CDISC Public Webinar – Standards Updates and Additions

19 June 2014

Strength *through Collaboration*

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Agenda

- Controlled Terminology, Batch 18, Publication Release

- Controlled Terminology, Batch 19, Public Review
  - Bernice Yost, CDISC

- CDISC Education and Events Updates*
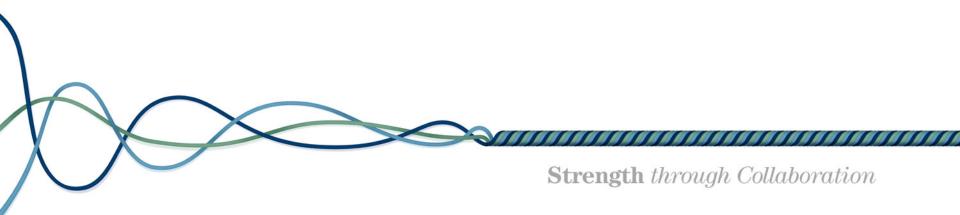 - Saad Yousef, CDISC

*After Q&A session

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The CDISC vision is to inform patient care & safety through higher quality medical research.

Strength *through Collaboration*

CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost

Strength *through Collaboration*

Controlled Terminology Agenda

- Package 18 Publication Release (27 June 2014)
  - What's new
  - What's changed

- Package 19 Public Review (20 June 2014 to 18 July 2014)
  - 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			
18	3/14/2014	3/21/2014	4/18/2014	5/16/2014	6/27/2014	CV	Device	ECG	General
18						Lab	PK	QS	SEND
18						Unit	Virology		
19	6/13/2014	6/20/2014	7/18/2014	8/15/2014	9/26/2014	CV	Device	ECG	General
19						Lab	Oncology	PK	QS
19						SEND	Spectype Speccond	Unit	Virology
20	9/5/2014	9/12/2014	10/10/2014	11/7/2014	12/19/2014				
20									
20									
21	12/12/2014	12/19/2014	1/23/2015	2/13/2015	3/27/2015				
21									
21									
22	3/13/2015	3/20/2015	4/17/2015	5/15/2015	6/26/2015				

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Controlled Terminology
Package 18 Publication Release

Controlled Terminology Package 18 Publication Release

- Questionnaires
    - Codelist Name Change
        - All questionnaire codelist names will have "QS-" added to the beginning of the codelist name
            - Fatigue Severity Scale Test Code
            - QS-Fatigue Severity Scale Test Code

    - Questionnaire Category
        - Codelist Name Change
            - Questionnaire Category
            - Category of Questionnaire

Controlled Terminology
Package 18 Publication Release

- Functional Tests
    - Codelist Names
        - All functional test codelist names will start with "FT-"
            - Functional tests are named, stand-alone task based evaluations designed to provide an assessment of mobility, dexterity, or cognitive ability. A functional test is not a subjective assessment of how the subject generally performs a task. Rather it is an objective measurement of the performance of the task by the subject in a specific instance. Functional tests have documented methods for administration and analysis and require a subject to perform specific activities that are evaluated and recorded. Most often, functional tests are direct quantitative measurements.
    - Functional Tests Category
        - Category of Functional Tests

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Controlled Terminology Package 18 Publication Release

- Questionnaires being released
    - Disability Rating Scale (DRS)
    - Glasgow Outcome Scale Extended (GOSE)
    - Mayo-Portland Adaptability Inventory-4 (MPAI-4)
    - Satisfaction with Life Scale (SWLS)

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Controlled Terminology Package 18 Publication Release

- Functional Tests being released
  - 6 Minute Walk Test (6MWT)
  - Hauser Ambulation Index (HAI)
  - Nine-Hole Peg Test (NHPT)
  - Paced Auditory Serial Addition Test (PASAT)
  - Symbol Digit Modalities Test (SDMT)
    - Total Score Only
  - Timed 25 Foot Walk (T25FW)
  - Timed Up and Go (TUG)

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Controlled Terminology Package 18 Publication Release

- Cardiovascular Terminology Team (CV)
  - American College of Cardiology/American Heart Association Task Force in Clinical Data Standards (TFDS) recently completed the 2014 ACC/AHA Key Data Elements and Definitions for Cardiovascular and Stroke End Points for Clinical Trials.

  - Submission Value Change
    - TIMI Flow Responses Codelist
      - TIMI-0   GRADE 0
      - TIMI-1   GRADE 1
      - TIMI-2   GRADE 2
      - TIMI-3   GRADE 3

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Controlled Terminology Package 18 Publication Release

- Device Terminology Team
  - New Term Added to Existing Codelist
    - Device Properties Test Name/Test Code
    - Device Events Category
    - Device In-Use Test Name/Test Code

Controlled Terminology Package 18 Publication Release

- ECG Terminology Team
  - Submission Value Change
    - ECG Test Name Codelist
      - Intraventricular and Intraatrial Conduction
      - Intraventricular-Intraatrial Conduction
        » The test name cannot be greater than 40 characters.

  - New Term Added to Existing Codelist
    - ECG Test Name/Code
    - ECG Test Method
    - ECG Result

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Controlled Terminology Package 18 Publication Release

- Lab Terminology Team (*Laboratory Test Codelists*)
  - Submission Value Change
    - Laboratory Test Code Codelist
      - PLSMCECE   Plasma Cells/Total Cells
      - PLSCECE
        » PLS is being used to represent plasma cells. PLSIxxxx for Immature Plasma cells, PLSMxxxx for Mature Plasma cells.

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

Controlled Terminology Package 18 Publication Release

- Lab Terminology Team (*Unit Codelist*)
  - Term Removed
    - Unit Codelist
      - cells/uL
        » The cells are described in the test value, so you do not need cells in the unit code.

  - New Term Added to Existing Codelist
    - Unit

Controlled Terminology Package 18 Publication Release

- PK Terminology Team
  - Submission Value Change
    - PK Parameter Units of Measure Codelist
      - mg/L/mg
      - ug/mL/mg (Micrograms per milliliter (concentration), divided by milligrams (dose))
        » The original units, mg/L/mg, contains concentration units, mg/L, and dose units, mg. Our new standard for concentration units is *g/mL (* stands for null, m, u, n, p, or f). The standard volume unit is now mL, not L. So we changed mg/L to ug/mL.

  - Term Removed
    - PK Parameter Units of Measure Codelist
      - h*mg/L/mg (Hours times milligrams per liter per milligram)
        » This is mathematically synonymous with an existing term
          h*ng/mL/mg (Hours times nanograms per milliliter per milligram)

Controlled Terminology Package 18 Publication Release

- PK Terminology Team continued
  - Code Change
    - PK Parameter Units of Measure Codelist
      - New <u>Code</u> will be assigned to the following terms:
        - » h*umol/L/g   (Hours times micromoles per liter (area under the curve), divided by grams (dose or weight))
        - » h*nmol/L/g   (Hours times nanomoles per liter (area under the curve), divided by grams (dose or weight))

  - New Term Added to Existing Codelist
    - Pharmacokinetic Parameters Name/Code

Controlled Terminology Package 18 Publication Release

- Virology Terminology Team
  - Code Change
    - Microorganism Codelist
      - New <u>Code</u> will be assigned to the following term:
        - » CORONAVIRUS

  - New Codelist
    - Viral Resistance Findings Test Name/Code
    - SDTM Species

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Controlled Terminology Package 18 Publication Release

- General Terminology Team
  - Term Removed
    - Anatomical Location Codelist
      - MUSCLE, DISTAL
        » Distal is in the Directionality Codelist
      - MUSCLE, PROXIMAL
        » Proximal is in the Directionality Codelist
      - GASTRIC
        » This term is a descriptor rather than a location.

  - New Codelist
    - Nervous System Physiology Test Code/Name
    - Pharmacogenomics Findings Test Code/Name
    - Death Details Test Code/Test Name

Controlled Terminology Package 18 Publication Release

- General Terminology Team continued:
  - New Term Added to Existing Codelist
    - Morphology Test Code/Test Name
    - Frequency
    - Procedure
    - Anatomical Location
    - Method
    - Units for Vital Signs Results

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Controlled Terminology Package 18 Publication Release

- SEND Terminology Team
  - Submission Value Change
    - Neoplasm Type Codelist
      - ADENOMA, ZYMBAL'S GLAND
      - ADENOMA, ZYMBAL'S GLAND, BENIGN
        » The word BENIGN was accidentally left off of the submission value. The definition is correct.

  - Term Removed
    - Method of Termination Codelist
      - ANESTHETIZED INTRAVENOUS KCL
      - BARBITURATE OVERDOSE INTRAPERITONEAL
      - BARBITURATE OVERDOSE INTRAVENOUS
        » This change was to eliminate redundancy and to align with the new rules established for the Method of Termination Codelist.

Controlled Terminology Package 18 Publication Release

- SEND Terminology Team continued
    - New Term Added to Existing Codelist
        - Neoplasm Type
        - Specimen
        - SEND Study Type
        - Method of Termination

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Controlled Terminology Package 19 Public Review

Controlled Terminology Package 19 Public Review

- Cardiovascular Terminology Team (CV)
  - New Codelist
    - Graft Type
    - Coronary Artery Thrombosis Method of Identification

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Controlled Terminology Package 19 Public Review

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

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Controlled Terminology Package 19 Public Review

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

Controlled Terminology Package 19 Public Review

- ECG Terminology Team continued
  - The ECG Terminology Team is comprised of US and international cardiologists, terminology experts currently using the CDISC terms, NCI EVS and CDISC team members. The team has made extensive efforts in standardizing the ECG Result values (EGSTRESC) and ECG Test Name/Code (EGTEST/EGTESTCD) values. The mapping codetable here-in is a comprehensive mapping of the result terms to their relevant test values. Users should refer to this for their data submissions. This will be maintained by the ECG Terminology Team and updated accordingly if/when new values are added to any of the relevant core terminology codelists that are the basis of this mapping codetable: EGSTRESC, EGTEST and EGTESTCD.

Controlled Terminology Package 19 Public Review

- ECG Terminology Team continued
  - Mapping Codetable

EGSTRESC	EGTESTCD	EGTEST
1ST DEGREE AV BLOCK	AVCOND	Atrioventricular Conduction
2:1 AV BLOCK	AVCOND	Atrioventricular Conduction
2ND DEGREE AV BLOCK	AVCOND	Atrioventricular Conduction
3RD DEGREE AV BLOCK	AVCOND	Atrioventricular Conduction
ADVANCED/HIGH GRADE AV BLOCK	AVCOND	Atrioventricular Conduction
ATRIOVENTRICULAR DISSOCIATION	AVCOND	Atrioventricular Conduction
AV MOBITZ I	AVCOND	Atrioventricular Conduction
AV MOBITZ II	AVCOND	Atrioventricular Conduction
ISORHYTHMIC DISSOCIATION	AVCOND	Atrioventricular Conduction
PAROXYSMAL AV BLOCK	AVCOND	Atrioventricular Conduction
SHORT PR INTERVAL	AVCOND	Atrioventricular Conduction
EARLY R WAVE TRANSITION	AXISVOLT	Axis and Voltage
LATE R WAVE TRANSITION	AXISVOLT	Axis and Voltage
LOW QRS VOLTAGE	AXISVOLT	Axis and Voltage
NORTHWEST AXIS	AXISVOLT	Axis and Voltage
POOR R WAVE PROGRESSION	AXISVOLT	Axis and Voltage
Q AXIS, LEFT AXIS DEVIATION	AXISVOLT	Axis and Voltage
Q AXIS, RIGHT AXIS DEVIATION	AXISVOLT	Axis and Voltage
QRS COMPLEX ABNORMALITY	AXISVOLT	Axis and Voltage

Controlled Terminology Package 19 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
  - Term Removed
    - Laboratory Test Name/Test Code Codelist
      - LIPASE   Triacylglycerol Lipase: A measurement of the pancreatic lipase in a biological specimen.

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

TESTCD	TEST	Synonym(s)	CDISC Definition
LIPASET	Lipase	Total Lipase	A measurement of the total lipase in a biological specimen.
LIPASEP	Lipase, Pancreatic	PNLIP; Pancreatic Triacylglycerol Lipase	A measurement of the pancreatic triacylglycerol lipase in a biological specimen.
LIPASEG	Lipase, Gastric	LIPF; Gastric Triacylglycerol Lipase	A measurement of the gastric triacylglycerol lipase in a biological specimen.
LIPASLAL	Lipase, Lysosomal Acid	Lysosomal Lipase; LIPA; LAL; Acid Cholesteryl Ester Hydrolase	A measurement of the lysosomal acid lipase in a biological specimen.

Controlled Terminology Package 19 Public Review

- Lab Terminology Team (*Specimen Type/Specimen Condition Codelists*)

  - New Term Added to Existing Codelist
    - Specimen Type

Controlled Terminology Package 19 Public Review

- Lab Terminology Team (*Unit Codelist*)
  - Submission Value Change
    - Unit Codelist
      - BAR   Bar Dosing Unit
      - DBAR
        » differentiate from Bar Unit of Pressure
      - uIU/mL Milli-International units per liter
      - mIU/L
        » makes this unit SI compliant
  - Term Removed
    - Unit Codelist
      - Um3   Cubic Micrometer: A unit of volume equal to 10E-18 liter or one cubic micrometer (Attoliter).
        » This was assigned to the wrong concept and will be removed. The correct concept is 10E-15 liter (Femtoliter).

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Controlled Terminology Package 19 Public Review

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

Controlled Terminology Package 19 Public Review

- PK Terminology Team
    - Codelist Name Change
        - PK Parameter Units of Measure Codelist
        - PK Units of Measure Codelist
            - Definition: Units of measure for pharmacokinetic data and parameters.
                - » The PK Units of Measure codelist will also be used by the PC domain.

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Controlled Terminology Package 19 Public Review

- PK Terminology Team continued
  - Submission Value Change
    - PK Parameter Units of Measure Codelist
      - L/mg/day   (L/day)/mg
      - L/g/day   (L/day)/g
      - L/mg/h   (L/h)/mg
      - L/mg/min   (L/min)/mg
      - L/g/h   (L/h)/g
      - L/g/min   (L/min)/g
      - L/ug/h   (L/h)/ug
      - L/ug/min   (L/min)/ug
      - L/ug/day   (L/day)/ug
        » Parentheses are needed to avoid ambiguity and we want to be consistent with our other terms

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Controlled Terminology Package 19 Public Review

- PK Terminology Team continued
  - Term Removed
    - PK Parameter Units of Measure Codelist
      - h*pg/mL/ug
      - h*pmol/L/ug
        - » They are mathematically synonymous with other terms.

- PK Terminology Team
  - New Term Added to Existing Codelist
    - Pharmacokinetic Parameters Name/Code

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Controlled Terminology Package 19 Public Review

- Virology Terminology Team
    - New Codelist
        - Disease-Specific Bacteria

    - New Term Added to Existing Codelist
        - SDTM Species

Controlled Terminology Package 19 Public Review

- General Terminology Team
  - Term Removed
    - Method Codelist
      - Angiogram
        » Angiogram is not a method. It is the product created when an Angiography is conducted. The correct method is Angiography and it will be added.

  - New Codelist
    - Analysis Reason
    - Analysis Purpose
    - Multiple Sclerosis Findings About Test Code/Name
    - Ophthalmic Exams
    - West Haven Hepatic Encephalopathy Grade
    - Hepatic Findings About Test Code/Name

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Controlled Terminology Package 19 Public Review

- General Terminology Team continued:
  - New Term Added to Existing Codelist
    - Anatomical Location
    - Directionality
    - SDTM Domain Abbreviation
    - Vital Signs Test Code/Test Name
    - Method
    - Subject Characteristic Code
    - Procedure
    - Nervous System Physiology Test Code/Test Name
    - Morphology Test Code/Test Name
    - Trial Summary Parameter

Controlled Terminology Package 19 Public Review

- Oncology Terminology Team
  - Codelist Name Change
    - Tumor Identification Results
    - Tumor and Lesion Identification Results

    - Oncology Tumor Properties Test Code
    - Tumor or Lesion Properties Test Code

    - Oncology Tumor Properties Test Name
    - Tumor or Lesion Properties Test Name

      – These codelists will also be used for Cardiovascular lesion identification and properties.

Controlled Terminology Package 19 Public Review

- Oncology Terminology Team continued
  - Term Removed
    - Tumor Response Result Codelist
      - NA (Not Applicable)
        » There is no NA in the RECIST Response Evaluation Criteria. (RECIST Guideline Version 1.1)

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Controlled Terminology Package 19 Public Review

- SEND Terminology Team
  - Codelist Removed
    - Vital Signs Test Code/Test Name
    - Units for Vital Signs Results
      - There are new codelists being added that will meet the needs of SEND.

Controlled Terminology Package 19 Public Review

- SEND Terminology Team continued
  - Submission Value Change
    - Strain/Substrain Codelist
      - ICO:OFA (SD)   OFA(SD)
      - CF-1   CF1
      - YUCATAN MICROPIG   MICRO YUCATAN MINIATURE SWINE
      - SINCLAIR MINIPIG   SINCLAIR MINIATURE SWINE
      - NIH MINIPIG   NIH SLA MINIATURE SWINE
      - YUCATAN MINIPIG   YUCATAN MINIATURE SWINE
      - CALIFORNIA   CALIFORNIAN
      - CEH/HEJ   C3H/HeJ
      - CD1 (ICR)   BR CD1(ICR)
      - HARTLEY ~~ALBINO~~ HAIRLESS
        - » These changes are being made to match up with other standards.

Controlled Terminology Package 19 Public Review

- SEND Terminology Team continued
  - Term Removed
    - Strain/Substrain Codelist
      - ACI:SEG
      - BROILER BREEDS
      - CHINESE SYRIAN GOLD
      - LAKEVIEW LVG
      - NEW ZEALAND BLACK
      - NEW ZEALAND HYBRID
      - NEW ZEALAND RED
      - NEW ZEALAND WHITE
      - CYNOMOLGUS MAURITIUS
      - COTTON
      - DOMESTIC SHORT HAIR
        - » This is to align with the new rules established for the Strain/Substrain Codelist

Controlled Terminology Package 19 Public Review

- SEND Terminology Team continued
  - New Codelist
    - SEND Vital Signs Test Code/Name
    - SEND Cardiovascular Test Code/Name
    - SEND Respiratory Test Code/Name
    - Non-Neoplastic Finding Type
    - Chronicity
    - Distribution

Controlled Terminology Package 19 Public Review

- SEND Terminology Team continued
  - New Term Added to Existing Codelist
    - Neoplasm Type
    - Specimen
    - Strain/Substrain
    - Species
    - SEND Trial Summary Parameter Test Code/Name
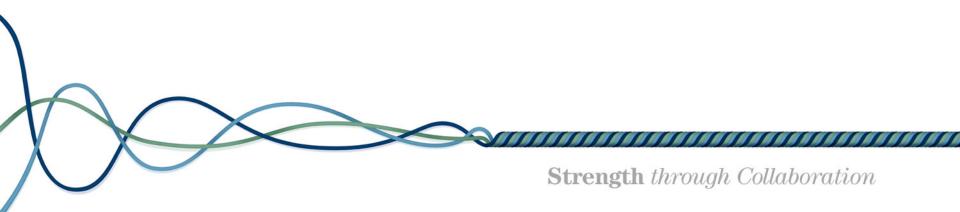
Questions?

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CDISC Education & Events Announcements

Saad Yousef, CDISC, Manager of Education and Membership Services

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ADaM IG v1.1 Review Period

- Released in early June for public review
- Deadline to submit comments 30 June
- Information on IG can be found at top of page of link below:

http://www.cdisc.org/adam

Upcoming Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
London (Reading, Berkshire), UK	1-4 July	SDTM, CDASH, ADaM	17 June	25 April; *expired*	QUINTILES
Durham, NC	22-25 July	SDTM, CDASH, ADaM	22 June	22 May; *expired*	Duke Clinical Research Institute DUKE UNIVERSITY MEDICAL CENTER
Seoul, South Korea	22-25 July	Global Approach, SDTM, CDASH	Info coming soon	None	EDUCATION
Seattle, WA	26-29 Aug	SDTM, CDASH, ADaM	25 July	3 March; expired	Ax10 PARTNERS IN RESEARCH
Brussels, Belgium	8-11 Sep	SDTM, CDASH, ADaM	8 Aug	3 March; *expired*	Business & Decision Life\Sciences

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Upcoming Interchange Events

- CDISC Asia-Pacific Interchange in Tokyo, Japan (28 Jul-1 Aug)
  - PMDA, FDA, and CDISC Board Members expected to speak at event. Registration to open soon!
  - **Education Courses Offered (28-30 July)**: SDTM, Define-XML, Controlled Terminology, CDASH, ADaM
  - **Main Conference**: 31 July-1 August

- CDISC International Interchange in Bethesda, MD (10-14 Nov)
  - Registration to open soon. Additional event details found here.

All interchange information can be found at www.cdisc.org/interchange

CDISC In-House Education

- Below courses readily available for 'in-house' training:
  - ADaM
  - BRIDG Deep Dive
  - CDASH
  - SDTM
  - SDTM for Medical Devices
  - SEND
  - *Others pending availability*

- For more information visit our website or submit request here.

Online Training

- SDTM online training course now available on CDISC Training Campus.

- CDASH and BRIDG Deep Dive coming soon.

- Account registration
  - Link: http://CDISC.trainingcampus.net

www.cdisc.org/online-courses

EDUCATION & EVENTS

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CDISC Interchanges

CDISC Days

Public Courses

CDISC Standards

Online Courses

Access CDISC online courses here!

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Launching of new CDISC Website

- Embedded videos
- Easier access to Member's Only Area
- Calendar with all Education events for easy review
- Better search tool
- And much more!

- New website to be rolled out very soon!

Next Public Webinar

- **<u>Agenda:</u>**
  - Protocol Concepts Guide
  - QT Studies
  - RDS

- **<u>Date</u>**: 24 July 2014, 11:00-12:30 PM EST
- **<u>Speakers:</u>**
  - Dave Gemzik, Medidata Solutions
  - John Owen, J&J
  - Sam Hume, CDISC

- Register here.

Webinar details also at www.cdisc.org/webinars

Next Member's Only Webinar

- **Topic**: SDTM: What Data Managers Need to Know
- **Date/Time**: 26 June 2014, 11:00-12:30 PM EST
- **Speaker**: Shannon Labout, CDISC

- 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.*