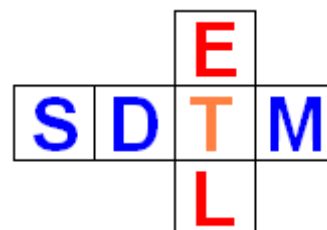# SDTM-ETL 5.0: The "properties.dat" File

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Introduction

One of the important files that comes with the software is the "properties.dat" file. It contains a number of settings and parameters that are read by the software at startup. It allows to customize the software for the user's environment and own wishes.

Editing the "properties.dat" file

The "properties.dat" file is located in the directory where also the software was installed, e.g.:
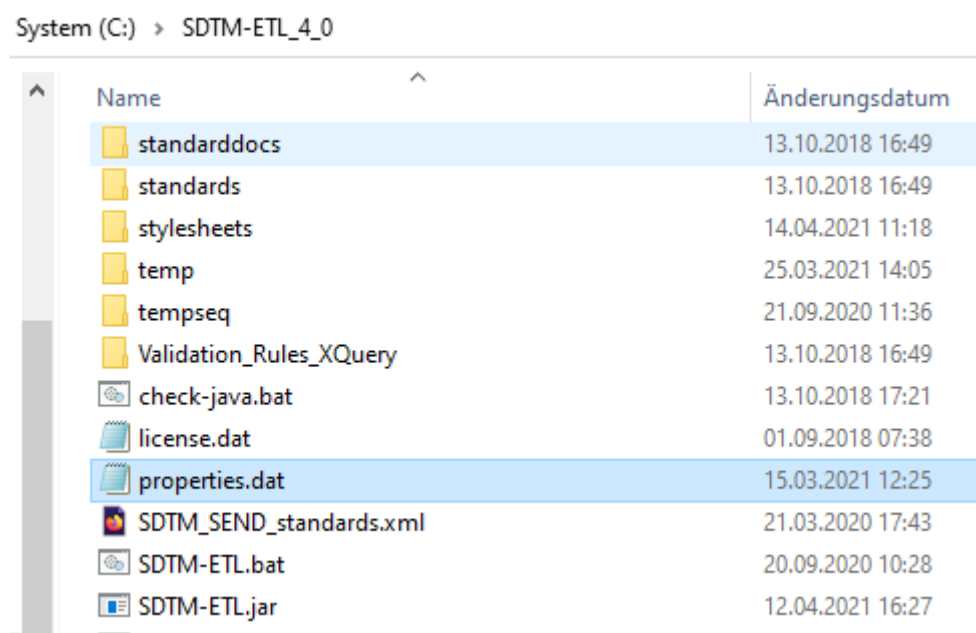
The best way to change the settings and parameters in the "properties.dat" file is to use a simple text editor line NotePad++ or NotePad. Do **NOT** use MS-Word, Excel or any office editors. These are mostly not suitable for simple text files like the "properties.dat" file.

When opening the file with e.g. NotePad++, the following (or similar) is displayed:

```
*properties.dat - Editor

Datei  Bearbeiten  Format  Ansicht  Hilfe
language=en
languagefixed=true
# logfilepath=C:\temp
loglevel=INFO
sasviewerlocation=C:\Program Files\SAS Institute\SAS System Viewer\Sv.exe
adobereaderlocation="C:\Program Files\Adobe\Acrobat DC\Acrobat\Acrobat.exe"
# CDISC Library API key
cdisclibraryapikey=███████████████████
# ChatGPT API key (without "Bearer")
chatgptapikey=sk-███████████████████
# other settings
advancedusage=true
skipodmvalidation=true
# Settings for SQL generation
useoraclesql=true
# As of SDTM-ETL v.4.4: for EDC systems that export ODM in "Typed ItemData" format
odmtypeditemdata=false
# As of SDTM-ETL v.4.4: set user-defined "default" mapping descriptions
adddefaultmappingdescriptions=true
# postpone ODM tree recalculation after loading a define.xml
postponeodmtreenoderecalculation=true
# set number of minutes between define.xml autosave
numminutesforautosave=15
# define1stylesheet=D:\CDISC_define\CRT_DataDefinitionFiles\StyleSheet\define1-0-0.xsl
define2stylesheet=D:\CDISC_Define_2_0_final\stylesheets\define2-0-0.xsl
define21stylesheet=D:\CDISC_Define_2_1_final\stylesheets\define2-1-0.xsl
# File paths for use with CORE (CDISC Open Rules Engine)
meddrafilepath=D:\meddra_19_0_english\MedAscii
loincfilepath=D:\LOINC\LOINC_2.78\LoincTable
# medrtfilepath=D:\MedRT
# uniifilepath=D:\UNII
# snomedversion=2024-09-01
# snomedurl=https://snowstorm.snomedtools.org/snowstorm/snomed-ct
# snomededition=SNOMEDCT-US
```

Important here is that lines that start with a "#", are lines that have been commented out, or just are comments. This is usually done to keep some earlier settings.

Once opened in a text editor, one can start changing the settings. After saving, they will be read the first time the software is started again.
Remark that some of the settings can also be changed from within the application. These are then however not saved to the "properties.dat" file.

All parameters are "key-value" pairs, where the key and value is separated by the "=" character. In case the "value" part contains one or more blanks (e.g. some Windows file paths), the whole value part must be embedded in double quotes. In the above example, this is e.g. the case for the parameter "adobereaderlocation".

<u>Settings that can be changed</u>

We will now go over the settings and parameters that can be changed.

1. parameter "language"

This allows to change the language of the application (menus, dialogs, ...). In 99% of the cases however, you will have a version that only supports the English language. So, unless

you have obtained a localized version of the software, do not change this setting.

2. parameter "languagefixed"

This parameter only works for the seldom case that you obtained a localized version of the software that supports multiple languages. When "languagefixed" is then set to "false", the user will be asked at startup which language must be used for the menus and dialogs.

3. parameter "loglevel"

This is an important parameter for the case that you encounter problems with the software and /or want to report a bug. When set to "INFO" (the default), the log file generated during the session will contain "information" messages, and "warning" and "error" messages when something goes wrong.
In case you encounter or suspect a reproducible bug, the best is to set "loglevel" to "DEBUG". This will generate a lot more messages in the log file, which you can then send to us. This will enable us to find the source of the bug.
Other valid values are "WARNING" (only warnings and errors will be reported) and "ERROR" (only errors will be reported). These will however usually not be used.

4. parameter "logfilepath"

During each new session, a log file is generated. By default, it is written in the "logs" directory that comes under where you installed the software. The date and time at which the log file was first created is part of the filename. For example:

Name	Änderungsdatum	Typ
SDTMETL_LOG_2021_4_21_8-41-20.txt	21.04.2021 08:41	Textdokument
SDTMETL_LOG_2021_4_21_8-41-37.txt	21.04.2021 08:41	Textdokument
SDTMETL_LOG_2021_4_21_8-42-53.txt	21.04.2021 08:52	Textdokument

the file "SDTMETL_LOG_2021_4_21_8-41-20.txt" was first created on April 21, at 8:41:20 local time.
It surely is a good idea to regularly clean up the directory where all the log files have been written to.

You might however want to write the log files to another directory than the default one. In such a case, provide the file path in the parameter "logfilepath". In case that path contains blanks (on Windows), you need to put the path name in double quotes.

5. parameter "sasviewerlocation"

If you use the old, free, classic "SASViewer", set the location of the executable for this parameter. This will enable the SDTM-ETL software to open the SASViewer from within the application itself.

6. parameter "adobereaderlocation"

Set the location of the executable of your "Adobe Acrobat Reader" for this parameter. This is especially important when you want to open SDTM-IG documents (at the correct section or

page) or an SDTM "Model" document from within the SDTM-ETL application. This will usually be the case when using the menu "View - CDISC Notes" (shortcut: CTRL-H) and then clicking the button "SDTM Spec v.x.y" or "SDTM-IG x.y":
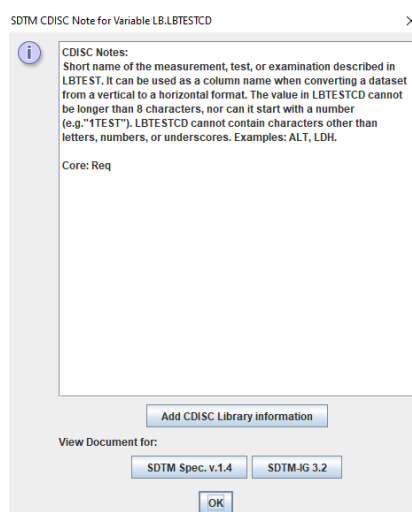

7. parameter "cdisclibraryapikey"

If you want to use the "CDISC Library API" for validation of the dataset and variable names and labels and CDISC Controlled Terminology", one will need an API-key for the CDISC Library. If your company is a CDISC member, you can obtain a key by following the instructions at https://www.cdisc.org/cdisc-library/api-account-request.

Then copy your obtained CDISC Library API key to the parameter "disclibraryapikey".

The menu where the CDISC Library is used is "CDISC Library" and the items under it:
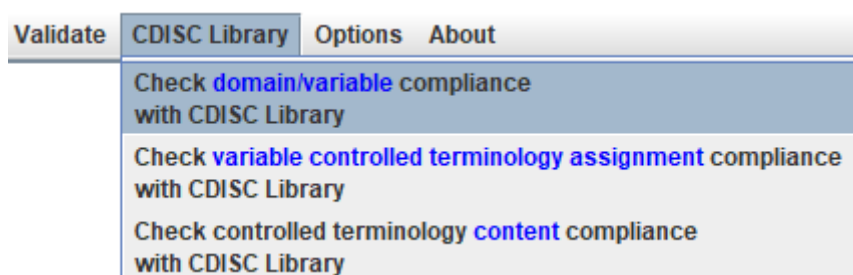
8. parameters "chatgptapikey"

As of version 4.3, the ChatGPT API has been implemented into SDTM-ETL. It allows to ask ChatGPT some simple questions like "To what SDTM domain must I map systolic blood pressure to?". Remark that this feature is currently purely experimental!

In order to use this feature, one will need to obtain a ChatGPT API key, which needs to be written into the properties.dat file.

9. parameter "chatgptmaxrequests"

ChatGPT may limit the number of requests you can do per hour, which is typically 50-70 (see e.g. https://www.wikihow.com/Chat-Gpt-How-Many-Requests-per-Hour). With the parameter

"chatgptmaxrequests", you can try to set this maximum to a higher value, e.g.:

chatgptmaxrequests = 200

There is however no guarantee for success ...

10. parameter "advancedusage"

It is highly recommended to keep the value of this parameter at "true". This parameter was introduced for a very few number of customers who want some checkboxes to be not visible in some of the dialogs.

11. parameter "skipodmvalidation"

When one loads the ODM file with the study metadata, this file is validated against the ODM standard. This can be irritating when one has done this validation already many times before. By setting "skipodmvalidation=true", the ODM validation when loading the ODM file with metadata will be skipped.

12. parameter "useoraclesql"

One of the options of SDTM-ETL is to generate SQL "CREATE TABLES" and "INSERT" files with the instructions to generate or populate relational database tables. The default is that these instructions are generated in "standard SQL" which is compatible with e.g. MySQL. When setting "useoraclesql=true", the instructions will however be written in Oracle-SQL, which is slightly different.

13. parameter "odmtypeditemdata"

ODM versions 1.x have two flavors of "ItemData" in the clinical data part. The most used flavor is "untyped ItemData", like:

<ItemData ItemOID="SYSBP" Value="100"/>

The other flavor is "typed ItemData", like:

<ItemDataInteger ItemOID="SYSBP">100</ItemData>

As "untyped" is most used, this is the default. Setting "odmtypeditemdata=true" will make the second flavor as the default. This is especially of importance when doing "batch execution". Also when set, "typed" will be proposed when starting the dataset generation execution".

14. parameter "adddefaultmappingdescriptions"

When generating mapping scripts in an automated way, comments (starting with a '#') will be added to the mapping script automatically, describing how the system came to the automatically generated mapping. Setting "adddefaultmappingdescriptions=false" will take care that such comments are not added. The default is "true".

15. parameter "postponeodmtreenoderecalculation"

After loading a define.xml with mappings, by default, the usage of each ODM node in any of these mappings will be recalculated. As this can take some time, when the parameter value is

set to "true", automatic and immediate recalculation of the usage of each of the ODM nodes in the mappings is postponed. In such a case, a dialog will pop up:
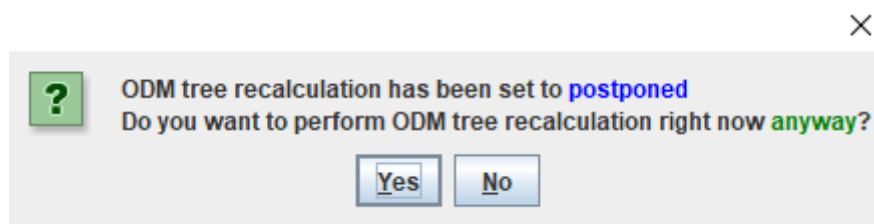
allowing the user to decide whether he/she wants to perform the recalculation right now or not.

In case of "No", a recalculation can later still always done using the menu "Navigate - Recalculate ODM tree nodes ...":
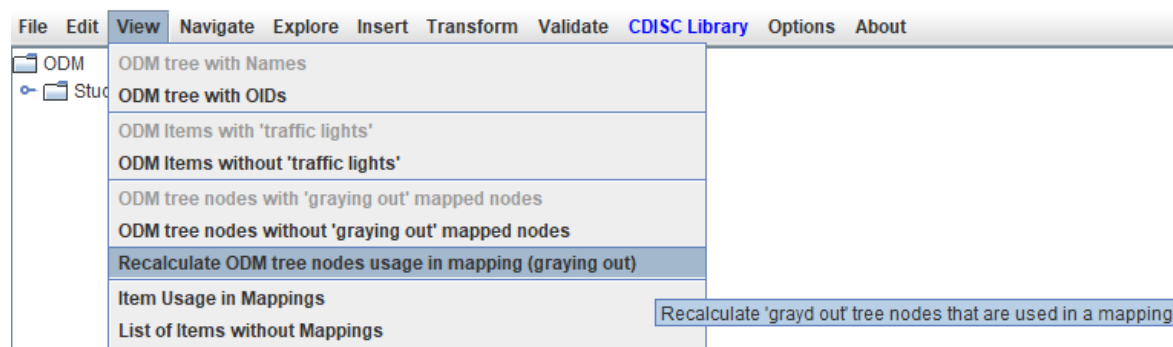
15. parameter "numminutesforautosave"

By default, SDTM-ETL saves the underlying define.xml every 15 minutes to the folder "define_autosave". With the parameter "numminutesforautosave", the number of minutes between automatically saving can be changed. An integer number is expected.

The "autosaved" define.xml file can always be used as "the last starting point" in case of a software crash, power failure, ...

16. parameter "define1stylesheet"

In case you are still using Define-XML version 1, this is the place where you can add the location of the stylesheet for generating a "human-friendly view" of the underlying define.xml (menu "View - define.xml in Browser", and "View - define.xml as HTML"). In case this parameter is absent or commented out, the software will try to find a suitable stylesheet from the "stylesheets" directory that comes with the software.
Remark that Define-XML 1.0 is not formally supported in SDTM-ETL anymore. Some customers however still receive a version that has some (but limited) support for Define-XML 1.0.

17. parameter "define2stylesheet"

Similarly, when using Define-XML version 2.0, this is the place where you can add the location of the stylesheet. Also here, in case this parameter is absent or commented out, the

software will try to find a suitable stylesheet from the "stylesheets" directory that comes with the software.

18. parameter "define21stylesheet"

Similarly, when using Define-XML version 2.1, this is the place where you can add the location of the stylesheet. Also here, in case this parameter is absent or commented out, the software will try to find a suitable stylesheet from the "stylesheets" directory that comes with the software.

19. parameters for use in CORE validation

CDISC CORE (CDISC Open Rules Engine) is gradually replacing the validation tool of a specific vendor, also at the FDA. SDTM-ETL fully supports CORE[1] (which is made open source by CDISC). In not too far future, it will also possible that users of SDTM-ETL and CORE will be able to add their own (e.g. for QC) rules to SDTM-ETL/CORE.

The parameters "meddrafilepath", "loincfilepath", "medrtfilepath", "uniifilepath", "snomedversion", "snomededition" and "snomedurl" allow to provide the CORE engine to know where to find the necessary files for those rules that are about one of these external dictionaries. Remark that "snomedurl" is currently purely experimental

Also remark that in SDTM-ETL, the CORE engine (directory CDISCCORE) can always be exchanged for a newer version when it becomes available: this does not at all require an update of the software itself.

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[1] We even contribute a lot to CORE as a volunteer, especially in helping implementing the "FDA Business Rules" and the "SEND validation rules v.1.5".