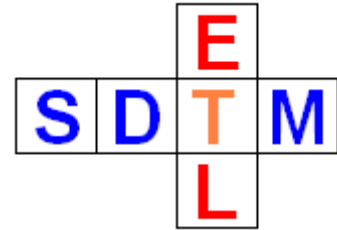


SDTM-ETL 5.0: Using the LOINC-SDTM-LB Mapping and similar functions



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Introduction

Many within the CDISC world still consider [LOINC](#) coding as a burden, due to the new FDA requirements that for laboratory tests at least, the LOINC code must be delivered in LBLOINC.

However, LOINC coding is not a burden, it is a blessing and a great opportunity.

LOINC is a pre-coordinated coding system for all kinds of medical tests, so not only for laboratory tests as many think. LOINC is used all over the world, and mandated to be used in laboratory reporting in many countries. So, if you get your lab results from the hospital or an external lab, there is a high probability that the LOINC code can be provided. But of course, one has to ask.

Due to the new FDA requirement, CDISC developed a mapping between the 2000+ most used LOINC codes and the SDTM lab domain. We have considerably extended this mapping to over 9,500 LOINC codes (over 18,000 mappings). These mappings also allows to automatically populate LBTESTCD, LBTEST, LBSPEC, LBLOC, LBMETHOD etc., and that is exactly what we have implemented in SDTM-ETL. This also means that when one has the LOINC code of the lab test (to be delivered by the lab of course), there is no need anymore to spend hours or days to puzzle out the categorization into the SDTM variables. One can simply auto-populate these variables starting from the LOINC code.

Also, the obtained LOINC can be used to fully automatically "standardize" results to either "SI" or "conventional" units. See the tutorial "[Performing Unit Conversions in SDTM-ETL](#)".

Getting the LOINC code and populating LBLOINC

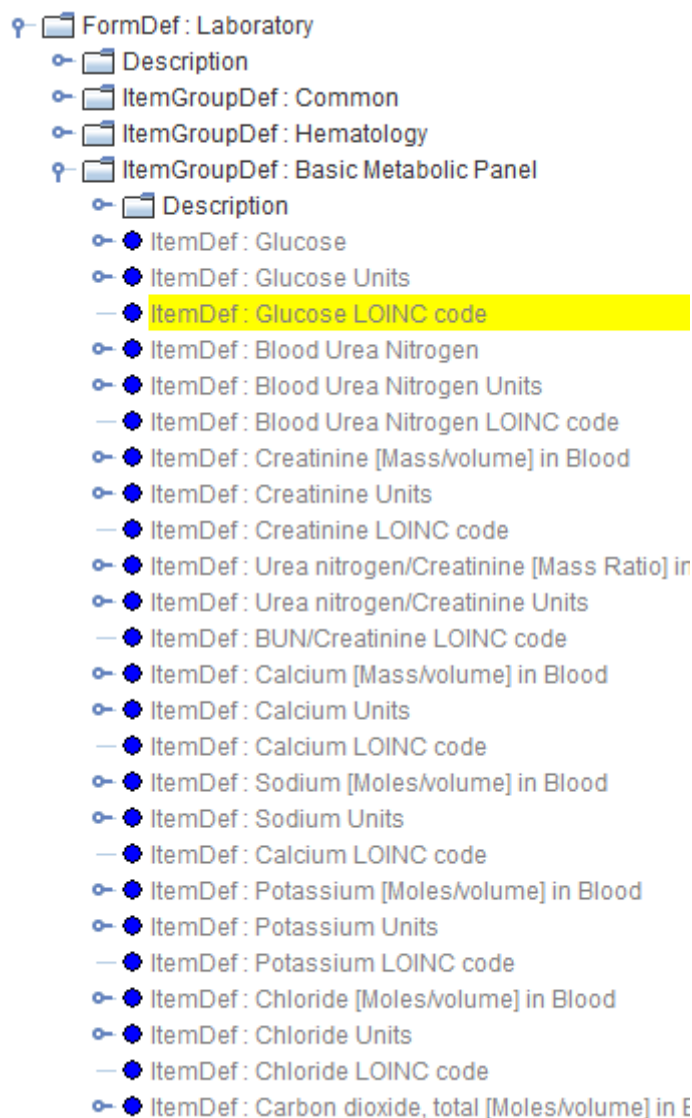
If one has the LOINC code of the lab test, it usually is already stored into the EDC system and thus can be exported into the ODM export. Using the normal drag-and-drop procedure, followed by using the wizards, one can then easily generate the mapping for LBLOINC.

In case LBLOINC was not provide it by the template, you can still add it using the menu "Insert – new SDTM Variable". Do also not forget to assign an "external codelist" (named "LOINC" of course) to the properties of the LBLOINC variable.

After that, you can choose to set the structure of the dataset either to the classic "one record per USUBJID per LBTESTCD".

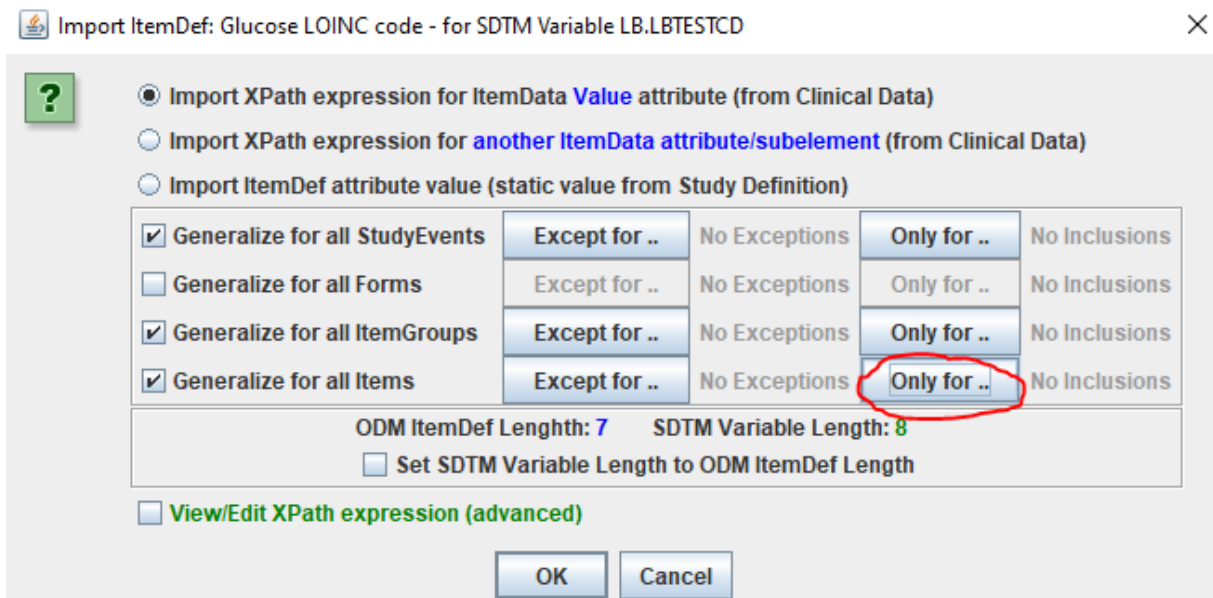
Generating the mappings for LBTESTCD, LBTEST, LBSPEC, LBMETHOD...

As the variable LBLOINC has been put near the end of the identifiers in LB (a major design errors in our opinion, as the LOINC code is the real identifier of the test, and NOT LBTESTCD), one cannot simple reuse \$LB.LBLOINC in the mappings for LB.LBTESTCD etc. So, one will need to just copy-paste the mapping for LBLOINC into the cells for LBTESTCD, LBTEST etc., or drag-and-drop again from the field in ODM for the LOINC code into the cells for **LBTESTCD**, **LBTEST** etc.. For example:

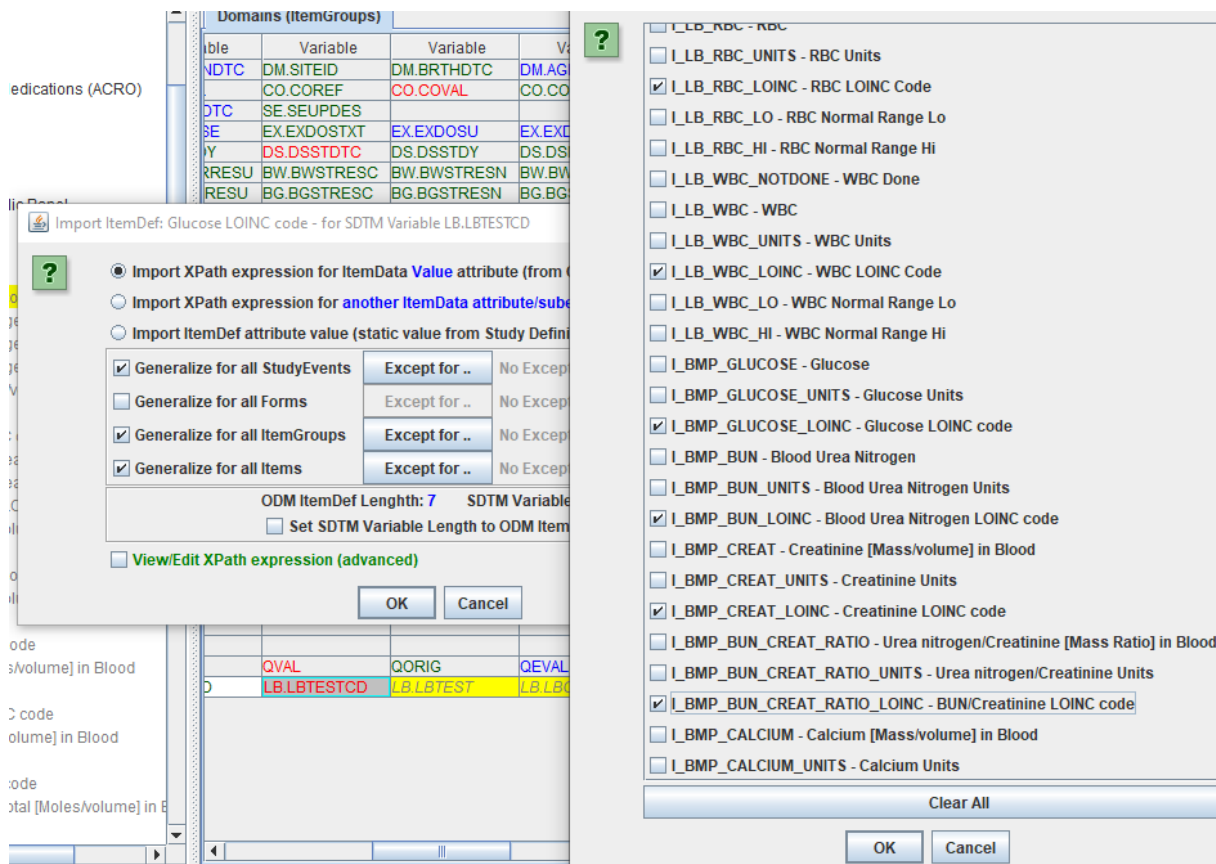


We see that there are several tests in the "Laboratory" form, each having a field for the result, for the unit, and for the LOINC code. When we then do a drag-and-drop of one of them to the

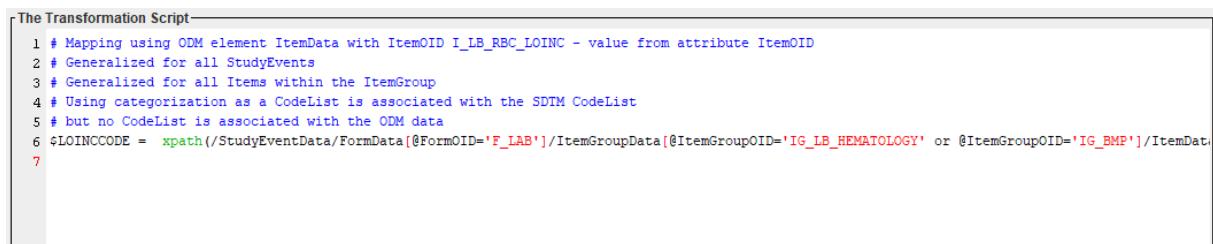
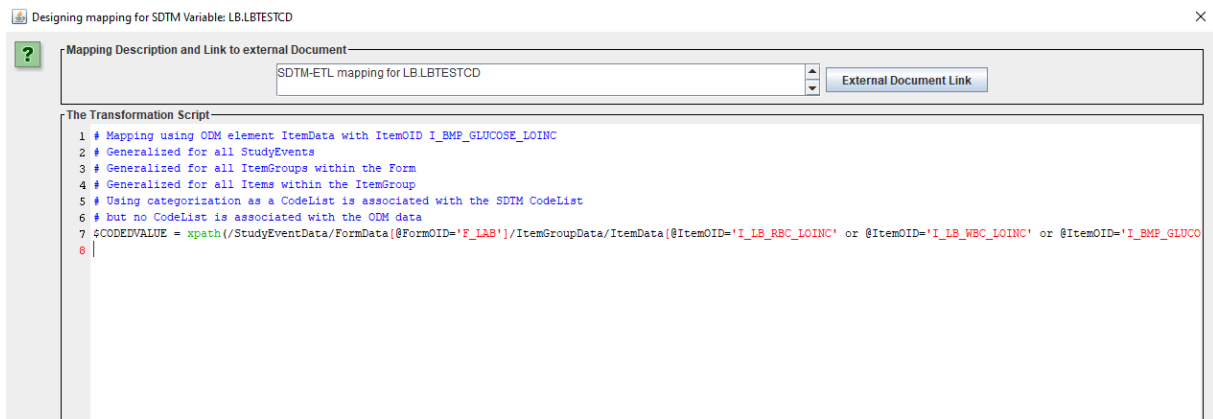
LBTESTCD cell, we select that we want to have this for all the visits ("Generalize for all StudyEvents") and for both of the groups ("Generalize for all ItemGroups") "hematology" and "basic metabolic panel":



And by clicking "Only for", then select all the LOINC Code" items



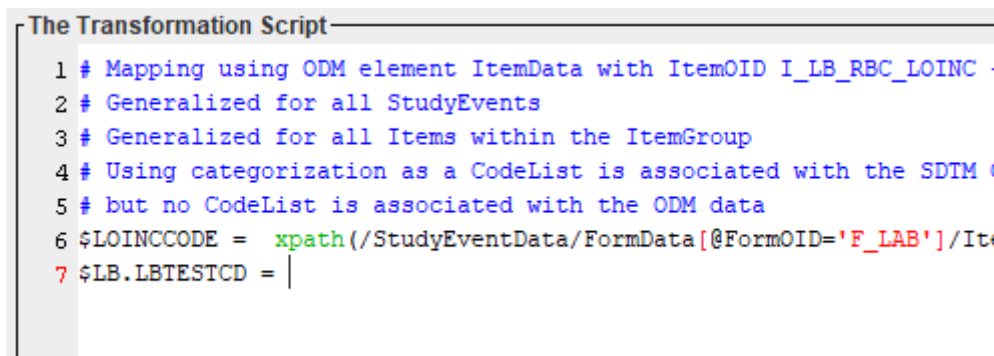
leading to the following mapping script:



Let us now go back to the cell for LBTESTCD.

We can now use one of the new functions of SDTM-ETL that will use a RESTful web service¹ to use the mapping between the most popular LOINC coded and SDTM-LB published by CDISC.

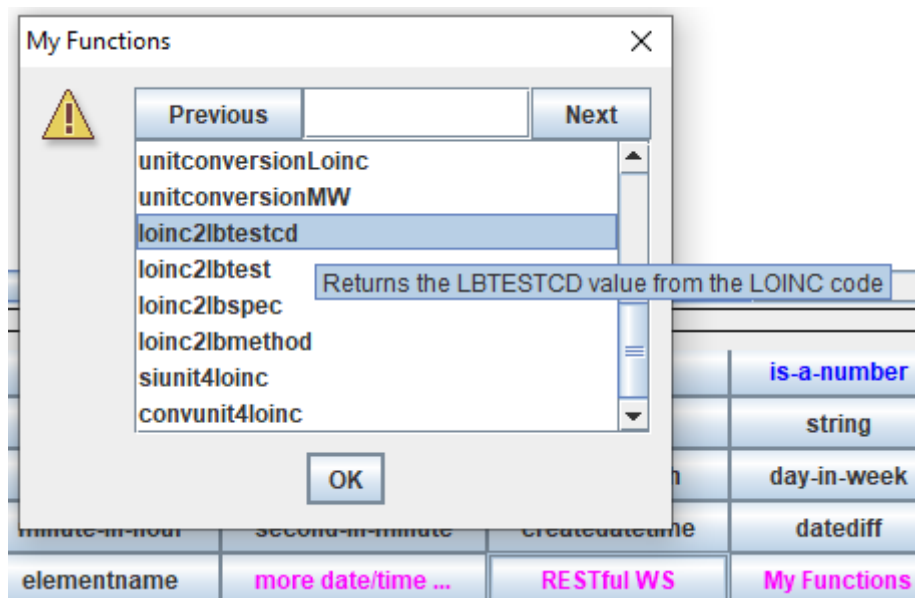
We just type the first part of the equation for retrieving the value of LBTESTCD from LBLOINC:



¹ The description of this RESTful web service can be found at: http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html

second-in-minute	createdatetime	datediff	
more date/time ...	RESTful WS	My Functions	

then click the button and then look for the function "loinc2lbtestcd":



It takes just one parameter, which is the LOINC code.

Clicking the entry "loinc2lbtestcd" will then add it to the mapping code. One then only needs to add the variable \$LOINCCODE as the argument, e.g.:

```

The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID IT.LOINCCODE
2 # Generalized for all StudyEvents
3 # Using categorization as a CodeList is associated with the SDTM C
4 # but no CodeList is associated with the ODM data
5 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/Item
6 $LB.LBTESTCD = rws:loinc2lbtestcd($LOINCCODE) ;

```

Very similar functions also exist for generating the mappings for LBTEST, LBSPEC and LBMETHOD starting from the LOINC code. These are:

- loinc2lbtest(string loinc2lbtestcd)
- loinc2lbspec(string loinc2lbtestcd)
- loinc2lbmethod(string loinc2lbtestcd)

It is advised to use the methods "loinc2lbspec" and "loinc2lbmethod" only when no explicit value for the specimen and/or analysis method is provided in the source data.

So, in our mapping scripts, we will then e.g. have:

```

The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID IT.LOINCCODE
2 # Generalized for all StudyEvents
3 # Using categorization as a CodeList is associated with the SDTM
4 # but no CodeList is associated with the ODM data
5 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/It
6 $LB.LBTEST = rws:loinc2lbtest($LOINCCODE) ;

```

```

The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID IT.LOINCCODE
2 # Generalized for all StudyEvents
3 # Using categorization as a CodeList is associated with the SDTM
4 # but no CodeList is associated with the ODM data
5 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/It
6 $SPECIMEN = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/Ite
7 if($SPECIMEN != '') {
8     $LB.LBSPEC = $SPECIMEN ;
9 } else {
10     $LB.LBSPEC = rws:loinc2lbspec($LOINCCODE) ;
11 }

```

```

The Transformation Script
1 # Mapping using ODM element ItemData with ItemOID IT.LOINCCODE
2 # Generalized for all StudyEvents
3 # Using categorization as a CodeList is associated with the SD
4 # but no CodeList is associated with the ODM data
5 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/
6 $LB.LBMETHOD = rws:loinc2lbmethod($LOINCCODE) ;

```

When we then execute the mappings on the clinical data, we get:

USUBJID	LB.LBTESTCD	LB.LBTEST	LB.LBCAT	LB.LBORRES	LB.LBORRESU	LB.LBSTRESN	LB.LBSTRESU	LB.LBLOINC	LB.LBSPEC
001	RBC	Erythrocytes		4.9	10 ⁶ /uL	4.9	10 ⁶ /uL	789-8	BLOOD
001	WBC	Leukocytes		6.2	10 ³ /uL	6.2	10 ³ /uL	6690-2	BLOOD
001	GLUC	Glucose		67.2	mg/dL	3.7301006	mmol/L	2339-0	BLOOD
001	UREAN	Urea Nitrogen		7.0	mg/dL	2.5	mmol/L	6299-2	BLOOD
001	CREAT	Creatinine		1.0	mg/dL	0.088403338	mmol/L	38483-4	BLOOD
001								44734-2	
001	CA	Calcium		8.75	mg/dL	2.1832427	mmol/L	49765-1	BLOOD
001	SODIUM	Sodium		140	mmol/L	140	mmol/L	2947-0	BLOOD
001	K	Potassium		4.2	mmol/L	4.2	mmol/L	6298-4	BLOOD
001	CL	Chloride		111	mmol/L	111	mmol/L	2069-3	BLOOD
001	CO2	Carbon Dioxide		26	mmol/L	26	mmol/L	20565-8	BLOOD
001	RBC	Erythrocytes		5.1	10 ⁶ /uL	5.1	10 ⁶ /uL	789-8	BLOOD
001	WBC	Leukocytes		6.4	10 ³ /uL	6.4	10 ³ /uL	6690-2	BLOOD
001	GLUC	Glucose		88.1	mg/dL	3.7800573	mmol/L	2339-0	BLOOD
001	UREAN	Urea Nitrogen		7.2	mg/dL	2.5714286	mmol/L	6299-2	BLOOD
001	CREAT	Creatinine		1.2	mg/dL	0.10608401	mmol/L	38483-4	BLOOD
001								44734-2	
001	CA	Calcium		8.9	mg/dL	2.2206697	mmol/L	49765-1	BLOOD
001	SODIUM	Sodium		137	mmol/L	137	mmol/L	2947-0	BLOOD
001	K	Potassium		4.0	mmol/L	4.0	mmol/L	6298-4	BLOOD

We see that all the values for LBTESTCD, LBTEST, LBSPEC and LBMETHOD (the latter not visible here) have automatically been populated, except for ... LOINC code 44734-2. The reason for this is that this LOINC code is NOT in the list of the 2000+ most popular test codes for which CDISC has published a mapping. This is also the reason that we decided to extend the mapping with several thousands of LOINC codes ourselves².

² Although we have already mappings for over 9,500 LOINC codes, we are still extending this. All additional mappings will also be incorporated into the RESTful web service. You can follow our progress at: http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html

In case no mapping for a LOINC code can be obtained from the RESTful web service (such as here for LOINC code 44734-2³), and the conversion cannot be fully automated, we need to do a little bit of manual work. First, we look up on the LOINC website what the LOINC code 44734-2 means. We find:

The screenshot shows the LOINC website interface. At the top, the browser address bar displays 'https://loinc.org/44734-2/'. Below the header, the LOINC code '44734-2' is listed next to its long common name 'Urea nitrogen/Creatinine [Mass Ratio] in Blood' and its status 'Active'. A section titled 'Part Descriptions' contains two entries: 'LP14492-0 Urea nitrogen' and 'LP32035-5 Creatinine'. Each entry includes a detailed description of the substance and its clinical relevance. The 'Urea nitrogen' description notes it is a waste product from protein metabolism, and the 'Creatinine' description notes it is a breakdown product of creatine phosphate. Sources are cited as Regenstrief LOINC and Human Metabolome Database.

Ok, this looks to be a pretty easy one. We then look up whether there is an entry for this in the CDISC Controlled Terminology. There are several ways to do it (e.g. by searching in the CDISC-CT Excel worksheet), but using the CDISC Library browser is of course more elegant:

The screenshot shows the CDISC Library browser interface. The search bar contains 'Urea/Creatinine'. The results show the 'Submission Value' as 'LBTESTCD', the 'Definition' as 'Terminology used for laboratory test codes of the CDISC Study Data Tabulation Model', the 'Nci Preferred Term' as 'CDISC SDTM Laboratory Test Code Terminology', and 'Synonyms' as 'Laboratory Test Code'. Below this, the 'SDTM Controlled Terminology Package 42 Effective 2020-06-26' is shown. A table lists the term 'Urea/Creatinine' with its submission value 'UREACRT', synonyms, definition, and preferred term 'Urea to Creatinine Ratio Measurement'.

Term	Submission Value	Synonyms	Definition	Preferred Term
C96645	UREACRT	Urea/Creatinine	A relative measurement (ratio or percentage) of the urea to creatinine in a biological specimen.	Urea to Creatinine Ratio Measurement

Finding that the LBTESTCD for this is "UREACRT". Similarly, we find that the corresponding LBTEST is "Urea/Creatinine".

We can now incorporate this information in our mapping script (here e.g. for LBTESTCD) using an if-statement:

³ The code 44734-2, with its mappings, has in the mean time being added to the RESTful web service.

```

6 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGr
7 # LOINC code 44734-2 is not covered by the LOINC to CDISC mapping
8 if($LOINCCODE = '44734-2') {
9     $TEMP = 'UREANCRT';
10 } else {
11     $TEMP = rws:loinc2lbtestcd($LOINCCODE);
12 }
13 print 'LBTESTCD from LOINC code = ' $TEMP;
14 $LB.LBTESTCD = $TEMP;

```

and similar for LBSPEC:

```

6 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroup
7 # LOINC code 44734-2 is not covered by the LOINC to CDISC mapping
8 if($LOINCCODE = '44734-2') {
9     $LB.LBSPEC = 'BLOOD';
10 } else {
11     $LB.LBSPEC = rws:loinc2lbspec($LOINCCODE);
12 }

```

Then executing the mappings again on the clinical data leads to:

USUBJID	LB.LBTESTCD	LB.LBTEST	LB.LBCAT	LB.LBORRES	LB.LBORRESU	LB.LBSTRESN	LB.LBSTRESU	LB.LBLOINC	LB.LBSPEC
001	RBC	Erythrocytes		4.9	10 ⁶ /uL	4.9	10 ⁶ /uL	789-8	BLOOD
001	WBC	Leukocytes		6.2	10 ³ /uL	6.2	10 ³ /uL	6690-2	BLOOD
001	GLUC	Glucose		67.2	mg/dL	3.7301006	mmol/L	2339-0	BLOOD
001	UREAN	Urea Nitrogen		7.0	mg/dL	2.5	mmol/L	6299-2	BLOOD
001	CREAT	Creatinine		1.0	mg/dL	0.088403338	mmol/L	38483-4	BLOOD
001	UREANCRT	Urea/Creatinine		9.6	g/g(creat)	9.6	g/g(creat)	44734-2	BLOOD
001	CA	Calcium		8.75	mg/dL	2.1832427	mmol/L	49765-1	BLOOD
001	SODIUM	Sodium		140	mmol/L	140	mmol/L	2947-0	BLOOD
001	K	Potassium		4.2	mmol/L	4.2	mmol/L	6298-4	BLOOD
001	CL	Chloride		111	mmol/L	111	mmol/L	2069-3	BLOOD
001	CO2	Carbon Dioxide		26	mmol/L	26	mmol/L	20565-8	BLOOD
001	RBC	Erythrocytes		5.1	10 ⁶ /uL	5.1	10 ⁶ /uL	789-8	BLOOD
001	WBC	Leukocytes		6.4	10 ³ /uL	6.4	10 ³ /uL	6690-2	BLOOD
001	GLUC	Glucose		68.1	mg/dL	3.7800573	mmol/L	2339-0	BLOOD
001	UREAN	Urea Nitrogen		7.2	mg/dL	2.5714286	mmol/L	6299-2	BLOOD
001	CREAT	Creatinine		1.2	mg/dL	0.10608401	mmol/L	38483-4	BLOOD
001	UREANCRT	Urea/Creatinine		9.3	g/g(creat)	9.3	g/g(creat)	44734-2	BLOOD
001	CA	Calcium		8.9	mg/dL	2.2206697	mmol/L	49765-1	BLOOD
001	SODIUM	Sodium		137	mmol/L	137	mmol/L	2947-0	BLOOD
001	K	Potassium		4.0	mmol/L	4.0	mmol/L	6298-4	BLOOD
001	CL	Chloride		119	mmol/L	119	mmol/L	2069-3	BLOOD
001	CO2	Carbon Dioxide		28	mmol/L	28	mmol/L	20565-8	BLOOD
001	RBC	Erythrocytes		5.4	10 ⁶ /uL	5.4	10 ⁶ /uL	789-8	BLOOD
001	WBC	Leukocytes		6.6	10 ³ /uL	6.6	10 ³ /uL	6690-2	BLOOD
001	GLUC	Glucose		73.2	mg/dL	4.0631453	mmol/L	2339-0	BLOOD
001	UREAN	Urea Nitrogen		7.3	mg/dL	2.6071429	mmol/L	6299-2	BLOOD
001	CREAT	Creatinine		0.9	mg/dL	0.079563005	mmol/L	38483-4	BLOOD
001	UREANCRT	Urea/Creatinine		8.2	g/g(creat)	8.2	g/g(creat)	44734-2	BLOOD
001	CA	Calcium		7.9	mg/dL	1.9711562	mmol/L	49765-1	BLOOD

Imagine that we did not have the LOINC code, and needed to puzzle out about suitable values of LBTESTCD, LBTEST, LBSPEC, LBMETHOD, ... ourselves ...! That is what I mean that LOINC is a blessing rather than a burden!

In the above screenshot with results, we also see that (surprise, surprise, ...) all values have been standardized to SI units in LBSTRESN/LBSTRESU. How this was fully automated is explained in the tutorial "[Performing Unit Conversions in SDTM-ETL](#)".

Generic mapping functions

One can also use the function "loinc2sdtmlb" that is taking two arguments:

loinc2sdtmlb(string loinccode, string sdtmvarname)

where the second argument is the SDTM variable name (which can also be a Non-Standard variable, but then need to be prefixed by "SUPPLB.").

For example:

```
$LB.LBTESTCD = loinc2sdtmlb('1751-7', 'LBTESTCD');
```

which is equivalent to using the function `rws:loinc2lbtested('1751-7')`.

The extra advantage of the current function "loinc2sdtmlb" is that it can also be used for the new "standard non-standard" variables (NSVs) such as "SUPPLB.LBRSSCL" (result scale).

The second argument is always the SDTM variable name for which the value need to be retrieved for. It also contains a number of "Supplemental Qualifier" variables. Here is a more complete list.

LBTESTCD (test code)	LBTEST (test name)	LBSPEC (location)	LBMETHOD (method)	LBTPPT (time point)	LBANMETH (analysis method)
LBPOS (position)	LBLOC (location)	LBFAST (fasting status)	SUPPLB. LBRESTYP (result type)	SUPPLB. LBRSSCL (result scale)	SUPPLB. LBSTOPO (test operational objective)
SUPPLB. LBLLOD (lower limit of detection)	SUPPLB. LBTSTCND (test condition)	SUPPLB. MTHSEN (method sensitivity)	SUPPLB. LBPTFL (point in time flag)	SUPPLB. LBPDUR (planned duration)	

Re-using existing mappings from an XML file ("caching")

Although the RESTful web service is fast, when there are thousands of lab data points, the generation of LBTESTCD, LBTEST, LBSPEC etc. using the above mentioned functions may still take considerable time.

In the folder "CDISC_CT" you will therefore find an XML file named "LOINC2SDTM_cached.xml" containing a few sample mappings. For example:

```

1  <?xml version="1.0" encoding="UTF-8"?>
2  <LOINC2SDTM>
3  <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
4    <LBTESTCD NCICode="C64431">ALB</LBTESTCD>
5    <LBTEST NCICode="C64431">Albumin</LBTEST>
6    <LBORRESU_Example NCICode="C42576">g/L</LBORRESU_Example>
7    <LBPOS/>
8    <LBLOINC>1751-7</LBLOINC>
9    <LBSPEC NCICode="C105706">SERUM OR PLASMA</LBSPEC>
10   <LBLOC/>
11   <LBMETHOD/>
12   <LBANMETH/>
13   <LBFAST/>
14   <LBTPT/>
15   <SUPPLB.LBPTFL>Y</SUPPLB.LBPTFL>
16   <SUPPLB.LBPDUR/>
17   <SUPPLB.LBRESTYP>MASS CONCENTRATION</SUPPLB.LBRESTYP>
18   <SUPPLB.LBRSLSCL>QUANTITATIVE</SUPPLB.LBRSLSCL>
19   <SUPPLB.LBTSTOPO/>
20   <SUPPLB.LBLLOD/>
21   <SUPPLB.LBTSTCND/>
22   <SUPPLB.LBMTHSEN/>
23   <Example_UCUM_Units>g/dL</Example_UCUM_Units>
24 </LOINC2SDTMMapping>
25 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
26   <LBTESTCD NCICode="C51946">RBC</LBTESTCD>
27   <LBTEST NCICode="C51946">Erythrocytes</LBTEST>
28   <LBORRESU_Example NCICode="C67308">10^12/L</LBORRESU_Example>

```

If there are LOINC codes for which you have many data points, you may add their mappings here as XML⁴. The easiest way to do so is by copy-paste results, by using the RESTful web service "LOINC to CDISC-SDTM-LB Extended Mapping" described at: http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html#loinc2lb_extended, and copying the obtained XML (starting from the LOINC2SDTMMapping tag) to the contents of the file "LOINC2SDTM_cached.xml".

The "generic" function "loinc2sdtmlb" will then first try to pick up the requested information from the file "LOINC2SDTM_cached.xml" and only use the RESTful web service when it cannot find the information in the XML file.

You are of course free to extend the file "LOINC2SDTM_cached.xml" with other mappings, including your own mappings when necessary.

Also, if you find a LOINC code that you need and that is not covered by the RESTful web service, please let us know and we will develop the mapping and add it.

Another way, available as of SDTM-ETL v.4.5 is to first retrieve all distinct LOINC values from a file with clinical data, and have the mappings (as RESTful web services responses) automatically populate (or extend) the "LOINC2SDTM_cached.xml" file. Like this for each distinct LOINC code in the clinical data, the RESTful web services is only called once, which, especially in the case of large files with clinical data, can save very much time.

The program to retrieve all distinct LOINC codes from a file with clinical data, and generate an XML file with the mappings, which can be used for caching, is named "LOINC2SDTMCacheFileExtender" and can be started from line command with:

⁴ Remark that the RWS still uses SDTMIG-3.3 "notation" for some of the variables, as it was developed in the pre-SDTMIG-3.4 era.

```
java -cp SDTM-ETL.jar  
com.xml4pharma.sdtmetl.loinc2sdtm.LOINC2SDTMCacheFileExtender
```

(as one line).

When you want to use this utility program often, you can of course also generate a "bat" file (e.g. named LOINC2SDTMCacheFileExtender.bat) and store the command in that file. A double-click in the explorer will then start the program.

When done so, the main window is displayed:

Extending the local LOINC-CDISC Mappings XML File

ODM File with Clinical Data:

Existing File with LOINC-CDISC Mappings in XML:

OID of the Item containing the LOINC Code:

LOINC2SDTM RESTful Web Service:

Edit

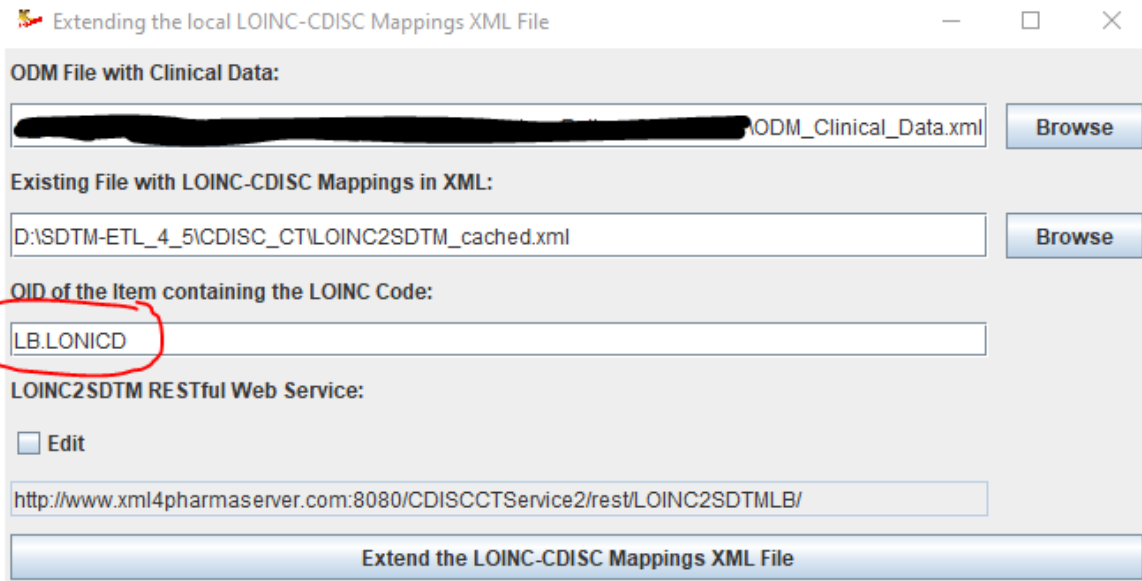
Extend the LOINC-CDISC Mappings XML File

The first text field then needs to be filled with the ODM file with clinical data from which you want to retrieve the distinct LOINC codes.

In the second text field, you provide the location of the "cache" file with mappings (usually already available in the "CDISC_CT" folder as "LOINC2SDTM_cached.xml", and which needs to be extended. You can however also want to generate a separate file.

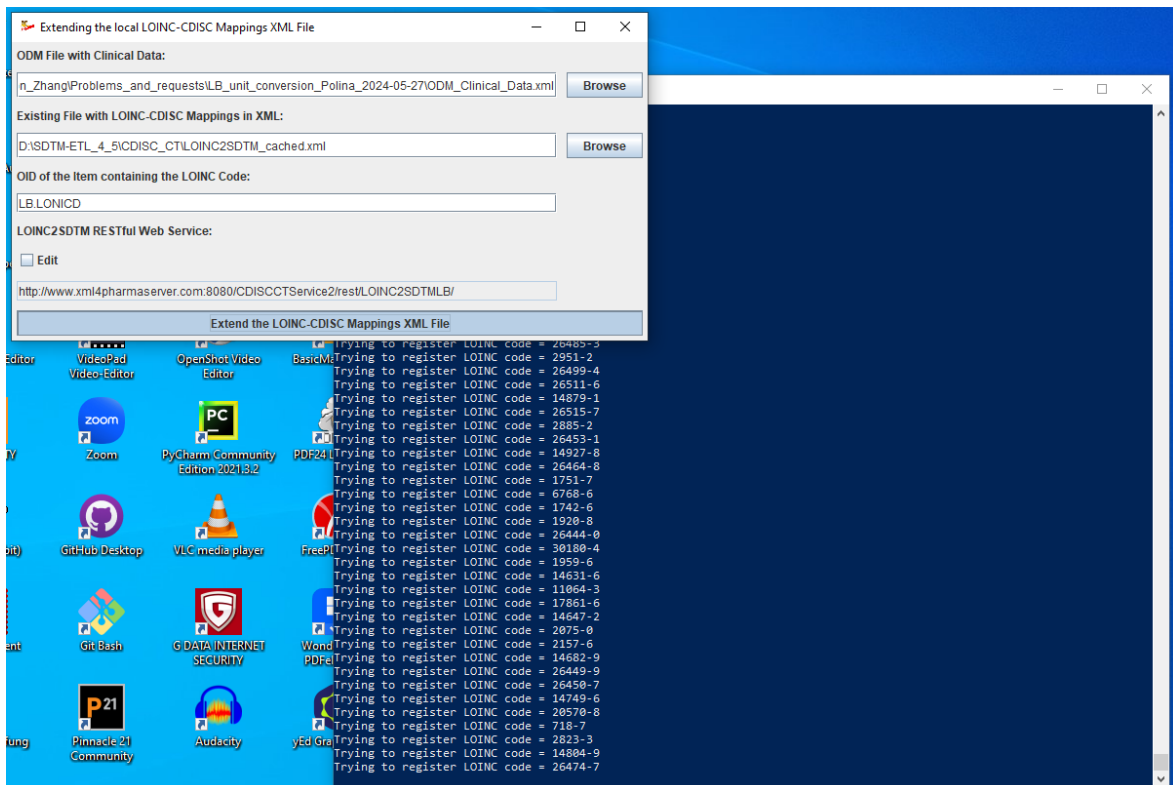
In the 3th text field you need to provide the ODM OID of the item with the LOINC code, which you can normally easily retrieve from the ODM tree as displayed in SDTM-ETL.

For example:



The "edit" checkbox is only necessary for customers who have their own instance of our LOINC to CDISC mapping RESTful web service installed, which then of course has another address.

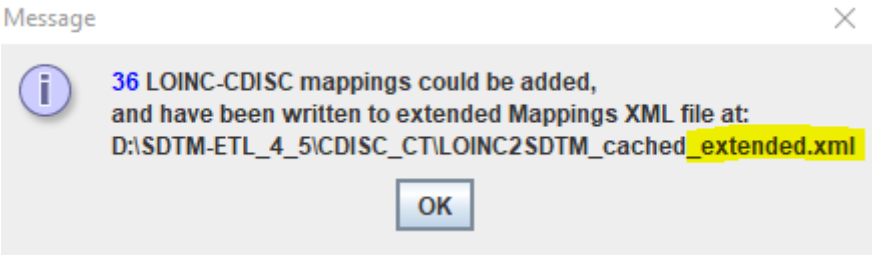
When then starting by clicking the "Extend the LOINC-CDISC Mapping XML File", one can follow the progress in the console:



and, when nearing completion:

```
Windows PowerShell
Mapping XML received from RESTful-WS =
<XML4PharmaServerWebServiceResponse ServerDateTime="2024-06-08T14:21:14" ><WebServiceRequest>http://www.xml4pharmaserver
.com:8080/CDISCTService2/rest/LOINC2SDTMLB/26453-1</WebServiceRequest><Response><LOINC2SDTMMapping MappingSource="CDISC
" TargetSDTMDomain="LB" ><LBTESTCD NCICode="C51946">RBC</LBTESTCD><LBTEST NCICode="C51946">Erythrocytes</LBTEST><LBORRESU
_Example NCICode="C67308">10^12/L</LBORRESU_Example><LBPOS></LBPOS><LBLOINC>26453-1</LBLOINC><LBSPEC NCICode="C12434">B
LOOD</LBSPEC><LBLOC></LBLOC><LBMETHOD></LBMETHOD><LBANMETH></LBANMETH><LBFAST></LBFAST><LBTP></LBTP><SUPPLB.LBPTFL>Y</SUP
PLB.LBPTFL><SUPPLB.LBPDUR></SUPPLB.LBPDUR><SUPPLB.LBRESTYP>NUMBER CONCENTRATION</SUPPLB.LBRESTYP><SUPPLB.LBRSLSCL>QUA
NTITATIVE</SUPPLB.LBRSLSCL><SUPPLB.LBTSTOPO></SUPPLB.LBTSTOPO><SUPPLB.LBLLD></SUPPLB.LBLLD><SUPPLB.LBLSLCL></SUPPLB.LB
TSTCND><SUPPLB.LBMTHSEN></SUPPLB.LBMTHSEN><Example_UCUM_Units>10*6/uL</Example_UCUM_Units></LOINC2SDTMMapping></Response
></XML4PharmaServerWebServiceResponse>
Trying to import mapping XML for LOINC code = 26453-1 into existing mapping DOM document
Response status = 200
Mapping XML received from RESTful-WS =
<XML4PharmaServerWebServiceResponse ServerDateTime="2024-06-08T14:21:14" ><WebServiceRequest>http://www.xml4pharmaserver
.com:8080/CDISCTService2/rest/LOINC2SDTMLB/14927-8</WebServiceRequest><Response><LOINC2SDTMMapping MappingSource="CDISC
" TargetSDTMDomain="LB" ><LBTESTCD NCICode="C64812">TRIG</LBTESTCD><LBTEST NCICode="C64812">Triglycerides</LBTEST><LBORRESU
_Example NCICode="C64387">mmol/L</LBORRESU_Example><LBPOS></LBPOS><LBLOINC>14927-8</LBLOINC><LBSPEC NCICode="C105706">
SERUM OR PLASMA</LBSPEC><LBLOC></LBLOC><LBMETHOD></LBMETHOD><LBANMETH></LBANMETH><LBFAST></LBFAST><LBTP></LBTP><SUPPL
B.LBPTFL>Y</SUPPLB.LBPTFL><SUPPLB.LBPDUR></SUPPLB.LBPDUR><SUPPLB.LBRESTYP>SUBSTANCE CONCENTRATION</SUPPLB.LBRESTYP><SUPPL
B.LBRSLSCL>QUANTITATIVE</SUPPLB.LBRSLSCL><SUPPLB.LBTSTOPO></SUPPLB.LBTSTOPO><SUPPLB.LBLLD></SUPPLB.LBLLD><SUPPLB.LBLSLCL></SUPPLB.LB
TSTCND><SUPPLB.LBMTHSEN></SUPPLB.LBMTHSEN><Example_UCUM_Units>mmol/L</Example_UCUM_Units></LOINC2SDTMMapping></Response>
Trying to import mapping XML for LOINC code = 14927-8 into existing mapping DOM document
Response status = 200
Mapping XML received from RESTful-WS =
<XML4PharmaServerWebServiceResponse ServerDateTime="2024-06-08T14:21:14" ><WebServiceRequest>http://www.xml4pharmaserver
.com:8080/CDISCTService2/rest/LOINC2SDTMLB/26464-8</WebServiceRequest><Response><LOINC2SDTMMapping MappingSource="CDISC
" TargetSDTMDomain="LB" ><LBTESTCD NCICode="C51948">WBC</LBTESTCD><LBTEST NCICode="C51948">Leukocytes</LBTEST><LBORRESU
_Example NCICode="C67255">10^9/L</LBORRESU_Example><LBPOS></LBPOS><LBLOINC>26464-8</LBLOINC><LBSPEC NCICode="C12434">BLOO
D</LBSPEC><LBLOC></LBLOC><LBMETHOD></LBMETHOD><LBANMETH></LBANMETH><LBFAST></LBFAST><LBTP></LBTP><SUPPLB.LBPTFL>Y</SUP
PLB.LBPTFL><SUPPLB.LBPDUR></SUPPLB.LBPDUR><SUPPLB.LBRESTYP>NUMBER CONCENTRATION</SUPPLB.LBRESTYP><SUPPLB.LBRSLSCL>QUANTI
TATIVE</SUPPLB.LBRSLSCL><SUPPLB.LBTSTOPO></SUPPLB.LBTSTOPO><SUPPLB.LBLLD></SUPPLB.LBLLD><SUPPLB.LBLSLCL></SUPPLB.LB
TSTCND><SUPPLB.LBMTHSEN></SUPPLB.LBMTHSEN><Example_UCUM_Units>10*3/uL</Example_UCUM_Units></LOINC2SDTMMapping></Response>
Trying to import mapping XML for LOINC code = 26464-8 into existing mapping DOM document
Response status = 200
Mapping XML received from RESTful-WS =
<XML4PharmaServerWebServiceResponse ServerDateTime="2024-06-08T14:21:14" ><WebServiceRequest>http://www.xml4pharmaserver
.com:8080/CDISCTService2/rest/LOINC2SDTMLB/2753-2</WebServiceRequest><Response><LOINC2SDTMMapping MappingSource="CDISC
" TargetSDTMDomain="LB" ><LBTESTCD NCICode="C45997">PH</LBTESTCD><LBTEST NCICode="C45997">pH</LBTEST><LBPOS></LBPOS><LBLO
INC>2753-2</LBLOINC><LBSPEC NCICode="C105706">SERUM OR PLASMA</LBSPEC><LBLOC></LBLOC><LBMETHOD></LBMETHOD><LBANMETH></LB
ANMETH><LBFAST></LBFAST><LBTP></LBTP><SUPPLB.LBPTFL>Y</SUPPLB.LBPTFL><SUPPLB.LBPDUR></SUPPLB.LBPDUR><SUPPLB.LBRESTYP>L
OG SUBSTANCE CONCENTRATION</SUPPLB.LBRESTYP><SUPPLB.LBRSLSCL>QUANTITATIVE</SUPPLB.LBRSLSCL><SUPPLB.LBTSTOPO></SUPPLB.LB
TSTOPO><SUPPLB.LBLLD></SUPPLB.LBLLD><SUPPLB.LBLSLCL></SUPPLB.LBLSLCL><SUPPLB.LBMTHSEN></SUPPLB.LBMTHSEN><Example_UCUM
_Units>[pH]</Example_UCUM_Units></LOINC2SDTMMapping></Response></XML4PharmaServerWebServiceResponse>
Trying to import mapping XML for LOINC code = 2753-2 into existing mapping DOM document
Done
```

and a message popping up:



So, when e.g. the original file LOINC2SDTM_cached.xml contained 2 mappings, the file LOINC2SDTM_cached_extended with contain additional 26 mappings, leading to a total of 38 mappings. E.g. (when opened in NotePad++):

```

LOINC2SDTM_cached_extended.xml x
1 <?xml version="1.0" encoding="UTF-8"?>
2 <LOINC2SDTM>
3   <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
4     <LBTESTCD NCICode="C64431">ALB</LBTESTCD>
5     <LBTEST NCICode="C64431">Albumin</LBTEST>
6     <LBORRESU_Example NCICode="C42576">g/L</LBORRESU_Example>
7     <LBPOS/>
8     <LBLOINC>1751-7</LBLOINC>
9     <LBSPEC NCICode="C105706">SERUM OR PLASMA</LBSPEC>
10    <LBLOC/>
11    <LBMETHOD/>
12    <LEANMETH/>
13    <LBFAST/>
14    <LBTP/>
15    <SUPPLB.LBPTFL>Y</SUPPLB.LBPTFL>
16    <SUPPLB.LBPDUR/>
17    <SUPPLB.LBRESTYP>MASS CONCENTRATION</SUPPLB.LBRESTYP>
18    <SUPPLB.LBRSLSCL>QUANTITATIVE</SUPPLB.LBRSLSCL>
19    <SUPPLB.LBSTOPO/>
20    <SUPPLB.LBLLOD/>
21    <SUPPLB.LBSTCND/>
22    <SUPPLB.LBMTHSEN/>
23    <Example_UCUM_Units>g/dL</Example_UCUM_Units>
24  </LOINC2SDTMMapping>
25  <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
47  <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
69  <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
91  <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
113 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
135 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
157 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
179 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
180   <LBTESTCD NCICode="C38037">BILI</LBTESTCD>
181   <LBTEST NCICode="C38037">Bilirubin</LBTEST>
182   <LBORRESU_Example NCICode="C48508">umol/L</LBORRESU_Example>
183   <LBPOS/>
184   <LBLOINC>14631-6</LBLOINC>
185   <LBSPEC NCICode="C105706">SERUM OR PLASMA</LBSPEC>
186   <LBLOC/>
187   <LBMETHOD/>
188   <LEANMETH/>
189   <LBFAST/>
190   <LBTP/>
191   <SUPPLB.LBPTFL>Y</SUPPLB.LBPTFL>
192   <SUPPLB.LBPDUR/>
193   <SUPPLB.LBRESTYP>SUBSTANCE CONCENTRATION</SUPPLB.LBRESTYP>
194   <SUPPLB.LBRSLSCL>QUANTITATIVE</SUPPLB.LBRSLSCL>
195   <SUPPLB.LBSTOPO/>
196   <SUPPLB.LBLLOD/>
197   <SUPPLB.LBSTCND/>
198   <SUPPLB.LBMTHSEN/>
199   <Example_UCUM_Units>umol/L</Example_UCUM_Units>
200 </LOINC2SDTMMapping>
201 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
223 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
245 <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">

```

When one is satisfied with the results, one can copy back the LOINC2SDTM_cached_extended.xml to file LOINC2SDTM_cached.xml, so that is automatically used when doing the SDTM generation.

Remark that the extraction of the distinct set of LOINC codes and getting the mappings from them is extremely fast. In our example case, the file with clinical data was 92 MB (several hundreds subjects), and the whole process took less than 10 seconds.

As one can think, then using this "cache" with LOINC-to-LB mappings, the execution time will be drastically reduced.

Creating the mapping without using a RESTful web service using the CDISC CSV file

In the ultimate case that one cannot use the RESTful web service, there is a second function.

It is using the CSV file, named "LOINC_to_LB_Mapping_Document_FINAL.csv" that was published by CDISC and can be found in the folder "CDISC-CT".

Using this function works nicely as well, but has two disadvantages:

- it is considerably slower, as the whole file needs to be parsed at each function call (the RESTful web service is 5-10 times faster, as the underlying database is indexed)
- the mappings are limited to those published by CDISC, which is far from sufficient (only 2000+ LOINC codes).

The function is named "loinc2sdtmlb_local" and has the same two arguments as the function "loinc2sdtmlb". The results are the same as for the "loinc2sdtmlb" are identical, except for that the "extended mappings" (developed by us) are of course not covered.

For example, for LBMETHOD:

```
6 $LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGroupC
7 $LB.LBMETHOD = loinc2sdtmlb_local($LOINCCODE, 'LBMETHOD');
```

Further work

We have also developed mappings for LOINC codes for COVID-19 tests to MB (Microbiology). A RESTful web service is also available for these mappings (see http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html#loinccorona2mb) but we have not added a function for this mapping yet to SDTM-ETL. The same applies for a mapping using VSLOINC (LOINC code for vital signs) and the SDTM-VS variables. Other mappings that are still in the mapping phase are for EG (ECG Test Results) and QS (Questionnaires). More may follow.