SDTM-ETL 3.1 User Manual and Tutorial

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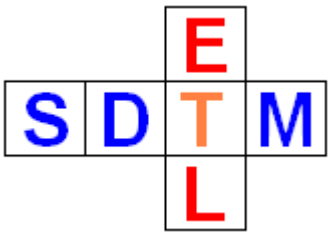


Working with the WhereClause in define.xml 2.0

As of define.xml 2.0, it is mandatory to define under which circumstances value level metadata is used, using so-called „WhereClauses“.
For example, for VSORRES, the value itself will differ depending on what the value of VSTESTCD is. For example, when VSTESTCD=DIABP (diastolic blood pressure), we expect the value to be an integer between 80 and 120 (mm[Hg]) or so. In case VSTESTCD=WEIGHT, we probably expect a floating point number. For some other tests, we might however expect a string, like „S“, „M“, „L“ or „XL“ in the case that the test is „FRMSIZE“ (frame size).

In this short tutorial, we will describe a somewhat more complicated example which is also described in the define.xml 2.0 specification: we will describe that the weight of a subject is described in pounds in case the country of the subject is the USA, and in kilograms in case the country of the subject is France or Germany[1]. Such a condition is described in define.xml 2.0 using a so-called „WhereClause“.

„WhereClause“ did not exist in define.xml 1.0. Instead, some people used nestes „ValueLists“ instead. In define.xml 2.0, nested Valuelists are not necessary anymore and should not be used.

Now, important is that we assign the „WhereClauses“ to the correct SDTM variable. Because in the mentioned example the information is about units used, the „WhereClauses“ needs to be assigned to VSORRESU.
In case that we state that mm[Hg] is an integer for VSTESTCD=SYSBP and DIABP, and that the value is of type „text“ enumerated to „S“, „M“, „L“ and „XL“ for VSTESTCD=“FRMSIZE“ the „WhereClauses“ needs to be assigned to VSORRES.

So what we need to express is:

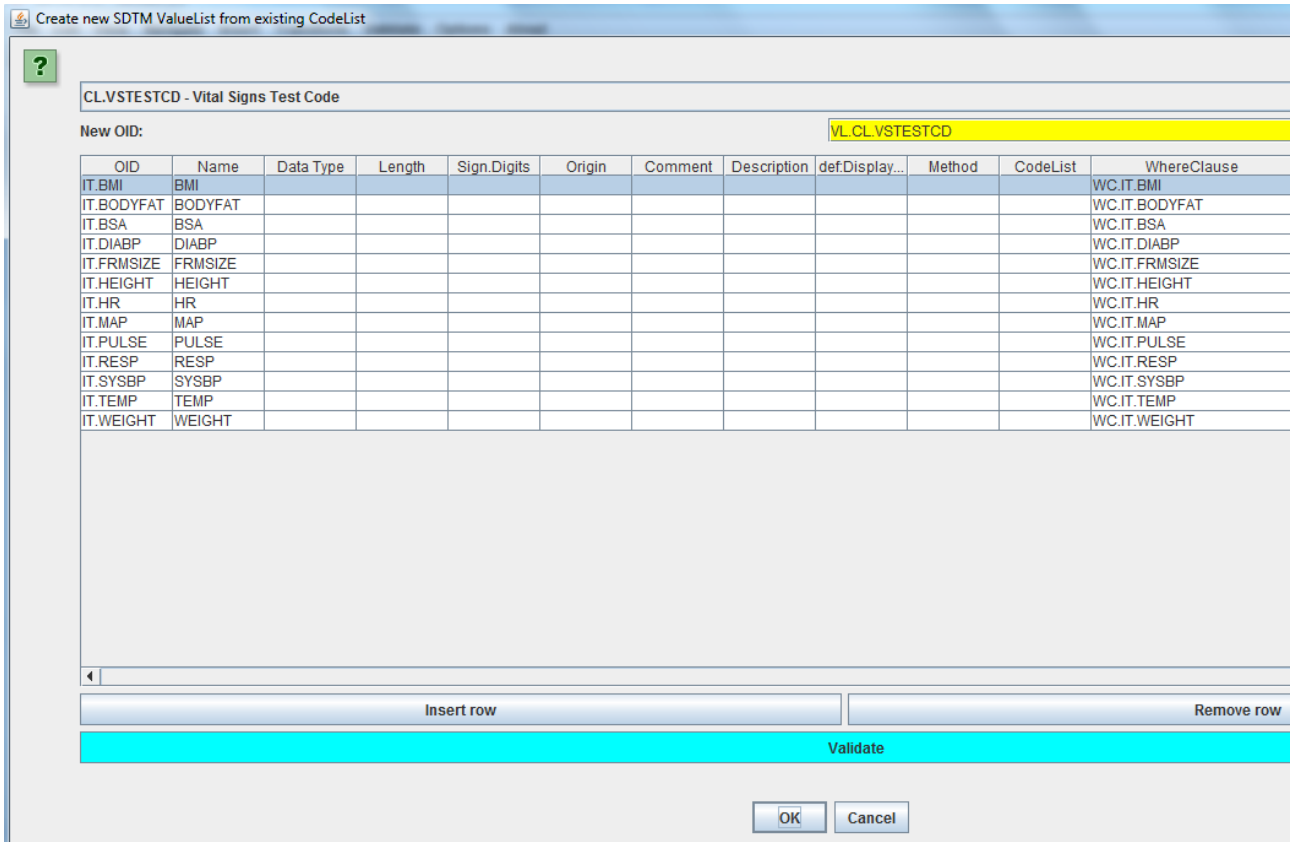
- the value of VSORRES is an integer in case VSTESTCD=DIABP or SYSBP
- the value of VSORRES is of type text and enumerated to „S“, „M“, „L“ and „XL“ when VSTESTCD=“FRMSIZE“
- the unit is „pounds“ when VSTESTCD=WEIGHT and DM.COUNTRY=USA
- the unit is „kilogram“ when VSTESTC=WEIGHT and DM.COUNTRY=GER or DM.COUNTRY=FRA

1 In the define.xml 2.0 specification, Mexico and Canada are mentioned for the use of kilograms, but using France and Germany is more clear especially for non-US users.

Creating a ValueList for VSORRES

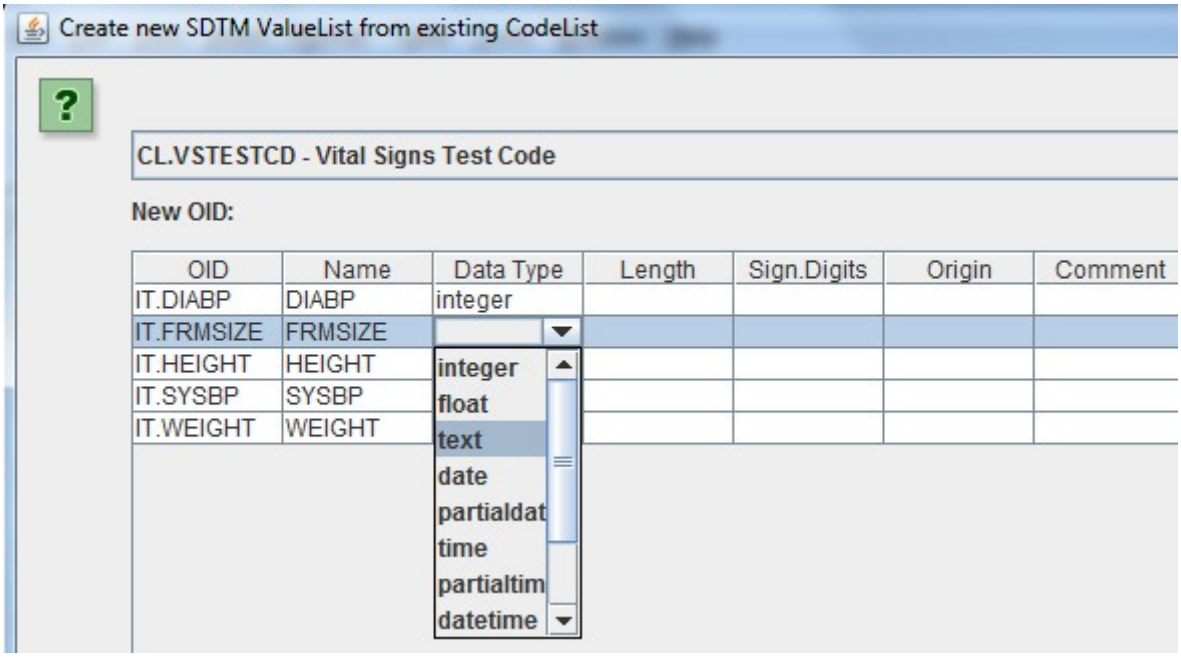
Let us first create a valuelist for VSORRES. We can either start from an existing codelist (Insert – Create New ValueList from existing CodeList“, leading to:

where we start from CL.VSTESTCD as our metadata will depend on the value of TESTCD. This leads to a new dialog with:



allowing us to assign metadata for each type of test. In this tutorial, we will limit ourselves to a few tests only, i.e. DIABP“, „SYSBP“, „HEIGHT“, „WEIGHT“ and „FRMSIZE“, so we can remove all other rows. We will however only show the „WhereClause“ for each of them, as they are all very similar, but with different values for the „check value“ (see further).
After having removed the unnessary[2] rows(using the „Remove row“ button), we can start adding the data types:

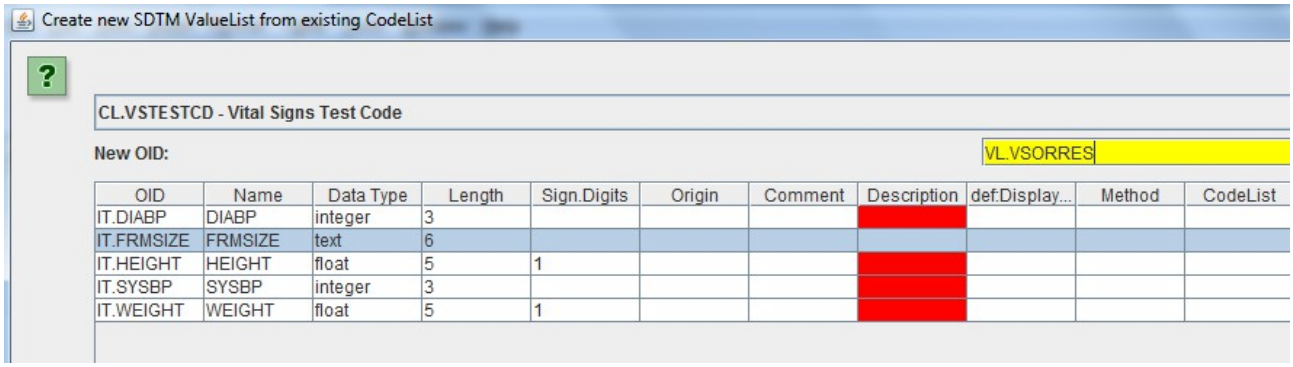
2 This depends of course on your own study.



and appropriate maximal lengths and number of digits after the decimal point („Significant Digits“):

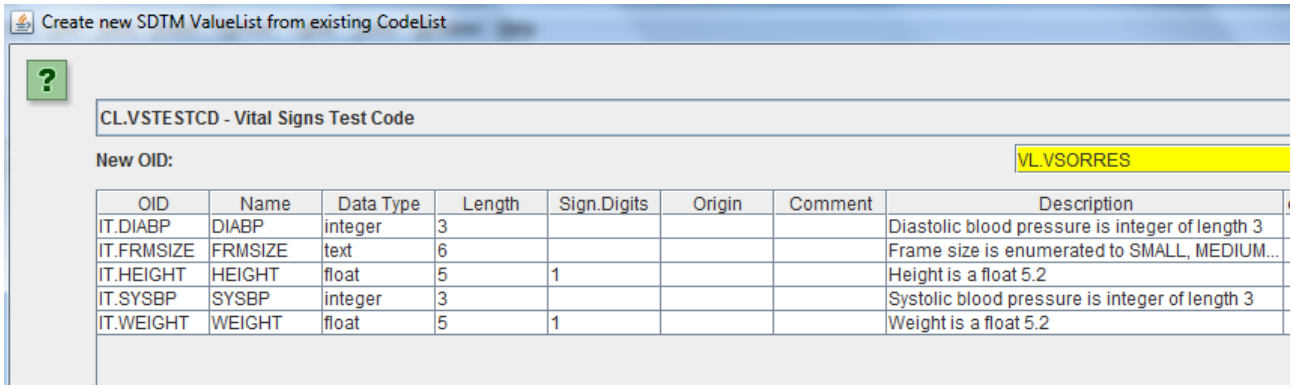
OID	Name	Data Type	Length	Sign.Digits	Origin	Comment
IT.DIABP	DIABP	integer	3			
IT.FRMSIZE	FRMSIZE		6			
IT.HEIGHT	HEIGHT	float	5	1		
IT.SYSBP	SYSBP	integer	3			
IT.WEIGHT	WEIGHT	float	5	1		

One can always click the „Validate“ button to check whether the combinations of filled fields makes sense.



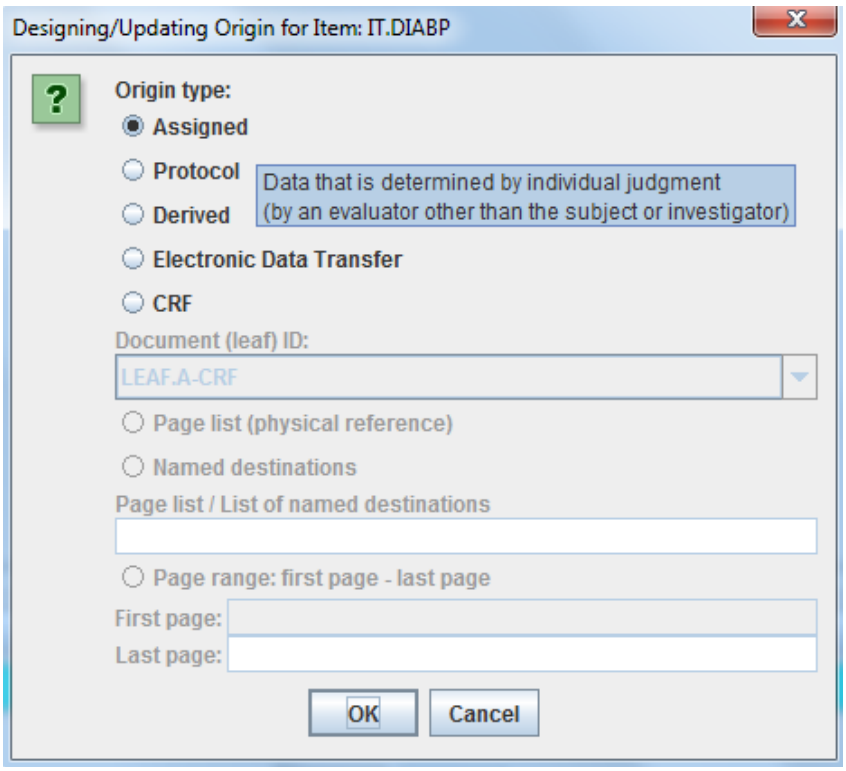
Also notice that we changed the OID into „VL.VSORRES“ to reflect that this is a valuelist for the variable VSORRES. We also see that the cells „Description“[3] are colored red, meaning we do need provide values there:

3 „Description“ replaces „def:Label“ in define.xml v.2.0



OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description
IT.DIABP	DIABP	integer	3				Diastolic blood pressure is integer of length 3
IT.FRMSIZE	FRMSIZE	text	6				Frame size is enumerated to SMALL, MEDIUM...
IT.HEIGHT	HEIGHT	float	5	1			Height is a float 5.2
IT.SYSBP	SYSBP	integer	3				Systolic blood pressure is integer of length 3
IT.WEIGHT	WEIGHT	float	5	1			Weight is a float 5.2

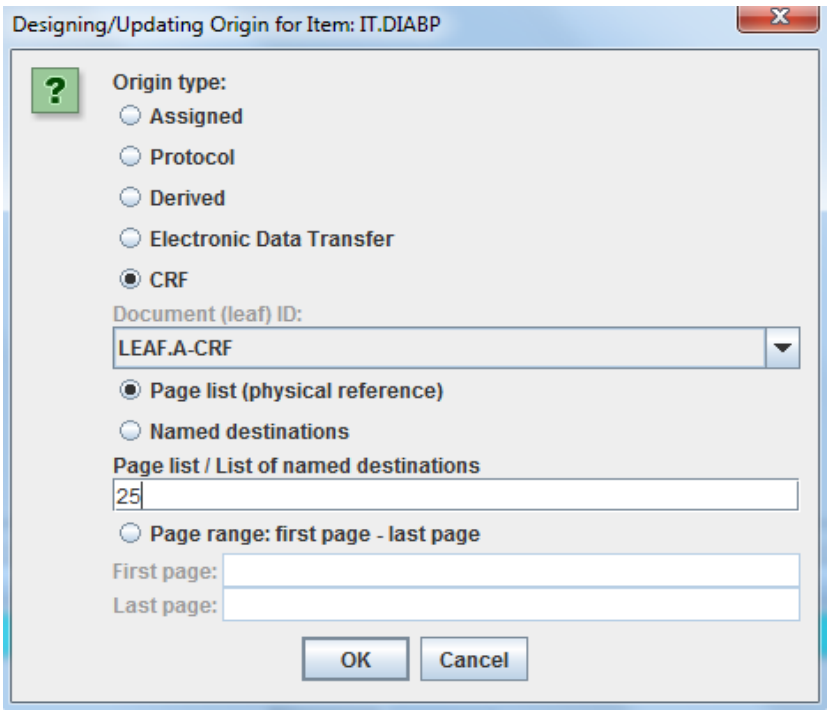
Now, we do also want to provide the reviewer the information what the source of the data is. This can of course depend of the test code. In our case, we had a CRF with all vital signs on one page. So when clicking the cell „Origin“ for „DIABP“ the following dialog is displayed:



where can select between:

- Assigned: judgement from evaluator not being the investigator
- Protocol: prescribed by the protocol
- Derived: calculated using some algorithm
- Electronic Data Transfer (eDT): e.g. ECG data, lab data
- CRF: case report form

In our case, we of course select „CRF“. Some other fields become available:



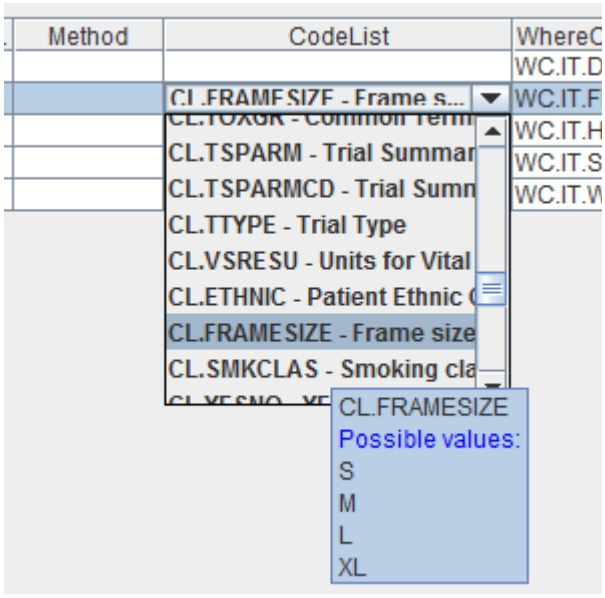
We can either choose between a single page or page list (e.g.: 21 24 27) or a PDF named destination or a page range where we then need to provide the first and last page. In our case, the field that goes into VSORRES for VSTESTCD=DIABP can be found on page 25 of the annotated CRF.
Clicking OK leads to:

OID	Name	Data Type	Length	Sign.Digits	Origin
IT.DIABP	DIABP	integer	3		CRF
IT.FRMSIZE	FRMSIZE	text	6		
IT.HEIGHT	HEIGHT	float	5	1	
IT.SYSBP	SYSBP	integer	3		
IT.WEIGHT	WEIGHT	float	5	1	

and we can now to the same for the other rows, leading to:

OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description
IT.DIABP	DIABP	integer	3		CRF		Diastolic blood pressure is integer of length 3
IT.FRMSIZE	FRMSIZE	text	6		CRF		Frame size is enumerated to SMALL, MEDIUM...
IT.HEIGHT	HEIGHT	float	5	1	CRF		Height is a float 5.2
IT.SYSBP	SYSBP	integer	3		CRF		Systolic blood pressure is integer of length 3
IT.WEIGHT	WEIGHT	float	5	1	CRF		Weight is a float 5.2

For „FRMSIZE“ we need to indicate that the value is enumerated. This is usually done by a CodeList, so we click the cell „CodeList“ for row „FRMSIZE“, leading to:

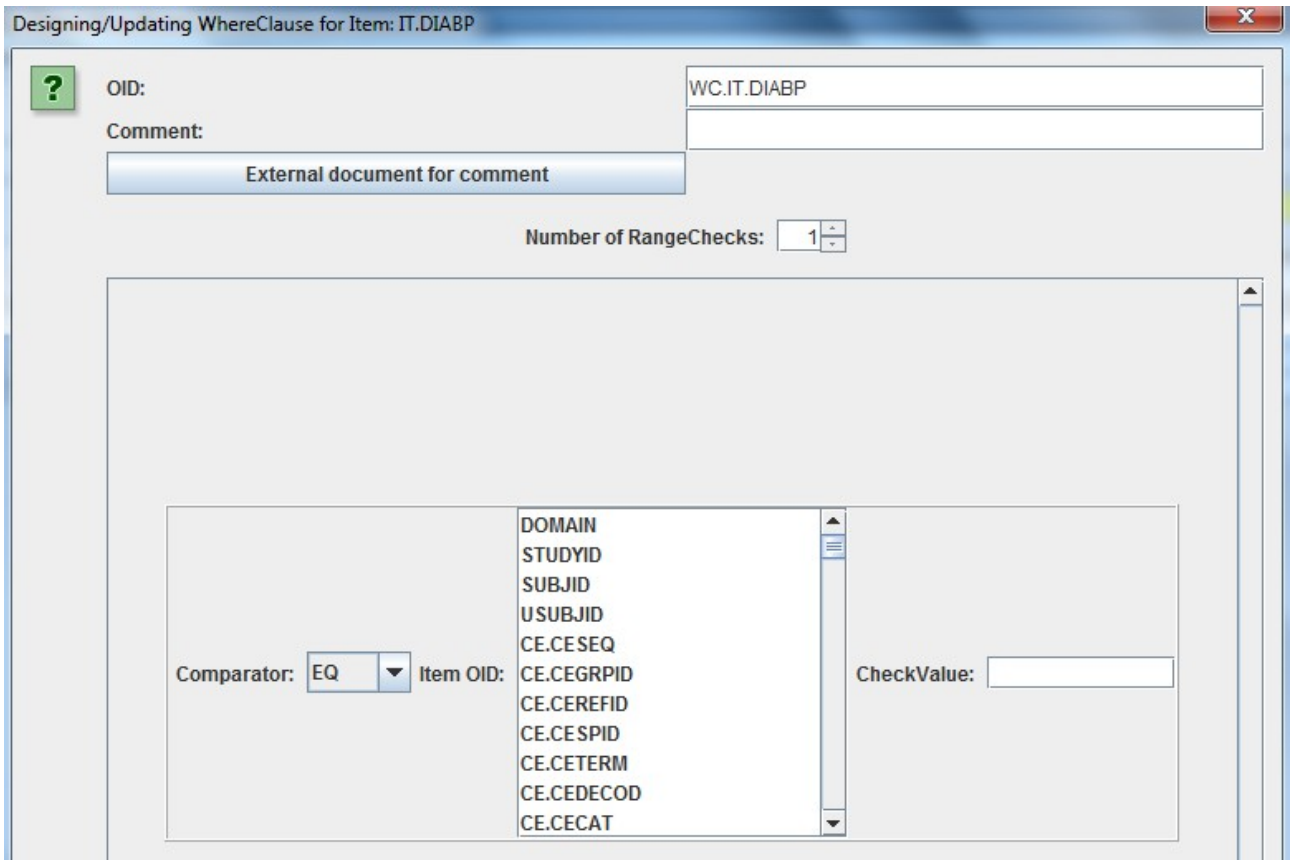


and scroll down until we find the appropriate codelist. Notice that the allowed values are displayed in a tooltip, making it easier to find the correct one.

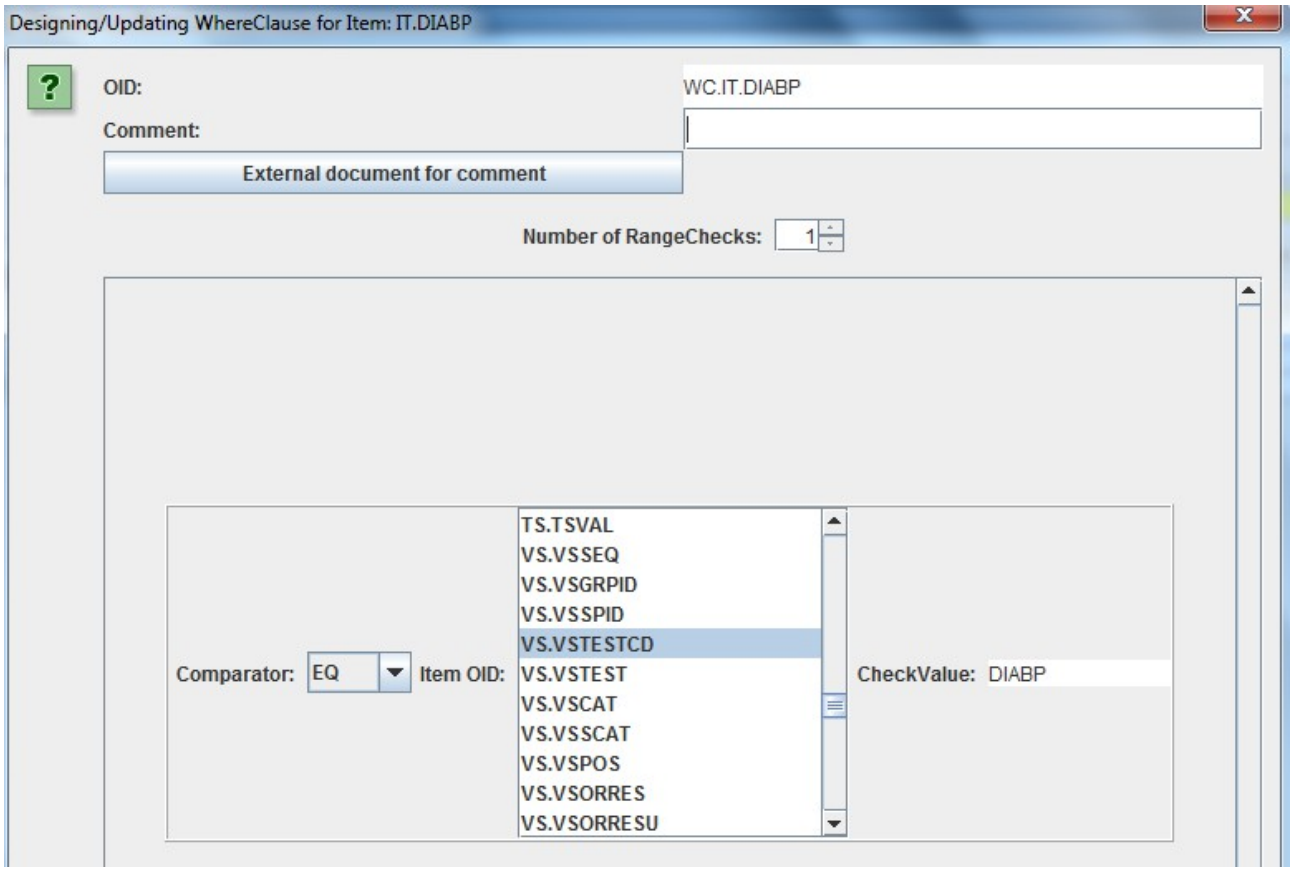
All we still need to do (mandatory) is to provide the „WhereClause“ for each row, indicating under which conditions the metadata (data type, length, enumeration) need to be used:

Method	CodeList	WhereClause
		WC.IT.DIABP
	CL.FRAMESIZE...	WC.IT.FRMSIZE
		WC.IT.HEIGHT
		WC.IT.SYSBP
		WC.IT.WEIGHT

In the „WhereClauses“, we will need to define that the metadata for „DIABP“ need to be used when VSTESTCD=DIABP (simple isn't it?). So clicking the cell WC.IT.DIABP (the system already provides a proposal for the identifier), the following dialog is displayed:

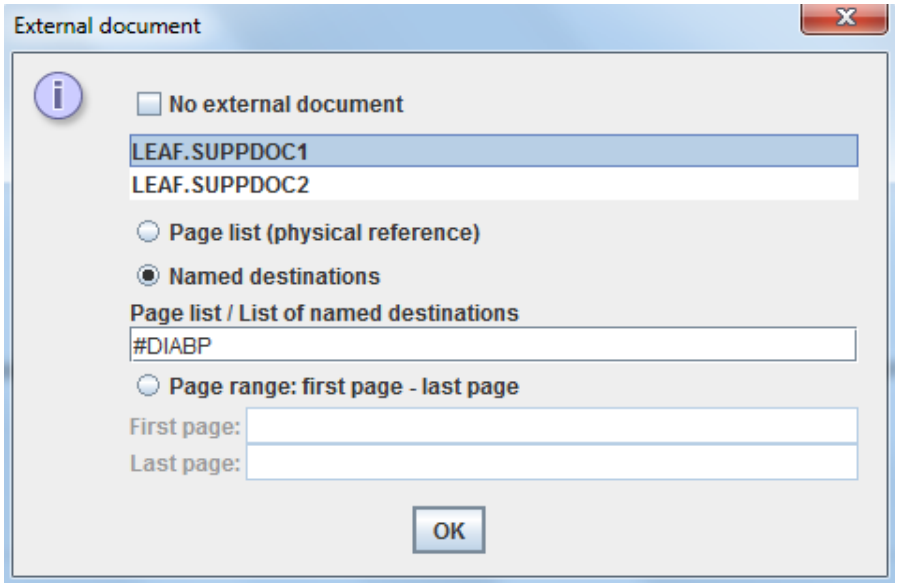


The only thing we need to state as condition is that: VSTESTCD=DIABP, which easily accomplished by:



using the comparator „EQ“ which means „equals to“, which is exactly what we want.

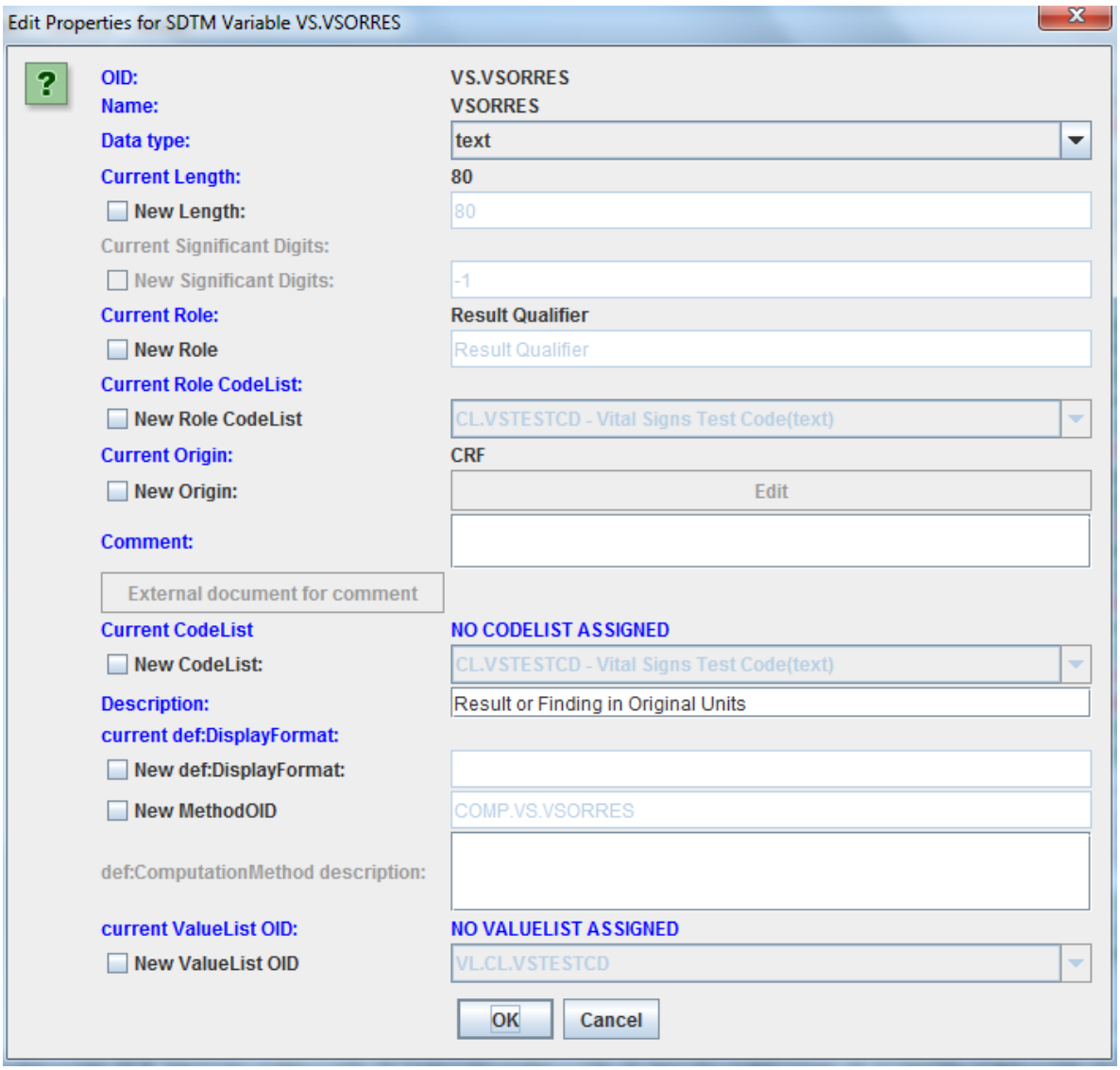
We can also add a comment, and for the comment, even a link to an external document.
Adding a comment is especially important when the condition is complex (see futher) so that one can a textual declaration of the condition. If the condition is very complex, one may also provide a link to a specific page or named destination of an external document by clicking the „External document for comment“ button, leading to:



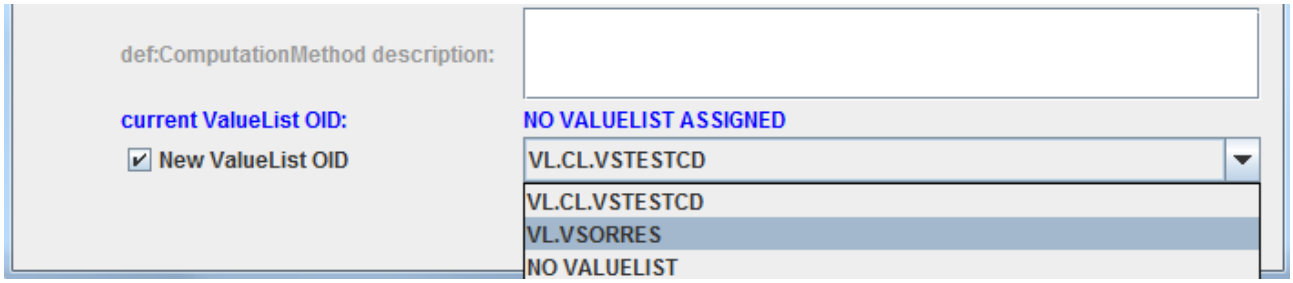
in this case to a named destination within a PDF document.

Of course we also need to create the „WhereClause“ for each other row, and adapt the condition accordingly (for example for „WEIGHT“, we must state VSTESTCD=WEIGHT).

One thing we should NOT forget, is to assign the new ValueList with all its „WhereClauses“ to the SDTM variable „VSORRES“. This is done by selecting VSORRES in the main table and then using the menu „Edit – SDTM Variable Properties“:



and then use the checkbox „New ValueList OID“, and selecting the newly created ValueList „VL.VSORRES“



In the define.xml, this will later look like:

```
<ItemDef DataType="text" Length="80" Name="VSORRES" OID="VS.VSORRES">
   <Description>
      <TranslatedText xml:lang="en">Result or Finding in Original Units</TranslatedText>
   </Description>
   <def:ValueListRef ValueListOID="VL.VSORRES"/>
</ItemDef>
```

and:

```
<def:ValueListDef OID="VL.VSORRES">
   <ItemRef ItemOID="IT.DIABP" Mandatory="No" OrderNumber="1">
      <def:WhereClauseRef WhereClauseOID="WC.IT.DIABP"/>
   </ItemRef>
   <ItemRef ItemOID="IT.FRMSIZE" Mandatory="No" OrderNumber="2">
      <def:WhereClauseRef WhereClauseOID="WC.IT.FRMSIZE"/>
   </ItemRef>
   <ItemRef ItemOID="IT.HEIGHT" Mandatory="No" OrderNumber="3">
      <def:WhereClauseRef WhereClauseOID="WC.IT.HEIGHT"/>
   </ItemRef>
   <ItemRef ItemOID="IT.SYSBP" Mandatory="No" OrderNumber="4">
      <def:WhereClauseRef WhereClauseOID="WC.IT.SYSBP"/>
   </ItemRef>
   <ItemRef ItemOID="IT.WEIGHT" Mandatory="No" OrderNumber="5">
      <def:WhereClauseRef WhereClauseOID="WC.IT.WEIGHT"/>
   </ItemRef>
</def:ValueListDef>
<def:WhereClauseDef OID="WC.IT.DIABP">
   <RangeCheck Comparator="EQ" SoftHard="Soft" def:ItemOID="VS.VSTESTCD">
      <CheckValue>DIABP</CheckValue>
   </RangeCheck>
</def:WhereClauseDef>
<def:WhereClauseDef OID="WC.IT.FRMSIZE">
   <RangeCheck Comparator="EQ" SoftHard="Soft" def:ItemOID="VS.VSTESTCD">
      <CheckValue>FRMSIZE</CheckValue>
   </RangeCheck>
```

The first picture showing how the ValueList VL.VSORRES is referenced by VSORRES, the second one showing the details and some (the first two from five) „WhereClause“ definitions. The details are then found in the corresponding „ItemDefs“:

```
<ItemDef DataType="integer" Length="3" Name="DIABP" OID="IT.DIABP">
   <Description>
      <TranslatedText xml:lang="en">Diastolic blood pressure is integer of length 3</TranslatedText>
   </Description>
   <def:Origin Type="CRF">
      <def:DocumentRef leafID="LEAF.A-CRF">
         <def:PDFPageRef PageRefs="25" Type="PhysicalRef"/>
      </def:DocumentRef>
   </def:Origin>
</ItemDef>
<ItemDef DataType="text" Length="2" Name="FRMSIZE" OID="IT.FRMSIZE">
   <Description>
      <TranslatedText xml:lang="en">Frame size is enumerated to SMALL, MEDIUM, LARGE</TranslatedText>
   </Description>
   <CodeListRef CodeListOID="CL.FRAMESIZE"/>
   <def:Origin Type="CRF">
      <def:DocumentRef leafID="LEAF.A-CRF">
         <def:PDFPageRef PageRefs="25" Type="PhysicalRef"/>
      </def:DocumentRef>
   </def:Origin>
</ItemDef>
```

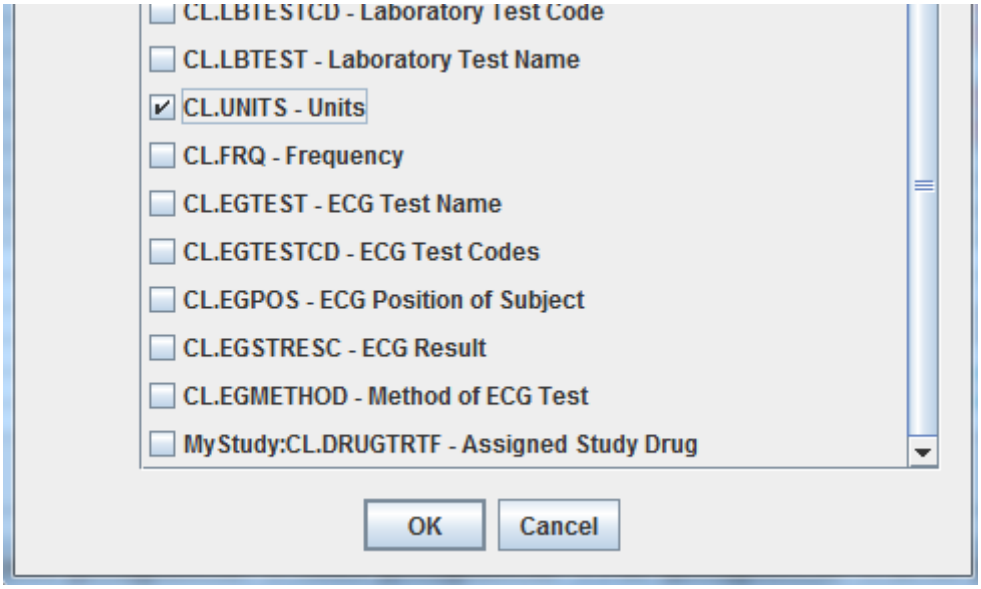
One nicely sees that it is stated that for DIABP, an integer is expected, whereas for FRMSIZE, a reference is made to the codelist CL.SIZE, listing the enumerations „S“ (small), „M“ (medium), and „L“ (large) and „XL“ (extra large):

```
<CodeList DataType="text" Name="Frame size" OID="CL.FRAMESIZE">
   <EnumeratedItem CodedValue="S"/>
   <EnumeratedItem CodedValue="M"/>
   <EnumeratedItem CodedValue="L"/>
   <EnumeratedItem CodedValue="XL"/>
</CodeList>
```

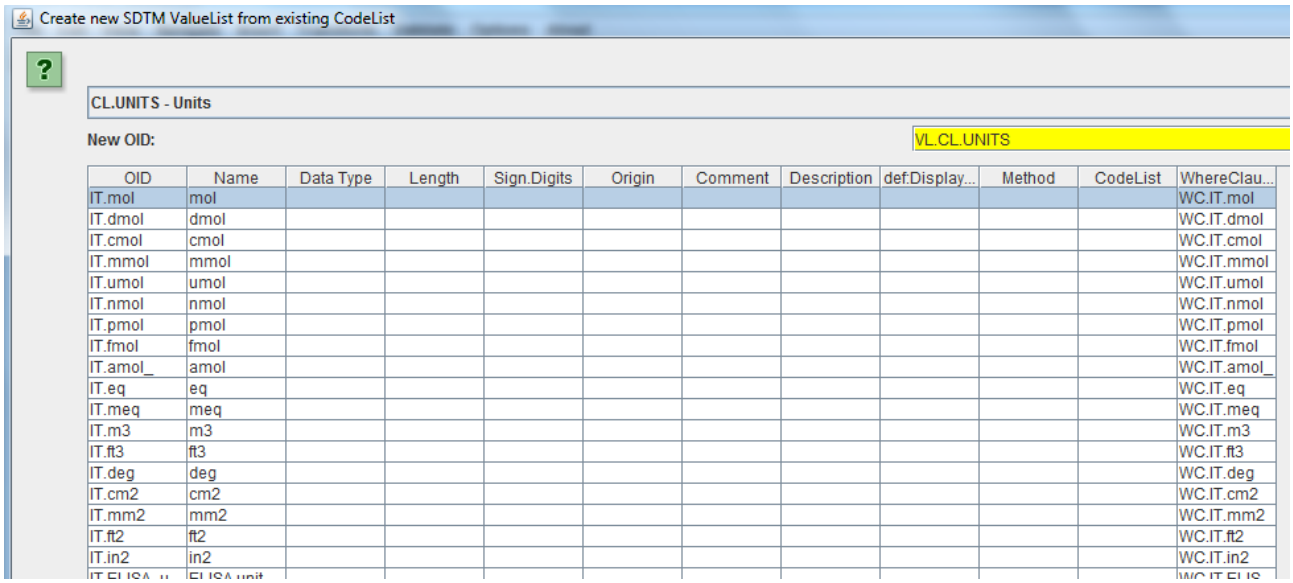
Creating a ValueList for VSORRESU

Where creating a valuelist for VSORRES (vital signs original result) was simple, we will make us ourselves a lot more difficult for VSORRESU (vital signs original results units). We will define that in case the weight of the subject was captured at a site in the USA, then the unit is „pounds“ whereas when the weight was captured at a site in Germany or France, the unit used is „kilograms“. We will also state that the unit used in „mmHg“ when the test code is either DIABP or SYSBP.

Also here, we can start from an existing codelist and then transform that to a valuelist using the menu „Insert – Create new ValueList from existing CodeList“:



This time we select the „units“ codelist, which is then transformed to a ValueList:



OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def:Display...	Method	CodeList	WhereClau...
IT.mol	mol										WC.IT.mol
IT.dmol	dmol										WC.IT.dmol
IT.cmol	cmol										WC.IT.cmol
IT.mmol	mmol										WC.IT.mmol
IT.umol	umol										WC.IT.umol
IT.nmol	nmol										WC.IT.nmol
IT.pmol	pmol										WC.IT.pmol
IT.fmol	fmol										WC.IT.fmol
IT.amol_	amol										WC.IT.amol_
IT.eq	eq										WC.IT.eq
IT.meq	meq										WC.IT.meq
IT.m3	m3										WC.IT.m3
IT.ft3	ft3										WC.IT.ft3
IT.deg	deg										WC.IT.deg
IT.cm2	cm2										WC.IT.cm2
IT.mm2	mm2										WC.IT.mm2
IT.ft2	ft2										WC.IT.ft2
IT.in2	in2										WC.IT.in2

Renaming it to „VL.VSORRESU“ and removing all unnecessary rows:

New OID: VL.VSORRESU

OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def:Display...	Method	CodeList	WhereClau...
IT.kg	kg										WC.IT.kg
IT.LB	LB										WC.IT.LB
IT.mmHg	mmHg										WC.IT.mm...

Of course we can also alter the OID and Name of the items, e.g.:

OID	Name	Data Type
IT.WEIGHT.EUROPE	Weight Units	
IT.WEIGHT.USA	Weight Units	
IT.BLOODPRESSURE	Blood pressure Units	

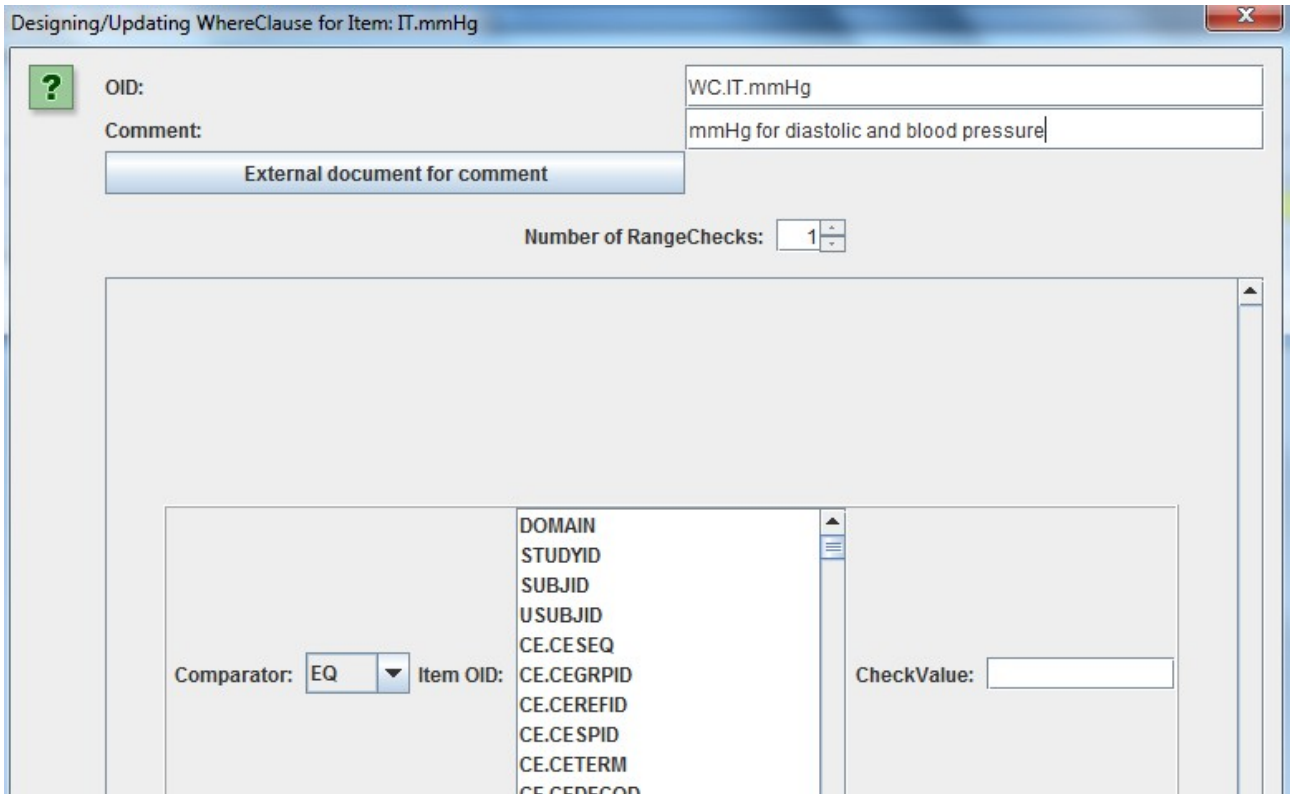
as the unit itself is given, the data type is „text“ in all cases, and again, we can state that the origin is a specific page of the CRF. In this case, it could however also „protocol defined“, as the source might simply have been the protocol stating „weight must be measured in pounds in the US, and in kilograms in France and Germany“. We will assume the latter:

CL.UNITS - Units

New OID: VL.VSORRESU

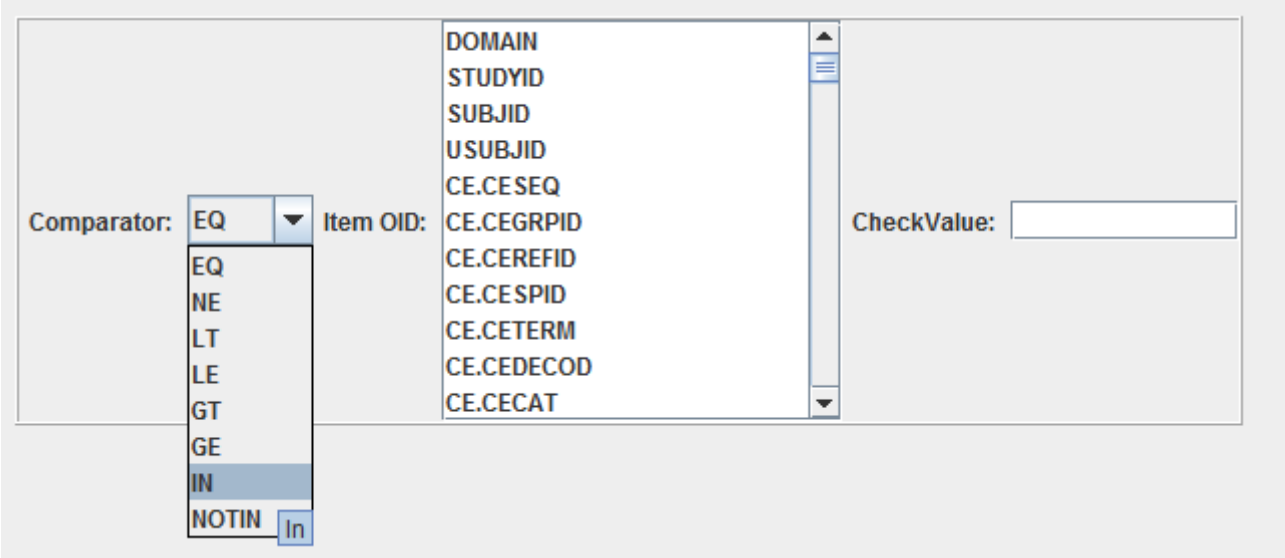
OID	Name	Data Type	Length	Sign.Digits	Origin	Comment	Description	def:Display...
IT.WEIGHT.EUROPE	Weight Units	text	2		Protocol		Weight: original units	
IT.WEIGHT.USA	Weight Units	text	2		Protocol		Weight: original units	
IT.BLOODPRESSURE	Blood pressure Units	text	4		Protocol		Blood pressure: original units	

also having assigned a short description. Now we still need to define under which conditions each of these should be used („Where Clause“). For „blood pressure“ we need to state that mmHg needs to be used when VSTESTCD=DIABP or VSTESTCD=DIABP. This is pretty easy to define:

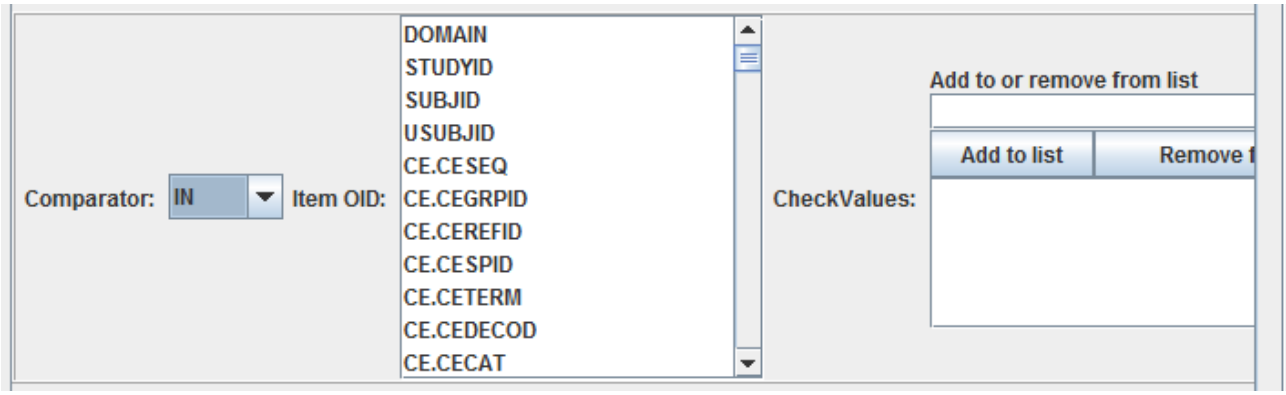


We cannnot simply state VSTESTCD=DIABP as we also need to state „or VSTESTCD_SYSBP“.

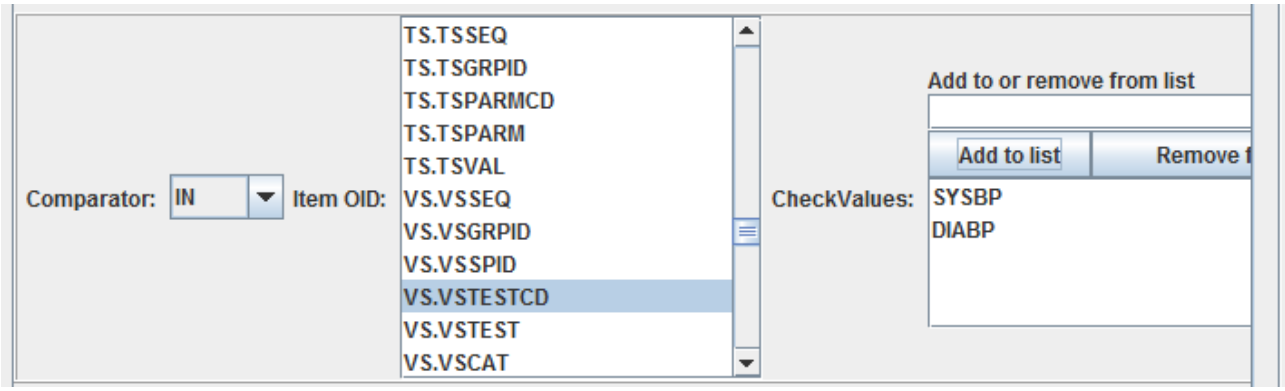
The simplest way we can do this is to select the comparator „IN“, meaning „in the set of ..“:



leading to a somewhat different screen:



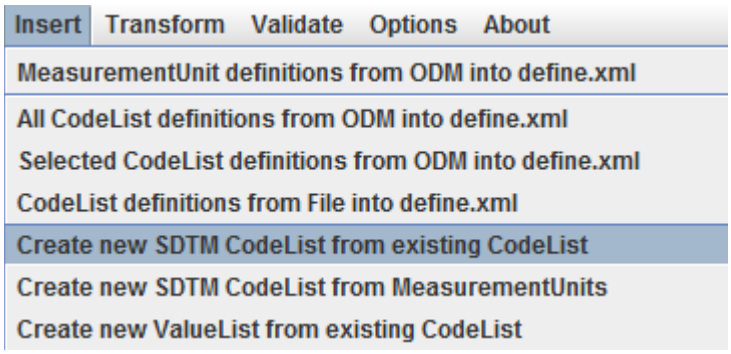
On the right, we can now use items, like „DIABP“ and „SYSBP“ and selecting VS.VSTESTCD in the middle („ItemOID“). Using the „Add to list“ button, this leads to:



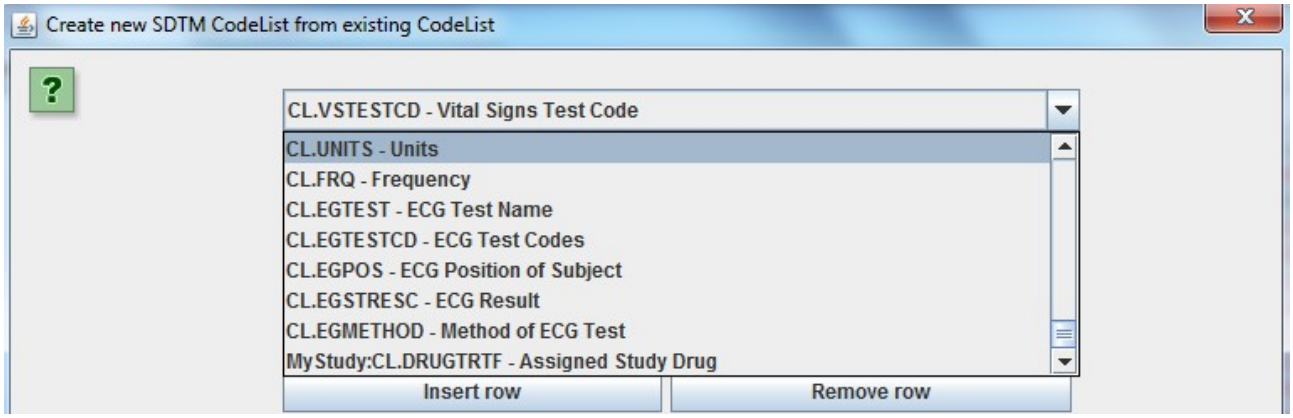
where we have stated that „the condition for using mmHg is that the value of VSTESTCD is in the set {“SYSBP“,DIABP“}“, which is exactly what we want.

Now there is one important thing that we forgot: „what is the value that is expected“ in VSORRESU itself? The only allowed one is „mmHg“, so we need to generate a CodeList with only one value which is „mmHg“.

We will leave the ValueList definitions for a moment, click OK until we are back in the main screen, and generate a new CodeList only containing „mmHg“. To do this use the menu „Insert – Create new CodeList from existing CodeList“:

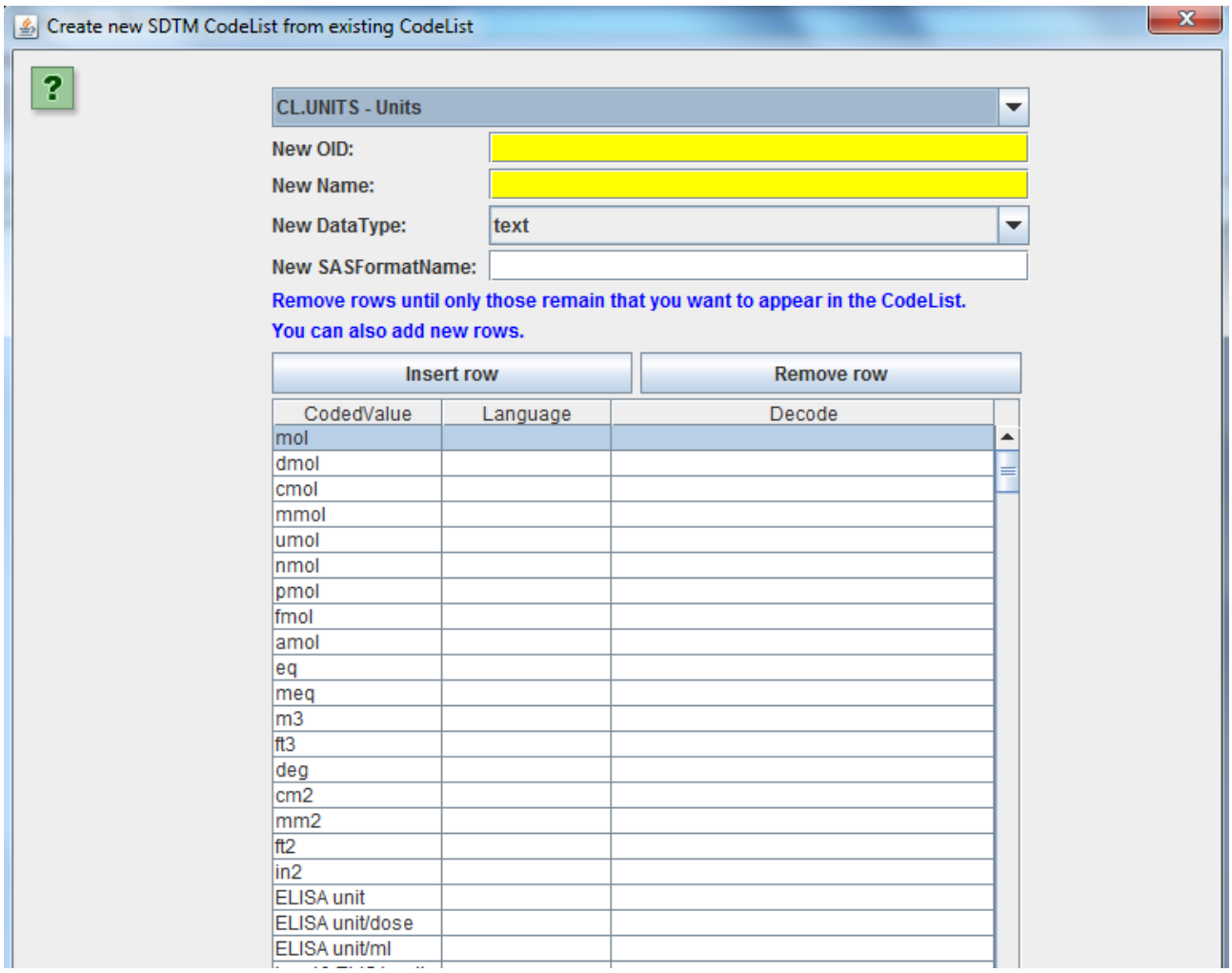


and select CL.UNITS for which we will make a sub-codelist:

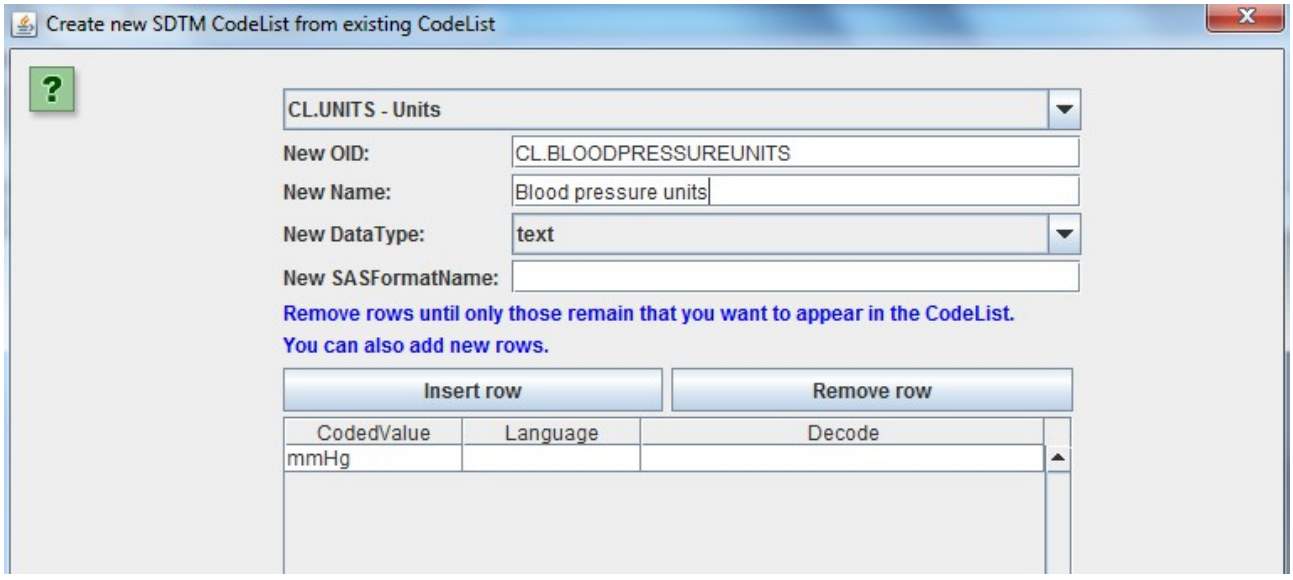


which then displays the full list of units available[4]:

4 Unfortunately the CDISC-CT develops one huge list of units without any system, and independent of the kind of test. We hope that CDISC will however soon switch to UCUM for units.



We now need to remove all unecessary rows until we only keep „mmHg“[5], and give the new codelist the OID „CL.BLOODPRESSUREUNITS“, as it keeps all the units (well, only one in this case) for measurements of blood pressure:

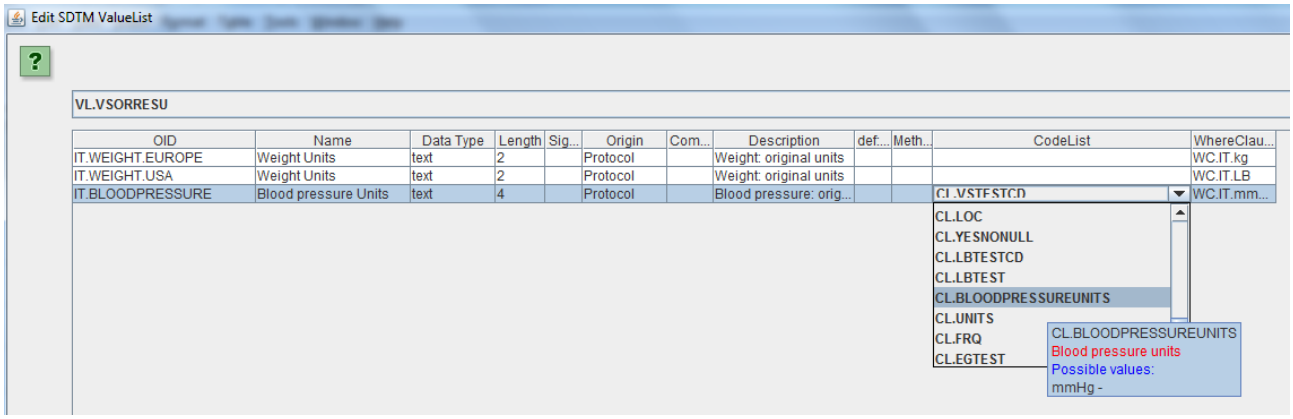


There will be other cases where the sub-codelist can contain more than one entry. Suppose for example that the US-based investigators always report „HEIGHT“ in „inches“, whereas some of

5 The corresponding international UCUM unit is however „mm[Hg]“

their colleagues report in centimeters and others in meters. In Europe, these investigators have tickboxes for „m“ and „cm“ on the CRF, from which they can choose.
As such, there is no way that we can define a „WhereClause“ for distinguishing between „cm“ and „m“ as it depends on the investigators habit (and may of the mood of the day...).

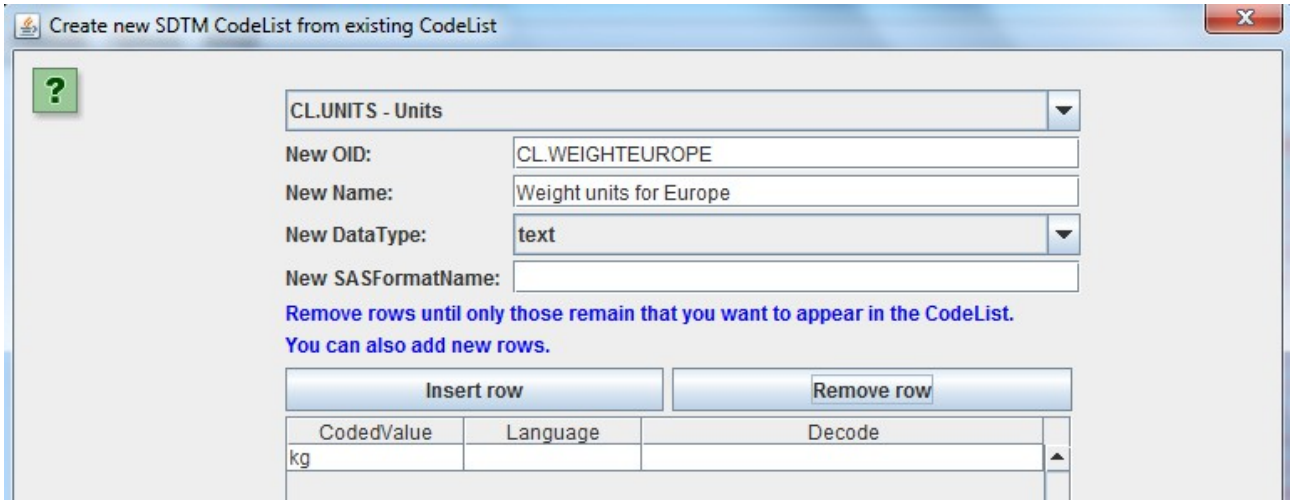
We can now go back to the ValueList VL.VSORRESU that we were editing and now assign the CodeList CL.BLOODPRESSUREUNITS to the item „Blood pressure units“ (IT.BLOODPRESSURE):



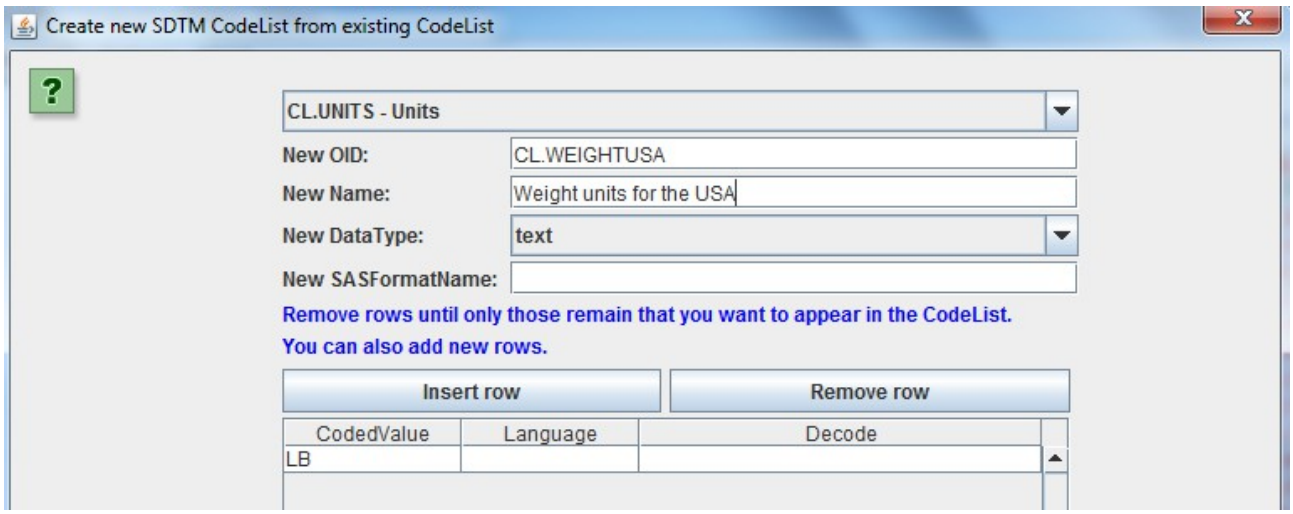
The „Where Clause“ was already added stating that the condition is VSTESTC in „IN“ the set of {„DIABP“, „SYSBP“}.

We now still need to repeat this for the use of weight units in the USA (IT.WEIGHTUSA) and in Europe (IT.WEIGHTEUROPE“). The exact names of the OIDs do not care, as long as we choose the correct attributes such as data type, origin, codelist, and then add a well-defined „WhereClause“.

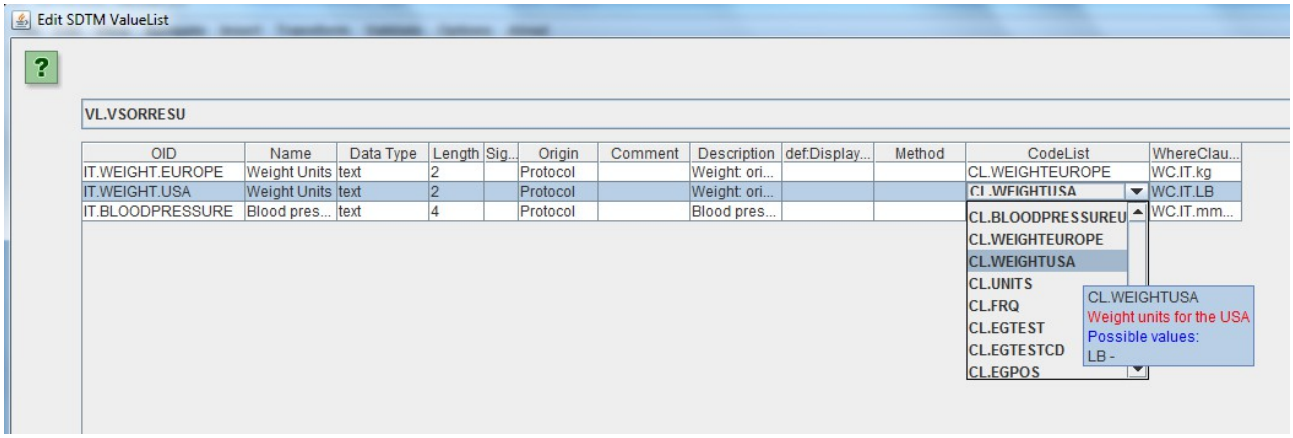
For the item „IT.WEIGHTEUROPE“ we once again need to create a codelist which only contains a single entry „kg“ (kilograms), e.g.:



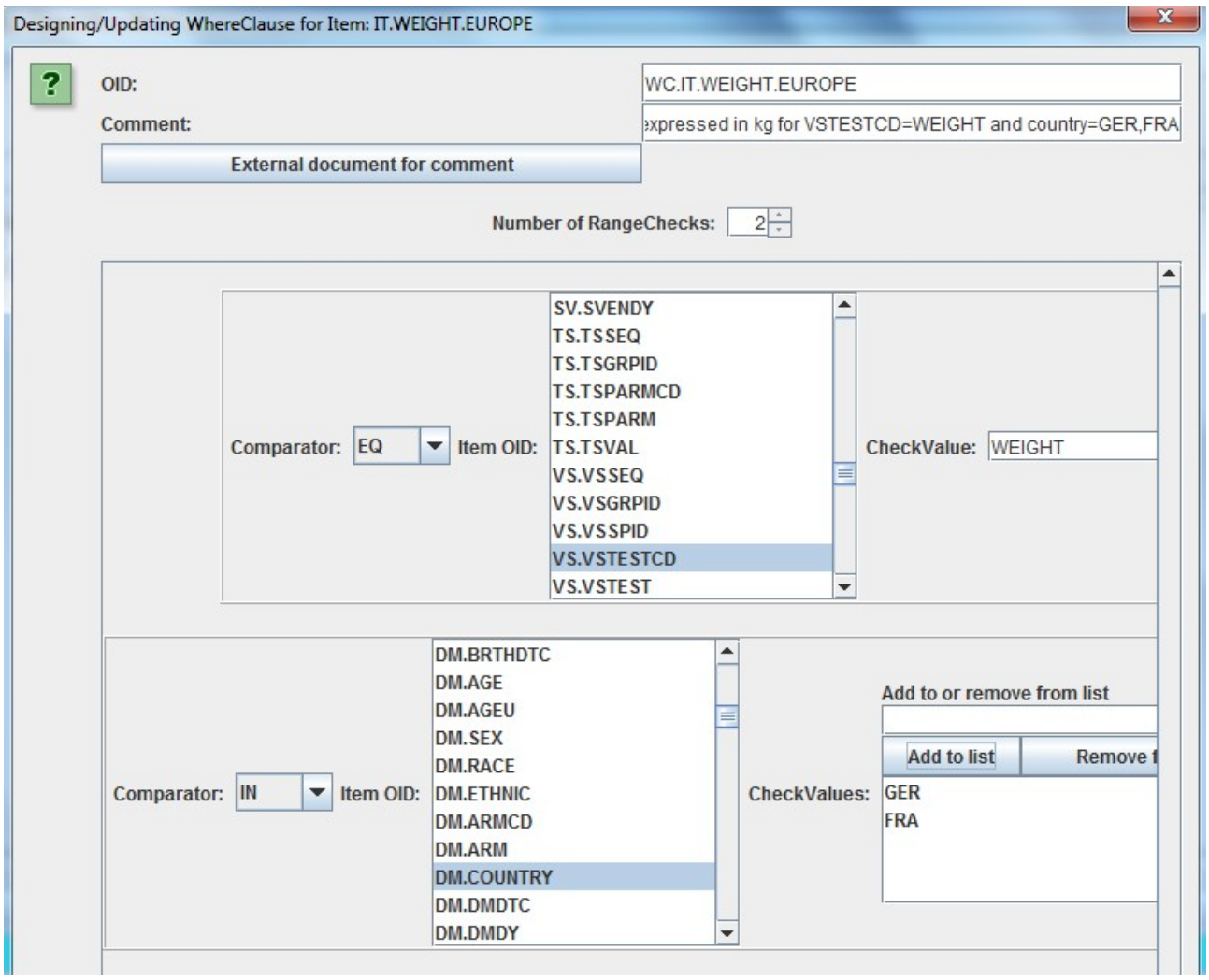
and a similar one but with different contents for „Weight units in the USA“:



and then assign them to their corresponding items in the valuelist:



All we now still need to do is to assign a „WhereClause“ for both. Let's start with „Weight units in Europe“. The first condition is of course that VSTESTCD=WEIGHT, the second being that the country is either Germany or France. The „WhereClause“ editor than looks like:

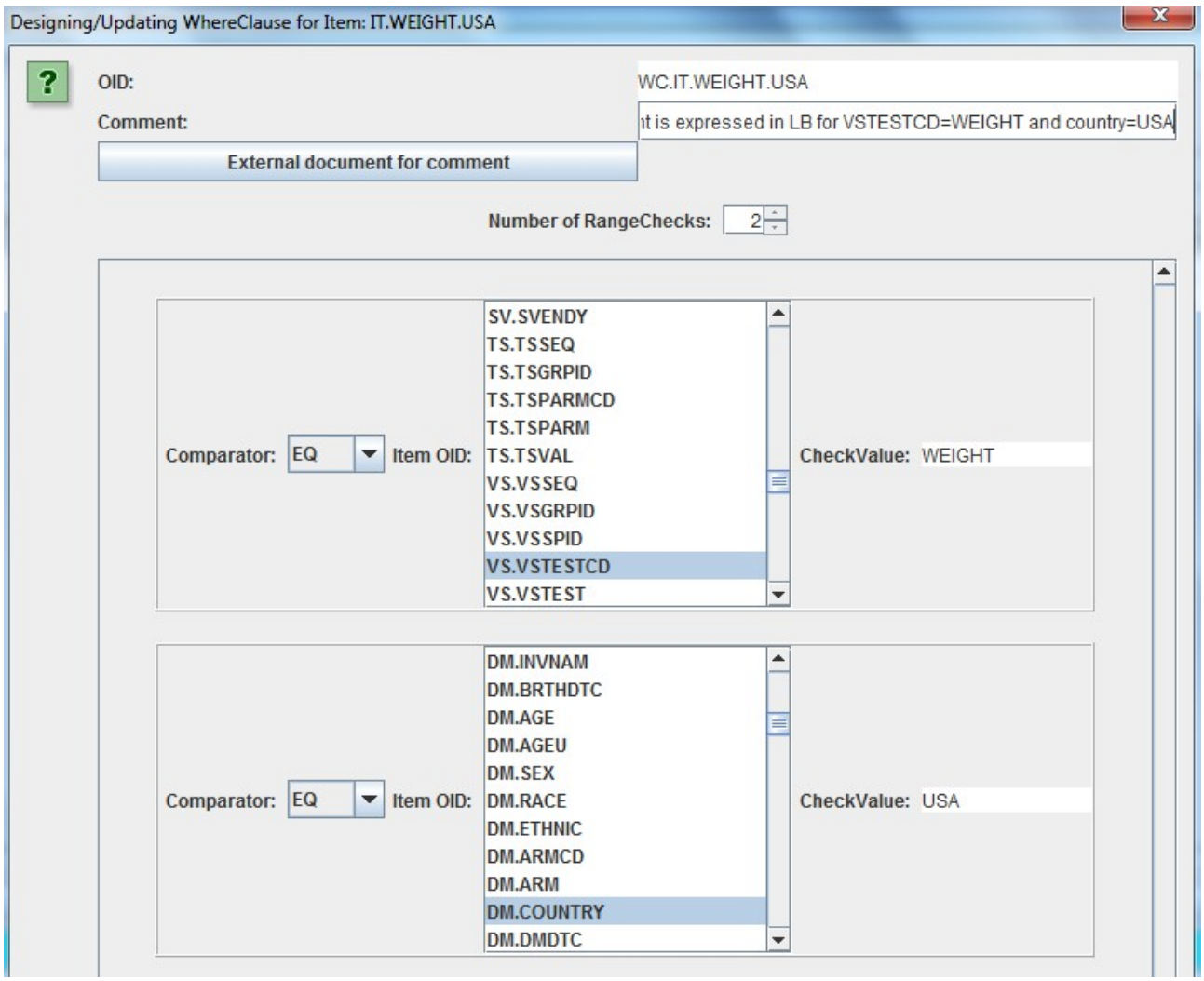


having two checks:

- VSTESTCD=WEIGHT
  and:
- DM.COUNTRY has either the value „GER“ (Germany) or „FRA“ (France).

Also remark that we changed the OID for the „WhereClause“ to make it more clear (although essentially it doesn't matter).

The „WhereClause“ for weight units in the USA is somewhat simpler:



defining two conditions:

- VSTESTCD=WEIGHT
  and:
  DM.COUNTRY=USA

```
<def:ValueListDef OID="VL.VSORRESU">
   <ItemRef ItemOID="IT.WEIGHT.EUROPE" Mandatory="No" OrderNumber="1">
      <def:WhereClauseRef WhereClauseOID="WC.IT.WEIGHT.EUROPE"/>
   </ItemRef>
   <ItemRef ItemOID="IT.WEIGHT.USA" Mandatory="No" OrderNumber="2">
      <def:WhereClauseRef WhereClauseOID="WC.IT.WEIGHT.USA"/>
   </ItemRef>
   <ItemRef ItemOID="IT.BLOODPRESSURE" Mandatory="No" OrderNumber="3">
      <def:WhereClauseRef WhereClauseOID="WC.IT.mmHg"/>
   </ItemRef>
</def:ValueListDef>
<def:WhereClauseDef OID="WC.IT.BMI" def:CommentOID="COM.WC.IT.BMI">
   <RangeCheck Comparator="EQ" SoftHard="Soft" def:ItemOID="VS.VSTESTCD">
      <CheckValue>BMI</CheckValue>
   </RangeCheck>
</def:WhereClauseDef>
```

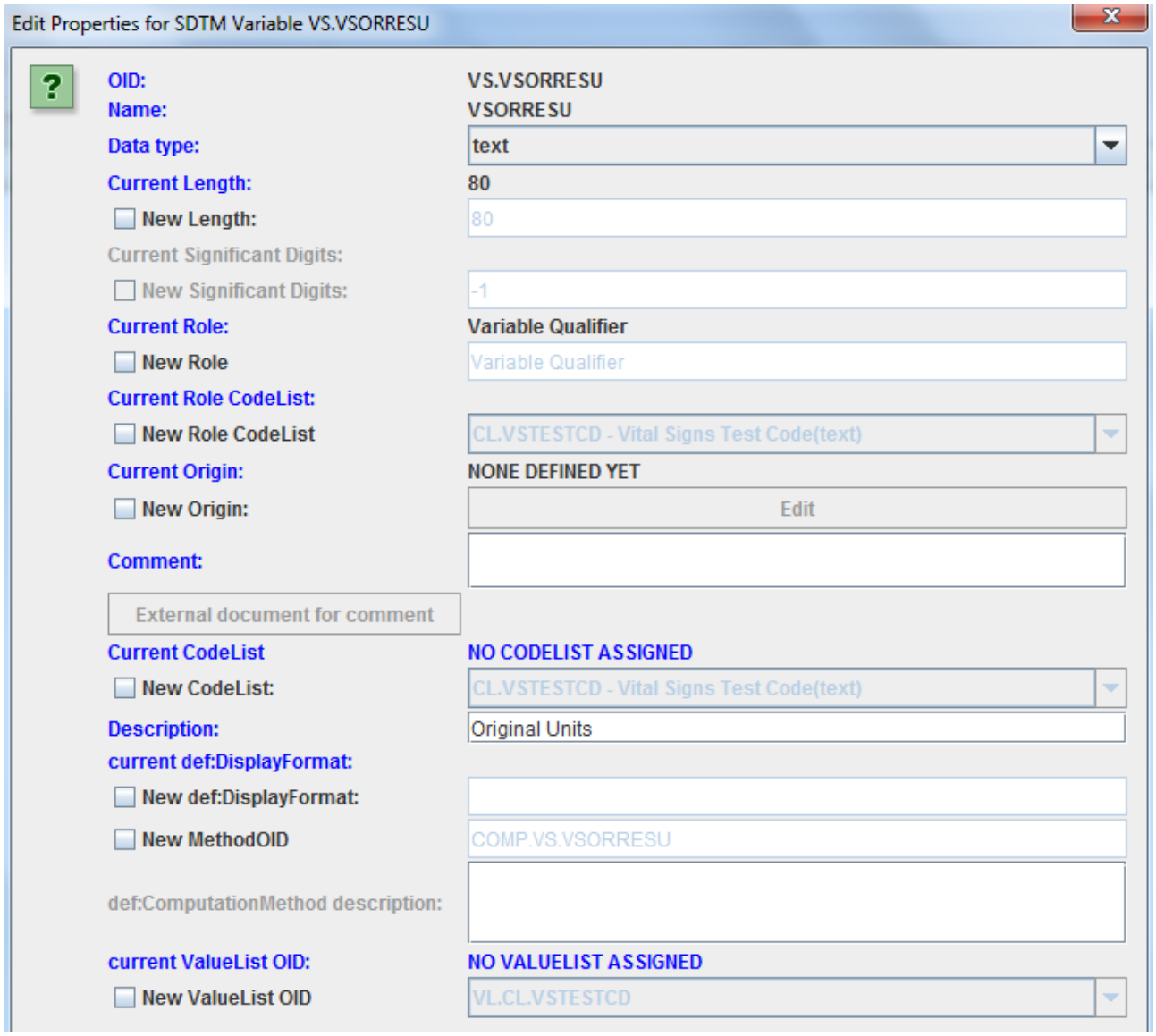
and e.g. the „WhereClause“ for units for weight in Germany and France:

```
<def:WhereClauseDef OID="WC.IT.WEIGHT.EUROPE" def:CommentOID="COM.WC.IT.WEIGHT.EUROPE">
   <RangeCheck Comparator="EQ" SoftHard="Soft" def:ItemOID="VS.VSTESTCD">
      <CheckValue>WEIGHT</CheckValue>
   </RangeCheck>
   <RangeCheck Comparator="IN" SoftHard="Soft" def:ItemOID="DM.COUNTRY">
      <CheckValue>GER</CheckValue>
      <CheckValue>FRA</CheckValue>
   </RangeCheck>
</def:WhereClauseDef>
```

and the corresponding comment:

```
<def:CommentDef OID="COM.WC.IT.WEIGHT.EUROPE">
   <Description>
      <TranslatedText xml:lang="en">weight is expressed in kg for VSTESTCD=WEIGHT and country=GER,FRA</TranslatedText>
   </Description>
</def:CommentDef>
```

Not a bad idea to check whether we really assigned our newly developed valuelist to VSORRESU:



It looks as we didn't, so we do it now using the checkbox „New ValueList OID“:

which appears in the define.xml as:

```
<ItemDef DataType="text" Length="6" Name="VSORRESU" OID="VS.VSORRESU">
   <Description>
      <TranslatedText xml:lang="en">Original Units</TranslatedText>
   </Description>
   <def:ValueListRef ValueListOID="VL.VSORRESU"/>
</ItemDef>
```

and in the HTML view (use „View – View define.ml in browser):

Value Level Metadata

Value Level Metadata - Vital Signs [VSORRES]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
DIABP	VSTESTCD EQ DIABP	integer	3		CRF Page 25	
FRMSIZE	VSTESTCD EQ FRMSIZE	text	6	["S", "M", "L", "XL"] <Frame size>	CRF Page 25	
HEIGHT	VSTESTCD EQ HEIGHT	float	5		CRF Page 25	
SYSBP	VSTESTCD EQ SYSBP	integer	3		CRF Page 25	
WEIGHT	VSTESTCD EQ WEIGHT	float	5		CRF Page 25	

Value Level Metadata - Vital Signs [VSORRESU]

Variable	Where	Type	Length / Display Format	Controlled Terms or Format	Origin	Derivation/Comment
Weight Units	VSTESTCD EQ WEIGHT AND COUNTRY IN ("GER" , "FRA")	text	2	["kg"] <Weight units for Europe>	Protocol	weight is expressed in kg for VSTESTCD=WEIGHT and country=GER,FRA
Weight Units	VSTESTCD EQ WEIGHT AND COUNTRY EQ USA	text	2	["LB"] <Weight units for the USA>	Protocol	weight is expressed in LB for VSTESTCD=WEIGHT and country=USA
Blood pressure Units	VSTESTCD IN ("SYSBP" , "DIABP")	text	4	["mmHg"] <Blood pressure units>	Protocol	mmHg for diastolic and systolic blood pressure

This finalizes our tutorial about the use of the „Where Clause“. Once again, when using „Where Clause“ you do not need nested value levels anymore, and in define.xml 2.0, you should not use nested valuelevel metadata descriptions.
We also showed how easy it is using SDTM-ETL to define the „Where Clauses“ in a user-friendly way using a graphical, easy-to-use dialog, and without any necessity to do XML editing.