

Agenda
18th Meeting

German CDISC User Group



Date: 18. Februar 2014

Location: Accovion GmbH
Helfmann-Park 10
65760 Eschborn
Raum 341 & 342 / 3. Stock

Update on LOINC and UCUM

Jozef Aerts

History

- Use of UCUM (for units) and LOINC (for lab tests) is common (if not mandatory) in electronic health records
- CDISC however decided to develop its own CT for units and lab tests
- As these are just lists without any system, they are not usable in practice and not interoperable with what is used in healthcare
 - nor with FDA-SPL

History

- LOINC-UCUM 1-day workshop at the German-speaking User Group Meeting in Berlin (September 2013)
- Formal request to CDISC (over the public comments list) to stop development of CT for units and lab tests and switch over to UCUM and LOINC
 - in order to guarantee interoperability with
 - healthcare
 - other submission standards in the FDA such as SPL

CDISC's response on use of UCUM

Use UCUM instead of [UNIT]
XXX Closed for Comment-Controlled Term Pkg 16 - General -
UNIT controlled terminology
<p>The design of the [UNIT] codelist is highly problematic. The CT contains as well units that really are units (i.e. have the same definition and meaning all over the world - example: g, m, sec, ...) but also a lot of "units" that are not units but presentation forms (like bottle, capsule, bar (of chocolate?) -not as unit of pressure). The latter (presentation forms / "dosing" units) do not belong in the [UNIT] codelist but should go into a separate codelist (or merged with the [FRM] codelist). It can then at the ValueList level in define.xml be described which one is used.</p> <p>For the real units (that have the same definition and meaning and represent exactly the same quantity everywhere in the world), CDISC should (just like HL7 does) strongly promote the usage of the UCUM (Universal Coding System for Units of Measure) system (P.S. the CDISC-CT for units is not a system, it is a list). UCUM is already mandatory in HL7-CDA, the international standard for exchange of electronic health record information. UCUM guarantees that results expressed in different units for the same property (e.g. for pressure: bar, cm[Hg],m[H2O],psi,...) can be interconverted automatically, which is impossible when using the CDISC-CT. As UCUM is a system and not a list, it is much more flexible than [UNIT] where we each time need to add a new entry when e.g. a "k" (kilo) prefix is necessary. UCUM is also very well established in healthcare (is clinical research a part of healthcare? I would say so ...). Also remark that the use of UCUM is already mandatory in FDA-SPL, so it is also already well established there.</p>

CDISC Disposition	Out of Scope
CDISC Disposition Description	rdempsey (10/21/2013 11:10 AM): This should be entered as a new term request not as a general comment in the comment tracker.
Document Impact	Low

But some unexpected support ...

Comment Title	Use UCUM instead of UNIT
Assigned To - Team Responder	
Document Being Commented On	XXX Closed for Comment-Controlled Term Pkg 16 - General -
Document Section	UNIT controlled terminology
Comment	I agree with Josef, CDISC should be moving to UCUM (for the reasons articulated by Josef).
Comment Author	sbishop
Comment Category	Select or Blank
CDISC Comment	No existing entries.
Current State	Closed
Assigned To - External Person	
Related Comments	No existing entries.
CDISC Disposition	Out of Scope
CDISC Disposition Description	rdempsey (10/21/2013 11:15 AM): This should be entered as a new term request not as a general comment in the comment tracker.
Document Impact	Low
Archive	

Simon Bishop is a CDISC veteran working for GSK

Also comments from other in the same direction are completely ignored



[Unit - 10⁵/L](#)

Should not be added. The addition of these could result in people not using the standards in ... There is no issue with **UCUM** and the lab team feels that when a lab reports a value in 10⁵/L ...

Authors: Bernice Yost Date: 1/23/2013

<http://cdiscportal.digitalinfuzion.com/CT/Lists/Comments/DispForm.aspx?ID=542>



[Unit - 10⁴/L](#)

Should not be added. The addition of these could result in people not using the standards in ... There is no issue with **UCUM** and the lab team feels that when a lab reports a value in 10⁴/L ...

Authors: Bernice Yost Date: 1/23/2013

<http://cdiscportal.digitalinfuzion.com/CT/Lists/Comments/DispForm.aspx?ID=543>



[Unit - 10⁸/L](#)

Should not be added. The addition of these could result in people not using the standards in ... There is no issue with **UCUM** and the lab team feels that when a lab reports a value in 10⁸/L ...

Authors: Bernice Yost Date: 1/23/2013

<http://cdiscportal.digitalinfuzion.com/CT/Lists/Comments/DispForm.aspx?ID=544>



[Unit - 10¹⁰/L](#)

Should not be added. The addition of these could result in people not using the standards in ... There is no issue with **UCUM** and the lab team feels that when a lab reports a value in 10¹⁰ ...

Authors: Bernice Yost Date: 1/23/2013

<http://cdiscportal.digitalinfuzion.com/CT/Lists/Comments/DispForm.aspx?ID=545>



[Unit - 10¹¹/L](#)

Should not be added. The addition of these could result in people not using the standards in ... There is no issue with **UCUM** and the lab team feels that when a lab reports a value in 10¹¹ ...

Authors: Bernice Yost Date: 1/23/2013

<http://cdiscportal.digitalinfuzion.com/CT/Lists/Comments/DispForm.aspx?ID=546>

Bernice Yost complaining about CT having no system, so list will grow to infinity

The answer of CDISC (on Bernice Yost's remarks)

CDISC Disposition	Not persuasive
CDISC Disposition Description	ctolk (1/23/2013 12:52 PM): There is no issue with UCUM and the lab team feels that when a lab reports a value in 10^10/L it should be reported in that unit.
Document Impact	Select or Blank
Archive	

LOINC

- Formal request to CDISC (using public comments list) to deprecate CDISC-CT for lab tests and use LOINC instead

Comment Title	Make LB-CT "deprecated" and replace by LOINC
Assigned To - Team Responder	
Document Being Commented On	XXX Closed for Comment-Controlled Term Pkg 16 - Lab -
Document Section	Controlled Term Pkg 16 - General
Comment	<p>The development of this CT goes in the complete wrong direction. Most terms are ambiguous and do not uniquely describe a single test. As there is no CT for LBCAT,LBSCAT,LBSPEC,LBMETHOD, the combination with these also does not uniquely describe tests, especially not when trying to compare lab values from different studies and sponsors. Also see my presentation at the CDISC German Speaking User Group in Berlin in september at: http://www.xml4pharma.com/publications/Use_of_LOINC_UCUM_in_SDTM_and_SEND.pdf. So why not use LOINC? CDISC seems to have implemented the wrong base as there is already a well-established</p>

CDISC's answer

Related Comments	No existing entries.
CDISC Disposition	Out of Scope
CDISC Disposition Description	rdempsey (10/21/2013 11:10 AM): This should be entered as a new term request not as a general comment in the comment tracker.
Document Impact	Low
Archive	

- Also the new team lead for CDISC-CT considers this
 - out of scope
 - of low impact

Some comments (from others) on usage of LOINC

CDISC needs to move to LOINC for Lab tests

Simon Bishop - GSK

XXX Closed for Comment-Controlled Term Pkg 16 - Lab -

Controlled Term Pkg 16 - Lab

I agree with Josef: CDISC should move to LOINC for lab test codes. The current CDISC CT is incomplete, slow growing and ill-defined. I suspect that there are many occasions when a lab test code is being used for different lab tests, with non-aggregatable test results, across the industry. This is not to the benefit of regulators, clinical labs, industry or patients.

Note that, more generally, I think CDISC should be using LOINC for more than just lab tests.

[sbishop](#)

Select or Blank

[rdempsey](#) (10/30/2013 12:06 PM): This should be entered as a new term request not as a general comment in the comment tracker.

Closed

No existing entries.

Out of Scope

No existing entries.

Low

CDISC
Answer

Thanks Simon!

Conclusions

- No change, no progress
- "Not invented here" syndrome persists
- There was some hope the new team lead would be more open for interoperability with healthcare
- The way the formal request was handled is really disappointing