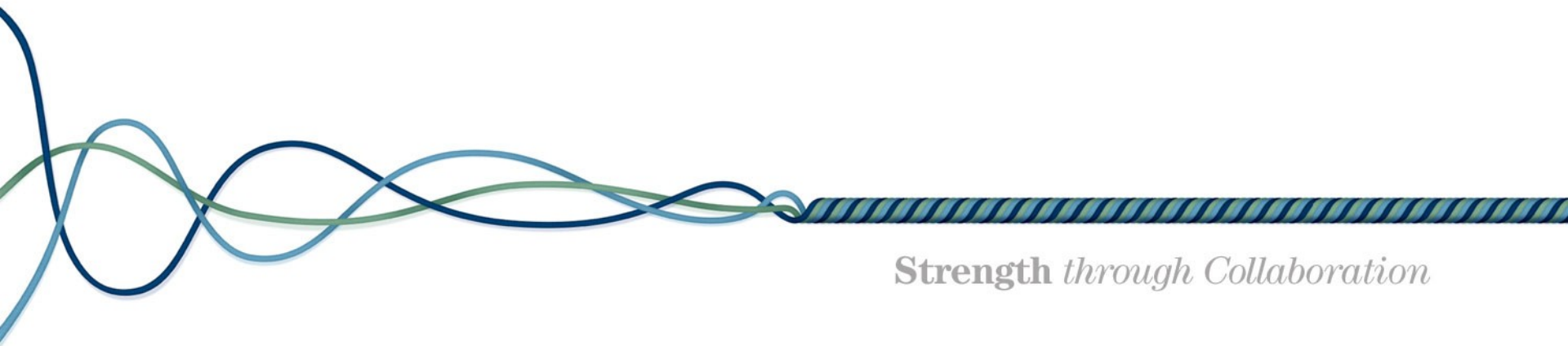


CDISC Public Webinar – Standards Updates and Additions

17 Dec 2015



Strength *through Collaboration*

Agenda

- Controlled Terminology Quarterly Updates
 - Bernice Yost, CDISC
- CDISC Online Education & Event Updates
 - John Ezzell, CDISC

Question & Answer

‘Panelist’: Question

OR

‘Presentation’: Question

Examples:

Bernice: What has change since the last update?

OR

CDISC: When can we start registering for the European Interchange?

CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost

Controlled Terminology Agenda

Package 24 Publication Release (18 Dec 2015)

- What's new

- What's changed

Package 25 Public Review (11 Dec 2015 to 15 Jan 2016)

- What's new

- What's changed

Controlled Terminology Publication Schedule

Package Number	Team Cutoff (requests must be received at least two months before this date)	Public Review Start Date (1 wk from Team Cutoff)	Public Review Closed Date (4 wks)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
21	12/12/2014	12/19/2014	1/23/2015	2/13/2015	3/27/2015	Device	ECG	General	Lab
21						Oncology	PK	QS	SEND
21						Spectype Speccond	Unit	Virology	
22	3/13/2015	3/20/2015	4/17/2015	5/15/2015	6/26/2015	CV	ECG	General	Lab
22						PK	QRS	SEND	Unit
22						Virology			
23	6/12/2015	6/19/2015	7/17/2015	8/14/2015	9/25/2015	CV	ECG	General	Lab
23						PK	QRS	SEND	Spectype Speccond
23						Unit	Virology		
24	9/4/2015	9/11/2015	10/9/2015	11/6/2015	12/18/2015	Device	ECG	General	Lab
24						Oncology	PGx	PK	SEND
24						Unit	Virology		
25	12/4/2015	12/11/2015	1/15/2016	2/12/2016	3/25/2016	General	Lab	Oncology	PGx
25						PK	SEND	Spectype Speccond	Unit
25						Virology			

Controlled Terminology Package 24 Publication Release

Controlled Terminology

Package 24 Publication Release

CDISC Clinical Data Element Glossary

CDISC's Clinical Data Element Glossary contains terms that were created to support an early version of a cardiovascular therapeutic area user guide that was ultimately left unpublished. The Clinical Data Element Glossary has been deprecated, and will be retired on 2015-12-18.

Controlled Terminology Package 24 Publication Release

SEND Vital Signs Reinstatement of Codelists

To ensure compatibility with SENDIG 3.0, the following codelists will be republished in the SEND controlled terminology publication on 2015-12-18 for use with the Vital Signs (VS) domain: VSTEST, VSTESTCD, and VSRESU. Accompanying reintroduction of these codelists into SEND, the SVSTST and SVSTSTCD codelists (which are subsets of VSTEST and VSTESTCD) are being retired in the SEND controlled terminology publication on 2015-12-18. It will continue to be the responsibility of the submitting organization to use the most appropriate domain for the data being transmitted.

Controlled Terminology

Package 24 Publication Release

Questionnaires, Ratings, and Scales (QRS)

New QRS Location

Keeping the QRS codelists separate from the SDTM codelists was a decision based on the limits of excel spreadsheets. This decision has been reversed and we will be merging the QRS codelists into the SDTM publication on 2015-12-18. The only content change will be in the codelist long name. Currently the long name starts with QS-, or FT-, or CC-. This prefix will be removed from the codelist long name only.

Controlled Terminology

Package 24 Publication Release

Questionnaires, Ratings, and Scales (QRS)

Category Codelist to Test Code/Name Codelist Relationship

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C100129		Yes	Category of Questionnaire	QSCAT	Category of Questionnaire	A grouping of observations within the Questionnaire domain.
C105166	C100129		Category of Questionnaire	ADCS-ADL	ADL01	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory (ADCS-ADL) (Galasko, D., Bennett, D., Sano, M., Ernesto, C., Thomas, R., Grundman, M., Ferris, S., and the ADCS. "An Inventory to Assess Activities of Daily Living for Clinical Trials in Alzheimer's Disease." Alzheimer's Disease and Associated Disorders, 1997. Volume 11(2): S33-S39).
C105140		No	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Questionnaire Test Code	ADCS-ADL TESTCD	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Questionnaire Test Code	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory test code.
C105283	C105140		Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Questionnaire Test Code	ADL0101	ADL01-Usual Eating Performance	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory - Regarding eating: which best describes {S} usual performance during the past 4 weeks?
C105139		No	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Questionnaire Test Name	ADCS-ADL TEST	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Questionnaire Test Name	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory test name.
C105283	C105139		Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Questionnaire Test Name	ADL01-Usual Eating Performance	ADL01-Usual Eating Performance	Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory - Regarding eating: which best describes {S} usual performance during the past 4 weeks?

Controlled Terminology

Package 24 Publication Release

Questionnaires, Ratings, and Scales (QRS)
Terminology Team

New Codelist:

Questionnaire

None

Functional Test

Trail Making Test (TMT)

Controlled Terminology

Package 24 Publication Release

Questionnaires, Ratings, and Scales (QRS) Terminology Team

New Codelist continued:

Clinical Classification

ASSIGN CVD 10-Year Risk Score (ASSIGN)

Atherosclerotic CVD 10-Year Risk Estimator (ASCVD)

Framingham Heart Study Cardiovascular Disease 10-Year Risk Score (FHS CVD)

Reynolds CVD 10-Year Risk Score

Tanner Scale Boy

Tanner Scale Girl

Positive and Negative Syndrome Scale (PANSS)

CDC Classification System for HIV Infection

WHO Disease Staging System for HIV Infection and Disease in Adults and Adolescents

WHO Disease Staging System for HIV Infection and Disease in Children

Glasgow Coma Scale (GCS NINDS Version)

JFK Coma Recovery Scale Revised (CRS-R)

Controlled Terminology

Package 24 Publication Release

Questionnaires, Ratings, and Scales (QRS) Terminology Team

Move Terms to a Different Codelist:

Functional Test

Alzheimer's Disease Neuroimaging Initiative's (ADNI) version of the Auditory Verbal Learning Test (AVLT) (Move from QS)

Clinical Classification

Extrapyramidal Symptom Rating Scale-Abbreviated (ESRS-A) (Move from QS)

Hamilton Anxiety Rating (HAMA) (Move from QS)

Hamilton Depression Rating Scale 21-Item (HAMD 21) (Move from QS)

West Haven Hepatic Encephalopathy Grade (WHEG) (Move from Hepatic Findings About Test Code/Name)

Controlled Terminology Package 24 Publication Release

Device Terminology Team

Codelist Name Change

Device Events Category Codelist

Category of Device Events

Controlled Terminology Package 24 Publication Release

ECG Terminology Team

New Term Added to Existing Codelist
ECG Test Code/Test Name

Controlled Terminology Package 24 Publication Release

General Terminology Team:

- New ADaM Codelist

 - Subject Trial Status

- New Codelist

 - Schizophrenia Findings About Test Code/Name

 - Medical History Event Date Type

 - Subject Status Test Code/Name

 - Subject Status Response

Controlled Terminology

Package 24 Publication Release

General Terminology Team:

- New Term Added to Existing Codelist

 - COPD Findings About Test Code/Name

 - Death Details Test Code/Name

 - Anatomical Location

 - Method

 - Procedure

 - Respiratory Test Code/Name

 - Subject Characteristics Test Code/Name

 - Trial Phase

 - Trial Summary Parameter Test Code/Name

 - Vital Signs Test Code/Name

Controlled Terminology Package 24 Publication Release

Lab Terminology Team (*Laboratory Test Codelists*)

Submission Value Change

Laboratory Test Name Codelist

HDL Cholesterol/LDL Cholesterol Ratio

HDL Cholesterol/LDL Cholesterol

Laboratory Test Code/Name Codelist

HAABIGM Hepatitis A Virus Antibody IgM

HAIGMAB Hepatitis A Virus IgM Antibody

New Term Added to Existing Codelist

Laboratory Test Code/Test Name

Controlled Terminology Package 24 Publication Release

Lab Terminology Team (*Unit Codelist*)

Submission Value Change

Unit Codelist

per min	/min
per sec	/sec

Term Removed

Unit Codelist

/mL	Please use $10^3/L$ (C105519)
/nL	Please use $10^9/L$ (C67255)
/pL	Please use $10^{12}/L$ (C67308)

New Term Added to Existing Codelist

Unit

Controlled Terminology

Package 24 Publication Release

Oncology Terminology Team

Codelist Name Change

RSTESTCD	Tumor Response Assessment Test Code
ONCRTSCD	Oncology Response Assessment Test Code
RSTEST	Tumor Response Assessment Test Name
ONCRTS	Oncology Response Assessment Test Name
RSSTRESC	Tumor Response Result
ONCRSR	Oncology Response Assessment Result

Controlled Terminology

Package 24 Publication Release

Oncology Terminology Team

Term Removed

Oncology Response Assessment Test Code/Name Codelist

NRADPROG Non-Radiological Progression

Please use Symptomatic Deterioration.

New Codelist

Treatment Intent

Treatment Setting

Tumor or Lesions Properties Test Result

Category of Oncology Response Test Assessment

Controlled Terminology Package 24 Publication Release

Oncology Terminology Team

New Term Added to Existing Codelist

Oncology Response Assessment Test Code/Name

Oncology Response Assessment Result

Oncology Tumor Properties Test Code/Name

Tumor and Lesion Identification Results

Controlled Terminology

Package 24 Publication Release

PGx (Pharmacogenomics/Genetics) Terminology
Team

New Codelist

Biospecimen Events Dictionary Derived Term

Biospecimen Characteristics Test Code/Test Name

Controlled Terminology

Package 24 Publication Release

PK Terminology Team

Submission Value Change

PK Units of Measure Codelist

L/kg/day	(L/day)/kg
L/kg/h	(L/h)/kg
L/kg/min	(L/min)/kg
mL/kg/day	(mL/day)/kg
mL/kg/h	(mL/h)/kg
mL/kg/min	(mL/min)/kg

Term Removed

PK Units of Measure Codelist

ng/mg of Creatinine

The analyte information should not be included in the Unit.

Controlled Terminology Package 24 Publication Release

PK Terminology Team

New Term Added to Existing Codelist

PK Units of Measure

Controlled Terminology Package 24 Publication Release

SEND Terminology Team

Submission Value Change

Neoplasm Type Codelist

CARCINOMA, TRANSITIONAL CELL, MALIGNANT

CARCINOMA, UROTHELIAL, MALIGNANT

Term Removed

Neoplasm Type Codelist

NEUROBLASTOMA, OLFACTORY, MALIGNANT

Please use CARCINOMA, NEUROEPITHELIAL, MALIGNANT

Controlled Terminology Package 24 Publication Release

SEND Terminology Team

New Codelist

- Nonclinical DART Sex
- Nonclinical DART Trial Phases
- Fetal Pathology Findings Test Code/Name
- Fetal Pathology Findings Result Category
- Fetal Findings Result
- Fetal Measurement Test Code/Name
- Pregnancy Findings Test Code/Name
- Pregnancy Findings Result Category
- Pregnancy Findings Result
- Implantation Findings Test Code/Name
- Implantation Findings Result Category
- Implantation Findings Result

Controlled Terminology

Package 24 Publication Release

SEND Terminology Team

- New Term Added to Existing Codelist

 - Non-Neoplastic Finding Type

 - Neoplasm Type

 - SEND Implementation Guide Version

 - Body Weight Gain Test Name/Code

 - Body Weight Test Name/Code

Controlled Terminology Package 24 Publication Release

Virology Terminology Team

Submission Value Change

Microorganism Codelist

BACTEROIDES TECTUS

STREPTOCOCCUS ANGINOSIS

BACTEROIDES PYOGENES

STREPTOCOCCUS ANGINOSUS

New Term Added to Existing Codelist

Microorganism

Controlled Terminology Package 25 Public Review

Controlled Terminology Package 25 Public Review

General Terminology Team

Submission Value Change

Trial Summary Parameter Test Name Codelist

Pharmacological Class of Invest. Therapy

Pharmacological Class

Remove Codelist

Common Terminology Criteria for Adverse Events V4.0

The SDTM implementation guide requires that we place the name and version of the AE grading scale in the define XML (in a similar way that it asks that we put the coding dictionaries and versions in the define XML). For this reason it makes no sense to actually store the grading scales as controlled terminology because they are governed by external controlled lists.

Controlled Terminology Package 25 Public Review

General Terminology Team

New Codelist

BRIDG Activity Mood

The modes that may be applied to an entity as it passes through various phases of a life cycle or business process.

Controlled Terminology Package 25 Public Review

General Terminology Team

New Term Added to Existing Codelist

ADaM Codelist: Derivation Type

Directionality

Epoch

Anatomical Location

Medical Evaluator

Method

Respiratory Test Code/Test Name

Trial Summary Parameter Test Code/Test Name

Vital Signs Test Code/Test Name

Controlled Terminology Package 25 Public Review

Lab Terminology Team (*Laboratory Test Codelists*)

Submission Value Change

Laboratory Test Name

Rheumatoid Factor Antibody IgG

Rheumatoid Factor IgG Antibody

Rheumatoid Factor Antibody IgM

Rheumatoid Factor IgM Antibody

Controlled Terminology

Package 25 Public Review

Lab Terminology Team (*Laboratory Test Codelists*)

Term Removed

Laboratory Test Code/Name

BUN	Blood Urea Nitrogen
BUNCREAT	BUN/Creatinine

Because Urea Nitrogen can be measured in substances other than Blood, Serum, or Plasma, CDISC requires a generic Urea Nitrogen term. To prevent having two ways to code the same concept, the BUN term is being removed. Blood Urea Nitrogen should now be coded as lab test UREA NITROGEN with a specimen type of Blood, Serum, or Plasma.

Controlled Terminology

Package 25 Public Review

Lab Terminology Team (*Laboratory Test Codelists*)

New Term Added to Existing Codelist

Laboratory Test Code/Test Name

New Codelist

Microscopic Findings Test Details

Terminology relevant to the additional descriptions of the test being performed to produce the microscopic result.

Controlled Terminology

Package 25 Public Review

Lab Terminology Team (*Spectype/Speccond Codelist*)

New Term Added to Existing Codelist

Specimen Type Codelist

Controlled Terminology Package 25 Public Review

Lab Terminology Team (*Unit Codelist*)

Submission Value Change

Unit Codelist

AU	Absorbance U
AU/min	Absorbance U/min

New Term Added to Existing Codelist

Unit Codelist

Controlled Terminology Package 25 Public Review

Oncology Terminology Team

New Codelist

Tumor or Lesion Properties Test Result

New Term Added to Existing Codelist

Category of Oncology Response Assessment

Oncology Tumor Properties Test Code/Test Name

Tumor Identification Test Code/Test Name

Controlled Terminology Package 25 Public Review

PGx (Pharmacogenomics/Genetics) Terminology
Team

New Term Added to Existing Codelist
Biospecimen Events Dictionary Derived Term

Controlled Terminology

Package 25 Public Review

PK Terminology Team

Term Removed

PK Units of Measure Codelist

mg/mL/h	Milligrams per milliliter per hour
mmol/mL/h	Millimoles per milliliter per hour
ng/mL/h	Nanograms per milliliter per hour
nmol/mL/h	Nanomoles per milliliter per hour
pg/dL	Picograms per deciliter
nU/mL	Nanounits per milliliter
nL	Nanoliter
h*nmol/L/umol	Hours times nanomoles/liter/micromole
ug/puff	Micrograms per puff
ug/inh	Micrograms per inhalation
pg/mg Creatinine	Picograms per milligram creatinine

Controlled Terminology

Package 25 Public Review

SEND Terminology Team

Submission Value Change

Neoplasm Type Codelist

GLIOMA, MIXED, MALIGNANT

MIXED GLIOMA, MALIGNANT

LYMPHOMA, MIXED, MALIGNANT

MIXED LYMPHOMA, MALIGNANT

MUELLERIAN TUMOR, MIXED, MALIGNANT

MIXED MULLERIAN TUMOR, MALIGNANT

PERIPHERAL NERVE SHEATH TUMOR, MALIGNANT

SCHWANNOMA, MALIGNANT

Controlled Terminology

Package 25 Public Review

SEND Terminology Team

Submission Value Change

Specimen Codelist

BULBOSPONGIOSUS

MUSCLE, BULBOSPONGIOSUS

FLUID, THORACIC

FLUID, PLEURAL

Controlled Terminology

Package 25 Public Review

SEND Terminology Team

Update C-code Mapping

Neoplasm Type Codelist

C27477 **C121932**

GIANT CELL TUMOR, BENIGN

The nomenclature has been updated and now this mapping is obsolete. No changes needed to the SEND submission value, synonyms, or definition.

Specimen Codelist

C12313 **CNEW**

GLAND, ENDOMETRIAL

C32068 **CNEW**

SAC, ANAL

Controlled Terminology Package 25 Public Review

SEND Terminology Team

Term Removed

Neoplasm Type Codelist

ADRENAL TUMOR, SUBCAPSULAR, UNDETERMINED
ADRENOCORTICAL NEOPLASM, UNDETERMINED
AMELOBLASTOMA, UNDETERMINED
ASTROCYTOMA, UNDETERMINED
CARCINOID TUMOR, UNDETERMINED
CHEMODECTOMA, UNDETERMINED
DECIDUOMA, UNDETERMINED
EPENDYMOMA, UNDETERMINED
GANGLIOGLIOMA, UNDETERMINED
GIANT CELL TUMOR, UNDETERMINED
GRANULOSA CELL TUMOR, UNDETERMINED
HAIR FOLLICLE NEOPLASM, UNDETERMINED
HEMANGIOPERICYTOMA, UNDETERMINED
HISTIOCYTOMA, FIBROUS, UNDETERMINED
HISTIOCYTOMA, UNDETERMINED
KERATOACANTHOMA, UNDETERMINED
LEIOMYOBLASTOMA, UNDETERMINED
LEYDIG CELL TUMOR, UNDETERMINED

The FDA requires non-clinical sponsors to identify Benign or Malignant so these would never be used.

Controlled Terminology Package 25 Public Review

SEND Terminology Team

Term Removed continued:

Neoplasm Type Codelist continued:

MAST CELL TUMOR, UNDETERMINED
MENINGIOMA, UNDETERMINED
MESOTHELIOMA, UNDETERMINED
MIXED TUMOR, UNDETERMINED
NEOPLASM, UNDETERMINED
NEURAL CREST TUMOR, UNDETERMINED
NEUROGLIAL TUMOR, UNDETERMINED
ODONTOGENIC TUMOR, UNDETERMINED
OLIGODENDROGLIOMA, UNDETERMINED
OSTEOCLASTOMA, UNDETERMINED
PARAGANGLIOMA, UNDETERMINED
PHEOCHROMOCYTOMA, COMPLEX, UNDETERMINED
PHEOCHROMOCYTOMA, UNDETERMINED
POLYP, ADENOMATOUS, UNDETERMINED
POLYP, UNDETERMINED
SERTOLI CELL TUMOR, UNDETERMINED
STROMAL TUMOR, GONADAL, UNDETERMINED
TERATOMA, UNDETERMINED
THYMOMA, UNDETERMINED

The FDA requires non-clinical sponsors to identify Benign or Malignant so these would never be used.

Controlled Terminology Package 25 Public Review

SEND Terminology Team

Term Removed continued:

Neoplasm Type Codelist continued:

ARRHENOBLASTOMA, BENIGN

ARRHENOBLASTOMA, MALIGNANT

This is a Sertoli only tumor in rodents so coding is not usable for SEND

CARCINOID TUMOR, MALIGNANT

Replace with NEUROENDOCRINE CELL TUMOR, MALIGNANT

CARCINOMA, NEUROENDOCRINE CELL, MALIGNANT

Replace with NEUROENDOCRINE CELL TUMOR, MALIGNANT

MESENCHYMAL TUMOR, MALIGNANT

Replace with RENAL MESENCHYMAL TUMOR, MALIGNANT

Controlled Terminology Package 25 Public Review

SEND Terminology Team

Term Removed continued:

SEND Trial Summary Parameter Test Code/Name Codelist

CLASS Class of Compound
Use PCLASS instead (C98768)

Specimen Codelist

ARTERY, SPERMATIC

FOOT/FOOTPAD

GLAND, ACCESSORY OCULAR

Not currently in use by SEND

BONE MARROW SMEAR

Bone Marrow is the specimen (which is currently published) and Smear is the specimen preparation method

GIZZARD

Replace with existing published term VENTRICULUS

GLAND, PERINEAL

Please use GLAND, ANAL SAC

Controlled Terminology

Package 25 Public Review

SEND Terminology Team

Move Term to a Different Codelist

Species to Strain/Substrain Codelist

BABOON

MARMOSET

Move to STRAIN codelist. SPECIES would be MONKEY.

New Term Added to Existing Codelist

Neoplasm Type

Non-Neoplastic Finding Type

Organ Measurement Test Code/Test Name

Specimen

SEND Trial Summary Parameter Test Code/Test Name

Controlled Terminology Package 25 Public Review

Virology Terminology Team

Submission Value Change

Microorganism Codelist

SALMONELLA SEROTYPE TYPHI

SALMONELLA ENTERICA SUBSP. ENTERICA SEROVAR TYPHI

New Term Added to Existing Codelist

Microorganism



Strength *through collaboration.*

If you are interested in contributing to the CDISC Terminology Initiative, please contact us...

Bernice Yost, byost@cdisc.org

Q&A Session



CDISC Education Events Announcements

Learn CDISC from CDISC!
Authoritative. Global. Vendor neutral.

Standard currently out for review

CTR-XML Version 1.0

Visit <http://cdisc.org/define-xml> for more information

Comments due 18 December 2015




Terminology P25

Visit <http://cdisc.org/terminology> for more information

Comments due 15 January 2016

Click [here](#) to submit your comments.

Upcoming North America Public Courses

Location	Dates	Courses Offered	Host
Morrisville, NC	9-12 Feb 2016	SDTM, CDASH, ADaM	
Audubon, PA	2-11 Mar 2016	Courses corresponding to standards listed in Data Standards Catalog. See web .	
Emeryville, CA	11-15 April 2016	Courses corresponding to standards listed in Data Standards Catalog. See web .	
Visit cdisc.org/public-courses for information on other CDISC Public Training events.			

Check CDISC website for up-to-date information on Public Courses

Upcoming Europe Public Courses and Events

Location	Dates	Courses Offered	Host
Berkshire, UK	26-29 Jan 2016	SDTM, ADaM, Define-XML	
Paris, France	8-11 Mar 2016	SDTM, ADaM, Define-XML	
Europe Interchange in Vienna, Austria	25-29 Apr 2016, Registration Opens Dec 2015 on CDISC Website: http://cdisc.org/interchange	TBA	

Registration deadline indicates online deadline. Onsite registration is available before each event begins. Additional 2016 public training events can be found @ <http://cdisc.org/public-courses>.

Full 2016 Public Training Schedule is online
Check CDISC website for up-to-date information on Public Courses

Next Members Only Webinar

Topic:

- Legacy Studies Submission Automation Using Metadata

Date: 28 Jan 2016, 10:00-11:30 AM CST

Speakers:

- Mark Wheeldon, Formedix

Register [here](#).

Webinar details also at www.cdisc.org/webinars

Any more questions?

Thank you for attending this webinar.

**CDISC's vision is to:
Inform Patient Care & Safety Through Higher Quality Medical Research**



Strength *through collaboration.*

CDISC Members Drive Global Standards

Thank you for your support!



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