# CDISC Public Webinar- Clostridium Difficile Associated Diarrhea Therapeutic Area User Guide

8th February 2018

10am CST

Strength *through Collaboration*

# Panelists

- Laura Butte, Senior Project Manager at Critical Path Institute (C-Path)
- Diane Corey, Data Manager and Standards Developer at Critical Path Institute (C-Path)
- Jordan Li, Biomedical Clinical Research Information Specialist at NCI/EVS

# Question & Answer

- ‘Panelist’: Question

OR

- ‘Presentation’: Question

Examples:

1) What should be supported by ADaM datasets?
2) Jack: Is there a limit to the number of variables that can be in ADSL?

# Content Disclaimer

All content in this presentation is for education and information only. References to any specific commercial product, process, service, or corporation are also for information only, and do not constitute endorsement, recommendation, or favoring by CDISC or the CDISC community.

# AGENDA

- Team Collaboration
- Introduction to Clostridium Difficile Associated Diarrhea
- CDAD TAUG Overview
  - Sections
  - Domains
  - Variables
  - Non-Standard Variables
  - Controlled Terminology
- Public Review Information
- Q&A

# CDAD TAUG Development Team

## Core Team Members

| Name | Institution/Organization |
|---|---|
| Daniel Olson - Team Lead | Critical Path Institute |
| Laura Butte – Project Manager | Critical Path Institute |
| Diane Corey | Critical Path Institute |
| Cheryl Dixon | FDA |
| Avery Goodwin | FDA |
| Jordan Li | NCI-EVS |
| Shrimant Mishra | FDA |
| Jalal Sheikh | FDA |

## CDISC Core Team Members

| Name | Institution/Organization |
|---|---|
| Diane Wold | CDISC |
| Dana Booth | CDISC |
| Jon Neville | CDISC |
| Rhonda Facile | CDISC |

# Introduction to CDAD

- *Clostridium difficile associated diarrhea (CDAD)* is a bacterial infection that includes diarrhea, fever, elevated white blood cell count and abdominal pain/tenderness.

- Risk factors of CDAD include recent antibacterial use, older age, weakened immune system, and prior episodes of CDAD.

- Treatment includes cessation of antibacterial and administration of approved antibacterial against *C. difficile*.

# Overview of TAUG Content

•**Section 1**, Introduction, provides an overall introduction to the purpose and goals of the Therapeutic Area Data Standards User Guide for CDAD.

•**Section 2,** Overview, provides some general information on CDAD.

•**Section 3**, Subject and Disease Characteristics, provides examples to support the modelling of identification of *C. difficile,* medical history of prior CDAD episodes, and drug resistance.

•**Section 4**, Disease Assessments, provides examples used to support the modelling of baseline severity, symptoms of CDAD, stool count and volume along with Questionnaires, Ratings and Scales.

# Overview of TAUG Content

•**Section 5**, Routine Data, provides examples used to support the modelling of stool sample collection data.

•**Section 6**, Appendices, provide additional background material and describe other supplemental material relevant to CDAD.

# Subject and Disease Characteristics
## *Identification and Diagnosis of C. difficile*

- *C. difficile* is first isolated from a fecal specimen on a selective medium.
- Toxin enzyme immunoassay (EIA) and cell cytotoxicity neutralization assay (CCCNA) methods are used to determine whether the strain of *C. difficile* isolated from culturing is toxigenic or non-toxigenic by testing for the presence of toxin A and/or B.
- Confirmatory polymerase chain reactions (PCRs) are performed to further verify and detect the presence of tcdA and tcdB DNA. tcdA and tcdB genes encode for Toxin A and B respectively.
- Specific hypervirulent strain variants can also be determined by PCR.
- Example in TAUG shows how these different tests can be modelled in the MB and PF domains.

# Identification of Toxigenic Clostridium difficile – Using the Microbiology (MB) Domain

*mb.xpt*

| Row | STUDYID | DOMAIN | USUBJID | SPDEVID | MBSEQ | MBGRPID | MBTESTCD | MBTEST | MBTSTDTL | MBORRES | MBORRESU | MBSTRESC | MBSTRESN | MBSTRESU | MBSPEC | MBMETHOD | VISITNUM | VISIT | MBDTC | MBMEDTYP | MBRRSTYP |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | MB | ABC-008 | ABC333 | 1 | 1 | MCORGIDN | Microbial Organism Identification CDAD-78 RESOLVED | | CLOSTRIDIUM DIFFICILE | | CLOSTRIDIUM DIFFICILE | | | STOOL | MICROBIAL CULTURE, SOLID | 2 | WEEK 2 | 2017-10-02 | Cycloserine-Cefoxitin Fructose Agar | |
| 2 | ABC | MB | ABC-008 | ABC333 | 2 | 1 | CDF | Clostridium difficile | COLONY COUNT | 77 | CFU/mL | 77 | 77 | CFU/mL | STOOL | MICROBIAL CULTURE, SOLID | 2 | WEEK 2 | 2017-10-02 | Cycloserine-Cefoxitin Fructose Agar | QUANTITATIVE |
| 3 | ABC | MB | ABC-008 | ABC333 | 3 | 1 | CDF | Clostridium difficile | COLONY COUNT | 1+ | | 1+ | | | STOOL | MICROBIAL CULTURE, SOLID | 2 | WEEK 2 | 2017-10-02 | Cycloserine-Cefoxitin Fructose Agar | ORDINAL |
| 4 | ABC | MB | ABC-008 | ABC111 | 4 | 1 | CDFGDH | C. difficile Glutamate Dehydrogenase | DETECTION | POSITIVE | | POSITIVE | | | STOOL | EIA | 2 | WEEK 2 | 2017-10-02 | | |
| 5 | ABC | MB | ABC-008 | ABC222 | 5 | 1 | CDFABTOX | Clostridium difficile A/B Toxin | DETECTION | POSITIVE | | POSITIVE | | | STOOL | EIA | 2 | WEEK 2 | 2017-10-02 | | |
| 6 | ABC | MB | ABC-008 | | 6 | 1 | CDFTCDAD | Clostridium difficile tcdA DNA | DETECTION | POSITIVE | | POSITIVE | | | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 | | |
| 7 | ABC | MB | ABC-008 | | 7 | 1 | CDFTCDBD | Clostridium difficile tcdB DNA | DETECTION | POSITIVE | | POSITIVE | | | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 | | |
| 8 | ABC | MB | ABC-008 | | 8 | 1 | CDFTCDCD | Clostridium difficile tcdC DNA | DETECTION | POSITIVE | | POSITIVE | | | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 | | |
| 9 | ABC | MB | ABC-008 | | 9 | 1 | TOXCDF | Toxigenic Clostridium difficile | INTERPRETATION | POSITIVE | | POSITIVE | | | STOOL | | 2 | WEEK 2 | 2017-10-02 | | |

**Dataset Debug Message**

When the JIRA issue(s) present in the dataset have been resolved, and their resolution has been confirmed by governance, please remove them.

**MB NSV Metadata**

| Variable | Label | Type | Role | Origin |
|---|---|---|---|---|
| MBMEDTYP | Medium Type | text | Non-Standard Record Qualifier | eDT |
| MBRRSTYP | Reported Result Scale Type | text | Non-Standard Record Qualifier | eDT |

# Identification of the Hypervirulent Strain of Clostridium difficile – MB and Pharmacogenomics/Genetics Findings (PF) domain

mb.xpt

**Rows 1-2:** Show the toxin B gene (tcdB DNA) and binary toxin gene (cdt DNA) are detected in subject ABC-852's stool sample.

**Row 3:** Indicates the subject ABC-852's sample is positive for toxigenic *C. difficile*.

**Row 4:** The results in MB row 2 and PF row 1 indicate that the subject ABC-852's sample is positive for 027/NAP1/BI strain.

**Rows 5-6:** Show the subject's stool sample is positive for toxin B gene and negative for the binary toxin gene.

**Row 7:** Indicates the subject ABC-877's sample is positive for toxigenic *C. difficile*.

**Row 8:** The results in MB row 6 and PF row 2 indicate that the subject ABC-877's sample is negative for the 027/NAP1/BI strain.

*mb.xpt*

| Row | STUDYID | DOMAIN | USUBJID | SPDEVID | MBSEQ | MBGRPID | MBLNKID | MBTESTCD | MBTEST | MBTSTDTL | MBORRES | MBSTRESC | MBSPEC | MBMETHOD | VISITNUM | VISIT | MBDTC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | MB | ABC-852 | ABC555 | 1 | 1 | | CDFTCDBD | Clostridium difficile tcdB DNA | DETECTION | POSITIVE | POSITIVE | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 |
| 2 | ABC | MB | ABC-852 | ABC555 | 2 | 1 | | CDFCDTD | Clostridium difficile cdt DNA | DETECTION | POSITIVE | POSITIVE | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 |
| 3 | ABC | MB | ABC-852 | ABC555 | 3 | 1 | | TOXCDF | Toxigenic Clostridium difficile | INTERPRETATION | POSITIVE | POSITIVE | STOOL | | 2 | WEEK 2 | 2017-10-02 |
| 4 | ABC | MB | ABC-852 | ABC555 | 3 | 1 | CD101 | 27NAP1BI | Clostridium difficile 027/NAP1/BI | INTERPRETATION | POSITIVE | POSITIVE | STOOL | | 2 | WEEK 2 | 2017-10-02 |
| 5 | ABC | MB | ABC-877 | ABC555 | 1 | 2 | | CDFTCDBD | Clostridium difficile tcdB DNA | DETECTION | POSITIVE | POSITIVE | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 |
| 6 | ABC | MB | ABC-877 | ABC555 | 2 | 2 | | CDFCDTD | Clostridium difficile cdt DNA | DETECTION | NEGATIVE | NEGATIVE | STOOL | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 |
| 7 | ABC | MB | ABC-877 | ABC555 | 3 | 2 | | TOXCDF | Toxigenic Clostridium difficile | INTERPRETATION | POSITIVE | POSITIVE | STOOL | | 2 | WEEK 2 | 2017-10-02 |
| 8 | ABC | MB | ABC-877 | ABC555 | 3 | 2 | CD102 | 27NAP1BI | Clostridium difficile 027/NAP1/BI | INTERPRETATION | NEGATIVE | NEGATIVE | STOOL | | 2 | WEEK 2 | 2017-10-02 |

pf.xpt

**Row 1:** Shows the single-base-pair deletion at nucleotide 117 in the tcdC gene in subject ABC-852.

**Row 2:** Shows there is no deletion at nucleotide 117 in the tcdC gene for subject ABC-877.

*pf.xpt*

| Row | STUDYID | DOMAIN | USUBJID | SPDEVID | PFSEQ | PFLNKID | NHOID | PFTESTCD | PFTEST | PFGENRI | PFCAT | PFORRES | PFORREF | PFGENLOC | PFSTRESC | PFRESCAT | PFSPEC | PFMETHOD | VISITNUM | VISIT | PFDTC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | ABC | PF | ABC-852 | ABC555 | 1 | CD101 | TOXIGENIC CLOSTRIDIUM DIFFICILE | NUC | Nucleotide | tcdC | MICROBIOLOGY | - | A | 117 | c.117A | DELETION | DNA | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 |
| 2 | ABC | PF | ABC-877 | ABC555 | 2 | CD102 | TOXIGENIC CLOSTRIDIUM DIFFICILE | NUC | Nucleotide | tcdC | MICROBIOLOGY | A | A | 117 | c.117A | NO DELETION | DNA | REAL-TIME POLYMERASE CHAIN REACTION ASSAY | 2 | WEEK 2 | 2017-10-02 |

# Subject and Disease Characteristics
## *Medical History*

- A history of CDAD is a risk factor for recurrence.
- The example represented in the Medical History (MH) domain in this TAUG shows details about the occurrence(s) of CDAD.
- If prior CDAD occurrences exist, the number of occurrences can be represented in the Findings About (FA) domain and linked back to the MH example using the RELREC domain.

# MH/FAMH Example

| USUBJID | MHSEQ | MKLNKID | MHTERM | MHDECOD | MHCAT | MHPRESP | MHOCCUR |
|---|---|---|---|---|---|---|---|
| CDAD-01-101 | 1 | 1 | Clostridium difficile | Clostridium difficile infection | PRIMARY DIAGNOSIS | Y | Y |
| CDAD-01-101 | 2 | 1 | Clostridium difficile | Clostridium difficile infection | PRIMARY DIAGNOSIS | Y | Y |
| CDAD-01-201 | 1 | | Clostridium difficile | Clostridium difficile infection | PRIMARY DIAGNOSIS | Y | N |

| MHDTC | MHSTDTC | MHENDTC | MHSTDY | MHENDY |
|---|---|---|---|---|
| 2014-05-05 | 2014-01-20 | 2014-01-29 | -256 | -247 |
| 2014-05-05 | 2014-02-15 | 2014-02-20 | -230 | -225 |
| 2014-05-25 | | | | |

| USUBJID | FASEQ | FALNKID | FATESTCD | FATEST | FAOBJ | FAORRES |
|---|---|---|---|---|---|---|
| CDAD-01-101 | 1 | 1 | NUMOCCUR | Number of Occurrences | Clostridium difficile infection | 2 |

| STUDYID | RDOMAIN | USUBJID | IDVAR | IDVARVAL | RELTYPE | RELID |
|---|---|---|---|---|---|---|
| CDAD-01 | MH | | MHLNKID | | MANY | MHFA |
| CDAD-01 | FAMH | | FALNKID | | ONE | MHFA |

# Subject and Disease Characteristics
## *Drug Resistance*

- After *C.difficile* is identified, drug resistance can be assessed using the agar dilution method (see section 3.1 for more examples of identification).

- The example represented in the Microbiology Susceptibility (MS) domain in this TAUG shows details about the susceptibility of *C.difficile* to Metronidazole.

- This example shows the minimal inhibitory concentration in the MSCONC/MSCONCU variables and whether *C.difficile* is resistant or susceptible in the MSORRES/MSSTRESC variables.

# MS Example

| USUBJID | NHOID | MSSEQ | MSLNKID | MSTESTCD | MSTEST | MSAGENT | MSCONC |
|---|---|---|---|---|---|---|---|
| CDAD-01-101 | CLOSTRIDIUM DIFFICILE | 1 | 1 | MIC | Minimum Inhibitory Concentration | Metronidazole | 32 |
| CDAD-01-201 | CLOSTRIDIUM DIFFICILE | 1 | 2 | MIC | Minimum Inhibitory Concentration | Metronidazole | 2 |

| MSCONCU | MSORRES | MSSTRESC | MSSPEC | MSMETHOD |
|---|---|---|---|---|
| ug/mL | RESISTANT | RESISTANT | STOOL | AGAR DILUTION |
| ug/mL | SUSCEPTIBLE | SUSCEPTIBLE | STOOL | AGAR DILUTION |

# Disease Assessments
## *QRS Instruments*

| Full Name and Abbreviation | Copyright Permission Status | Supplement Status |
|---|---|---|
| ATLAS (age, treatment with systemic antibiotics during CDI therapy, leukocyte count,<br>serum albumin, and serum creatinine) score | Public Domain | In progress |
| Bristol Stool Form Scale (BSFS) | Requested | |
| Clostridium difficile Health-related Quality-of-Life Questionnaire (CDiff32) | Requested | |

# Disease Assessments
## *Symptoms of CDAD*

- Here the presence of pre-specified symptoms are represented in the Clinical Events (CE) domain.

*ce.xpt*

| Row | STUDYID | DOMAIN | USUBJID | CESEQ | CEGRPID | CETERM | CECAT | CESEV | CEPRESP | CEOCCUR | CEDTC | CESTDTC | CEENDTC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | CDAD-01 | CE | CDAD-01-001 | 1 | 101 | FEVER | CDIFF SYMPTOMS | MODERATE | Y | Y | 2018-01-28 | 2018-01-27 | 2018-02-07 |
| 2 | CDAD-01 | CE | CDAD-01-001 | 2 | 101 | ABDOMINAL PAIN | CDIFF SYMPTOMS | MILD | Y | Y | 2018-01-28 | 2018-01-27 | 2018-02-07 |
| 3 | CDAD-01 | CE | CDAD-01-001 | 3 | 101 | ABDOMINAL TENDERNESS | CDIFF SYMPTOMS | MILD | Y | Y | 2018-01-28 | 2018-01-27 | 2018-02-07 |

# Routine Data
# *Stool Sample Collection*

**Row 1:** Shows the date and time of the stool sample collection from subject CDAD-01-001.
**Rows 2-3:** Show the date and time that the stool sample was collected from subject CDAD-01-002 (row 2) and frozen (row 3). The Frozen sample was stored in a container using BEREFID to show the container number.

*be.xpt*

| Row | STUDYID | DOMAIN | USUBJID | BESEQ | BEREFID | BETERM | BEDECOD | VISITNUM | VISIT | VISITDY | BEDTC | BESTDTC | BEENDTC | BEST | BESPEC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | CDAD-01 | BE | CDAD-01-001 | 1 | ST123 | Collected | COLLECTING | 1 | SCREENING | -1 | 2018-01-31T13:05 | 2018-01-31T13:05 | | -1 | STOOL |
| 2 | CDAD-01 | BE | CDAD-01-002 | 1 | ST124 | Collected | COLLECTING | 1 | SCREENING | -1 | 2018-01-31T15:00 | 2018-01-31T15:00 | | -1 | STOOL |
| 3 | CDAD-01 | BE | CDAD-01-002 | 2 | ST124 | Frozen | FREEZING | 1 | SCREENING | -1 | 2018-01-31T17:00 | 2018-01-31T17:00 | | -1 | STOOL |

**BE NSV Metadata**

| Variable | Label | Type | Role | Codelist | Origin |
|---|---|---|---|---|---|
| BESPEC | Specimen Type | text | Non-Standard Record Qualifier | SPECTYPE | CRF |

*lb.xpt*

| Row | STUDYID | DOMAIN | USUBJID | LBSEQ | LBREFID | LBTESTCD | LBTEST | LBORRES | LBORRESU | LBSTRESC | LBSTRESN | LBSTRESU | LBSPEC | V |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | CDAD-01 | LB | CDAD-01-001 | 1 | ST123 | VOLUME | Volume | 200 | mL | 200 | 200 | mL | STOOL | |
| 2 | CDAD-01 | LB | CDAD-01-002 | 1 | ST124 | VOLUME | Volume | 250 | mL | 250 | 250 | mL | STOOL | |

# Disease Assessments
## *Stool Count/Volume Data*

- Unformed stool count or stool volume information may be used to evaluate efficacy endpoints.
- The resolution of diarrhea is often defined as either an unformed stool count of <3 per day or a decrease in volume of stool of 75% compared to the volume at admission.

*ce.xpt*

| Row | STUDYID | DOMAIN | USUBJID | CESEQ | CESPID | CETERM | CEDECOD | CECAT | CEPRESP | CEOCCUR | CESTDTC | CEENDTC |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | CDAD-01 | CE | CDAD-01-001 | 1 | 101 | Unformed Stool Production | Diarrhea | CDIFF SYMPTOMS | Y | Y | 2018-01-27 | 2018-02-07 |
| 2 | CDAD-01 | CE | CDAD-01-002 | 1 | 102 | Unformed Stool Production | Diarrhea | CDIFF SYMPTOMS | Y | Y | 2018-01-27 | 2018-02-07 |

*face.xpt*

| Row | STUDYID | DOMAIN | USUBJID | FASEQ | FASPID | FATESTCD | FATEST | FAOBJ | FACAT | FAORRES | FAORRESU |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | CDAD-01 | FA | CDAD-01-001 | 1 | 101 | EPSDNUM | Number of Episodes | Diarrhea | CDIFF SYMPTOMS | 10 | |
| 2 | CDAD-01 | FA | CDAD-01-001 | 2 | 101 | EPSDNUM | Number of Episodes | Diarrhea | CDIFF SYMPTOMS | 6 | |
| 3 | CDAD-01 | FA | CDAD-01-002 | 1 | 102 | VOL | Volume | Diarrhea | CDIFF SYMPTOMS | 800 | mL |
| 4 | CDAD-01 | FA | CDAD-01-002 | 2 | 102 | VOL | Volume | Diarrhea | CDIFF SYMPTOMS | 400 | mL |

| | FAEVLINT |
|---|---|
| 2 | -PT24H |
| 3 | -PT24H |
| 2 | -PT24H |
| 3 | -PT24H |

# Disease Assessments
## *Baseline Severity*

- The severity level in this example is based on the number of unformed stools in a 24-hour period.
- A baseline flag (–LOBXFL) of 'Y' is used to indicate that the record is taken from the baseline visit.

*face.xpt*

| Row | STUDYID | DOMAIN | USUBJID | FASEQ | FASPID | FATESTCD | FATEST | FAOBJ | FACAT | FAORRES |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | CDAD-01 | FA | CDAD-01-001 | 1 | 100 | EPSDNUM | Number of Episodes | Diarrhea | CDIFF SYMPTOMS | 6 |
| 2 | CDAD-01 | FA | CDAD-01-001 | 2 | 100 | SEV | Severity/Intensity | Diarrhea | CDIFF SYMPTOMS | MODERATE |

| FASTRESC | FASTRESN | FALOBXFL | VISITNUM | VISIT | FADTC | FADY | FAEVLINT |
|---|---|---|---|---|---|---|---|
| 6 | 6 | Y | 2 | VISIT 1 | 2018-02-02 | 1 | -PT24H |
| MODERATE | | Y | 2 | VISIT 1 | 2018-02-02 | 1 | -PT24H |

# Domains

- No new domains were submitted for this version of the TAUG
- The following Domains are referenced in the TAUG

| Datasets | Description | Section Description |
|---|---|---|
| MB | Microbiology Specimen | Identification and Diagnosis, Drug Susceptibility |
| PF | Pharmacogenomics/Genetics Findings | Identification and Diagnosis |
| DI | Devices | Identification and Diagnosis |
| FA | Findings About | Medical History, Baseline Severity and Stool Count/Volume |
| MH | Medical History | Medical History |
| MS | Microbiology Susceptibility | Drug Susceptibility |
| CE | Clinical Events | Baseline Severity, Symptoms and Stool Count/Volume |
| BE | Biospecimen Events | Stool Sample Collection |
| LB | Laboratory Test Results | Stool Sample Collection |

# New Variables

- No new variables were submitted for approval to become SDTM variables for this user guide

# Non-Standard Variables

| Parent Domain | Variable | Label | SAS Data Type | XML Data Type | Codelist/Controlled Terms | Role | Description | Comments |
|---|---|---|---|---|---|---|---|---|
| MB | MBMEDTYP | Medium Type | char | text | Culture Medium Type/SDTM-CLTMDTYP | Non-Standard Record Qualifier | The type of medium in which the specimen was cultured. | |
| MB | MBRRSTYP | Reported Result Scale Type | char | text | N/A | Non-Standard Record Qualifier | A textual description of the type of the original result; examples are but not limited to: Quantitative, Qualitative, Ordinal, Narrative, etc. | May be controlled for CT development. |

# Public Review Information

- Review Package Contents
  - Made available only on the CDISC WIKI
  - Reviewers are requested to make any comments directly via JIRA
  - Wiki and JIRA use the same credentials, so if you can see the TAUG-CDAD page in the WIKI, then you can use JIRA.
  - Links/Instructions are provided in the Public Review announcement email

# Public Review Information – cont.

TAUG-CDAD compiled

- Allows review of entire document as a single document
- View is more prone to errors when entering comments into JIRA.

TAUG-CDAD sections

- Allows review of each section separately
- Easy navigation between sections using navigation label at the bottom of the page
- Reviews can also jump back and forth between sections
- Tables, and tables representing datasets (including any attendant row captions or footnotes), are inside expandable sections. Clicking on an indented line “ > “reveal the content within.

CDAD Examples and Concept Maps

- Allows all the SDTM examples and concept maps used in the TAUG-CDAD to be viewed in 1 section.

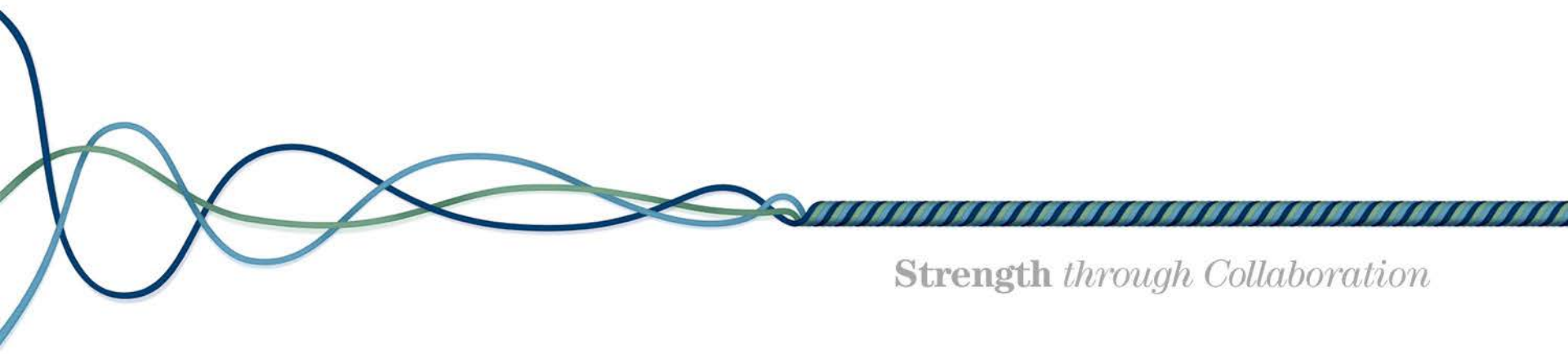
# Public Review Information – cont.

Keep the JIRA-CDAD page and the WIKI CDAD Therapeutic User guide open in separate window

- Comments can be entered without navigating back and forth between the Wiki and JIRA.
- Always check to make sure the project selected in JIRA is CDAD.


- Add scope suggestions for future versions
- **If you have no edits or comments to a page, c**lick 'Like' at the bottom of the page. This will help us determine who has read each page.

# Controlled Terminology



# Summary of Controlled Terminology Developed for the KT TA Project

| Batch | Details | Status |
|---|---|---|
| 1 | ▪ New TEST-CD terminology for MB<br>▪ New codelist for CDFATSCD/CDFATS; New values added to the CDFATSCD/CDFATS codelist | ▪ MBTEST-CD terminology is currently under review and will be published with P34 on 2018-06-29.<br>▪ CDFATSCD/CDFATS codelists and valid values are currently being reviewed by the General terminology team and are tentatively scheduled for P34 CT release in June 2018. |
| 2 | ▪ New values added to Culture Medium Type/CLTMDTYP codelist | ▪ CLTMDTYP terminology is under review and is tentatively scheduled for P34 June 2018 release. |

# Q&A

# Upcoming CDISC Webinars

- **Members-Only Tech Webinar – Getting Started with SHARE API v1.0**

- Join the CDISC SHARE Team for a technology webinar introducing the CDISC SHARE Application Programming Interface (API), which is available free to CDISC Platinum Members as a 2018 Member benefit.
- The CDISC SHARE API, a RESTful web service, allows real-time access to standards in a variety of formats (XML, RDF and JSON) for programmatic use by developers to create CDISC metadata libraries within your metadata repositories, support CDISC standards in electronic case report forms, and use within clinical research and learning health systems. The API facilitates the implementation of CDISC standards to further automate clinical research processes.

  - 13 Feb 2018 – 10am CST
  - For registration, visit our webinars page at www.cdisc.org/education/webinars

*Any more questions?*

*Thank you for attending this webinar.*

**CDISC's vision is to:**
**Inform Patient Care & Safety Through Higher Quality Medical Research**