" enough to derive them themselves.

Using APIs

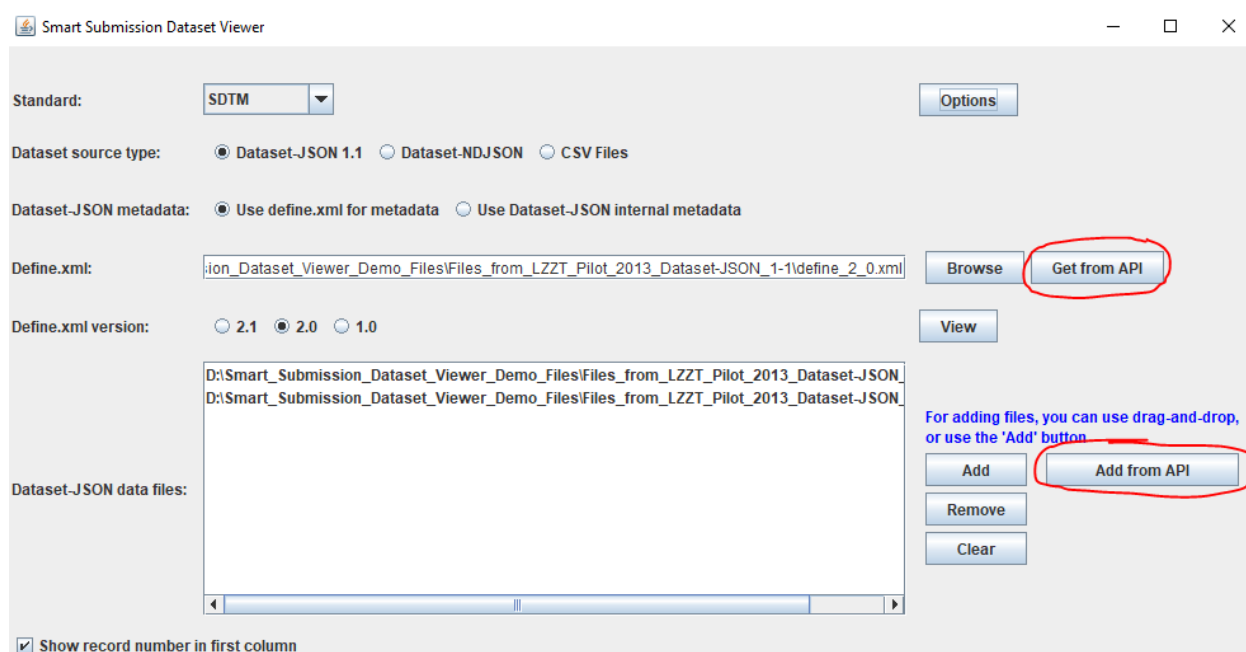
IMPORTANT REMARK: everything described in this section is purely experimental!

It is meant for demonstration purposes to show how APIs and RESTful Web Services (RWS) can be used to retrieve information from other or remote systems, not only full datasets, but also selected information, making the review process considerably more easy.

It also demonstrates that with the use of Dataset-JSON, it becomes in principle possible to evolve to "rolling submissions", in which SDTM/SEND and possibly also ADaM data already becomes available as soon as the first data points have been collected, as also the process of conversion from source data to especially SDTM and SEND can easily be made "rolling", thanks to modern conversion tools.

Such "rolling submissions" also would enable regulatory authorities to make final decisions within a short time after the last data point was collected, which would mean that new therapies can become available at least 1 to 2 years earlier than is currently the case.

In the main window, one may have noticed the buttons "Get from API" for define.xml, and "Add from API" for the datasets themselves:



Just for demonstration purposes, we have build an SDTM dataset containing the information of the "LZZT Pilot" (no, not in XPT format ...), and developed a simple API, again, just for demo purposes, so nothing formal, to retrieve information from that database and load it into the viewer.

A number of "GET" queries have been added to a file "APICallList.txt", which comes with the distribution, and which can be edited/extended by the user:

APICallList.txt - Editor

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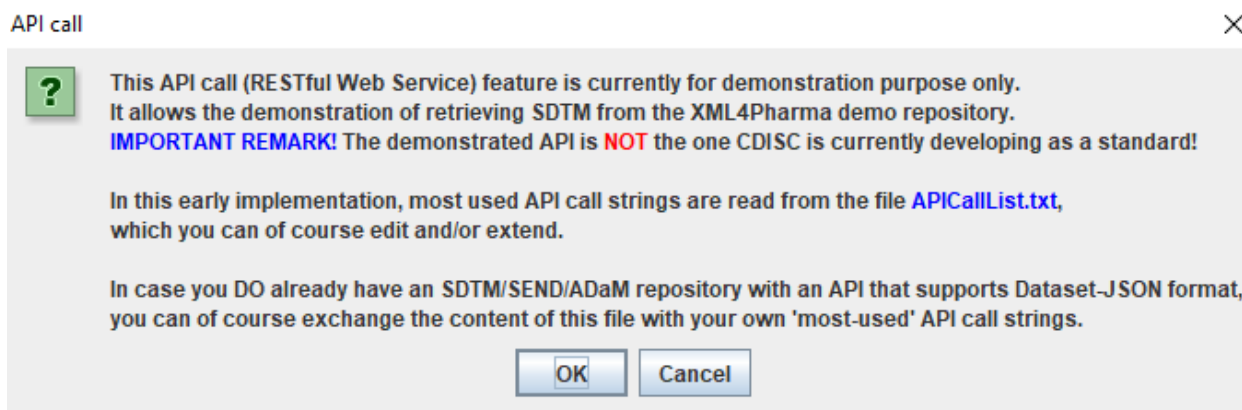
```

http://www.xml4pharmaserver.com:8080/SubmissionService/rest/DefineXML/CDISCPIL0T01
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/DM
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/VS
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/AE
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/AE?variable=AETERM&comparator=eq&value=FATIGUE
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/AE?variable=AESEV&comparator=eq&value=SEVERE
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/DM?variable=BRTHDTC&comparator=lt&value=1950-01-01
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/VS?variable=VSTESTCD&comparator=eq&value=PULSE
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/VS?variable=VSTESTCD&variablevalue=SY5BP&resultvariable=VSORRES&comparator=le&value=100
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/studies/CDISCPIL0T01/datasets/VS?variable=USUBJID&comparator=eq&value=CDISC003

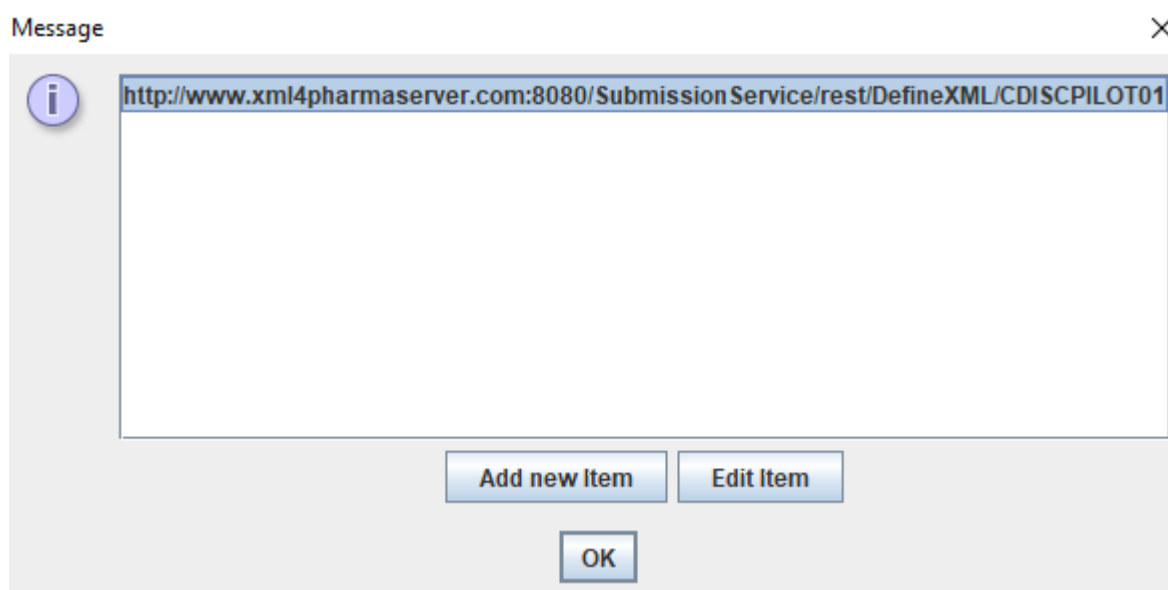
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/SingleSubject/CDISCPIL0T01/subject/CDISC003
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/SingleDataSetAndSubject/CDISCPIL0T01/dataset/DM/subject/CDISC003
http://www.xml4pharmaserver.com:8080/SubmissionService/rest/SingleDataSetAndSubject/CDISCPIL0T01/dataset/AE/subject/CDISC003

```

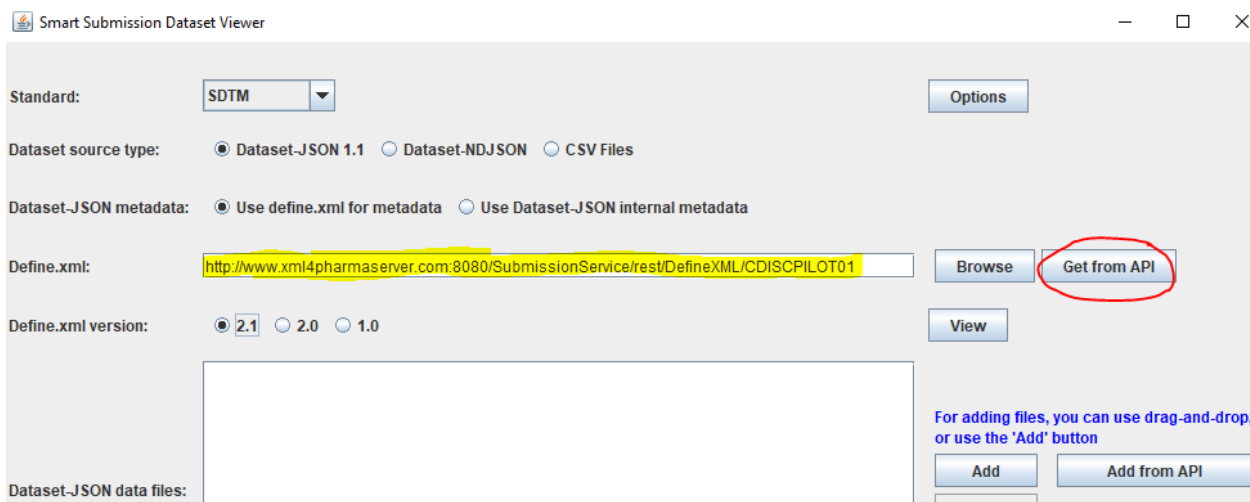
When then clicking the button "Get from API" for the define.xml, first some explanation is displayed:



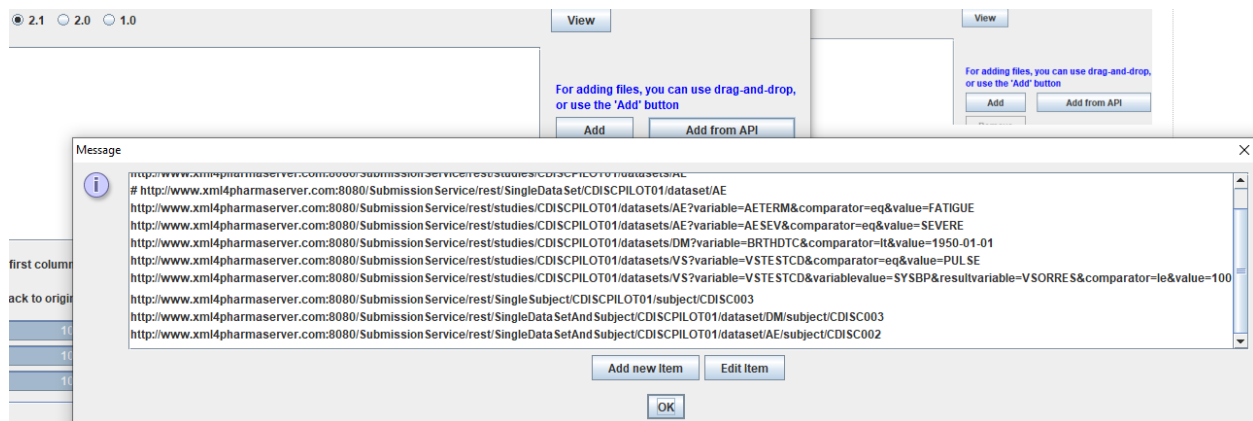
and then this list is read, and the available "GET" commands regarding the define.xml is displayed:



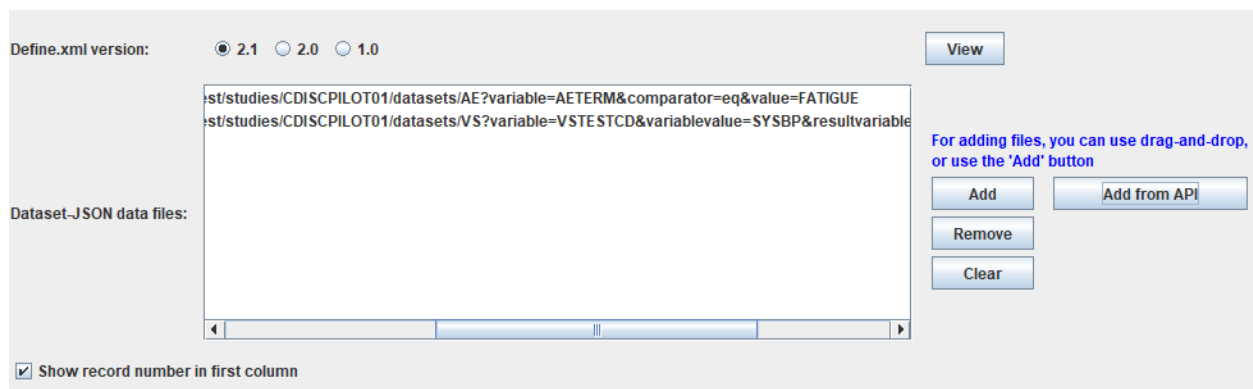
to which one can add new ones, or edit the existing ones, though this currently doesn't make sense, or it must be that one has implemented a similar API on an own server that has an SDTM database. When selecting the first one, and clicking "OK", the text field for define.xml is populated:



Similarly, when one clicks the "Add from API" button for the datasets themselves, the list is read and the "GET" instructions made available:



Just for the demo, let us select the one about "AE with AETERM is fatigue" and the one "VSTESTCD where VSTESTCD=SYSBP and VSORRES less or equal 100", leading to:



When then hitting "Start", the query is submitted to the server, and some Dataset-JSON is generated by the server and send back to our application as the "response", and then used by the viewer, leading to:

File Tools View Search Options						
AE_variable=AETERM_comparator=eq_value=FATIGUE.json				VS_variable=VSTESTCD_variablevalue=		
STUDYID	DOMAIN	USUBJID	AESEQ	AELNKID	AETERM	AELLT
CDISCPLOT01	AE	CDISC001	2	2	FATIGUE	

showing that the database has only 1 record with AETERM=FATIGUE, and

Standard: SDTM - IG version: 3.3 - CT version = 2020-12-18												
File Tools View Search Options												
AE_variable=AETERM_comparator=eq_value=FATIGUE.json				VS_variable=VSTESTCD_variablevalue=SYSBP_resultvariable=VSORRES_comparator=le_value=100.json								
STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPPOS	VSORRES	VSORRESU	VSSTRES	VSSTRESN	VSSTRESU	
CDISCPLOT01	VS	CDISC001	40	SYSBP	Systolic Blood Pressure	STANDING	98	mmHg	98	98	mmHg	
CDISCPLOT01	VS	CDISC001	41	SYSBP	Systolic Blood Pressure	SUPINE	99	mmHg	99	99	mmHg	
CDISCPLOT01	VS	CDISC001	42	SYSBP	Systolic Blood Pressure	STANDING	99	mmHg	99	99	mmHg	
CDISCPLOT01	VS	CDISC001	43	SYSBP	Systolic Blood Pressure	STANDING	99	mmHg	99	99	mmHg	
CDISCPLOT01	VS	CDISC012	63	SYSBP	Systolic Blood Pressure	STANDING	90	mmHg	90	90	mmHg	
CDISCPLOT01	VS	CDISC012	89	SYSBP	Systolic Blood Pressure	SUPINE	100	mmHg	100	100	mmHg	
CDISCPLOT01	VS	CDISC012	91	SYSBP	Systolic Blood Pressure	STANDING	90	mmHg	90	90	mmHg	
CDISCPLOT01	VS	CDISC017	98	SYSBP	Systolic Blood Pressure	SUPINE	99	mmHg	99	99	mmHg	
CDISCPLOT01	VS	CDISC017	99	SYSBP	Systolic Blood Pressure	STANDING	99	mmHg	99	99	mmHg	
CDISCPLOT01	VS	CDISC017	100	SYSBP	Systolic Blood Pressure	STANDING	100	mmHg	100	100	mmHg	

providing all the vital signs record for which the systolic blood pressure is less or equal to 100 mmHg.

Using such RESTful Web Services is much more efficient than having to load full datasets (or pre-filtered ones) and then having the reviewer to have to start filtering. It also does not require a high quality define.xml as is the case for the "pre-loading filtering" feature, which already can save a lot of time. One can easily imagine a simple application on top of the viewer that has a user-friendly graphical user interface and takes care of assembling the queries. And of course, one can also imagine AI to be used to do so, where the user simply talks to and says (or types): "Viewer, give me vital signs records for all the subjects with a systolic blood pressure lower than 100 for study XYZ ...".

Once again, please notice that what is presented in this section is not part of any formal standard, is not endorsed by CDISC, but was just developed to demonstrate the power of RESTful Web Services and API for reviewing submissions.

The "properties.dat" file

The "properties.dat" file allows to steer the behavior of the software. This file is immediately read after starting the software. The software comes with a sample properties.dat file in which some settings are "commented out". These are lines that start with a "#" character.

For example:

 properties.dat - Editor

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```
#logfilepath=C:\temp
loglevel=INFO
# Minimum amount of memory (in MB) that must always be available during loading
#minmemorynecessary=5
# Fill in your CDISC Library API key here if you want the CDISC Library features
cdisclibraryapikey=abcdefghijklmnopqrstuvwxyz12345
# Whether the question about converting XPT files to Dataset-JSON format is asked at startup
skipXPTQuestion=false
```

In the first line (here commented out), the user can set to which folder the log files will be written. The default is that they are written to a folder named "logs" that is under the folder to which the software was installed.

The second line allows to set the "logging level". Under normal circumstances, one will set it to "INFO". If one encounters problems, best it to set it to "DEBUG". In that case, much more information is written into the log file, which you can then send to us to understand the issue, and helps the developers to further improve the software. Other possible settings are "WARNING" and "ERROR". For both of these, the log file will be much smaller, as it will only be written when a warning or error is thrown.

The next line is something that one mostly will have commented out. It defines the minimum amount of memory that must always be free during loading of the dataset. If, during loading, the amount of memory threatens to fall under this minimum, the system will issue a warning and try to do some "garbage collection". Change this setting only when you are a developer and have access to the source code.

The "Smart Submission Dataset Viewer" has some validation options that use the "[CDISC Library](#)". In order to be able to use these, you will require a "CDISC Library API Key" which you can obtain from CDISC for free. See the [CDISC Library API documentation](#) for more details. When you have obtained one, copy-paste it into the "properties.dat" file.

When you start the software, you will be asked whether you first want to convert SAS-XPT files to Dataset-JSON, or whether you already have such, and wants to start with these.

When setting skipXPTQuestion=true", the system will skip this first dialog and immediately jump to the main window.