

# COVID-19 User Guide Project Review

## Presented by:

David R. Bobbitt, President and CEO

Kit Howard, Sr. Director, Standards Development and Education

Dr. Diane Wold, Sr. Director, Standards Development

Bess Leroy, Head of Standards Development

Amy Palmer, Head of Standards Development

Jon Neville, Sr. Standards Developer

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, US NCI Enterprise Vocabulary Services [C]



6 MAY 2020



## Today's Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources



# Housekeeping

# Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
  - To access – make sure that you create a login for the CDISC website if you haven't already
  - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!





# Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.



# Our Presenters

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6 MAY 2020

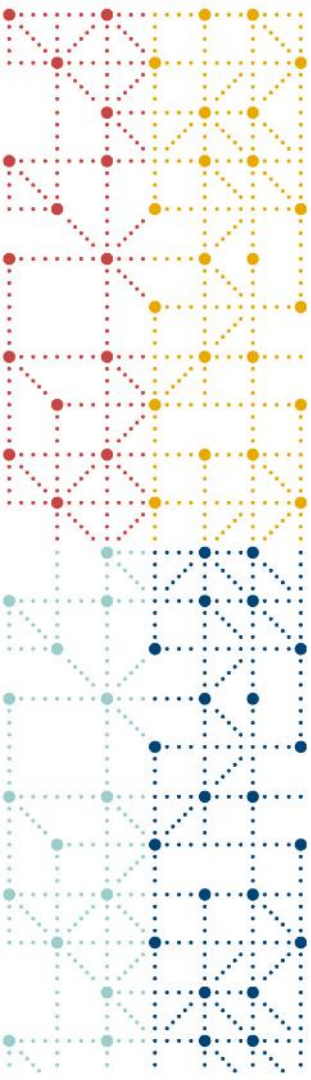


# COVID-19 Task Force

*Being the global community*

David R. Bobbitt, MSc, MBA  
President and CEO





[Adversity] doesn't change who you are. It reveals who you are.

—Michelle Obama





**Thank you to the Task Force members**





Jennifer Alf  
Rebecca Baker  
Cathy Bezek  
Dana Booth  
Assia Bouhadouza  
Stephanie Chen  
Karen Fanouillere  
Nikki Flores  
Nate Freimark  
Praveen Garg  
Tom Guinter  
Ajay Gupta  
Brian Harris

Keith Hibbetts  
Kit Howard  
Chris Kaiser  
Smitha Karra  
Kalynn Kennon  
Bess LeRoy  
Laura Merson  
Erin Muhlbradt  
Jon Neville  
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Nik Pemble  
Chris Price

Heather Ribaud  
Justin Ritz  
Lauren Shinaberry  
Trisha Simpson  
Lorraine P. Spencer  
Will Stevens  
Alana St. Clair  
Sarah Strobino  
Helena Sviglin  
Peter Van Reusel  
Robin White  
Diane Wold  
Jennifer Xio

abbvie





**Thank you to our community**



# WE'RE ALL IN THIS TOGETHER.

WE'RE ALL IN THIS TOGETHER.

Nous sommes  
tous là dedans

我們榮辱與共

हम सब इसमें एक साथ हैं

Wir sitzen alle im  
selben Boot

Vi är alla i detta  
tillsammans

Мы все в  
этом вместе

一丸となって困難を乗り越えましょう

We zitten allemaal  
in hetzelfde schuitje

نحن جميعا في  
هذا معا

Siamo tutti insieme

# CDISC Response to COVID-19

6 May 2020







# Agenda

1. Project Background
2. Scope and Content Development
3. Interim User Guide for COVID-19
  - Diagnostics and Virology
4. Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic
  - Relationships to COVID-19
5. Resources for Public Health Researchers
6. Controlled Terminology COVID-19 Package 41a Publication



# Project Background

- Need identified for a *CDISC Interim User Guide for COVID-19*
- CDISC convened a Task Force in Late March 2020
  - Industry stakeholders
  - Regulatory
  - Academia
  - Key CDISC data standards staff
- Development did not follow formal Standards Development Process (CDISC COP-001)
- Development of the Guide on CDISC wiki
- Published on CDISC Website on 21 April 2020
  - <https://www.cdisc.org/standards/therapeutic-areas/covid-19>

**NOW AVAILABLE: Interim User Guide for COVID-19**

# Defining and Refining the Scope

- Quickly realized that we had two areas of focus beyond an Interim User Guide for COVID-19 for new studies
  - Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic
  - Resources for Public Health Researchers – WHO Annotated Forms and Mapping Spreadsheet
- QRS Supplement in development for National Early Warning Scale 2 (NEWS2)
- Off-cycle COVID-19 Controlled Terminology Release scheduled for 8 May 2020

# Content Development

- Task Force identified scope and provided use-cases and CRFs
- CDISC staff members developed modeling
- Reused existing approved modeling approaches when available, leveraging previous TA work and SDTMIG examples
  - Influenza
  - Tuberculosis
  - Malaria
  - Ebola
  - HIV
  - Virology
  - Vaccines
  - Chronic Kidney Disease
  - Duchenne Muscular Dystrophy
  - Asthma
  - COPD
  - SDTMIG v3.4
  - CDASHIG v2.1



# Meeting Schedule

- Task Force met weekly
- Ongoing Studies Team met twice weekly
- CDISC Standards Development Team met daily
- QRS development occurred during QRS CT and Subteam meetings
- CT development involved ongoing coordination with NCI-EVS



# Review Process and Timelines

- All development on CDISC wiki and publicly viewable for transparency
- Public could create JIRA issues to provide comments throughout the development process
- Batches of examples were sent to Task Force daily and feedback requested within 3 days
- CDISC staff resolved comments



# Interim User Guide for COVID-19



# Interim User Guide Topics Covered

- Risk Factors
  - Pre-existing Medical Conditions
  - Personal Protective Equipment (PPE)
  - Travel
  - Contacts
  - Substance Use
  - Exposure to Animals
- Onset of Disease
- Signs and Symptoms
- Laboratory Test Results
- Diagnostics and Virology
  - Virus Identification
  - Antibody Testing
  - SARS-CoV-2 Viral Load
- Vital Signs and Urine Output
- Concomitant Medications
- Respiratory Findings
  - Imaging
  - Pulmonary Function Tests
- Cardiac Events/Findings
- Hospitalization
- Procedures
  - Assisted Ventilation and Oxygen Treatments
  - Renal Treatment
- Vaccines
- Questionnaires, Ratings, and Scales

# Environmental and Social Factors (ER) Draft Domain

- The Environmental and Social Factors (ER) domain represents data that was collected to assess the factors that might influence a subject's disease or medical condition via environmental contact or through participation in activities associated with increased or decreased risk.
- Used in COVID-19 Interim User Guide to represent data on travel, contacts, personal protective equipment, and exposure to animals
- This domain went through public review during the TB v2.0 TAUG public review. It also went through public review as part of SDTMIG v3.3 batch 3.
  - Held out from publication due to maturity concerns
    - Unclear if a single observation class (Events) is adequate to cover all use-cases
  - Publicly available on the CDISC Wiki



# Diagnostics and Virology



# Diagnostics and Virology Section Overview

- This section includes the following examples:
  - **Virus identification-** testing for the presence of SARS-CoV-2 in a subject sample
  - **Antibody Testing-** detection of IgG and IgM (terminology also exists for testing of SARS-Cov-2 IgA antibody)
  - **Viral load testing**
    - Quantification of SARS-CoV-2 RNA by quantitative PCR
    - Threshold Cycle value
- Sources of input
  - Published literature
  - Task Force member feedback
  - Prior examples from existing CDISC therapeutic-area user guides

# Virus Identification

- The example follows SDTMIG conventions (v3.2-3.3) by representing these data in the MB domain

USUBJID	MBSEQ	MBREFID	MBGPRID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC	MBLOC	MBMETHOD
ABC-01-601	1	60101	1	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	DETECTION	POSITIVE	POSITIVE	ENDOTRACHEAL FLUID		QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
ABC-01-722	2	72201	1	SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2	DETECTION	NEGATIVE	NEGATIVE	SWABBED MATERIAL	THROAT	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

- MBTEST/MBTESTCD represent the name of the virus
- Since we are only interested in detecting the presence of virus (versus quantifying it) MBTSTDTL=DETECTION
- Results are expressed as POSITIVE / NEGATIVE

# Antibody Testing

- As of SDTMIG v3.3, this concept is still represented in MB

DOMAIN	USUBJID	MBSEQ	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBSTRESC	MBSPEC
MB	COVID-ABC-011	1	13668	SAR2IGM	SARS-CoV-2 IgM Antibody	DETECTION	POSITIVE	POSITIVE	SERUM
MB	COVID-ABC-011	2	13668	SAR2IGG	SARS-CoV-2 IgG Antibody	DETECTION	NEGATIVE	NEGATIVE	SERUM
MB	COVID-ABC-022	1	23433	SAR2IGGM	SARS-CoV-2 IgG/IgM Antibody	DETECTION	POSITIVE	POSITIVE	SERUM

- Based on the 3 most common antibody detection tests: IgG, IgM, and combination IgG/IgM
- Since we are not quantifying antibodies, the modeling approach is similar to virus detection with regard to MBTEST, MBTSTDTL, and results of POSITIVE / NEGATIVE
- If the assay were designed quantify antibodies, we would use MBTSTDTL=QUANTIFICATION, with numeric results and appropriate units

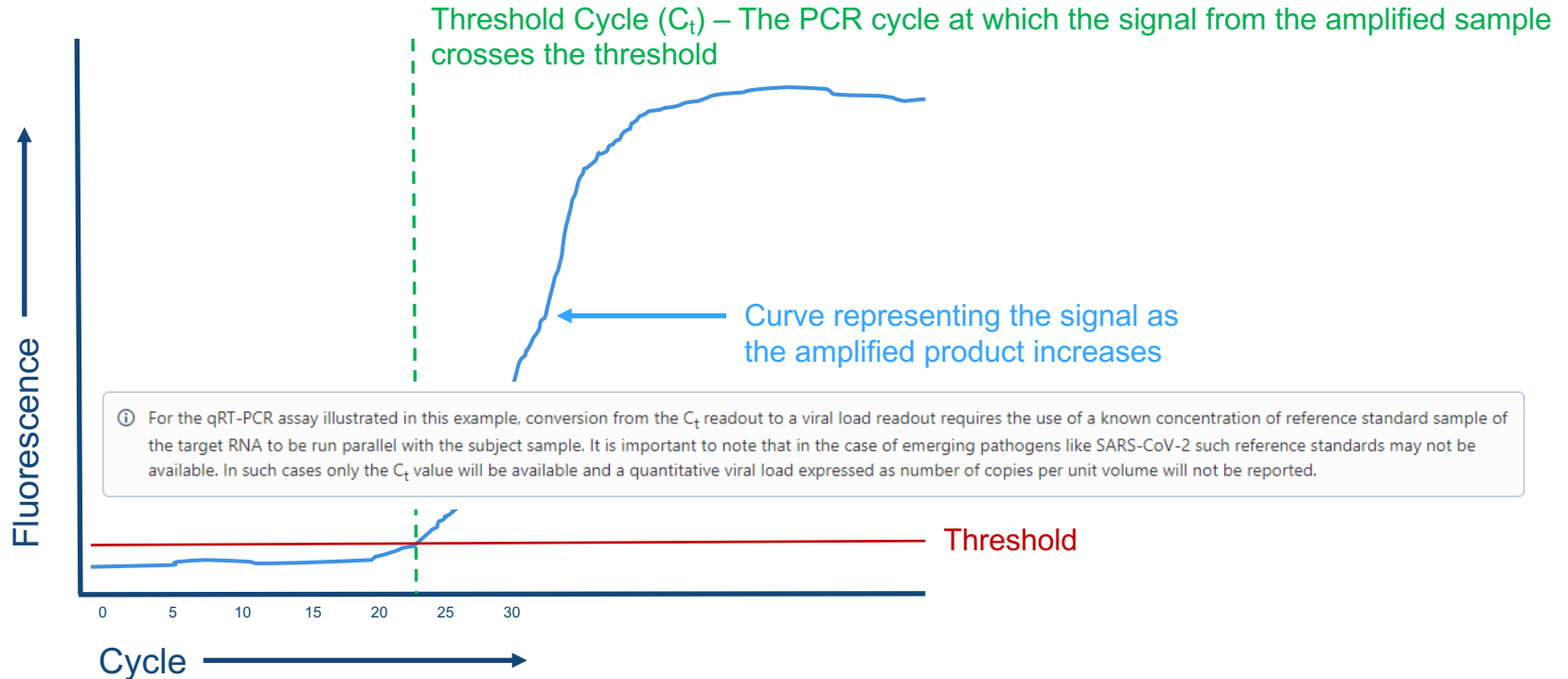


# Viral Load

MBGRPID	MBREFID	MBTESTCD	MBTEST	MBTSTDTL	MBORRES	MBORRESU	MBSTRESC	MBSTRESN	MBSTRESU	MBSPEC	MBMETHOD
1	001-02	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	3.9	log 10 copies/mL	3.9	3.9	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
1	001-02	SAR2RNA	SARS-CoV-2 RNA	THRESHOLD CYCLE	27.43		27.43	27.43		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
2	001-03	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	4.7	log 10 copies/mL	4.7	4.7	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
2	001-03	SAR2RNA	SARS-CoV-2 RNA	THRESHOLD CYCLE	23.11		23.11	23.11		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
3	001-04	SAR2RNA	SARS-CoV-2 RNA	VIRAL LOAD	4.5	log 10 copies/mL	4.5	4.5	log 10 copies/mL	SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
3	001-04	SAR2RNA	SARS-CoV-2 RNA	THRESHOLD CYCLE	23.22		23.22	23.22		SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
	001-05	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
	001-06	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION
	001-07	SAR2RNA	SARS-CoV-2 RNA		TARGET NOT DETECTED		TARGET NOT DETECTED			SPUTUM	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION

- The example follows one subject over 6 visits
- All records: MBTEST= SARS-CoV-2 RNA
- Test may quantify RNA (viral load) and/or Threshold Cycle; MBTSTDTL distinguishes these, and when both are present, GRPID is used to group both by subject-visit
- When SARS-CoV-2 RNA isn't detected in the subject sample, MBTSTDTL is null

# Quantitative Reverse-Transcriptase PCR (qRT-PCR)



# Summary

- All concepts represented in MB (LB is not appropriate for these concepts)
- Pay attention to the value of MBTSTDTL based on what the test is reporting
  - DETECTION, QUANTIFICATION, VIRAL LOAD, THRESHOLD CYCLE
- Always check controlled terminology. More controlled terminology exists than what is shown in the examples
  - SARS-CoV-2 IgA Antibody
  - “copies/mL” is also valid for viral load



# Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic



# Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic

- Listing of COVID-19 Related Impacts as Part of CSR
- Relationships to COVID-19
- Protocol Deviations
- Disposition
- Missed Visits
- Missed Assessments
- Changes to Drug Accountability
- Changes to Adverse Event Data Collection
- Changes in Exposure
- Transfer to Another Site
- Trial Summary to Provide Pandemic Relationship

GUIDANCE DOCUMENT

# FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency

*Guidance for Industry, Investigators, and Institutional Review Boards*

MARCH 2020

Download the Final Guidance Document

Final

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<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency>



# Multiple Approaches

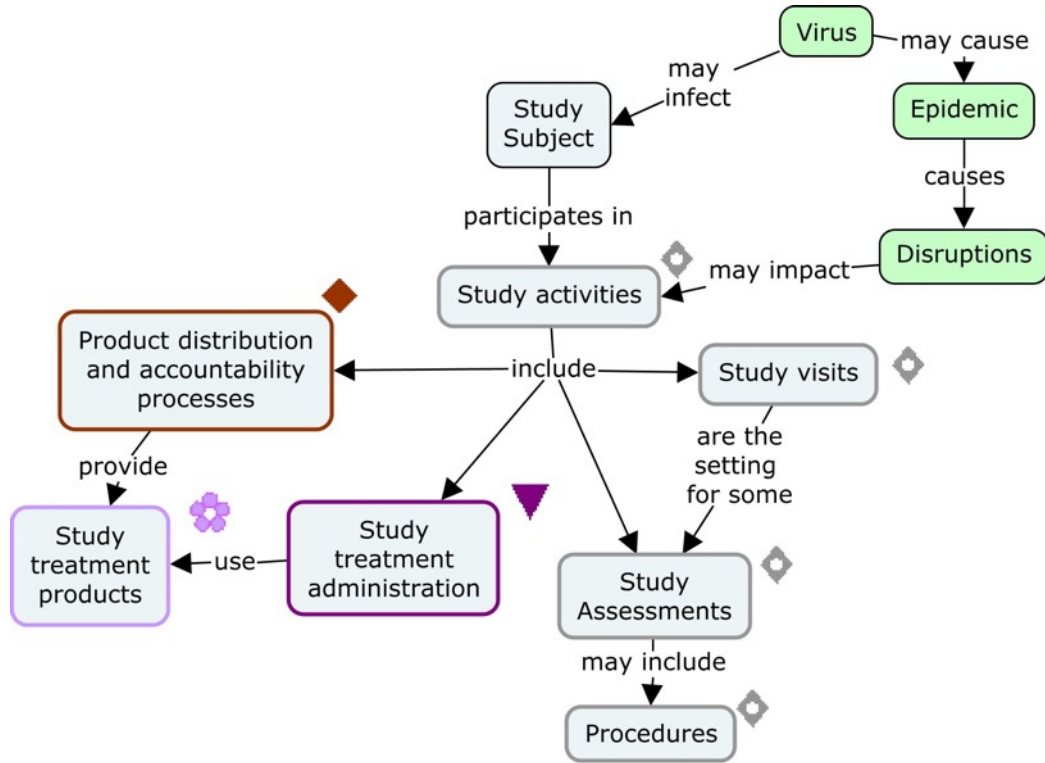
- It may not be possible to update case report forms (CRFs) for ongoing trials
- Collection of relevant information can be performed multiple ways
  - Key words such as "COVID-19" in existing text fields
  - Comments on the CRF
  - Documentation outside the regular CRF
- Instead of showing one way to model the data in SDTM, multiple options were shown
- Data about impacts of the epidemic, whether from CRFs or other sources, may be represented different ways
  - Standard SDTM variables,
  - Non-standard variables (NSVs),
  - Custom domains
  - Flag SDTM dataset records that document epidemic impacts using indicator NSVs



## Relationships to COVID-19



# Direct and Indirect Relationships to COVID-19



# Which study subjects contracted COVID-19?

- COVID-19 as an Adverse Event
  - Coding in MedDRA depends on MedDRA version
- Adverse Events related to COVID-19
  - Use non-standard variable (NSV) Epi/Pandemic Related Indicator
- What treatments were given for COVID-19?
  - Use existing standard variable Indication (--INDC)



# Possible Disruptions

- Scheduled activities missed
  - Missed visits
  - Missed assessments
  - Missed study drug treatments
- Scheduled activities modified
  - Remote visits and assessments
  - Assessments at an alternate facility
  - Remote study drug distribution and return
  - Changes in study drug administration
- Protocol Deviations
  - Subject-level deviations
  - Site-level deviations
- Early subject withdrawals
- Site shut-downs and subject transfers



# Why did these disruptions occur? Which reasons were related to COVID-19?

- Use “reason” variables
  - Standard variables such as Reason Not Done, Indication, Reason for Adjustment, Reason for Discontinuation, DSTERM in the Disposition Domain
  - Established non-standard variables such as Reason (e.g., for a protocol deviation), Reason for Occur Value (e.g., reason a treatment was not given), Reason for Interruption
  - New non-standard variables as needed
- If desired, use additional non-standard indicator variables to flag reasons that were related to COVID-19.

# Modifications to Scheduled Activities

- For activities originally scheduled as in-person, use NSV Contact Mode
  - For remote visits
  - For study treatment shipped directly to subjects
  - For data on amount of study treatment used collected by phone
- For tests and examination, use --NAM and--EVAL to record a different lab or a different evaluator



# Missed Visits

- May be recorded in existing Protocol Deviations domain
  - Missing an originally scheduled visit may not be a deviation under a later protocol amendment
  - NSV: Reason for Deviation
  - NSV: Epi/Pandemic Related Indicator
- Custom Visit Events domain can be used to record both visits that occurred and those that were missed.
  - NSV: Reason for Occur Value (i.e., reason visit did not occur)
  - NSV: Epi/Pandemic Related Indicator
  - NSV: Contact Mode



# Site-Level Protocol Deviations

- Identify subjects affected by the deviation
- Choose one of the following approaches
  - Record the deviation for each affected subject
  - Use POOLDEF to assign an identifier to the affected subjects as a pool, then record the deviation using POOLID



# Site Transfers

- Choose one of the following approaches:
  - Custom domain Site Transfers
  - Record site transfers in the Disposition domain using DSCAT of “OTHER EVENT”
- In either case, record the additional site as supplemental qualifier in the Demographics domain.





# Resources for Public Health Researchers



# Resources for Public Health Researchers

- Novel Coronavirus (nCoV) Acute Respiratory Infection Clinical Characterisation Data Tool
  - Developed by the World Health Organization (WHO) and the International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC)
  - Data tool is being used as the foundation for many COVID-19 research studies globally by more than 40 countries
- SDTM and CDASH Annotations and Excel Mapping File created by CDISC team published on CDISC website

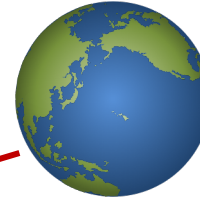
# WHO / ISARIC / IDDO Collaboration

International Severe Acute Respiratory  
emerging Infection Consortium



Infectious Diseases  
Data Observatory

# WHO / ISARIC / IDDO Collaboration

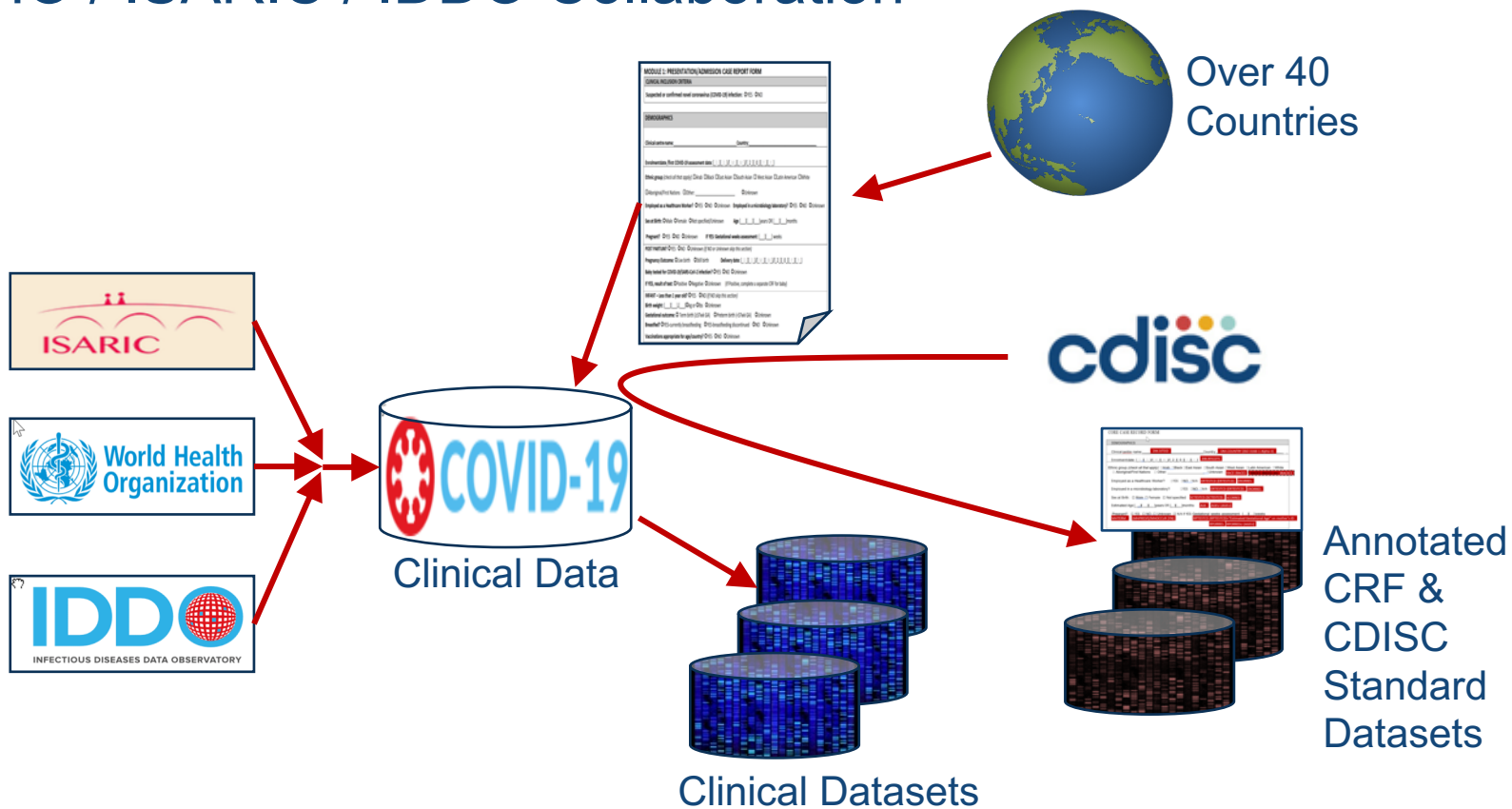


Over 40 Countries

A screenshot of a "COVID-19 PATIENT/CLINICIAN CASE REPORT FORM". The form contains various fields for patient information, including name, date of birth, gender, and clinical details like symptoms and test results. The text is small and partially illegible but clearly shows a structured data entry form.

Clinical Datasets

# WHO / ISARIC / IDDO Collaboration



# CDISC's Participation: Annotated CRFs

## CORE CASE RECORD FORM



DEMOGRAPHICS	
Clinical centre name:	DM.SITEID Country: DM.COUNTRY {ISO-3166-1 Alpha-3}
Enrolment date:	[ D ][ D ]/[ M ][ M ]/[ 2 ][ 0 ][ Y ][ Y ] DM.RFICDTC
Ethnic group (check all that apply):	<input type="checkbox"/> Arab <input type="checkbox"/> Black <input type="checkbox"/> East Asian <input type="checkbox"/> South Asian <input type="checkbox"/> West Asian <input type="checkbox"/> Latin American <input type="checkbox"/> White <input type="checkbox"/> Aboriginal/First Nations <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unknown RACE {RACE} RACE1, RACE2, etc. {RACEC}
Employed as a Healthcare Worker?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A ERTESTCD {ERTESTCD} ERORRES
Employed in a microbiology laboratory?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A ERTESTCD {ERTESTCD} ERORRES
Sex at Birth:	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Not specified SCTESTCD {SCTESTCD} SCORRES
Estimated Age	[ ][ ][ ] years OR [ ][ ][ ] months AGE AGEU {AGEU}
Pregnant?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Unknown <input type="checkbox"/> N/A If YES: Gestational weeks assessment: [ ][ ][ ] weeks MHTERM (MHPRESP)/MHOCCUR {YN} RPTTESTCD {RPTTESTCD}="Estimated Gestational Age" on mother's ID RPORRES RPORRESU {AGEU}

# CDISC's Participation: Annotated CRFs

## CORE CASE RECORD FORM



DM

DM

DEMOGRAPHICS	
Clinical centre name:	DM.SITEID Country: DM.COUNTRY {ISO-3166-1 Alpha-3}
Enrolment date:	[ D ][ D ]/[ M ][ M ]/[ 2 ][ 0 ][ Y ][ Y ] DM.RFICDTC
Ethnic group (check all that apply):	<input type="checkbox"/> Arab <input type="checkbox"/> Black <input type="checkbox"/> East Asian <input type="checkbox"/> South Asian <input type="checkbox"/> West Asian <input type="checkbox"/> Latin American <input type="checkbox"/> White <input type="checkbox"/> Aboriginal/First Nations <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unknown RACE {RACE} RACE1, RACE2, etc. {RACEC}
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Sex at Birth:	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Not specified SCTESTCD {SCTESTCD} SCORRES
Estimated Age	[ ][ ][ ]years OR [ ][ ][ ]months AGE AGEU {AGEU}
Pregnant?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> Unknown <input type="checkbox"/> N/A If YES: Gestational weeks assessment: [ ][ ][ ]weeks MHTERM (MHPRESP)/MHOCCUR {YN} RPTTESTCD {RPTTESTCD}="Estimated Gestational Age" on mother's ID RPORRES RPORRESU {AGEU}



# CDISC's Participation: Annotated CRFs

## CORE CASE RECORD FORM



ER  
SC  
MH/RP

DEMOGRAPHICS	
Clinical centre name:	DM.SITEID Country: DM.COUNTRY {ISO-3166-1 Alpha-3}
Enrolment date:	[ D ][ D ][ / ][ M ][ M ][ / ][ 2 ][ 0 ][ Y ][ Y ] DM.RFICDTC
Ethnic group (check all that apply):	<input type="checkbox"/> Arab <input type="checkbox"/> Black <input type="checkbox"/> East Asian <input type="checkbox"/> South Asian <input type="checkbox"/> West Asian <input type="checkbox"/> Latin American <input type="checkbox"/> White <input type="checkbox"/> Aboriginal/First Nations <input type="checkbox"/> Other: _____ <input type="checkbox"/> Unknown RACE {RACE} RACE1, RACE2, etc. {RACEC}
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Employed in a microbiology laboratory?	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A ERTESTCD {ERTESTCD} ERORRES
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Estimated Age	[ ][ ][ ] years OR [ ][ ][ ] months AGE AGEU {AGEU}
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# CDISC's Participation: Mapping Spreadsheet

	B	C	D	E	F
	Domain	SDTM Variable	Value	CDASH Variable If Different from SDTM	Notes
1					
8					
9	DM	RACE		CRACE	While this item indicates that ethnic group is collected, the concept described most closely matches RACE in CDISC. The RACEs listed on the CRF do not correspond to CDISC RACE codelist. Capture in CRACE using the RACE CT and map into SDTM RACE as needed.
10	SUPP.DM	RACEOTH			
11					
12	ER	ERTERM	EMPLOYED AS A HEALTHCARE WORKER		
13	ER	ERPRES	Y		
14	ER	EROCCUR	Y; N; NA		
15	ER	ERCAT	COVID-19 RISK FACTOR		
16					
22	SC	SCTESTCD	SEXRBRTH		
23	SC	SCTEST	Sex Reported at Birth		
24	SC	SCORRES	M; F; U		"U" corresponds to "Not Specified" on the CRF
25					
26	DM	AGE			
27	DM	AGEU	YEARS; MONTHS		

# Outcomes



Twelve annotated CRF pages  
Mapping file with 950 variables, associated metadata, implementation recommendations and CDASH equivalent variables



Most concepts mapped with minimal adjustment  
A few concepts required non-standard variables or new modeling



CRFs and mapping file facilitate production of SDTM tables for combination with data from other sources  
Perhaps future efforts can be designed to align a little more closely



# Controlled Terminology for CDISC COVID-19 Guidance

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist,  
MSC Inc. and NCI-EVS [c]

05.06.2020

The CDISC logo consists of the word "cdisc" in a bold, blue, lowercase sans-serif font. Above the letters "i", "d", and "c" are three small colored dots: a red dot above the "i", a yellow dot above the "d", and a teal dot above the "c".

cdisc



# Agenda

1. Publication timeline
2. COVID-19 (Package 41a) Publication Release (2020-05-08)
3. Questions



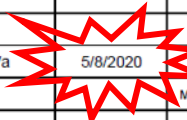
# Controlled Terminology COVID-19 Package 41a Publication

2020-05-08

# Controlled Terminology Publication Schedule

CDISC 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			
39	6/14/2019	6/21/2019	7/19/2019	8/16/2019	9/27/2019	Devices	ECG	General	Lab
39						Microbiology	Oncology	PK	Protocol Entities
39						SDTM Domain	SEND	SEND-AR	Unit
40	9/13/2019	9/20/2019	10/18/2019	11/8/2019	12/20/2019	ADaM	Define-XML	Device	General
40						CDISC Glossary	Lab	Microbiology	Oncology
40						PK	Protocol Entities	QRS	SDTM Domain
40						SEND	Spectype Speccond	Unit	
41	12/13/2019	12/20/2019	1/17/2020	2/14/2020	3/27/2020	ADaM	Define-XML	Device	ECG
41						General	Lab	Microbiology	Oncology
41						PK	Protocol Entities	QRS	SDTM Domain
41						SEND	Spectype Speccond	Unit	
41a	4/20/2020	n/a	n/a	n/a	5/8/2020	CDASH	CDISC Glossary	General	Lab
41a						Microbiology	PK	QRS	Spectype Speccond
41a						Unit			
42	3/13/2020	3/20/2020	4/17/2020	5/15/2020	6/26/2020	ADaM	Define-XML	Device	General
42						Lab	Microbiology	Oncology	PK
42						Protocol Entities	QRS	SEND	Unit
43	6/12/2020	6/19/2020	7/17/2020	8/14/2020	9/25/2020				
43									
43									
44	9/11/2020	9/18/2020	10/16/2020	11/13/2020	12/18/2020				
44									
44									







# Agenda

1. Publication timeline
2. COVID-19 (Package 41a) Publication Release (2020-05-08)
3. Questions

# Controlled Terminology Package 41a Publication Release

- Updates to SDTM, SEND, CDASH, and CDISC Glossary Terminology
- CDISC CT Version Date: 2020-05-08
- Therapeutic Area Support:
  - QRS Terminology to support: COVID-19 Therapeutic Area User Guide.
  - SDTM/CDASH/Glossary Terminology to support: COVID-19 Therapeutic Area User Guide.

# Controlled Terminology Package 41a Publication Release

- General Terminology Team:
  - New Terms Added to Existing Codelists:
    - PROCEDUR; RETEST-CD; SCTEST-CD; TSPARM-CD; VSTEST-CD; RACEC
  - 4 New Codelists:
    - Health Care Encounters Dictionary Derived Term (HODECOD)
    - Mode of Subject Contact (CNTMODE)
    - COVID-19 Findings About Test Name (C19FAT)
    - COVID-19 Findings About Test Code (C19FATCD)
  - No changes to published terms

# Controlled Terminology Package 41a Publication Release

- CDISC Glossary Team
  - 8 additions to the CDISC Glossary:
    - epidemic
    - pandemic
    - endemic disease
    - immediately life-threatening disease or condition
    - medical countermeasure
    - morbidity rate
    - mortality rate
    - pre-approval access

# Controlled Terminology Package 41a Publication Release

- CDISC CDASH Terminology
  - New Terms Added to Existing Codelists: **Race As Collected (RACEC)**
  - To support the WHO ISARIC CRF annotation

# Controlled Terminology Package 41a Publication Release

- Laboratory Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST-CD; METHOD; CLMETH; SPECTYPE
  - 4 changes to published terms:
    - FIO2/Fraction of Inspired Oxygen: Definition updated to better differentiate this term from FIO2/PAO2
    - PO2/Partial Pressure Oxygen: Synonyms added
- Units of Measure
  - 2 changes to published terms
    - mL/24h added as a synonym to C67410/mL/day in the UNIT and PKUNIT codelists – to support the WHO ISARIC CRF annotation

# Controlled Terminology Package 41a Publication Release

- Microbiology Terminology Team
  - New Terms Added to Existing Codelists:
    - MICROORG; MBTEST-CD

## MBTESTCD

## MBTEST

SARSCOV2	Severe Acute Resp Syndrome Coronavirus 2
SAR2IGG	SARS-CoV-2 IgG Antibody
SAR2IGM	SARS-CoV-2 IgM Antibody
SAR2IGA	SARS-CoV-2 IgA Antibody
SAR2IGGM	SARS-CoV-2 IgG/IgM Antibody
MERSRNA	MERS-CoV RNA
SAR2RNA	SARS-CoV-2 RNA
RSV	Respiratory Syncytial Virus
ADENOVIR	Adenoviridae
CRONAVIR	Coronaviridae
MERSRNA	MERS-CoV RNA
SAR2RNA	SARS-CoV-2 RNA

# Controlled Terminology Package 41a Publication Release

- Microbiology Terminology Team
  - 2 changes to 1 existing term
    - MICROORG: CDISC Submission value of SARS CORONAVIRUS updated to SEVERE ACUTE RESPIRATORY SYNDROME-RELATED CORONAVIRUS. Also 'SARS-CoV' added as a synonym to this term.
  - New terms from P42 being published early with this package:
    - MICROORG: SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2
    - MBTEST/CD: Severe Acute Resp Syndrome Coronavirus 2/SARSCOV2



# QRS Controlled Terminology Package 41a Publication Release

- New Codelists:
  - **Clinical Classification (RS)**
    - National Early Warning Score 2 (NEWS2)
    - Richmond Agitation-Sedation Scale (RASS)
    - Riker Sedation-Agitation Scale (SAS)

# Controlled Terminology Package 41a Publication Release

- SEND Terminology Team
  - New Terms Added to Existing Codelists:
    - LBTEST/CD; VSTEST/CD
  - 6 changes to existing terms -> LBTEST/CD, UNIT, PKUNIT as described previously

\*Because SEND makes use of some SDTM terminology, SEND Terminology will also be updated with this package release to reflect changes in shared codelists.



# P41a Codetable Updates

- Updates with P41a
  - RACEC\_ETHNICC\_Mapping
  - SC\_Codetable\_Mapping
  - TS\_Codetable\_Mapping
  - VS\_Codetable\_Mapping
  - Unit-UCUM\_Codetable

# Controlled Terminology Package 41a Publication

No Additions or Changes being proposed by the following codelist-associated teams:

- ADaM Team
- Define-XML Team
- Medical Devices Team
- ECG Terminology Team
- Oncology Terminology Team
- CDISC PGx Terminology Team
- Protocol Entities Terminology Team



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

Erin Muhlbradt, [muhlbradtee@mail.nih.gov](mailto:muhlbradtee@mail.nih.gov)  
Dana Booth, [dbooth@cdisc.org](mailto:dbooth@cdisc.org)

CDISC New term request form:  
<https://ncitermform.nci.nih.gov/ncitermform/?version=cdisc>





# Q&A

# Audience Questions



How do we apply the guidelines if we are using SDTM 3.2 for a study?

# Audience Questions

Use of non-standard variables to flag COVID. What is recommendation: SDTM/ADaM? FDA preference (i.e. need for SDTM)?





# Audience Questions



Will there be a distinction between acquiring the illness and the restrictions on travel, i.e. for protocol deviations?

# Audience Questions

Will you have CRF examples in this TAUG? And did you map the CDC Covid Person Under Investigation CRF to CDASH and SDTM?



# Audience Questions



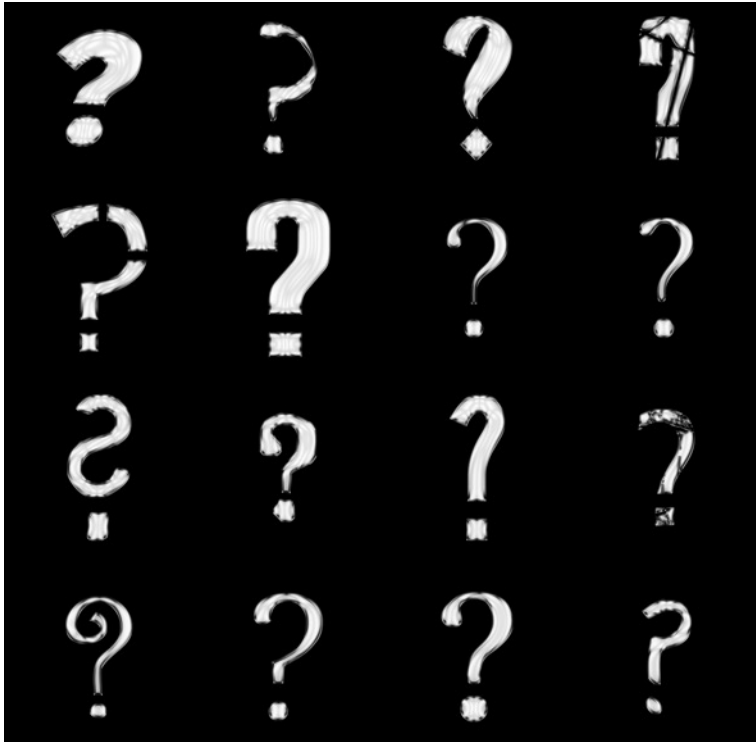
When will the NEWS2 supplement be available?

# Audience Questions

What's the most suitable domain to map Antibody information between IS and MB?



# Audience Questions



NSV will be captured in SUPPxx domain and not in parent domain, correct?

# Audience Questions

Should we capture non-standard indicator variables onto Supplementary dataset or it will be added into main SDTM domains?





# Audience Questions



Diane - What was the rationale behind suggesting the use of a custom dataset VE (Visit Events)? The visit events are already mapped in the appropriate SV dataset. The additional findings about these visits (such as occurrence, contact mode) can perfectly be mapped into the FA (Findings About Events or Interventions) dataset.

# Audience Questions

@Diane: It seems to me that the custom Visit Events domain would be useful to have routinely, not just in disrupted studies. Will the SDTM team consider adding this to the SDTMIG?





# Audience Questions



Diane - Is there any guidance on reporting COVID-19 related deviations which are no longer a deviation following an emergency protocol amendment. These should also be reported to FDA.

# Audience Questions

At page #44 of presentation, why is 'sex at birth' annotated for SC domain instead of DM domain?



# Audience Questions



Do the Non std vars reside in parent domains? If yes, can you give an example? Thanks.

# Audience Questions

What was the rationale behind mapping some information to NSV and others SUPPQUAL in the Interim User Guide for COVID-19?



# Audience Questions



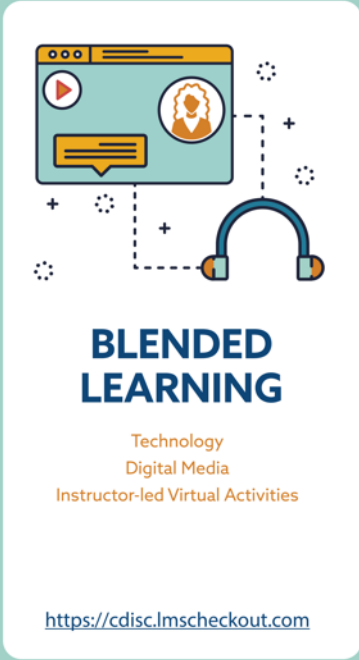
Erin: Will Package 41a be a comprehensive, or incremental to just covered COVID-19 specific codelists & terms?



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China	29 May - 3 July	Weekly	Mandarin

\*Includes 19 modules & weekly Q&A sessions

CDASH Blended Learning**			
	Duration	Live Q&A	Language
Americas	26 May - 9 June	Weekly	English
Europe	27 May - 10 June	Weekly	English
Japan	28 May - 11 June	Weekly	Japanese
China	29 May - 12 June	Weekly	Mandarin

\*\*Includes eight modules & weekly Q&A sessions



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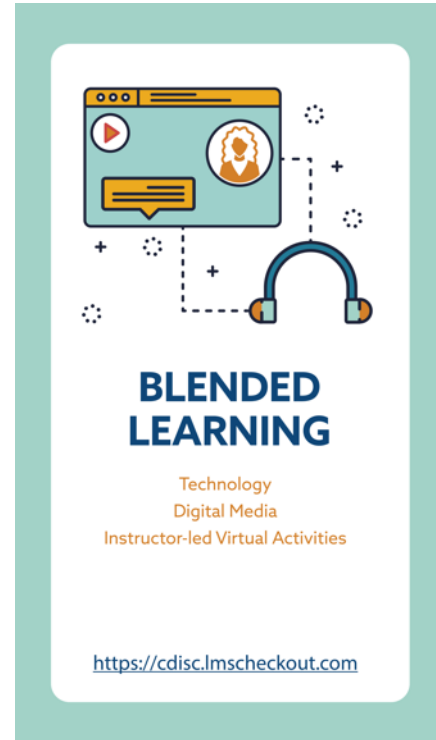
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7 JUL 2020	Controlled Terminology Updates for Q3
13 OCT 2020	Controlled Terminology Updates for Q4



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THU 14 MAY 2020

11:00 AM - 12:30 PM Eastern US Standard Time

## Presenters:

Saad Yousef, Senior Manager, Education Operations, CDISC



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### Presenters:

Sam Hume, VP of Data Science, CDISC

Anthony Chow, Director of Data Science, CDISC



The graphic features a central illustration with a lightbulb, a document icon, a person icon, and a speech bubble, all connected by dashed lines and plus signs. Below the illustration, the text reads 'CDISC WEBINARS' in large blue letters, followed by 'Technology', 'Digital Media', and 'Great Ideas!' in smaller orange text. At the bottom, the CDISC logo is displayed, and the URL 'www.cdisc.org/events/education/webinars' is provided.

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