SDTM-ETL 4.5 User Manual and Tutorial

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Mapping Units of Measure

Table of Contents

Table of Contents	1
Introduction	
Copying ODM units of measure to SDTM/SEND define	1
Mapping ODM Units of Measurement to SDTM/SEND CDISC Controlled Terminology units	
Standardized units and UCUM	
Conclusions	

Introduction

Units of measure can be handled and mapped to SDTM/SEND units of measure in different ways. Main reason is that ODM has several mechanisms to store and handle units of measure.

The classic one, but not used by many EDC systems, is to store the units in the ODM element "BasicDefinitions", and then referencing these, as well in the ODM metadata as in the clinical data, using the element "MeasurementUnitRef".

The second one is to just define the unit of measure as a data point, using "ItemDef" in the metadata, and "ItemData" in the clinical data.

And then there is <u>UCUM</u> (Unified Code for Units of Measure), which is used in healthcare and a standard in the medical informatics world, but unfortunately (due to the "not-invented-here syndrome) not (yet) used by CDISC.

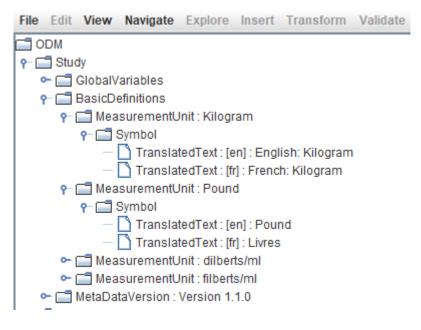
On the SDTM/SEND side, in many cases, variables representing units of measure (e.g. –ORRESU) is under CDISC controlled terminology, i.e. having a CDISC codelist. Better were that CDISC moves to UCUM, as unit conversions can easily be automated using UCUM, which is not possible at all with CDISC units.

In some cases, one will however also want its own codes for units of measure, also on the SDTM/SEND side.

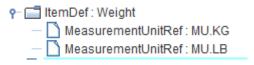
We will discuss each of these options in detail.

Copying ODM units of measure to SDTM/SEND define

In ODM, in some implementations, the units of measure to be used are stored in the "BasicDefinitions" element. When this is so, one will find these in the ODM tree on the left side, e.g.:

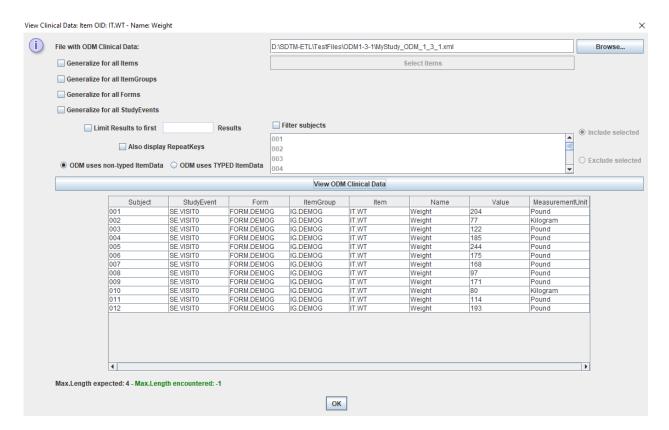


For data points that use these units, one will find a reference to them e.g.



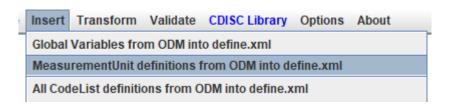
Essentially meaning that, in the (e)CRF, there was a choice between using "kg" or "pounds" as the unit of measure for "weight".

This also means that in the clinical data, one may find data points for which "kg" was used, and others for which "pounds" was used. For example, when using the menu "View - ODM Clinical Data":



One may now want to copy these units of measure from the ODM side to the SDTM/SEND define.xml and then transform this into a codelist. Very often, this will not be necessary, as one wants to use the already associated CDISC codelist. However, and especially in SEND, there will be no suitable associated codelist (e.g. for PK measurements) and one wants to use the units from the ODM.

To copy the units of measure from the ODM into the define.xml representing the SDTM/SEND data, use the menu "Insert - Measurement Unit definitions from ODM into define.xml":

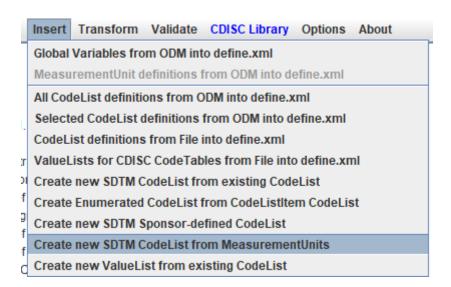


leading e.g. to:



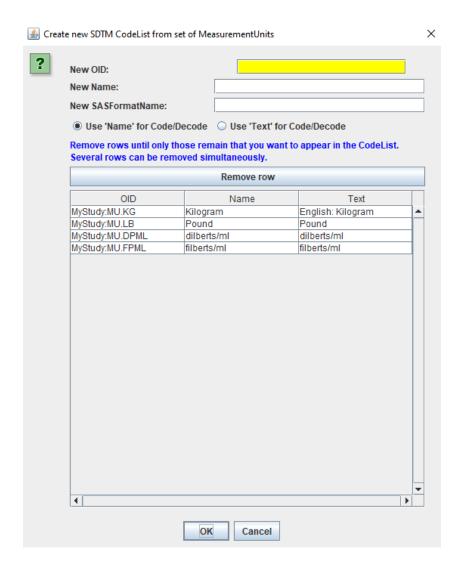
As define.xml does not formally support the "BasicDefinitions" element, in most cases, one will want to transform these into an SDTM or SEND codelist.

This can be done by using the menu "Insert - Create new SDTM¹ CodeList from MeasurementUnits":

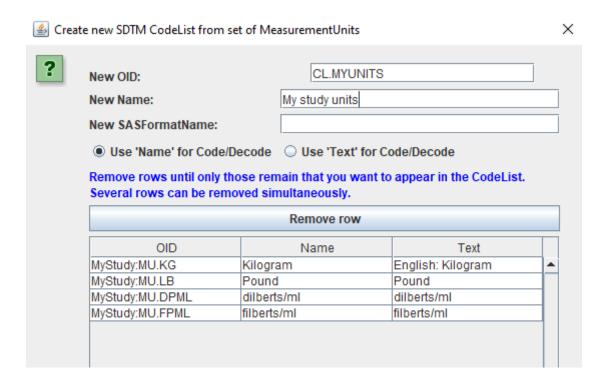


Which will pop up a new dialog:

¹ In the case SEND is used, the menu item will state "Create new SEND CodeList from MeasurementUnits"



One then needs to at least fill the fields "New OID" and "New Name". For example:

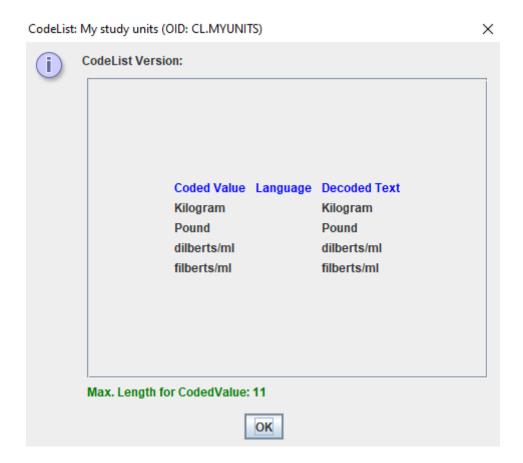


One can still add or remove rows in this table, and has the option to either use the value of "Name" or of "Text" to appear in the "Decode" child elements of the codelist.

After clicking OK, one can use the generated codelist, e.g. assigning it to SDTM/SEND variables.

One can also still edit it, make subset codelists (menu "Insert - Create new SDTM CodeList from existing CodeList"), or use it as a basis for other codelists.

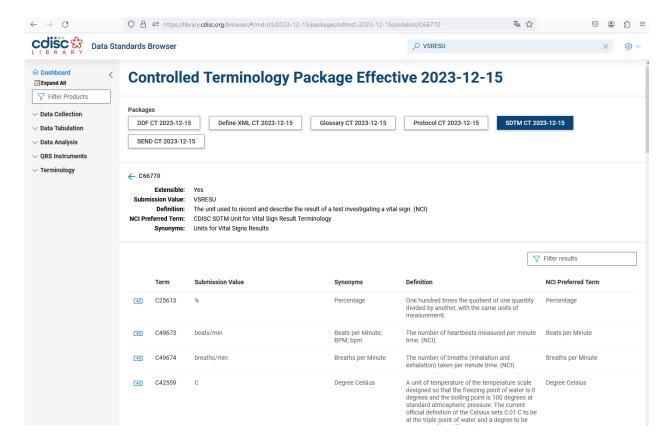
For visualization of the generated codelist, when one has assigned it to an SDTM/SEND variable, use the menu "View - SDTM Codelist" or "View - SEND CodeList", e.g. leading to:



Mapping ODM Units of Measurement to SDTM/SEND CDISC Controlled Terminology units

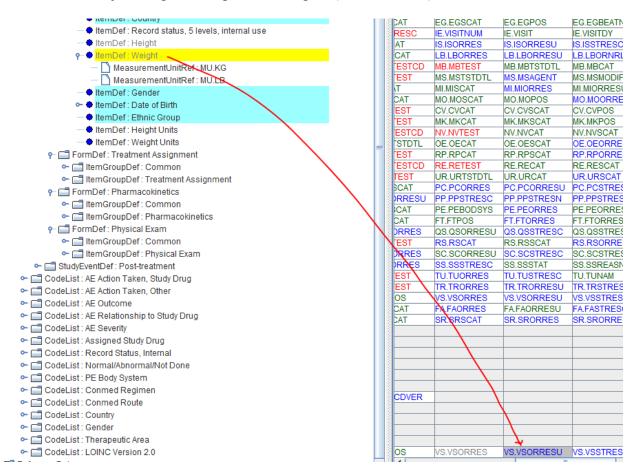
For EDC systems that support the "BasicDefinitions" mechanism for the units of measure in the ODM export, one can map these to the CDISC controlled terms used in SDTM or SEND directly.

Let us try to do this for VS, i.e. map the units from the ODM to the CDISC codelist VSRESU (NCI code C66770). According to the CDISC Library:

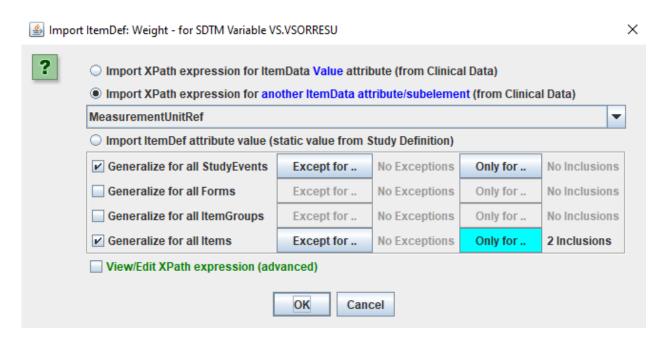


When we already have provided the mapping for VSTESTCD, VSTEST, VSORRES, we can also generate the mapping for VSORRESU.

In order to do so, just drag-and-drop from "Weight" (OID="IT.HT") to the cell VS.VSORRESU:

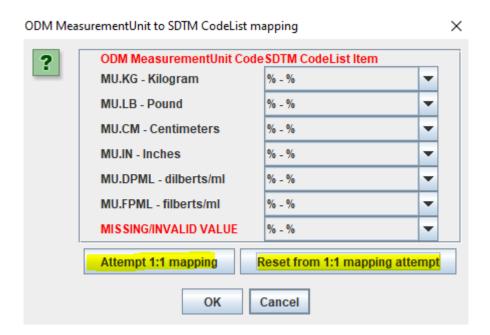


The "mapping wizard" dialog shows up:

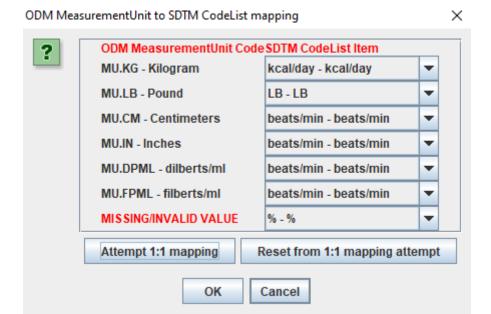


As the wizard sees that we have a "MeasurementUnitRef" child element on the ODM side, and we wish to map to an -ORRESU variable, it already suggests that we use the value of "MeasurementUnitRef". The "Only for ..." on "Generalize for all Items" is retained from our prior mappings for VSTESTCD, VSTEST and VSORRES, as we want to limit to "Height" and "Weight" ("Gender" in the same group does not go into VS).

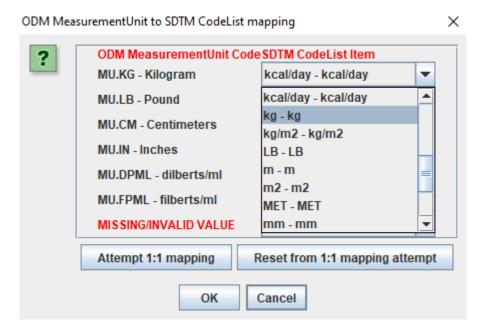
After clicking "OK" we get the part that allows us to define the mappings:



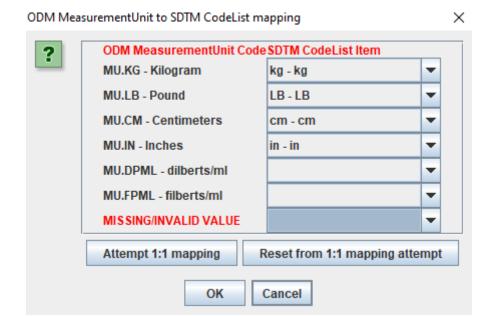
New in version 4.5 are the buttons "Attempt 1:1 mapping" and "Reset from 1:1 mapping attempt". When "Attempt 1:1 mapping is clicked", the system will try to generate a mapping based world similarity, e.g. with the result:



with the "best guessed" values ordered within each dropdown, e.g.:



In our case, the "best guessed" mapping is not very good, so we may still need to do some "manual" mapping, e.g.:



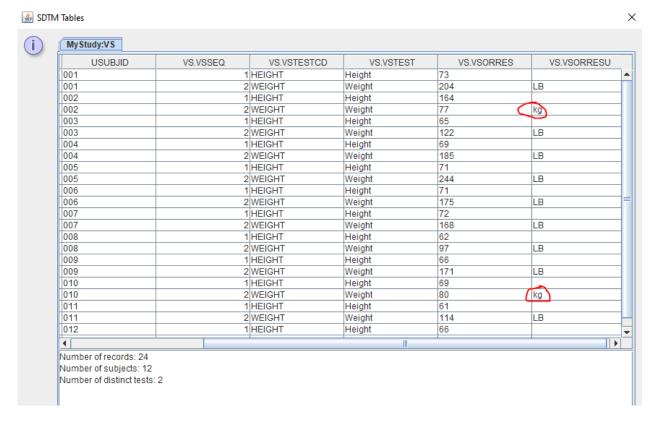
where we leave mappings for "dilberts/ml" and "filberts/ml" out as they will not be used for the vital signs units mappings anyway.

Leading to the automatically created mapping script:

```
| Mapping using ODM element ItemData with ItemData it in ItemData with ItemData (@TomData (@
```

Notice the "/MeasurementUnitRef/@MeasurementUnitOID" in the XPath selection in line 4. The next lines than transform the ODM unit into the SDTM unit from the CDISC VSRESU codelist.

When then executing the mappings (using "Transform - Generate Transformation (XSLT) Code for ...", the final result is e.g.:

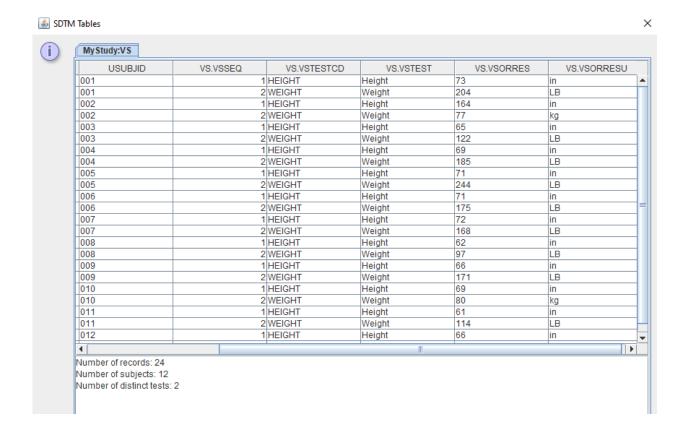


Where we see that for most subjects, weight was collected in pound (CDISC-code "LB") but for a few, weight was collected in kilograms (CDISC-code "kg").

We also see that no unit was assigned for "HEIGHT". Reason for this that there wasn't a choice for the unit for "height", but was always collected in inches (CDISC-code "in"). So we need to extend the code somewhat, and have the assignment being based on the value of VSTESTCD. For example:

```
The Transformation Script-
 1 # Mapping using ODM element ItemData with ItemOID IT.WT - value from attribute MeasurementUnitOID of subelement
 2 # Generalized for all StudyEvents
 3 # Generalized for all Items within the ItemGroup
 4 # Mapped to SDTM CodeList CL.C66770.VSRESU
 5 $CODEDVALUE = xpath(/StudyEventData/FormData[@FormOID='FORM.DEMOG']/ItemGroupData[@ItemGroupOID='IG.DEMOG']/Ite
 6 $NEWCODEDVALUE = '';
 7 if ($CODEDVALUE == 'MU.KG') {
    $NEWCODEDVALUE = 'kg'
 9 } elsif ($CODEDVALUE == 'MU.LB') {
10
    $NEWCODEDVALUE = 'LB';
11 } elsif ($CODEDVALUE == 'MU.DPML') {
12 $NEWCODEDVALUE = '';
13 } elsif ($CODEDVALUE == 'MU.FPML') {
    $NEWCODEDVALUE = '';
14
15 } else {
    $NEWCODEDVALUE = '';
16
17 }
18 if ($VS.VSTESTCD = 'WEIGHT')
        $VS.VSORRESU = $NEWCODEDVALUE:
19
20 } elsif($VS.VSTESTCD = 'HEIGHT') {
         $VS.VSORRESU = 'in';
21
22 } else {
         $VS.VSORRESU = 'TODO';
23
24 }
```

Essentially hardcoding that for the case of "HEIGHT", always "inches" (CDISC-code "in") needs to be assigned. This then ultimately leads to the results:



Standardized units and UCUM

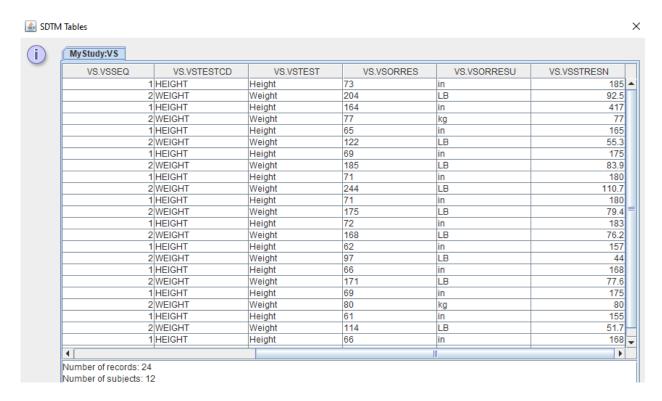
A big problem with the CDISC controlled terminology for units is that is does not allow to automate unit conversion, which is often needed for populating –STRESN variables. For example for our case, in case we want to have "cm" and "kg" for the "standardized" results, there is no other way than to hardcode the conversion factors. This means a lot of manual work. For example, for VSSTRESN, we will need a (too) long manually generated script like:

```
The Transformation Script-
 1 # Conversion to standardized units kg (for weight) and cm (for height)
 2 if ($VS.VSTESTCD = 'HEIGHT' and $VS.VSORRESU = 'in') {
         # convert to centimeters
         $TEMP = number($VS.VSORRES) * 2.54;
 4
         $VS.VSSTRESN = round($TEMP,0);
 6 } elsif($VS.VSTESTCD = 'WEIGHT' and $VS.VSORRESU = 'LB') {
         # convert to kilograms
         $TEMP = number($VS.VSORRES) * 0.4536;
 8
        $VS.VSSTRESN = round($TEMP,1);
 9
10 } elsif($VS.VSTESTCD = 'WEIGHT' and $VS.VSORRESU = 'kg') {
        $VS.VSSTRESN = $VS.VSORRES;
11
12 } else {
        $VS.VSSTRESN = 'TODO';
13
14 }
   4
```

where we use rounding to an integer for conversion to centimeters and to one character after the decimal point for conversion to kilograms.

Also remark the use of the "number()" function, as in our mapping language, variable values are essentially always strings, and need to be converted to a number for mathematical operations.

The total result then is:

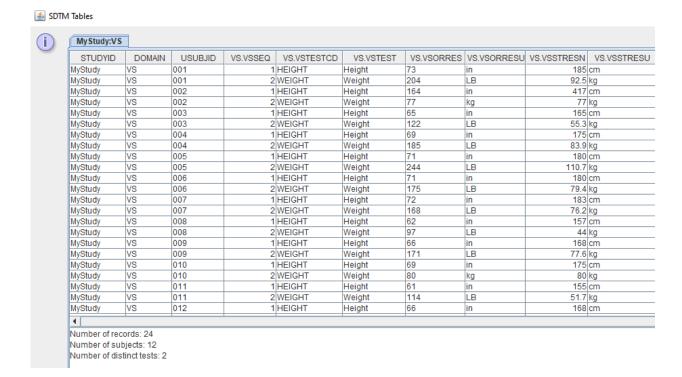


but we then still need to add the mapping for VSSTRESU too:

```
The Transformation Script

1 if ($VS.VSTESTCD = 'HEIGHT') {
2  $VS.VSSTRESU = 'cm';
3 } elsif ($VS.VSTESTCD = 'WEIGHT') {
4  $VS.VSSTRESU = 'kg';
5 } else {
6  $VS.VSSTRESU = 'TODO';
7 }
```

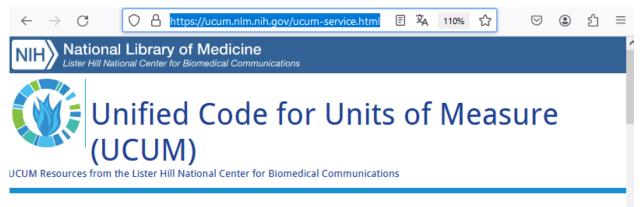
and the total result being:



So, a lot of manual code, and that only for two vital signs tests!

The whole medical world is using <u>UCUM</u> notation for units, except for CDISC (reason: "not-invented-here syndrome). UCUM is not a "list" (CDISC-CT for units just is a list) and does, in contradiction to CDISC, allow for automated unit conversions.

There is even a free RESTful web service for it provided by the National Library of Medicine (NLM) for which the description can be found at https://ucum.nlm.nih.gov/ucum-service.html:



UCUM Web Service

This is a set of web services (APIs) for programs to use when working with units from the Unified Code for Units of Measure (UCUM) system. These are the same APIs as those that are running at xml4pharmaserver.com, and are based on that website's web service code which has been donated to the U.S. National Library of Medicine by FH-Prof. Jozef Aerts and Mr. Milos Ilic MSc, Institute of eHealth, University of Applied Sciences FH Joanneum in Graz Austria.

Currently, three web services are available:

- UCUM unit Conversion web service
- UCUM unit validation web service
- · UCUM unit to base units conversion

Such RESTful web services can be used in any software, even in SAS or R.

Just suppose that our collection system already uses UCUM for units, which will usually (>99%) the case when the data comes from electronic health records².

The UCUM notation for the above units is:

Designation	UCUM notation
centimeters	cm
inches	[in i]
kilograms	kg
pouns	[lb av]

Where one sees that for some cases, the UCUM notation is equal to the CDISC controlled term ("cm" and "kg") whereas it is very different for others.

A more complete oversight of "Commonly Used UCUM Codes for Healthcare Units" can be found at: https://download.hl7.de/documents/ucum/ucumdata.html



Commonly Used UCUM Codes for Healthcare Units

Document Instructions

This document contains a list of UCUM codes for commonly used units in clinical lab value reporting. The tables below display the valid UCUM code, descriptive n general type. You may browse the list, use the links to the left to jump to a specific unit type, or use the search box to the left to search for a particular unit.

Additional Resources

To save a copy of these tables to your computer, right click on the desired link and choose "Save Target As..." or "Save Link As..."

Commonly Used UCUM Codes (XML Format)
Commonly Used UCUM Codes (TSV Format)

How To Download UCUM Codes from CDC PHIN VADS

Unit Types

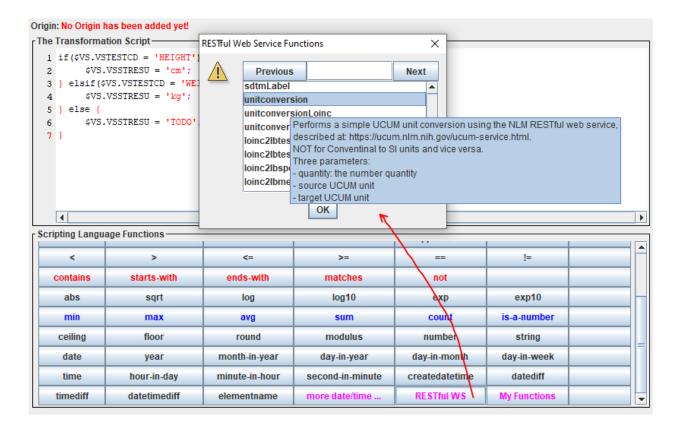
Most Common Healthcare Units

Valid UCUM Code	Descriptive Name
%	Percent
/uL	PerMicroLiter
[iU]/L	InternationalUnitsPerLiter
10*3/uL	ThousandsPerMicroLiter
10*6/uL	MillionsPerMicroLiter
fL	FemtoLiter
g/dL	GramsPerDeciLiter
g/L	GramsPerLiter
g/mL	GramsPerMilliLiter
kPa	KiloPascal
m[iU]/mL	MilliInternationalUnitsPerMilliLiter
meq/L	MilliEquivalentsPerLiter
ma/dL	MilliGramsPerDeciLiter

Our scripting language has a number of functions that use the NLM RESTful web service to have automated unit conversion using UCUM notation for the units.

These functions can be found when, in the mapping editor, clicking the button (located near the bottom) "RESTful WS", then popping up a list of available functions with tooltips with explanations:

² As well HL7 CDA as FHIR normally use UCUM notation for all units.



For example, although this is fully counterproductive in this case, we could use:

```
The Transformation Script-
  1 # Conversion to standardized units kg (for weight) and cm (for height)
  2 if($VS.VSTESTCD = 'HEIGHT' and $VS.VSORRESU = 'in') {
          # convert to centimeters
  3
          # $TEMP = number($VS.VSORRES) * 2.54;
  4
          $TEMP = rws:unitconversion($VS.VSORRES, '[in i]', 'cm');
  5
          $VS.VSSTRESN = round($TEMP,0);
  6
    } elsif($VS.VSTESTCD = 'WEIGHT' and $VS.VSORRESU = 'LB') {
  7
          # convert to kilograms
  8
          # $TEMP = number($VS.VSORRES) * 0.4536;
  9
          $TEMP = rws:unitconversion($VS.VSORRES,'[lb_av]','kg');
 10
          $VS.VSSTRESN = round($TEMP,1);
 11
 12 } elsif($VS.VSTESTCD = 'WEIGHT' and $VS.VSORRESU = 'kg') {
          $VS.VSSTRESN = $VS.VSORRES;
 13
 14 } else {
          $VS.VSSTRESN = 'TODO';
 15
 16 }
 17
```

Using the "rws:unitconversion" function.

Essentially, doings so only makes sense when the units come in UCUM notation already in the source data.

It however shows once again that CDISC should move to UCUM notation for units instead of mandating to use it's "own invented wheel".

Conclusions

There are several possibilities for mapping units of measure from the source (ODM) to the target SDTM or SEND variables. When the units of measure are defined as datapoints (i.e. using "ItemDef"), the mapping is as for any other data point, with the difference that usually, a mapping to CDISC units will be needed, for which there is a wizard. Alternatively, the units defined in the ODM "BasicDefinitions" can be imported into the define.xml and transformed to a codelist. When the ODM uses the "MeasurementUnitRef" mechanism for units, when doing drag-and-drop from the "ItemDef" to an SDTM/SEND cell, the software will already suggest to use the value of "ItemData/MeasurementUnitRef/@MeasurementUnitOID" that can then be mapped to CDISC units using the provided wizard.

SDTM-ETL also supports automatic unit conversion when the units are provided in UCUM notation. Due to the nature of the CDISC-CT (just lists) this is unfortunately not possible with CDISC units.