ADaM Office Hours

Nancy Brucken, IQVIA
Daphne Ewing, CSL Behring
Nate Freimark, The Griesser Group
Brian Harris, AstraZeneca
Trevor Mankus, Pinnacle 21
Sandra Minjoe, ICON
Luke Reinbolt, Navitas Data Sciences
Paul Slagle, IQVIA
Cindy Stroupe, UCB Pharmaceuticals
Tatiana Sotingco, Janssen R&D
Mario Widel, Reata Pharmaceuticals

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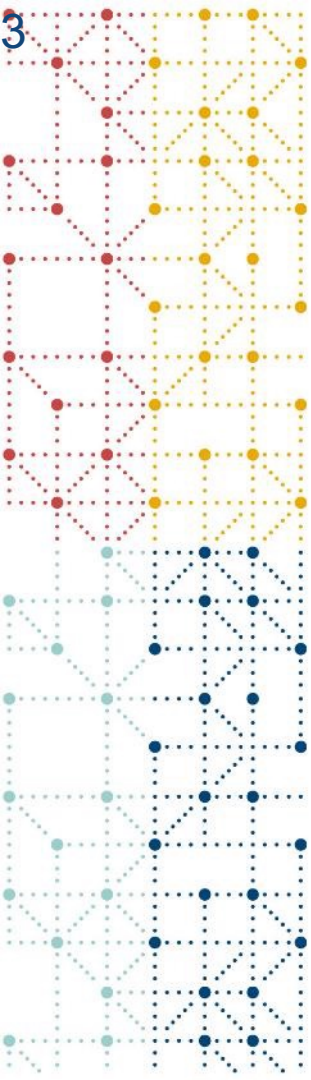
THU 2 JUN 2022
11:00AM-12:30PM ET

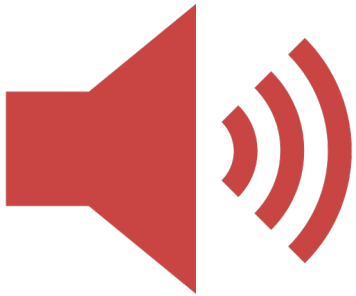
Today’s Agenda

1. Housekeeping
2. Feature Presentation
3. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping



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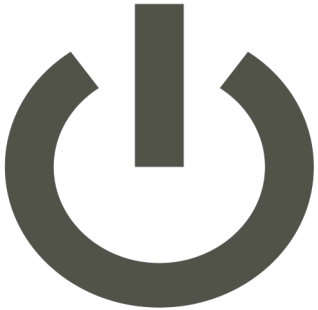
Housekeeping

Submit questions at any time via the Questions tool on your Zoom app

Housekeeping



Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping

A recording of this webinar and the slides will be available in the **Members Only** section of CDISC website

Our Presenters

Nancy Brucken IQVIA	**Luke Reinbolt** Navitas Data Sciences
Daphne Ewing CSL Behring	**Paul Slagle** IQVIA
Nate Freimark The Griesser Group	**Cindy Stroupe** UCB Pharmaceuticals
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ADaM Office Hours

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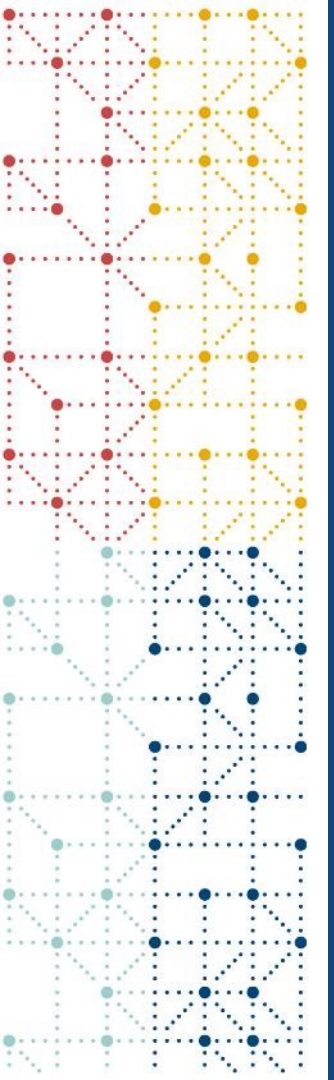
THU 2 JUN 2022
11:00AM-12:30PM ET

ADaM Office Hours

06.02.2022



ADaM Implementation Guide

Version 1.3

ADaMIGv1.3: Why update the IG at this time?

Balancing incremental improvement with stability of standards

- As part of the ADaM team's review of the FDA Study Data Technical Conformance guide (sdTCG), items were noted where modifications to the ADaM Implementation Guide could be beneficial by having better alignment between the two documents
  - Add more clarity on the inclusion of SDTM variables in ADaM datasets
  - Require relative timing variable (from either SDTM or ADaM) in repeated measures datasets

- The ADaM team decided to explore creating minor update to the ADaMIG
  - to demonstrate responsiveness to the FDA
  - to potentially address other minor issues that have accumulated

ADaMIGv1.3: Minor Update to Address Specific Issues

Location	Type	Description	Rationale	Rule?
Section 1.3.1	Modification	Added 1.3 to text prior to table	Updated for this version	No
Table 1.3.1.1	New	Added column for ADaMIG v1.3; Added rows for other ADaM docs being published this year; Updated Rules document version & date	Updated for this version	No
Section 2.2	Clarification	The first paragraph of this section was modified to clarify the inclusion of SDTM variables in ADaM datasets to assist traceability.	To align with FDA sdTCG	No
Section 3.3.3	Modification	The following was added to the 1st paragraph: *If a dataset contains more than one record within a parameter and within a subject, then an SDTM or ADaM relative timing variable must be present.*	To align with FDA sdTCG	No
Table 3.3.3.1	Modification	Added to CDISC notes for ADY (and similar text to ASTDY & AENDY): *If a dataset contains more than one record per parameter per subject then a SDTM or ADaM relative day timing variable must be included (ADY would meet this requirement).*	To align with FDA sdTCG	Yes
Table 3.3.4.1.1	Modification	Added the text noting that BASETYPE does not need to be populated if BASE or BASEC is not populated.	Addresses pre-BL recs	Yes
Appendix B	New	Version history now includes changes from v1.2 to v1.3	Updated for this version	No

ADaMIGv1.3: Conformance Rules Updated in Parallel

Check Number	ADaM Structure Group	Machine Testable Failure Criteria	Message Type
131	BDS	Within a given value of PARAMCD where either BASE or BASEC are populated, BASETYPE is populated for at least one record and is not populated for at least one record	Error
152	BDS	BASETYPE is populated, BASE is populated, and BASE is not equal to AVAL where ABLFL is equal to Y for a given value of PARAMCD and BASETYPE for a subject	Error
165	BDS	BASETYPE is populated, BTOXGR is populated, and BTOXGR is not equal to ATOXGR where ABLFL is equal to Y for a given value of PARAMCD and BASETYPE for a subject	Error
168	BDS	BASETYPE is populated, BNRIND is populated, and BNRIND is not equal to ANRIND where ABLFL is equal to Y for a given value of PARAMCD and BASETYPE for a subject	Error
353	BDS	BASETYPE is populated, ByIND is populated, and ByIND is not equal to AyIND where ABLFL is equal to Y for a given value of PARAMCD and BASETYPE for a subject	Error

ADaMIGv1.3: Introducing Dataset Metadata Tables

Table 2.3.1.1 Data Structure

Data Structure Name	Data Structure Description	Class of Dataset	CDISC Notes
ADSL	Subject Level Analysis Dataset	SUBJECT LEVEL ANALYSIS DATASET	ADSL contains one record per subject, regardless of the type of clinical trial design. ADSL contains variables such as subject-level population flags, planned and actual treatment variables, demographic information, randomization factors, subgrouping variables, stratification factors, and important dates. ADSL is used to provide key facts about the subject that are analysis-enabling or which facilitate interpretation of analysis. The process for adding ADSL variables into BDS datasets is set by the producer of the datasets.

The Data Structure Description & CDISC Notes are intended to provide information to assist producers in preparing their datasets and are not intended to be metadata submitted in define.xml.

ADaMIGv1.3: Introducing Dataset Metadata Tables (cont)

Table 2.3.2.1 Data Structure

Data Structure Name	Data Structure Description	Class of Dataset	SubClass of Dataset	CDISC Notes
BDS	Basic Data Structure	BASIC DATA STRUCTURE		A BDS dataset contains one or more records per subject, per analysis parameter, per analysis timepoint. Analysis timepoint is conditionally required, depending on the analysis. In situations where there is no analysis timepoint, the structure is one or more records per subject per analysis parameter.
TTE	Basic Data Structure Time-to-Event	BASIC DATA STRUCTURE	TIME-TO-EVENT	Datasets in the SubClass TIME-TO-EVENT must have a Class of BASIC DATA STRUCTURE and meet all the principles of that class. A TTE dataset is used specifically for survival or time-to-event analyses and includes the following: (1) time from a defined starting point (e.g., the date of randomization or of an intervention) to the time of occurrence of the event of interest; and (2) an indication that a subject's time to event has been censored and for what reason.

The Data Structure Name, Data Structure Description, and CDISC Notes are intended to provide information to assist producers in preparing their datasets and are not intended to be metadata submitted in define.xml.

ADaM Occurrence Data Structure (OCCDS) Implementation Guide

Version 1.1

ADaM OCCDS v1.1: Improvements & Enhancements

After great effort and two public reviews, here is a list of key updates:

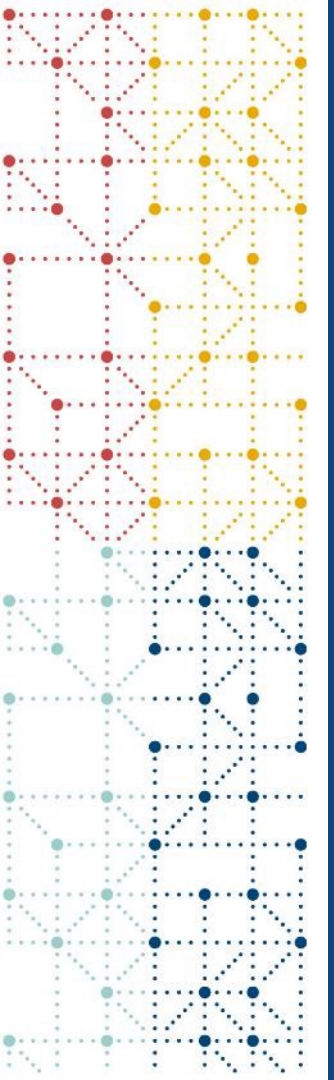
- Added a subclass of ADVERSE EVENT
- Introduced “U” prefix for Unmodified SDTM variables when combining multiple SDTM domains (e.g. MHTERM, AETERM becomes UTERM)
- Added SRCSEQ, SRCDOM, and ASEQ for traceability
- Added ADECODy for Analysis Dictionary-Derived Term y
- Text Updated to be consistent with updates made in v1.2 of ADaMIG
- Added 3 new examples
  - AE that change over time collecting this information in FA
  - Analysis of AEs from multiple input domains (AE, CE)
  - Analysis of Protocol deviations
- Added additional treatment-emergent and on-treatment variables.

ADaM OCCDS v1.1 (cont)

Table 3.1.1 Data Structure

Data Structure Name	Data Structure Description	Class of Dataset	Subclass of Dataset	CDISC Notes
OCCDS	Occurrence Data Structure	OCCURRENCE DATA STRUCTURE		Generally these are 1 record per record in SDTM domain (optional: per coding path, per Analysis Period and/or Phase. See Section 1.1, Purpose, for examples of when the analysis data structure might not be one record per record in SDTM domain.)
AE	Occurrence Data Structure Adverse Event	OCCURRENCE DATA STRUCTURE	ADVERSE EVENT	Datasets in the SubClass ADVERSE EVENT must have a Class of OCCURRENCE DATA STRUCTURE and meet all the principles of that class. The SDTM input dataset for the ADVERSE EVENT SubClass is always AE, with some additional information from SUPPAE, FA, and ADSL. See Section 3.1.2, SubClass ADVERSE EVENT, for more details.

The Data Structure Name, Data Structure Description, and CDISC Notes are intended to provide information to assist producers in preparing their datasets and are not intended to be metadata submitted in define.xml.



ADaM Implementation Guide for Non-compartmental Analysis (ADNCA)

Version 1.1

ADaM ADNCA v1.0: New Sub-class of BDS

Details the typical dataset that can be submitted to create PK parameters:

Table 4.1 Data Structure				
Data Structure Name	Data Structure Description	Class of Dataset	Subclass of Dataset	CDISC Notes
ADNCA	Basic Data Structure Non-Compartmental Analysis	BASIC DATA STRUCTURE	NON-COMPARTMENTAL ANALYSIS	Dataset designed to support NCA . Primarily sourced from SDTM PC and supplemented by information from the EX, EC, or other relevant domains.

The Data Structure Name, Data Structure Description, and CDISC Notes are intended to provide information to assist producers in preparing their datasets and are not intended to be metadata submitted in define.xml.

ADaM Implementation Guide for Medical Devices

Version 1.0

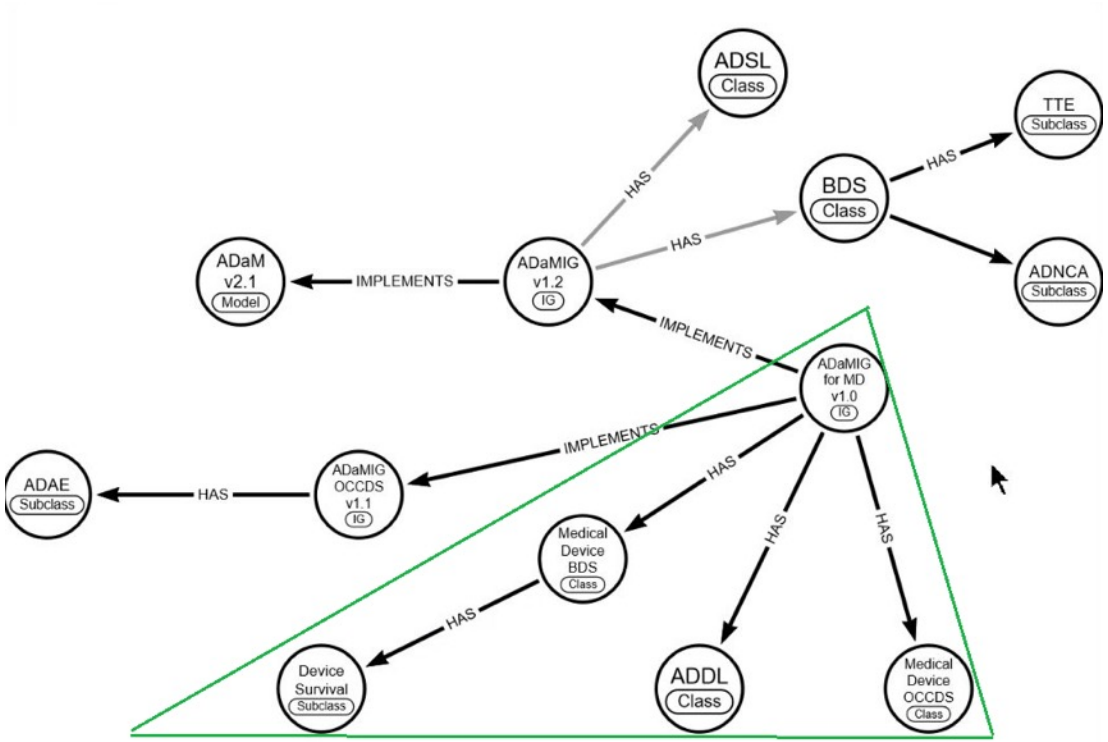
ADaM Implementation Guide for Medical Devices v1.0

Addresses typical needs for clinical trials analyzing medical device data.

- The guide introduces three new classes of data structures
  - ADDL → ADaM Device Level Analysis dataset
  - MDOCCDS → Medical Devices Occurrence Data Structure
  - MDBDS → Medical Devices Basic Data Structure

- One new subclass data structure under MDBDS for device survival analysis
  - Medical Device time-to-event MDTTE

ADaM Implementation Guide for Medical Devices v1.0



Other Current & Forthcoming Publications

1. Other Current Publications
2. ADaM Questionnaire Supplements (ADQRS)
3. ADaM Oncology Examples
4. ADaM Traceability Examples
5. Other future publications

Other Current ADaM Publications

The following are companions to the above publications:

- ADaM Model Document v2.1
  - ADaM v2.1 was released December 2009 and, although most of the content in the document still applies today, an important considerations document has been created to aid the ADaM user, outlining developments not described in ADaM v2.1:

- ADaM Conformance v4.0
  - Contains rule sets for each version of the ADaMIG and incorporates all conformance rules from above publications

Other Current ADaM Publications (cont)

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

- The guidance provides recommendations for addressing the analysis needs for data analysis and reporting in clinical trials impacted by the pandemic
- The guidance focuses on ADSL and OCCDS metadata and provides examples

Other Current ADaM Publications (cont)

ADaM Traceability Examples (Published 12May2022)

- Good traceability in a submission unambiguously shows the data lineage, allows reviewers to reproduce results and identify supporting source data
- Current ADaM documents describe need & provide elements supporting traceability
  - ADaM Model v2.1
    - Foundational principle: “provide traceability between the analysis data and its source data”
  - ADaMIG:
    - “ADaM datasets and metadata must clearly communicate how the ADaM datasets were created”
  - OCCDS
    - “In general, include all variables from the SDTM dataset and corresponding supplemental qualifiers that are needed for analysis or traceability “
- This document
  - provides various simple and complex traceability examples using current ADaM dataset structures
  - contains no new guidance, recommendations, or standards

Current/Forthcoming: ADaM Questionnaire Supplements

- Published first ADaM QRS supplement which describes the structure of a typical dataset that could be used for summarization and analysis of the Geriatric Depression Scale Short Form (GDS-SF)
- Sent out for **public review** (through **23Jun2022**), Generalized Anxiety Disorder – 7-Item (GAD-7) questionnaire supplement.
- Published 4 ‘readme’ files, which provide rationale for not developing ADaM supplements for corresponding single-item instruments
- Finalized templates for creating ADaM QRS supplements and ‘readme’ files

Forthcoming: ADaM Oncology Examples

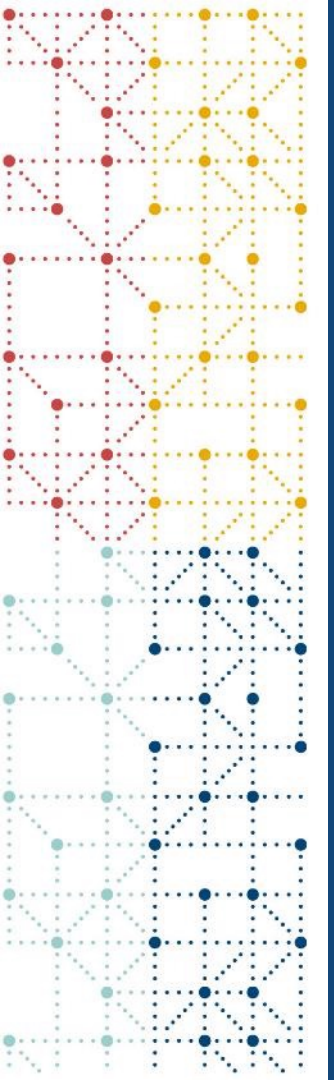
- Details various oncology analysis needs using current ADaM dataset structure
- First version of Document is currently in **public review** (through **27Jun2022**)
  - Adverse Events
  - Biomarkers
  - Blood Transfusions
  - Survival Analysis
    - Including PARQUAL
- Subsequent versions will include additional topics

Future of ADaM Documents

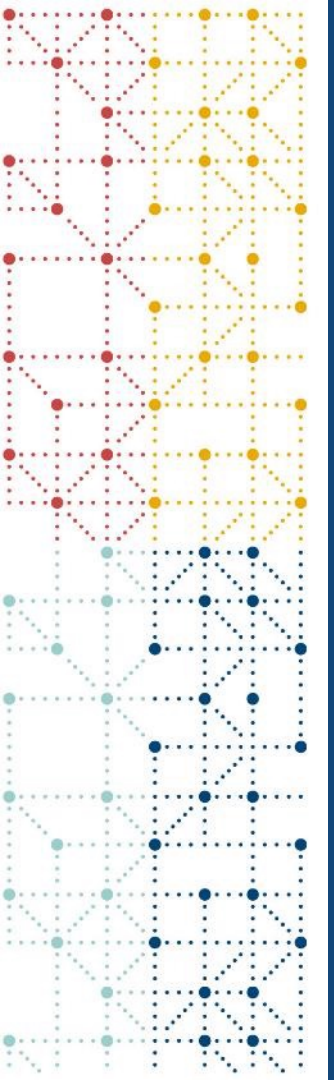
- Can we provide additional implementation guidance?
  - such as for Population PK?
- Should all or some of the publications be combined?
- Can we improve internal consistency within ADaM?
- Can we better serve the user community?

Acknowledgements to Document Leads

- Deb Bauer
  OCCDS IG v1.1
- Nancy Brucken
  ADQRS
- Liana Forman
  COVID-19 Guidance
- Luke Reinbolt
  ADNCA IG
- Julia Yang
  Medical Devices IG
- Paul Slagle
  Oncology Examples.
- Tatiana Sotingco
  Previous ADaM Team Lead
- Wayne Zhong
  Traceability Examples



Questions & Answers



Questions & Answers

Audience Questions

How do I code 'SCREEN FAILURE' from DM to ADSL? 'SCREEN FAILURE' is no longer populated in ARM, but in ARMNRS. If I leave ARM as null for the screen failures, Pinnacle complains ARM value is null in ADSL

Audience Questions

What is population PK (PPK)?

Audience Questions

How do you make population PK (PPK) data CDISC compliant?

Audience Questions

What are some challenges to making PPK BDS like?

Audience Questions

For oncology studies, how do you handle PARAMCD/PARAM for individual tumor measurements in ADTR?

Audience Questions

If a test is NOT DONE, should we include it in ADaM dataset, e.g., ADVS, and add a ANL0xFL to indicate its usage (eg, listing)?

Audience Questions

Any decisions on changing integrated file names with a leading "I" such as IADSL? Saw this online but P21 doesn't accept

Audience Questions

The Order of Variables in ADaM Datasets is not defined. If it is defined, it is easier for us to maintain consistency

Audience Questions

While PRAMTYP has been deprecated, is it a non compliance if someone still uses it to indicate that parameter is derived?

Audience Questions

When will the team build the IG for IVD (In-vitro Diagnostic)?

Audience Questions

Is it possible to create ADaM domains straight from raw data or does it have to be from SDTM domains? If yes, is it valid?

Audience Questions

Should ADNCA be used in all cases of handling PK data at the ADaM level regardless of if PK parameter analysis is being done?

Audience Questions

ADNCA IG structure supports only PK concentration data. For the companies which are not using Software to derive the PK parameters like Cmax, Tmax and AUC can we derive those parameters in ADAM OTHER? Do we have some examples we can refer?

Audience Questions

Q: Could you please provide the location Oncology examples document that is out for public review?

A:

https://wiki.cdisc.org/display/ADAMONC/ADaM+Oncology+Examples+Home

Audience Questions

What happened to the integrated ADaMs effort, e.g. for ISS, ISE, etc.?

Audience Questions

Can you give an example of a study / situation where following will be true? A set of analysis timing variables can be included in ADSL only if the definitions for all the variables in the set are fixed across the study

Audience Questions

Ideally csr reports are one proc away from ADAM and considering multiple statistics that might require from one ADAM dataset it could make really complex ADAM design in return at times..Is there any guidance on that like how much allowed in ADAM or could leave it to CSR development.

Audience Questions

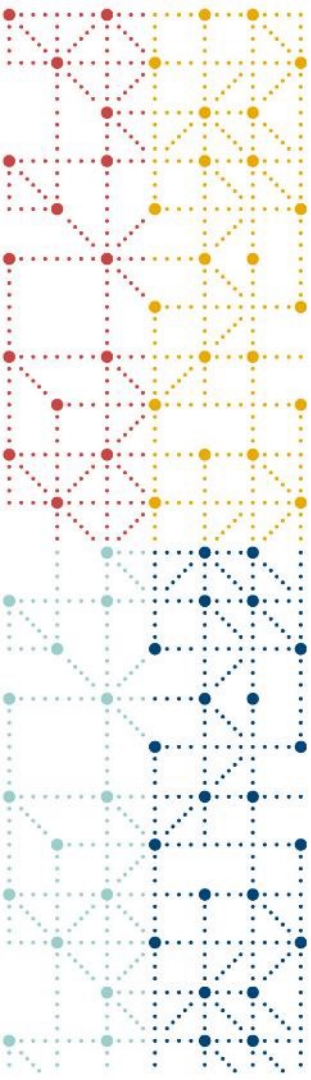
How do we technically volunteer to be on a team and help? I think would like to be on the team for ISS/ISE as fell victim to thinking the names IADSL etc were OK...currently working with a CRO for merging phase 2 and phase 3 studies and trying to be compliant.

Audience Questions

Any specific reason why draft variable PARQUAL was not eaventually made a standard variable?

Audience Questions

Is it prohibited for users to create CATy variables?



Upcoming Events

July

Asia

Virtual Training Event

Regional discounts will appear at checkout.

September

US

Virtual Training Event

- Information available at: www.cdisc.org
- Register at: https://learnstore.cdisc.org/
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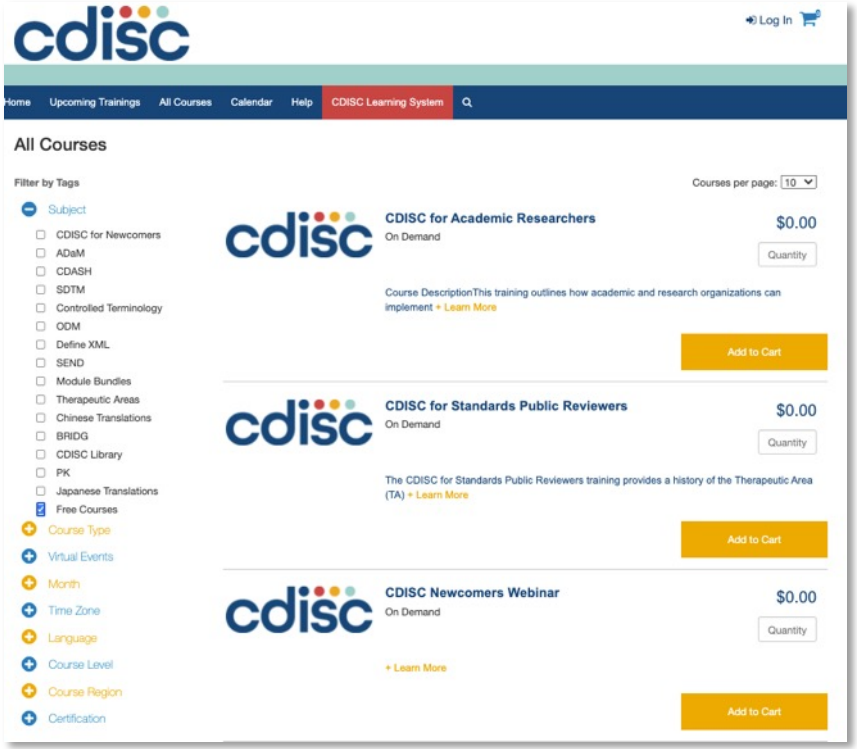

Http://learnstore.cdisc.org

Upcoming Webinars

Date	Title
7 JUN	CORE Volunteer Onboarding Training Webinar
27 JUN	The TMF Reference Model Group and CDISC Affiliation: What's Next?
28 JUN	Controlled Terminology Updates: P50 Publication / P51 Public Review
30 JUN	COSA Spotlight for Q2
4 OCT	Controlled Terminology Updates: P51 Publication / P52 Public review

Future topics:
QRS Quarterly Updates
COSA Quarterly Spotlights

2022 CHINA INTERCHANGE

CDISC VIRTUAL CONFERENCE

29-30 JULY

2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX

WITH STANDARDS – UNLOCK THE POWER OF DATA

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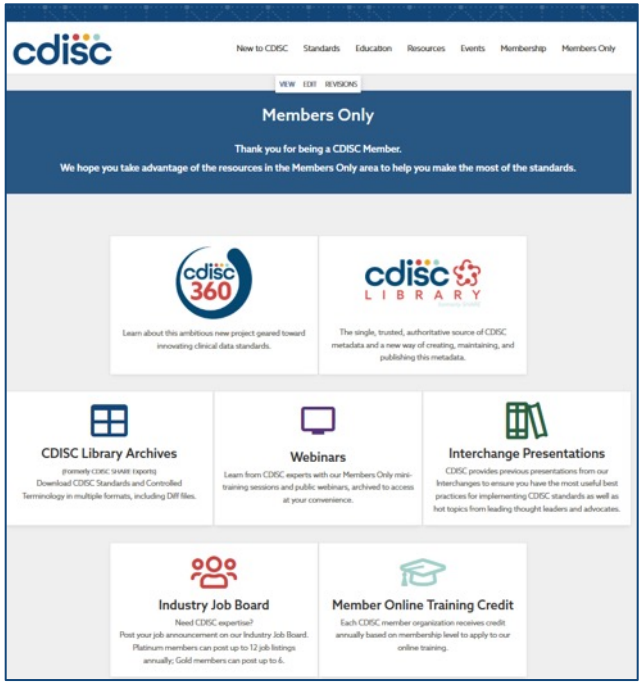
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits
- To gain visibility in the marketplace



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