CDISC Public Webinar – Standards Updates and Additions

25 Sep 2014
Agenda

• Controlled Terminology, Batch 19, Publication Release

• Controlled Terminology, Batch 20, Public Review
  ▪ Bernice Yost, CDISC

• CDISC Therapeutic Area Data Standards: User Guide for Influenza (Version 1.0 Draft)
  ▪ Jon Neville, C-Path
  ▪ Laura Butte, C-Path

• CDISC Education and Events Updates*
  ▪ Saad Yousef, CDISC

*After Q&A session
Question & Answer

• ‘Presenter’: Question
OR
• ‘Presentation’: Question

Examples:

Laura: When will the standard be published?
OR
Influenza: When is the review period over?
CDISC CONTROLLED TERMINOLOGY

Presented by Bernice F. Yost
Controlled Terminology

Agenda

• Package 19 Publication Release (26 Sep 2014)
  ▪ What’s new
  ▪ What’s changed

• Package 20 Public Review (12 Sep 2014 to 10 Oct 2014)
  ▪ What’s new
  ▪ What’s changed
# Controlled Terminology Publication Schedule

<table>
<thead>
<tr>
<th>Package Number</th>
<th>Team Cutoff (requests must be received at least two months before this date)</th>
<th>Public Review Start Date (1 wk from Team Cutoff)</th>
<th>Public Review Closed Date (4 wks)</th>
<th>Final Changes to NCI EVS (4 wks)</th>
<th>Publication Date (6 wks)</th>
<th>Codelists to be Included</th>
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Controlled Terminology
Package 19 Publication Release

• Terminology Changes File
  ▪ Programmatically generated
  ▪ Column C change type has changed from Type I, II, III to Add, Update or Remove.
## Controlled Terminology Package 19
Publication Release

<table>
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<th>B</th>
<th>C</th>
<th>D</th>
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Controlled Terminology
Package 19 Publication Release

• Questionnaire Terminology Team
  ▪ Questionnaires being released
    • Columbia Suicide Severity Rating Scale: Lifetime/ Recent (C-SSRS LIFETIME/RECENT)
    • Extrapyramidal Symptom Rating Scale-Absbrieviated (ESRS-A)
    • Craig Handicap and Assessment Reporting Technique (CHART-SF)
Controlled Terminology Package 19 Publication Release

• Cardiovascular Terminology Team
  ▪ New Codelist
    • Graft Type
Controlled Terminology
Package 19 Publication Release

• Device Terminology Team
  ▪ New Term Added to Existing Codelist
    • Device In-Use Test Code/Test Name
    • Device Tracking and Disposition Event Dictionary Derived Term
Controlled Terminology
Package 19 Publication Release

• ECG Terminology Team
  ▪ Term Removed
    • ECG Test Code/Test Name Codelist
      – PAXIS: Summary (Mean) P Axis
        » The mean (average) direction (range -180 degrees to 180 degrees) of the electrical potential generated by atrial depolarization in a particular plane (usually the frontal plane).
        » NCI Preferred Term: Mean P Axis
      – P_AXIS: P Wave Axis
        » A numerical representation of the electrocardiographic vector assessed at maximum deviation of the P wave from the isoelectric baseline, usually reported for the frontal plane.
      – QRSAXIS: Summary (Mean) QRS Axis
        » The mean (average) direction of the electrical potential generated by ventricular depolarization.
        » NCI Preferred Term: Mean QRS Axis
      – QRS_AXIS: QRS AXIS
        » A numerical representation of the electrocardiographic vector assessed at maximum deviation of the QRS complex from the isoelectric baseline, usually reported for the frontal plane.
      – TAXIS: Summary (Mean) T Wave Axis
        » The mean (average) direction of the electrical potential generated by ventricular repolarization.
        » NCI Preferred Term: Mean T Wave Axis
      – T_AXIS: T Wave Axis
        » A numerical representation of the electrocardiographic vector assessed at maximum deviation of the T wave from the isoelectric baseline, usually reported for the frontal plane.
Controlled Terminology
Package 19 Publication Release

• ECG Terminology Team continued:
  ▪ New Term Added to Existing Codelist
    • ECG Test Code/Test Name
    • ECG Lead
Controlled Terminology Package 19 Publication Release

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

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<tr>
<th>TESTCD</th>
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<th>Synonym(s)</th>
<th>CDISC Definition</th>
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<td>Lipase</td>
<td>Total Lipase</td>
<td>A measurement of the total lipase in a biological specimen.</td>
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<td>LIPASEP</td>
<td>Lipase, Pancreatic</td>
<td>PNLIP; Pancreatic Triacylglycerol Lipase</td>
<td>A measurement of the pancreatic triacylglycerol lipase in a biological specimen.</td>
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<td>LIPASEG</td>
<td>Lipase, Gastric</td>
<td>LIPF; Gastric Triacylglycerol Lipase</td>
<td>A measurement of the gastric triacylglycerol lipase in a biological specimen.</td>
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<td>LIPASLAL</td>
<td>Lipase, Lysosomal Acid</td>
<td>Lysosomal Lipase; LIPA; LAL; Acid Cholesteryl Ester Hydrolase</td>
<td>A measurement of the lysosomal acid lipase in a biological specimen.</td>
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Controlled Terminology
Package 19 Publication Release

• Lab Terminology Team (Specimen Type/Specimen Condition Codelists)
  ▪ New Term Added to Existing Codelist
    • Specimen Type
Controlled Terminology Package 19 Publication Release

• Lab Terminology Team (*Unit Codelist*)
  ▪ Term Removed
    • Unit Codelist
      – Um3  Cubic Micrometer: A unit of volume equal to 10E-18 liter or one cubic micrometer (Attoliter).
        » This was assigned to the wrong concept and will be removed. The correct concept is 10E-15 liter (Femtoliter).

▪ New Term Added to Existing Codelist
  • Unit Codelist
Controlled Terminology
Package 19 Publication Release

• PK Terminology Team
  ▪ Codelist Name Change
    • PK Parameter Units of Measure Codelist
    • PK Units of Measure Codelist
      – Definition: Units of measure for pharmacokinetic data and parameters.
        » The PK Units of Measure codelist will also be used by the PC domain.
Controlled Terminology
Package 19 Publication Release

• PK Terminology Team continued
  ▪ Submission Value Change
    • PK Parameter Units of Measure Codelist
      – L/mg/day (L/day)/mg
      – L/g/day (L/day)/g
      – L/mg/h (L/h)/mg
      – L/mg/min (L/min)/mg
      – L/g/h (L/h)/g
      – L/g/min (L/min)/g
      – L/ug/h (L/h)/ug
      – L/ug/min (L/min)/ug
      – L/ug/day (L/day)/ug

  » Parentheses are needed to avoid ambiguity and we want to be consistent with our other terms
Controlled Terminology Package 19 Publication Release

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

• PK Terminology Team
  ▪ New Term Added to Existing Codelist
    • PK Parameters Code/PK Parameters
Controlled Terminology Package 19 Publication Release

- Virology Terminology Team
  - New Term Added to Existing Codelist
    - SDTM Species
Controlled Terminology
Package 19 Publication Release

• General Terminology Team
  ▪ Term Removed
    • Method Codelist
    – Angiogram
      » Angiogram is not a method. It is the product created when an Angiography is conducted. The correct method is Angiography and it will be published in Package 19.

▪ New Codelist
• Analysis Reason
• Analysis Purpose
• Multiple Sclerosis Findings About Test Code/Test Name
• Ophthalmic Exams
• West Haven Hepatic Encephalopathy Grade
• Hepatic Findings About Test Code/Test Name
Controlled Terminology Package 19 Publication Release

• General Terminology Team continued:
  ▪ New Term Added to Existing Codelist
    • Anatomical Location
    • Directionality
    • SDTM Domain Abbreviation
    • Vital Signs Test Code/Test Name
    • Method
    • Procedure
    • Nervous System Physiology Test Code/Test Name
    • Morphology Test Code/Test Name
    • Trial Summary Parameter
Controlled Terminology Package 19 Publication Release

• Oncology Terminology Team
  ▪ Codelist Name Change
    • Tumor Identification Results
    • Tumor and Lesion Identification Results
  
  • Oncology Tumor Properties Test Code
  • Tumor or Lesion Properties Test Code
  
  • Oncology Tumor Properties Test Name
  • Tumor or Lesion Properties Test Name

  – These codelists will also be used for cardiovascular lesion identification and properties.
Controlled Terminology
Package 19 Publication Release

• Oncology Terminology Team continued
  ▪ Term Removed
    • Tumor Response Result Codelist
      – NA (Not Applicable)
        » There is no NA in the RECIST Response Evaluation Criteria. (RECIST Guideline Version 1.1)
Controlled Terminology
Package 19 Publication Release

• SEND Terminology Team
  ▪ Submission Value Change
    • Strain/Substrain Codelist
      – ICO:OFA (SD) OFA(SD)
      – CF-1 CF1
      – YUCATAN MICROPIG MICRO YUCATAN MINIATURE SWINE
      – SINCLAIR MINIPIG SINCLAIR MINIATURE SWINE
      – NIH MINIPIG NIH SLA MINIATURE SWINE
      – YUCATAN MINIPIG YUCATAN MINIATURE SWINE
      – CALIFORNIA CALIFORNIAN
      – CEH/HEJ C3H/HeJ
      – CD1 (ICR) BR CD1(ICR)
      – HARTLEY ALBINO HAIRLESS

  » These changes are being made to match up with other standards.
Controlled Terminology
Package 19 Publication Release

• SEND Terminology Team continued
  ▪ Term Removed
    • Strain/Substrain Codelist
      – ACI:SEG
      – BROILER BREEDS
      – CHINESE SYRIAN GOLD
      – LAKEVIEW LVG
      – NEW ZEALAND BLACK
      – NEW ZEALAND HYBRID
      – NEW ZEALAND RED
      – NEW ZEALAND WHITE
      – CYNOMOLGUS MAURITIUS
      – COTTON
      – DOMESTIC SHORT HAIR
        » This is to align with the new rules established for the Strain/Substrain Codelist
Controlled Terminology
Package 19 Publication Release

• SEND Terminology Team continued
  ▪ New Term Added to Existing Codelist
    • Neoplasm Type
    • Specimen
    • Strain/Substrain
    • Species
Controlled Terminology
Package 20 Public Review
Controlled Terminology Package 20 Public Review

- Cardiovascular Terminology Team
  - Codelist Name Change
    - Cardiovascular Test Code/Test Name – CVEXAMCD/CVEXAM
      - A terminology codelist to describe the findings test code from a cardiac examination.
    - Cardiovascular Test Code/Test Name – CVTESTCD/CVTEST
      - A terminology codelist to describe the test code for a physiological examination of the cardiovascular system.
  - TIMI Flow Responses – TIMIFLOW
  - TIMI Flow Responses – TIMIFLRS
Cardiovascular Terminology Team continued

• Submission Value Change
  • TIMI Flow Responses Codelist
    – Grade 0 TIMI Grade 0
    – Grade 1 TIMI Grade 1
    – Grade 2 TIMI Grade 2
    – Grade 3 TIMI Grade 3

• Submission Value Change
  • Coronary Artery Dominance Codelist
    – LEFT DOMINANCE LEFT DOMINANT
    – RIGHT DOMINANCE RIGHT DOMINANT
Controlled Terminology Package 20 Public Review

• Cardiovascular Terminology Team continued
  ▪ New Codelist
    • Cardiovascular Findings About Test Code/Test Name
    • Cardiovascular Findings About Results
    • Coronary Thrombus TIMI Grade Responses
    • Coronary Artery Dissection NHLBI Grade Responses
  
  ▪ New Term Added to Existing Codelist
    • Cardiovascular Test Code/Test Name
    • Coronary Vessel Disease Extent
    • Morphology Test Code/Test Name
Controlled Terminology Package 20 Public Review

• Device Terminology Team
  ▪ Submission Value Change
    • Device Identifier Long Name
      – Model
      – Model Number
Controlled Terminology Package 20 Public Review

• ECG Terminology Team
  ▪ New Term Added to Existing Codelist
    • ECG Test Code/Test Name
    • ECG Result
Controlled Terminology Package 20 Public Review

• Lab Terminology Team (*Laboratory Test Codelists*)
  ▪ Submission Value Change
    • Test Name: Amyloid Beta Precursor Protein
    • Test Code: APP  APPB
      – APPT = Total Amyloid Precursor Protein
      – APPA = Amyloid Precursor Protein Alpha
      – APPB = Amyloid Precursor Protein Beta

  ▪ Term Removed
    • Protein: A measurement of a group of complex organic macromolecules composed of one or more alpha-L-amino acid chains in a biological specimen.
      – NCI Preferred Term is Total Protein Measurement
    • Total Protein: A measurement of the total protein (albumin and globulin) in a biological specimen.
Controlled Terminology Package 20 Public Review

- Lab Terminology Team (*Laboratory Test Codelists*)
  - New Term Added to Existing Codelist
    - Laboratory Test Code/Test Name
    - Microscopic Findings Test Code/Test Name
Controlled Terminology Package 20 Public Review

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

  ▪ New Term Added to Existing Codelist
    • Specimen Type
Controlled Terminology
Package 20 Public Review

• Lab Terminology Team (*Unit Codelist*)
  ▪ Submission Value Change
    • Unit Codelist
      – uIU/mL  Micro-International Unit per milliliter
        » Synonyms: Micro-International Unit per milliliter; mIU/L; mcIU/mL; uIU/mL
      – mIU/L  Milli-International Units per Liter
        » makes this unit SI compliant
      – IN Inch
      – in
  ▪ Term Removed
    • Unit Codelist
      – g/g Creatinine
      – g/mol Creatinine
      – ug/g Creatinine
        » The lab rule is that if the test code/test name has Creatinine in it then it does not need to be in the unit code. Please use g/g (C70453) or g/mol (C73721) or mg/kg (C67401).
Controlled Terminology Package 20 Public Review

- Lab Terminology Team (Unit Codelist continued)
  - New Term Added to Existing Codelist
    - Unit Codelist
Controlled Terminology
Package 20 Public Review

• PK Terminology Team
  ▪ Submission Value Change
    • PK Parameters Code/PK Parameters Codelist
      – PK Parameters: Conc  Concentration
      – PK Parameters Code: CONC
        » Definition: The quantity of a specified substance in a unit volume or weight of another substance.

      – PK Parameters: Average Conc  Average Concentration
      – PK Parameters Code: CAVG
        » Definition: AUCTAU divided by TAU.
Controlled Terminology Package 20 Public Review

• PK Terminology Team continued
  ▪ Term Removed
    • PK Parameter Units of Measure Codelist
      – nmol/L/umol  Nanomoles per liter per micromole
        » Our standard rule is to dose normalize by mg or ug, not molar units.

• PK Terminology Team
  ▪ New Term Added to Existing Codelist
    • PK Parameter Units of Measure
Controlled Terminology Package 20 Public Review

- Virology Terminology Team
  - Term Removed
    - Microorganism Codelist
      - ENTEROBACTER TAYLORAE
        » ENTEROBACTER TAYLORAE is a synonym to the term ENTEROBACTER CANCEROGENUS

- New Term Added to Existing Codelist
  - Microorganism
Controlled Terminology Package 20 Public Review

• General Terminology Team
  ▪ Move Terms to a Different Codelist
    • Consensus Cardiac Classification System Test Code/Test Name
      – TIMI Flow (TIMIFLOW)
        » A grading system for coronary blood flow based on the classification developed by the Thrombolysis in Myocardial Infarction Group. It classifies coronary blood flow into four classes based upon the angiographic appearance of the blood vessels.
      – ACC/AHA Lesion Complexity Class (LSNCPCLS)
        » A classification system for coronary stenosis based upon characteristics that influence the difficulty of percutaneous coronary revascularization.

• Morphology Test Code/Test Name
  – A terminology codelist based on the test codes for macroscopic assessments that are seen by the naked eye or observed via procedures such as imaging modalities, endoscopy, or other technologies.
Controlled Terminology Package 20 Public Review

• General Terminology Team continued
  ▪ Term Removed
    • Units for Vital Signs Results Codelist
      – Ohm
        » A unit of electrical resistance equal to the resistance between two points on a conductor when a potential difference of one volt between them produces a current of one Ampere. Ohm is also used to measure impedance and reactance for complex resistance. A measurement in ohms is the reciprocal of a measurement in Siemens.

▪ New Codelist
  • Ophthalmic Focus of Study Specific Interest
Controlled Terminology Package 20 Public Review

• General Terminology Team continued:
  ▪ New Term Added to Existing Codelist
    • Anatomical Location
    • Respiratory Test Code/Test Name
    • Reproductive System Findings Test Code/Test Name
    • Evaluator
    • Method
    • Route of Administration
    • Morphology Test Code/Test Name
    • Trial Summary Parameter Test Code/Test Name
Controlled Terminology Package 20 Public Review

• Oncology Terminology Team
  ▪ New Term Added to Existing Codelist
    • Oncology Tumor Properties Test Code/Test Name
    • Tumor Identification Test Code/Test Name
Controlled Terminology Package 20 Public Review

• SEND Terminology Team
  ▪ Submission Value Change
    • Neoplasm Type Codelist
      – ADENOMA, BASAL CELL, BENIGN
      – BASAL CELL TUMOR, BENIGN
      » Update submission value to be more precise. Adenoma is a bit of a misnomer (though not incorrect) since basal cell tumors do not form glandular structures.
Controlled Terminology Package 20 Public Review

- SEND Terminology Team continued
  - New Term Added to Existing Codelist
    - Neoplasm Type
    - Specimen
Influenza Therapeutic-area User Guide (TAUG) v1.0, Public Review

Presented by Jon Neville,
Critical Path Institute
Project Background

• **Goal**
  
  *To create an Influenza Therapeutic Area User Guide covering vaccines and therapeutics as part of the CFAST program*

• **Focus**

  *Diagnosis, drug resistance, viral load, immune titers, labs and other routine data*

• **Inputs**

  *Pharma surveys, Clinicaltrials.gov, FDA guidance, United States Critical Illness & Injury Trials Group (USCIITG)*
## CFAST Therapeutic Area Projects Status

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<th>Project Manager</th>
<th>Proposal Approval Date</th>
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**Key:**

- **Stage completed**
- **Stage ongoing**

All Months reflect when stage is or is projected to be completed.
Review Cycles Summary

- **Internal Review**
  - Concluded 8/25
  - Team received and responded to 120 comments

- **SRC Review**
  - 9/8- received and addressed 27 comments
  - Approval to post for public review on 9/17

- **Public Review**
  - Happening now!
  - Anyone welcome to review and comment
  - Comment period closes **10/20/2014**
Concepts Covered in V1.0

- Diagnosis and laboratory confirmation of infection
- Viral resistance
- Symptoms and sequelae
- Viral Load
- Immune response
- Assessments of respiration and perfusion
- Adverse events of special interest
- Healthcare encounters
Influenza Guide Layout

CDISC Therapeutic Area Data Standards: User Guide for Influenza (Version 1.0 Draft)

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Crash Course on Influenza nomenclature

Influenza

\(\text{has types}\)

\begin{itemize}
  \item Influenza A
  \item Influenza B
  \item Influenza C
\end{itemize}

Subtypes

\(\text{have} \rightarrow \text{strains}\)

\begin{itemize}
  \item such as
  \item H1N1
\end{itemize}

\textbf{Uncommon}

\begin{itemize}
  \item such as
  \item A/Fujian/411/2002 (H3N2)
\end{itemize}
Diagnosis and Laboratory Confirmation of Infection
Viral Resistance SDTM Example- Nomenclature Issue

2.3.1 Examples for Influenza Drug Sensitivity Testing

Example 1
This example shows a longitudinal assessment of genetic variation in the influenza neuraminidase gene from two subjects. These assessments look for changes in the Arginine (R) residue at position 292 in the neuraminidase protein over a period of five days, because this change is known to confer drug resistance. PFORRES shows the one letter amino acid abbreviation more commonly seen in literature. PFSTRESC shows the result using standard Human Genome Variation Society (HGVS) nomenclature.

Some Required and Expected variables have been omitted in consideration of space and clarity. Controlled terminology is still under development, thus some values in the examples are not CDISC controlled terms. Verify demonstrated terminology against current standards before adopting.

Row 1: Shows that the baseline assessment found no variation in R292 for subject INF01-01. Note that the experimental result (PFORRES) and the reference result (PFORREF) are the same. The standard result (PFSTRESC) value of “p.(=)” indicates there is no change detected.

Rows 2-3: Show that R292 residue mutated to Lysine (K) on day 2 and remained that way through day 5 for subject INF01-01. Note that the experimental result (PFORRES) has changed to “K.”

Rows 4-6: Show that the baseline, day 2, and day 5 assessments found no variation in R292 for subject INF01-02.

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</table>
Viral Resistance SDTM Example - Nomenclature Issue, cont’d

Example 2
This example shows how to represent data from an NA inhibition assay that is assessing influenza susceptibility to a neuraminidase inhibitor during an antiviral treatment trial. This assessment was done at three time points over a five-day period. Each time point compares a known reference strain to a subject-derived sample strain that has previously been identified as being of the same lineage based on genetic markers (thus the strain name ending in “-like”). Information about sample collection method, analysis software, and software version used to calculate the IC50 values are represented in SUPPVR and linked to the parent domain via VRSEQ. Information about the commercial kit used are represented in the Device Identifiers domain (DI), and linked to the VR domain via SPDEVID. Note that the values in VRGENTYP and VRGENRI are chosen based on the target molecule of the study drug, a neuraminidase inhibitor.

Some Required and Expected variables have been omitted in consideration of space and clarity. Controlled terminology is still under development, thus some values in the examples are not CDISC controlled terms. Verify demonstrated terminology against current standards before adopting it.

Rows 1, 4, and 7:
- Show the response of the virus extracted from the subject based on drug concentrations required to produce 50% inhibition of the standard virus growth.

Rows 2, 5, and 8:
- Show a reference viral sample response based on drug concentrations required to produce 50% inhibition of the standard virus growth.

Rows 3, 6, and 9:
- Show the fold change of the response of the virus extracted from the subject compared to the reference viral sample response based on drug concentrations required to produce 50% inhibition of the standard virus growth. This is the subject sample result divided by the reference result.

Row 10:
- Shows the net assessment of the trend in fold change (rows 3, 6 and 9) based on how the sample virus susceptibility to drug changed with respect to the control strain over the three time points. VRORRES/VRSTRESC show “Reduced Susceptibility”.

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Nomenclature Issue, summary

• Influenza nomenclature is a three-level hierarchy:
  ▪ Species (type) → Subtype → Strain

• Current VR & draft PF domains allow for two levels:
  ▪ Species → Strain
  ▪ New proposed variable “substrain” in future batch release? Even if so, not a perfect alignment

• Discussions with PGx/Virology teams, other CFAST TAs, and IMI Vaccines project team are ongoing to align on clinical concepts and terminology needs; guides may evolve in time
Viral Shedding/ Viral Load

Subject participates in

Sample collection has method
results in

Respiratory sample participates in

Viral load assessment is either

Validated Kit/Protocol used to process the specimen uses

qRT-PCR assay gives

Results have values are represented as

log10 Influenza RNA copies/mL stored in LB Domain

may have LLOQ

Quantitative cell culture gives

Results have values are represented as

Quantification of infectious units: Plaque forming units (PFU), or 50% Tissue Culture Infectious Doses (log10 TCID50/mL) stored in
Immune Response

**Microneutralization Titer**

- 2-fold serum dilution series is introduced to

  96-well plates w/ Influenza virus (100 TCID50/well)

  incubated (1hr)

  MDCK cells added

  incubated (18-20hrs)

  ELISA

  gives

  **Result**

  expressed as

  **MN titer**

  (inverse of most dilute sample that causes 50% plaque reduction or 50% reduction in infected wells)

- **HI Titer**

  2-fold serum dilution series is introduced to

  96-well plates w/ virus (100 HA Units/well)

  incubation (1hr)

  RBCs added

  incubation (18-20hrs)

  ring of inhibition visually interpreted

  gives

  **Result**

  expressed as

  **HI titer**

  (inverse of most dilute sample that inhibits hemagglutination)

Subject participates in

Blood sample collection

results in

Blood serum specimen

may participate in either

CDISC 2014

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Two Outcome Assessment Instruments and a new (draft) CC Domain

• Influenza intensity and impact Questionnaire (Flu-iiQ™)
  ▪ Flu-iiQ™ will be available as a standalone QS supplement

• Acute Physiology and Chronic Health Evaluation II (APACHE II) Severity of Disease Classification
  ▪ APACHE II required a new findings domain- Clinical Classifications (CC). This draft domain completed internal review 9/24/14 and is targeted for SDTMIG v3.2 Batch 2
  ▪ CC standalone supplement to be developed pending provisional release of CC domain
One other item worth noting…

TAUG Influenza v1.0 is piloting a new approach to the Clinical Events (CE) domain at the request of SRC:

• As in the AE domain, --OCCUR is not used; CE contains only events which *actually occurred*.

• For pre-specified events that did not occur, the responses of “No” are represented in Findings About Clinical Events (FACE), just as in AE.

• SRC/SDS would like feedback on this approach; its adoption into future SDTMIGs is subject to feedback.
Reviewing and commenting

Go to www.cdisc.org/therapeutic, scroll down to: Standards Posted for Comment:

Influenza Therapeutic Area Data Standard User Guide v 1 (TAUG-Influenza) Now Available for Public Review – Comments Due 20 October 2014

The CFAST Influenza team is pleased to announce the availability of the Influenza Draft Data Standard User Guide v1.0 for a 30-day public review. The TAUG-Influenza describes the most common clinical concepts relevant to studies of Influenza, including therapeutic interventions and vaccines. The guide also shows examples of how these concepts are represented in the Study Data Tabulation Model (SDTM). The content of this guide focuses on diagnosis, virus-typing, drug resistance, viral load, immune titers, symptoms and sequelae.

For Reviewers:
Reviewers are asked to comment on the content contained in the guide and to take note of the issues outlined in section 1.6 (known issues) in particular when submitting comments.

Please submit your comments using the CDISC commenting tool located on the CDISC website located here.

Instructions on how to use the comment tool are located here.
Quick Summary

• TAUG-Influenza v1.0 in public review until 10/20/14
• The guide focuses on SDTM… CDASH and ADaM may be coming in a v2.0 in 2015, contingent upon funding and CFAST approval
• Not all concepts represented in the guide were discussed in this presentation.
• If you plan to review and comment, please take note of section 1.6, which covers the known issues (some were discussed here today)
• Comments and questions may also be forwarded to Laura Butte, Project Manager, at LButte@c-path.org
Questions?
CDISC Education & Events Announcements

Saad Yousef, CDISC, Manager of Education and Membership Services
Standards currently out for review

• Terminology Package 20
  ▪ Comments due 10 Oct
  ▪ Visit http://www.cdisc.org/terminology for more information.

• New Draft Standard Analysis Results Metadata v1.0 for Define-XML v2.0
  ▪ Comments due 14 Oct 2014
  ▪ Visit www.cdisc.org/adam for more information.

• Influenza Therapeutic Area Data Standard User Guide v1.0
  ▪ Comments due 20 Oct 2014
  ▪ Visit www.cdisc.org/therapeutic for more information.

Click here to submit your comments.
(http://cdisc.org/standards-and-implementations)
## Upcoming International Public Course Events

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Registration Deadline</th>
<th>Discounts?</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tokyo, Japan</td>
<td>10-12 Dec 2014</td>
<td>SDTM, ADaM</td>
<td>12 Nov 2014</td>
<td>1 Oct 2014</td>
<td></td>
</tr>
</tbody>
</table>

Registration deadline indicates online deadline. Offline registration forms for each event can be found [here](http://cdisc.org/public-courses). Additional 2015 public training events can be found @ [http://cdisc.org/public-courses](http://cdisc.org/public-courses).
### Upcoming USA Public Course Events

<table>
<thead>
<tr>
<th>Location</th>
<th>Dates</th>
<th>Courses Offered</th>
<th>Registration Deadline</th>
<th>Discounts?</th>
<th>Host</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carlsbad, CA</td>
<td>27-30 Jan 2015</td>
<td>SDTM, CDASH, ADaM</td>
<td>27 Dec 2014</td>
<td>Expired</td>
<td>SynteractHCR</td>
</tr>
<tr>
<td>Morrisville, NC</td>
<td>10-13 Feb 2015</td>
<td>SDTM, CDASH, ADaM</td>
<td>10 Feb 2015</td>
<td>Expired</td>
<td>SynteractHCR</td>
</tr>
<tr>
<td>Chicago, IL</td>
<td>24-27 Mar 2015</td>
<td>SDTM, CDASH, ADaM</td>
<td>24 Feb 2015</td>
<td>Expired</td>
<td>Astellas</td>
</tr>
<tr>
<td>Palo Alto, CA</td>
<td>14-17 Apr 2015</td>
<td>SEND, ODM, Dataset-XML, Define-XML</td>
<td>14 Mar 2015</td>
<td>Expired</td>
<td>Jazz Pharmaceuticals</td>
</tr>
</tbody>
</table>

Registration deadline indicates online deadline. Offline registration forms for each event can be found [here](http://cdisc.org/public-courses). Additional 2015 public training events can be found @ [http://cdisc.org/public-courses](http://cdisc.org/public-courses).
Upcoming Interchange Events

- CDISC International Interchange in Bethesda, MD (10-14 Nov)
  - Courses Offered:
    - ADaM
    - BRIDG Deep Dive
    - CDASH
    - Dataset-XML
    - Define-XML
    - Healthcare Link
    - SEND
    - SDTM
    - SDTM-Medical Devices
  - eSHARE Demo’s
  - Main Conference
    - Distinguished speakers from CDISC, gov’t, academia, NPOs, and private sector

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](https://www.cdisc.org/private-courses) or submit request here.
Online Training

- SDTM, CDASH, and BRIDG Deep Dive modules available for sale on CDISC Training Campus (http://CDISC.trainingcampus.net)

- All members should contact training@cdisc.org to retrieve company-specific discount code.
Next Public Webinar

• **Agenda:**
  - SDTM IG Batch 2
  - TBD

• **Date:** 23 Oct 2014, 11:00-12:30 PM EST

• **Speakers:**
  - TBD

• Register [here](#).

*Webinar details also at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*
Next Members Only Webinar

• **Topic**: Managing CDISC Version Changes
• **Date/Time**: 2 Oct 2014, 11:00-12:30 PM EST
• **Speaker**: Lauren Shinaberry, Business & Decision Life Sciences

• Register [here](#).

*Webinar details also at [www.cdisc.org/webinars](http://www.cdisc.org/webinars)*
Following Members Only Webinar

- **Topic**: Null Flavor: A Tool for Handling Missing and Awkward Data
- **Date/Time**: 9 Oct 2014, 11:00-12:30 PM EST
- **Speaker**: Diane Wold, GSK

Register [here](#).

*Webinar details also at [www.cdisc.org/webinars](http://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