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)
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Subject participates in Blood Draw

Blood Draw consists of

- Negative Control Specimen Collection
- Positive Control Specimen Collection
- Specimen Collection for Subject Testing

Results in

- Nil Tube
- Mitogen Tube
- TB Antigen Tube

Extraction of Plasma

- Negative Control Plasma
- Positive Control Plasma

Measurement of Interferon-\gamma

- Negative Control Result
- Positive Control Result

Assay Interpretation Process

May result in

- Positive Result
- Negative Result
- Indeterminate Result
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-specified 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).

Example:

<table>
<thead>
<tr>
<th>ug/ml antibiotic</th>
<th>MIC 0.25 µg/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
</tr>
</tbody>
</table>
Microbiology Susceptibility Examples in SDTMIG 3.2: Why They Don’t Work

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

1. Susceptibility testing data spread across three rows to add clarity around test and results
2. Cumbersome for end-users
1. Virology team felt that viral resistance data could not be adequately supported by the MS domain so the Viral Resistance (VR) domain was created.

2. Created:
   a. Descriptive test codes without the drug name
   b. New variables for: species and drug name

3. Now have a structure works great for MIC, IC50 etc.!

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?

<table>
<thead>
<tr>
<th>Row</th>
<th>USUBJID</th>
<th>VRSEQ</th>
<th>VRTESTCD</th>
<th>VRTEST</th>
<th>VRSPCIES</th>
<th>VRDRUG</th>
<th>VRORRES</th>
<th>VRORRESU</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>INFO01-01</td>
<td>1</td>
<td>IC50S</td>
<td>IC50 Subject Result</td>
<td>INFLUENZA A</td>
<td>Investigamavir</td>
<td>0.20</td>
<td>nM</td>
</tr>
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<td>IC50 Reference Control Result</td>
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<td>3</td>
<td>IC50FCR</td>
<td>IC50 Fold Change from Reference</td>
<td>INFLUENZA A</td>
<td>Investigamavir</td>
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<table>
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<td>1 (cont)</td>
<td>NEURAMINIDASE INHIBITION ASSAY</td>
<td>1</td>
</tr>
<tr>
<td>2 (cont)</td>
<td>NEURAMINIDASE INHIBITION ASSAY</td>
<td>1</td>
</tr>
<tr>
<td>3 (cont)</td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>
Proposal for one all-encompassing MS domain

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:
  - \texttt{FATESTCD=OCCUR}; \texttt{FATEST=Occurrence Indicator}
  - \texttt{FAOBJ} is the pre-specified finding of interest
  - \texttt{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 TAUUGs have used very specific TESTCDs/TESTs which have been difficult to control and limit reusability.
## Pre-Specified Imaging Examples in TB v1.0

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<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MOSEQ</th>
<th>MOREFID</th>
<th>MOTESTCD</th>
<th>MOTEST</th>
<th>MOORRES</th>
<th>MOORRESU</th>
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<tr>
<td>1</td>
<td>ABC</td>
<td>MO</td>
<td>ABC-01-101</td>
<td>1</td>
<td>1234</td>
<td>CAVIT</td>
<td>Cavitation</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>ABC</td>
<td>MO</td>
<td>ABC-01-101</td>
<td>2</td>
<td>1234</td>
<td>FIBCNT</td>
<td>Fibrotic Lesion Count</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>ABC</td>
<td>MO</td>
<td>ABC-01-101</td>
<td>3</td>
<td>1234</td>
<td>FIBDIAM</td>
<td>Fibrotic Lesion, Longest Diam</td>
<td>14</td>
<td>mm</td>
</tr>
<tr>
<td>4</td>
<td>ABC</td>
<td>MO</td>
<td>ABC-01-101</td>
<td>4</td>
<td>1234</td>
<td>FIBCALC</td>
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<td>N</td>
<td></td>
</tr>
<tr>
<td>5</td>
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<td>MO</td>
<td>ABC-01-101</td>
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<td>1234</td>
<td>INFILTRS</td>
<td>Infiltrates</td>
<td>N</td>
<td></td>
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<td>MO</td>
<td>ABC-01-101</td>
<td>6</td>
<td>1234</td>
<td>GRANULOM</td>
<td>Granulomas</td>
<td>Y</td>
<td></td>
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<td>1234</td>
<td>VOLLOSS</td>
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<td>N</td>
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<td>8</td>
<td>1234</td>
<td>VOLCOLPS</td>
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<td>Extent of Disease</td>
<td>25</td>
<td>%</td>
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<td>MO</td>
<td>ABC-01-101</td>
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<td>1234</td>
<td>PLEURTHK</td>
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<td>Costophrenic Angle Obliteration</td>
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<td>MO</td>
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<td>1234</td>
<td>TRACHDEV</td>
<td>Tracheal Deviation</td>
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<td>MO</td>
<td>ABC-01-101</td>
<td>16</td>
<td>1234</td>
<td>ADENOPH</td>
<td>Adenopathy</td>
<td>N</td>
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<td>MO</td>
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<td>Adenopathy</td>
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<td>20</td>
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<td>MO</td>
<td>ABC-01-101</td>
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<td>PERCARDE</td>
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<tr>
<td>21</td>
<td>ABC</td>
<td>MO</td>
<td>ABC-01-101</td>
<td>21</td>
<td></td>
<td>INTP</td>
<td>Interpretation</td>
<td>Abnormal, consistent with Tuberculosis</td>
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Pre-specified Findings Proposal

<table>
<thead>
<tr>
<th>USUBJID</th>
<th>RETESTCD</th>
<th>RETEST</th>
<th>REXMTRG</th>
<th>REORRES</th>
<th>RESTRESC</th>
<th>REUSTRES</th>
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<tbody>
<tr>
<td>001</td>
<td>TRGREEXM</td>
<td>Target Respiratory</td>
<td>Cavitation</td>
<td>PRESENT</td>
<td>PRESENT</td>
<td>Cavitation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exam</td>
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<td></td>
</tr>
<tr>
<td>001</td>
<td>TRGREEXM</td>
<td>Target Respiratory</td>
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<td>ABSENT</td>
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</tr>
<tr>
<td>002</td>
<td>REEXM</td>
<td>Respiratory</td>
<td>Cavitation</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Examination</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>002</td>
<td>REEXM</td>
<td>Respiratory</td>
<td>Infiltration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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/TESTTs which have been difficult to control and limit reusability.

• Use --TSTDTL to represent the pre-specified finding
  • Currently --TSTDTL is poorly 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 --STRESP to represent the “Unified Result”
  • For solicited findings that are absent, --STRESP still must be populated (SDTM-IG 3.2 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
thank you!
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
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

• Final SRC review comments have been addressed

• Public Review Release date 04 November 2015

• Review comments closing date 07 December 2015
• Public Review Period

[Calendar for November and December 2015 with marked dates]
• 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
  • Location => [http://portal.cdisc.org/CT/default.aspx](http://portal.cdisc.org/CT/default.aspx)
  • Instructions => [http://portal.cdisc.org/CT/Pages/CCTT-Help.aspx](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**

<table>
<thead>
<tr>
<th>Batch</th>
<th>Details</th>
<th>Status</th>
</tr>
</thead>
</table>
| 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.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MHSEQ</th>
<th>MHTERM</th>
<th>MHEVTYP</th>
<th>MHCAT</th>
<th>MHPRESP</th>
<th>MHOCCUR</th>
<th>MHDT</th>
<th>MHSTDTC</th>
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<td>101</td>
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<td>SYMPTOMS</td>
<td>COPD HISTORY</td>
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<td>2012-09-28</td>
<td>2010-04-01</td>
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<td>COPD HISTORY</td>
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<td>Y</td>
<td>2012-09-28</td>
<td>2011-10-31</td>
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</table>
RE is a provisional domain used in the Asthma TAUG
RE was released in SDTMIG 3.3 Batch 2

<table>
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<tr>
<th>RE</th>
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<th>L</th>
<th>4.64</th>
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<td>3.73</td>
<td>L</td>
<td>3.38</td>
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RE NSV Metadata

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<tr>
<th>Variable</th>
<th>Label</th>
<th>Type</th>
<th>Length</th>
<th>Controlled Terms</th>
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<tr>
<td>BRESFL</td>
<td>Best Results Flag</td>
<td>Char</td>
<td>1</td>
<td>Y</td>
<td>Non-Standard Record Qualifier</td>
<td>eDT</td>
</tr>
</tbody>
</table>
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)
### Lab Metadata Display

<table>
<thead>
<tr>
<th>Biomedical Concept Name</th>
<th>Description</th>
<th>Category</th>
<th>Analyte</th>
<th>Lab Test Code (c-code)</th>
<th>Body Location</th>
<th>Method</th>
<th>Specimen Type (c-code)</th>
<th>Result Type</th>
<th>Unit Type</th>
<th>LONC Code if available</th>
<th>Notes / Questions / Issues</th>
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<tbody>
<tr>
<td>Concentration of Neutrophils in Bronchial Lavage Fluid</td>
<td>A measurement of the neutrophils concentration in a bronchial lavage fluid specimen.</td>
<td>Chem</td>
<td>Neutrophils</td>
<td>NEUT (C03231)</td>
<td>LAVAGE FLUID (C102411)</td>
<td>Quantitative</td>
<td>Number Concentration</td>
<td>Not available</td>
<td>Not in LONC for this Specimen Type</td>
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<td></td>
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<tr>
<td>Concentration of Neutrophils in Sputum</td>
<td>A measurement of the neutrophils concentration in a sputum specimen.</td>
<td>Chem</td>
<td>Neutrophils</td>
<td>NEUT (C03231)</td>
<td>SP/TUM (C13278)</td>
<td>Quantitative</td>
<td>Number Concentration</td>
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<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Concentration of Neutrophils in Bronchial Tissue</td>
<td>A measurement of the neutrophils concentration in a bronchial tissue specimen.</td>
<td>Chem</td>
<td>Neutrophils</td>
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<td>TISSUE (C12801)</td>
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<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Concentration of Neutrophils in Blood</td>
<td>A measurement of the neutrophils concentration in a blood specimen.</td>
<td>Chem</td>
<td>Neutrophils</td>
<td>NEUT (C03231)</td>
<td>BLOOD (C12434)</td>
<td>Quantitative</td>
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<td>Not in LONC for this Specimen Type</td>
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<td></td>
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<tr>
<td>Neutrophils/Leukocytes in Bronchial Lavage Fluid</td>
<td>A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a bronchial lavage fluid specimen.</td>
<td>Chem</td>
<td>Neutrophils per Leukocytes</td>
<td>NEUT/LEU (C06427)</td>
<td>LAVAGE FLUID (C102411)</td>
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<td>Number Fraction</td>
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<td>Not in LONC for this Specimen Type</td>
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</tr>
<tr>
<td>Neutrophils/Leukocytes in Sputum</td>
<td>A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a sputum specimen.</td>
<td>Chem</td>
<td>Neutrophils per Leukocytes</td>
<td>NEUT/LEU (C06427)</td>
<td>SP/TUM (C13278)</td>
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<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Neutrophils/Leukocytes in Bronchial Tissue</td>
<td>A relative measurement (ratio or percentage) of the neutrophils to leukocytes in a bronchial tissue specimen.</td>
<td>Chem</td>
<td>Neutrophils per Leukocytes</td>
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<td>TISSUE (C12801)</td>
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<td>Number Fraction</td>
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<td>Chem</td>
<td>Neutrophils per Leukocytes</td>
<td>NEUT/LEU (C06427)</td>
<td>BLOOD (C12434)</td>
<td>Quantitative</td>
<td>Number Fraction</td>
<td>Not available</td>
<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Concentration of Interferon Gamma in Bronchial Lavage Fluid</td>
<td>A measurement of the interferon gamma in a bronchial lavage fluid specimen.</td>
<td>Chem</td>
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<td>Concentration of Interferon Gamma in Sputum</td>
<td>A measurement of the interferon gamma in a sputum specimen.</td>
<td>Chem</td>
<td>Interferon Gamma (Filir)</td>
<td>FNG (C01999)</td>
<td>SP/TUM (C13278)</td>
<td>Ordinal</td>
<td>Arterial Concentration</td>
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<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Concentration of Interferon Gamma in Bronchial Tissue</td>
<td>A measurement of the interferon gamma in a bronchial tissue specimen.</td>
<td>Chem</td>
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<td>FNG (C01999)</td>
<td>TISSUE (C12801)</td>
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<td>Not in LONC for this Specimen Type</td>
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<td>Concentration of Interferon Gamma in Blood</td>
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<td>Chem</td>
<td>Interferon Gamma (Filir)</td>
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<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Concentration of Interleukin 1 beta (IL-1b) in Plasma or Serum</td>
<td>A measurement of interleukin 1 beta in a plasma or serum specimen.</td>
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<td>Concentration of Interleukin 1 beta (IL-1b) in Sputum</td>
<td>A measurement of interleukin 1 beta in a sputum specimen.</td>
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<tr>
<td>Concentration of Interleukin 1 beta (IL-1b) in Tissue</td>
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<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Mass Concentration of Fibrinogen in Plasma</td>
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<td>Concentration of Fibrinogen in Sputum</td>
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<td>Not available</td>
<td>Not in LONC for this Specimen Type</td>
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<tr>
<td>Concentration of C Reactive Protein in Serum or Plasma</td>
<td>Concentration of C Reactive Protein in Serum or Plasma.</td>
<td>Chem</td>
<td>C Reactive Protein</td>
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<td>Concentration of C Reactive Protein in Sputum</td>
<td>Concentration of C Reactive Protein in Sputum.</td>
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<td>Concentration of C Reactive Protein in Serum or Plasma</td>
<td>Concentration of C Reactive Protein in Serum or Plasma.</td>
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</table>
Q&A Session
CDISC Education Events
Announcements

Learn CDISC from CDISC!
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

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morrisville, NC</td>
<td>9-12 Feb 2016</td>
<td>SDTM, CDASH, ADaM</td>
<td>SynteractHCR</td>
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<tr>
<td>Audubon, PA</td>
<td>2-11 Mar 2016</td>
<td>Courses corresponding to standards listed in Data Standards Catalog. See web.</td>
<td>Bioclinica</td>
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<tr>
<td>Emeryville, CA</td>
<td>11-15 April 2016</td>
<td>Courses corresponding to standards listed in Data Standards Catalog. See web.</td>
<td>Santen</td>
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</table>

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

Check CDISC website for up-to-date information on Public Courses
<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berkshire, UK</td>
<td>26-29 Jan 2016</td>
<td>SDTM, ADaM, Define-XML</td>
<td>Quintiles</td>
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<tr>
<td>Paris, France</td>
<td>8-11 Mar 2016</td>
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<td>Sanofi</td>
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<tr>
<td>Europe Interchange in Vienna, Austra</td>
<td>25-29 Apr 2016, Registration Opens Dec 2015 on CDISC Website: <a href="http://cdisc.org/interchange">http://cdisc.org/interchange</a></td>
<td>CDISC</td>
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</table>

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

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Register by:</th>
<th>Early Registration Discounts</th>
<th>Host</th>
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<tbody>
<tr>
<td>Tokyo, Japan</td>
<td>14-18 Dec 2015</td>
<td>SDTM, CDASH, ADaM, ODM, Define-XML</td>
<td>13 Nov 2015</td>
<td>13 Nov 2015</td>
<td>CAC EXICARE Corporation</td>
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</tbody>
</table>

Visit [http://cdisc.org/public-courses](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**
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- Your instructor delivers training
- Training when your staff needs it
- Official CDISC Education certificates

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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](http://www.cdisc.org/webinars)
Any more questions?

Thank you for attending this webinar.

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Inform Patient Care & Safety Through Higher Quality Medical Research
CDISC Members Drive Global Standards

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