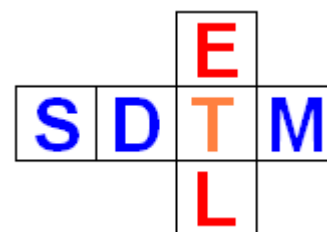# SDTM-ETL 4.0 User Manual and Tutorial

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Working with the "Findings About" domain

When SDTM was first developed, there were about 20 domains, and everybody (except a few) was expecting that this number would not increase very much. In the latest SDTM-IG version 3.3 there are over 70 domains, and even that was not sufficient, as it did not cover well the use case of findings that are related to interventions and to events.

For this case, the FA domain "Findings about Events and Interventions" was created. In the SDTM-IG 3.2 it is described as:

6.4.1 When to Use Findings About

It is intended, as its name implies, to be used when collected data represent "findings about" an Event or Intervention that cannot be represented within an Event or Intervention record or as a Supplemental Qualifier to such a record. Examples include the following:

- Data or observations that have different timing from an associated Event or Intervention as a whole: For example, if severity of an AE is collected at scheduled time points (e.g., per visit) throughout the duration of the AE, the severities have timing that are different from that of the AE as a whole. Instead, the collected severities represent "snapshots" of the AE over time.
- Data or observations about an Event or Intervention which have Qualifiers of their own that can be represented in Findings variables (e.g., units, method): These Qualifiers can be grouped together in the same record to more accurately describe their context and meaning (rather than being represented by multiple Supplemental Qualifier records). For example, if the

and so on.

The SDTM-IG lets implementers the choice between a single FA dataset, and a series of "splitted" datasets for findings about different existing SDTM "Events" and "Interventions" domains. In the latter case one may e.g. have an "FAMH" dataset ("Findings About Medical History") and an "FAAE" ("Findings About Adverse Events") dataset.
The name "splitted" is confusing, as one will usually not split a single FA dataset in datasets such as FAMH and FAAE, but one will create a single "FA" instance for "Medical History" and one for "Adverse Events" right from the start.

This tutorial explains how to proceed for both cases.

As of SDTM-ETL v.4.0, when one "drags-and-drops" the FA row to the bottom (after the last template domain row), or when one selects the FA row from the template and then uses the menu "Edit – Copy Domain" followed by "Edit – Paste Domain", the following dialog is displayed:
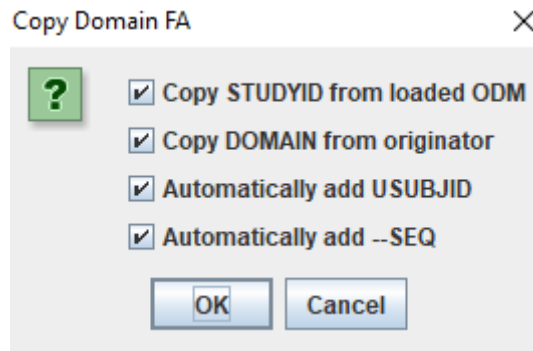
Which is the usual dialog asking whether mappings for STUDYID, DOMAIN, USUBJID, and FASEQ can be automatically generated (recommended when using standard ODM as the source).

After clicking OK, the following (new) wizard is displayed:
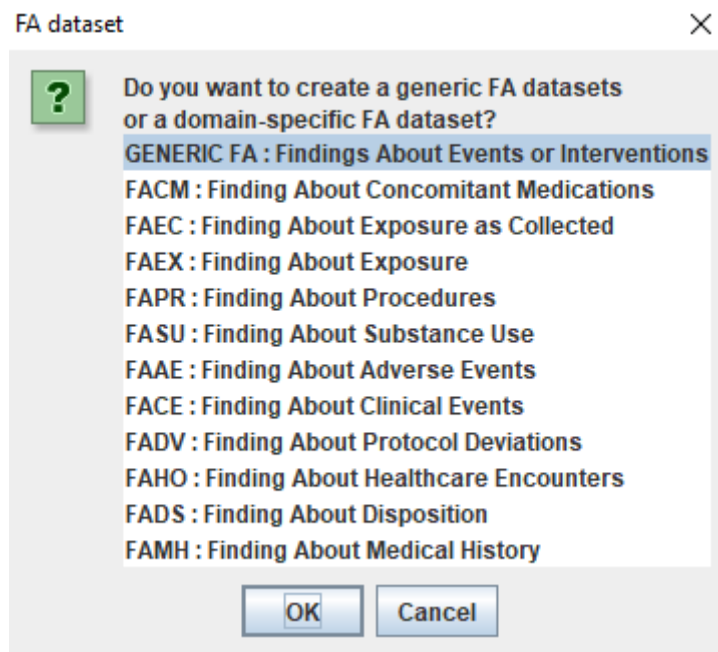
The software automatically looks up all "Interventions" and "Events" domains in the template, also sponsor-defined ones, and then creates a list of "FA domain specific" domains such as "FACM", FAEC, … The first entry however is "Generic FA", meaning that a single FA instance will be created, which should then contain all "Findings About" entries, independent of what the related domain is. If one selects "Generic FA", a single row is created at the bottom, from which one can start the mappings to a "generic" FA dataset:

SR	STUDYID	DOMAIN	USUBJID	SR.SRSEQ	SR.SRGRPID	SR.SRREFID	SR.SRSPID	SR.SRTESTCD	SR.SRTEST	SR
RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	RELTYPE	RELID			
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL	QORIG	QE
MyStudy:FA	STUDYID	DOMAIN	USUBJID	FA.FASEQ	FA.FAGRPID	FA.FASPID	FA.FATESTCD	FA.FATEST	FA.FAOBJ	FA.

This is the simplest case and does not deviate from the usual case for any other domain.

One can then start generating the mappings in the usual way.

In a number of cases however, one will want to generate "domain-specific" FA datasets, such as FAMH ("Findings About Medical History") or FACE ("Findings About Clinical Events"). For example, when one wants to create an FAMH dataset instance, one would choose:
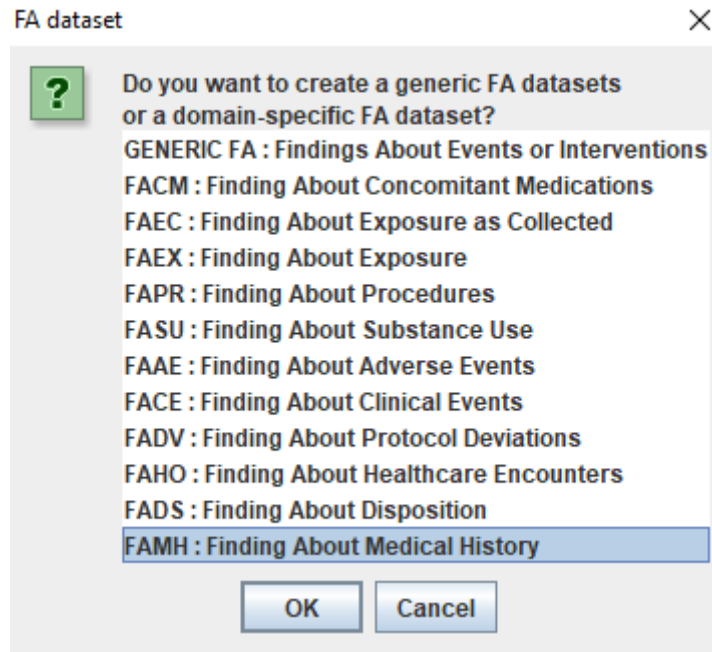
meaning that an FAMH dataset will be created.

After clicking OK, a new wizard is displayed:
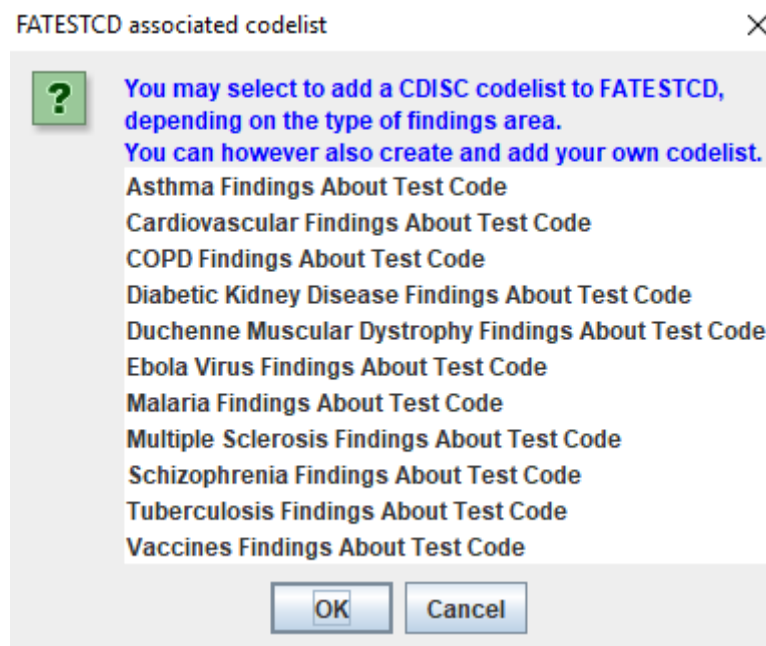
In the SDTM-IG 3.2, it is stated that the codelist "FATESTCD" needs to be used for the variable FATESTCD:

| FASPID | Sponsor-Defined Identifier | Char | | Identifier | Sponsor-defined reference explicit line identifier or d Line number on a CRF. |
| FATESTCD | Findings About Test Short Name | Char | (FATESTCD) | Topic | Short name of the measur can be used as a column r horizontal format. The val nor can it start with a num characters other than lette |

However, the newer versions of CDISC Controlled Terminology (CDISC-CT) do NOT contain this codelist. Closer inspection of all the CDISC-CT of the last years show that it was deleted in September 2016.

Instead, a number of disease-specific "FATESTCD" codelists have been developed by the CDISC-CT team. All these obey to the pattern "–FATSCD", and the corresponding codelist for "FASTEST" obeys to the pattern "—FATS". For example, for "COPD Findings About Test Code", the identifier is "CPFATSCD" and the NCI code is "C122007".

In the wizard, when hovering the mouse over an entry, all the allowed values for that codelist is displayed. For example, for "CPFATSCD":
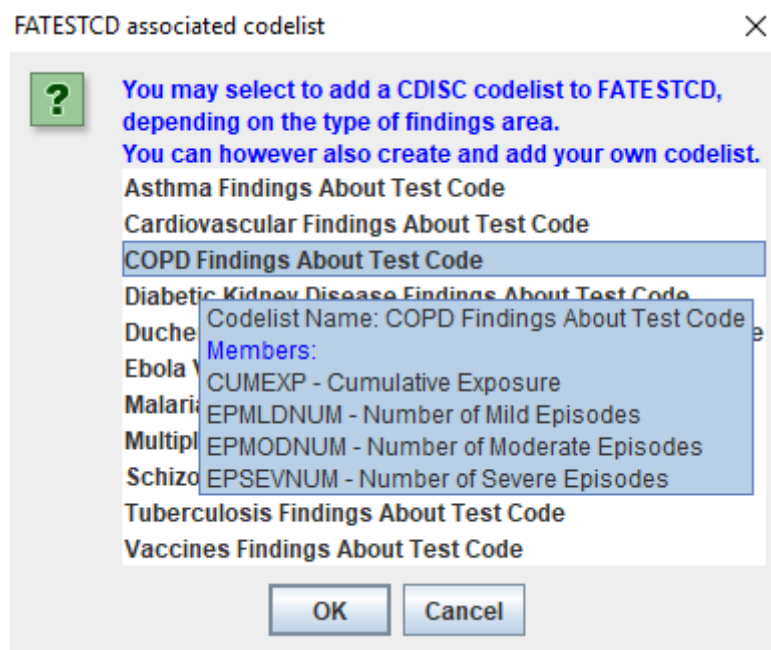
This allows to easier find a suitable codelist.
It is not mandatory to select an "—FATSCD" codelist, one can also not select anything (or click the Cancel button). One can then still later attach a codelist to both variables, and/or create a new one and attach it.
Also, when selecting an "—FATSCD" codelist, also the corresponding "—FATS" codelist will be loaded.

For example, when the "COPD Findings About Test Code" is selected, and OK is clicked, the FAMH instance is created:

RELREC	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL
SUPPQUAL	STUDYID	RDOMAIN	USUBJID	IDVAR	IDVARVAL
MyStudy:FAMH	STUDYID	DOMAIN	USUBJID	FAMH.FASEQ	FAMH.FAGRPID

And the "COPD Findings About Test Code" is attached to FATESTCD:

And the corresponding codelist is attached to FATEST:

One can now start mapping as in the usual case, for example for all findings about medical history of COPD.