CDISC Public Webinar – Standards Updates and Additions

15 SEP 2016

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Agenda

- CT Updates
  - Package 27 Publication Release
  - Package 28 Public Review
  - Bernice Yost, Director of Terminology, CDISC

- CDISC Online Education & Event Updates
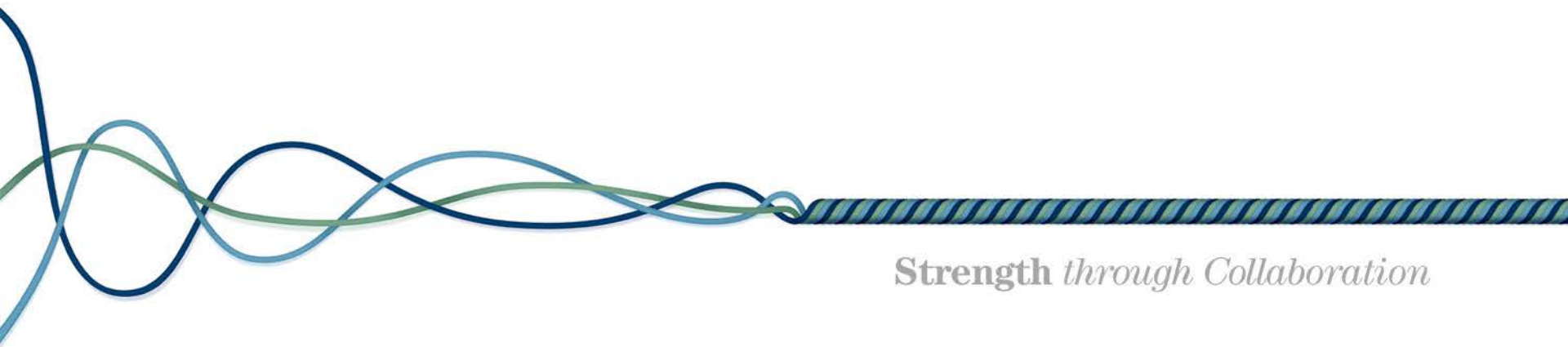 - John Ezzell, CDISC

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Question & Answer

- 'Panelist': Question

OR

- 'Presentation': Question

Examples:

Rachael: What are the differences between the DKD Diabetes User Guide?

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CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost

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Controlled Terminology Agenda

- Package 27 Publication Release (30 Sep 2016)
  - What's new
  - What's changed

- Package 28 Public Review (09 Sep 2016 to 07 Oct 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			
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									
28	9/2/2016	9/9/2016	10/7/2016	11/4/2016	12/16/2016				
28									
28									
29	12/9/2016	12/16/2016	1/27/2017	2/17/2017	3/31/2017				
29									
29									
30	3/17/2017	3/24/2017	4/21/2017	5/19/2017	6/30/2017				
30									
30									
31	6/16/2017	6/23/2017	7/21/2017	8/18/2017	9/29/2017				

Controlled Terminology
Package 27 Publication Release

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Controlled Terminology Package 27 Publication Release

- Cardiovascular Terminology Team:
  - Move Terms to a Different Codelist
    - Morphology Test Code/Test Name codelist: all cardiovascular terms are being moved to the Cardiovascular Test Code/Test Name codelist.
      - Mean Vessel Diameter
      - Minimum Vessel Lumen Diameter
      - Percent Diameter Stenosis
      - Etc.

  - Codelist Removed
    - Cardiac Valvular Regurgitation Severity
    - Cardiac Valvular Stenosis Severity
      - The ACC and ASE and FDA are working on the terminologies for valvular stenosis and valvular regurgitation.

Controlled Terminology Package 27 Publication Release

- Cardiovascular Terminology Team:
  - Submission Value Change
    - Morphology Test Code/Test Name Codelist to Cardiovascular Test Code/Test Name Codelist
      - Test Name: Late Loss
        - » **Late Lumen Loss**
      - Test Code: LATELOSS
        - » **LLMLOSS**
      - Definition: The difference between the mean minimum lumen diameter (MLD) assessed immediately after an index procedure and the MLD assessed at follow-up angiography.

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

Controlled Terminology Package 27 Publication Release

- General Terminology Team:
  - Move Terms to a Different Codelist
    - Morphology Test Code/Test Name codelist: all terms are being moved to their corresponding physiology codelist
      - Ophthalmic Exam Test Code/Test Name
      - Nervous System Physiology Test Code/Test Name
      - Gastrointestinal Test Code/Test Name

Controlled Terminology Package 27 Publication Release

- General Terminology Team:
  - Codelist Removed
    - Country
      - The information is already handled by ISO 3166 3-letter country codelist.
    - Morphology Test Code/Test Name
      - Morphology tests will go to the corresponding physiology codelist.
    - Findings About Test Code/Test Name
      - Each Therapeutic Area will have their own findings about codelist
    - Treatment Episode
    - Treatment Failure
    - Reason Treatment Not Administered
      - TB Therapeutic Area

Controlled Terminology Package 27 Publication Release

- General Terminology Team
  - Codelist Name Change
    - Size   Size Response
    - Skin Classification   Fitzpatrick Skin Classification Response
    - Marital Status   Marital Status Response
    - Skin Type   Skin Type Response
    - Diagnosis Group   Diagnosis Group Response
    - Trial Phase   Trial Phase Response
    - Control Type   Control Type Response
    - Study Type   Study Type Response
    - Route of Administration   Route of Administration Response
    - Intervention Type   Intervention Type Response
    - Trial Blinding Schema   Trial Blinding Schema Response
    - Sex of Participants   Sex of Participants Response
    - Intervention Model   Intervention Model Response
    - Trial Type   Trial Type Response

Controlled Terminology
Package 27 Publication Release

- General Terminology Team
  - New Codelist
    - Gastrointestinal Test Code/Test Name
      - A terminology codelist based on the test codes for physiological findings related to the gastrointestinal system.
    - Race As Collected
      - A terminology codelist relevant to the race of an individual as collected on the case report form.
    - Ethnicity As Collected
      - A terminology codelist relevant to the ethnicity of an individual as collected on the case report form.

Controlled Terminology Package 27 Publication Release

- General Terminology Team
  - New Term Added to Existing Codelist
    - Trial Type
    - Route
    - Anatomical Location
    - Musculoskeletal System Finding Test Code/Test Name
    - Method
    - Study Type
    - Respiratory Test Code/Test Name

Controlled Terminology Package 27 Publication Release

- Lab Terminology Team (*Laboratory Test Codelists*)
    - Submission Value Change
        - Laboratory Test Code/Test Name
            - Test Name: Plasma Cells/Total Cells
                » **Mature Plasma Cells/Total Cells**
            - Test Code: PLSCECE
                » **PLSMCECE**
            - Test Definition: A relative measurement (ratio or percentage) of the mature plasma cells (plasmacytes) to total cells in a biological specimen (for example a bone marrow specimen).

            The intention of the term was to measure mature plasma cells/total cells. Therefore the submission value update is being done to decrease ambiguity in use of this term.

Controlled Terminology Package 27 Publication Release

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

Controlled Terminology Package 27 Publication Release

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

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Controlled Terminology Package 27 Publication Release

- Lab Terminology Team (*Unit Codelist*)
  - Term Removed
    - Unit Codelist
      - mL/g (C67411) - retire
      - L/kg   (C73725)
        - » mathematical synonyms
        - » Concept C67411 will be retired and the mL/g will now be a synonym to L/kg (C73725).

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Controlled Terminology Package 27 Publication Release

- Lab Terminology Team (*Unit Codelist*)
  - Term Removed continued:
    - Unit Codelist
      - /dL (C105514) – retire
        » This concept, C105514, does NOT assume 1 in the numerator and has been used incorrectly. If you really need /dL, please submit a new term request with an example of a test that uses this unit. You could convert the value and use 10^3/L (C105519).
      - /L (C105515) – retire
        » This concept, C105515, does NOT assume 1 in the numerator and has been used incorrectly. If you really need /L, please submit a new term request with an example of a test that uses this unit. You could convert the value and use 10^3/L (C105519).
      - /uL (C67254) - retire
        » This concept, C67254, does NOT assume 1 in the numerator and has been used incorrectly. If you really need /uL, please submit a new term request with an example of a test that uses this unit. You could use 10^6/L (C67452).

Controlled Terminology Package 27 Publication Release

- Lab Terminology Team (*Unit Codelist*)

  - New Term Added to Existing Codelist
    - Unit

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Controlled Terminology Package 27 Publication Release

- Oncology Terminology Team
  - Codelist Removed
    - Neoplasm Type
      - This codelist will be in use by SEND only. SDS oncology team will consider how tumors should best be represented in SDTM datasets along with proposal for alternate terminology.

  - Codelist Name Change
    - Tumor Identification Test Code/Test Name
      - **Tumor or Lesion Identification Test Code/Test Name**
    - Tumor and Lesion Identification Test Results
      - **Tumor or Lesion Identification Test Results**
        » consistency with domain name update

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Controlled Terminology Package 27 Publication Release

- Oncology Terminology Team
  - Submission Value Change
    - Oncology Response Assessment Result Codelist
      - Non-CR/Non-PD
        - » **NON-CR/NON-PD**

          Only the casing of the submission value is changing for consistency with other terms in the codelist beginning with 'Non-'. Case change does not change the meaning of the term.

  - New Term Added to Existing Codelist
    - Oncology Response Assessment Result
    - Category of Oncology Response Assessment

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Controlled Terminology Package 27 Publication Release

- Oncology Terminology Team
  - Mapping Document
    - RECIST 1.1
      - Oncology Response Assessment Test Code/Test Name
      - Oncology Response Assessment Result

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Controlled Terminology
Package 27 Publication Release

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

Controlled Terminology Package 27 Publication Release

- PK Terminology Team
  - New Codelist
    - PK Units of Measure - Weight kg (PKUWKG)
      - Units of measure for pharmacokinetic data and parameters normalized by weight in kilograms.
    - PK Units of Measure - Weight g (PKUWG)
      - Units of measure for pharmacokinetic data and parameters normalized by weight in grams.
    - PK Units of Measure - Dose mg (PKUDMG)
      - Units of measure for pharmacokinetic data and parameters normalized by dose amount in milligrams.
    - PK Units of Measure - Dose ug (PKUDUG)
      - Units of measure for pharmacokinetic data and parameters normalized by dose amount in micrograms.

Controlled Terminology
Package 27 Publication Release

- PK Terminology Team
  - Move Terms to a Different Codelist
    - PK Units of Measure Codelist
      - (mL/day)/g (C120772) – c-code is being retired
        » PK Units of Measure - Weight g
      - (L/day)/kg (C73755)
        » Mathematical synonyms
        » Concept C120772 will be retired and the (mL/day)/g will now belong to the concept of C73755.
        » PK Units of Measure - Weight kg

Controlled Terminology Package 27 Publication Release

- PK Terminology Team
  - Move Terms to a Different Codelist (example: C119351)
    - PK Units of Measure - Weight kg (PKUWKG)
      - ug/mL/kg
    - PK Units of Measure - Weight g (PKUWG)
      - ng/mL/g
    - PK Units of Measure - Dose mg (PKUDMG)
      - pg/mL/mg
    - PK Units of Measure - Dose ug (PKUDUG)
      - fg/mL/ug

      » Synonym: ug/mL/kg; ng/mL/g; pg/mL/mg; fg/mL/ug
      » Definition: Micrograms per milliliter (concentration), divided by kilograms (weight) or nanograms per milliliter (concentration), divided by grams (weight) or picograms per milliliter (concentration), divided by milligrams (dose) or femtograms per milliliter (concentration), divided by micrograms (dose).

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Controlled Terminology Package 27 Publication Release

- SEND Terminology Team
  - Submission Value Change
    - Neoplasm Type Codelist
      - MIXED GLIOMA, BENIGN
        - » **GLIOMA, MIXED, BENIGN**
      - MIXED GLIOMA, MALIGNANT
        - » **GLIOMA, MIXED, MALIGNANT**
      - MIXED LYMPHOMA, MALIGNANT
        - » **LYMPHOMA, MIXED, MALIGNANT**
      - MIXED MULLERIAN TUMOR, MALIGNANT
        - » **MULLERIAN TUMOR, MIXED, MALIGNANT**
      - MIXED SERTOLI-LEYDIG CELL TUMOR, BENIGN
        - » **SERTOLI-LEYDIG CELL TUMOR, MIXED, BENIGN**
      - MIXED TUMOR, BENIGN
        - » **TUMOR, MIXED, BENIGN**
      - MIXED TUMOR, MALIGNANT
        - » **TUMOR, MIXED, MALIGNANT**

          MIXED is a modifier and as such should be in the middle of the CDISC submission value. This also follow INHAND preferred nomenclature. *(International Harmonization of Nomenclature and Diagnostic Criteria)*

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Controlled Terminology Package 27 Publication Release

- SEND Terminology Team
  - Term Removed
    - Specimen Codelist
      - GLAND, URETHRAL
        - » No one seems to be using this term currently as a specimen.
      - LYMPH NODE, PERITONEAL
        - » There isn't a named thing called a Peritoneal Lymph Node in anatomy lexicon. Team suggests that someone map this to LYMPH NODE and then use ANTREG to describe location as Peritoneum or use SUPPQUAL to describe general location.
      - LYMPH NODE, SUBLUMBAR
        - » There are inconsistent definitions for what this is within the literature and this does not commonly show up in anatomy textbooks. Either use the MULTIPLE convention or map to a specific lymph node in the CT.
      - LYMPH NODE, THORACIC
        - » Either use the MULTIPLE convention or map to a specific lymph node in the CT.
      - SPERMATIC CORD
        - » No one seems to be using this term currently as a specimen; please use more specific term like VAS DEFERENS.

Controlled Terminology Package 27 Publication Release

- SEND Terminology Team
  - Term Removed continued:
    - Specimen Codelist
      - LYMPH NODE, SUPRAPHARYNGEAL (C77656) - retire
      - LYMPH NODE, RETROPHARYNGEAL (C77649)

        » Concept C77656 will be retired and the Suprapharyngeal Lymph Node will now be a synonym to Lymph Node, Retropharyngeal (C77649).

Controlled Terminology Package 27 Publication Release

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - Non-Neoplastic Finding Type
    - Strain/SubStrain
    - Specimen
    - Category for Clinical Observation

Controlled Terminology Package 27 Publication Release

- Virology Terminology Team
  - Move Terms to a Different Codelist
    - Viral Resistance Findings Test Code/Test Name codelist: all terms are being moved to the Microbiology Susceptibility Test Code/Test Name codelist
      - TB TAUG - The VR domain will be deprecated and all VR terminology will be moved to a new Microbiology Susceptibility codelist

  - Codelist Removed
    - Viral Resistance Findings Test Code/Test Name

Controlled Terminology Package 27 Publication Release

- Virology Terminology Team
  - Submission Value Change
    - Microorganism Codelist
      - ARCANOBACTERIUM PYOGENES
        - »**TRUEPERELLA PYOGENES**
      - BACTEROIDES UREOLYTICUS
        - »**CAMPYLOBACTER UREOLYTICUS**
          - Change in NCBI Taxonomy

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Controlled Terminology Package 27 Publication Release

- Virology Terminology Team
  - New Codelist
    - Microbiology Susceptibility Test Code/Test Name

  - New Term Added to Existing Codelist
    - Microorganism
    - Microbiology Test Code/Test Name
    - Culture Medium Type

Controlled Terminology Package 27 Publication Release

- Questionnaires, Ratings, and Scales (QRS) Terminology Team
  - New Codelist:
    - Questionnaire
      - Functional Assessment of Chronic Illness Therapy-Fatigue Version 4
      - National Comprehensive Cancer Network/Functional Assessment of Cancer Therapy-Kidney Symptom Index-19 Version 2
      - National Comprehensive Cancer Network/Functional Assessment of Cancer Therapy-Bladder Symptom Index-18 Version 2
      - Functional Assessment of Cancer Therapy-Breast Version 4
      - Functional Assessment of Cancer Therapy-Ovarian Symptom Index
      - National Comprehensive Cancer Network/Functional Assessment of Cancer Therapy-Ovarian Symptom Index-18 Version 2

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Controlled Terminology
Package 28 Public Review

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Controlled Terminology Package 28 Public Review

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

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Controlled Terminology Package 28 Public Review

- Device Terminology Team:
  - New Codelist
    - Device-In-Use Response

  - New Term Added to Existing Codelist
    - Device In-Use Test Name/Test Code

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Controlled Terminology Package 28 Public Review

- ECG Terminology Team:

    - New Term Added to Existing Codelist
        - ECG Result

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Controlled Terminology Package 28 Public Review

- General Terminology Team
  - Codelist Name Change
    - Trial Indication Type → **Trial Intent Type Response**

      » The codelist name needed to be updated to remove the confusion and incorrect usage of trial indication type codelist, trial indication type response, trial indication type test, and trial indication test.

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Controlled Terminology Package 28 Public Review

- General Terminology Team
  - Submission Value Change
    - Trial Summary Parameter Test Code/Test Name
      - Test Name: Trial Indication Type
        - » **Trial Intent Type**
      - Test Code: TINDTP

      - Test Name: Trial Indication
        - » **Trial Disease/Condition Indication**
      - Test Code: INDIC

        - » The submission value needed to be updated to remove the confusion and incorrect usage of trial indication type codelist, trial indication type response, trial indication type test, and trial indication test.

Controlled Terminology Package 28 Public Review

- General Terminology Team
  - Term Removed
    - ADaM Derivation Type Codelist
      - TIME MATCHED (C125936)
        - » This value does not appear to indicate how an analysis value was derived which is the purpose of this codelist - you possibly might have TIME MATCHED - LOCF or TIME MATCHED - BLOCF as a valid value but TIME MATCHED in and of itself does not appear to be a valid DTYPE value.

Controlled Terminology Package 28 Public Review

- General Terminology Team
  - New Codelist
    - Urinary System Test Code/Test Name
    - Diabetic Kidney Findings About Test Code/Test Name

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Controlled Terminology Package 28 Public Review

- General Terminology Team
  - New Term Added to Existing Codelist
    - Evaluator
    - Anatomical Location
    - Method
    - Respiratory Test Code/Test Name
    - Relationship to Subject
    - Skin Response Test Code/Test Name

Controlled Terminology Package 28 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
    - Submission Value Change
        - Laboratory Test Code/Test Name
            - Test Name: Cytokeratin Fragment 21-1
                - » **Cytokeratin 19 Fragment 21-1**
            - Test Code: CYFRA211

            The submission value for the test name was updated to avoid confusion with other cytokeratin fragments.

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Controlled Terminology Package 28 Public Review

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

Controlled Terminology Package 28 Public Review

- SEND Terminology Team
  - C-Code Change
    - SEND Trial Summary Parameter Test Code/Test Name Codelist
      - Principal Investigator
      - Study Director
      - Sponsor's Monitor
      - Sponsoring Organization

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Controlled Terminology Package 28 Public Review

- Lab Terminology Team (*Unit Codelist*)
  - Submission Value Change
    - Unit
      - ugeq/L (microgram equivalents of solute per liter of solution)
        - » **ugEq/L**

          The symbol for Equivalent is Eq. The E in the submission value and synonym should be upper case. This will make it consistent with the other equivalent terms that are published.

  - Term Removed
    - Unit Codelist
      - HPF (High Powered Field)
        - » Please use C96619 (/HPF).
      - LPF (Low Powered Field)
        - » Please use C96620 (/LPF).

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Controlled Terminology Package 28 Public Review

- Lab Terminology Team (*Unit Codelist*)

  - New Term Added to Existing Codelist
    - Unit

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Controlled Terminology Package 28 Public Review

- Oncology Terminology Team
    - New Term Added to Existing Codelist
        - Oncology Response Assessment Result

Controlled Terminology Package 28 Public Review

- SEND Terminology Team
  - New Term Added to Existing Codelist
    - SEND Trial Summary Parameter Test Code/Test Name
    - Neoplasm Type
    - Specimen

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Controlled Terminology Package 28 Public Review

- Virology Terminology Team

  - New Term Added to Existing Codelist
    - Microorganism

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Q&A

CDISC Online Education
& Event Updates

John Ezzell, CDISC

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Upcoming Webinars

Presenter	Topic	Webinar Date
Jozef Aerts, CEO, XML4Pharma	Define-XML and ODM-XML	6 OCT 2016
Dr. Lauren Becnel, Senior Director of Biomedical Informatics and Alliances, CDISC	BRIDG Overview	3 NOV 2016

Webinar details and registration at www.cdisc.org/webinars

Standard currently out for review

- **SDTMIG v3.3 Batch 3**
  - Comments due 21 OCT 2016
- **Asthma v1.1**
  - Comments due 30 SEP 2016
- **Influenza v1.1**
  - Comments due 30 SEP 2016
- **Pain v1.1**
  - Comments due 30 SEP 2016
- **Schizophrenia v1.1**
  - Comments due 30 SEP 2016
- **Virology v2.1**
  - Comments due 30 SEP 2016

UPCOMING NORTH AMERICA PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends:	Late fees kick(ed) in:	Host
Bethesda, MD	26-30 Sep 2016	See web.	Ended	26 Aug	CDISC
Miami, FL	23-27 Jan 2017	SDTM, CDASH, ADaM Primer, ADaM T&A	23 Oct 2016	23 Dec 2106	biorasi CLINICAL RESEARCH OPTIMIZED Powered by TALOS
Raleigh, NC	27 Feb – 3 Mar 2017	SDTM, CDASH, ADaM Primer, ADaM T&A	28 Nov 2016	28 Jan 2017	ucb
Audubon, PA	3-7 Apr 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, CT, Define-XML	3 Jan 2017	3 Mar 2017	BIOCLINICA SEE MORE CLEARLY
Toronto, ON	5-9 June 2017	SDTM, CDASH, ADaM Primer, ADaM T&A, Define-XML	6 Mar 2017	5 May 2017	McDOUGALL SCIENTIFIC INSIGHTS YOU CAN TRUST

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING EUROPE PUBLIC COURSES

Location	Dates	Courses Offered:	Discount period ends	Late fees kick(ed) in:	Host
Copenhagen, Denmark	3-7, 24-26 Oct 2016	SDTM, SEND, ADaM Primer, ADaM T&A, Define-XML	Ended	3 Sep	SCUBED
Basel, Switzerland	7-11 Nov 2016	SDTM, ADaM Primer, ADaM T&A, Define-XML	Ended	7 Oct	ACTELION
London, UK	24-28 Apr 2017	TBD	TBD	TBD	CDISC

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

UPCOMING ASIA PUBLIC COURSES

Location	Dates	Courses Offered	Discount period ends:	Late fees kick(ed) in:	Host
Beijing, China	18-21 Oct 2016	SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML	18 Sep	None	TRUST 信立达
Shanghai, China	24-27 Oct	SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML	24 Sep	None	PAREXEL.
Tokyo, Japan	5-9 Dec	SDTM, CDASH, ADaM Primer, ADaM T&A, ODM, Define-XML	Ended	5 Nov	Croit

Visit cdisc.org/public-courses for information on other CDISC Public Training events.

CDISC Online Training Production Update

- Just Released
  - Breast Cancer TA Online Training
  - ADaM Module 3 Online Training

Online Courses in Development
TA Alzheimer's
TA QT Studies
TA Vaccines
TA Prostate Cancer
TA Rheumatoid Arthritis
TA Pain
ADaM Modules 4-8
CT Module 1 & 2
Define-XML

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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Authoritative. Global. Vendor neutral.