

CDASH Office Hours

Dana Booth, Sr. Project Manager, Foundational Standards, QRS Co-lead, CDISC

Melissa Binz, Head of the Center for Data Standards and Quality, Pfizer

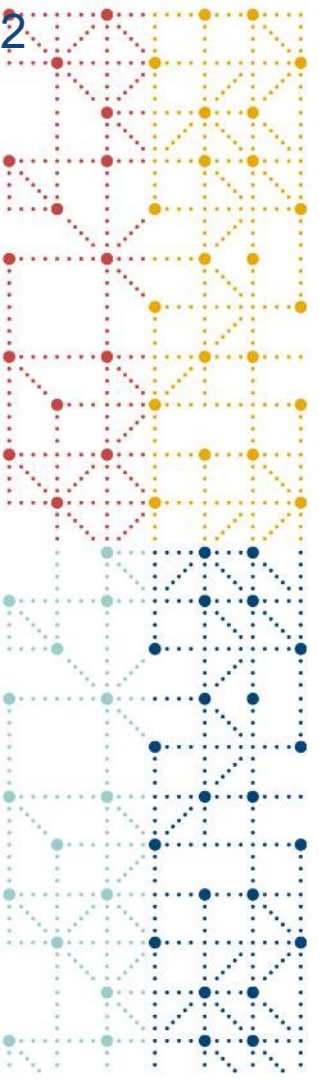
Nikki Flores, Assoc. Director for Data Collection Standards, Gilead

Lorraine Spencer, Associate Director of Clinical Data Standards and Reporting, Abbvie



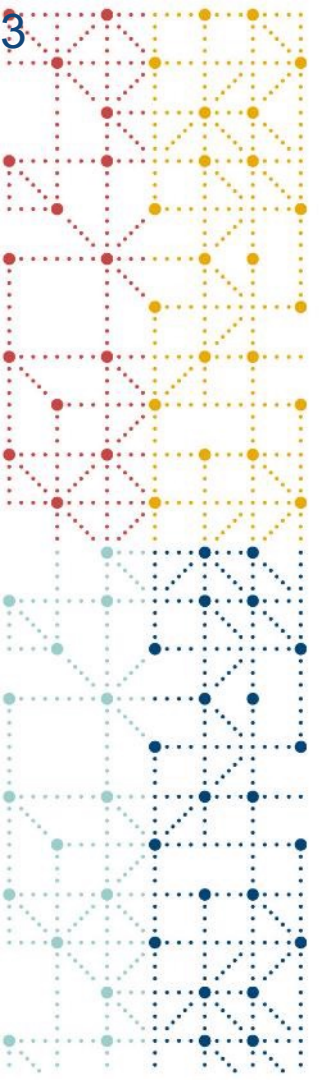
TUE 25 MAY 2022

11:00AM-12:30PM ET



Today's Agenda

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



Housekeeping

Housekeeping



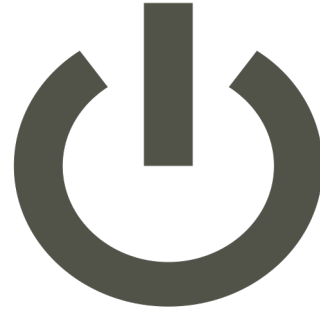
You will remain on **mute**

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

Melissa Binz

Head of Center for Data Standards
and Quality
Pfizer

Nikki Flores

Assoc. Director for Data Collection
Standards
Gilead

Dana Booth

Sr. Project Manager, Foundational
Standards, QRS Co-lead
CDISC

Lorraine Spencer

Associate Director of Clinical Data
Standards and Reporting
Abbvie

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CDASH Office Hours

May 25, 2022



cdisc

Agenda

Time (minutes)	Item	Who
2	Welcome and agenda walkthrough	Melissa Binz
5	CDASH Model/IG update	Nikki Flores
5	Sexual Orientation/Gender Identity SOGI	Melissa Binz
5	CDASH eCRF Portal (CRF Library project) update	Melissa Binz
remaining	Q&A	



CDASH Model/IG

Melissa Binz – CDASH Lead

Nikki Flores – Subteam Lead
Dana Booth – Project Manager



Domain Subteams – Phase 1

Domain	Domain Name	Current Status
CV	Cardiovascular Events Findings	<ul style="list-style-type: none">• Team is done with deliverables• Ready for team review
MK	Musculoskeletal System Findings	<ul style="list-style-type: none">• Team is done with deliverables• Ready for team review
NV	Nervous System Findings	<ul style="list-style-type: none">• In Progress
UR	Urinary System Findings	<ul style="list-style-type: none">• Team is done with deliverables• Ready for team review

Working group information can be found in:
[Phase 1 - CDASHIG alignment with SDTMIG V3.3 - CDASHIG Subteam](#)

Domain Subteams – Phase 2

Domain	Domain Name	Current Status
GF	Genomic Findings	<ul style="list-style-type: none">In Progress
CP	Cell Phenotype Findings	<ul style="list-style-type: none">In Progress
Model	New variables to incorporate in model	<ul style="list-style-type: none">Not Yet Started
Various domain updates	(see link below)	<ul style="list-style-type: none">Not Yet Started

Sign-up and add your name here:

[Phase 2 - CDASHIG alignment with SDTMIG V3.4 - CDASHIG Subteam](#)



Sexual Orientation and Gender Identity (SOGI)

Co-leads: Chris Battiston and Mitra Swartley

The logo for CDISC (Clinical Data Interchange Standards Consortium) features the lowercase letters "cdisc" in a dark blue, sans-serif font. Above the letter "i" are four small, colored dots: red, yellow, orange, and light blue.

Sexual Orientation/Gender Identity (SOGI) and CDASH

- Monthly meetings have begun for the SOGI team - if you're interested in getting involved, please contact Chris (chris.Battiston@wchospital.ca) or Mitra (swartleymitra@gmail.com).
- Looking to develop guidance around collection of sexual orientation, gender, and gender identity information.
- Currently looking for the following:
 - Institutional SOPs
 - “Good” and “bad” examples of SOGI questions you've used / seen
 - Articles and other resources (Fenway, NIH, NSAEM have already been reviewed but if you have any that you find particularly useful please send them)

Thank you so much to the people that have volunteered so far and to CDISC for approving this project! Looking forward to sharing further updates at future meetings....



CDASH eCRF Portal – Phase 2 Update

Co-leads: Varma Nadimpalli, Erica Gonzales, & Alana St. Clair



Project Update

- Full team meets every other week to decide on content and metadata to include in the eCRFs from the TAUG concepts
- On the off weeks, a sub-team meets to work on development of the eCRFs in Formedix Ryze
- Reviewing and making updates to the internal review comments for the eCRFs for the COVID-19 TAUG
 - All the eCRFs are also drafted in Ryze
- Completed Breast Cancer eCRF development
 - All the eCRFs are being drafted in Ryze
- Started working on Prostate Cancer eCRFs

CRF	Domains
Radiation Therapy	PR
Tumor Identification/Results Target Lesions	TU, TR
Tumor Identification/Results Non-Target Lesions	TU, TR
Tumor Identification/Results New Lesions	TU, TR
Disease Response	RS
Pathology	MI

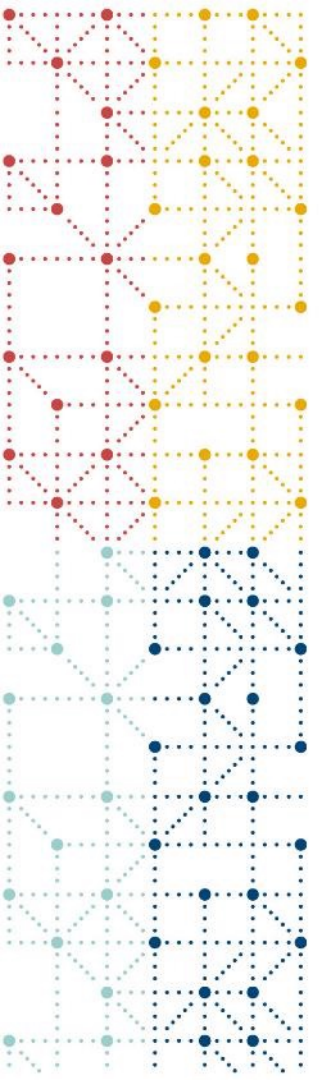
Call for Volunteers!

VOLUNTEER

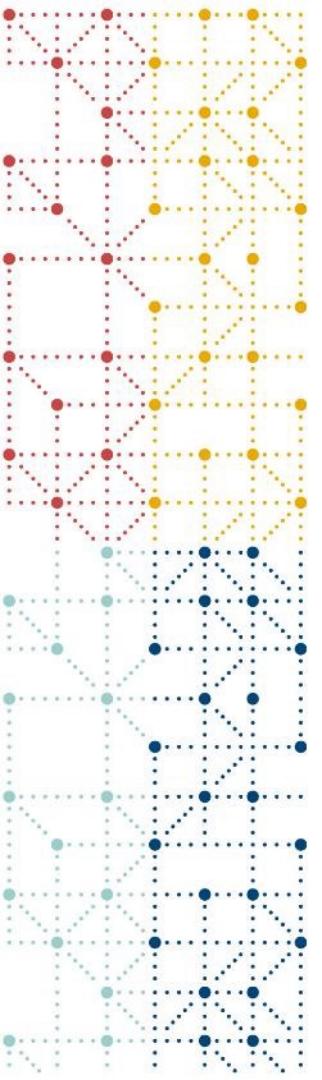


Many Hands Make Light Work

- **SOGI** – mtgs 1/month + additional work ~1H/wk
- **eCRF Portal** – meetings + additional work ~1-2 H/wk
- **CDASHIG - Class leads and Domain leads NEEDED!**
 - Time commitment:
 - Subteam meetings every 2 weeks ~1H (managed by subteam lead)
 - Additional work outside meetings ~1-2H
- **Questions? Contact: Melissa Binz, Nikki Flores, and/or Dana Booth**



Thank You



Questions & Answers

Audience Questions



What are the advantages of using CDISC standards?

Info:

<https://learnstore.cdisc.org/Course/view/cdisc-newcomers-webinar-1>

<https://www.cdisc.org/events/webinar/cdisc-newcomers-are-you-new-here-0>

Audience Questions

How can I get a certificate and what are resources?

Info:

<https://www.cdisc.org/education/cdisc-standards-certification>

<https://learnstore.cdisc.org/Course/index?tags=Certification%7CCDISC%20tabulate>



Audience Questions



How can I start with CDASH implementation for an organization that is newly adopting CDASH?

Audience Questions

Some CDASH recommendations cannot be implemented with common EDC system like Rave. What do you suggest we do when this happens?



Audience Questions



What's the difference between CDASH variables and SDTM variables? How are they related?

Audience Questions

With Controlled Terminology Codelists, it is recommended to store the actual value or numeric code? For example, with the AESEV code list.



Audience Questions



Do we have to add variable on SDTM to trace back to CRF (like ADaM trace to SDTM)?

Audience Questions

Any such initiatives for Hematology?



Audience Questions



Is there any subteam working on CDASH-MD? If so, can you share the current progress?

Audience Questions

Is there any plan to include CDASH as a formal submission part in clinical trail submission?



Audience Questions



In our company, we have annotated CRF both with CDASH and SDTM: the 1st is for eDC set-up and the other is for Stat team (analysis). Is it a good practice?

Audience Questions

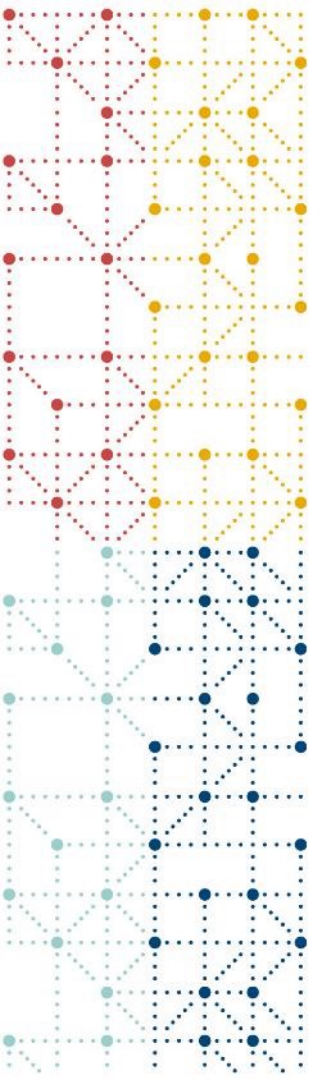
Looking at the AE eCRF, is
CTCAE grading standard?
I've always used that vs.
"mild, moderate, severe"
like in the template.



Audience Questions



Any advice on biomarker eCRF development? We have struggled with overlap in cell phenotype (CP), microscopic findings (MI), genomic findings (GF), microbiology (MB), and laboratory (LB) domains.



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/>
- Contact us at: training@cdisc.org



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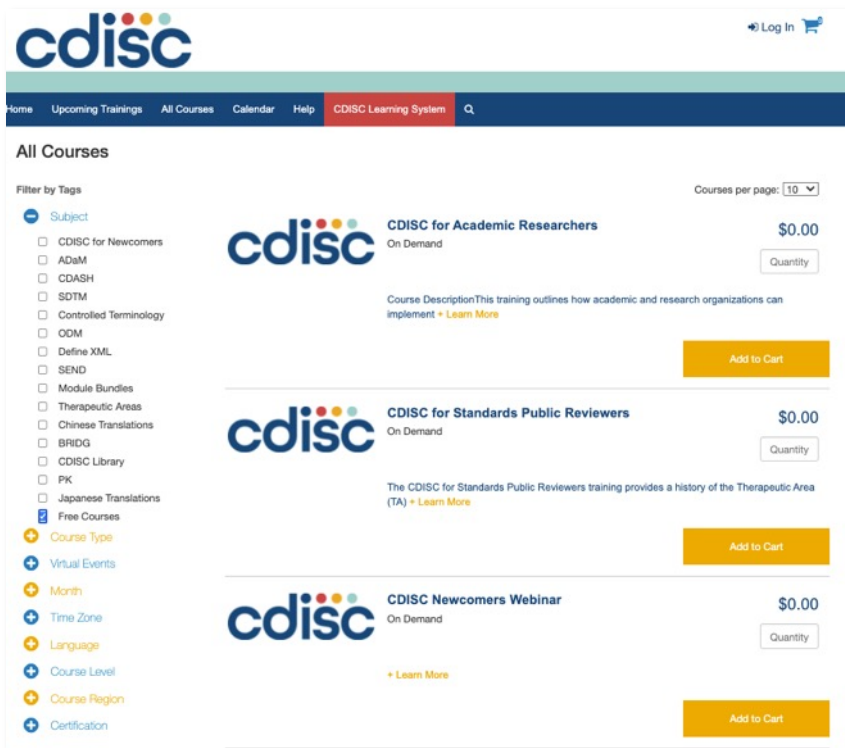


WEBINARS



WORKSHOPS

Free CDISC Courses



The screenshot displays the CDISC Learning System interface. At the top, the CDISC logo is on the left, and a 'Log In' button with a shopping cart icon is on the right. A navigation bar below the logo contains links for 'Home', 'Upcoming Trainings', 'All Courses', 'Calendar', 'Help', and 'CDISC Learning System'. The 'All Courses' page is active, showing a list of three free courses. On the left, there is a 'Filter by Tags' section with a 'Subject' dropdown and a list of checkboxes for various topics like 'CDISC for Newcomers', 'ADaM', 'CDASH', etc. Below the list are expandable sections for 'Course Type', 'Virtual Events', 'Month', 'Time Zone', 'Language', 'Course Level', 'Course Region', and 'Certification'. The main content area shows three course cards, each with the CDISC logo, title, 'On Demand' status, '\$0.00' price, a 'Quantity' input field, and an 'Add to Cart' button. The first course is 'CDISC for Academic Researchers', the second is 'CDISC for Standards Public Reviews', and the third is 'CDISC Newcomers Webinar'. Each card also includes a brief description and a '+ Learn More' link.

cdisc Log In

Home Upcoming Trainings All Courses Calendar Help **CDISC Learning System**

All Courses

Filter by Tags Courses per page: 10

Subject

- CDISC for Newcomers
- ADaM
- CDASH
- SDTM
- Controlled Terminology
- ODM
- Define XML
- SEND
- Module Bundles
- Therapeutic Areas
- Chinese Translations
- BRIDG
- CDISC Library
- PK
- Japanese Translations
- Free Courses

Course Type

Virtual Events

Month

Time Zone

Language

Course Level

Course Region

Certification

cdisc **CDISC for Academic Researchers** **\$0.00**
On Demand

Course Description This training outlines how academic and research organizations can implement [+ Learn More](#)

cdisc **CDISC for Standards Public Reviews** **\$0.00**
On Demand

The CDISC for Standards Public Reviews training provides a history of the Therapeutic Area (TA) [+ Learn More](#)

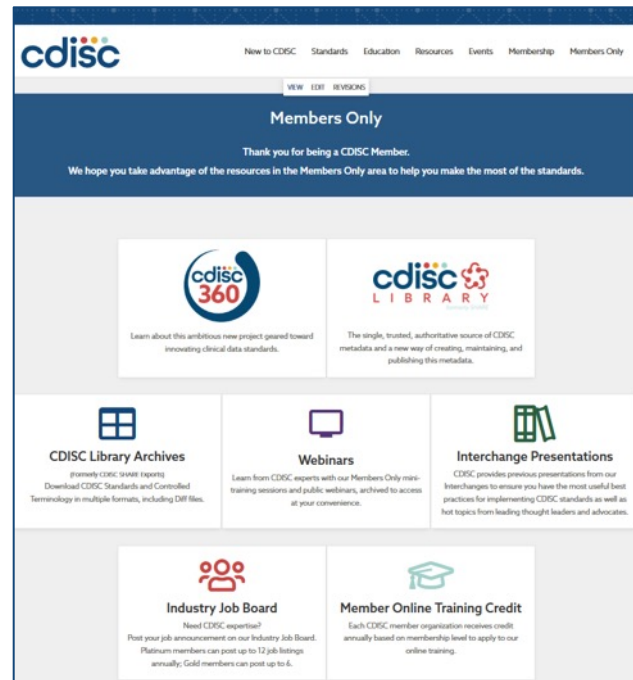
cdisc **CDISC Newcomers Webinar** **\$0.00**
On Demand

[+ Learn More](#)

[Http://learnstore.cdisc.org](http://learnstore.cdisc.org)

Why Become a Member?

- To ensure the CDISC standards remain open and free
- To support CDISC in the development and maintenance of global standards
- To work with the CDISC community and be a voice in the development of clinical research standards
- To impact the development of regulatory requirements for submissions
- To access members only resources and benefits
- To gain visibility in the marketplace



The screenshot displays the CDISC website's 'Members Only' section. At the top, the CDISC logo is on the left, and navigation links for 'New to CDISC', 'Standards', 'Education', 'Resources', 'Events', 'Membership', and 'Members Only' are on the right. Below the navigation is a 'VIEW EDIT REVISIONS' link. The main heading is 'Members Only' with a sub-heading 'Thank you for being a CDISC Member.' and a message: 'We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.'

The content is organized into several tiles:

- cdisc 360:** Learn about this ambitious new project geared toward renovating clinical data standards.
- cdisc LIBRARY:** The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing the metadata.
- CDISC Library Archives:** Browse CDISC credit reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars:** Learn from CDISC experts with our Members Only training sessions and public webinars, archived to access at your convenience.
- Interchange Presentations:** CDISC provides previous presentations from our Interchanges to ensure you have the most useful best practices for implementing CDISC standards as well as hot topics from leading thought leaders and advocates.
- Industry Job Board:** Need CDISC expertise? Post your job announcement on our Industry Job Board. Platinum members can post up to 12 job listings annually. Gold members can post up to 6.
- Member Online Training Credit:** Each CDISC member organization receives credit annually based on membership level to apply to our online training.

CDISC MEMBERSHIP

Become a Member!

Join nearly 500 member organizations that contribute to bringing clarity to data.

Already a Member?

Thank you! It is our members' support which enables us to develop standards, keeping it free and accessible to all.

JOIN US



Email: membership@cdisc.org



Thank you!



Contact the Events inbox:
events@cdisc.org



Contact Education inbox:
training@cdisc.org



Contact Bernard directly:
bklinke@cdisc.org