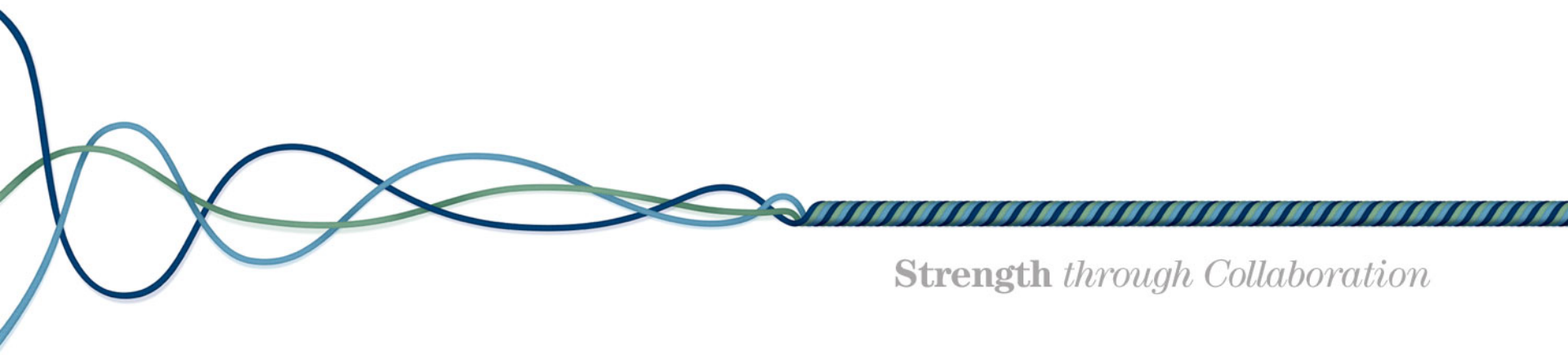
CDISC Public Webinar – Standards Updates and Additions

Nov 17 2015



Agenda

- Tuberculosis v2 TA Public Review
  - Bess LeRoy, C-Path
  - Laura Butte, C-Path
  - Jon Neville, C-Path
- COPD TA Public Review
  - Sherwood Barbee, Quintiles
- CDISC Online Education & Event Updates
  - John Ezzell, CDISC

Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

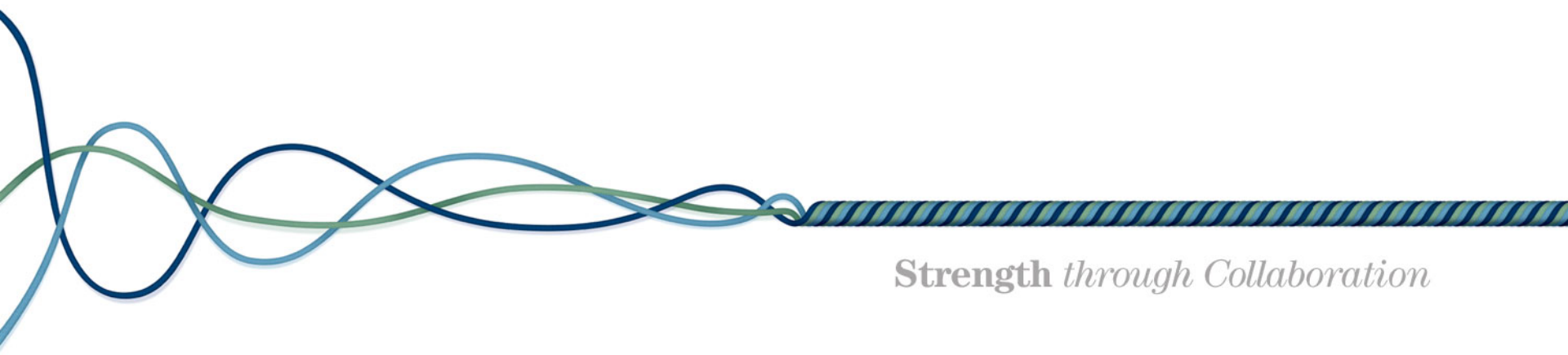
Bess: What is new for TB in V2?

OR

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

Tuberculosis Therapeutic-area User Guide (TAUG) v2.0, Public Review

Presented by Bess LeRoy
Critical Path Institute



Project Background

- Goal
  - Update Tuberculosis v1.0 to
    - Add pediatric content
    - Extend drug susceptibility testing content
    - Address modeling approaches that have changed
    - Add concept maps
    - Update to latest TAUG format

- Inputs
  - Tuberculosis v1.0
  - CPTR DSI-WG
  - DCRI Pediatric Data Elements
  - FDA reviewers
  - User feedback

Review Status Summary

- Internal Review
  - Concluded September 21st
  - Team received and responded to ~112 comments
- CDISC SRC Review
  - Received and addressed ~72 comments
  - Approval to post for public review on 10/27/2015
- Public Review
  - **Happening now!**
  - Anyone welcome to review and comment
  - Comment period closes **11/30/2015**

Concepts Covered in v2.0

- Pediatric Concepts
- **Environmental Risk Factors (new domain)**
- Bacteriologic Confirmation of TB and Specimen Handling
- **Phenotypic and Genotypic Drug Susceptibility Testing (new variables)**
- Source and Contact Case Investigation
- Skin and Blood Tests for Detection of TB Infection
- **Chest Radiograph (new variables)**
- Drug Regimens
- Signs and Symptoms

Changes from v1.0

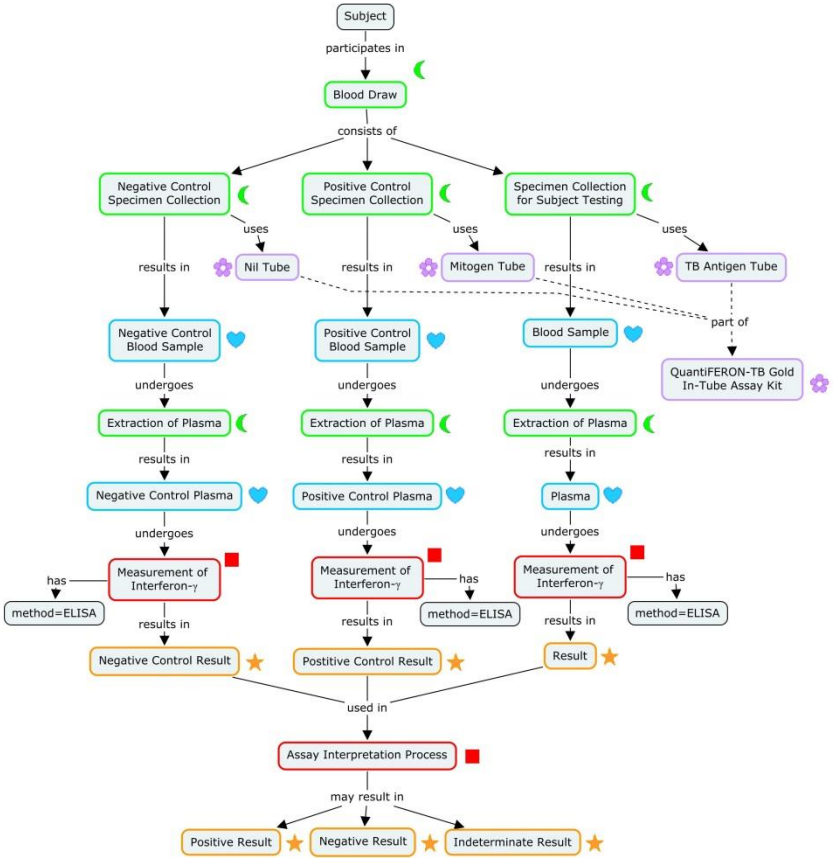
- Follows the CFAST process including improved document structure
- Alignment with the most current version of SDTM
- Incorporate new content
  - Duke pediatric data elements
  - Genotypic drug susceptibility testing
  - Specimen handling
- Make improvements based on user feedback
- Proposed Environmental Risk Factors (ER) domain to represent risk factors related to TB exposure
  - Moved from Subject Characteristics (SC)

Changes from v1.0

- Three proposed variables to be added to the Microbiology Susceptibility (MS) domain to represent pre-defined drug name, concentration, and units.
  - --DRUG (Drug Name)
  - --CONC (Concentration)
  - --CONCU (Concentration Units)
- New approach to represent pre-specified findings (imaging, microscopic findings, and microbiology) using two proposed variables.
  - --EXMTRG (Exam Target)
  - --USTRES (Unified Standardized Result)

Guide Layout- CFAST TAUG Style

CONTENTS



Guide Layout- CFAST TAUG Style

WIKI: It can be found here: Link

- Fully developed in the CDISC Wiki
- Internal review using the Wiki, and JIRA for comments
- First to use the Wiki and JIRA for public review.

It is organized in several formats.

You can:

•Read the entire document in one piece: TAUG-TB v2.0draft compiled

•Read by section: TAUG-TB v2.0draft by section

•Browse the examples: TAUG-TB Examples or

•Jump to a specific section: Link

Topic 1: Drug Resistance Testing

- Genotypic tests examine the organism for the presence of specific genetic mutations that are known to cause resistance to certain drugs. Represented in the PF domain.

- Phenotypic tests assess the ability of an organism to grow in the presence of a drug. The organism is exposed to varying concentrations of each drug. Represented in the MS

Phenotypic Drug Resistance Testing

Drug resistance testing

may assess

Whether or not the bacteria is susceptible or resistant when grown on a plate or in a tube with a pre-specificed amount of drug

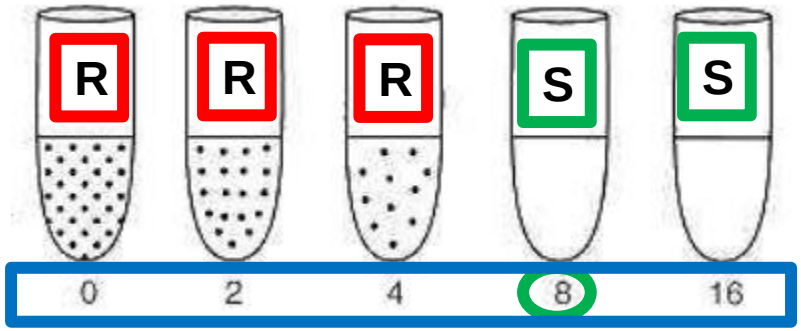
result is

susceptible or resistant (qualitative)

Drug concentration that inhibits growth of a virus or bacteria

result is

drug concentration with units (quantitative)



ug/ml antibiotic

Microbiology Susceptibility Examples in SDTMIG 3.2: Why They Don't Work

Row	USUBJID	MSSEQ	MSGRPID	MSREFID	MSTESTCD	MSTEST	MSCAT	MSORRES	MSORRESU
1	ABC-001-002	1	1	CENTABC	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.25	ug/dL
2	ABC-001-002	2	1	CENTABC	AMOXCLAV	Amoxicillin /Clavulanate	SUSCEPTIBILITY	1	ug/dL
3	ABC-001-002	3	2	LOCXYZ	DRUGA	Sponsor Drug	SUSCEPTIBILITY	0.5	ug/dL
4	ABC-001-002	4	2	LOCXYZ	AMOXCLAV	Amoxicillin /Clavulanate	SUSCEPTIBILITY	0.5	ug/dL

Row	MSRESCAT	MSMETHOD	VISITNUM
1 (cont)	SUSCEPTIBLE	E-TEST	1
2 (cont)	RESISTANT	E-TEST	1
3 (cont)	SUSCEPTIBLE	MACRO BROTH DILUTION	1
4 (cont)	RESISTANT	MACRO BROTH DILUTION	1

1. Sometimes the drug concentration is the result of the test and sometimes it is a pre-defined part of the test: the current model cannot support both structures.
2. Drug name is the test:
   a. Doesn't tell you what the test is (i.e. MIC)
   b. Controlled terminology team will not control drug names
3. No where to represent information on the pathogen that is being tested. Must link back to the identification record in MB.

Fixing MS: Attempt 1
TB v1.0 TAUG

Row	USUBJID	MSSEQ	MSLNKID	MSTESTCD	MSTEST	MSCAT	MSORRES	MSORRESU
1	ABC-01-101	1	LNK03	GROWTH	Growth	DST	NEGATIVE	
2	ABC-01-101	2	LNK03	DSTDRUG	Drug Susceptibility Test Name	DST	Isoniazid	
3	ABC-01-101	3	LNK03	DSTCONC	Drug Susceptibility Test Concentration	DST	0.1	mcg/mL

Row	MSMETHOD	VISITNUM
1 (cont)	MICROBIAL CULTURE, LIQUID	1
2 (cont)	MICROBIAL CULTURE, LIQUID	1
3 (cont)	MICROBIAL CULTURE, LIQUID	1

1. Susceptibility testing data spread across three rows to add clarity around test and results
2. Cumbersome for end-users

Fixing MS: Attempt 2
Virology v1.0

Row	USUBJID	VRSEQ	VRTESTCD	VRTEST	VRSPCIES	VRDRUG	VRORRES	VRORRESU
1	INF01-01	1	IC50S	IC50 Subject Result	INFLUENZA A	Investigamavir	0.20	nM
2	INF01-01	2	IC50R	IC50 Reference Control Result	INFLUENZA A	Investigamavir	0.21	nM
3	INF01-01	3	IC50FCR	IC50 Fold Change from Reference	INFLUENZA A	Investigamavir	0.95	

Row	VRMETHOD	VISITNUM
1 (cont)	NEURAMINIDASE INHIBITION ASSAY	1
2 (cont)	NEURAMINIDASE INHIBITION ASSAY	1
3 (cont)		1

But…

- Now we have a VR domain and an MS domain. Does it make sense to create a new resistance domain for each non-host organism ....fungi, parasites, worms etc.?
- The virology group did not create a corresponding virus identification domain analogous to MB. Can MB be used for all pathogen identification? **YES!**
- How do we harmonize efforts and make one set of domains work for all relevant data?

Proposal for one all-encompassing MS domain

Row	USUBJID	MSSEQ	MSTESTCD	MSTEST	NHOID	MSDRUG	MSCONC	MSCONCU	MSORRES	MSORRESU
1	ABC-01-101	1	DS	Drug Susceptibility	MYCOBACTERIUM TUBERCULOSIS	Isoniazid	0.015	ug/L	RESISTANT	
2	ABC-01-101	2	DS	Drug Susceptibility	MYCOBACTERIUM TUBERCULOSIS	Isoniazid	0.03	ug/L	RESISTANT	
3	ABC-01-101	3	DS	Drug Susceptibility	MYCOBACTERIUM TUBERCULOSIS	Isoniazid	0.06	ug/L	SUSCEPTIBLE	
4	ABC-01-101	4	MIC	Minimum Inhibitory Concentration	MYCOBACTERIUM TUBERCULOSIS	Isoniazid			0.06	ug/L

Row	MSSTRESC	MSSTRESN	MSSTRESU	MSMETHOD	VISITNUM
1 (cont)	RESISTANT			MICRO BROTH DILUTION	1
2 (cont)	RESISTANT			MICRO BROTH DILUTION	1
3 (cont)	SUSCEPTIBLE			MICRO BROTH DILUTION	1
4 (cont)	0.06	0.06	ug/mL	MICRO BROTH DILUTION	1

Add two new variables to accommodate test results when the drug concentration is a pre-specified part of the test.

Topic 2: Representing Pre-Specified Findings

- Unlike the Events and Interventions General Observation Class, the Findings General Observation Class does not allow the use of the --OCCUR variable.
- Historically, pre-specified findings have been represented in Findings About where:
  - FATESTCD=OCCUR; FATEST=Occurrence Indicator
  - FAOBJ is the pre-specified finding of interest
  - FAORRES is “Y”, ”N”; “Present”, “Absent”; etc.
- However, imaging findings are typically represented in the MO domain which does not have a Findings About structure and thus the --OBJ variable is not available.
- Past TAUGs have used very specific TESTCDs/TESTs which have been difficult to control and limit reusability.

Pre-Specified Imaging Examples in TB v1.0

mo.xpt

Row	STUDYID	DOMAIN	USUBJID	MOSEQ	MOREFID	MOTESTCD	MOTEST	MOORRES	MOORRESU
1	ABC	MO	ABC-01-101	1	1234	CAVIT	Cavitation	Y	
2	ABC	MO	ABC-01-101	2	1234	FIBCNT	Fibrotic Lesion Count	1	
3	ABC	MO	ABC-01-101	3	1234	FIBDIAM	Fibrotic Lesion, Longest Diam	14	mm
4	ABC	MO	ABC-01-101	4	1234	FIBCALC	Fibrotic Lesion Calcification	N	
5	ABC	MO	ABC-01-101	5	1234	INFILTRS	Infiltrates	N	
6	ABC	MO	ABC-01-101	6	1234	GRANULOM	Granulomas	Y	
7	ABC	MO	ABC-01-101	7	1234	VOLLOSS	Volume Loss	N	
8	ABC	MO	ABC-01-101	8	1234	VOLCOLPS	Volume Collapse	N	
9	ABC	MO	ABC-01-101	9	1234	EXTDISEAS	Extent of Disease	25	%
10	ABC	MO	ABC-01-101	10	1234	MILITTB	Miliary Tuberculosis	N	
11	ABC	MO	ABC-01-101	11	1234	APICLCAP	Apical Cap	N	
12	ABC	MO	ABC-01-101	12	1234	PLEUREFF	Pleural Effusion	N	
13	ABC	MO	ABC-01-101	13	1234	PLEURTHK	Pleural Thickening	N	
14	ABC	MO	ABC-01-101	14	1234	CPANGLOB	Costophrenic Angle Obliteration	N	
15	ABC	MO	ABC-01-101	15	1234	TRACHDEV	Tracheal Deviation	N	
16	ABC	MO	ABC-01-101	16	1234	ADENOPTH	Adenopathy	N	
17	ABC	MO	ABC-01-101	17	1234	ADENOPTH	Adenopathy	Y	
18	ABC	MO	ABC-01-101	18	1234	CALC	Calcification	N	
19	ABC	MO	ABC-01-101	19	2468	CARDIOMG	Cardiomegaly	Y	
20	ABC	MO	ABC-01-101	20	2468	PERCARDE	Pericardial Enlargement	N	
21	ABC	MO	ABC-01-101	21		INTP	Interpretation	Abnormal, consistent with Tuberculosis	

Pre-specified Findings Proposal

USUBJID	RETESTCD	RETEST	REXMTRG	REORRES	RESTRESC	REUSTRES
001	TRGREEXM	Target Respiratory Exam	Cavitation	PRESENT	PRESENT	Cavitation
001	TRGREEXM	Target Respiratory Exam	Infiltration	ABSENT	ABSENT	
002	REEXM	Respiratory Examination		Cavitation	Cavitation	Cavitation
002	REEXM	Respiratory Examination		Infiltration	Infiltration	Infiltration

- Add a variable called Exam Target (--EXMTRG) to hold the pre-specified finding of interest
- Add a variable called Unified Standardized Result (--USTRES) to hold the ***standardized*** unified result so both solicited and non-solicited findings can be easily used together

Alternate Modeling Options Explored

- Add --PRESP to Findings domains
  - Still requires very specific TESTCDs/TESTs which have been difficult to control and limit reusability.

- Use --TSTDTL to represent the pre-specified finding
  - Currently --TSTDTL is not well defined and has very few approved use cases. This option has been discussed among several SDS sub-team groups and there is concern that this is a misuse of this variable.

- Use --STRESC to represent the “Unified Result”
  - For solicited findings that are absent, --STRESC still must be populated (SDTMIG v3.2 Section 4.1.5.1.1) thus adding noise.
  - It is sub-optimal to standardize solicited results of "Y" to potentially thousands of different terms

Topic 3: Environmental Risk Factors

- The Environmental Risk Factors (ER) domain is an events domain for representing data collected to assess potential exposures to, or risk factors associated with, diseases through environmental contact or through participation in activities associated with risk.
- In the case of infectious diseases this includes known exposures to infected persons or animals as well as potential exposures via environmental circumstances or high-risk behaviors.
- For non-infectious diseases it may include other risk factors such as participation in contact sports, exposure to pesticides or other hazardous materials, etc.

Environmental Risk Factors (cont.)

- Risk factors not directly associated with exposure to environmental factors, such as genetic risk factors, age, sex, or weight, would not be represented in the ER domain.
- The contact event is represented in ERTERM, with appropriate timing variables used to represent the timeframe of the contact event. ERTERM should be a brief description of the contact event (e.g., DIRECT CONTACT WITH LIVE STOCK, PARTICIPATION IN CONTACT SPORTS, etc.).
- Additional details further characterizing the event in ERTERM should be represented in Findings About (FAER) (e.g., Livestock species handled, contact sports participated in, etc.)

Quick Summary

- TAUG-Tuberculosis v2.0 available for public review until **11/30/15**
- Three proposed variables to be added to the Microbiology Susceptibility (MS) domain to represent pre-defined drug name, concentration, and units.
- New approach to represent pre-specified findings (imaging, microscopic findings, and microbiology) using two proposed variables
- New ER domain for representing data collected to assess potential exposures to, or risk factors associated with, diseases through environmental contact or through participation in activities associated with risk
- Not all concepts represented in the guide were discussed in this presentation
- If you plan to review, please take note of **section 1.6**, **known issues** (some were discussed here today)
- We are on track to publish by Q1 of 2016

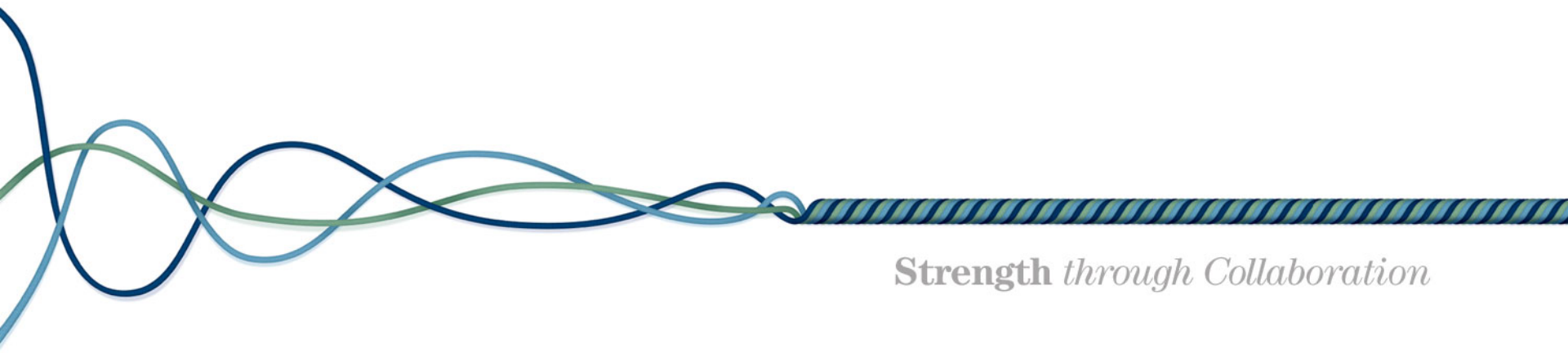
Comments may also be sent to Laura Butte, Project Manager, at LButte@c-path.org

Chronic Obstructive Pulmonary Disease

Public Review Education Webinar Presentation

November 17, 2015

Sherwood Barbee



AGENDA

- *Introduction to Chronic Obstructive Pulmonary Disease*
- *TAUG Review Stage and Public Review Timeline*
- *Controlled Terminology*
- *MH and RE Domains*
- *Analysis Data Model (ADaM)*
- *Biomedical Concept Data*

Introduction to Chronic Obstructive Pulmonary Disease

- Chronic Obstructive Pulmonary Disease (COPD) is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases.

- COPD is the fourth leading cause of death in the world.[1]

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease (Updated 2015). http://www.goldcopd.org/uploads/users/files/GOLD_Report_2015_Sept2.pdf (accessed October 2015).

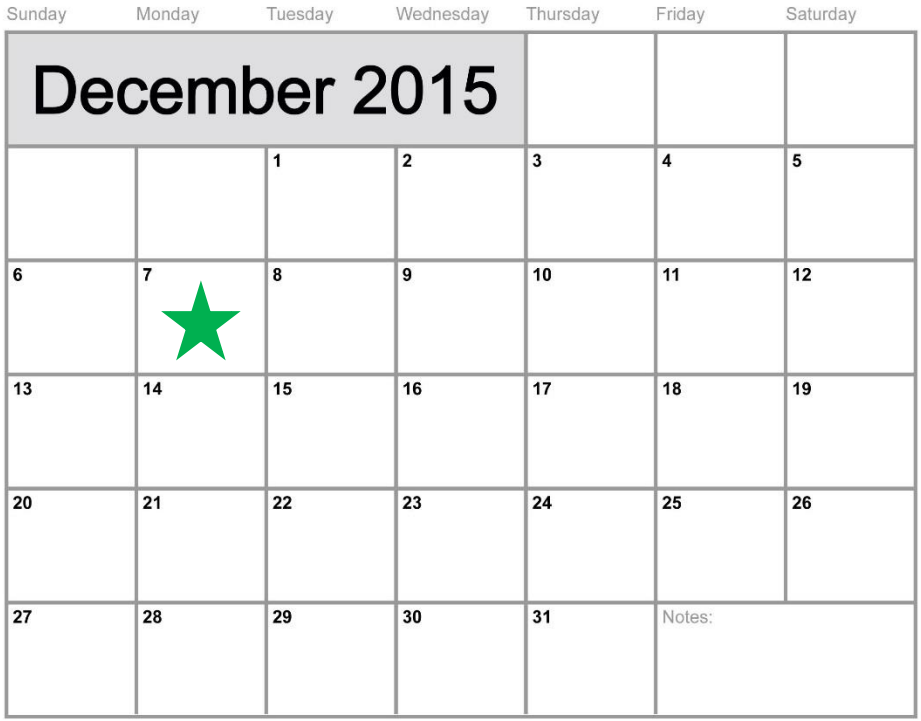
Chronic Obstructive Pulmonary Disease – TAUG Review Stage

Stage 0	Stage 1	Stage 2	Stage 3a	Stage 3b	Stage 3c	Stage 4
Scoping & Planning	Identification/ Modeling of Research Concepts	Development of Draft Standards	Internal Review	Public Review	Public Release	Maintenance & Education

- Final SRC review comments have been addressed
- Public Review Release date 04 November 2015
- Review comments closing date 07 December 2015

Public Review Time Period

- Public Review Period



Public Review

- Review Package Contents (will be made available on the CDSIC Portal)
  - Readme File
  - TAUG File in PDF format
  - CDASH Metadata Excel File
  - Biomedical Concept Labs
    - Template and Metadata for Labs
    - Template and Metadata for Questionnaires

- CDISC Public Comment Tracker
  - Portal Account Creation => http://portal.cdisc.org/CT/pages/membershiprequest.aspx?Source=/CT
  - Location => http://portal.cdisc.org/CT/default.aspx
  - Instructions => http://portal.cdisc.org/CT/Pages/CCTT-Help.aspx

- Recommend to check the Known Issues Section 1.6 prior to review of the TAUG

Controlled Terminology

- Summary of Controlled Terminology Developed during the COPD Project

Batch	Details	Status
1	•New test terminology for LB, RE •New codelists for COPD Findings About Test Name/Test Code (CPFATS/CPFATSCD) •New terminology for METHOD	Released with P22 and P23 publications on 6/26/2015 and 09/25/2015
2	•New test terminology for RE	Released with P22 publication on 6/26/2015; Will be published with P24 on 12/18/2015
3	•New test terminology for RE, COPD Findings About Test Name/Test Code •Modification to test terminology for RE	Will be published with P24 on 12/18/2015

MH Domains

MH is a standard domain with the addition of a new domain specific variable, MHEVTYP that is part of the soon to be published SDTM v.1.5.

mh.xpt

Row	STUDYID	DOMAIN	USUBJID	MHSEQ	MHTERM	MHEVTYP	MHCAT	MHPRESP	MHOCCUR	MHDTC	MHSTDTC
1	ABC-123	MH	101	1	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	SYMPTOMS	COPD HISTORY	Y	Y	2012-09-28	2010-04-01
2	ABC-123	MH	101	2	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	DIAGNOSIS	COPD HISTORY	Y	Y	2012-09-28	2011-10-31

RE Domains

RE is a provisional domain used in the Asthma TAUG
RE was released in SDTMIG 3.3 Batch 2

re.xpt

Row	STUDYID	DOMAIN	USUBJID	RESEQ	RETESTCD	RETEST	REORRES	REORRESU	REORREF	...	REMETHOD	REREPNUM
1	XYZ	RE	XYZ-087	1	FVC	Forced Vital Capacity	4.35	L	4.64	...	SPIROMETRY	1
2	XYZ	RE	XYZ-087	2	FVC	Forced Vital Capacity	4.45	L	4.64	...	SPIROMETRY	2
3	XYZ	RE	XYZ-087	3	FVC	Forced Vital Capacity	4.54	L	4.64	...	SPIROMETRY	3
4	XYZ	RE	XYZ-087	5	FVCPP	Percent Predicted Forced Vital Capacity	98	%		...	SPIROMETRY	
5	XYZ	RE	XYZ-087	6	FEV6	Forced Expiratory Volume in 6 Seconds	3.73	L		...	SPIROMETRY	1
6	XYZ	RE	XYZ-087	7	FEV6	Forced Expiratory Volume in 6 Seconds	3.88	L		...	SPIROMETRY	2
7	XYZ	RE	XYZ-087	8	FEV6	Forced Expiratory Volume in 6 Seconds	3.78	L		...	SPIROMETRY	3

Row	VISITNUM	VISIT	REDTC	BRESFL
1 (cont)	4	VISIT 4	2013-09-27	
2 (cont)	4	VISIT 4	2013-09-27	
3 (cont)	4	VISIT 4	2013-09-27	Y
4 (cont)	4	VISIT 4	2013-09-27	
5 (cont)	4	VISIT 4	2013-09-27	
6 (cont)	4	VISIT 4	2013-09-27	Y
7 (cont)	4	VISIT 4	2013-09-27	

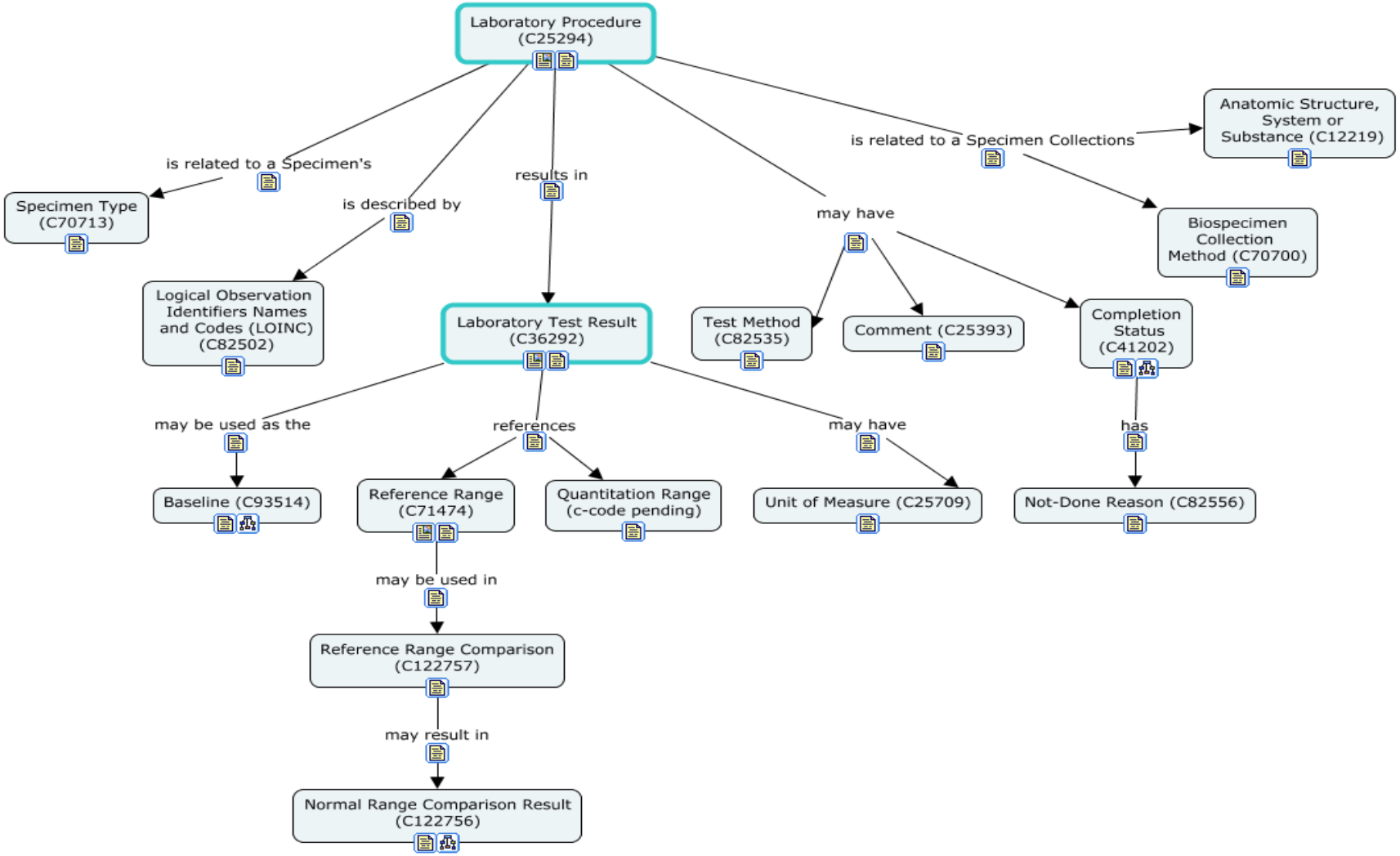
RE NSV Metadata

Variable	Label	Type	Length	Controlled Terms	Role	Origin
BRESFL	Best Results Flag	Char	1	Y	Non-Standard Record Qualifier	eDT

Analysis Data Model (ADaM)

- ADSL (important COPD baseline values)
  - CAT score at Baseline
  - FEV1 and FEV1/FVC at Baseline
  - Number of mild/moderate/severe exacerbations in 12 months prior to study
  - Last exacerbation date prior to dosing
- ADEXAC (OCCDS dataset to capture each exacerbation event assessment)
  - AETERM (records that were assessed for exacerbation)
  - Variable to indicate if the AE was an exacerbation of COPD
  - Variables to capture/calculate severity of exacerbation
    - Symptoms - (fever, cough, etc.)
    - Hospitalization/ER visit/Death tied to event
    - Severity of exacerbation
- ADXACSUM (BDS dataset capturing subject-level values based on ADEXAC)
  - Total exacerbations (AVAL=0 for subjects with no exacerbations)
  - Total severe exacerbations (AVAL=0 for subjects with no severe exacerbations)
  - Time to first exacerbation (no Kaplan-Meier analysis was done therefore no time-to-event dataset was created)

Labs Biomedical Concept



Lab Metadata Display

Biomedical Concept Name	Description	Category	Analyte	Lab Test Code (c-code)	Body Location	Method	Specimen Type (c-code	Result Typ	Unit Type	LOINC Code if availa	Notes / Questions / Issues
Concentration of Neutrophils in Bronchial Lavage Fluid	A measurement of the neutrophils concentration in a bronchial lavage fluid specimen.	Chem	Neutrophils	NEUT (C63321)	BRONCHUS (C12683)	Not applicable	LAVAGE FLUID (C103411)	Quantitative	Number Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Neutrophils in Sputum	A measurement of the neutrophils concentration in a sputum specimen.	Chem	Neutrophils	NEUT (C63321)	Not applicable	Not applicable	SPUTUM (C13278)	Quantitative	Number Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Neutrophils in Bronchial Tissue	A measurement of the neutrophils concentration in a bronchial tissue specimen.	Chem	Neutrophils	NEUT (C63321)	BRONCHUS (C12683)	Not applicable	TISSUE (C12801)	Quantitative	Number Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Neutrophils in Blood	A measurement of the neutrophils concentration in a blood specimen.	Chem	Neutrophils	NEUT (C63321)	Not applicable	Not applicable	BLOOD (C12434)	Quantitative	Number Concentration	26499-4	
Neutrophils/Leukocytes in Bronchial Lavage Fluid	A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a bronchial lavage fluid specimen.	Chem	Neutrophils per Leukocytes	NEUTLE (C64827)	BRONCHUS (C12683)	Not applicable	LAVAGE FLUID (C103411)	Quantitative	Number Fraction	Not available	Not in LOINC for this Specimen Type
Neutrophils/Leukocytes in Sputum	A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a sputum specimen.	Chem	Neutrophils per Leukocytes	NEUTLE (C64827)	Not applicable	Not applicable	SPUTUM (C13278)	Quantitative	Number Fraction	27932-3	
Neutrophils/Leukocytes in Bronchial Tissue	A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a bronchial tissue specimen.	Chem	Neutrophils per Leukocytes	NEUTLE (C64827)	BRONCHUS (C12683)	Not applicable	TISSUE (C12801)	Quantitative	Number Fraction	71598-7	
Neutrophils/Leukocytes in Blood	A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a blood specimen.	Chem	Neutrophils per Leukocytes	NEUTLE (C64827)	Not applicable	Not applicable	BLOOD (C12434)	Quantitative	Number Fraction	Not available	Not in LOINC without method of automatic count or manual lcount
Concentration of Interferon Gamma in Bronchial Lavage Flu	A measurement of the interferon gamma in a bronchial lavage fluid specimen.	Chem	Interferon-gamma (IFN-γ)	IFNG (C81996)	BRONCHUS (C12683)	Not applicable	LAVAGE FLUID (C103411)	Ordinal	Arbitrary Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Interferon Gamma in Sputum	A measurement of the interferon gamma in a sputum specimen.	Chem	Interferon-gamma (IFN-γ)	IFNG (C81996)	Not applicable	Not applicable	SPUTUM (C13278)	Ordinal	Arbitrary Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Interferon Gamma in Bronchial Tissue	A measurement of the interferon gamma in a bronchial tissue specimen.	Chem	Interferon-gamma (IFN-γ)	IFNG (C81996)	BRONCHUS (C12683)	Not applicable	TISSUE (C12801)	Ordinal	Arbitrary Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Interferon Gamma in Tissue	A measurement of the interferon gamma in a bronchial tissue specimen.	Chem	Interferon-gamma (IFN-γ)	IFNG (C81996)	Not applicable	Not applicable	BLOOD (C12434)	Ordinal	Arbitrary Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Interleukin -1β (IL-1β) in Plasma or Serum	A measurement of interleukin 1 beta in a plasma or serum specimen.	Chem	Interleukin -1β (IL-1β)	INTLK1B (C112323)	Not applicable	Not applicable	SERUM/PLASMA (C105706)	Quantitative	Mass Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Interleukin -1β (IL-1β) in Sputum	A measurement of interleukin 1 beta in a sputum specimen.	Chem	Interleukin -1β (IL-1β)	INTLK1B (C112323)	Not applicable	Not applicable	SPUTUM (C13278)	Quantitative	Mass Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of Interleukin -1β (IL-1β) in Tissue	A measurement of interleukin 1 beta in a tissue specimen.	Chem	Interleukin -1β (IL-1β)	INTLK1B (C112323)	Not applicable	Not applicable	TISSUE (C12801)	Quantitative	Mass Concentration	Not available	Not in LOINC for this Specimen Type
Mass Concentration of Fibrinogen in Plasma	A mass concentration measurement of the fibrinogen in a plasma specimen.	Chem	Fibrinogen (FBG)	FIBRINO (C64606)	Not applicable	Not applicable	PLASMA (C13356)	Quantitative	Mass Concentration	Not available	Not in LOINC Not clear which Unit Type is correct. LOINC has several. Included 2 here based on Diane Wold suggestion.
Arbitrary Concentration of Fibrinogen in Plasma	An arbitrary concentration measurement of the fibrinogen in a plasma specimen.	Chem	Fibrinogen (FBG)	FIBRINO (C64606)	Not applicable	Not applicable	PLASMA (C13356)	Ordinal	Arbitrary Concentration	Not available	Not clear which Unit Type is correct. LOINC has several. Included 2 here based on Diane Wold suggestion.
Concentration of Fibrinogen in Sputum	A measurement of the fibrinogen in a sputum specimen.	Chem	Fibrinogen (FBG)	FIBRINO (C64606)	Not applicable	Not applicable	PLASMA (C13356)	Unknown	Unknown	Not available	Not in LOINC for this Specimen Type
Concentration of C Reactive Protein in Serum or Plasma	Concentration of C Reactive Protein in Serum or Plasma	Chem	CRP	CRP (C64548)	Not applicable	Not applicable	SERUM/PLASMA (C105706)	Quantitative	Mass Concentration	11039-5	
Concentration of C Reactive Protein in Sputum	Concentration of C Reactive Protein in Sputum	Chem	CRP	CRP (C64548)	Not applicable	Not applicable	SPUTUM (C13278)	Quantitative	Mass Concentration	Not available	Not in LOINC for this Specimen Type
Concentration of C Reactive Protein in Serum or Plasma	Concentration of C Reactive Protein in Serum or Plasma	Chem	CRP	CRP (C64548)	Not applicable	HIGH SENSITIVITY (c-code pending)	SERUM/PLASMA (C105706)	Quantitative	Mass Concentration	30522-7	

Q&A Session

CDISC Education Events Announcements

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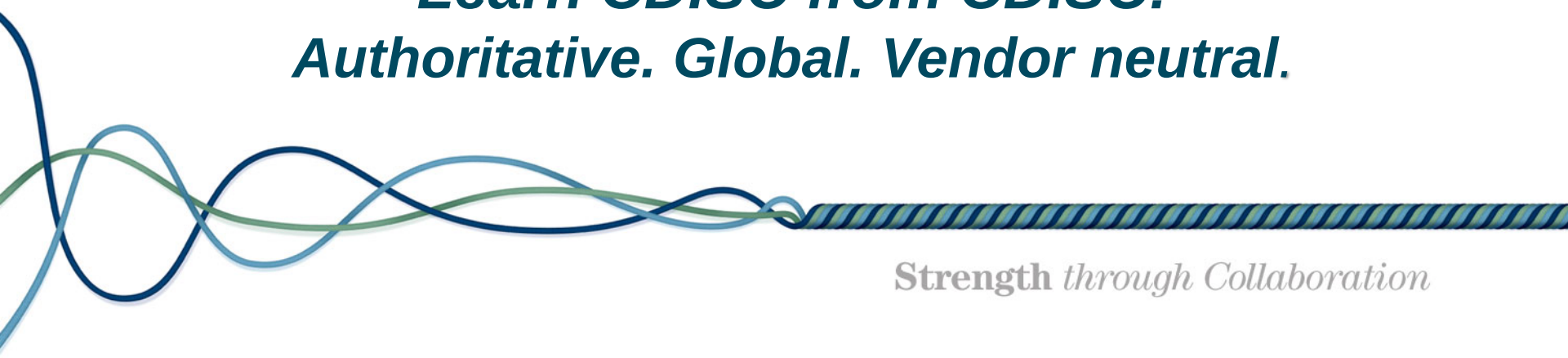


Standard currently out for review

- Tuberculosis v2 TA User Guide
  - Visit http://cdisc.org/therapeutic for more information
  - Comments due 30 November 2015
- COPD TA User Guide
  - Visit http://cdisc.org/therapeutic for more information
  - Comments due 7 December 2015
- Breast Cancer TA User Guide
  - Visit http://cdisc.org/therapeutic for more information
  - Comments due 9 December 2015
- CTR-XML Version 1.0
  - Visit http://cdisc.org/define-xml for more information
  - Comments due 18 December 2015

Click here to submit your comments.

Upcoming North America Public Courses and Events

Location	Dates	Courses Offered	Host
Morrisville, NC	9-12 Feb 2016	SDTM, CDASH, ADaM	SynteractHCR
Audubon, PA	2-11 Mar 2016	Courses corresponding to standards listed in Data Standards Catalog. See web.	BIOCLINICA
Emeryville, CA	11-15 April 2016	Courses corresponding to standards listed in Data Standards Catalog. See web.	Santen

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

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

Upcoming Europe Public Courses and Events

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

Registration deadline indicates online deadline. Onsite registration is available before each event begins. Additional 2015 public training events can be found @ http://cdisc.org/public-courses.

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

Upcoming Asia Public Courses and Events

Location	Dates	Courses Offered	Register by:	Early Registration Discounts	Host
Tokyo, Japan	14-18 Dec 2015	SDTM, CDASH, ADaM, ODM, Define-XML	13 Nov 2015	*13 Nov 2015*	CAC EXICARE Corporation

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

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

In-House Classroom Training

www.cdisc.org/private-courses

Benefits:

- Learn with your group using specific use cases and implementation questions
- On-location authorized instructor
- Cost-effective group training

Private (In-House) Courses

Learn CDISC from CDISC!

Private, in-house courses, delivered to your staff by an authorized instructor, are available to any organization, regardless of membership status. CDISC member organizations will receive discounted pricing.

To request information about private courses, please complete the form found at the button below.

CLICK HERE!
To request CDISC In-House Training

Someone from the Education team will contact you within a few days to discuss your training request.

If you have any questions regarding CDISC in-house training please e-mail us at **training@cdisc.org.**

EDUCATION

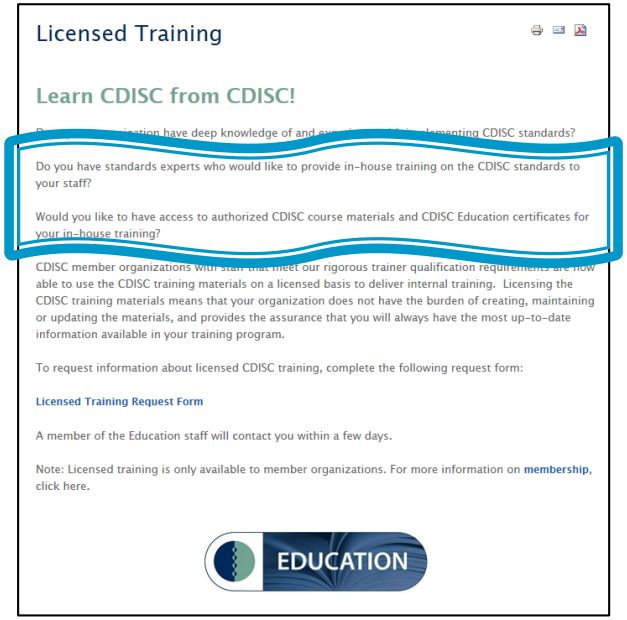
Licensed Training - *Exclusively for our Members*

http://www.cdisc.org/licensed-training-subpage

Benefits:

- Standard qualification and training process
- All materials developed by standards teams
- Your instructor delivers training
- Training when your staff needs it
- Official CDISC Education certificates

You get the best training, just when you need it, and save time and money!



Licensed Training

Learn CDISC from CDISC!

Do you have standards experts who would like to provide in-house training on the CDISC standards to your staff?

Would you like to have access to authorized CDISC course materials and CDISC Education certificates for your in-house training?

CDISC member organizations with staff that meet our rigorous trainer qualification requirements are now able to use the CDISC training materials on a licensed basis to deliver internal training. Licensing the CDISC training materials means that your organization does not have the burden of creating, maintaining or updating the materials, and provides the assurance that you will always have the most up-to-date information available in your training program.

To request information about licensed CDISC training, complete the following request form:

Licensed Training Request Form

A member of the Education staff will contact you within a few days.

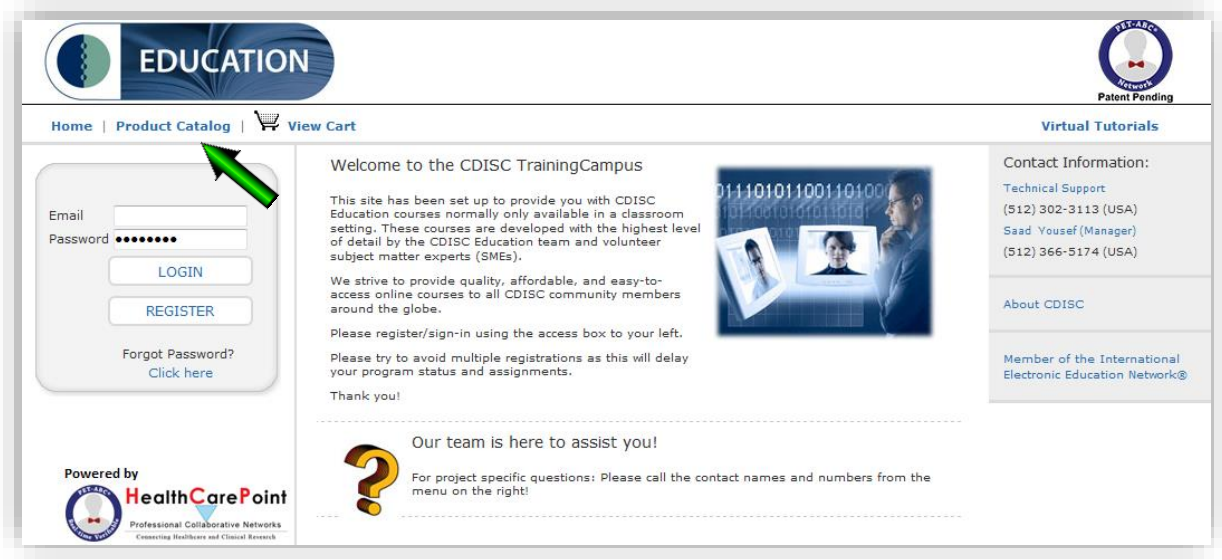
Note: Licensed training is only available to member organizations. For more information on membership, click here.

EDUCATION

CDISC Online Training

Cdisc.trainingcampus.net

- Online training created with support from CDISC standards development teams
- New CDISC trainings developed in tandem with standards development



Next Members Only Webinar

- **Agenda:**
  - Ophthalmology (OE) Domain
- **Date**: 19 Nov 2015, 10:00-11:30 AM CST
- **Speakers:**
  - Kim Truett, KCT Data
- 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

CDISC Members Drive Global Standards

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