CDISC Public Webinar – Standards Updates and Additions

25 Sep 2014

Strength *through Collaboration*

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

Strength *through Collaboration*

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

Package Number	Team Cutoff (requests must be received at least two months before this date)	Public Review Start Date (1 wk from Team Cutoff)	Public Review Closed Date (4 wks)	Final Changes to NCI EVS (4 wks)	Publication Date (6 wks)	Codelists to be Included			
18	3/14/2014	3/21/2014	4/18/2014	5/16/2014	6/27/2014	CV	Device	ECG	General
18						Lab	PK	QS	SEND
18						Unit	Virology		
19	6/13/2014	6/20/2014	7/18/2014	8/15/2014	9/26/2014	CV	Device	ECG	General
19						Lab	Oncology	PK	QS
19						SEND	Spectype Speccond	Unit	Virology
20	9/5/2014	9/12/2014	10/10/2014	11/7/2014	12/19/2014	CV	Device	ECG	General
20						Lab	Oncology	PK	QS
20						SEND	Spectype Speccond	Unit	Virology
21	12/12/2014	12/19/2014	1/23/2015	2/13/2015	3/27/2015				
21									
21									
22	3/13/2015	3/20/2015	4/17/2015	5/15/2015	6/26/2015				

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Controlled Terminology
Package 19 Publication Release

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.

CDISC

Controlled Terminology Package 19 Publication Release

	A	B	C	D	E	F	G	H	I	J
1	Release Date	Request Code	Change Type	NCI Code	CDISC Term Type	CDISC Codelist (Short Name)	CDISC Codelist (Long Name)	Change Summary	Original	New
2	2014-09-26	CDISC-1089	Add	C117736	Term	SPEC	Specimen	Add new term to existing codelist	- - -	MUSCLE, VASTUS MEDIALIS
3	2014-09-26	33118	Add	C117748	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Lipase
4	2014-09-26	CDISC-1077	Update	C90436	CDISC Definition	DSDECOD	Standardized Disposition Term	Update CDISC Definition	An indication that the study subject was sacrificed at a predetermined time before the end of the	An indication that the study subject was sacrificed at a predetermined time before the end of the
5	2014-09-26	CDISC-1077	Update	C90436	CDISC Synonym	DSDECOD	Standardized Disposition Term	Add new CDISC Synonym	- - -	Planned Interim Sacrifice
6	2014-09-26	CDISC-1077	Update	C90436	CDISC Synonym	DSDECOD	Standardized Disposition Term	Remove CDISC Synonym	PLANNED INTERIM SACRIFICE	- - -
7	2014-09-26	CDISC-1077	Update	C90445	CDISC Definition	DSDECOD	Standardized Disposition Term	Update CDISC Definition	An indication that the subject did not receive treatment for a specific period of time following	An indication that the subject did not receive treatment for a specific period of time following
8	2014-09-26	CDISC-1077	Update	C90445	CDISC Synonym	DSDECOD	Standardized Disposition Term	Add new CDISC Synonym	- - -	Planned Recovery Sacrifice
9	2014-09-26	CDISC-1077	Update	C90445	CDISC Synonym	DSDECOD	Standardized Disposition Term	Remove CDISC Synonym	PLANNED RECOVERY SACRIFICE	- - -
10	2014-09-26	CDISC-1077	Update	C90465	CDISC Definition	DSDECOD	Standardized Disposition Term	Update CDISC Definition	An indication that the subject was sacrificed at the end of the planned treatment period.	An indication that the subject was sacrificed at the end of the protocol-defined treatment or
11	2014-09-26	CDISC-1077	Update	C90465	CDISC Synonym	DSDECOD	Standardized Disposition Term	Add new CDISC Synonym	- - -	Planned Terminal Sacrifice
12	2014-09-26	CDISC-1077	Update	C90465	CDISC Synonym	DSDECOD	Standardized Disposition Term	Remove CDISC Synonym	PLANNED TERMINAL SACRIFICE	- - -
13	2014-09-26	CDISC-1077	Update	C106580	CDISC Definition	DSDECOD	Standardized Disposition Term	Update CDISC Definition	An indication that the subject was sacrificed prior to the end of the planned treatment period, and	An indication that the subject was sacrificed before the end of the protocol-defined treatment or
14	2014-09-26	33118	Add	C117748	Term	LBTESTCD	Laboratory Test Code	Add new term to existing codelist	- - -	LIPASET
15	2014-09-26	N/A	Remove	C62121	Term	EGTEST	ECG Test Name	Remove term entirely from codelist	Summary (Mean) P Axis	- - -
16	2014-09-26	N/A	Remove	C62132	Term	EGTEST	ECG Test Name	Remove term entirely from codelist	Summary (Mean) QRS Axis	- - -
17	2014-09-26	N/A	Remove	C62146	Term	EGTEST	ECG Test Name	Remove term entirely from codelist	Summary (Mean) T Wave Axis	- - -
18	2014-09-26	32728	Add	C117749	Term	LBTEST	Laboratory Test Name	Add new term to existing codelist	- - -	Soluble Tumor Necrosis Factor Receptor
19	2014-09-26	32728	Add	C117749	Term	LBTESTCD	Laboratory Test Code	Add new term to existing codelist	- - -	TNFSR
20	2014-09-26	33192	Add	C117754	Term	DIR	Directionality	Add new term to existing codelist	- - -	TEMPORAL

SEND Terminology Changes

Ready

100%

CDISC

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-Abbreviated (ESRS-A)
    - Craig Handicap and Assessment Reporting Technique (CHART-SF)

CDISC

Controlled Terminology Package 19 Publication Release

- Cardiovascular Terminology Team
  - New Codelist
    - Graft Type

CDISC

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

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

Controlled Terminology Package 19 Publication Release

- Lab Terminology Team (*Specimen Type/Specimen Condition Codelists*)
  - New Term Added to Existing Codelist
    - Specimen Type

CDISC

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.

CDISC

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

CDISC

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

Controlled Terminology Package 20 Public Review

- 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

CDISC

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

CDISC

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

CDISC

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).

CDISC

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.

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Controlled Terminology Package 20 Public Review

- SEND Terminology Team continued
  - New Term Added to Existing Codelist
    - Neoplasm Type
    - Specimen

CDISC

Influenza Therapeutic-area User Guide (TAUG) v1.0, Public Review

Presented by Jon Neville,
Critical Path Institute

Strength *through Collaboration*

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

Therapeutic Area	Coordinating Organization(s) / Project Manager	Proposal Approval Date	Stage 0 / Scoping & Planning	Stage 1 / Concept Modeling	Stage 2 / Standards Development	Stage 3a / Internal Review	Stage 3b / Public Review	Stage 3c / Projected Publication
Alzheimer's Disease v2	C-Path Jon Neville	Jan 13	Jan	Mar	Jun	Sep	Q4	*Published Dec 2013*
Asthma v1	CDISC Rhonda Facile	Nov 12	Jan	Mar	Jun	Jul	Q4	*Published Nov 2013*
Multiple Sclerosis v1	C-Path Bess LeRoy	Mar 13	May	Oct	Nov	Jan	April	*Published May 2014*
Cardiovascular Endpoints v1	CDISC/DCRI Amy Palmer	Jun 13	Jul	Sep	Nov	Feb	May	*Q414*
Diabetes v1	TCB Rachael Zirkle	Apr 13	May	Aug	Dec	Apr	May	*Published Sep 11, 2014*
QT Studies v1	TCB John Owen	Aug 13	Oct	Feb	Mar	Jul	Sep	*Q414*
Traumatic Brain Injury v1	CDISC Rhonda Facile	Oct 13	Sep	Oct	Nov			*Q215*
Chronic Hepatitis C Virus v1	TCB John Owen	Nov 13	Feb	Apr	Jul	Oct	Nov	*Q414*
Schizophrenia v1	CDISC/DCRI Amy Palmer	Nov 13	May	July	Aug	Oct	Nov	*Q414/Q115*
Breast Cancer v1	TCB Pam Harvey	Nov 13	Aug	Sep	Nov			*2015*
Influenza v1	C-PATH Laura Butte	Feb 14	May	July	Aug	Sep	Oct	*Q414*
Dyslipidemia v1	TCB John Glover	Dec 13	May	Sep	Oct			*Q115*
COPD v1	TCB John Glover	Nov 13	Aug	Oct	Dec			*Q315*

Key| Stage completed | Stage ongoing | All Months reflect when stage is or is projected to be completed.

CDISC

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

TABLE OF CONTENTS

Crash Course on Influenza nomenclature
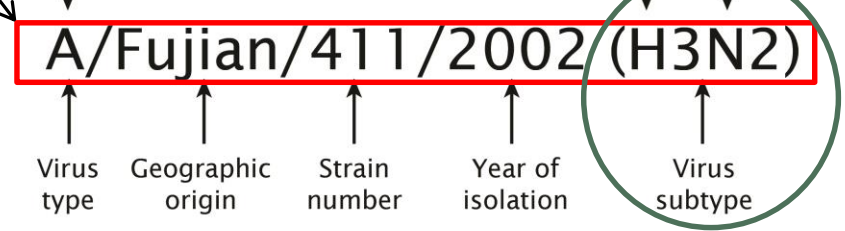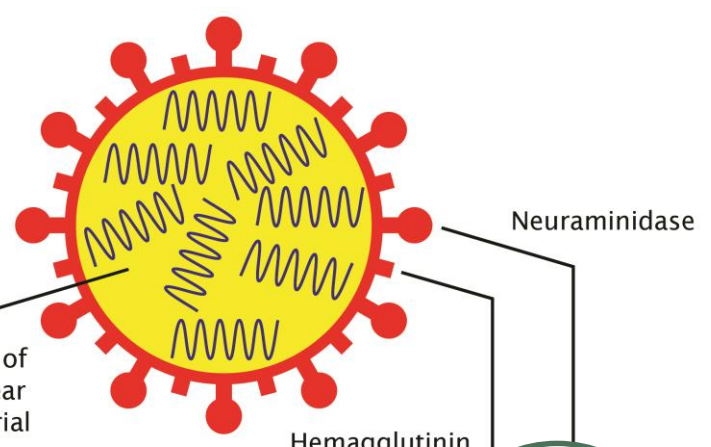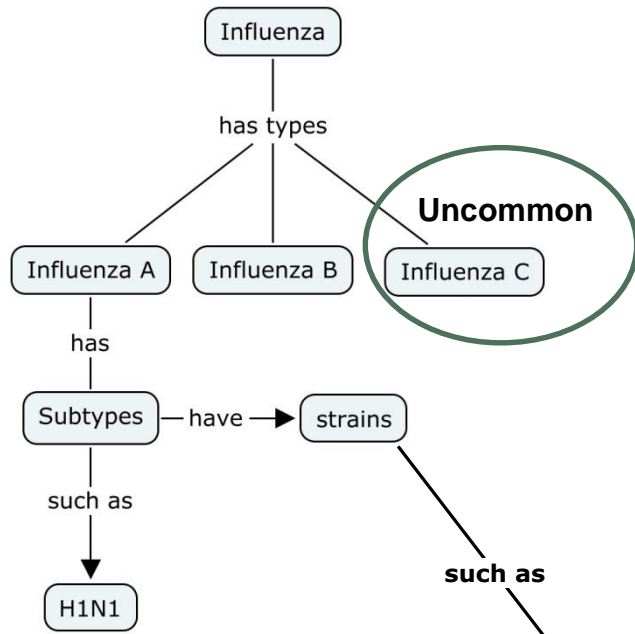
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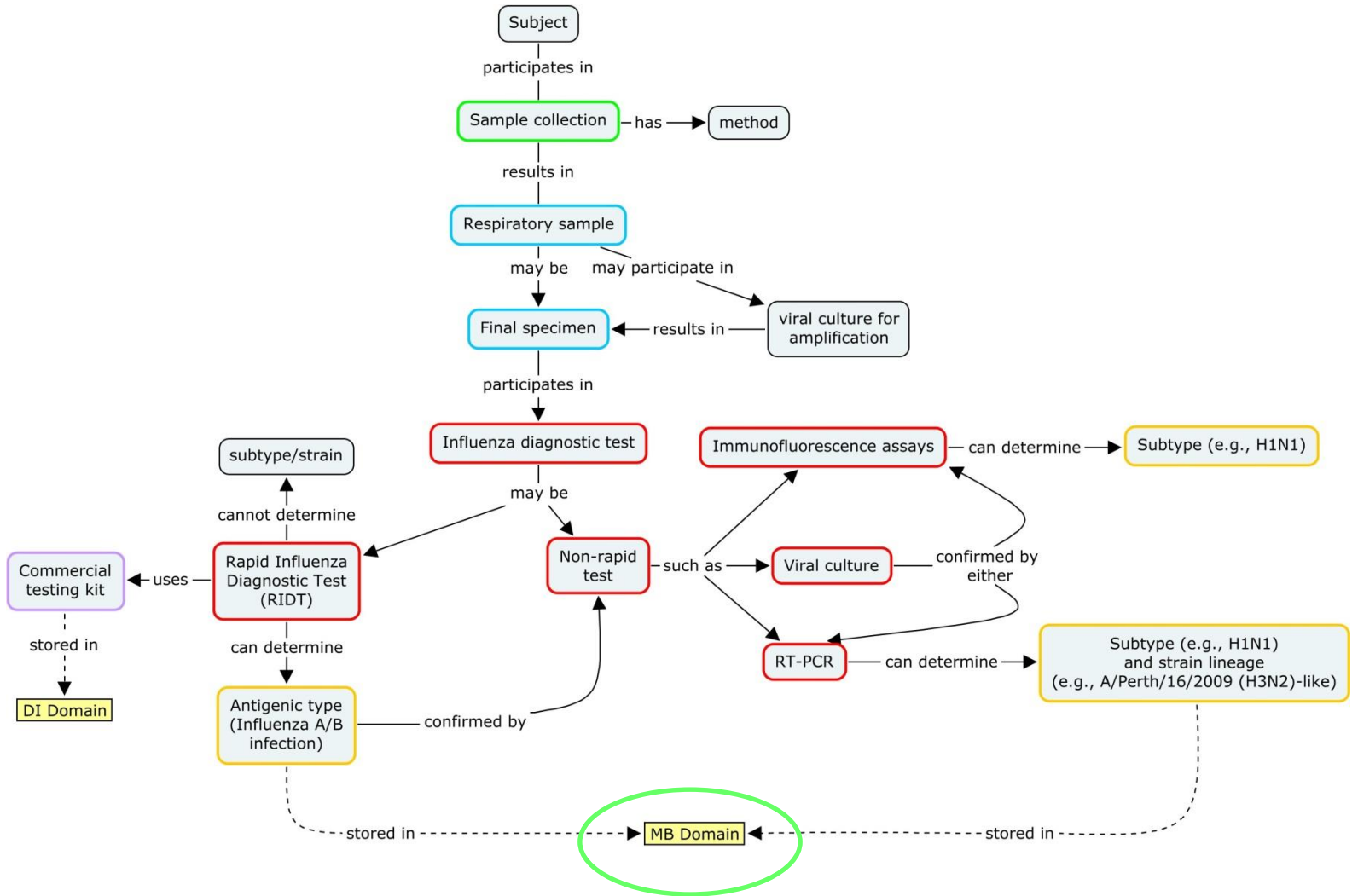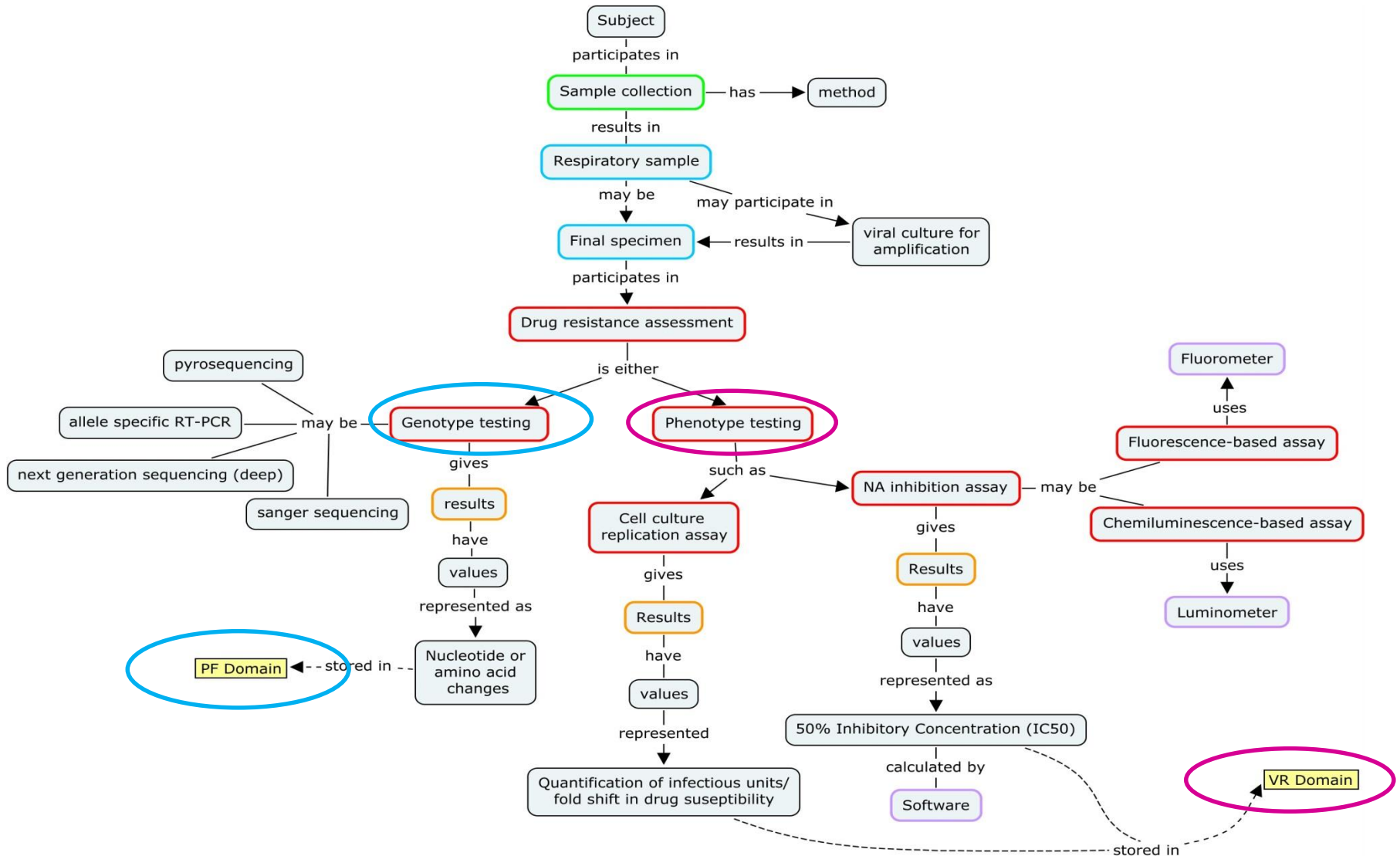
Viral Resistance

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[17]. 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 it.

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.

pf.xpt

Row	STUDYID	DOMAIN	USUBJID	PFSEQ	PFGENTYP	PFGENRI	PFTESTCD	PFTEST	PFCAT
1	INFLU123	PF	INF01-01	1	PROTEIN	NEURAMINIDASE	AA	AMINO ACID	PROTEIN VARIATION
2	INFLU123	PF	INF01-01	2	PROTEIN	NEURAMINIDASE	AA	AMINO ACID	PROTEIN VARIATION
3	INFLU123	PF	INF01-01	3	PROTEIN	NEURAMINIDASE	AA	AMINO ACID	PROTEIN VARIATION
4	INFLU123	PF	INF01-02	1	PROTEIN	NEURAMINIDASE	AA	AMINO ACID	PROTEIN VARIATION
5	INFLU123	PF	INF01-02	2	PROTEIN	NEURAMINIDASE	AA	AMINO ACID	PROTEIN VARIATION
6	INFLU123	PF	INF01-02	3	PROTEIN	NEURAMINIDASE	AA	AMINO ACID	PROTEIN VARIATION

Row	PFSPCIES	PFSTRAIN	PFORRES	PFORREF	PFGENLOC	PFSTRESC	VISITNUM	VISIT	PFDTC
1 (cont)	INFLUENZA A	H3N2	R	R	292	p.(=)	1	BASELINE	2012-03-01
2 (cont)	INFLUENZA A	H3N2	K	R	292	p.Arg292Lys	2	DAY 2	2012-03-02
3 (cont)	INFLUENZA A	H3N2	K	R	292	p.Arg292Lys	3	DAY 5	2012-03-05
4 (cont)	INFLUENZA A	H3N2	R	R	292	p.(=)	1	BASELINE	2012-03-01
5 (cont)	INFLUENZA A	H3N2	R	R	292	p.(=)	2	DAY 2	2012-03-02
6 (cont)	INFLUENZA A	H3N2	R	R	292	p.(=)	3	DAY 5	2012-03-05

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".

vr.xpt

Row	STUDYID	DOMAIN	USUBJID	SPDEVID	VRSEQ	VRGRPID	VRREFID	VRGENTYP	VRGENRI	VRTESTCD	VRTEST
1	INFL123	VR	INF01-01	10	1	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50T	IC50 Subject Sample Result
2	INFL123	VR	INF01-01	10	2	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50R	IC50 Reference Control Result
3	INFL123	VR	INF01-01		3	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50FCR	IC50 Fold Change from Reference
4	INFL123	VR	INF01-01	12	4	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50T	IC50 Subject Sample Result
5	INFL123	VR	INF01-01	12	5	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50R	IC50 Reference Control Result
6	INFL123	VR	INF01-01		6	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50FCR	IC50 Fold Change from Reference
7	INFL123	VR	INF01-01	12	7	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50T	IC50 Subject Sample Result
8	INFL123	VR	INF01-01	12	8	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50R	IC50 Reference Control Result
9	INFL123	VR	INF01-01		9	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	IC50FCR	IC50 Fold Change from Reference
10	INFL123	VR	INF01-01		10	1	SAMPMU0101	PROTEIN	NEURAMINIDASE	ICNETAS	Inhibitory Concentration Net Assessment

| Row	VRSPCIES	VRSTRAIN	VRDRUG	VRORRES	VRORRESU	VRSTRESC
1 (cont)	INFLUENZA A	A/California/7/2009 (H1N1)-like	Investigamavir	0.20	nM	0.20
2 (cont)	INFLUENZA A	A/California/7/2009 (H1N1)	Investigamavir	0.21	nM	0.21
3 (cont)	INFLUENZA A		Investigamavir	0.95		0.95
4 (cont)	INFLUENZA A	A/California/7/2009 (H1N1)-like	Investigamavir	0.21	nM	0.21
5 (cont)	INFLUENZA A	A/California/7/2009 (H1N1)	Investigamavir	0.22	nM	0.22
6 (cont)	INFLUENZA A		Investigamavir	0.95		0.95
7 (cont)	INFLUENZA A	A/California/7/2009 (H1N1)-like	Investigamavir	4.18	nM	4.18
8 (cont)	INFLUENZA A	A/California/7/2009 (H1N1)	Investigamavir	0.20	nM	0.20
9 (cont)	INFLUENZA A		Investigamavir	21		21
10 (cont)	INFLUENZA A		Investigamavir	Reduced Susceptibility		Reduced Susceptibility

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

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Viral Shedding/ Viral Load
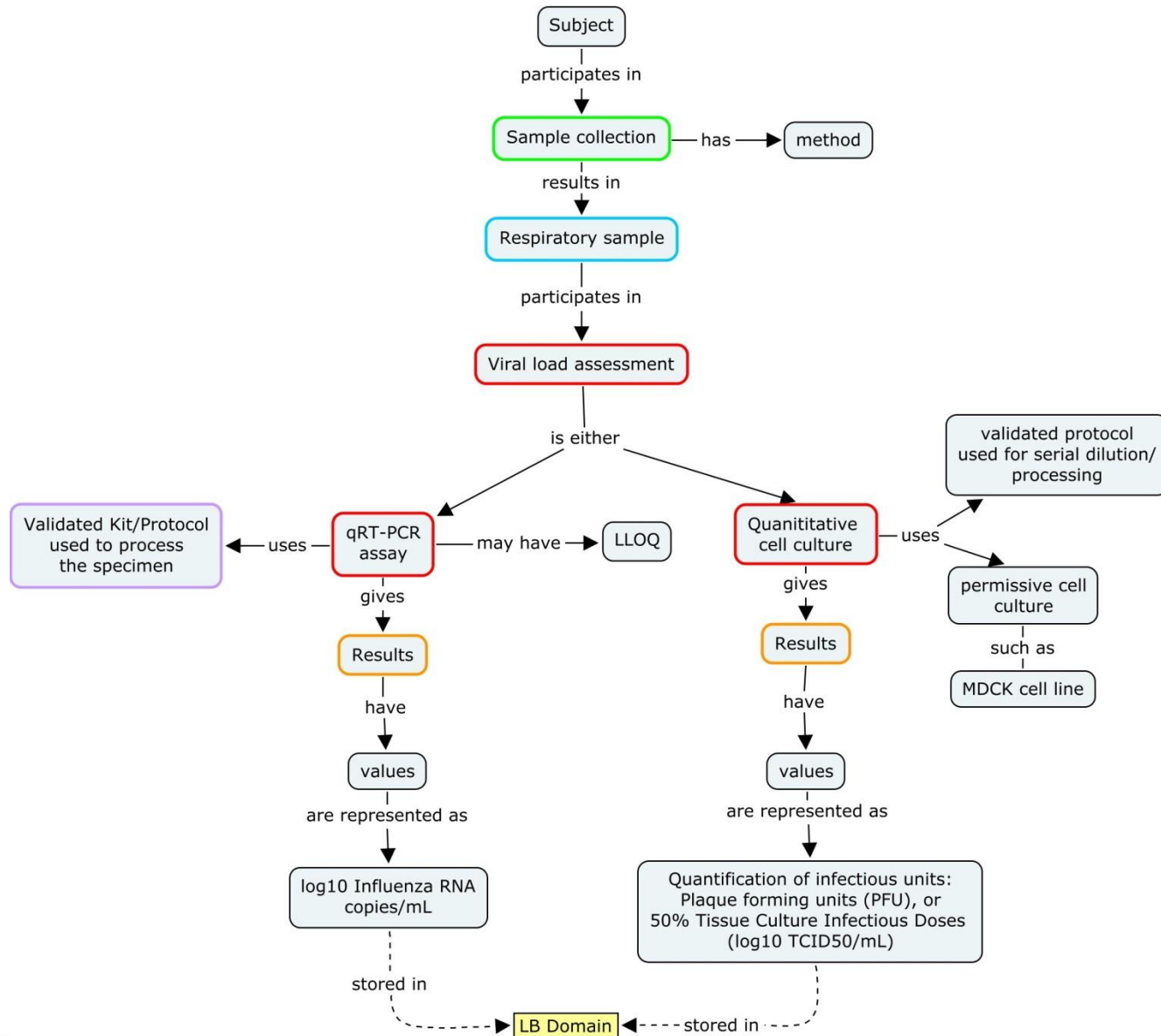
Immune Response
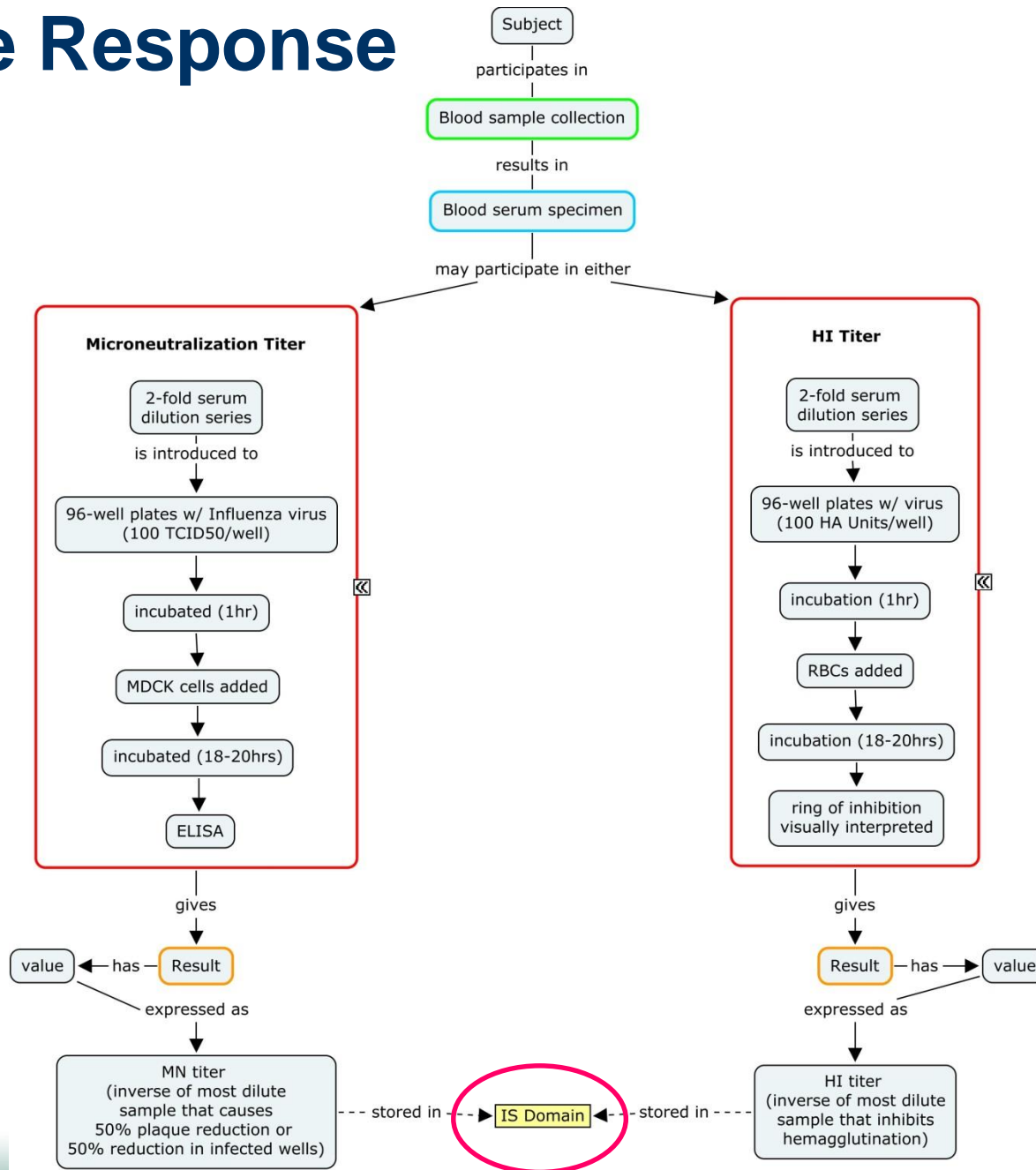
Two Outcome Assessment Instruments and a new (draft) CC Domain

- 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

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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

Strength *through Collaboration*

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

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Shanghai, China	21-24 Oct 2014	SDTM, CDASH, ODM, ADaM, Terminology, Define-XML	7 Oct 2014	Expired	gsk do more feel better live longer
Beijing, China	27-30 Oct 2014	SDTM, CDASH, ODM, ADaM, Terminology, Define-XML	13 Oct 2014	Expired	PPD®
Copenhagen, Denmark	27-30 Oct 2014	SEND, ODM, Define-XML, Dataset-XML	10 Oct 2014	Expired	novo nordisk®
Tokyo, Japan	10-12 Dec 2014	SDTM, ADaM	12 Nov 2014	1 Oct 2014	EXICARE CAC EXICARE Corporation

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

Upcoming USA Public Course Events

Location	Dates	Courses Offered	Registration Deadline	Discounts?	Host
Carlsbad, CA	27-30 Jan 2015	SDTM, CDASH, ADaM	27 Dec 2014	Expired	SynteractHCR
Morrisville, NC	10-13 Feb 2015	SDTM, CDASH, ADaM	10 Feb 2015	Expired	SynteractHCR
Chicago, IL	24-27 Mar 2015	SDTM, CDASH, ADaM	24 Feb 2015	Expired	astellas Leading Light for Life
Palo Alto, CA	14-17 Apr 2015	SEND, ODM, Dataset-XML, Define-XML	14 Mar 2015	Expired	Jazz Pharmaceuticals

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

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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 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

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

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

Any more questions?

Thank you for attending this webinar.

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Inform Patient Care & Safety Through Higher Quality Medical Research

Strength *through collaboration.*

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