CDISC Response to COVID-19

Bess LeRoy, CDISC
Agenda

1. COVID-19 Project Overview
2. What are the COVID-19 Materials?
3. How Did We Do It?
4. Lessons Learned – Pros and Cons
5. Impact Report
6. Next Steps
COVID-19 Project Overview
CDISC COVID-19 Project Overview

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)

Three sets of documents published on CDISC Website on 21 April 2020
  - CDISC Interim User Guide for COVID-19
  - Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic
  - Resources for Public Health Researchers

COVID-19 Controlled Terminology posted 08 May 2020 – an additional publication from NCI-EVS
  - https://www.cdisc.org/standards/therapeutic-areas/covid-19

What are the COVID-19 Materials?
What is included in the COVID-19 materials produced by CDISC?

- COVID-19 Interim User Guide
- COVID-19 Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic
- Resources for Public Health Researchers

→ Focus on CDASH and SDTM
COVID-19 Interim User Guide Topics

- 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

→ Substantial content covered
Example from COVID-19 Interim User Guide

### 6.1 Virus Identification

Identification of viruses from a collected sample is represented in the Microbiology Specimen (MB) domain.

**Example 1**

This example shows the results of tests to detect SARS-CoV-2, the virus that causes COVID-19, in 2 different subjects.

**Row 1:** Shows a subject who tested positive for SARS-CoV-2 by quantitative reverse transcriptase polymerase chain reaction (PCR) of an endotracheal fluid specimen.

**Row 2:** Shows a subject who tested negative for SARS-CoV-2 by quantitative reverse transcriptase PCR of a throat swab specimen.

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>MBSEQ</th>
<th>MBREFID</th>
<th>MBGPRID</th>
<th>MBTESTDC</th>
<th>MBTEST</th>
<th>MBTSTDL</th>
<th>MBORRES</th>
<th>MBSTRESC</th>
<th>MBSPEC</th>
<th>MBLOC</th>
<th>MBMETHOD</th>
<th>VISITNUM</th>
<th>VISIT</th>
<th>MBDTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ABC</td>
<td>MB</td>
<td>ABC-01-601</td>
<td>1</td>
<td>60101</td>
<td>1</td>
<td>SARS-CoV2</td>
<td>Severe Acute Resp Syndrome Coronavirus 2</td>
<td>DETECTION</td>
<td>POSITIVE</td>
<td>POSITIVE</td>
<td>ENDOTRACHEAL FLUID</td>
<td>QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION</td>
<td>1</td>
<td>SCREENING</td>
<td>2020-03-27T14:15</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>ABC</td>
<td>MB</td>
<td>ABC-01-722</td>
<td>2</td>
<td>72201</td>
<td>1</td>
<td>SARS-CoV2</td>
<td>Severe Acute Resp Syndrome Coronavirus 2</td>
<td>DETECTION</td>
<td>NEGATIVE</td>
<td>NEGATIVE</td>
<td>SWABBED MATERIAL</td>
<td>QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION</td>
<td>1</td>
<td>SCREENING</td>
<td>2011-04-01T10:00</td>
<td></td>
</tr>
</tbody>
</table>
Guidance for Ongoing Studies Disrupted by the COVID-19 Pandemic

- Developed by a separate team, but worked on the same wiki space for transparency
  - 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
Example from Ongoing Studies Disrupted by COVID-19

4 Protocol Deviations

COVID-19 disruptions may lead to protocol deviations at the site level. The SDTMIG DV domain represents deviations at the subject level, but does not provide a mechanism for representing deviations using a site identifier. In addition, a deviation at the site level might not affect all subjects at that site (e.g., subjects who have completed the study, future subjects). A site-level deviation can be represented in DV in 2 ways, as illustrated by the following examples.

Example 1

In this example, when a protocol deviation that affected subjects occurred at a site, the sponsor determined which subjects were affected by the deviation and recorded the deviation for each subject at the site. The sponsor used DVCAT = “SITE DEVIATION” to identify site-level deviations.

Rows 1, 2, 4, 8: Show subjects who were affected by a site shutdown due to a flooded basement, a problem not related to COVID-19.
Rows 3, 5-7, 9: Show subjects were affected when all transportation in the country was down due to COVID-19.

dv.rpt

<table>
<thead>
<tr>
<th>Row</th>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>USUBJID</th>
<th>DVSEQ</th>
<th>DVREDID</th>
<th>DVSPID</th>
<th>DVTERM</th>
<th>DVDECOD</th>
<th>DVCAT</th>
<th>DVSCAT</th>
<th>EPOCH</th>
<th>DVSTDTC</th>
<th>DVENDTC</th>
<th>DVREAS</th>
<th>DVPRELI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>CVD-3</td>
<td>DV</td>
<td>300</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SITE shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>Flooded basement</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>CVD-3</td>
<td>DV</td>
<td>301</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>SITE shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>Flooded basement</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>CVD-3</td>
<td>DV</td>
<td>302</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>All transportation in country down due to COVID-19</td>
<td>Y</td>
</tr>
<tr>
<td>4</td>
<td>CVD-3</td>
<td>DV</td>
<td>303</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>Flooded basement</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>CVD-3</td>
<td>DV</td>
<td>306</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>All transportation in country down due to COVID-19</td>
<td>Y</td>
</tr>
<tr>
<td>6</td>
<td>CVD-3</td>
<td>DV</td>
<td>307</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>All transportation in country down due to COVID-19</td>
<td>Y</td>
</tr>
<tr>
<td>7</td>
<td>CVD-3</td>
<td>DV</td>
<td>309</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>All transportation in country down due to COVID-19</td>
<td>Y</td>
</tr>
<tr>
<td>8</td>
<td>CVD-3</td>
<td>DV</td>
<td>312</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>All transportation in country down due to COVID-19</td>
<td>Y</td>
</tr>
<tr>
<td>9</td>
<td>CVD-3</td>
<td>DV</td>
<td>312</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Site shut down</td>
<td>SITE DEVIATION</td>
<td>TREATMENT</td>
<td>2020-02-17</td>
<td>2020-02-20</td>
<td>All transportation in country down due to COVID-19</td>
<td>Y</td>
</tr>
</tbody>
</table>

DV NSV Metadata

<table>
<thead>
<tr>
<th>Variable</th>
<th>Label</th>
<th>Type</th>
<th>CodeList</th>
<th>Role</th>
<th>Origin</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVREAS</td>
<td>Reason for Deviation</td>
<td>text</td>
<td>DVCODES</td>
<td>Non-standard Record Qualifier</td>
<td>CRF</td>
<td>DVCODES is a sponsor-defined code list.</td>
</tr>
<tr>
<td>DVPRELI</td>
<td>Epipandemic Related Indicator</td>
<td>text</td>
<td>NY</td>
<td>Non-standard Record Qualifier</td>
<td>CRF</td>
<td></td>
</tr>
</tbody>
</table>

cdisc
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
# CORE CASE RECORD FORM

## DEMOGRAPHICS

<table>
<thead>
<tr>
<th>Clinical centre name:</th>
<th>DM.SITEID</th>
<th>Country: DM.COUNTRY (ISO-3166-1 Alpha-3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolment date:</td>
<td>DM.RFICDTC</td>
<td></td>
</tr>
<tr>
<td>Ethnic group (check all that apply):</td>
<td>Arab ☐ Black ☐ East Asian ☐ South Asian ☐ West Asian ☐ Latin American ☐ White ☐ Aboriginal/First Nations ☐ Other: Unknown ☐ RACE (RACE) ☐ RACE1, RACE2, etc (RACEC)</td>
<td></td>
</tr>
<tr>
<td>Employed as a Healthcare Worker?</td>
<td>YES ☐ NO ☐ N/A ERTESTCD (ERTESTCD) ERORRES</td>
<td></td>
</tr>
<tr>
<td>Employed in a microbiology laboratory?</td>
<td>YES ☐ NO ☐ N/A ERTESTCD (ERTESTCD) ERORRES</td>
<td></td>
</tr>
<tr>
<td>Sex at Birth:</td>
<td>Male ☐ Female ☐ Not specified SCTESTCD (SCTESTCD) SCORRES</td>
<td></td>
</tr>
<tr>
<td>Estimated Age [<strong>][</strong>][<strong>] years OR [</strong>][__] months</td>
<td>AGE AGEU (AGEU)</td>
<td></td>
</tr>
<tr>
<td>Pregnant?</td>
<td>YES ☐ NO ☐ Unknown ☐ N/A If YES: Gestational weeks assessment: [<strong>][</strong>] weeks MHTERM (MHPRESP)/MHOCUR (NY) RTESTCD (RTESTCD) = “Estimated Gestational Age” on mother’s ID RPORRES RPORRESU (AGEU)</td>
<td></td>
</tr>
</tbody>
</table>
# ISARIC/WHO Core CRF Excel Mapping File

<table>
<thead>
<tr>
<th>CRF Item</th>
<th>Domain</th>
<th>SDTM Variable</th>
<th>SDTM Value</th>
<th>CDASH Variable if Different from SDTM</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was pathogen testing done during this illness episode?</td>
<td>MBTESTCD</td>
<td>MBALL</td>
<td>MBPERF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBTEST</td>
<td>Microbiology Data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBORRES Y</td>
<td></td>
<td></td>
<td></td>
<td>If MBPERF is yes, question not mapped; proceed to subsequent questions</td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td></td>
<td></td>
<td></td>
<td>If MBORRES is no, MAP test, set MBSTAT=NOT DONE</td>
<td></td>
</tr>
<tr>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
<td>DO NOT MAP</td>
<td></td>
</tr>
</tbody>
</table>

### Influenza

<table>
<thead>
<tr>
<th>CRF Item</th>
<th>Domain</th>
<th>SDTM Variable</th>
<th>SDTM Value</th>
<th>CDASH Variable if Different from SDTM</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBTESTCD</td>
<td>HASENI</td>
<td>HAS</td>
<td>HAEN2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBTEST</td>
<td>HAemophilus influenzae</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBORRES POSITIVE</td>
<td></td>
<td></td>
<td></td>
<td>Corresponds to result of &quot;YES Confirmed&quot; on CRF</td>
<td></td>
</tr>
<tr>
<td>MBORRES PRESUMPTIVE</td>
<td></td>
<td></td>
<td></td>
<td>Corresponds to result of &quot;YES Probable&quot; on CRF</td>
<td></td>
</tr>
<tr>
<td>MBORRES NEGATIVE</td>
<td></td>
<td></td>
<td></td>
<td>Corresponds to result of &quot;No&quot; on CRF</td>
<td></td>
</tr>
</tbody>
</table>

#### If yes Influenza:

<table>
<thead>
<tr>
<th>CRF Item</th>
<th>Domain</th>
<th>SDTM Variable</th>
<th>SDTM Value</th>
<th>CDASH Variable if Different from SDTM</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBTESTCD</td>
<td>MICORG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBTEST</td>
<td>Microbial Organism Identification</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBORRES INF1N2</td>
<td></td>
<td></td>
<td></td>
<td>New term request for microorganism codelet</td>
<td></td>
</tr>
<tr>
<td>INF1N1 2009</td>
<td></td>
<td></td>
<td></td>
<td>New term request for microorganism codelet, existing term doesn’t differentiate 2009 from other H1N1s. Note: CRF read “A/H1N1/09/”</td>
<td></td>
</tr>
<tr>
<td>INF1N9</td>
<td></td>
<td></td>
<td></td>
<td>Term already exists</td>
<td></td>
</tr>
<tr>
<td>INF1N1</td>
<td></td>
<td></td>
<td></td>
<td>Term already exists</td>
<td></td>
</tr>
<tr>
<td>INF1N2</td>
<td></td>
<td></td>
<td></td>
<td>Term already exists</td>
<td></td>
</tr>
<tr>
<td>INF1N9</td>
<td></td>
<td></td>
<td></td>
<td>Term already exists</td>
<td></td>
</tr>
<tr>
<td>INF1N1</td>
<td></td>
<td></td>
<td></td>
<td>Term already exists</td>
<td></td>
</tr>
<tr>
<td>[Other specified influenza type]</td>
<td></td>
<td></td>
<td></td>
<td>See microorganism codelet. If specific term not available, new terminology would have to be requested</td>
<td></td>
</tr>
</tbody>
</table>

### Coronavirus

<table>
<thead>
<tr>
<th>CRF Item</th>
<th>Domain</th>
<th>SDTM Variable</th>
<th>SDTM Value</th>
<th>CDASH Variable if Different from SDTM</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBTESTCD</td>
<td>CRONAVIR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBTEST</td>
<td>Coronavirus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBORRES POSITIVE</td>
<td></td>
<td></td>
<td></td>
<td>Corresponds to result of &quot;YES Confirmed&quot; on CRF</td>
<td></td>
</tr>
<tr>
<td>MBORRES PRESUMPTIVE</td>
<td></td>
<td></td>
<td></td>
<td>Corresponds to result of &quot;YES Probable&quot; on CRF</td>
<td></td>
</tr>
<tr>
<td>MBORRES NEGATIVE</td>
<td></td>
<td></td>
<td></td>
<td>Corresponds to result of &quot;No&quot; on CRF</td>
<td></td>
</tr>
</tbody>
</table>

#### If yes Coronavirus:

<table>
<thead>
<tr>
<th>CRF Item</th>
<th>Domain</th>
<th>SDTM Variable</th>
<th>SDTM Value</th>
<th>CDASH Variable if Different from SDTM</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBTESTCD</td>
<td>MICORG</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBTEST</td>
<td>Microbial Organism Identification</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBORRES SARS-CoV-2</td>
<td></td>
<td></td>
<td></td>
<td>SARS-CoV-2 is currently under review in CT v2. Note the CRF says &quot;Novel CoV&quot;.</td>
<td></td>
</tr>
<tr>
<td>MERS-CoV</td>
<td></td>
<td></td>
<td></td>
<td>MERS-CoV would have to be a new term request for Microorganism Codelet</td>
<td></td>
</tr>
<tr>
<td>[Other specified CoV]</td>
<td></td>
<td></td>
<td></td>
<td>Terminology would have to be requested</td>
<td></td>
</tr>
</tbody>
</table>

### RSV

<table>
<thead>
<tr>
<th>CRF Item</th>
<th>Domain</th>
<th>SDTM Variable</th>
<th>SDTM Value</th>
<th>CDASH Variable if Different from SDTM</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBTESTCD</td>
<td>RSV</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBTEST</td>
<td>Respiratory Syncytial Virus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBORRES SARS-CoV-2</td>
<td></td>
<td></td>
<td></td>
<td>CRF doesn’t specify antigen/antibody/TNA</td>
<td></td>
</tr>
<tr>
<td>MBORRES MERS-CoV</td>
<td></td>
<td></td>
<td></td>
<td>CRF doesn’t specify antigen/antibody/TNA</td>
<td></td>
</tr>
<tr>
<td>MBORRES DETECTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
How Did We Do It?
To Action!
Dedicated CDISC Development Team

- CDISC Leadership made the decision to dedicate staff 100% to the development
- Small group of CDISC standards staff
  - Created examples
  - Compiled existing content, modified for COVID-19
  - Daily stand-up meeting at the end of each work day
  - Evening and weekend work
Convened a Focused Group of Volunteers

**Responsible for:**

- Scoping
- Sharing sample CRFs
- Being Dedicated Reviewers
  - Posted new content on a daily basis – asked for feedback within 3 days
  - Wiki was open and transparent

- Initial plan to create one guide for both COVID-19 Studies and Impacts to Ongoing Studies, but quickly realized they needed to be two distinct publications

- Two sets of Volunteer SMEs
  - COVID-19 Interim Guide – volunteers conducting or planning COVID-19 studies
  - Guide for Ongoing Studies – volunteers mainly from existing Foundational Teams
Lessons Learned – Pros and Cons
Lessons Learned - Pros

• Can be **flexible** to address rapidly changing public health emergencies

• Can develop draft standards quickly with **dedicated and focused** developers

• Can **release** draft standards **quickly** for implementation

• Not needing to achieve **consensus** allows more rapid development and publication

• Communication turn-around in a **small, dedicated** team is very efficient

• Very **focused** development

• People are **altruistic** and wanted to help
Lessons Learned - Cons

• Scoping is very rapid, so **key concepts** may not be considered

• Difficult to develop an **“end-to-end”** standard (for example, ADaM concepts not developed due to compressed timeline)

• Not a fully consensus-based standard due to lack of **Public Review**
  • Not enough time for regulatory feedback
  • Has led to inconsistencies between guidance and standards

• Role for **volunteers** is limited

• Development is primarily done by **paid staff**

• Work on other projects is **halted**

• Overtime/weekend work - **unrealistic workload**, not sustainable over a long period of time
Impact Report
COVID-19 RESOURCES IMPACT REPORT

The CDISC community developed a package of resources to help researchers structure data in response to the COVID-19 global pandemic.

CDISC surveyed our stakeholders to learn how they are using these resources to drive more efficient and meaningful research.

Usage by Resource Type*

- Disrupted Studies Resources: 50%
- Annotated Case Report Form: 10%
- Interim User Guide: 49%

*Some are utilizing more than one resource
Community Awareness

- First Heard of These Resources
  - Via CDISC Email: 39%
  - CDISC Website: 41%
  - Word of Mouth: 7%
  - Other: 13%

- Overall Awareness of Resources
  - Not Aware: 17%
  - Aware: 83%

User Satisfaction

- 47% Extremely Satisfied
- 44% Satisfied
- 7% Neutral
- 2% Moderately Dissatisfied

Overall Satisfaction: 91%
Next Steps
Finalizing the COVID-19 Materials

• Posting both the Interim User Guide and Guidance for Ongoing Studies for Public Review

• Address inconsistencies with the FDA’s Technical Conformance Guide for Missed and Modified Visits due to the COVID-19 Pandemic
• Modifications to the existing SV domain to include visits that do not occur

• Addition of new variables to SV domain

3. CDISC Document: Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic

It is the current preference of the Agency that for all clinical studies, not limited to those impacted by COVID-19, subject visit data for scheduled (whether or not they occurred), and unscheduled visits be submitted in one single dataset structured as the current CDISC Subject Visits (SV) domain. It is also Agency preference that three non-standard variables (NSVs) for missed visits, --REASON (Reason for Occur Value), --EPCHGI (Epi/Pandemic Related Change Indicator), and --CNTEOD (Contact Mode), outlined in the CDISC document “Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic” be included within the SV domain and not within the supplemental SUPPSV domain or in other SDTM datasets. Submitting subject visits information in one single structured dataset allows both the human and technology consumer of this information to operate efficiently and with confidence that all visit data are considered during regulatory review.

As always, consult with the relevant FDA review division for the best approach in a specific application. Further updates to Agency thinking regarding how to submit data for studies that may have been impacted by the COVID-19 pandemic will be posted in updates to the Study Data Technical Conformance Guide.
CDISC ADaM Guidance

- The ADaM team has proposed developing CDISC ADaM guidance for ongoing studies disrupted by the COVID-19 pandemic

- Volunteer driven with support from CDISC (e.g., wiki, publishing, and high-level oversight)
  - Request for volunteers
    - Original COVID-19 Task Force
    - All ADaM volunteers
  - ADaM Leadership Team support
  - FDA support (4 FDA participants)

- Builds from the previously published "CDISC Guidance for Ongoing Studies Disrupted by COVID-19 Pandemic" document

- Work expected to be complete by the end of October
Thank You!