

Keeping control in a changing world

AGENDA

- Versioning
- Current issues
- Improvements



A wine



A wine – two bottles



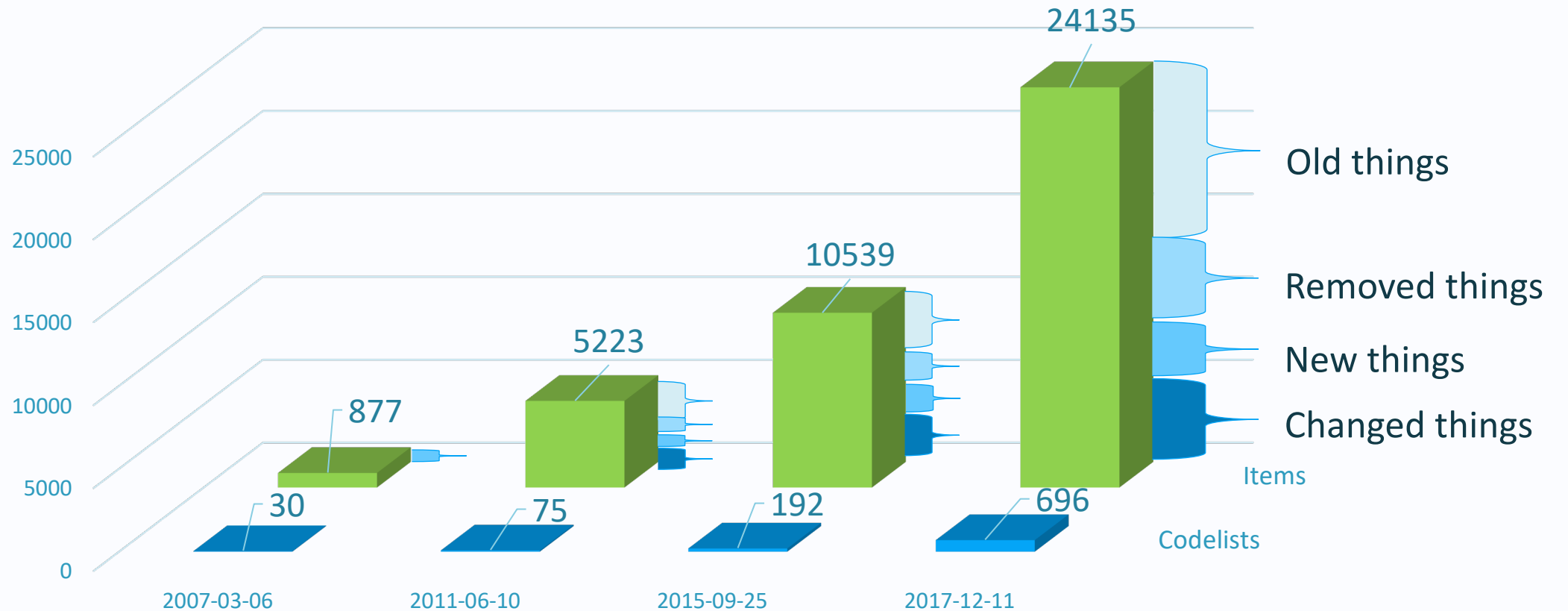
A wine – two bottles



CDISC Terminology



CDISC Terminology History



The BUN mystery

March 2016

	Mon 21	Tue 22	Wed 23	Thu 24	Fri 25	Sat 26
all-day						
08:00						
09:00						
10:00					Check new SDTM CT	
11:00						
12:00				Run validation		
13:00						
14:00						
15:00						
16:00						
17:00						

- Ongoing project, 8 trials
- Project decision:
Always use latest SDTM CT
- Everything runs smoothly

- Validation tools report of incorrect submission value!
- BUN has been stolen!



The BUN mystery – whodunnit?



Code List Item Changes

Show 10 entries

Search: urea nitro

Identifier	Label	Submission Value	2015-03-27	2015-06-26	2015-09-25	2015-12-18	2016-03-25	2016-06-24	2016-09-30	2016-12-13	2017-03-31	2017-06-30	2017-09-29	2017-12-22
C125949	Urea Nitrogen Measurement	UREAN					✓	-	-	-	-	-	-	-
C125950	Urea Nitrogen to Creatinine Ratio Measurement	UREANCRT					✓	-	-	-	-	-	-	-
C61019	Blood Urea Nitrogen Measurement	BUN	-	-	-	-	✗							
C74753	Blood Urea Nitrogen To Creatinine Ratio Measurement	BUNCREAT	-	-	-	-	✗							

2015-12-18

Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCH	Acylcholine Acylhydrolase; Butyrylcho
C61019	BUN	Blood Urea Nitrogen
C75352	BUPREN	Buprenorphine

SDTM

LBTESTCD	LBTEST	LBORRES	LBORRESU
BUN	Blood Urea Nitrogen	7,1	mmol/L

2016-03-25

Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCH	Acylcholine Acylhydrolase; Butyrylcholine
C61019	BUN	Blood Urea Nitrogen
C125949	UREAN	Urea Nitrogen
C75352	BUPREN	Buprenorphine

SDTM

LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSPEC
UREA	Urea Nitrogen	7,1	mmol/L	BLOOD

Linking data together

Question Details ^

Label:

Lab test

Question Text:

Laboratory test

Mapping:

LBTESTCD = BUN

Terminology: Lab test ^

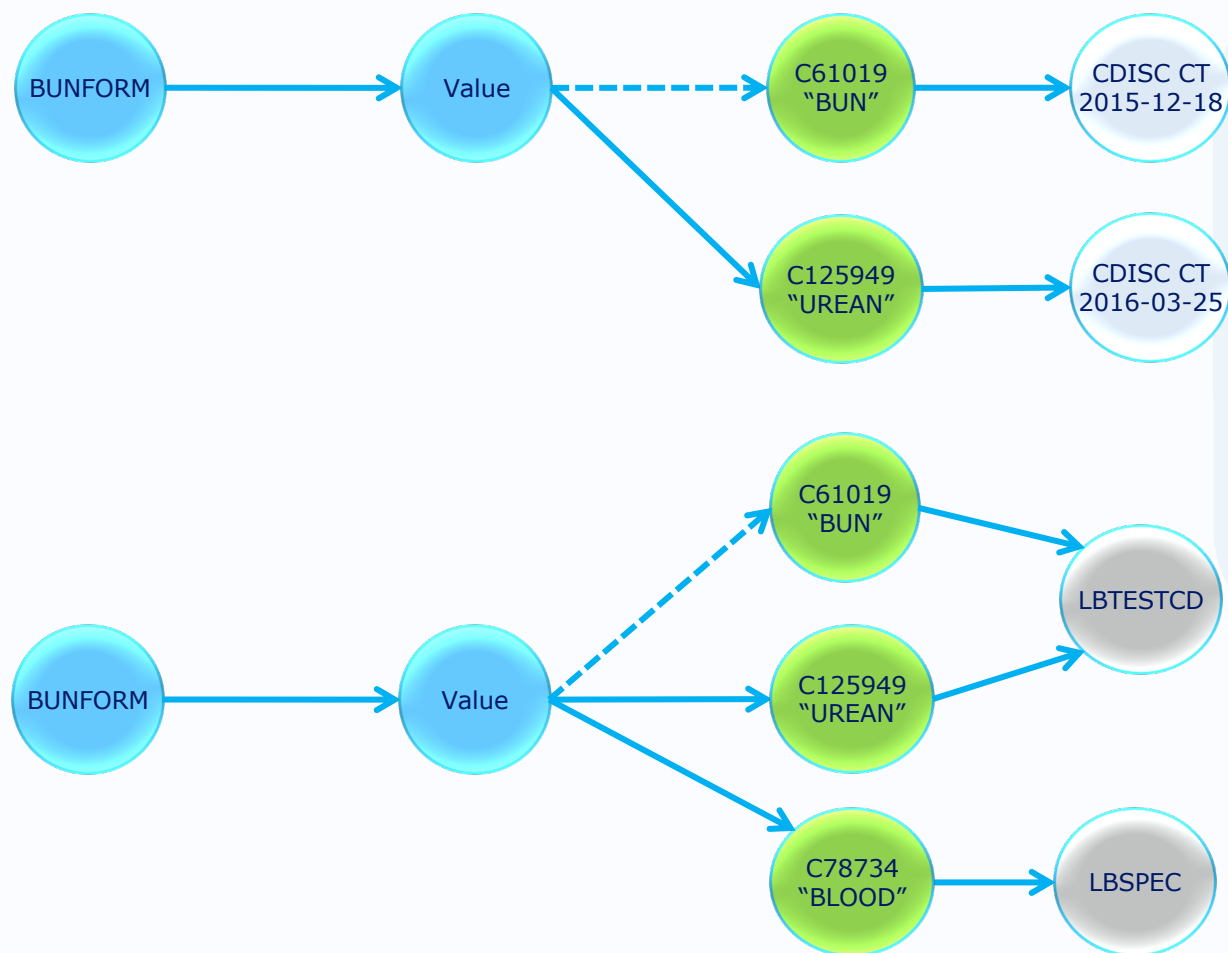
Show 10 entries Search:

Ordinal	Item	Notation	Preferred Term
1	C61019	BUN	Blood Urea Nitrogen Measurement

Annotated CRF: Urea Nitrogen Lab UREAN (V0.1.0, 1, Incomplete)

Urea Nitrogen Lab	LB=Laboratory Data	
Laboratory Test		
Date	LBDTC	D D / M M M / Y Y Y Y H H : M M
Laboratory test	LBTESTCD = BUN	☐ Blood Urea Nitrogen Measurement
Value	LBORRES when LBTESTCD=BUN	# # # . # #

Linking data together – in the background



Impact analysis

Show: CDISC Terminology 2016-03-25 CDISC Terminology (V44.0.0, 44, Standard)

Details

Identifier	Label	Owner	Status	Version	Version Label	
CDISC Terminology	CDISC Terminology 2016-03-25	CDISC	Standard	44.0.0	2016-03-25	Impact

Impact Analysis: CDISC Terminology 2016-03-25

Items Impacted

Show 10 entries

Search:

Identifier	Label	Version	Version Label	
CDISC Terminology	CDISC Terminology 2015-12-18	43.0.0	2015-12-18	Show
QS VAS	Visual Analog Scale	0.1.0		Show
BUNFORM	Urea Nitrogen Lab	0.1.0		Show

Showing 1 to 3 of 3 entries

Previous 1 Next

What is a version?



2015-12-18

Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCHE	Acylcholine Acylhydrolase; Butyrylcho
C61019	BUN	Blood Urea Nitrogen
C75352	BUPREN	Buprenorphine



2016-03-25

Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCHE	Acylcholine Acylhydrolase; Butyrylcholine
C125949	UREAN	Urea Nitrogen
C75352	BUPREN	Buprenorphine

Exists in

Exists in

Exists in

Exists in

BUCHE

BUPREN

What is a version?



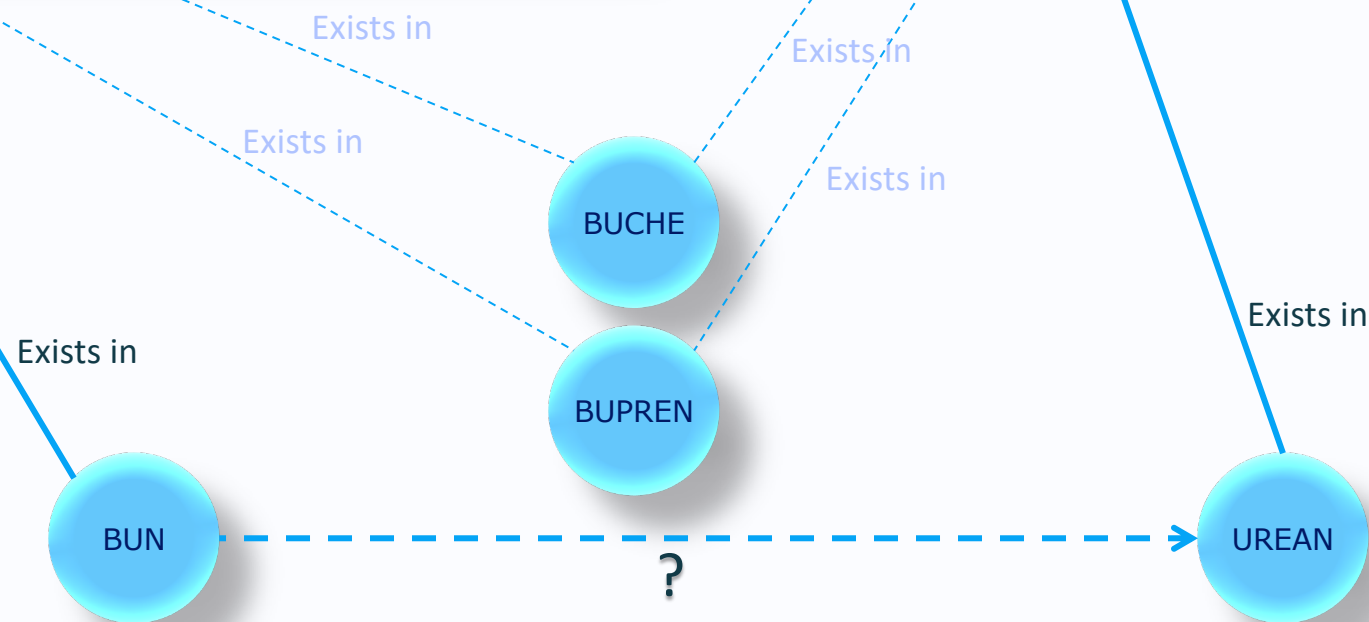
2015-12-18



2016-03-25

Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCH	Acylcholine Acylhydrolase; Butyrylcho
C61019	BUN	Blood Urea Nitrogen
C75352	BUPREN	Buprenorphine

Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCH	Acylcholine Acylhydrolase; Butyrylcholine
C125949	UREAN	Urea Nitrogen
C75352	BUPREN	Buprenorphine



Codelist changes

Changes: CDISC Terminology CDISC Terminology

Show 10 entries

Search:

Identifier	Label	Submission Value	2015-03-27	2015-06-26	2015-09-25	2015-12-18	2016-03-25	2016-06-24	2016-09-30	2016-12-13	2017-03-31	2017-06-30	2017-09-29	2017-12-22	
C120991	CDISC Clinical Classification MELD Test Code Terminology	MELD01TC	✓	—	—	✎	✎	—	—	—	—	—	—	—	Changes
C120992	CDISC Clinical Classification NSA-16 Test Name Terminology	NSA01TN	✓	✎	—	✎	✎	—	—	—	—	—	—	—	Changes
C120993	CDISC Clinical Classification NSA-16 Test Code Terminology	NSA01TC	✓	—	—	✎	✎	—	—	—	—	—	—	—	Changes
C122006	CDISC SDTM COPD Findings About Test Name Terminology	CPFATS		✓	—	✎	—	—	—	—	—	—	—	—	Changes
C122007	CDISC SDTM COPD Findings About Test Code Terminology	CPFATSCD		✓	—	✎	—	—	—	—	—	—	—	—	Changes
C123650	CDISC SDTM Tumor and Lesion Identification Test Result Terminology	TUIDRS			✓	✎	—	—	✎	—	✎	✎	✎	—	Changes
C123652	CDISC Questionnaire EXACT Test Name Terminology	EXACT1TN			✓	✎	✎	—	—	—	—	—	—	—	Changes
C123653	CDISC Questionnaire EXACT Test Code Terminology	EXACT1TC			✓	✎	✎	—	—	—	—	—	—	—	Changes
C123654	CDISC Functional Test AVL2-REY Test Name Terminology	AVL02TN			✓	✎	✎	—	—	—	—	—	—	—	Changes
C123655	CDISC Functional Test AVL2-REY Test Code Terminology	AVL02TC			✓	✎	✎	—	—	—	—	—	—	—	Changes

- 10 Codelists
- 12 releases of CDISC SDTM Controlled Terminology
- How many versions?

Codelist items - How many versions can you see?

Changes: CDISC SDTM Reason for Non-Completion Terminology C66727

Code List Item Changes			12 releases of CDISC SDTM Terminology												4 different versions of the codelist??	
Show 10 entries			2015-03-27				2016-03-25				2017-03-31				2017-12-22	
Identifier	Label	Submission Value	2015-03-27	2015-06-26	2015-09-25	2015-12-18	2016-03-25	2016-06-24	2016-09-30	2016-12-13	2017-03-31	2017-06-30	2017-09-29	2017-12-22		
C142349	Protocol-Specified Withdrawal Criterion Met	PROTOCOL-SPECIFIED WITHDRAWAL CRITERION MET													✓	Changes
C17649	Other	OTHER	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C25250	Complete	COMPLETED	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C25742	Pregnancy	PREGNANCY	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C25746	Recovery	RECOVERY	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C28554	Dead	DEATH	-	-	-	-	-	-	-	-	-	-	-	-	✎	Changes
C35571	Progressive Disease	PROGRESSIVE DISEASE	-	-	✎	-	-	-	✎	-	-	-	-	-	-	Changes
C38155	Recurrent Disease	DISEASE RELAPSE	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C41331	Adverse Event	ADVERSE EVENT	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C48226	Lack of Efficacy	LACK OF EFFICACY	-	-	-	-	-	-	-	-	-	-	-	-	-	Changes

- 10 Items from codelist C66727
- 12 releases of CDISC SDTM Terminology
- 3 releases with changes
- 4 different versions of the codelist??

Protocol Deviation vs. Procotol Deviation

Changes: CDISC SDTM Reason for Non-Completion Terminology C66727

Code List Item Changes

Show 15 entries

Search: protocol v

Identifier	Label	Submission Value	2015-03-27	2015-06-26	2015-09-25	2015-12-18	2016-03-25	2016-06-24	2016-09-30	2016-12-13	2017-03-31	2017-06-30	2017-09-29	2017-12-22	
C142185	Protocol Violation	PROTOCOL VIOLATION												✓	Changes
C48251	Protocol Violation	PROTOCOL DEVIATION	-	-	-	-	-	-	-	-	-	-	-	✗	Changes
C50996	Protocol Deviation	PROTOCOL DEVIATION												✓	Changes

StudyDesign: Disposition - Study Discontinuation () [DS_UseCase1]

Disposition - Study Discontinuation [igDS_UseCase_1]

1.* What was the date of Completion / Discontinuation?

Req / Req / Req (2012-2014)

2.* What was the subject's status? [Status]

[DSDECOD]
[A:ADVERSE
EVENT]

[DSAENO]
Adverse Event
Specify AE ID

N10

[A:COMPLETED]

Completed

[A:PROTOCOL
VIOLATION]

[DSTERM_C48251]
Protocol Violation
Specify Protocol Violation

A50

Show: CDISC Terminology 2017-12-22 CDISC Terminology (V51.0.0, 51, Standard)

Details

Identifier	Label	Owner	Status	Version	Version Label	
CDISC Terminology	CDISC Terminology 2017-12-22	CDISC	Standard	51.0.0	2017-12-22	Impact Change Instructions

Impact Analysis: CDISC Terminology 2017-12-22

Items Impacted

Show 5 entries

Search:

Identifier	Label	Version	Version Label	
BC C25299	Diastolic Blood Pressure (BC C25299)	1.0.0	0.1	Show
CDASH DISP	CDASH Disposition	0.1.0		Show
CDISC Terminology	CDISC Terminology 2015-09-25	42.0.0	2015-09-25	Show
CDISC Terminology	CDISC Terminology 2015-12-18	43.0.0	2015-12-18	Show
CDISC Terminology	CDISC Terminology 2017-06-30	49.0.0	2017-06-30	Show

Showing 6 to 10 of 22 entries

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SDTM Terminology Changes 2016-03-25

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Study Data Tabulation Model (SDTM)

SDTM is an international standard for clinical research data, and is approved by the FDA as a standard electronic submission format. CDISC Questionnaires, Ratings, and Scales terminology is included in the SDTM terminology publication. NCI EVS maintains and distributes SDTM controlled terminology as part of NCI Thesaurus. More information is available at CDISC's [SDTM Web page](#) .

- Download from the [CDISC SDTM directory](#) on an NCI File Transfer Protocol (FTP) site in [Excel](#), [text](#), [odm.xml](#), [pdf](#), [html](#) and [OWL/RDF](#) formats.
- Download changes from the previous release in [Excel](#) or [text](#) formats. 

SDTM Terminology Changes 2016-03-25

BUN**UREAN**

Change Type	NCI Code	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	New	Change Implementation Instructions	Prev Codelist	Prev Term	New Codelists	New Terms
Add	C125949	LBTEST	Laboratory Test Name	Add new term to existing codelist	Urea Nitrogen	Urea Nitrogen can be measured in substances other than Blood, Serum, or Plasma. This concept will replace C61019.	C67154	C61019	C67154	C125949

Show: CDISC Terminology 2016-03-25 CDISC Terminology (V44.0.0, 44, Standard)

Details

Identifier	Label	Owner	Status	Version	Version Label	
CDISC Terminology	CDISC Terminology 2016-03-25	CDISC	Standard	44.0.0	2016-03-25	Impact Change Instructions

Change Instructions: CDISC Terminology 2016-03-25 CDISC Terminology (V44.0.0, 44, Standard)

Show 15 entries

Search: urean

Parent Item	Item	Submission Value	Comments	References
C65047	C125950	UREANCRT	Urea Nitrogen can be measured in substances other than Blood, Serum, or Plasma. This concept will replace C74753.	C74753, BUNCREAT
C65047	C125949	UREAN	Urea Nitrogen can be measured in substances other than Blood, Serum, or Plasma. This concept will replace C61019.	C61019, BUN

Show: Blood Urea Nitrogen Measurement C61019

Details

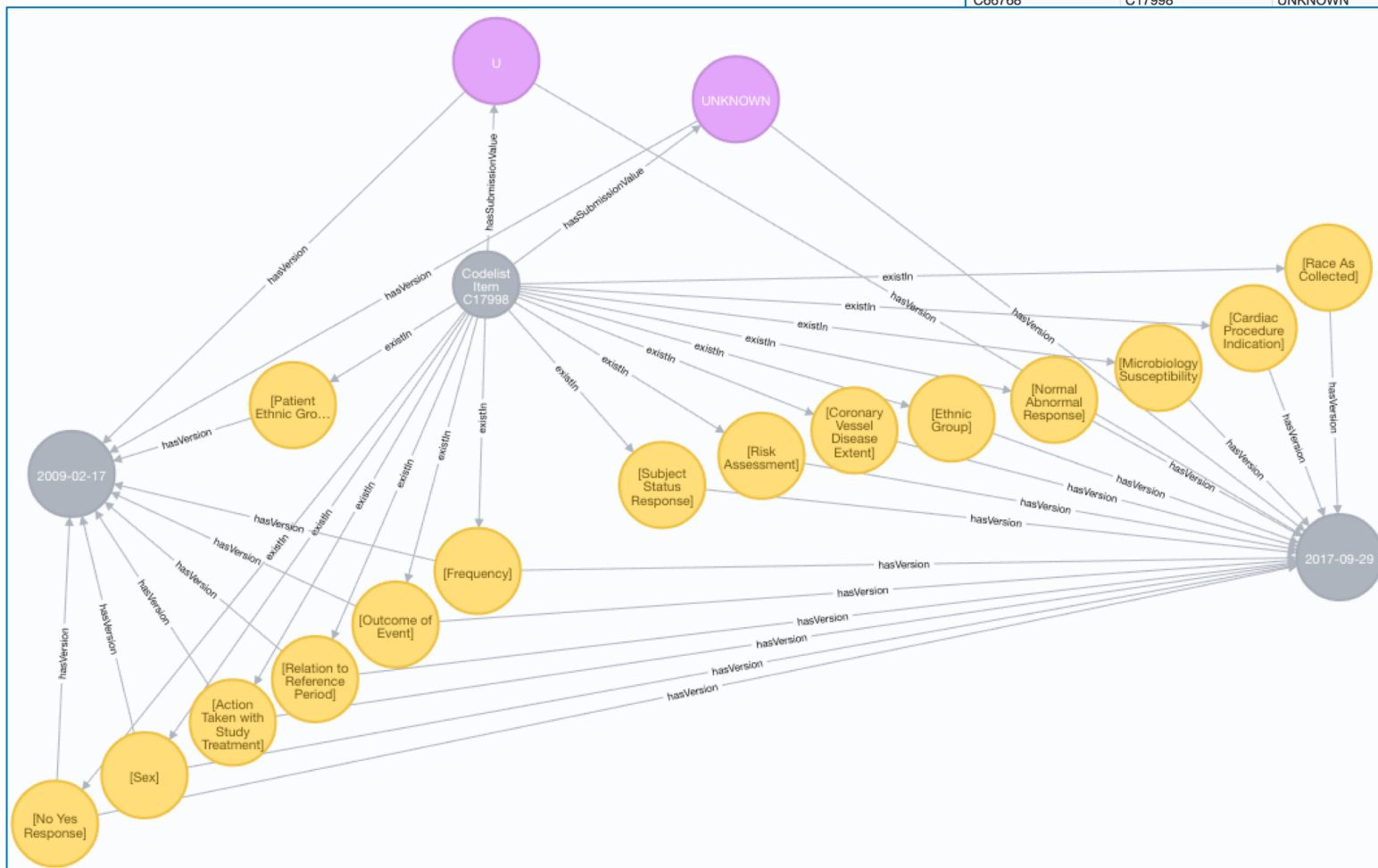
Label	Identifier	Submission Value	Preferred	Synonym	Definition
Blood Urea Nitrogen Measurement	C61019	BUN	Blood Urea Nitrogen Measurement	Blood Urea Nitrogen	A measurement of the urea nitrogen in a blood specimen.

codelist(15)

submissionValue(2)

version(2)

Code List	Item	Submission Value	Preferred Term	Synonym	Definition
C101834	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C101848	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C101850	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C101859	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C124304	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C128689	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C66728	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C66731	C17998	U	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C66742	C17998	U	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C66767	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
C66768	C17998	UNKNOWN	Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
			Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
			Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)
			Unknown	U; Unknown	Not known, not observed, not recorded, or refused. (NCI)



Summary

- Standards are complex
 - Subtle changes can have a huge impact
- We need to take control
 - More precise version management
- Semantic Technologies are mature
 - Can express standards more precise
- Learn by doing
 - Linked data enables us for the future



Thank you for your attention



www.s-cubed-global.com



www.a3informatics.com

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