

Smart Submission Dataset Viewer: Web Services

By XML4Pharma Last update: 2018-12-15

Introduction

We have developed a number of "RESTful" based webservices¹, and have implemented these, together with an already existing webservice from the National Library of Medicine (Medline Plus Connect) in the "Smart Submission Dataset Viewer".

In this document, we explain and demonstrate the use of these web services in order to get additional information about table values in the SDTM/SEND/ADaM tables.

IMPORTANT

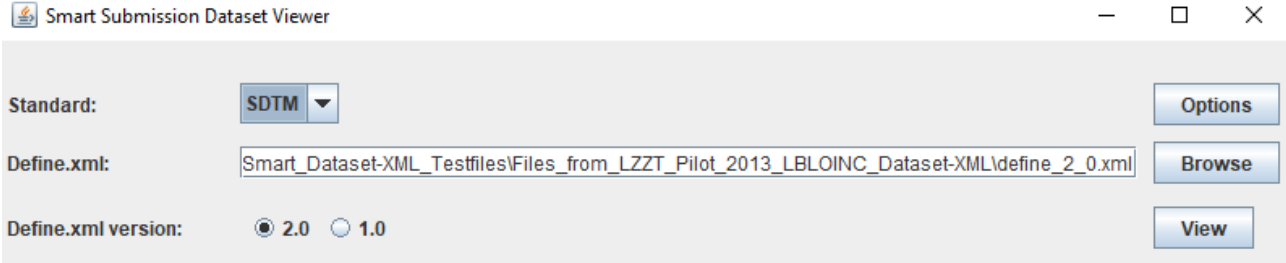
Web services connect to other computers on the internet. So in order to use them, your computer will need to be connected to the internet.

Part of the currently implemented web services use port 8080 on <http://www.xml4pharmaserver.com>, so your firewall might need to be configured to allow to communicate to port 8080 of the XML4PharmaServer service.

Example files

Of course you can immediately start trying out these web services using your own SDTM/SEND/ADaM Dataset-XML files, but for a jumpstart, you can best use the sample files in the directory "Files_from_LZZT_Pilot_2013_LBLOINC_Dataset-XML" can be obtained from our [documentation website](#).

So, after having started the software, select the "define.xml" file from this directory, and check the radiobutton "2.0" for "define.xml version":



The screenshot shows the 'Smart Submission Dataset Viewer' application window. It has a title bar with a standard icon, the text 'Smart Submission Dataset Viewer', and window control buttons (minimize, maximize, close). The main area contains three rows of controls. The first row is labeled 'Standard:' and has a dropdown menu currently showing 'SDTM', with an 'Options' button to its right. The second row is labeled 'Define.xml:' and has a text box containing the file path 'Smart_Dataset-XML_Testfiles\Files_from_LZZT_Pilot_2013_LBLOINC_Dataset-XML\define_2_0.xml', with a 'Browse' button to its right. The third row is labeled 'Define.xml version:' and has two radio buttons, '2.0' (which is selected) and '1.0', with a 'View' button to its right.

Now load a number of Dataset-XML files from the directory. For the demonstration, we only need "DM.xml", "LB.xml" and "VS.xml":

¹The entire specification and API of these web services can be found at:
<http://xml4pharmaserver.com/WebServices/index.html> .

Smart Submission Dataset Viewer

Standard: SDTM Options

Define.xml: Smart_Dataset-XML_Testfiles\Files_from_LZZT_Pilot_2013_LBLOINC_Dataset-XML\define_2_0.xml Browse

Define.xml version: ☒ 2.0 ☐ 1.0 View

C:\Smart_Dataset-XML_Testfiles\Files_from_LZZT_Pilot_2013_LBLOINC_Dataset-XML\DM.xml
C:\Smart_Dataset-XML_Testfiles\Files_from_LZZT_Pilot_2013_LBLOINC_Dataset-XML\LB.xml
C:\Smart_Dataset-XML_Testfiles\Files_from_LZZT_Pilot_2013_LBLOINC_Dataset-XML\VS.xml

Add

Now click the "Options" button, which opens the following dialog:

Options

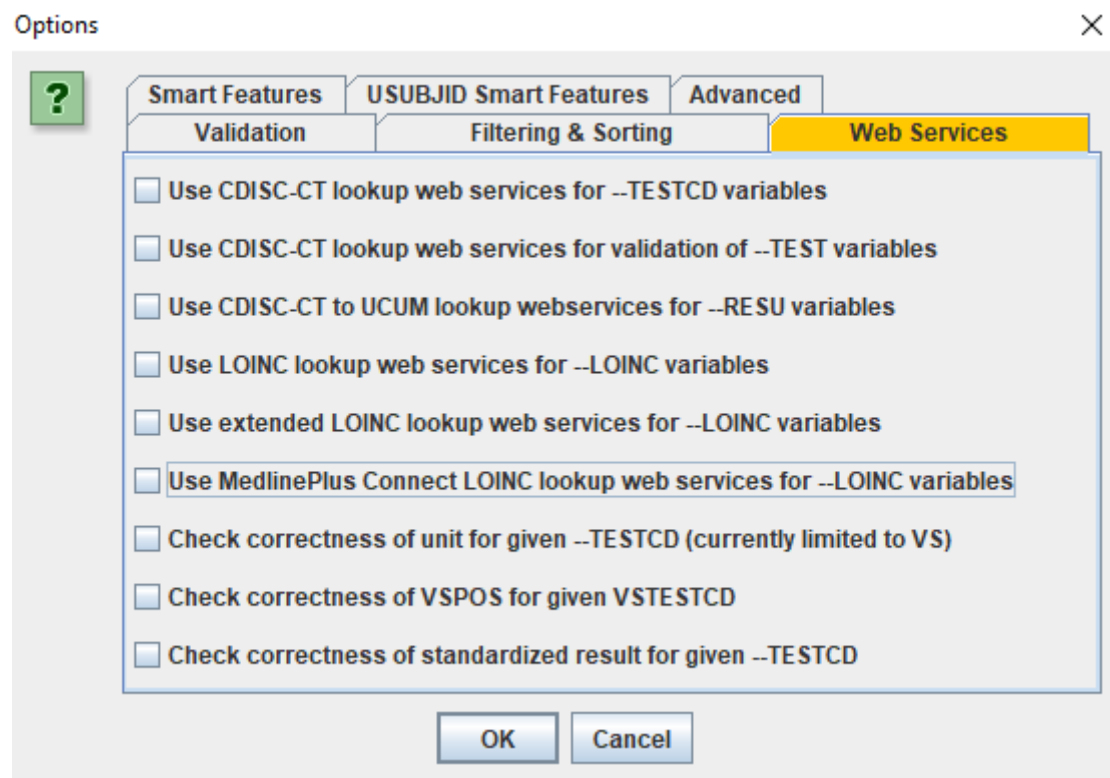
? Smart Features USUBJID Smart Features Advanced

Validation Filtering & Sorting Web Services

☒ Check Study OID against define.xml
☐ Check uniqueness of USUBJID in DM/ADSL dataset
☐ Check USUBJID versus DM/ADSL dataset
☐ Check dataType correctness
☐ Check age from birthdate and reference start date
☐ Check values against reference range
☐ Check values against codelist
☐ Check --DY values
☐ Check --STRESN/--STRESC relationship for FINDINGS datasets
☐ Check --ORRES/--STAT/--REASND/--DRVFL relationship for FINDINGS datasets
☐ Check uniqueness of USUBJID/SEQ combinatons - **COMPUTING INTENSIVE**

OK Cancel

You can switch on/off a number of options for validation, for filtering and sorting, for cross-domain interaction ("Smart Features"), but also for the use of web services. So, if you click the "Web Services" tab, the following options are presented:



Please note that by default, all the web services options are switched off. So, if you want to use them, you will need to check the checkbox, and then click "OK".

Currently (2015-01-25) the following web services have been implemented:

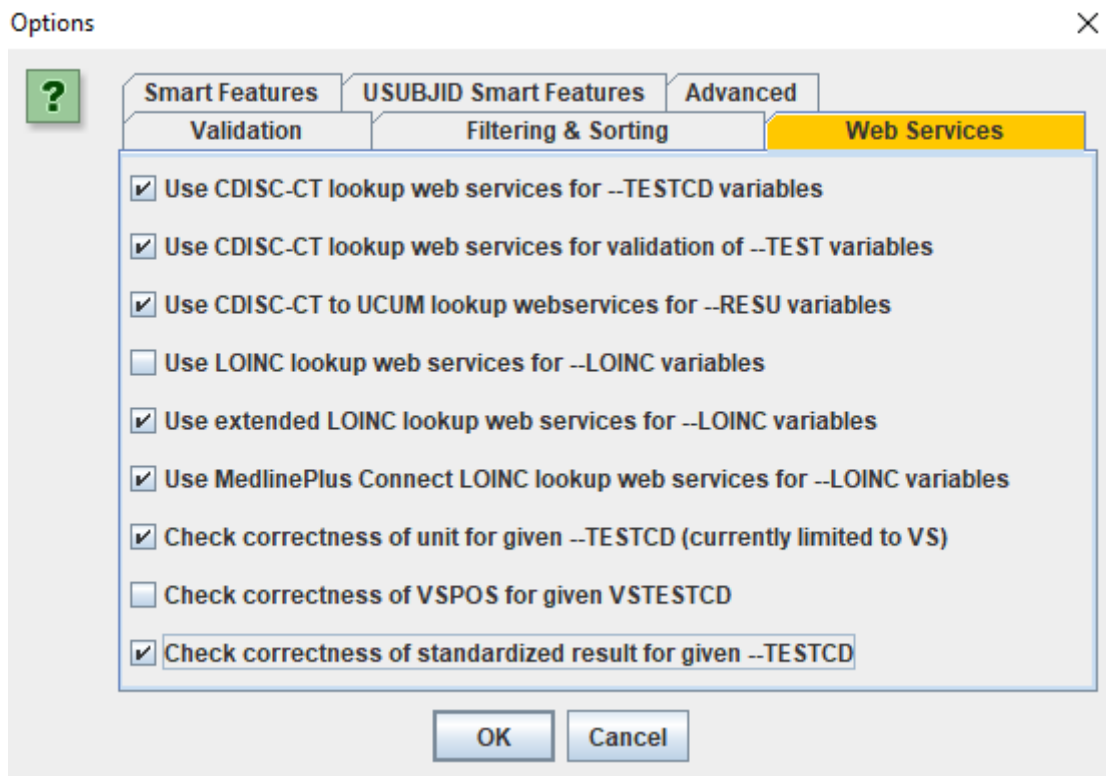
- CDISC-CT lookup services for –TESTCD variable:
 - when used, and the user hovers the mouse over cell with a test code, the web service is triggered, and the test name and the NCI code of the test are displayed as a tooltip
 - when the user right-clicks in the cell with a test code, additional information about the test is retrieved from the service and displayed in a separate window.
- CDISC-CT lookup services for validation of –TEST values.
- CDISC-CT UCUM lookup service for –RESU (e.g. --STRESU, --ORRESU) variable values
 - when used, and the user right-clicks in the cell with a unit, the web service is triggered and the corresponding UCUM is presented in a dialog message. If the unit is not a valid value from the CDISC [UNIT] codelist, a warning message is displayed
- LOINC lookup web service
 - If you have received your lab data including the LOINC code (you should), then it is strongly encouraged to also populate the SDTM variable LBLOINC, as this is the only way a reviewer (in your company or at the FDA) can find out which lab test was exactly performed (the CDISC LBTESTCD is ambiguous).
 - When used, and the user hovers the mouse over a cell with a LOINC value, the web service is triggered, and additional information (LOINC name and LOINC long name) is displayed as a tooltip.
- Medline Plus Connect web service for laboratory tests
 - When used, and the user right-clicks the cell with a LOINC code, the LOINC code is submitted to the "Medline Plus Connect" web services of the National Library of Medicine" that returns a URL (web address). On Windows, your favorite browser will open and automatically navigate to the web page of the National Library of Medicine, which displays a large amount of information about the selected text.
- Check correctness of the given unit (--ORRESU, --STRESU) for the given test code (--

TESTCD). This feature has currently only be implemented for VS (vital signs) datasets, as CDISC has not published testcode / unit lists for other domains than VS. As soon as more such lists will be available, these will be implemented as a web service.

- Check correctness of VSPOS (vital signs position) for the given VSTESTCD. For example "SITTING" is not a valid VSPOS for VSTESTCD=HEIGHT.
- Check correctness of standardized results (if any) for the given test code. Currently only implemented for VSSTRESC, RSSTRESC and CVFARS.

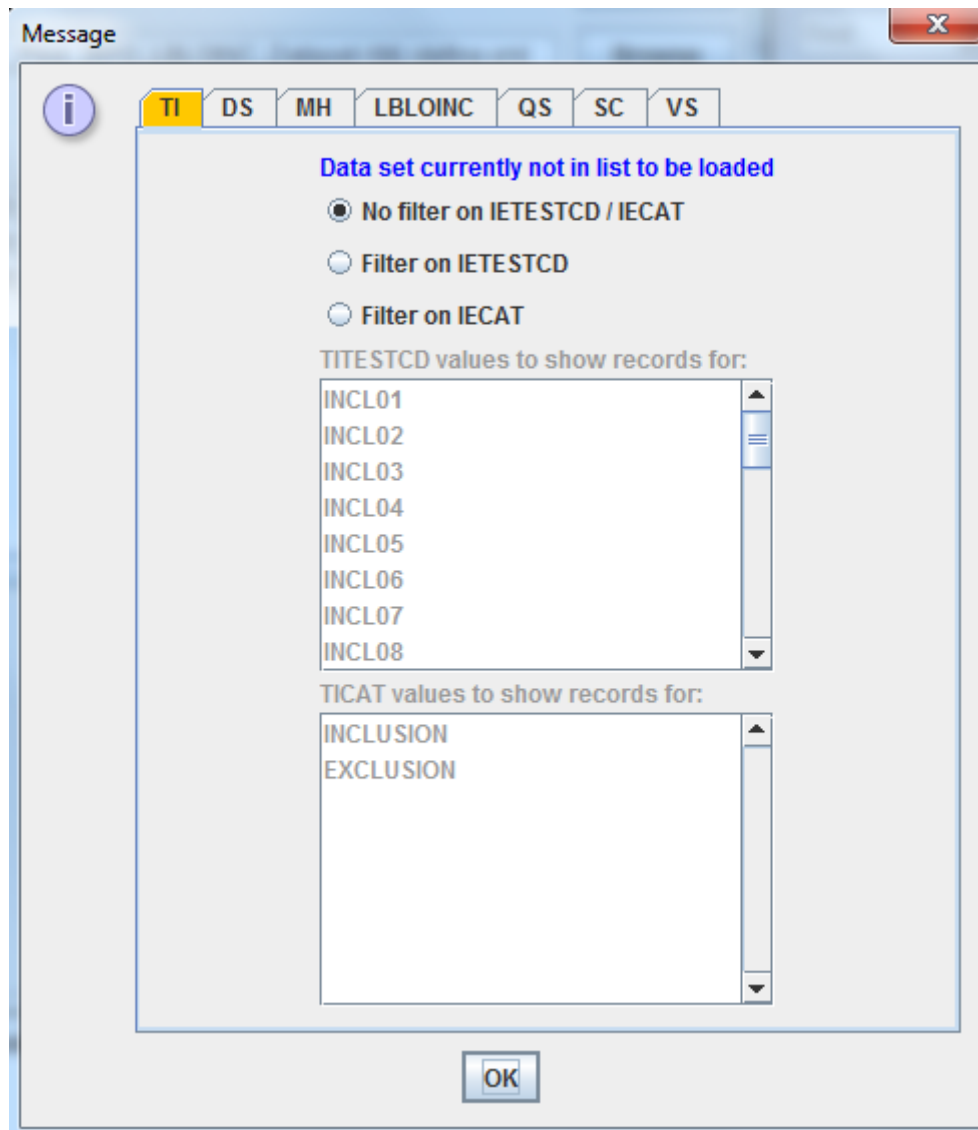
We will now demonstrate these web services.

First, check all the checkboxes, indicating that you want to use all the currently available web services:



and click OK to confirm.

Now, in the main window, click the button "Start". After a few moments, the following dialog will display:



This dialog allows you to filter data during loading. Especially for large data sets such as "LB" or "QS" it really makes sense to apply a filter, not only for computer memory reasons, but also as otherwise you might get a few million rows in your tables, which will be very hard to inspect or analyze. So especially for large data sets, it is recommended to always use a filter. The tabs that are displayed here indicate for which data sets filtering can be applied based either on the –TESTCD or –CAT variables².

When selecting the "LB" tab, we get:

²This only works when a CodeList is defined for the –TESTCD and/or –CAT variable in the define.xml.

Message ×

i TI DS MH **LB** QS SC VS

File: LB.xml - size = 64MB
Large file - you may want to apply a filter

☒ No filter on LBTESTCD / LBCAT
☐ Filter on LBTESTCD
☐ Filter on LBCAT

LBTESTCD values to show records for:

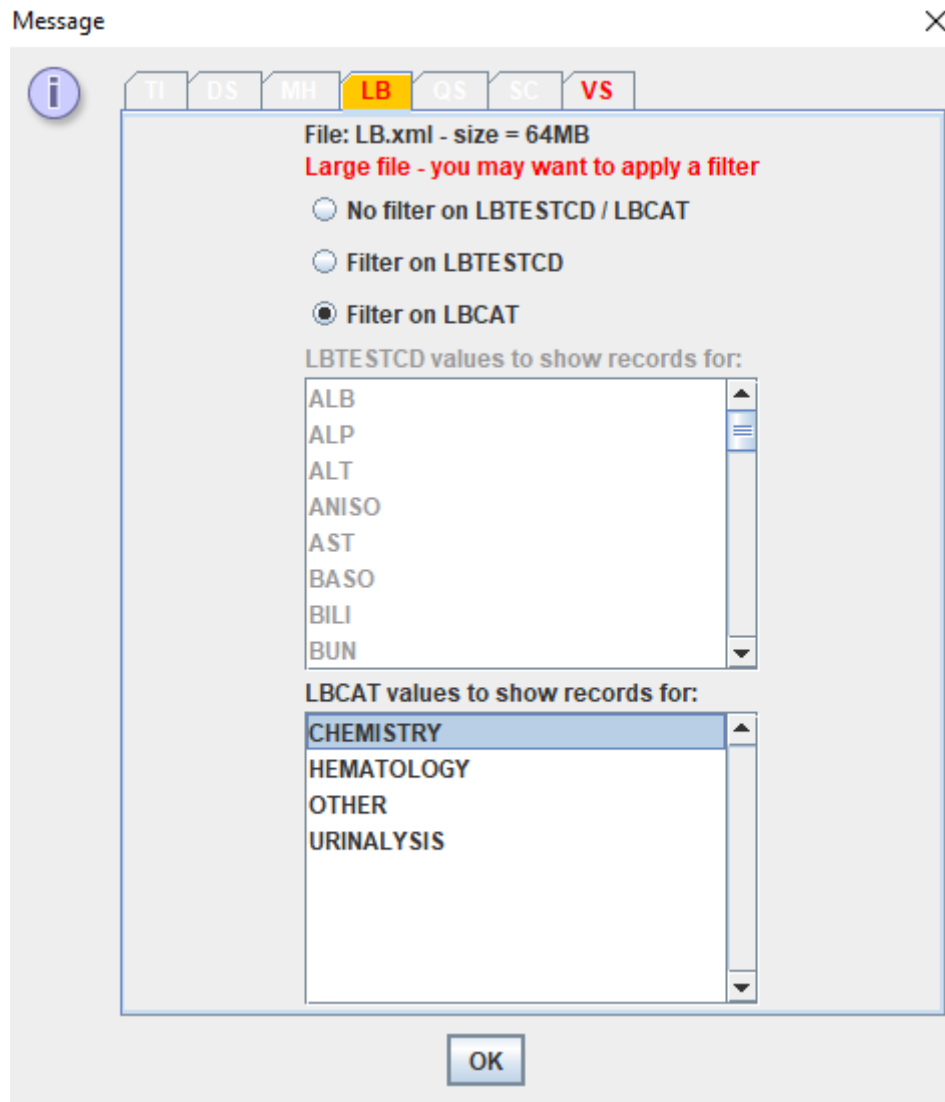
ALB	▲
ALP	☰
ALT	
ANISO	
AST	
BASO	
BILI	
BUN	▼

LBCAT values to show records for:

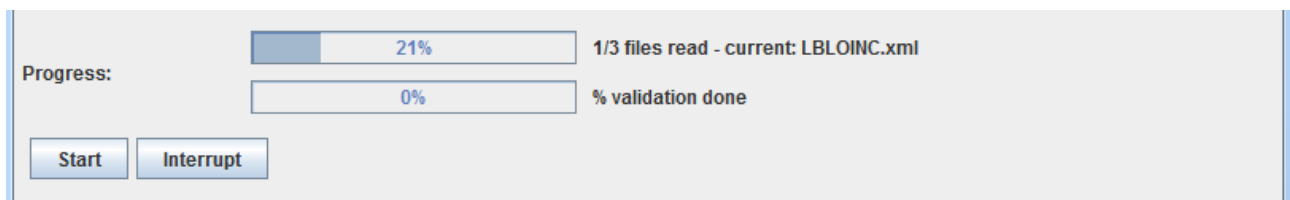
CHEMISTRY	▲
HEMATOLOGY	
OTHER	
URINALYSIS	▼

OK

We can either filter on one or more test codes (filter on TESTCD), or one or more of the categories (filter on LBCAT). In our case, and just for the demo, we will select on the category "CHEMISTRY":



After clicking "OK", the datasets will start to load. You can follow the progress on the "progress bar" near the bottom:



Once the tables are displayed, let us first inspect the "VS" (vital signs) table:

File Tools Search Options									
DM	LB	VS							
STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSPOS	VSORRES	VSORRESU	VSSTRES
CDISCPIL...	VS	01-701-1015	1	DIABP	Diastolic Bl...	SUPINE	64	mmHg	64
CDISCPIL...	VS	01-701-1015	2	DIABP	Diastolic Bl...	STANDING	83	mmHg	83
CDISCPIL...	VS	01-701-1015	3	DIABP	Diastolic Bl...	STANDING	57	mmHg	57
CDISCPIL...	VS	01-701-1015	4	DIABP	Diastolic Bl...	SUPINE	68	mmHg	68
CDISCPIL...	VS	01-701-1015	5	DIABP	Diastolic Bl...	STANDING	59	mmHg	59
CDISCPIL...	VS	01-701-1015	6	DIABP	Diastolic Bl...	STANDING	71	mmHg	71
CDISCPIL...	VS	01-701-1015	7	DIABP	Diastolic Bl...	SUPINE	56	mmHg	56
CDISCPIL...	VS	01-701-1015	8	DIABP	Diastolic Bl...	STANDING	51	mmHg	51
CDISCPIL...	VS	01-701-1015	9	DIABP	Diastolic Bl...	STANDING	61	mmHg	61
CDISCPIL...	VS	01-701-1015	10	DIABP	Diastolic Bl...	SUPINE	67	mmHg	67
CDISCPIL...	VS	01-701-1015	11	DIABP	Diastolic Bl...	STANDING	61	mmHg	61
CDISCPIL...	VS	01-701-1015	12	DIABP	Diastolic Bl...	STANDING	65	mmHg	65

When using with the web services, I usually move the "TEST" (here "VSTEST") to the right, as it is redundant – it is much better using the webservice, as this is more reliable:

File Tools Search Options										
DM	LB	VS								
STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
CDISCPIL...	VS	01-701-1015	1	DIABP	SUPINE	64	mmHg	64	64	mmHg
CDISCPIL...	VS	01-701-1015	2	DIABP	STANDING	83	mmHg	83	83	mmHg
CDISCPIL...	VS	01-701-1015	3	DIABP	STANDING	57	mmHg	57	57	mmHg
CDISCPIL...	VS	01-701-1015	4	DIABP	SUPINE	68	mmHg	68	68	mmHg
CDISCPIL...	VS	01-701-1015	5	DIABP	STANDING	59	mmHg	59	59	mmHg
CDISCPIL...	VS	01-701-1015	6	DIABP	STANDING	71	mmHg	71	71	mmHg
CDISCPIL...	VS	01-701-1015	7	DIABP	SUPINE	56	mmHg	56	56	mmHg
CDISCPIL...	VS	01-701-1015	8	DIABP	STANDING	51	mmHg	51	51	mmHg
CDISCPIL...	VS	01-701-1015	9	DIABP	STANDING	61	mmHg	61	61	mmHg
CDISCPIL...	VS	01-701-1015	10	DIABP	SUPINE	67	mmHg	67	67	mmHg
CDISCPIL...	VS	01-701-1015	11	DIABP	STANDING	61	mmHg	61	61	mmHg
CDISCPIL...	VS	01-701-1015	12	DIABP	STANDING	65	mmHg	65	65	mmHg

Also notice the highlighted rows, which are the "last non-empty observation before first treatment" records, calculated "on the fly" (there is no need for –LOBXFL in SDTM!).

If one now holds the mouse over a cell with a "VSTESTCD" value, the web service is triggered and additional information is displayed as a tooltip. For example for "DIABP":

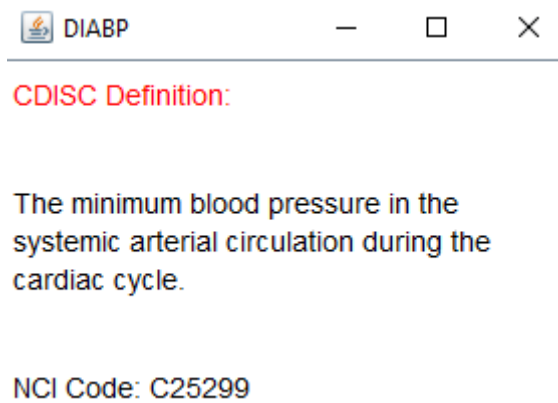
VS						
MAIN	USUBJID	VSSEQ	VSTESTCD	VSPOS	VSORRES	VSORRESU
	01-701-1015	1	DIABP	SUPINE	64	mmHg
	01-701-1015	2	DIABP	STANDING	83	mmHg
	01-701-1015	3	DIABP	DIABP (VSTESTCD) Diastolic Blood Pressure NCI: C25299		mmHg
	01-701-1015	4	DIABP			mmHg
	01-701-1015	5	DIABP			mmHg

It does not only show the test name, but also the corresponding NCI code.

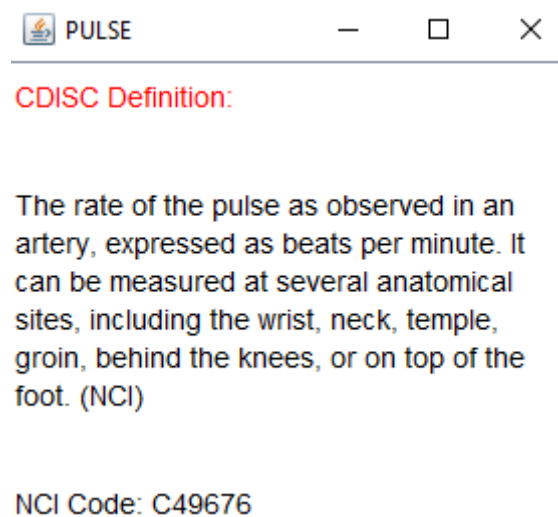
This opens great opportunities. For example, we hope that in the near future, we can query SHARE, the CDISC metadata repository, e.g. returning the information which units are allowed or usual for this test³.

³It does not make sense to submit a blood pressure with "ml" as unit, but this would currently go unnoticed, as "ml" is an allowed value from the [UNIT] codelist.

Now right-click the same cell. The web service is again triggered, and the following window pops up:



or e.g. for "PULSE":



Now let us navigate to the LB table by clicking the "LB" tab:

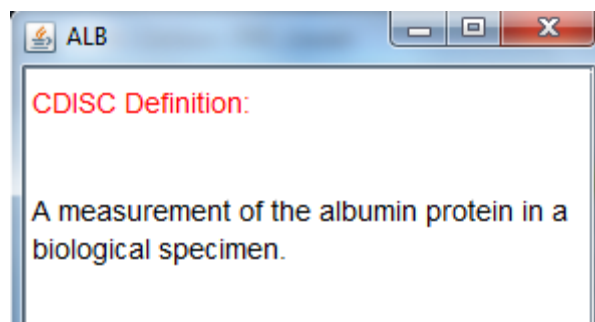
STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORN
CDISCPIL...	LB	01-701-1015	1	ALB	Albumin	CHEMISTRY	3.8	g/dL	3.3
CDISCPIL...	LB	01-701-1015	39	ALB	Albumin	CHEMISTRY	3.9	g/dL	3.3
CDISCPIL...	LB	01-701-1015	74	ALB	Albumin	CHEMISTRY	3.8	g/dL	3.3
CDISCPIL...	LB	01-701-1015	104	ALB	Albumin	CHEMISTRY	3.7	g/dL	3.3
CDISCPIL...	LB	01-701-1015	134	ALB	Albumin	CHEMISTRY	3.8	g/dL	3.3
CDISCPIL...	LB	01-701-1015	164	ALB	Albumin	CHEMISTRY	3.8	g/dL	3.3
CDISCPIL...	LB	01-701-1015	199	ALB	Albumin	CHEMISTRY	3.7	g/dL	3.3
CDISCPIL...	LB	01-701-1015	229	ALB	Albumin	CHEMISTRY	3.7	g/dL	3.3
CDISCPIL...	LB	01-701-1015	259	ALB	Albumin	CHEMISTRY	3.8	g/dL	3.3
CDISCPIL...	LB	01-701-1015	294	ALB	Albumin	CHEMISTRY	3.8	g/dL	3.3
CDISCPIL...	LB	01-701-1015	2	ALP	Alkaline Ph...	CHEMISTRY	34	U/L	35

Also here, when I have the web services available, I usually move the "LBTEST" column to the right, and instead move the "LBLOINC" column to the left, as this is an important variable.

Again, hovering the mouse over a cell with a LBTESTCD value, additional information is displayed:

File Tools Search Options							
DM	LB	VS					
STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBCAT	LBORRES	LBORRE
CDISCPIL...	LB	01-701-1015	1	ALB	CHEMISTRY	3.8	g/dL
CDISCPIL...	LB	01-701-1015	39	ALB	CHEMISTRY	3.9	g/dL
CDISCPIL...	LB	01-701-1015	74	ALB	CHEMISTRY	3.8	g/dL
CDISCPIL...	LB	01-701-1015	104	ALB	ALB (LBTESTCD)	RY	3.7
CDISCPIL...	LB	01-701-1015	134	ALB	Albumin	RY	3.8
CDISCPIL...	LB	01-701-1015	164	ALB	NCI: C64431	RY	3.8
CDISCPIL...	LB	01-701-1015	199	ALB	CHEMISTRY	3.7	g/dL
CDISCPIL...	LB	01-701-1015	229	ALB	CHEMISTRY	3.7	g/dL
CDISCPIL...	LB	01-701-1015	259	ALB	CHEMISTRY	3.8	g/dL

and a right mouse click provides:



However, when hovering the mouse over an LBLOINC cell (which I usually move to the left, as it is the REAL identifier of the test), another web service is triggered and the most important information about the LOINC test code is displayed as a tooltip:

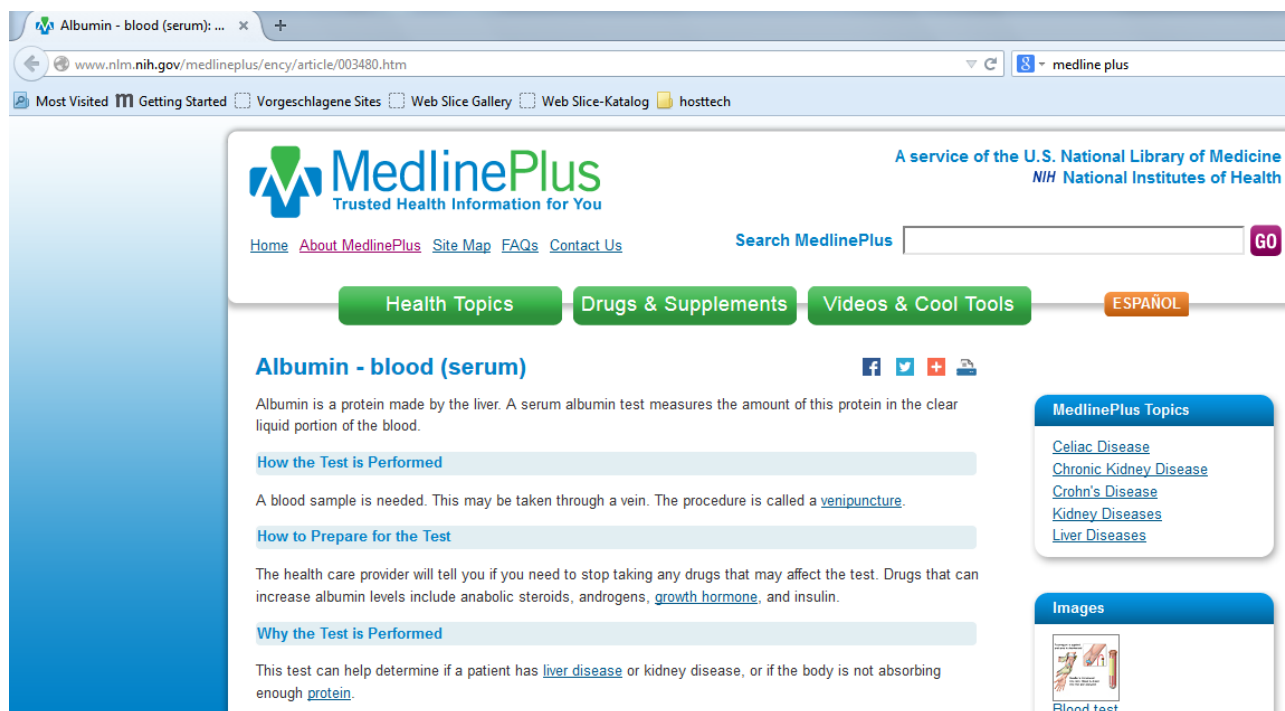
LBSEQ	LBTESTCD	LBLOINC	LBCAT	LBORRES	LBORRESU	LBORNRL0	LBORNRH
1	ALB	1751-7	CHEMISTRY	3.8	g/dL	3.3	4.9
39	ALB	1751-7	CHEMISTRY	3.9	g/dL	3.3	4.9
74	ALB	1751-7	CHEMISTRY	3.8	g/dL	3.3	4.9
104	ALB	1751-7	1751-7 (LBLOINC) LOINC Name: Albumin:MCnc:Pt:Ser/Plas:Qn LOINC Common Name: Albumin [Mass/volume] in Serum or Plasma Component/Compound: Albumin Property: MCnc Time Aspect: Pt System: Ser/Plas Scale: Qn Example UCUM Units: g/dL				
134	ALB	1751-7					
164	ALB	1751-7					
199	ALB	1751-7					
229	ALB	1751-7					
259	ALB	1751-7					
294	ALB	1751-7					
2	ALP	6768-6					
40	ALP	6768-6					
75	ALP	6768-6	CHEMISTRY	4.1	U/L	3.5	11.5

The full LOINC name is given: "Albumin:MCnc:Pt:Ser/Plas:Qn"⁴ meaning "A quantitative albumin test as a mass concentration in serum/plasma as a point in time". Each LOINC code uniquely describes a laboratory test (there are over 78,000 of them), which is unfortunately not true for the CDISC-CT codes (LBTESTCD).

⁴This full name consists of 5 fields, separated by a colon (":") representing the 5 dimensions of a LOINC code.

Remark here that you can choose between a "simple" LOINC lookup (giving the most essential information only) and the "extended" LOINC lookup (giving the above information).

When one right-clicks a cell with a LBLOINC value, the "Medline Plus Connect" web service from the National Library of Medicine is triggered, submitting the LOINC code to the service, and after a few seconds⁵, your favorite browser will open and display extensive information about the given test as provided by the National Library of Medicine. E.g. For "1751-7":



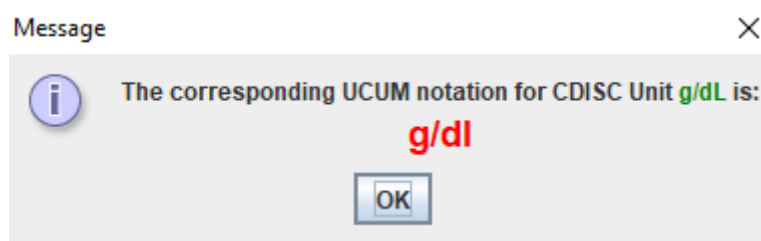
As this is just a normal web page, you can follow its links, providing you even more information about the test.

Just for a good understanding, the MedlinePlus Connect service for laboratory tests does not accept CDISC-CT codes, as these do not uniquely identify laboratory tests. Only LOINC codes are accepted. Also notice that the use of LOINC codes for laboratory tests is mandated by the US "Meaningful Use" program, and in many countries for the use of electronic health records – CDISC codes are never used.

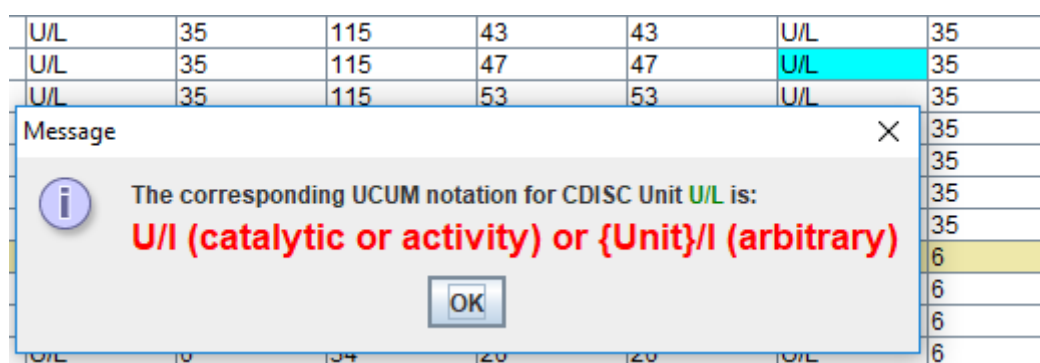
Now, have a look at the LBORRESU column. This provides the "original result units" which is bound to the CDISC-CT codelist [UNIT]. In future however, CDISC will definitely need to move to the UCUM notation for units, not only because the whole medical industry is using UCUM units (the use of UCUM is mandated in EHRs based on HL7-CDA and by "Meaningful Use"), but also for FDA-internal purposes. For example, the use of UCUM notation for units is mandated in "Structured Product Label" (SPL).

If one right-clicks on the LBORRESU cell with "g/dL" the following message shows up:

⁵We have noticed that this web service is not always 100% available, so you might find cases where nothing seems to happen. This can e.g. happen when the service is down or slow.



This is nothing spectacular, as some of the CDISC units are very similar to the UCUM units (also "g/dL" is allowed in UCUM). On the other hand, some CDISC units are ambiguous, like e.g. "U" which is both used for "arbitrary units" (e.g. anything arbitrary) as for the unit of catalytic activity (umol/min). So if we encounter "U/L", it will depend on the kind of test that was performed what the meaning of "U/L" is. Therefore, when "U/L" is right-clicked, the following message will be displayed:



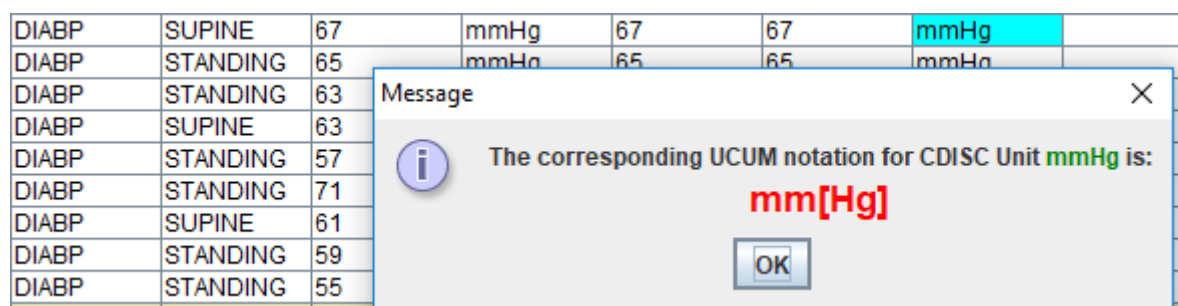
In this case, probably "catalytic activity unit" (1U = 1 umol/min) was meant, as the test is "ALP" which is:

ALP	6768-6	CHEMIST
ALP	6768-6	CHEMIST
ALP	ALP (LBTESTCD)	EMIST
ALP	Alkaline Phosphatase	EMIST
ALP	NCI: C64432	EMIST

and "alkaline phosphatase" is an enzyme, so the test is about catalytic activity.

A few interesting ones can also be found in the "VS" table.

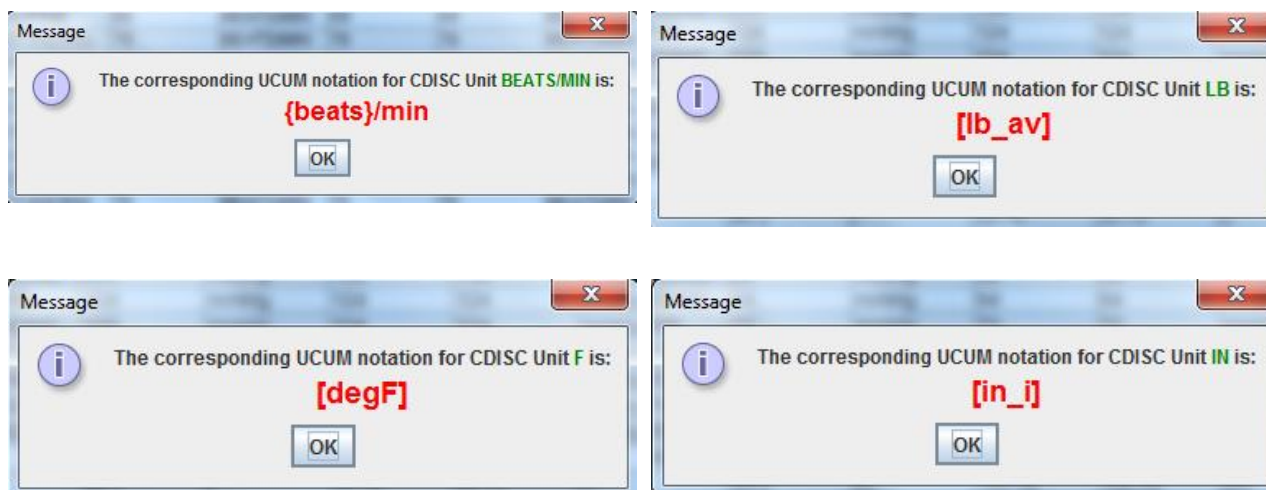
When clicking a VSORRESU cell with "mmHg" the following is displayed:



with the UCUM notation being "mm[Hg]". The reason is that the square brackets provide the context of the real unit "mm", i.e. answering the question of "millimeter of what?". Another UCUM notation for a pressure is e.g. "m[H2O]" meaning "meter of water column".

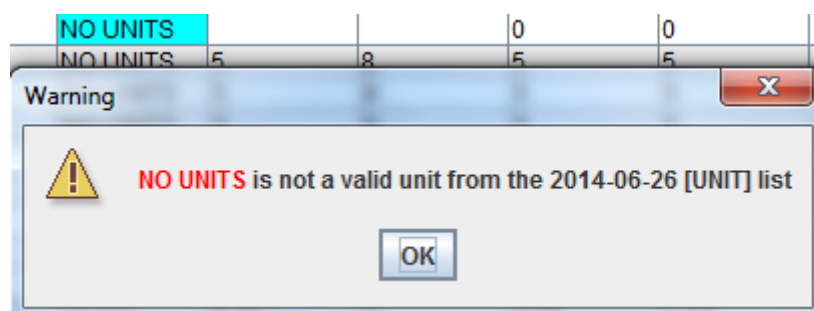
One of the great advantages of UCUM is that it makes interconversion of units easy through the provision of the "ucum-essence.xml" file, which easily allows to generate software for executing interconversions. A [RESTful web service](#) for such conversions [has been developed by us in the past](#), and has been donated to and is now available from the [National Library of Medicine](#). The other advantage of UCUM is that it is not a list, but a multi-dimensional system, so that it will be seldomly necessary to make a request for a new term, unlike for the CDISC [UNIT] codelist.

A few other interesting UCUM units as provided by the web service are:



Where curly brackets are "annotations" (see the UCUM specification for details), and units containing square brackets usually are non-SI units.

If the unit from --RESU is not a CDISC unit, there is not much the web service can do, and you will e.g. obtain the following message:



Currently only for VS datasets, it is possible to check for each unit value (variables VSORRESU, VSSTRESU) whether it is a valid value for the given test code. This web service is based on the list developed by Anthony Chow of CDISC⁶.

When the checkbox "Check correctness of unit for given --TESTCD" in Options / Web Services is checked, one may e.g. obtain the following "warning" cells:

⁶See "VS Test_Unit Codetable" at <https://www.cdisc.org/share-value-level-metadata-library>

VSTESTCD	V...	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU
PULSE	P...		80	BEATS/MIN	80	80	BEATS/MIN
SYSBP	S...	SITTING	122	mm[Hg]	122	122	cm
SYSBP	S...	SITTING	146	mmHg	146	146	mmHg
SYSBP	S...	SITTING	142	mmHg	142	142	mmHg
SYSBP	S...	SITTING	140	mmHg	140	140	mmHg
WEIGHT	...		154	LB	69.9	69.9	kg
WEIGHT	...		156	LB	70.8	70.8	kg
WEIGHT	...		159	LB	72.1	72.1	kg
WEIGHT	...		157	LB	71.2	71.2	kg
DIABP	D...	SITTING	60	mmHg	60	60	mmHg
DIABP	D...	SITTING	70	mmHg	70	70	mmHg
DIABP	D...	SITTING	70	mmHg	70	70	mmHg
DIABP	D...	SITTING	68	cm	68	68	mmHg
FRMSIZE	B...		MEDIUM		MEDIUM		
HEIGHT	H...	SITTING	60.5	IN	153.7	153.7	cm

The second row reports that "mm[Hg]" is not allowed for SYSBP (systolic blood pressure) although "mm[Hg]" is a correct UCUM unit for blood pressure⁷. Unfortunately, CDISC still does not support UCUM units (in contrast with the rest of the world).

The third-last row reports that "cm" is not a valid unit for "diastolic blood pressure" (DIABP), which is indeed the case.

When one holds the mouse over a such a cell, more information is provided by a tooltip:

DIABP	D...	SITTING	70	mmHg	70	70	mmHg		
DIABP	D...	SITTING	68	cm	68	68	mmHg		
FRMSIZE	B...		MEDIUM		MEDIUM				
HEIGHT	H...	SITTING	60.5	IN	WARNING: unit 'cm' is not a valid UNIT for Test Code 'DIABP' (VSORRESU)				

When in "Options – Web Services", the checkbox "Check correctness of VSPOS for given VSTESTCD" is checked, VSPOS values are checked using another web service. One may then e.g. find:

FRMSIZE	B...		MEDIUM		MEDIUM			
HEIGHT	H...	SITTING	60.5	IN	153.7	153.7	cm	
PULSE	P...		70	BEATS/MIN	70	70	BEATS/MIN	
PULSE	P...		WARNING: VSPOS 'SITTING' is not valid VSPOS value for Test Code 'HEIGHT'					
PULSE	P...		84	BEATS/MIN	84	84	BEATS/MIN	
PULSE	P...		84	BEATS/MIN	84	84	BEATS/MIN	
SYSBP	S...	SITTING	110	mmHg	110	110	mmHg	
SYSBP	S...	SITTING	130	mmHg	130	130	mmHg	
SYSBP	S...	SITTING	118	mmHg	118	118	mmHg	
SYSBP	S...	SITTING	170	mmHg	170	170	mmHg	
WEIGHT	...		120	LB	54.4	54.4	kg	

stating that "SITTING" is not a valid value for test code "HEIGHT".

As already stated, these two "plausibility" web services (value of a variable depending on the value of –TESTCD) is currently limited to the VS dataset.

Of course, it would be great if such a web service was also available for LB (laboratory) datasets. Until now however, it is not possible to develop such a "ruleset", as in LB, the value of

⁷Healthcare almost exclusively uses UCUM notation for units in electronic health records.

the unit is dependent on several other variables than LBTESTCD:

- LBSPEC (specimen type)
- LBMETHOD (method)

unfortunately, this is not sufficient for setting the "preferred" unit. What is missing is the information whether (e.g. for concentration) it is a mass concentration or a molar concentration. Essentially what is missing (i.e. not covered by SDTM) is:

- kind of property measured (e.g. concentration, concentration decay (as function of time), catalytic activity, ..., each having other associated units)
- the scale of the measurement, e.g. "quantitative", "qualitative".

For example, a glucose test (LBTESTCD=GLUC), in urin (LBSPEC=URIN), measured using a test strip (LBMETHOD=DIPSTICK) can either have no units (because the result value is either "POSITIVE" or "NEGATIVE" or have the preferred unit "mg/dL", depending on whether a quantitative or qualitative test was performed.

All the information for uniquely describing a lab test is given by its LOINC code, including preferred units. For example:

5792-7 Glucose [Mass/volume] in Urine by Test strip

NAME

Fully-Specified Name:

Component

Glucose

PART DEFINITION/DESCRIPTION(S)

Glucose (Glc), a monosaccharide (or simple sugar) also known as grape sugar, blood sugar, or corn sugar, is an i measured in blood samples. Eating or fasting prior to taking a blood sample has an effect on the result. Higher th

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Source: Wikipedia, URL: [Glucose](https://en.wikipedia.org/wiki/Glucose)

BASIC ATTRIBUTES

Class/Type:	UA/Lab
Common Lab Results Rank:	#73
Last Updated:	2006/10/26
Mass or Substance Property:	M
Order vs. Obs.:	Both
Status:	Active

EXAMPLE UNITS

Unit	Source Type
mg/dL	EXAMPLE UCUM UNITS
mg/dL	ORIGINAL SUBMISSION
mg/dL	REGENSTRIEF

So there are two ways lists of units for lab tests can be developed and implemented:

- a) CDISC allows to put the LOINC code (e.g. 5792-7) in LBTESTCD
- b) CDISC makes LBLOINC at least "expected" (currently it is "permissible")

Opportunities for the future

Standards avoid that formats and terminology are reinvented over and over again in different (pharma) companies. Web services can avoid that the implementation of standards in pharma companies is reinvented over and over again.

The web services that have been implemented here, and for which the full description and API will be published soon. The description of the "LOINC webservice" of the National Library of Medicine is already available here. It also has similar services for other standards such as RXCUI and SNOMED-CT and ICD-10.

For CDISC submissions, this is only the beginning. Much more is possible. For example once UCUM notation is allowed⁸ for –RESU variables, we can start developing web services e.g. To automatically convert "observed" values to "standardized" values. For example, if some investigators reported blood pressure in "pounds per square inch" (UCUM: [psi]), such original results can automatically be converted into standard units (e.g. "mm[Hg]"). This however requires for each test (SYSBP, DIABP, ...) CDISC publishes (if possible electronically) what the "standard" unit for that specific test is. Such a list has already been published recently for "vital signs" (VS) by Anthony Chow on the CDISC website, and is expected to be implemented in CDISC SHARE.

Web Services and CDISC SHARE

CDISC SHARE will exactly contain the information that can be very well served by web services. We hope that SHARE will be able to answer (in an electronic way) simple questions like:

- which are the valid units for a specific (lab) test?
- when the value of SDTM variable A has the value X, what are the allowed values of variable B?
- How many mm[Hg] is 2.3 [psi] (blood pressure)?
- ...

Currently, our web services may serve as an example for the SHARE developers to demonstrate what is technically possible. On the longer term, we hope our web services become superfluous as they are also provided by SHARE.

⁸Unfortunately, the use of UCUM notation in SDTM/SEND/ADaM for units is still not allowed. CDISC developed its own, competing, list of units.