



S-CUBED

Breaking the Silos:
Which Term Are You Using in that Study?

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PHUSE SDE Beerse
2019-08-11



Agenda

- Current status of CDISC Terminology
- The Future of Standards
- Why do we need to change?
- Examples of current challenges
 - and why they don't need to be challenges

A bottle of wine



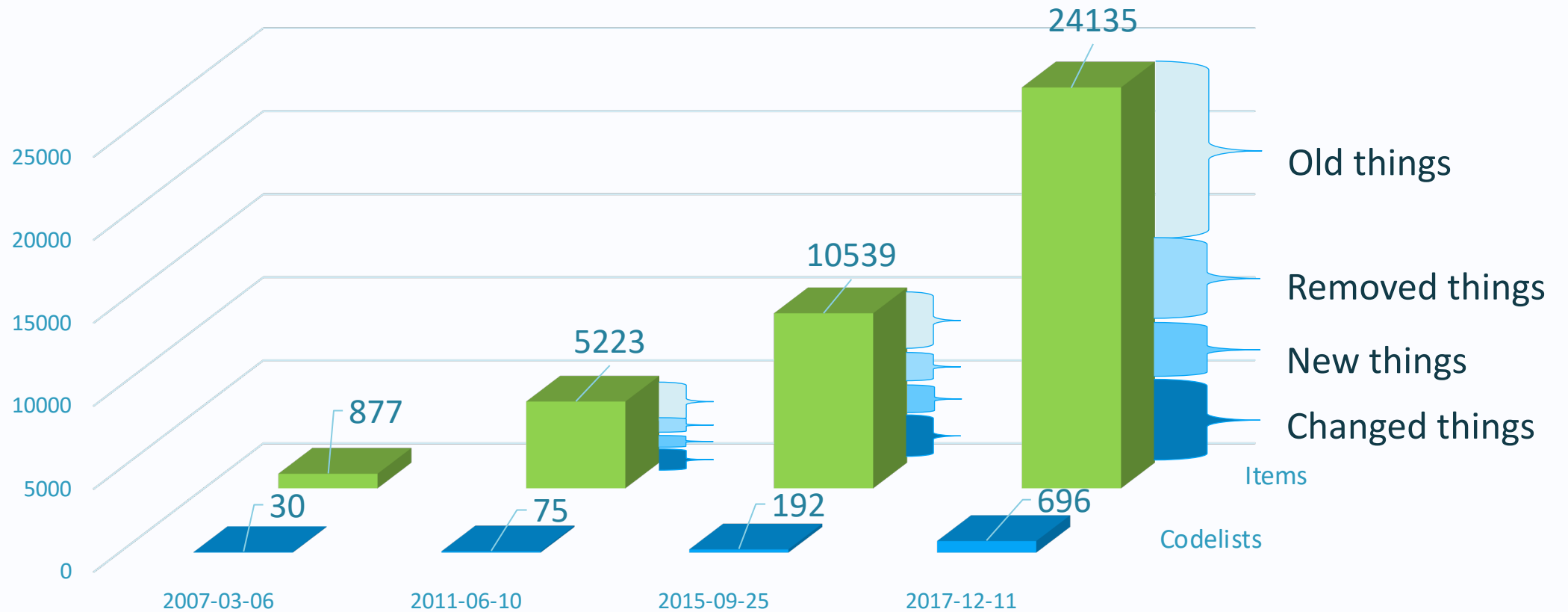
A wine – two bottles



CDISC Terminology



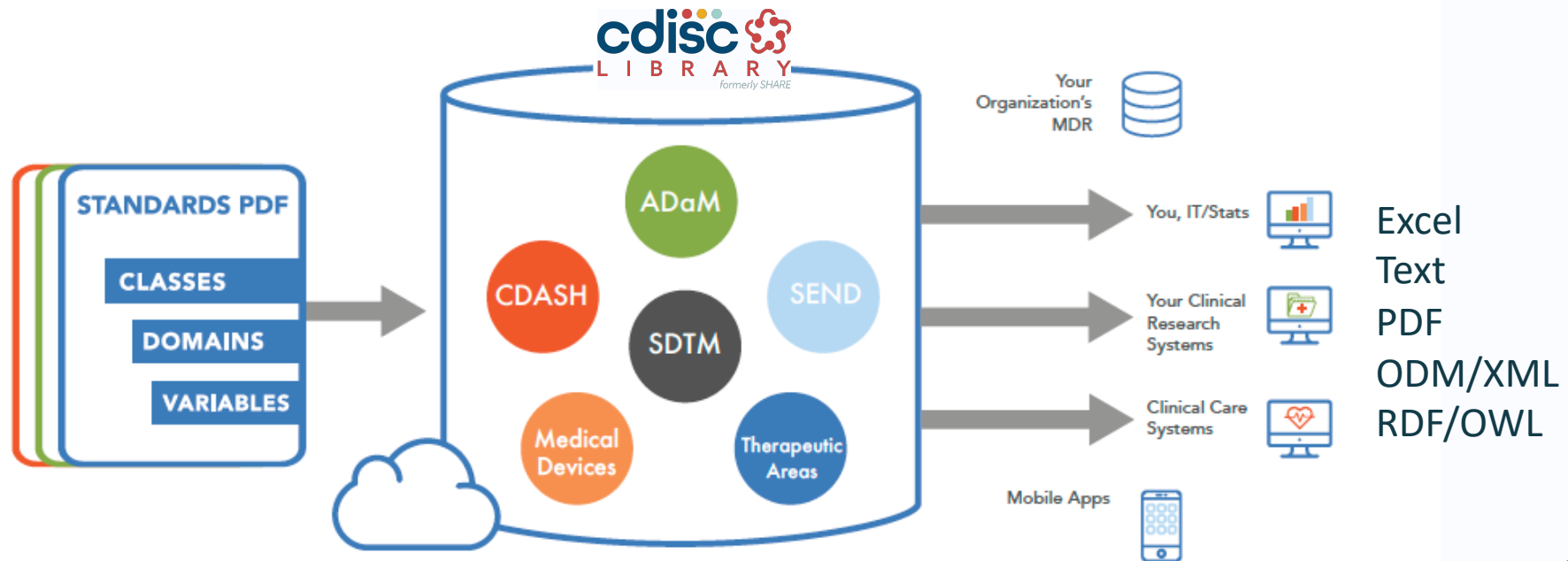
CDISC Terminology History



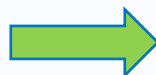
Accessing CDISC Standards today



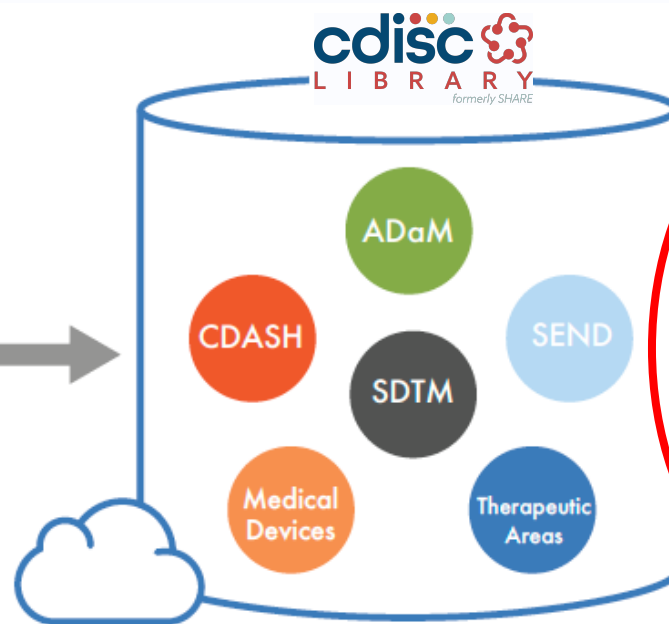
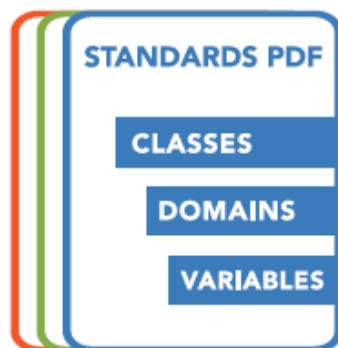
PDF Standards source



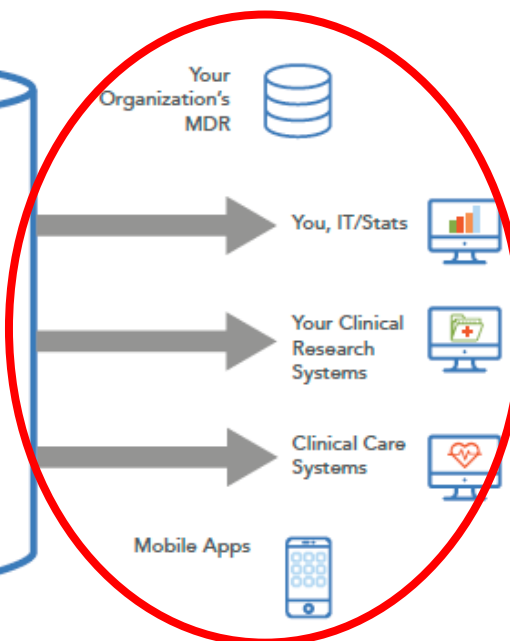
Accessing CDISC Standards today



PDF Standards source



Access via API



Excel
Text
PDF
ODM/XML
RDF/OWL

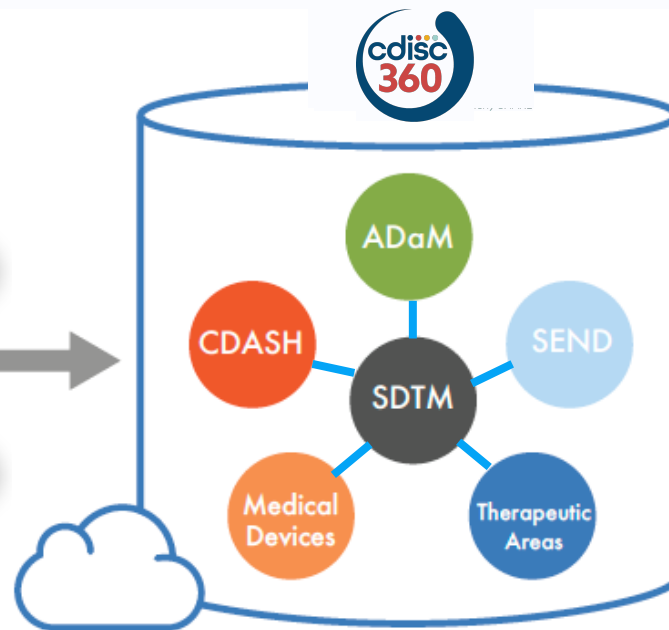
Accessing CDISC Standards in the future



Access via API



PDF Standards no longer
source for standards



Your
Organization's
MDR



You, IT/Stats



Your Clinical
Research
Systems



Clinical Care
Systems



Mobile Apps



Excel
Text
PDF

ODM/XML

RDF/OWL

Downloads of
less importance

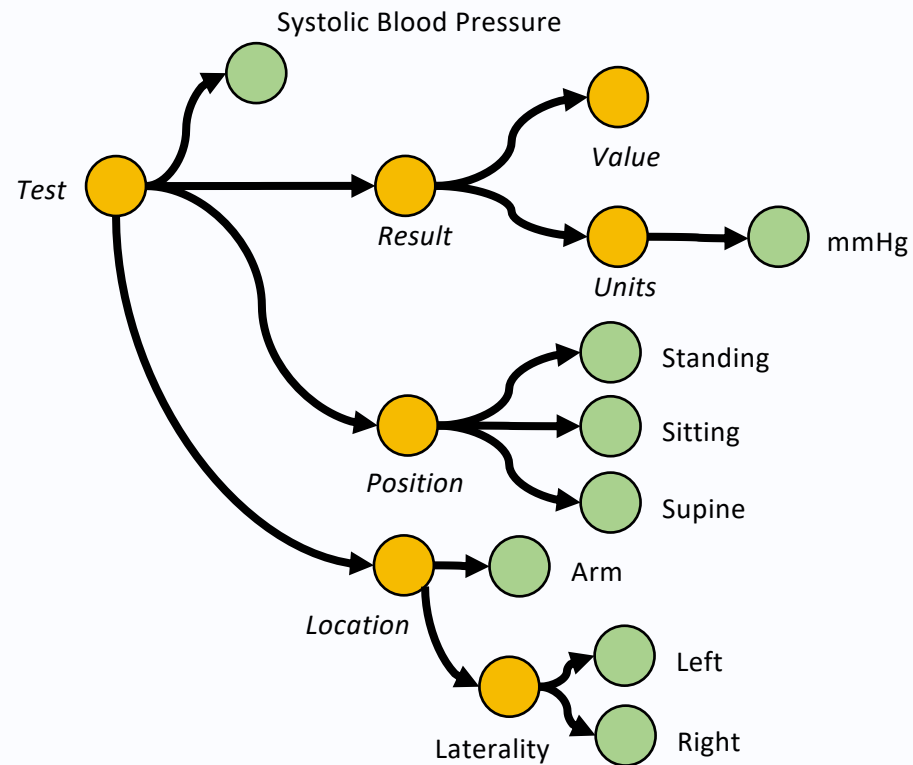
Replaces PDF Standards with machine understandable linked standards
Biomedical Concepts



Biomedical Concepts

What is it?

Complicated words for something quite simple



A collection of variables

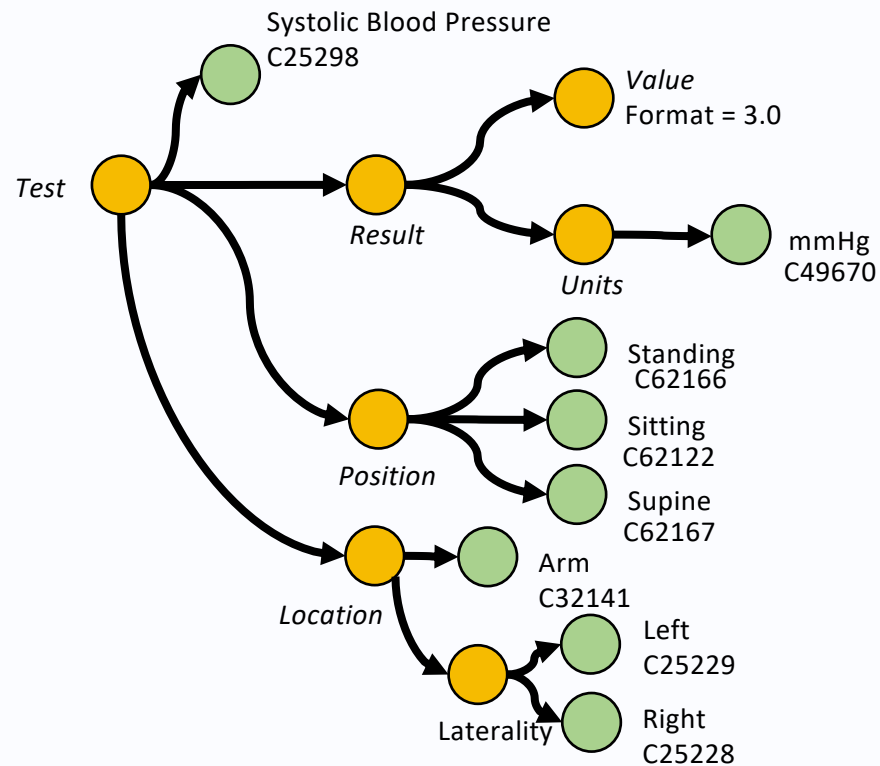
A real-world entity

Something a physician would recognize

Biomedical Concepts

What is it?

Complicated words for something quite simple



A collection of variables

A real-world entity

Something a physician would recognize

At the same time it contains the details required for a data manager or programmer

E.g. links to CDISC terminology

Biomedical Concepts

What is it?

Complicated words for something quite simple

Vital Signs - Blood Pressure		VS=Vital Signs
Blood Pressure		
Common collection details		
Date of examination	VSDTC where VSTESTCD=SYSBP	D D / M M / Y Y : Y Y : H H : M M
Position	VSLOC where VSTESTCD=SYSBP	☐ Supine Position ☐ Standing ☐ Sitting
Side		☐ Left ☐ Right ☐ Bilateral
Indicate if examination was not performed	VSSTAT where VSTESTCD=SYSBP	☐ Not Done
If not done, please specify reason	VSREASND where VSTESTCD=SYSBP	S : 2 : 0 :
Unit	VSORRESU where VSTESTCD=SYSBP	☐ Millimeter of Mercury ☐ Pascal
Systolic Blood Pressure		
Systolic Blood Pressure	VSORRES where VSTESTCD=SYSBP	# : # : #

A collection of variables

A real-world entity

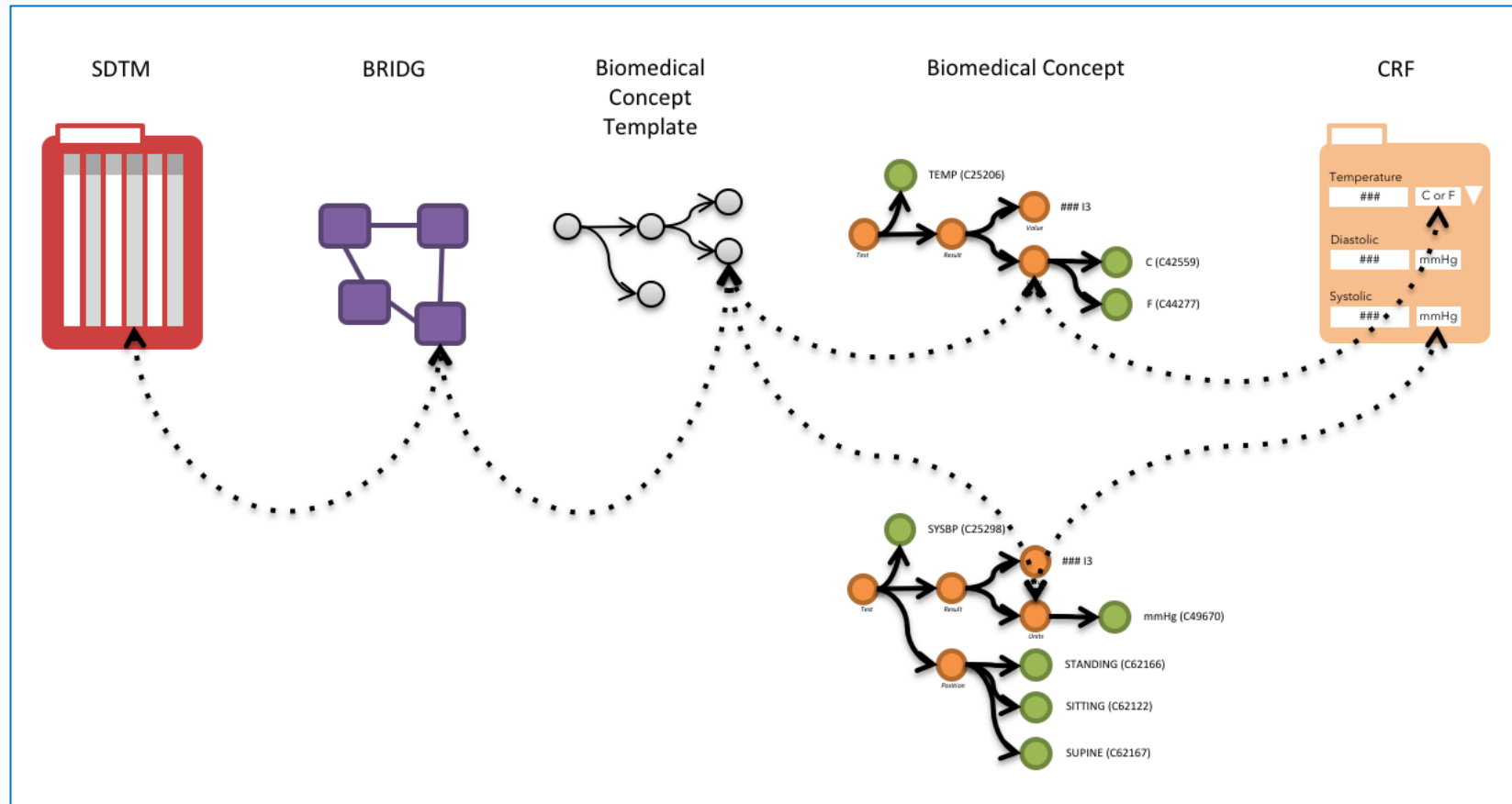
Something a physician would recognize

At the same time it contains the details required for a data manager or programmer

E.g. links to CDISC terminology

And when viewed in the study it is represented as a CRF or the SDTM annotated aCRF

Biomedical Concepts



Definition of what something is and what it consists of
(so not the structure)

Why is this change happening?

- We need to be in control
 - Too many documents to manage
 - Computers/Machines need to help us
- Development/Implementation is slow
 - We don't understand the impact of changes
 - Better ways of versioning is needed
 - E.g. no company is able to implement all 4 releases/year of SDTM CT
- We need more precise ways of expressing our standards
 - The world isn't tabular
- Traceability
 - Protocol, CRF, SDTM, ADaM, Report different sides of the same coin

Example 1: FDA Technical Conformance Guide

CDER Common Data Standards Issues Document
(Version 1.0/May 2011)

Please include the variables EPOCH, ELEMENT, and ETCD (element code) f

CDER Common Data Standards Issues Document
(Version 1.1/December 2011)

Please include the variables EPOCHfor every c

STUDY DATA TECHNICAL CONFORMANCE GUIDE

Technical Specifications Document

February 2014

December 2014

October 2015

March 2016

July 2016

October 2016

November 2016

March 2017

October 2017

March 2018

October 2018

TSPARMCD value	TSPARM value
TAUG	TAUG and version used
TECHSP	Technical Specification and version used
SDTMIG	SDTMIG version used
SDTM	SDTM model version used

SDTM Terminology 2018-12-21

CDISC Submission Value

CTAUG	CDISC Therapeutic Area User Guide
FDATCHSP	FDA Technical Specification
SDTIGVER	SDTM IG Version
SDTMVER	SDTM Version

Would you follow CDISC or FDA?

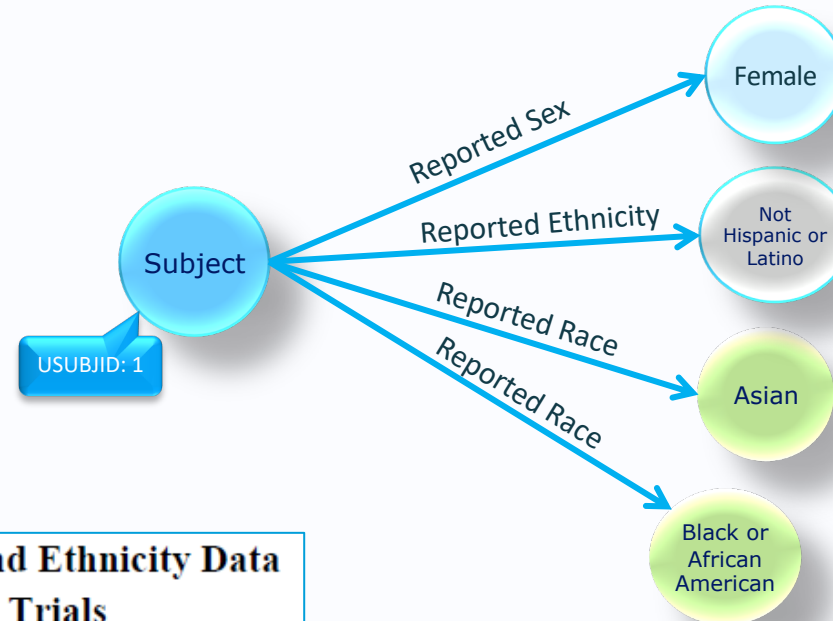
Example 2: Race/Ethnicity

MULTIPLE

StudyDesign: Demographics (DM_1)		
Demographics [DM_UseCase1]		
1.*	Sex	☒ Female ☐ Male
2.*	Ethnicity	☐ Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not reported ☐ Unknown
3.*	Race	☐ American Indian or Alaska Native ☒ Asian ☒ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White

Usubjid	Sex	Race	Ethnicity
1			

RACE1	ASIAN
RACE2	BLACK OR AFRICAN AMERICAN



**Collection of Race and Ethnicity Data
in Clinical Trials**

We recommend offering an option of selecting one or more racial designations or additional subgroup designations. Recommended forms for the instruction accompanying the multiple response questions are “Mark one or more” and “Select one or more.”

Example 3: 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!



-CUBED

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

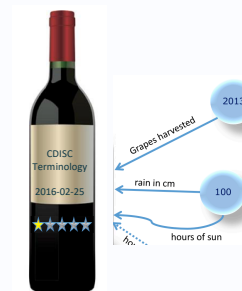
SDTM

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

What is a version?



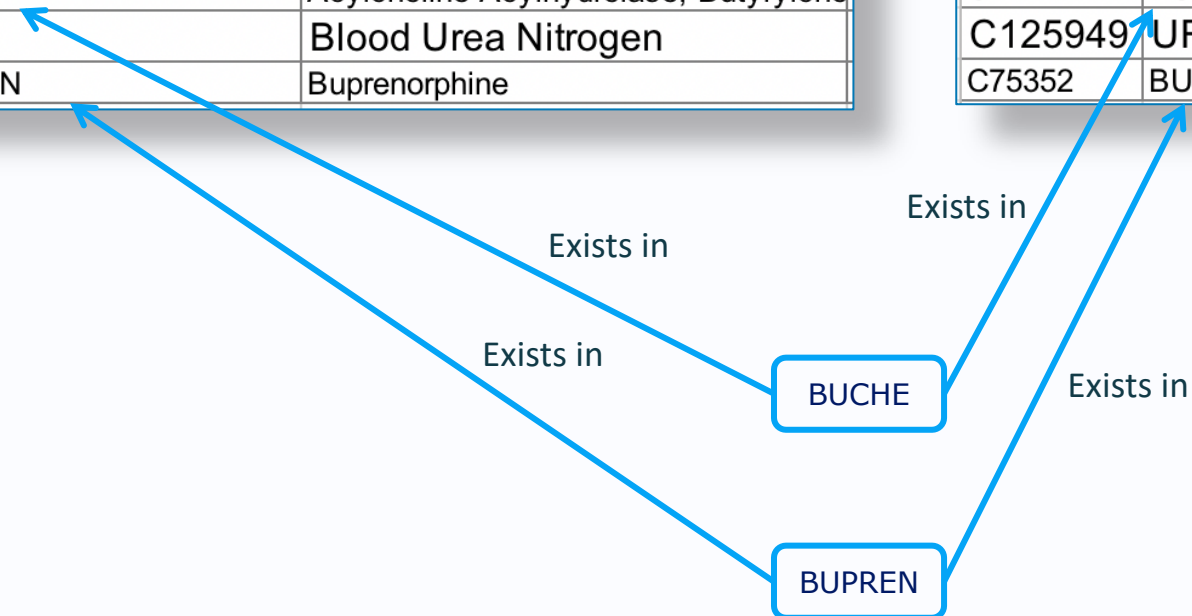
2015-12-18



2016-03-25

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

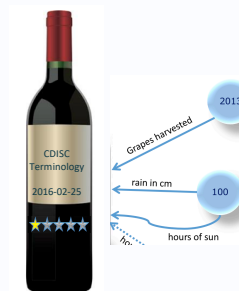
Code	CDISC Submission Value	CDISC Synonym(s)
C111142	BUCHÉ	Acylcholine Acylhydrolase; Butyrylcholine
C125949	UREAN	Urea Nitrogen
C75352	BUPREN	Buprenorphine



What is a version?



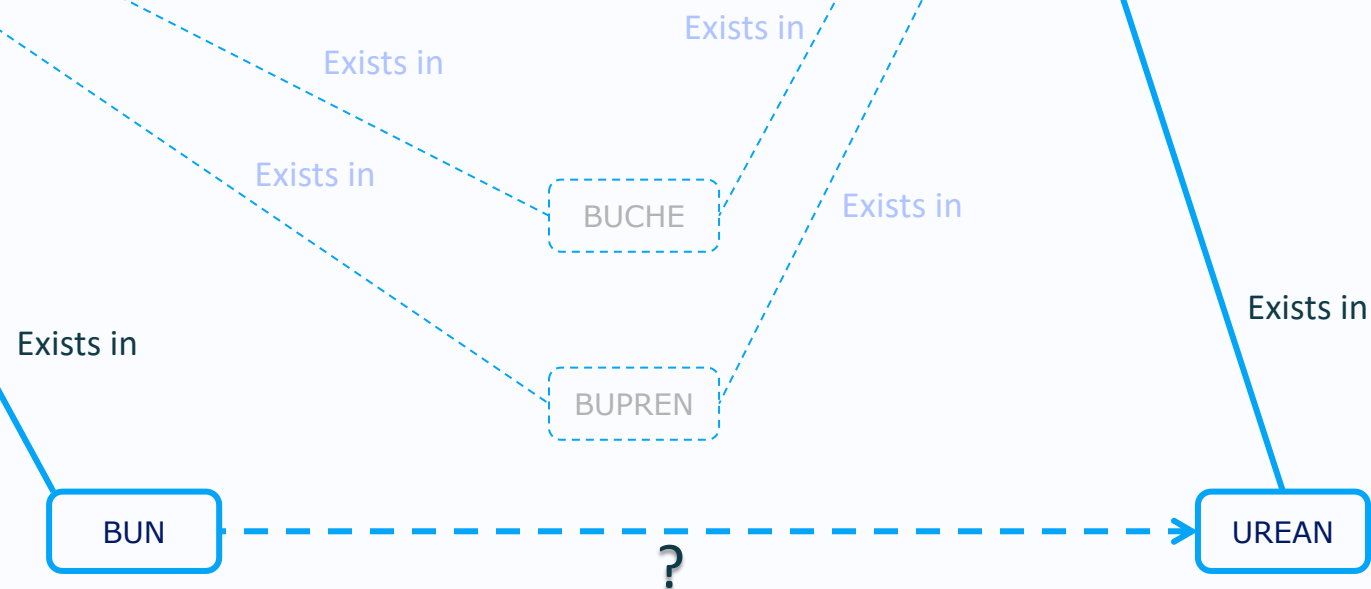
2015-12-18



2016-03-25

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

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C111142	BUCH	Acylcholine Acylhydrolase; Butyrylcholine
C125949	UREAN	Urea Nitrogen
C75352	BUPREN	Buprenorphine

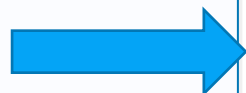
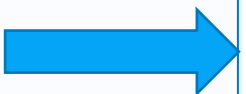
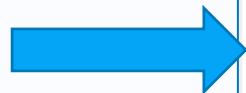


The Versions

Format	Year	Ver	Date	SDTM	QS	QS-FT	COA	QRS	CDASH	ADaM
1	2007	1	06/03/2007	06/03/2007						
		2	20/04/2007	20/04/2007						
		3	26/04/2007	26/04/2007						
		4	31/05/2007	31/05/2007						
2	2008	5	05/06/2007	05/06/2007						
		6	15/01/2008	15/01/2008						
		7	25/01/2008	25/01/2008						
		8	26/08/2008	26/08/2008						
3	2009	9	22/09/2008	22/09/2008						
		10	24/09/2008	24/09/2008						
		11	30/09/2008	30/09/2008						
		12	09/10/2008	09/10/2008						
4	2010	13	15/10/2008	15/10/2008						
		14	17/02/2009	17/02/2009						
		15	18/02/2009	18/02/2009						
		16	01/05/2009	01/05/2009						
5	2011	17	06/07/2009	06/07/2009						
		18	06/10/2009	06/10/2009						
		19	05/03/2010	05/03/2010					05/03/2010	05/03/2010
		20	08/04/2010	08/04/2010					-	-
5	2012	21	02/07/2010	02/07/2010					-	-
		22	06/10/2010	06/10/2010					-	06/10/2010
		23	22/10/2010	22/10/2010					-	--"
		24	07/01/2011	07/01/2011					07/01/2011	07/01/2011
5	2013	25	08/04/2011	08/04/2011					08/04/2011	-
		26	10/06/2011	10/06/2011					-	-
		27	22/07/2011	22/07/2011					22/07/2011	22/07/2011
		28	09/12/2011	09/12/2011					09/12/2011	-
5	2014	29	23/03/2012	23/03/2012	23/03/2012				-	-
		30	29/06/2012	29/06/2012	29/06/2012				29/06/2012	-
		31	03/08/2012	03/08/2012	03/08/2012				-	-
		32	21/12/2012	21/12/2012	21/12/2012				21/12/2012	-
5	2015	33	12/04/2013	12/04/2013	12/04/2013				-	-
		34	28/06/2013	28/06/2013	28/06/2013				28/06/2013	-
		35	04/10/2013	04/10/2013	04/10/2013				04/10/2013	-
		36	20/12/2013	20/12/2013	20/12/2013				20/12/2013	-
5	2016	37	28/03/2014	28/03/2014	28/03/2014				28/03/2014	-
		38	27/06/2014	27/06/2014	27/06/2014	27/06/2014			-	-
		39	26/09/2014	26/09/2014	26/09/2014	26/09/2014			26/09/2014	26/09/2014
		40	06/10/2014	06/10/2014	-	-			-	-
5	2017	41	19/12/2014	19/12/2014			19/12/2014		-	-
		42	27/03/2015	27/03/2015			27/03/2015		27/03/2015	-
		43	26/06/2015	26/06/2015				26/06/2015	-	-
		44	25/09/2015	25/09/2015				25/09/2015	-	-
5	2018	45	18/12/2015	18/12/2015					-	18/12/2015
		46	25/03/2016	25/03/2016					25/03/2016	25/03/2016
		47	24/06/2016	24/06/2016					-	-
		48	30/09/2016	30/09/2016					30/09/2016	30/09/2016
5	2019	49	16/12/2016	16/12/2016					16/12/2016	16/12/2016
		50	31/03/2017	31/03/2017					-	31/03/2017
		51	30/06/2017	30/06/2017					-	-
		52	29/09/2017	29/09/2017					29/09/2017	29/09/2017
5	2020	53	22/12/2017	22/12/2017					-	-
		54	30/03/2018	30/03/2018					30/03/2018	-
		55	29/06/2018	29/06/2018					29/06/2018	-
		56	28/09/2018	28/09/2018					28/09/2018	-
5	2021	57	21/12/2018	21/12/2018					21/12/2018	21/12/2018
		58	29/03/2019	29/03/2019					29/03/2019	29/03/2019
		59	28/06/2019	28/06/2019					28/06/2019	-

Codelist item changes - QSCAT

12 releases



Changes: C100129, Category of Questionnaire

Show 10 entries

Search:

Identifier	Label	Submission Value	2016-06-24	2016-09-30	2016-12-16	2017-03-31	2017-06-30	2017-09-29	2017-12-22	2018-03-30	2018-06-29	2018-09-28	2019-03-29	2019-06-28	
C155326	Functional Assessment of Cancer Therapy-Bladder Version 4 Questionnaire	FACT-BL V4										✓	1 -	-	Changes
C43524	Brief Symptom Inventory 18	BSI-18	-	-	-	-	-	-	-	-	-	-	-	-	Changes
C66957	European Quality of Life Five Dimension Three Level Questionnaire	EQ-5D-3L	-	-	1 -	-	-	-	-	2 -	-	-	-	-	Changes
C100763	Clinical Global Impression Questionnaire	CGI	-	-	-	-	✍	-	-	-	-	-	✗		Changes
C100767	Hamilton Depression Rating Scale 17 Item Questionnaire	HAMD 17	✗					1 ✓							Changes
C138337	Functional Assessment of Cancer Therapy-Kidney Symptom Index-15 Questionnaire	FKSI-15						✓	✗						Changes
C147584	Functional Assessment of Chronic Illness Therapy-Dyspnea 10 Item Short Form Questionnaire	FACIT-DYSPNEA SF								✓	✗				Changes
C74982	Mini-Mental Status Exam	MMSE	-	-	-	-	✍	-	-	-	✗				Changes

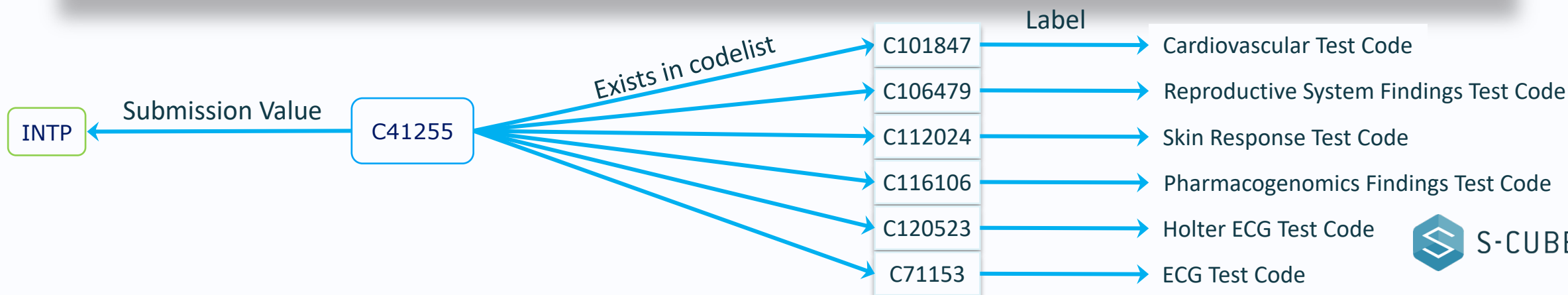
Showing 231 to 240 of 240 entries

Previous 1 ... 20 21 22 23 24 Next

Codelist items - INTP

Code List	Item	Submission Value	Preferred Term	Synonym	Definition
Search ...	C41255	INTP	Search ...	Search ...	Search ...
C101847	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the
C106479	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the
C112024	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the
C116106	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the
C117743	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the
C120523	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the
C66741	C41255	INTP	Interpretation	Interpretation	An act or process of elucidation; explication, or explanation of a thing via the assignment of objects from the domain to the

In your SDTM submission...
...do you know from which codelist you picked your INTP?



COMMUNITY MDR Codelist items - Unknown

Search: Controlled Terminology CT (V59.0.0, 59, Standard)

Show 10 entries

Two Submission Values!

Overall Search ...

Clear All

Code List	Item	Submission Value	Preferred Term	Synonym	Definition
Search ...	C17998	Search ...	Search ...	Search ...	Search ...
C101834	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C101848	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C101850	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C101859	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C124304	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C127265	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C128689	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C128690	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C66728	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C66731	C17998	U	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)

Showing 1 to 10 of 19 entries

Close

C17998

Submission Value

UNKNOWN

Submission Value

U

17 Codelists

Sex codelist

No Yes Response

Previous

1

2

Next

BED

COMMUNITY MDR Codelist items - Unknown

Search: Controlled Terminology CT (V59.0.0, 59, Standard)

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Pr
C17998	C66767		Action Taken with Study Treatment	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C101859		Cardiac Procedure Indication	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C101850		Coronary Vessel Disease Extent	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C66790		Ethnic Group	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C128690		Ethnicity As Collected	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C71113		Frequency	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C85495		Microbiology Susceptibility Testing Result Category	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C127265		Mode of Disease Transmission	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C66742		No Yes Response	U	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C101834		Normal Abnormal Response	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C66768		Outcome of Event	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C74457		Race	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C128689		Race As Collected	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C66728		Relation to Reference Period	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C101848		Risk Assessment	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C66731		Sex	U	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown
C17998	C124304		Subject Status Response	UNKNOWN	U; UNK; Unknown	Not known, not observed, not recorded, or refused. (NCI)	Unknown

C128690	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C66728	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C66731	C17998	U	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)

Showing 1 to 10 of 19 entries

< Close

C17998

Submission Value

UNKNOWN

17 Codelists

Submission Value

U

Sex codelist

No Yes Response

Previous

1

2

Next

BED

COMMUNITY MDR Codelist items - Unknown

Search: Controlled Terminology CT (V59.0.0, 59, Standard)

Does your define know ?

Sex [C66731] [CDISC/NCI SDTM 2015-12-18]

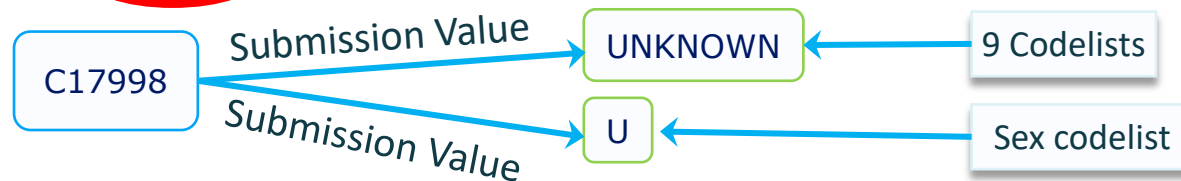
The term "UN" was changed to "UNDIFFERENTIATED" for codelist "SEX" on the 2014-03-28 CT release. Referencing the codelist from a newer release since the new release includes other codelists used in the study.

Permitted Value (Code)	Display Value (Decode)
F [C16576]	Female
M [C20197]	Male
U [C17998]	Unknown
UNDIFFERENTIATED [C17998]	Undifferentiated

C128689	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C128690	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C66728	C17998	UNKNOWN	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)
C66731	C17998	U	Unknown	Unknown; U; UNK	Not known, not observed, not recorded, or refused. (NCI)

Showing 1 to 10 of 19 entries

< Close



Previous 1 2 Next

BED

Where did Protocol deviation go ...

Differences: C66727, Completion/Reason for Non-Completion

Show 10 entries

Search:

Date	Identifier	Submission Value	Preferred Term	Synonym	Definition
2007-04-20	C66727	NCOMPLT	CDISC SDTM Reason for Non-Completion Terminology	Completion/Reason for Non-Completion; NCOMPLT	The reason that a subject was discontinued from a clinical trial.
2007-05-31	↓	↓	↓	Completion/Reason for Non-Completion; NCOMPLT Completion/Reason for Non-Completion	↓
2008-08-26	↓	↓	↓	↓	↓
2008-09-22	↓	↓	↓	↓	↓
2009-02-17	↓	↓	↓	↓	↓
2009-05-01	↓	↓	↓	↓	↓
2009-07-06	↓	↓	↓	↓	The reason that a subject was discontinued from a clinical trial. The status of the subject's completion of the study or a segment of the study, or the reason the subject discontinued the study or segment of the study.
2012-06-29	↓	↓	↓	↓	↓
2012-08-03	↓	↓	↓	↓	↓
2013-04-12	↓	↓	↓	↓	↓

Showing 1 to 10 of 20 entries

Previous 1 2 Next

Changes: C66727, Completion/Reason for Non-Completion

Show 10 entries

Search: Deviation

Identifier	Label	Submission Value	2017-09-29	2017-12-22	2018-06-29	2018-12-21	
C48251	Protocol Violation	PROTOCOL DEVIATION	-	×			Changes
C50996	Protocol Deviation	PROTOCOL DEVIATION		✓	-	-	Changes

Showing 1 to 2 of 2 entries

Previous 1 Next

Start ⏮ ⏪ ⏩ ⏭ End

BED

Where did Protocol deviation go ...

Changes: C66727, Completion/Reason for Non-Completion

Show 10 entries

Search: Deviation

Identifier	Label	Submission Value	2017-09-29	2017-12-22	2018-06-29	2018-12-21	
C48251	Protocol Violation	PROTOCOL DEVIATION	-	×			Changes
C50996	Protocol Deviation	PROTOCOL DEVIATION		✓	-	-	Changes

Showing 1 to 2 of 2 entries

Previous 1 Next

Start ◀ ◀ ▶ ▶ End

An event or decision that stands in contrast to the guidelines set out by the protocol. (NCI)

Completion/Reason for Non-Completion

C48251

C50996

Definition

Submission Value

Submission Value

Definition

PROTOCOL DEVIATION

A variation from processes or procedures defined in a protocol. Deviations usually do not preclude the overall evaluability of subject data for either efficacy or safety, and are often acknowledged and accepted in advance by the sponsor. ...

Summary

- We need to take control
- Linked data represents data more closer to the real world
 - Adds precision
 - Speed up development and implementation
 - Better version management
- Biomedical Concepts important for harmonising our world
 - No longer need a perfect structures
- Launch of  **COMMUNITY MDR**
 - Browse all versions of CDISC Terminology
 - Watch <http://www.s-cubed.global.com>

Thank you for listening

www.s-cubed-global.com

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