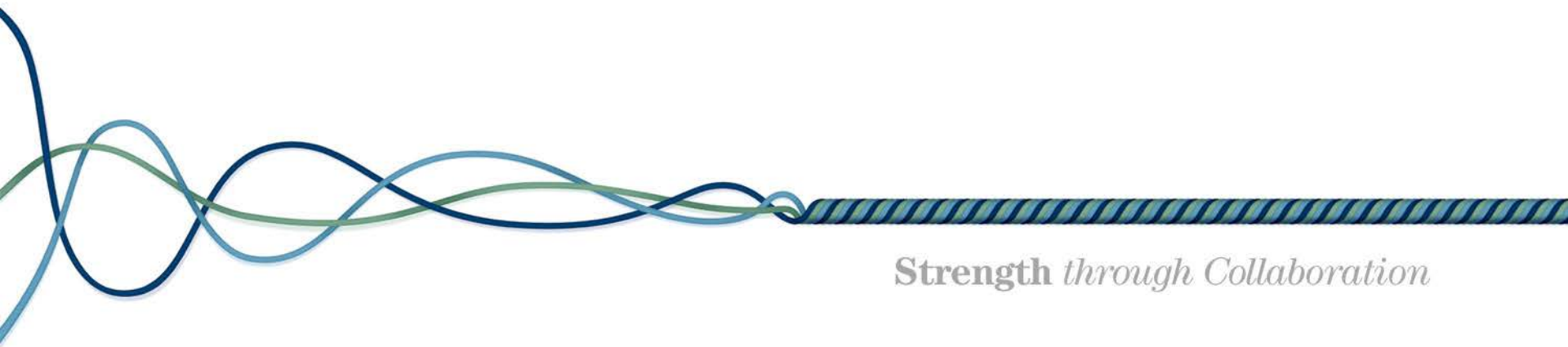


# CDISC Public Webinar – Standards Updates and Additions

Mar 24 2016



**Strength** *through Collaboration*

# Agenda

- Controlled Terminology
  - P25 Terminology Publication Release
  - P26 Public Review
  - Bernice Yost, CDISC
- CDISC Online Education & Event Updates
  - John Ezzell, CDISC

# Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

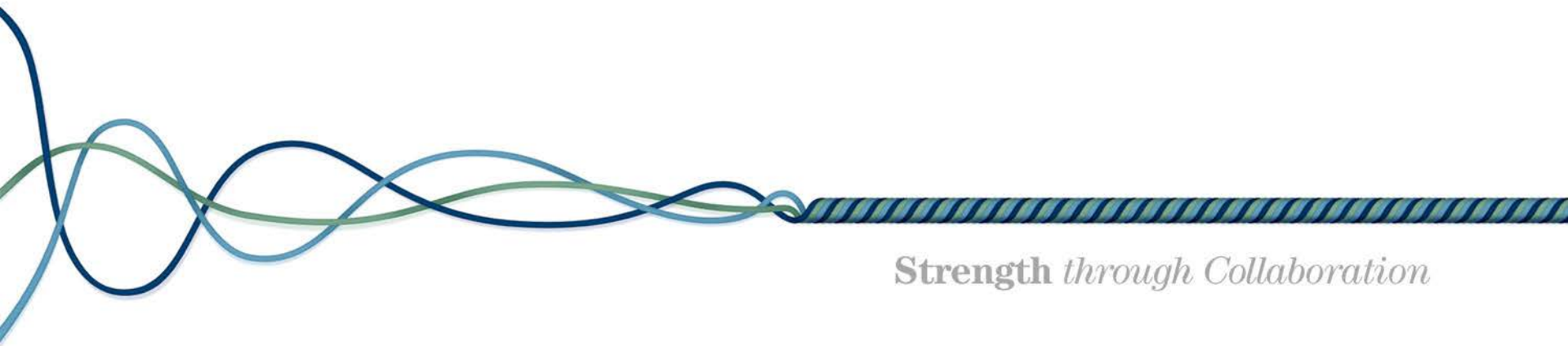
Kit: Where are standards documents in the Wiki?

OR

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

# CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost



**Strength** *through Collaboration*

# Controlled Terminology Agenda

- Package 25 Publication Release (25 Mar 2016)
  - What's new
  - What's changed
- Package 26 Public Review (18 Mar 2016 to 15 Apr 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			
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			
26	3/11/2016	3/18/2016	4/15/2016	5/13/2016	6/24/2016	CV	Device	General	Lab
26						Oncology	SEND	Spectype Speccond	Unit
26						Virology			
27	6/10/2016	6/17/2016	7/15/2016	8/19/2016	9/30/2016				
27									
27									

# **Controlled Terminology Package 25 Publication Release**

# Controlled Terminology

## Package 25 Publication Release

- General Terminology Team
  - Submission Value Change
    - Trial Summary Parameter Test Name Codelist
      - Pharmacological Class of Invest. Therapy
      - **Pharmacologic Class**
        - » Definition: The pharmacological class of the investigational product.
  - 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 Publication Release

- 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 Publication Release

- 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 Publication Release

- Lab Terminology Team (*Laboratory Test Codelists*)
  - Submission Value Change
    - Laboratory Test Name
      - Rheumatoid Factor Antibody IgG (recently published)
      - **Rheumatoid Factor IgG Antibody**
        - » Does not follow the lab terminology rules
      - Rheumatoid Factor Antibody IgM (recently published)
      - **Rheumatoid Factor IgM Antibody**
        - » Does not follow the lab terminology rules

# Controlled Terminology

## Package 25 Publication Release

- 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 Publication Release

- 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 Publication Release

- Lab Terminology Team (*Spectype/Speccond Codelist*)
  - New Term Added to Existing Codelist
    - Specimen Type Codelist

# Controlled Terminology Package 25 Publication Release

- Lab Terminology Team (*Unit Codelist*)
  - Submission Value Change
    - Unit Codelist
      - AU **Absorbance U**
      - AU/min **Absorbance U/min**
        - » AU can mean absorbance unit or allergy unit.
  - New Term Added to Existing Codelist
    - Unit Codelist

# Controlled Terminology Package 25 Publication Release

- Oncology Terminology Team
  - New Codelist
    - Tumor or Lesion Properties Test Result
      - Terminology relevant to the results from the assessment or measurement of a tumor, lesion or site of disease.
  - 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 Publication Release

- PGx (Pharmacogenomics/Genetics) Terminology Team
  - New Term Added to Existing Codelist
    - Biospecimen Events Dictionary Derived Term

# Controlled Terminology

## Package 25 Publication Release

- 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 Publication Release

- SEND Terminology Team
  - Move Term to a Different Codelist
    - Species to Strain/Substrain Codelist
      - BABOON
      - MARMOSSET
        - » Move to STRAIN codelist. SPECIES would be MONKEY.

# Controlled Terminology Package 25 Publication Release

- 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**
        - To make consistent with all Mixed tumors.
      - PERIPHERAL NERVE SHEATH TUMOR, MALIGNANT
        - » **SCHWANNOMA, MALIGNANT**
        - FDA has requested that SEND align with INHAND terminology for its tumor types.

# Controlled Terminology Package 25 Publication Release

- SEND Terminology Team
  - Submission Value Change continued:
    - Specimen Codelist
      - BULBOSPONGIOSUS
        - » **MUSCLE, BULBOSPONGIOSUS**  
To make consistent with all muscle specimen names.
      - FLUID, THORACIC
        - » **FLUID, PLEURAL**  
Incorrectly coded.

# Controlled Terminology Package 25 Publication Release

- 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

- Incorrectly coded to endometrium.

- C32068 **CNEW**

- » SAC, ANAL

- Incorrectly coded to anal gland.

# Controlled Terminology

## Package 25 Publication Release

- 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 Publication Release

- 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 Publication Release

- 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 Publication Release

- SEND Terminology Team
  - Term Removed continued:
    - SEND Trial Summary Parameter Test Code/Name Codelist
      - CLASS            Class of Compound
        - » Use PCLAS instead (C98768)  
Definition: The pharmacological class of the investigational product.

# Controlled Terminology Package 25 Publication Release

- SEND Terminology Team
  - Term Removed continued:
    - 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 Publication Release

- SEND Terminology Team
  - 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 Publication Release

- Virology Terminology Team
  - Submission Value Change
    - Microorganism Codelist
      - SALMONELLA SEROTYPE TYPHI
        - » **SALMONELLA ENTERICA SUBSP. ENTERICA SEROVAR TYPHI**
  - New Term Added to Existing Codelist
    - Microorganism

# Controlled Terminology

## Package 25 Publication Release

- Questionnaires, Ratings, and Scales (QRS)  
Terminology Team
  - Codelist Name Change
    - The codelist short names (blue row) are being updated to include the codelist synonym from the Category codelist followed by TC for test code and TN for test name.

Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
Category of Clinical Classification	CCCAT	Category of Clinical Classification	A grouping of observations within the Clinical Classification domain.
Category of Clinical Classification	APACHE II	APCH1	Acute Physiology and Chronic Health Evaluation II (APACHE II) (Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. Critical Care Medicine 1985; 13(10):818-29).

Codelist Name	CDISC Submission Value
Acute Physiology and Chronic Health Evaluation II Clinical Classification Test Code	APACHE II TESTCD APCH1TC
Acute Physiology and Chronic Health Evaluation II Clinical Classification Test Name	APACHE II TEST APCH1TN

# Controlled Terminology

## Package 25 Publication Release

- Questionnaires, Ratings, and Scales (QRS) Terminology Team
  - New Codelist:
    - Questionnaire
      - Arizona Sexual Experience Scale-Female
      - Arizona Sexual Experience Scale-Male
      - Patient Health Questionnaire Screener Version
      - Expanded Disability Rating Scale Postacute Interview (DRS-PI) Caregiver
      - Expanded Disability Rating Scale Postacute Interview (DRS-PI) Survivor

# **Controlled Terminology Package 26 Public Review**



# Controlled Terminology Package 26 Public Review

- Cardiovascular Terminology Team
  - New Term Added to Existing Codelist
    - Cardiovascular Test Code/Test Name

# Controlled Terminology Package 26 Public Review

- General Terminology Team:
  - Move Terms to a Different Codelist
    - Contact Setting codelist: all terms are being moved to a new codelist called Environmental Setting.
    - Directly Observed Therapy Location codelist: all terms are being moved to a new codelist called Environmental Setting.
  - Codelist Removed
    - Contact Setting
    - Directly Observed Therapy Location

# Controlled Terminology Package 26 Public Review

- General Terminology Team:
  - New Codelist
    - Observational Study Model
      - The terminology relevant to the trial design for observational studies.
    - Observational Study Time Perspective
      - The terminology relevant to the temporal relationship between the observation period and time of subject enrollment in an observational study.
    - Observational Study Biospecimen Retention
      - The terminology relevant to whether biospecimens were retained and contain DNA within an observational study.
    - Observational Study Sampling Method
      - The terminology relevant to the method by which the study population is selected in an observational study.
    - Contact Role for Clinical Study
      - The terminology relevant to the role that the responsible individual or entity plays with respect to being a contact for the study.

# Controlled Terminology

## Package 26 Public Review

- General Terminology Team:
  - New Codelist continued:
    - Mode of Disease Transmission
      - The terminology relevant to the mechanism by which a disease is transmitted.
    - Tuberculosis Findings About Test Code/Test Name
      - Terminology relevant to the test codes/names that describe findings about a tuberculosis event or intervention.
    - Environmental Setting
      - Terminology relevant to the surroundings or environment.
    - Case Finding
      - Terminology relevant to how actively a search was performed for identifying individuals with a particular disease.
    - Musculoskeletal System Finding Test Code/Test Name
      - A terminology codelist to describe the test code for a physiological examination of the musculoskeletal system.

# Controlled Terminology

## Package 26 Public Review

- General Terminology Team:
  - New Term Added to Existing Codelist
    - Anatomical Location
    - Method
    - Trial Summary Parameter Test Code/Name
    - Trial Type
    - Relationship to Subject

# Controlled Terminology

## Package 26 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
  - New Term Added to Existing Codelist
    - Laboratory Test Code/Test Name
    - Microscopic Findings Test Code/Test Name
    - Microscopic Findings Test Details

# Controlled Terminology Package 26 Public Review

- Lab Terminology Team (*Spectype/Speccond Codelists*)
  - New Term Added to Existing Codelist
    - Specimen Type

# Controlled Terminology Package 26 Public Review

- Lab Terminology Team (*Unit Codelist*)
  - New Term Added to Existing Codelist
    - Unit



# Controlled Terminology Package 26 Public Review

- Oncology Terminology Team
  - New Codelist
    - Disease Presentation Type
      - Terminology relevant to the symptoms and/or clinical manifestation of a disease.

# Controlled Terminology Package 26 Public Review

- Oncology Terminology Team
  - New Mapping Codetables
    - Category of Oncology Response Assessment codelist
      - RECIST 1.0
        - » Oncology Response Assessment Test Code/Test Name (ONCRTSCD/ONCRTS) and the Oncology Response Assessment Result (ONCRSR).
      - RECIST 1.1
        - » Oncology Response Assessment Test Code/Test Name (ONCRTSCD/ONCRTS) and the Oncology Response Assessment Result (ONCRSR).
    - Tumor Response Assessment Test Code/Test Name codelists (TUTESTCD/TUTEST) and the Tumor and Lesion Identification Test Results codelist (TUIDRS).

# Controlled Terminology Package 26 Public Review

- SEND Terminology Team
  - Submission Value Change
    - Non-Neoplastic Finding Type Codelist
      - OBSTRUCTIVE UROPATHY
      - **MURINE OBSTRUCTIVE UROPATHY**
        - » New C-code required – incorrectly assigned to Urinary System Disorder. The correct concept is Mouse Urological Syndrome.

# Controlled Terminology Package 26 Public Review

- SEND Terminology Team
  - Term Removed
    - Specimen Codelist
      - BRUNNER'S GLAND
      - DUCT, THYROGLOSSAL
      - EPICARDIUM
      - JOINT, STIFLE
      - LYMPH NODE, RETROSACRAL
        - » Not being used as a specimen but rather would be a location or anatomical region of the finding.

# Controlled Terminology Package 26 Public Review

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - Neoplasm Type
    - Specimen
    - Fetal Pathology Findings Result

# Controlled Terminology Package 26 Public Review

- Virology Terminology Team

- Submission Value Change

- SDTM Species Codelist

- KOCURIA RHIZOPHILA

- » **MICROCOCCUS LUTEUS**

- C86513 is the correct concept for Micrococcus Luteus. Kocuria Rhizophila is a new concept that will receive a new c-code.

- Microorganism Codelist

- KOCURIA RHIZOPHILA

- » **MICROCOCCUS LUTEUS**

- C86513 is the correct concept for Micrococcus Luteus. Kocuria Rhizophila is a new concept that will receive a new c-code.

# Controlled Terminology Package 26 Public Review

- Virology Terminology Team
  - New Codelist
    - Culture Medium Type
      - Terminology relevant to the type of medium used to culture a specimen.
  - New Term Added to Existing Codelist
    - Microorganism
    - SDTM Species



## **Strength *through collaboration.***

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

Bernice Yost, [byost@cdisc.org](mailto:byost@cdisc.org)



# Q&A



# CDISC Online Education & Event Updates

John Ezzell, CDISC



**Strength** *through Collaboration*

# UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered	Early registration discount:	Host
Emeryville CA	11-15 Apr	Courses corresponding to standards listed in Data Standards Catalog. See <a href="#">web</a> .	Expired	
North Chicago, IL	23-27 May	<a href="#">SDTM, CDASH, ADaM Primer, ADaM T&amp;A</a>	Expired	
Toronto, ON	24-27 May	<a href="#">SDTM, CDASH, ADaM Primer, ADaM T&amp;A</a>	Expired	

*Visit [cdisc.org/public-courses](https://cdisc.org/public-courses) for information on other CDISC Public Training events.*

# UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered	Early registration discount:	Host
Europe Interchange in Vienna, Austria	25-29 Apr	Avoid late fees and register by Fri Mar 25 for CDISC <a href="#">CT</a> , <a href="#">BRIDG Deep Dive</a> , <a href="#">SEND</a> and <a href="#">Healthcare Link</a> public courses in Vienna. Act Now!	Expired	
Frankfurt, Germany	13-17 Jun	<a href="#">SDTM</a> , <a href="#">ADaM Primer</a> , <a href="#">ADaM T&amp;A</a> , <a href="#">Define-XML</a>	Expired	
Brussels, Belgium	5-9 Sep	<a href="#">SDTM</a> , <a href="#">CDASH</a> , <a href="#">ADaM Primer</a> , <a href="#">ADaM T&amp;A</a>	6 Jun	
Copenhagen, Denmark	Oct 2016	SDTM, SEND, ADaM Primer, ADaM T&A, Define-XML	3 Jul	
Visit <a href="http://cdisc.org/public-courses">cdisc.org/public-courses</a> for information on other CDISC Public Training events.				

# UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Early Registration Discounts	Host
Tokyo, Japan	23-29 Mar	<u>SDTM, CDASH, ADaM, ODM, Define-XML</u>	Expired	
Ho Chi Minh City, Vietnam	29-31 Mar	<u>SDTM, CDASH</u>	Expired	
Tokyo, Japan	30 May – 3 Jun	See <u>web</u> .	Expired	
Visit <a href="https://cdisc.org/public-courses">cdisc.org/public-courses</a> for information on other CDISC Public Training events.				

# 2016 Members-Only Mini-Trainings

Presenter	Topic	Webinar Date
Lauren Shinaberry, AbbVie	Reference Time Points	April 7, 2016
Melanie Paules, GSK; Barrie Nelson & Diane Wold, CDISC	SDTM Trial Disease Assessment Domain	May 5, 2016
Fred Wood, Accenture	The Need for Human Intelligence in Assessing SDTM Conformance	Jun 9, 2016
Dr. Paul Harris, Vanderbilt University	ODM and CDASH integration in EDCs	July 11, 2016

Webinar details and registration at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)

# Standard currently out for review

- Terminology Package 26 –
  - Visit [cdisc.org/terminology](http://cdisc.org/terminology) for more information
  - Comments due April 15, 2016

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

*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!**



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