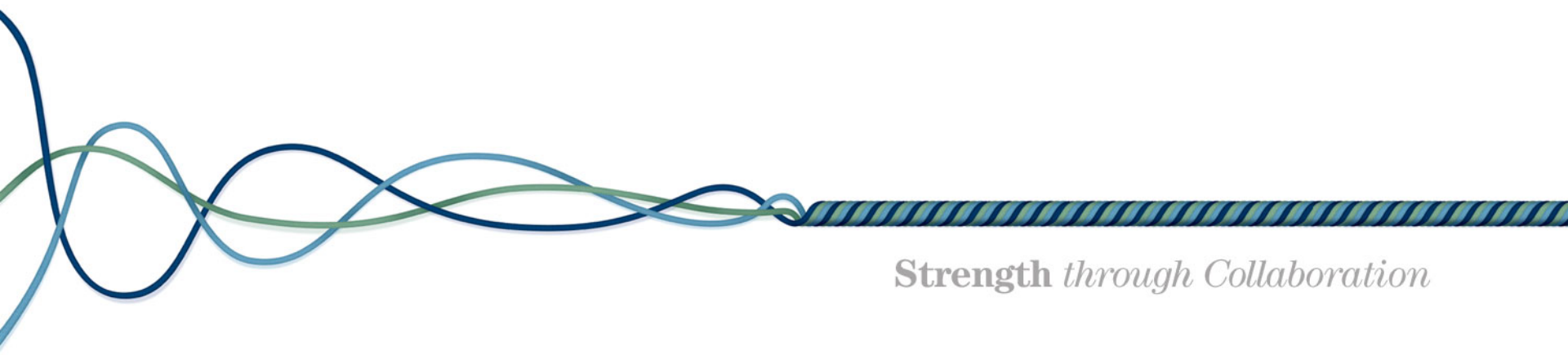
# CDISC Public Webinar – Standards Updates and Additions

24 April 2014



# Agenda

- ADaM General Occurrence Model
  - Sandra Minjoe, Accenture
- SDTMIG v3.3 Batch 1
  - Diane Wold, GSK
  - Bess LeRoy, Critical Path Institute
- Controlled Terminology, Batch 17
  - Bernice Yost, CDISC
- CDISC Education and Events Announcements*
  - Saad Yousef, CDISC

**Time permitting*

# Question & Answer

- ‘Presenter’: Question

OR

- ‘Presentation’: Question

Examples:

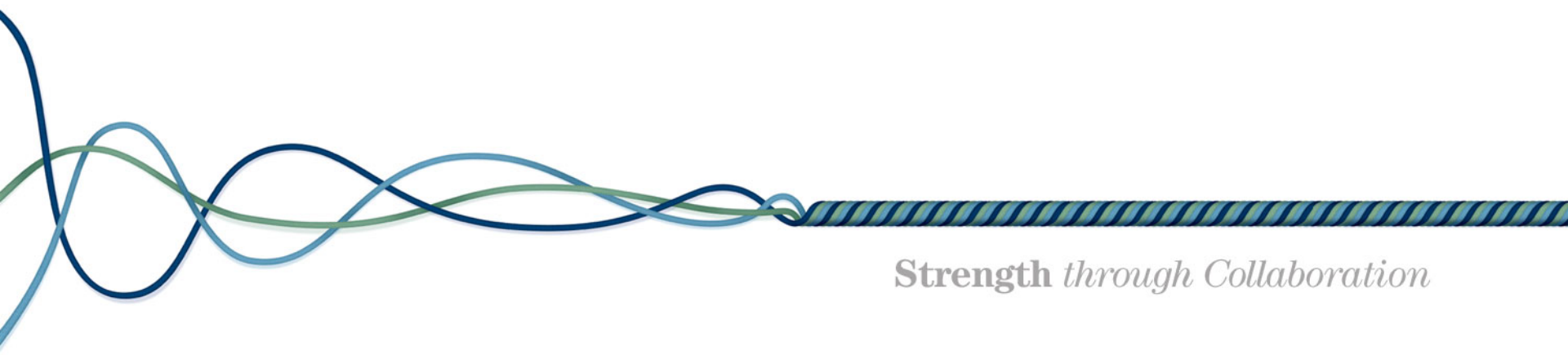
Sandra: What does ADaM stand for?

Or

SDTM:  What does SDTM stand for?

# ADaM Occurrence Data Structure: Summary of New Appendix

Presented by Sandra Minjoe



# Current ADaM Documents

- ADaM Model Document 2.1
- ADaMIG 1.0
- Appendices
  - Examples
  - ADAE
  - ADTTE
- Compliance checks
- Updated Pilot 1 data

# ADaM Documents In Progress

- Updated ADaMIG
- ODS document
- Analysis Results Metadata Specification for Define-XML v2
- Document to cover multivariate analyses
- Compliance checks to cover ADAE and ADTTE
- ISS/ISE Integration

# Agenda

- Rationale
- Features of the Model
- Use Cases
- Release Plan

# Rationale

- History
  - ADAE document only covered Adverse Events
  - Analysis need: count subjects by different levels of MedDRA hierarchy
  - ADAE is similar to the SDTM event structure AE
- How to apply ADAE structure for similar analysis needs?
  - Con Med and Medical History data and analysis needs are very similar to AEs
  - Other data?
- ODS was developed to expand ADAE

# Features of the Model

- Combination of input data and analysis needs determines the dataset structure required
  - Input data: usually events and interventions
  - Analysis need: subject count analysis, where a subject may be represented multiple times in a category
- Document gives examples of when to use ODS and when to use BDS
  - Data that can fit into BDS should not use ODS

# Features of the Model

- No need for AVAL or AVALC
  - Occurrences are counted in analysis
  - Typically one or more records for each occurrence
- Dictionary is often used for coding the occurrence
  - Typically a well-structured hierarchy of categories and terminology
  - Remapping of hierarchy to BDS would lose meaning
- Data content typically not modified for analysis needs
  - No need for analysis versions of the variables that hold the dictionary hierarchy or category terms

# Features of the Model

311 Typically, the following Analysis Dataset Metadata is specified as follows:

312 **Table 4.1.1 Example of ADaM ODS Dataset Metadata[1],**

| Dataset Name | Dataset Description | Dataset Location | Dataset Structure | Key Variables of Dataset | Class of Dataset | Documentation |
|---|---|---|---|---|---|---|
| ADXXXXXX | <Dataset label> | adxxxxxx.xpt | one record per record in SDTM domain (optional: per coding path, per Analysis Period and/or Phase) | *List variables, such as USUBJID, --SEQ* | ODS | *Example: Dictionary used is MedDRA V11.1* |

# Features of the Model

- Variables broken down within section by
  - Dictionary terms (e.g., MedDRA, WHO-DRUG)
  - Input SDTM domain (e.g., AE, CM, MH)

**Table 4.2.3.1 MedDRA Dictionary Coding Variables**

| Variable Name | Variable Label | Type | Code List / Controlled Terms | Core | CDISC Notes |
|---|---|---|---|---|---|
| --TERM | Reported Term* | Char | | Req | XX.--TERM |
| --DECOD | Dictionary-Derived Term | Char | MedDRA | Cond | XX.--DECOD<br>This is typically one of the primary variables use brought in from the SDTM domain. Equivalent MedDRA). As mentioned above, all other SDTM supplemental qualifiers needed for analysis or tr included. Include the dictionary version in the v<br>Conditional on whether coded and used for anal Event data. |
| --BODSYS | Body System or Organ Class | Char | MedDRA | Cond | XX.--BODSYS<br>This is typically one of the primary variables use brought in from the SDTM domain. As mention domain variables and supplemental qualifiers ne should also be included. Include the dictionary<br>Conditional on whether coded and used for anal Event data. |
| --BDSYCD | Body System or Organ Class Code | Num | MedDRA | Perm | XX.--BDSYCD<br>This would be copied from the SDTM domain o |

**Table 4.2.3.2 Concomitant Medications Dictionary Coding Variables**

| Variable Name | Variable Label | Type | Code List / Controlled Terms | Core | CDISC Notes |
|---|---|---|---|---|---|
| CMTRT | Reported Name of Drug, Med, or Therapy | Char | | Req | CM.CMTRT |
| CMDECOD | Standardized Medication Name | Char | WHO Drug | Cond | CM.CMDECOD<br>This is typically one of the primary variables use brought in from the SDTM CM domain. Include variable metadata.<br>Conditional on whether coded and used for analy |
| PREFCODE | Preferred Term Code | Char | WHO Drug | Perm | SUPPCM.QVAL where QNAM="PREFCODE"<br>This would be copied from the SDTM CM suppl Include the dictionary version in the variable me |
| CMCLAS | Medication Class | Char | WHO Drug | Perm | CM.CMCLAS<br>Include the dictionary version in the variable me |
| CMCLASCD | Medication Class Code | Char | WHO Drug | Perm | CM.CMCLASCD<br>Include the dictionary version in the variable me |
| DCLzC | ATC Level z Code | Char | WHO Drug | Cond | Corresponds to the ATC Level Code for WHO D<br>Conditional, based on analysis at multiple levels |
| DCLzT | ATC Level z Text | Char | WHO Drug | Cond | Corresponds to the ATC Level Text for WHO Dr<br>Conditional, based on analysis at multiple levels |

# Use Cases

- Adverse Events
- Concomitant Medications
- Medical History
- Other
  - Clinical Events
  - Lab Events

# Use Case: Adverse Events

- Developed ODS document by starting with ADAE appendix
  - All ADAE examples from that appendix document were copied
  - Made minor changes, such as to labels, to generalize
  - Dataset class changed from ADAE to ODS

- Don’t panic – ADAE remains essentially unchanged

# Use Case: Concomitant Medications

- WHO Drug coding is typically used for Concomitant Medications
  - Copy to the analysis dataset the WHO Drug terms and codes from SDTM CM that are needed for analysis
- Similar to ADAE, not all dictionary terms need to be included
  - SDTM CM/SUPPCM dataset will contain full suite of terms

# Use Case: Concomitant Medications

## 9. Example 5: Analysis of Concomitant Medications

This example displays a simple summary of all concomitant medications. The example is based on a two treatment parallel design study. The display summarizes (1) the number of patients in each treatment group who took a concomitant medication and (2) the rate of occurrence in each treatment group. In this example, analysis results metadata have not been included. As stated in the ADaMIG, analysis results metadata are not needed or even advisable for every analysis included in a clinical study report or submission.

### 9.1 Analysis Display Example Layout:

**Table 9.1.1 Example of Summary of Concomitant Medications[1]**

Table 14.1.5

Summary of Concomitant Medications by Medication Class and Preferred Term

Analysis Population: Safety

| Medication Class/Preferred Term | Treatment A (N=4) | Treatment B (N=5) | Total (N=9) |
|---|---|---|---|
| | | | |
| **Any Concomitant Medication** | 4 (100.0%) | 4 (80.0%) | 8 (88.9%) |
| | | | |
| **ANALGESICS** | 2 (50.0%) | 2 (40.0%) | 4 (44.4%) |
| PARACETAMOL | 2 (50.0%) | 2 (40.0%) | 4 (44.4%) |
| **ANTIBACTERIALS FOR SYSTEMIC USE** | 1 (25.0%) | 1 (20.0%) | 2 (22.2%) |
| AMOXICILLIN | 1 (25.0%) | 1 (20.0%) | 2 (22.2%) |

# Use Case: ADCM Dictionary Metadata

704 **9.2 Sample ADCM Variable Metadata:**

705 **Table 9.2.1 Example of ADCM Variable Metadata**

| Dataset Name | Variable Name | Variable Label | Variable Type | Display Format | Codelist / Controlled Terms | Source / Derivation |
|---|---|---|---|---|---|---|
| ADCM | STUDYID | Study Identifier | text | $3 | | CM.STUDYID |
| ADCM | USUBJID | Unique Subject Identifier | text | $11 | | CM.USUBJID |
| ADCM | CMSEQ | Sequence Number | integer | 3.0 | | CM.CMSEQ |
| ADCM | CMTRT | Reported Name of Drug, Med or Therapy | text | $200 | | CM.CMTRT |
| ADCM | CMMODIFY | Modified Reported Name | text | $200 | | CM.CMMODIFY |
| ADCM | CMDECOD | Standardized Medication Name | text | $200 | WHODRUG | CM.CMDECOD<br>WHO Drug Dictionary March 2012 |
| ADCM | PREFCODE | Preferred Term Code | text | $200 | WHODRUG | CM.PREFCODE<br>WHO Drug Dictionary March 2012 |
| ADCM | ATC1C | ATC Level 1 Code | text | $200 | WHODRUG | ATC Level 1 Code<br>WHO Drug Dictionary March 2012 |
| ADCM | ATC2C | ATC Level 2 Code | text | $200 | WHODRUG | ATC Level 2 Code<br>WHO Drug Dictionary March 2012 |
| ADCM | ATC3C | ATC Level 3 Code | text | $200 | WHODRUG | ATC Level 3 Code<br>WHO Drug Dictionary March 2012 |
| ADCM | ATC1T | ATC Level 1 Text | text | $200 | WHODRUG | ATC Level 1 Text<br>WHO Drug Dictionary March 2012 |
| ADCM | ATC2T | ATC Level 2 Text | text | $200 | WHODRUG | ATC Level 2 Text<br>WHO Drug Dictionary March 2012 |
| ADCM | ATC3T | ATC Level 3 Text | text | $200 | WHODRUG | ATC Level 3 Text |

# Use Case: ADCM Dictionary Data

728 **Table 9.3.1 Sample ADCM Data**

729

| Row | STUDYID | USUBJID | CMSEQ | CMTRT | CMMODIFY | CMDECOD | PREFCODE | ATC1C | ATC2C | ATC3C | ATC1T |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | ABC-001 | 1 | TYLENOL | TYLENOL | PARACETAMOL | N02BE | N | N02 | N02B | NERVOUS SYSTEM |
| 2 | ABC | ABC-001 | 2 | TYLENOL | TYLENOL | PARACETAMOL | N02BE | N | N02 | N02B | NERVOUS SYSTEM |
| 3 | ABC | ABC-001 | 3 | TYLENOL | TYLENOL | PARACETAMOL | N02BE | N | N02 | N02B | NERVOUS SYSTEM |
| 4 | ABC | ABC-001 | 4 | TYLENOL | TYLENOL | PARACETAMOL | N02BE | N | N02 | N02B | NERVOUS SYSTEM |
| 5 | ABC | ABC-001 | 5 | CONTACMS | CONTACMS | CONTACMS | N02BE | N | N02 | N02B | NERVOUS SYSTEM |
| 6 | ABC | ABC-001 | 6 | FLONASE | FLONASE | FLUTICASONE PROPIONATE | R01AD | R | R01 | R01A | RESPIRATORY SYS |
| 7 | ABC | ABC-002 | 1 | AMOXICILLIN | ROBITUSSIN | NOVAHISTINE DMX | R05FA | R | R05 | J01CA | RESPIRATORY SYS |

# Use Case: ADCM Indicator Flags

**Table 4.2.5.4 Concomitant Medications Indicator Variables**

| Variable Name | Variable Label | Type | Code List / Controlled Terms | Core | CDISC Notes |
|---|---|---|---|---|---|
| ONTRTFL | On-Treatment Flag | Char | Y | Cond | Character indicator of whether the observation occurred while the subject was on treatment.<br>Example derivation:<br>If ADSL.TRTSDT <= ASTDT <= ADSL.TRTEDT then ONTRTFL = 'Y'<br>This variable is conditional on whether the concept of on-treatment is a feature of the study and used in analysis. |

**Table 4.2.5.5 Adverse Events and Concomitant Medications Indicator Variables**

| Variable Name | Variable Label | Type | Code List / Controlled Terms | Core | CDISC Notes |
|---|---|---|---|---|---|
| PREFL | Pre-treatment Flag | Char | Y | Cond | Character indicator of whether the observation occurred before the subject started treatment.<br>Example derivation:<br>If ASTDT < ADSL.TRTSDT then PREFL='Y'<br>This variable is conditional on whether the concept of pre-treatment is a feature of the study and used in analysis. |
| FUPFL | Follow-up Flag | Char | Y | Cond | Character indicator of whether the observation occurred while the subject was on follow-up.<br>Example derivation:<br>If ASTDT > ADSL.TRTEDT then FUPFL='Y'<br>This variable is conditional on whether the concept of follow-up is a feature of the study and used in analysis. |

# Use Case: ADCM Occurrence Flags

| Row | ATC2T | ATC3T | ATC1FL | ATC2FL | ATC3FL | AOCCFL | AOCCPFL | CMINDC |
|---|---|---|---|---|---|---|---|---|
| 1 | ANALGESICS | OTHER ANALGESICS AND ANTIPYRETICS | Y | Y | Y | Y | Y | HEADACHE |
| 2 | ANALGESICS | OTHER ANALGESICS AND ANTIPYRETICS | | | | | | HEADACHE |
| 3 | ANALGESICS | OTHER ANALGESICS AND ANTIPYRETICS | | | | | | HEADACHE |
| 4 | ANALGESICS | OTHER ANALGESICS AND ANTIPYRETICS | | | | | | HEADACHE |
| 5 | ANALGESICS | OTHER ANALGESICS AND ANTIPYRETICS | | | | | Y | COLD |
| 6 | NASAL PREPARATIONS | DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOP | Y | Y | Y | | Y | CHOLESTEROL |

# Use Case: Concomitant Medications

- Most variables are from CM + SUPPCM + ADSL
  - Include any variables needed for analysis
- Additional derived variables
  - Indicator and Occurrence flags needed for analysis

- Other than the different dictionary used (WHO-Drug vs. MedDRA) the structure is very similar to ADAE

# Use Case: Medical History

- Two examples included
  - Terms mapped to MedDRA
    - Very similar to ADAE examples
  - Terms pre-specified and not coded for analysis

# Use Case: Uncoded Medical History

## 11. Example 7: Analysis of Medical History Pre-specified Events

In the example data shown below, the data is gathered on a case report form that contains a pre-specified category (in this case diabetes history), including a checkbox to indicate whether or not the subject had this condition. Diabetes history is not coded.

Analysis of the number of subjects with and without pre-specified events is an option for medical history. This option does not have a counterpart in adverse events analysis, because the AE domain does not allow for the collection of pre-specified events with MHOCCUR of N.

# Use Case: Uncoded Medical History

792 **11.1 Analysis Display Example Layout:**

793 The data are analyzed here by counting the number of unique subjects per treatment group,
794 MHCAT, MHTERM, and MHOCCUR. The values of MHOCCUR are formatted from Y and N
795 to more readable values (e.g., 'Y=Reported History') for presentation. In this case, we are basing
796 the denominator on only the subjects in the population of interest who have records in ADMH
797 with MHCAT='DIABETES HISTORY'. An alternative analysis would be to base the
798 denominator on the number of subjects in the population (typically defined by the number of
799 subjects with appropriate population flags in ADSL). The choice of denominator will be based
800 on statistical judgment and should be clearly described in the programming specifications. The
801 choice of denominator should also be clearly identified somewhere on the report (for instance, in
802 the title or footnotes).

803 **Table 11.1.1 Example of Summary of Medical History[1]**

Summary of Diabetes History Events
Safety Population: Subjects with Diabetes History Data

| Diabetes History Category | Active Drug (N=4) | Placebo (N=4) | Total (N=8) |
|---|---|---|---|
| **DIABETES HISTORY** | | | |
| DIABETES MELLITUS | | | |
| N=No Reported History | 3 (75.0%) | 4 (100.0%) | 7 (87.5%) |
| Y=Reported History | 1 (25.0%) | 0 | 1 (12.5%) |

804

# Use Case: Uncoded MH Data

824 **11.3.1 Sample Medical History Data for Pre-specified Events:**

| Row | USUBJID | MHSEQ | MHTERM | MHCAT | MHPRESP | MHOCCUR | MHSTDTC | MHENDTC | MHENRTPT | MHENTPT |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC-001 | 6 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 2 | ABC-002 | 1 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 3 | ABC-003 | 1 | DIABETES MELLITUS | DIABETES HISTORY | Y | Y | 2001-03 | | ONGOING | SCREENING |
| 4 | ABC-004 | 3 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 5 | ABC-005 | 4 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 6 | ABC-006 | 6 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 7 | ABC-007 | 5 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 8 | ABC-008 | 6 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |
| 9 | ABC-009 | 1 | DIABETES MELLITUS | DIABETES HISTORY | Y | N | | | | |

825

# Use Case: Medical History

- When summarized via dictionary terms
  - Similar to ADAE
  - Uses same flags
- When summarized without dictionary terms
  - MHCAT and MHOCCUR are used for analysis

# Use Cases: Summary

- Document contains
  - Examples of AE, CM, MH analysis needs and data structures
  - Description of how to apply for other analysis needs, including
    - Lab Events
    - Clinical Events

# ODS vs BDS

- Dataset structure choice is based on
  - Analysis needs
  - Need for parameters vs. dictionary component

# Release Plan

- Will be released for public comments within a few weeks
  - Potentially at the same time as the new ADaMIG
- Comment period will be 6 weeks
- Please watch for CDISC announcement and provide comments!

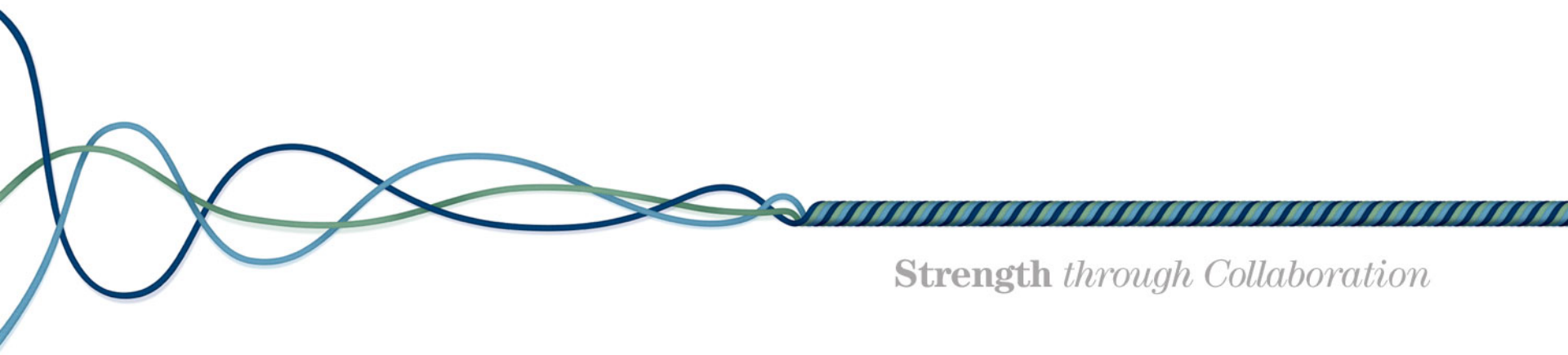
- Remember: this is a draft version

# ADaM Occurrence Sub-Team

- Jian Chen
- Jim Gaiser
- Jingyee Ko
- Linda Collins
- Mario Widel
- Monika Kawohl
- Nancy Brucken
- Paul Stutzman
- Paula Martin
- Sandra Minjoe
- Trevor Mankus

# SDTMIG 3.3
# Batch 1 for Public Review

Presented by Diane Wold and Bess LeRoy



# Overview

- Respiratory System Findings
- Cardiovascular System Findings
- Procedure Agents
- Functional Tests
- How to Submit Comments

# Respiratory System Findings (RE)

- A physiology findings domain, one of several domains used to represent tests/examinations that assess functioning of a particular body system
- Developed as part of the Asthma TA project
- Examples show pulmonary function tests
  - Controlled terminology for test names has been approved; additional test names may be requested
  - Additional examples may be added in future, if needed
- Introduces 3 new variables

# REORREF and RESTREFN

- These new variables were created to hold a *single reference value*, rather than a *reference range*
  - Pulmonary function test results are compared to a predicted normal value
  - Similar situations may arise for other kinds of tests
- Since this is a value with units, variables for original units and standard units were created
  - The units themselves are in REORRESU and RESTRESU, as for the normal range variables
  - A character reference variable (--STREFC) can be created if a use case arises

# REIRESFL – Inadequate Results Flag

- Created to allow flagging of results which may be problematic
  - Similar to SPCCND, which provides information on specimens whose condition may indicate that results of tests on the specimen are problematic
- Created as a flag, rather than a reason for concern, since in the asthma use case, there could be several reasons for concern
  - Chose to propose that reasons be represented in supplemental qualifiers (REIRREA1, REIRREA2, etc.)
  - Alternative would be a “reason inadequate” variable, which would use the MULTIPLE mechanism when necessary.

# Request for comments on --IRESFL

- Are there use cases for this variable in other domains, or other therapeutic areas?
- What are your thoughts on the choice between a this flag variable and a variable that would record a reason for concern?
- Should this idea be broadened beyond “inadequate results”?

# Cardiovascular System Findings

- This is a physiology findings domain
- Developed as part of the Therapeutic Area User Guide for Cardiovascular Disease (TAUG-CV)
- No new variables proposed
- CV Domain is part of the TAUG-CV package currently posted for public review
- Comments on the CV domain can be submitted to the TAUG-CV or to SDTMIG 3.3 Batch 1
  - Comments from both sources will be collated and addressed by the team

# Procedure Agents (AG)

- An interventions domain used to record substances administered as part of a procedure
  - Developed as part of the Asthma TA project, to handle agents given as part of challenge tests and reversibility assessments
  - Also used in the Diabetes TA project, to handle agents given in glucose and meal tolerance tests
  - Other anticipated use cases include contrast agents, radioactive tracers, and other substances used in imaging
- No new variables proposed as part of this domain

# AG vs. other Interventions Domains

- The choice of domain for representing interventions depends on the context in which a substance is used, not just on the nature of the substance
  - Example: an opioid could be a study treatment, a concomitant medication, or a drug of abuse recorded in the substance use domain, depending on the study and individual circumstances
- Proposed guidance on choosing the domain in which to represent a substance administration is expected in a later SDTMIG 3.3 Batch
  - Comments on what should be included in this guidance would be appreciated

# Functional Tests (FT)

- A findings domain used to represent tests/examinations that are task-based evaluations that provide an assessment of the subject's mobility, dexterity, or cognitive ability
  - They are not subjective assessments of how the subject generally performs a task. Rather they are an objective measurement of the performance of the task by the subject in a specific instance
  - Examples include the 25 Foot Walk Test and the 6 Minute Walk Test
- Developed as part of the Multiple Sclerosis TA project
- Introduces 1 new variable

# Repetition Number (--REPNUM)

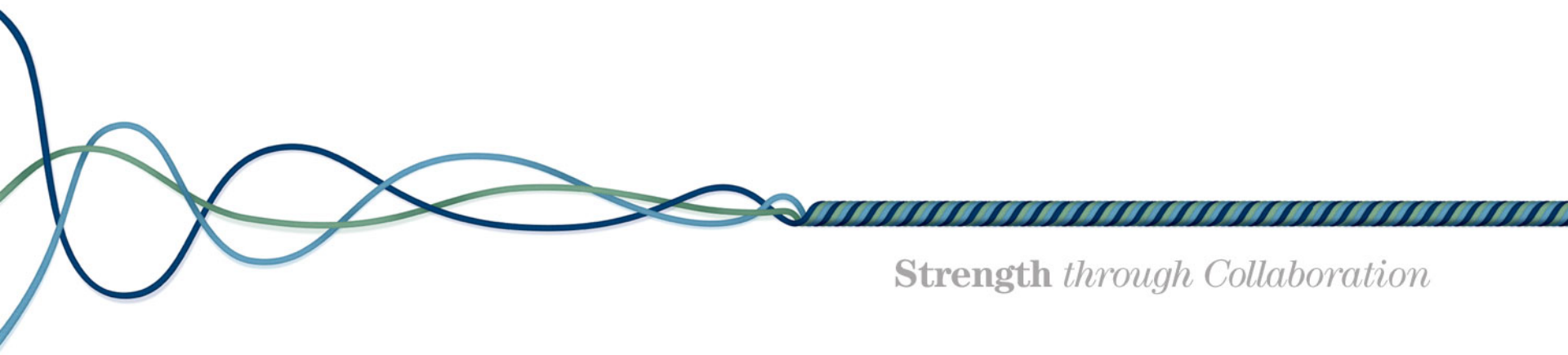
- Used to indicate the chronological order of repeated tests
- Enables the reuse of --TESTCD and --TEST values when tests are repeated
- When records are related to the first trial of the task the variable FTREPNUM should be set to 1, when records are related to the second trial of the task FTREPNUM should be set to 2, and so forth
- Follows the same controlled terminology and supplement development process as Questionnaires.

# Comments

- SDTMIG 3.3 Batch 1 will be submitted soon
- Comment period will be 30 days
- Comments should be submitted through the Public Comment Tracker on the CDISC portal

# Controlled Terminology, Batch 17

Presented by Bernice Yost, CDISC



# How do I Access Terminology?

- Go to the CDISC Web site
  - Click on “Standards and Innovations”
  - Click on “Foundational Standards”
  - Click on “Terminology”

- Then click on
  - “CDISC Controlled Terminology” hyperlink at the bottom of page.

# Terminology Resources: NCI Enterprise Vocabulary Services (EVS), Dictionaries, FedMed, FDA, CDISC, and NCPDP Terminology

**Terminology Resources**

- NCI Dictionaries
- Federal Medication Terminologies
- FDA Terminology
- **CDISC Terminology**
- NCPDP Terminology

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## CDISC Terminology

Clinical Data Interchange Standards Consortium (CDISC) is an international, non-profit organization that develops and supports global data standards for medical research. CDISC is working actively with EVS to develop and support controlled terminology for a wide spectrum of clinical and nonclinical studies. CDISC terminology goes through an extensive process of content development and public review before it is declared ready for release. CDISC controlled terminology is versioned by date. All previous versions of CDISC controlled terminology can be found by clicking on the directory links below and going into the Archive subdirectory.

CDISC's **Study Data Tabulation Model (SDTM)** is an international standard for clinical research data, and is approved by the FDA as a standard electronic submission format. NCI EVS maintains and distributes SDTM controlled terminology as part of NCI Thesaurus. More information is available at CDISC's SDTM Web page. SDTM terminology is available for direct download from the CDISC SDTM directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml, pdf, html and OWL/RDF formats.

CDISC **Questionnaire (QS) Terminology** contains standardized, controlled terminology for commonly used questionnaires in biomedical and therapeutic area research. NCI EVS maintains and distributes Questionnaire controlled terminology as part of NCI Thesaurus. More information is available at CDISC's Questionnaire Web page. Questionnaire terminology can be used for both collection (CDASH) and submission (SDTM) data sets, and is available for direct download from the CDISC Questionnaire directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml, pdf, html and OWL/RDF formats.

Source: NCI-EVS

Professionals

Cancer Trends Progress Report: 2011/2012 Update

CDISC also leads the **Clinical Data Acquisition Standards Harmonization (CDASH)** project, which develops clinical research study content standards in collaboration with sixteen partner organizations including NCI. NCI EVS maintains and distributes CDASH controlled terminology as part of NCI Thesaurus. More information is available at CDISC's CDASH Web page. CDASH terminology is a subset of SDTM terminology and is available for direct download from the CDISC CDASH directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml, pdf, html and OWL/RDF formats.

CDISC also leads the **Analysis Data Model (ADaM)** project, which supports efficient generation, replication, review and submission of analysis results from clinical trial data. NCI EVS maintains and distributes ADaM controlled terminology as part of NCI Thesaurus. ADaM terminology is available for direct download from the CDISC ADaM directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml, pdf, html and OWL/RDF formats.

CDISC also leads the **Standard for the Exchange of Nonclinical Data (SEND)** project, which guides the organization, structure and format of standard nonclinical tabulation data sets for interchange between organizations such as sponsors and CROs and for submission to a regulatory authority such as the FDA. NCI EVS maintains and distributes SEND controlled terminology as part of NCI Thesaurus. SEND terminology is available for direct download from the CDISC SEND directory on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml, pdf, html and OWL/RDF formats.

The CDISC New Term Request web page handles suggestions for both new terminology and changes to existing terminology. The CDISC Term Request Tracking Excel spreadsheet helps members of the CDISC community review and comment on all submitted requests.



Source: NCI-EVS

# Controlled Terminology Webpage – Publication Release

**Update 28 March 2014**

SDTM, SEND, Questionnaire, and CDASH Controlled Terminology files have been updated on NCI EVS. The dates of the new files are 2014- 03- 28. These terminology files replace all older SDTM, SEND, Questionnaire, and CDASH terminology files and include terms from Review Package 17. There are approximately 222 new questionnaire terms and 177 new terms across the three additional files.

CDSIC approved controlled terminology is maintained and distributed as part of NCI Thesaurus and is available for direct download from the CDISC website on an NCI File Transfer Protocol (FTP) site in Excel, text, odm.xml, pdf and html formats at the following web- link.

New requests or changes to existing terminology can be accessed through the New Term Request Page via the link to CDISC Controlled Terminology below. Scroll down to the last paragraph.

CDISC Controlled Terminology

Please post any comments, questions or suggestions to CDISC's Public Discussion Forum

# Controlled Terminology Webpage – Public Review

## Terminology Call for Public Review Package 19 - Comments Due by 18 July 2014

CDISC Controlled Terminology Package 19 is ready for public review. The public review package consists of 9 spreadsheets (Package_19_Public_Review.zip):

- Laboratory Tests
- Units of Measure
- Cardiovascular
- ECG
- PK
- General – These terms include codelists that do not fall into any of the other groups
- Devices
- Virology
- SEND

**Use this link to register/login to the Tracker so you can access the review documents.**

**CDISC will be using the Public Comment Tracker on the CDISC Portal for this review.**
Click here for directions on how to access and use the Public Comment Tracker Tool.

Detailed information on using the tracker can also be found via "Help" after clicking on Public Comment Tracker.

# Additional Files on the Controlled Terminology Webpage

Terminology

- Click here to view the Team Charter
- Click here to view the CDISC Controlled Terminology Publication Schedule
- Click here to view the CDISC Controlled Terminology Multiple Term Request Spreadsheet
- Click here to view the CDISC Controlled Terminology Requests Denied

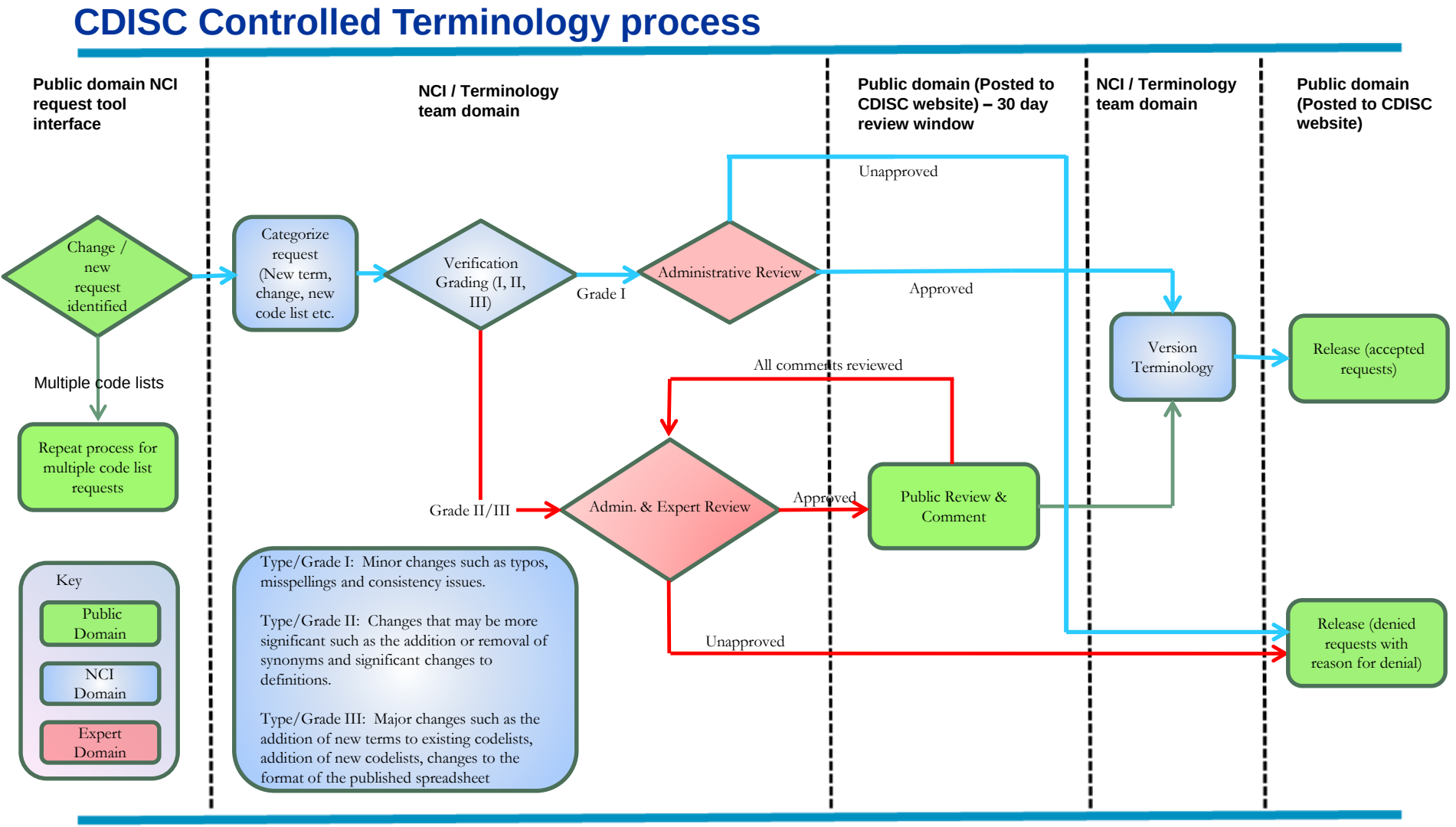
# Controlled Terminology Publication Schedule

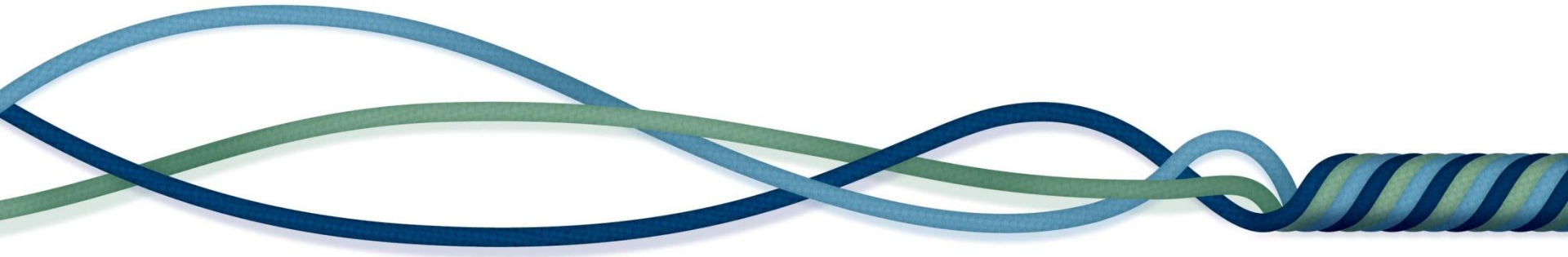
| Package Number | Team Cutoff (requests must be received at least two months before this date) | Public Review Start Date (1 wk from Team Cutoff) | Public Review Closed Date (4 wks) | Final Changes to NCI EVS (4 wks) | Publication Date (6 wks) | Codelists to be Included | | | |
|---|---|---|---|---|---|---|---|---|---|
| 15 | 6/21/2013 | 6/28/2013 | 7/26/2013 | 8/23/2013 | 10/4/2013 Delayed due to government shutdown | Device | ECG | General | Lab |
| 15 | | | | | | PK | QS | SEND | Unit |
| 15 | | | | | | Virology | | | |
| 16 | 9/13/2013 | 9/27/2013 | 10/25/2013 | 11/8/2013 | 12/20/2013 | Device | ECG | General | Lab |
| 16 | | | | | | Oncology | PK | QS | SEND |
| 16 | | | | | | Spectype Speccond | Unit | Virology | |
| 17 | 12/13/2013 | 12/20/2013 | 1/24/2014 | 2/14/2014 | 3/28/2014 | Device | ECG | General | Lab |
| 17 | | | | | | PK | QS | SEND | Spectype Speccond |
| 17 | | | | | | Unit | Virology | | |
| 18 | 3/14/2014 | 3/21/2014 | 4/18/2014 | 5/16/2014 | 6/27/2014 | CV | Device | ECG | General |
| 18 | | | | | | Lab | PK | SEND | Unit |
| 18 | | | | | | Virology | | | |
| 19 | 6/13/2014 | 6/20/2014 | 7/18/2014 | 8/15/2014 | 9/26/2014 | | | | |
| 19 | | | | | | | | | |
| 19 | | | | | | | | | |
| 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 | | | | |

# Controlled Terminology Requests Denied

| Codelist Name | Original Request | Original Requestor Notes | Request Type | Request Code | Requestor | Requestor Company | Final Decision Reason for Request Denied | Final Decision Date | Package Number |
|---|---|---|---|---|---|---|---|---|---|
| TPHASE | SDTM - TPHASE | Please add the option Phase 1b Trial to the list as we have had a number of trials denoted as 1b recently | Modify Existing Term | 32499 | John Swithenbank | Covance | Do not add.<br>We are very hesitant to introduce a term here that isn't supported by a regulatory source. DO NOT ADD (at this time). | 2013-07-26 | 16 |
| VSTEST-CD | TESTCD = CDIABP<br>TEST = Central Diastolic Blood Pressure | All above TESTCD fields are not present currently in VS domain. File emailed separately. | New Term Request | 32848 | Monika Paliwal | Bioclinica | Do not add.<br>This is DIA BP with a location. So based on that, we will not add. | 2013-08-23 | 16 |
| VSTEST-CD | TESTCD = CSYSBP<br>TEST = Central Systolic Blood Pressure | All above TESTCD fields are not present currently in VS domain. File emailed separately. | New Term Request | 32848 | Monika Paliwal | Bioclinica | Do not add.<br>This is SYS BP with a location. So based on that, we will not add. | 2013-08-23 | 16 |
| VSTEST-CD | TESTCD = CPP<br>TEST = Central Pulse Pressure | All above TESTCD fields are not present currently in VS domain. File emailed separately. | New Term Request | 32848 | Monika Paliwal | Bioclinica | Do not add.<br>This is Pulse Pressure with a location. So based on that, we will not add. | 2013-08-23 | 16 |
| LOC | Please add abdomen | We require an anatomical location for reported abdominal pain. Until diagnostics are performed, the cause of the pain could be located either in the "Abdominal Cavity" (for which abdomen is currently listed as a synonym) or the "Abdominal Wall" (which is not now noted as a synonym). We feel that the more broad term is necessary to accurately represent the reported symptom. | New Term Request | 32894 | Lorraine Spencer | Takeda Pharmaceuticals | Do not add.<br>Already a synonym to another term. | 2013-08-16 | 16 |

# Terminology Process Flow Diagram





# Strength *through collaboration.*

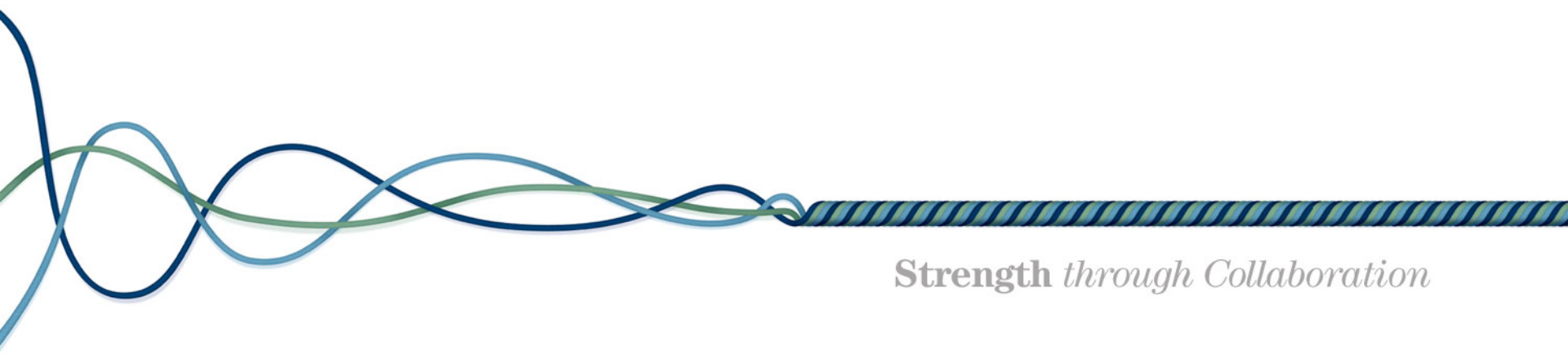
If you are interested in contributing to the CDISC Terminology Initiative, please contact us…

Bernice Yost, byost@cdisc.org

# Questions?

# CDISC Education & Events Announcements

Saad Yousef, CDISC, Manager of Education and Membership Services



# Upcoming Public Course Events

| Location | Dates | Courses Offered | Registration Deadline | Discounts? | Host |
|---|---|---|---|---|---|
| Cambridge, MA | 13-16 May | SDTM, CDASH, ADaM | Offline registration only | 11 Jan; *expired* | sanofi aventis |
| Tokyo, Japan | 19-21 May | SDTM, CDASH | 5 May | *None* | CDISC |
| South San Francisco, CA | 10-13 June | SDTM, CDASH, ADaM | 27 May | 12 April; *expired* | Genentech |
| London (Reading, Berkshire), UK | 1-4 July | SDTM, CDASH, ADaM | 17 June | 25 April | QUINTILES |
| Seattle, WA | 26-29 Aug | SDTM, CDASH, ADaM | 25 July | 3 March; expired | Axio |
| Brussels, Belgium | 8-11 Sep | SDTM, CDASH, ADaM | 8 Aug | 3 March; *expired* | Business & Decision Life Sciences |

# 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*

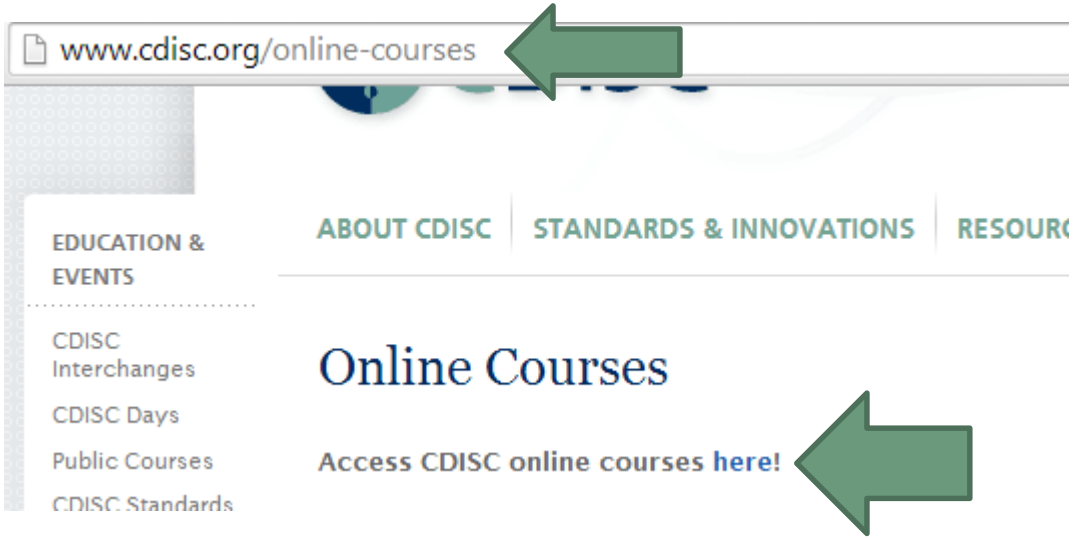
# CDISC In-House Education

- 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



# Next Public Webinar

- **Agenda:**
  - How to review and comment on CDISC Standards
  - TBA
- **Date**: 22 May 2014, 11:00-12:30 PM EST
- **Speakers:**
  - Kit Howard, CDISC
  - TBA

- Register here.

*Webinar details also at www.cdisc.org/webinars*

# Next Member's Only Webinar

- **Topic**: SDS-XML Submission Datasets
- **Date/Time**: 08 May 2014, 11:00-12:30 PM EST
- **Speaker**: Sally Cassells, Next Step Clinical Systems
  - *Others TBD*

- 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**