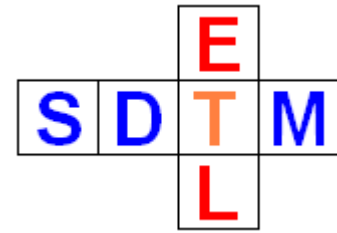


SDTM-ETL 4.4 User Manual and Tutorial

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Troubleshooting: Most common mistakes and errors

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Introduction

The SDTM-ETL software makes development and execution of mappings between collected data (usually as CDISC-ODM) and SDTM or SEND easy. But still, users need to take decisions, and use the many wizards and dialogs in a wise way. In some cases, automatically scripts must be extended or adapted, or (very seldom) written from scratch.

Making mistakes is human, and also here, mistakes can be made, which lead to errors or unexpected results. The current document tries to make an inventory of most common mistakes and errors and how to either avoid or correct them.

Usually, the SDTM-ETL software will report such errors during execution of the mapping scripts, when using the menu "Transform - Generate Transformation (XSLT) Code for ...", or later, after execution was started. We will explain most of the common error messages, and discuss measures to be taken to correct the scripts or the mapping strategy.

This document will regularly be updated with comments from our users.

Most common error messages during "compilation" of the mapping scripts

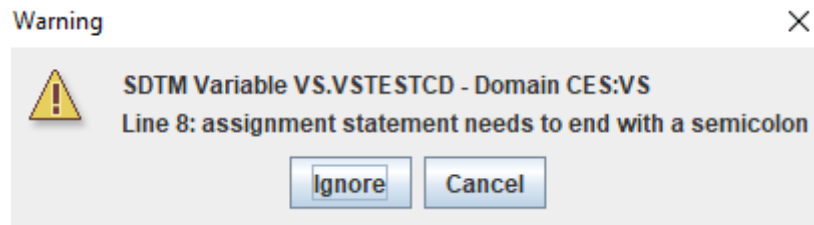
The mapping scripts are, when the menu "Transform - Generate Transformation (XSLT) Code for ..." is used, transformed into [XSLT](#) (XML Transformation Language), which is then executed on

the ODM-XML file with clinical data.

During generation of the XSLT, the software already checks a number of things, and the validity of the generated XSLT.

Here are the most common error messages generated:

- "assignment statement needs to end with a semicolon"



This is an obvious error that can occur when automatically generated mapping scripts have been edited, or written developed from scratch. When we then look into the script for VSTESTCD at line 8, we find:

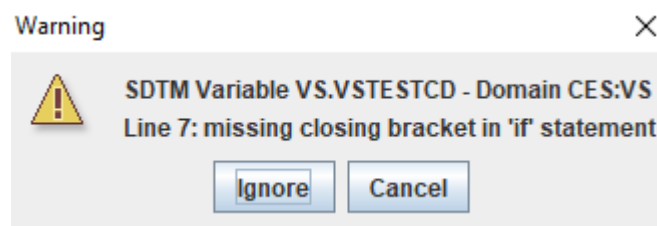
```
The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID I_DIABP - value from attribute I
2 # Generalized for all StudyEvents
3 # Generalized for all Items within the ItemGroup
4 # Mapping for ODM Items [I_WEIGHT, I_SYSBP, I_DIABP] to SDTM CodeList VS.VSTESTCD
5 # with CodeList OID 'CL.C66741.VSTESTCD.SUBSET'
6 $CODEDVALUE = xpath(/StudyEventData/FormData[@FormOID='F_WEEK_1_2']/ItemGroupData[
7 if ($CODEDVALUE == 'I_WEIGHT') {
8     $NEWCODEDVALUE = 'WEIGHT'
9 } elseif ($CODEDVALUE == 'I_SYSBP') {
10    $NEWCODEDVALUE = 'SYSBP';
```

Where we see that a semicolon, which is needed to indicate the end of a programming statement is failing. One can e.g. see in line 10 what is needed.

In such a case, one can use the "Ignore" button, in which case the software will try to automatically correct the generated XSLT, but there is no guarantee that this will always work.

- "missing closing bracket in 'if' statement"

Is another obvious error, e.g.



Which can easily be retraced in the mapping script:

```
The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID I_DIABP - value from attribute ItemOID
2 # Generalized for all StudyEvents
3 # Generalized for all Items within the ItemGroup
4 # Mapping for ODM Items [I_WEIGHT, I_SYSBP, I_DIABP] to SDTM CodeList VS.VSTESTCD
5 # with CodeList OID 'CL.C66741.VSTESTCD.SUBSET'
6 $CODEDVALUE = xpath(/StudyEventData/FormData[@FormOID='F_WEEK_1_2']/ItemGroupData[@ItemGroupOID='
7 if ($CODEDVALUE == 'I_WEIGHT') {
8     $NEWCODEDVALUE = 'WEIGHT';
9 } elseif ($CODEDVALUE == 'I_SYSBP') {
10     $NEWCODEDVALUE = 'SYSBP';
```

- "variable name needs to start with a '\$'"



Just like in Perl, PHP and JavaScript, variables are denoted by starting with a dollar (\$) character. This is a consequence of our mapping script language being "untyped", meaning that variables are not explicitly assigned a data type (like "string", "integer", ...), like e.g. in Java. See [here](#) for some explanation.

Also here, as the line number is provided, this error is easy to trace back:

```
The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID I_DIABP - value from att
2 # Generalized for all StudyEvents
3 # Generalized for all Items within the ItemGroup
4 # Mapping for ODM Items [I_WEIGHT, I_SYSBP, I_DIABP] to SDTM CodeList VS.V
5 # with CodeList OID 'CL.C66741.VSTESTCD.SUBSET'
6 $CODEDVALUE = xpath(/StudyEventData/FormData[@FormOID='F_WEEK_1_2']/ItemGr
7 if ($CODEDVALUE == 'I_WEIGHT') {
8     NEWCODEDVALUE = 'WEIGHT';
9 } elseif ($CODEDVALUE == 'I_SYSBP') {
10     $NEWCODEDVALUE = 'SYSBP';
11 } elseif ($CODEDVALUE == 'I_DIABP') {
```

Most common error messages during execution of the mapping scripts

- "Typed" versus "Untyped" ODM clinical data.

Once the XSLT generated, it can be applied to a file with clinical data in ODM format. One must remark here that there are two "flavors" of ODM "ClinicalData", i.e. "untyped" and "typed". Most EDC systems export ODM clinical data in the "untyped" flavor, which is characterized by

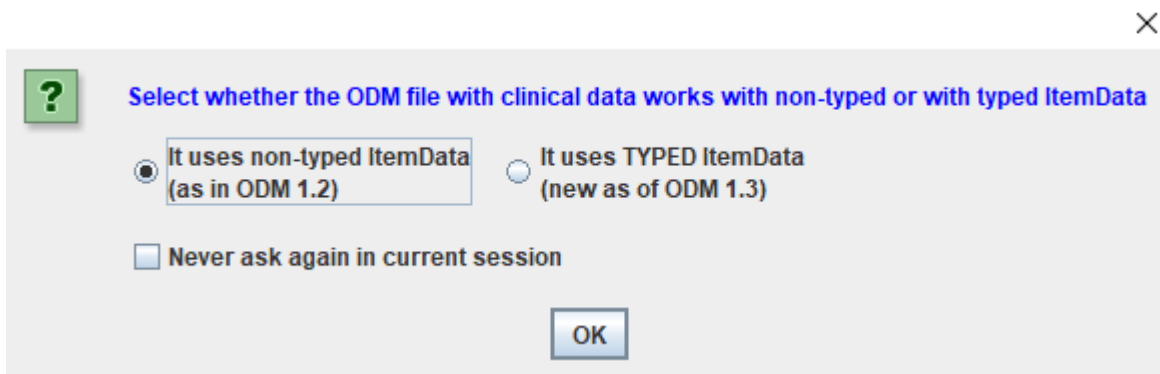
having the value of the data point in a "Value" attribute. For example:

```
<ItemGroupData ItemGroupOID="IG_DM">
  <ItemData ItemOID="I_BRTHDT" Value="1957-05-07"/>
  <ItemData ItemOID="I_SEX" Value="F"/>
  <ItemData ItemOID="I_RACE" Value="CAUCASIAN"/>
</ItemGroupData>
```

Some (but less common) EDC systems however export the clinical data in the "typed" flavor, which is characterized by that the name of the "ItemData..." element has the data type in it, and that the value of the data point comes as XML "text content". For example:

```
<ItemGroupData ItemGroupOID="DATATYPE" ItemGroupRepeatKey="ALL ELEMENT" TransactionType="Insert">
  <ItemDataPartialDate ItemOID="ID.PD">1959-12</ItemDataPartialDate>
  <ItemDataPartialTime ItemOID="ID.PT">12</ItemDataPartialTime>
  <ItemDataPartialDatetime ItemOID="ID.PDT">1959-12-11T12</ItemDataPartialDatetime>
  <ItemDataDurationDatetime ItemOID="ID.DDT">P03Y11M07DT16H</ItemDataDurationDatetime>
  <ItemDataIntervalDatetime ItemOID="ID.IDT">19591211/20031107T1624</ItemDataIntervalDatetime>
  <ItemDataIncompleteDatetime ItemOID="ID.NDT">1959---11T12:34:56-05:00</ItemDataIncompleteDatetime>
</ItemGroupData>
```

Therefore, when one starts the execution, the system will request to indicate which "flavor" is used in your dataset with clinical data:



?

Select whether the ODM file with clinical data works with non-typed or with typed ItemData

It uses non-typed ItemData (as in ODM 1.2) It uses TYPED ItemData (new as of ODM 1.3)

Never ask again in current session

OK

One should then select the correct "flavor". If one is 100% sure and does not want that the systems asks for it each time the mappings are executed, check the checkbox "Never ask again in current session".

One can also preset the choice in the "properties.dat" file when one will always work with files from the same (type of) EDC system, e.g.

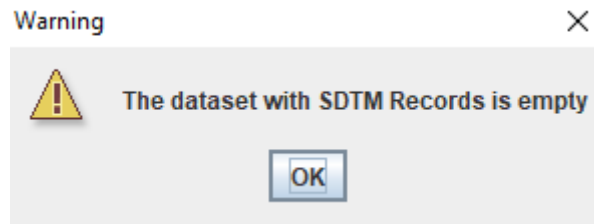
```
skipoamvalidation=true
# As of SDTM-ETL v.4.4: for EDC systems that export ODM in "Typed ItemData" format
odmtypeditemdata=true
# As of SDTM-ETL v.4.4: set user-defined "default" mapping descriptions
addefaultmappingdescriptions=true
# postpone ODM tree recalculation after loading a define.xml
```

indicating that the "default" is "typed ItemData".

Now, what happens if one makes the false choice?

In such a case, nothing special will happen, no errors will be generated, the mappings will just execute, but as, at least for the variables for which the value is extracted from the ODM file with

clinical data (all these where an "xpath(...)" statement occurs in the mapping script), no SDTM/SEND values will be generated. In the best case, a message:

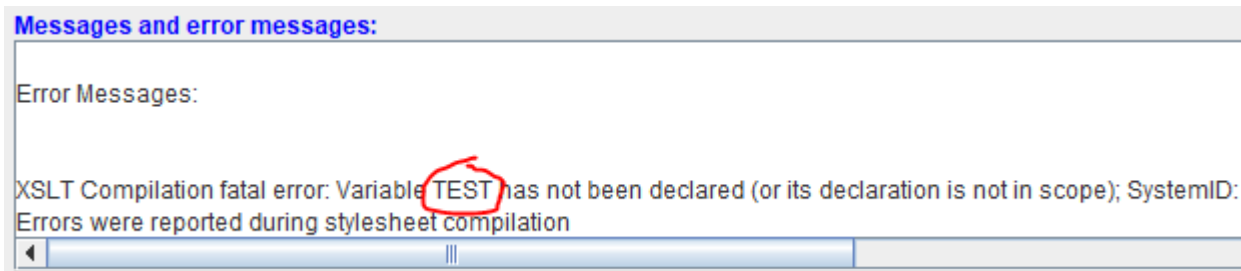


will appear.

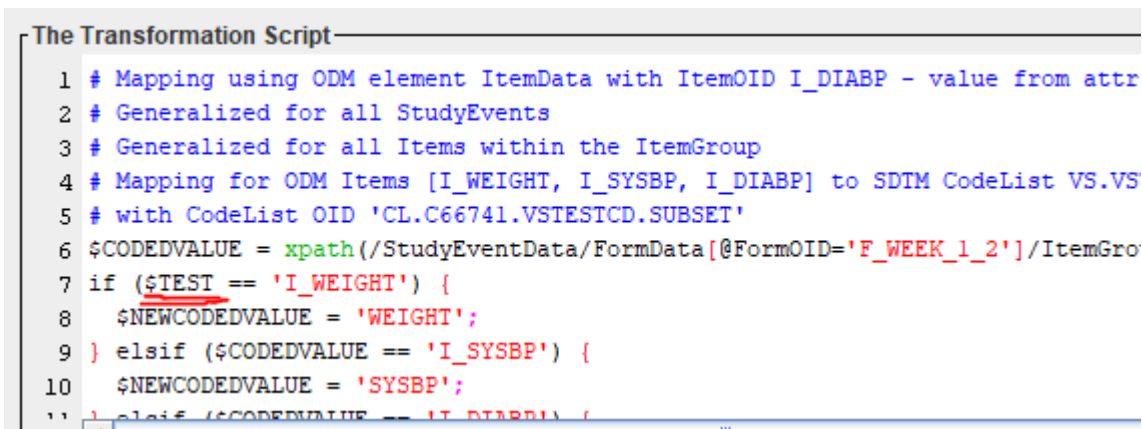
So, in the case that this message appears, one should first always ask oneself "is my clinical data in the 'untyped' or in the 'typed' flavor?" and "did I make the right choice when the system asked be about it?". There can of course also be other reasons why the generated datasets are empty.

- "Variable xxx has not been declared (or its declaration is not in scope)"

This error message means that a variable was used (i.e. read in an operation), but the variable was not declared before. E.g.:



where in the mapping script we find:



where we see that the variable "\$TEST" is used in an "if" statement, but was never declared before. In this case, it is obvious that "\$TEST" must be replaced by "\$CODEDVALUE".

Rather often, this error is at the end of the script, in the last assignment, e.g.:

Messages and error messages:

XSLT Compilation fatal error: Variable VS.VSTESTCD has not been declared (or its declaration is not in scope); System
XSLT Compilation fatal error: Variable VS.VSTESTCD has not been declared (or its declaration is not in scope); System
XSLT Compilation fatal error: Variable VS.VSTESTCD has not been declared (or its declaration is not in scope); System
Errors were reported during stylesheet compilation

Which is less obvious as the script is:

```
The Transformation Script
8  $NEWCODEDVALUE = 'WEIGH1';
9  } elseif ($CODEDVALUE == 'I_SYSBP') {
10 $NEWCODEDVALUE = 'SYSBP';
11 } elseif ($CODEDVALUE == 'I_DIABP') {
12 $NEWCODEDVALUE = 'DIABP';
13 } elseif ($CODEDVALUE == '') {
14 $NEWCODEDVALUE = '';
15 } else {
16 $NEWCODEDVALUE = 'NULL';
17 }
18 $RESULT = $NEWCODEDVALUE;
```

Which seems to be correct ...

Reason is that it is expected that the last statement in the mapping script always does the assignment to the SDTM/SEND variable that the script is meant for. In this case, the script is for VS.VSTESTCD, so the last assignment should be:

$VS.VSTESTCD = $NEWCODEDVALUE;$

P.S.: there is no need that variable names are all uppercase, except for the SDTM/SEND variable itself, it is just a coding style ...

The source for this kind of errors is often more difficult to find out, as the error message does not state in which script the error was made (as the script was already transformed to XSLT). Therefore, it is good custom to always test a mapping immediately after it was developed. If the error then occurs, it is clear that the source of it is the last mapping script that was developed.

- "No mapping provided for a 'looping' variable"

When one "instantiates" a domain for adding mappings for it, I.e. Drag-and-drop it from a template row to the bottom, a message appears, e.g.:

i After having created a study-specific instance of a domain (i.e. dataset), it is always recommended to first check and/or adapt the looping structure, i.e. the structure 'One record per VARIABLE1 per VARIABLE2 per ...'. The structure suggested by the SDTM-IG is NOT always suitable for your study. For example, for EG, if you do not have time points in visits the 'structure' will reduce to:
One record per EGTESTCD per VISITNUM per USUBJID
 instead of:
One record per EGPTNUM per EGTESTCD per VISITNUM per USUBJID

You can change the looping structure by using the menu 'Edit - SDTM Domain Properties', or by double clicking the first cell in the row designated 'CES:EG'.

Don't show me again

OK

Stating that one should first decide on the "structure" of the dataset, i.e. over which SDTM/SEND variables the system will iterate when generating the dataset. In most cases, it will be sufficient to have following "structures" for the following SDTM/SEND "classes":

Class	"Looping" variables	Structure as displayed
Findings	1. USUBJID 2. xxTESTCD	One record per xxTESTCD per USUBJID
Events	1. USUBJID 2. xxTERM	One record per xxTERM per USUBJID
Interventions	1. USUBJID 2. xxTRT	One record per xxTRT per USUBJID

where "xx" designates the domain code.

So, the first step after "instantiating" a domain, one should always at least check the "structure". This can be done by a double-click on the first cell (defining the dataset/domain) of the new generated row. E.g. for "EG":

TR	STUDYID	DOMAIN	USUBJID
RS	STUDYID	DOMAIN	USUBJID
VS	STUDYID	DOMAIN	USUBJID
FA	STUDYID	DOMAIN	USUBJID
SR	STUDYID	DOMAIN	USUBJID
RELREC	STUDYID	RDOMAIN	USUBJID
SUPPQUAL	STUDYID	RDOMAIN	USUBJID
CES:DM	STUDYID	DOMAIN	USUBJID
CES:LB	STUDYID	DOMAIN	USUBJID
CES:VS	STUDYID	DOMAIN	USUBJID
CES:EG	STUDYID	DOMAIN	USUBJID

leading to the dialog:

Name : EG
OID : CES:EG
Domain: EG
SAS Dataset Name: EG
Purpose : Tabulation
Comment:
External document for comment

IsReferenceData No (Subject-related data) Yes (Reference data)
Repeating : Yes (more than 1 record per subject) No (1 record per subject)

Standard: SDTMIG Version: 3.2 Status: Final Comment

def:ArchiveLocationID : Location.EG
def:Class : FINDINGS
KeySequence : Set domain keys and sequence
Description : ECG Test Results
Dataset will have no data:

Structure: Number of levels for looping : 2

Level 1 USUBJID
Level 2 EG.EGTESTCD

STUDYID Apply on Subject Level
STUDYID Apply on Subject Level
STUDYID Apply on Subject Level
STUDYID Apply on Subject Level

Validate

OK Cancel

where, in the lower part, the "looping variables" are defined.
When one then clicks the button "Validate" one sees:

Structure: Number of levels for looping : 2

Level 1 USUBJID
Level 2 EG.EGTESTCD

STUDYID Apply on Subject Level
STUDYID Apply on Subject Level
STUDYID Apply on Subject Level
STUDYID Apply on Subject Level

Validate One record per EG.EGTESTCD per USUBJID

Usually, for a "Findings" domain, this will be sufficient, as when one then uses "Generalize for all StudyEvents" (i.e. "visits") when developing the mapping for EGTESTCD, the system will automatically know that it needs to iterate over the visits anyway.

Some users however want to be more explicit, e.g. as they develop "special" mapping scripts for "VISIT"¹, and then change the "structure" e.g. to:

Structure: Number of levels for looping : 3

Level 1: USUBJID

Level 2: EG.VISIT

Level 3: EG.EGTESTCD

Apply on Subject Level

Apply on Subject Level

Apply on Subject Level

Apply on Subject Level

Apply on Subject Level

Validate One record per EG.EGTESTCD per EG.VISIT per USUBJID

In such a case, it is important that the chosen "structure" is logical and hierarchical correct. For example it doesn't make sense to have EG.EGTESTCD as the first level, and USUBJID as the second.

In the SDTM/SEND table on the right, one can easily recognize the looping variables, as they have a blue-cyan border, e.g.:

EG.EGSPID	EG.EGTESTCD	EG.EGTEST	EG.VISITNUM	EG.VISIT	EG.VISITDY
-----------	-------------	-----------	-------------	----------	------------

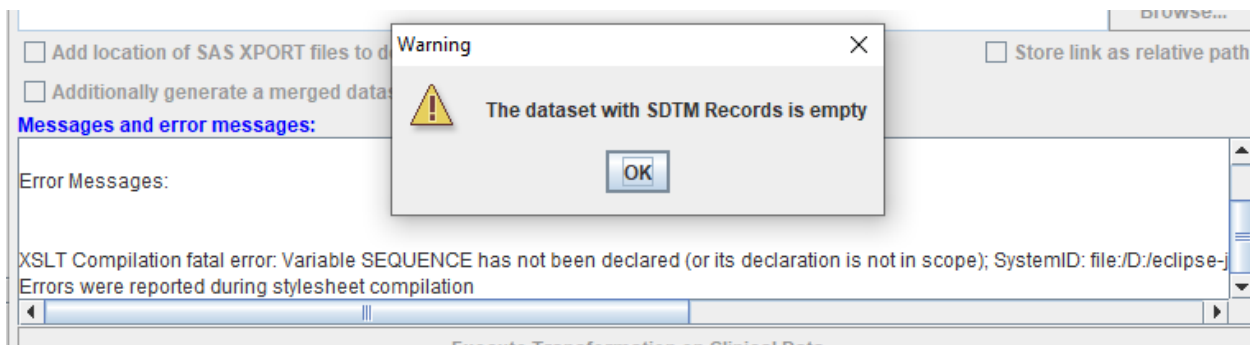
Important now is that one always has a mapping for each of the "looping" variables when executing the mappings on clinical data. Suppose for example that we added a mapping for "EG.VISIT" (usually derived from the ODM "StudyEventOID"), but not yet for EG.EGTESTCD.

When one then executes the mappings, the following warning will be displayed:

¹ This may e.g. happen when several "StudyEvents" represent a single "visit" (in the sense of SDTM/SEND), i.e. several "StudyEvents" are contracted into a single "visit".



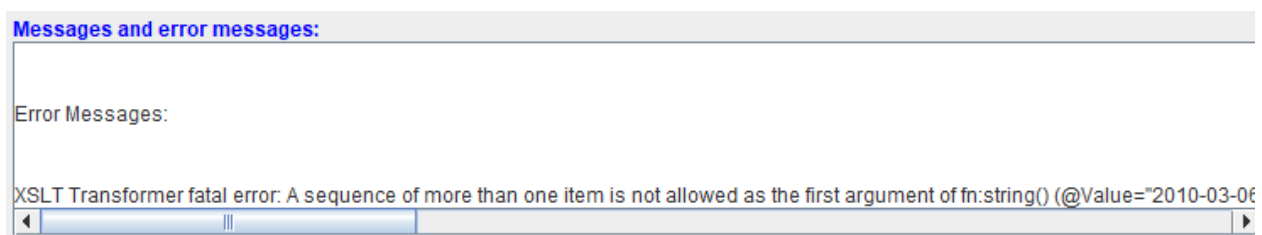
Some users however choose to ignore this warning and do continue (which is possible), leading to e.g.:



for which it is not immediately obvious what the source of the problem is.

P.S. Users have reported to us that in the case the "looping variables" have not been selected adequately, and for one of more of them no mapping has been provided, this had led to a "Fatal Error" during execution of the mapping.

- "A sequence of more than one item is not allowed as the first argument of fn:string()"



This is a typical error that often occurs and that users make desperate ...

What does it mean?

It means that for a variable (in this case DMDTC), a list of variables has been retrieved, whereas a single value is expected. For DM, which has a structure of "one record per subject", one can of course only have one DM collection date, not a list of them.

So, for this case, let us have a look at our mapping script:

```
Mapping Script Editor for SDTM Variable DM.DMDTC
1 # Mapping using ODM element ItemData with ItemOID I_VISIT
2 # Generalized for all StudyEvents
3 $DM.DMDTC = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGroupOID='IG_COMMON']/ItemData[@ItemOID='I_VISIT']/@Value);
```

We see that in the selection path, there is no condition for "StudyEventData" (selection conditions are always in square brackets), so that the script will retrieve all values of "I_VISIT" (which represents the visit date) from the lab form (that is however used in all or at least several visits). Maybe in the case, the date from the lab form was used because there was nothing better ...

What can one do in such a case?

* take care that only the visit in which the demographics was collected, which can be taken care of by not using the button "Generalize for all StudyEvents". This would e.g. lead to:

```
The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID I_VISIT
2 $DM.DMDTC = xpath(/StudyEventData[@StudyEventOID='BASELINE']/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGr
3
```

* take the first date that is in the list. E.g.:

```
The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID I_VISIT
2 # Generalized for all StudyEvents
3 $DATES = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGroupOID='IG_COMMON']/Item
4 $DM.DMDTC = $DATES[1];
```

This assumes however that in the source (the ODM) the visits are in chronological order

* select the earliest date from the list. E.g.:

```
The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID I_VISIT
2 # Generalized for all StudyEvents
3 $DATES = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGroupOID='IG_COMMON']/It
4 $DM.DMDTC = earliestdate($DATES);
```

Using the function "earliestdate". This however assumes that all the dates as retrieved from the ODM source is in ISO-8601 format.

- "Invalid byte 1 of 1-byte UTF-8 sequence"

Java works with Unicode / UTF-8 encoding, SAS Transport 5 (XPT format) with US-ASCII (a subset of UTF-8 encoding). These are rather different from the (mostly default) Microsoft "Codepoint 1255" or "Windows 1255" encoding, which is incompatible ...

We have seen this error occurring when users have either:

a) a source XML file that is not completely UTF-8 encoded

This can occur when the extraction from the database was not done in UTF-8 encoding, or when the XML was generated from Excel file without using the option "Tools - Web options - Encoding - Unicode (UTF-8)". See e.g. <https://www.youtube.com/watch?v=jdCEXU-9GHE>.

We have also seen this when users copied text from a Word or Excel document (which uses "Windows 1255" into a correctly encoded ODM-XML file or into a correctly CSV export from Excel (or anything else) to generate the ODM-XML file. In such cases, the result is an XML file with a mixture of encodings, which, as can be expected, causes problems.

b) an SDTM-ETL script in which text from e.g. a Word-document (typically using "Windows 1255" encoding) was copy-pasted. For example:

```
15 } elseif($ITEM = 'ML.CAL_MLOCCUR_DEC') {
16 $FA.FAOBJ = 'Was the solid meal < 500 calories or ≥ 500 calories?';
17 } elseif($ITEM = 'ML.FAT_MLOCCUR_DEC') {
18 $FA.FAOBJ = 'Was the meal low fat or high fat?';
19 } elseif($ITEM = 'ML.LIQUID_MLOCCUR_DEC') {
20 $FA.FAOBJ = 'Did the patient receive a liquid meal?';
21 } elseif($ITEM = 'ML.MLPAIN_DEC') {
22 $FA.FAOBJ = 'An increase in the patient's abdominal pain within 2 hours o:
```

Where the characters "≥" and the skew quote "'" are "Windows 1255" characters that are not only not supported by US-ASCII (when generating XPT files), but also can cause problems during the transformation. In such a case, one can better use e.g. ">=" and the "straight" quote.

Essentially, one should always be extremely careful when using copy-paste from MS files in applications that either use UTF-8 encoding or US-ASCII.