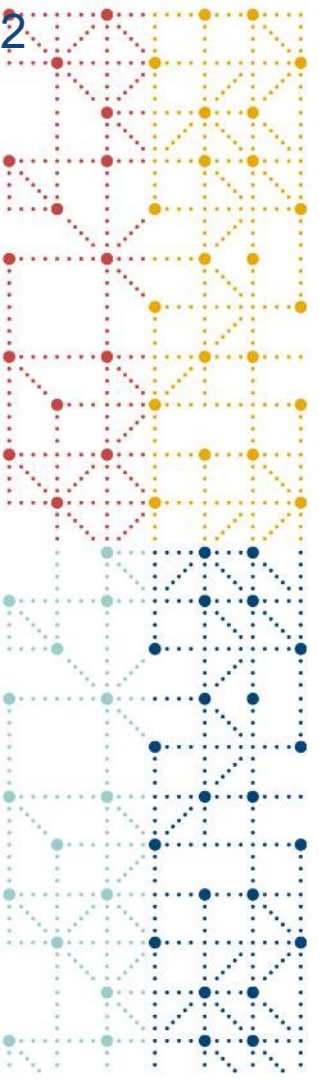




Digital Data Flow Phase 4 Public Information Webinar

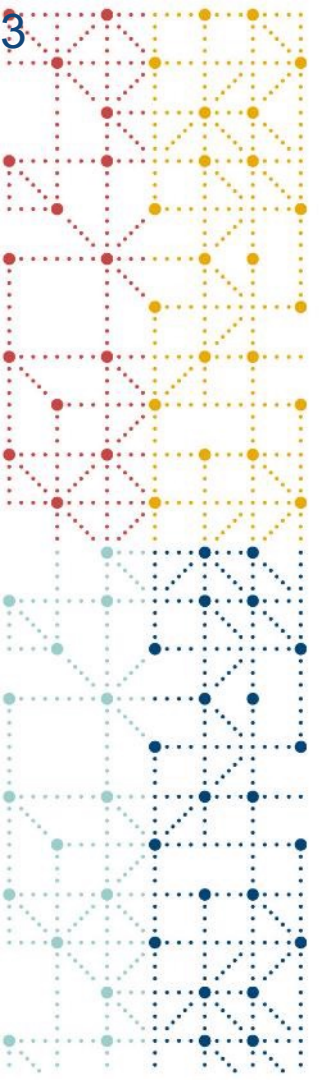
cdisc

TUE 2 JUL
11:00AM – 12:00PM US ET



Today's Agenda

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



Housekeeping

Housekeeping



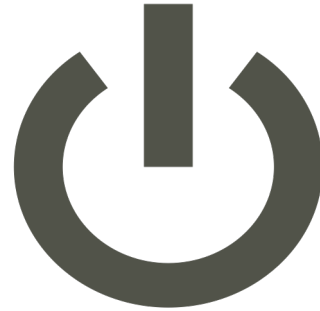
You will remain on **mute**

Housekeeping



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

Housekeeping



Audio Issues?

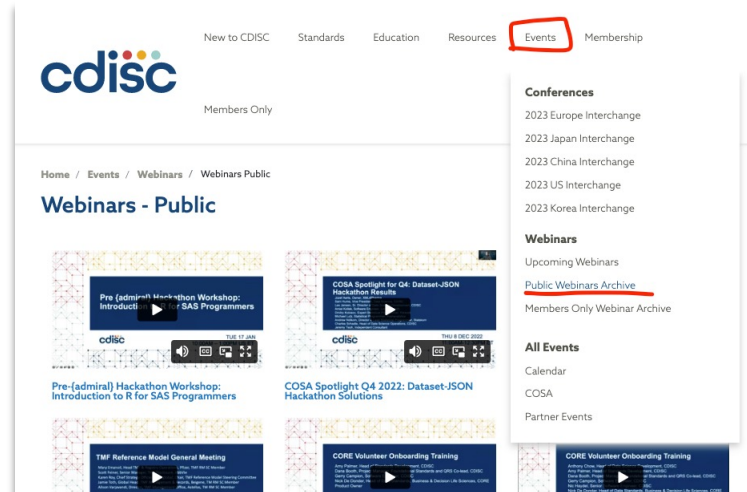
First, close and restart your Zoom App
Second, check your local internet connection strength

Housekeeping



Webinar Recording

A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.

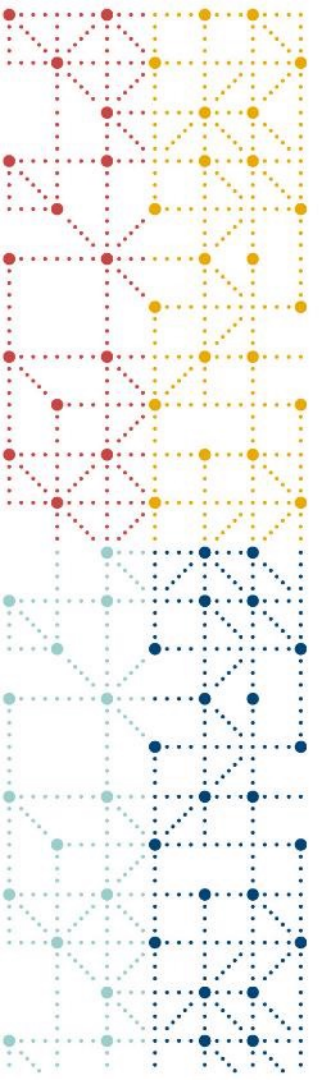




Digital Data Flow Phase 4 Public Information Webinar

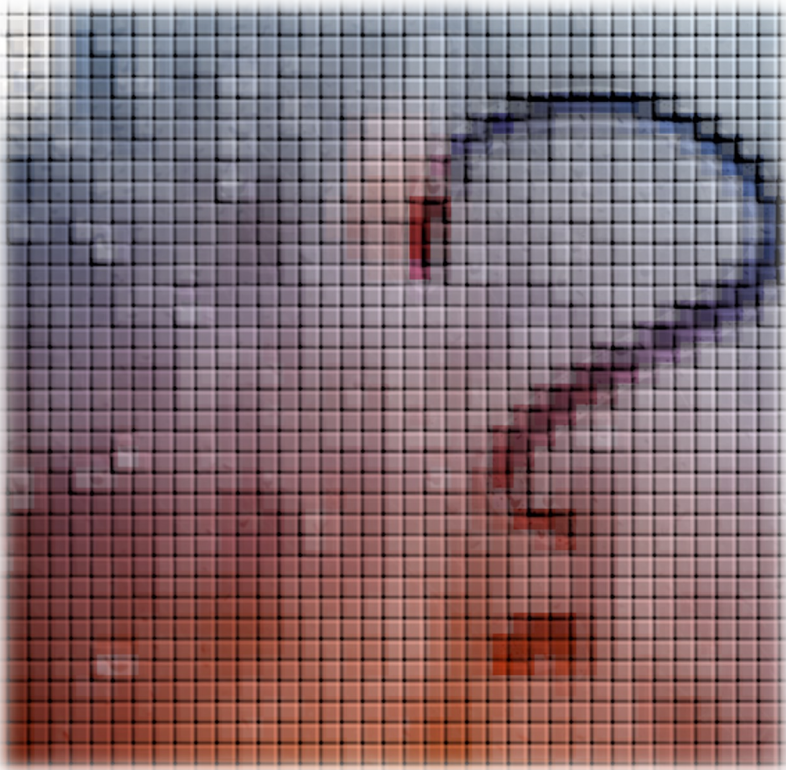
cdisc

TUE 2 JUL
11:00AM – 12:00PM US ET



Questions & Answers

Audience Questions



Will it be possible to use USDM data elements to pre-populate data in TMF document templates?

Audience Questions

ICH M11 template, specifications, and guidance are planned to be implemented in November 2025. Is TransCelerate planning to have its CPT aligned with ICH M11, including technical specifications that will allow DDF and integration with PRISM, by November 2025?

DDF and USDM development is aligning directly with M11 technical specifications as they emerge so there is no dependency on the TransCelerate CPT.



Audience Questions



For those currently using the TransCelerate CPT, I am wondering if/when that template will have capabilities that allow DDF and integration with PRISM?

Audience Comment

Question to Dave: In your planned US workshop you just mentioned, will the protocol data be entered via Excel template (like in Berlin) or via OpenStudyBuilder?

DAVE IH:
We will use the Excel but also have some new “toys”. OSB can only export in USDM, does not use it internally and also does not store the entire protocol document

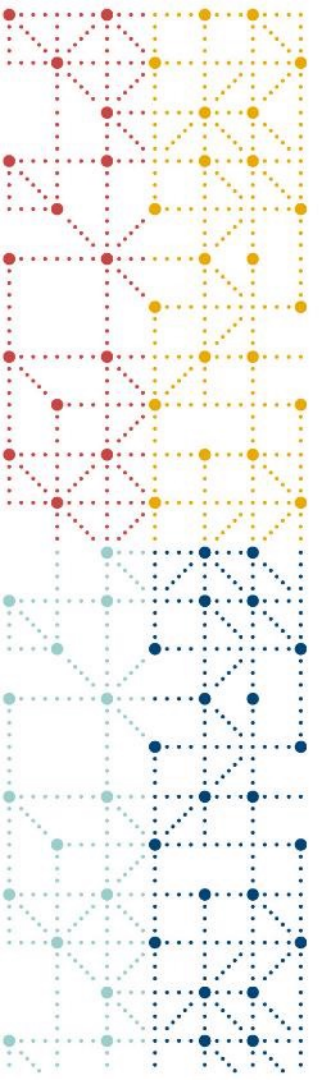
Audience Questions

DAVE IH:
**Dangerous question :)
Depends on how you
measure it obviously,
but I would say as a
rough guide 30% - 40%
area.**

**(probably for Dave):
Between the two extremes of
100% document-based and
100% data-based, where
would you put ICH M11 as far
as you can tell?**





Audience Questions








Upcoming Events

Upcoming Webinars

Date	Title	
TUE 2 JULY	Digital Data Flow Project Phase 4 Informational Webinar	
TUE 16 JULY	Level Up Your Clinical Data Skills with CDISC Education	
TUE 17 SEP	TMF Reference Model General Meeting – Q3	
TUE 24 SEP	CDISC Open Source Alliance Quarterly Spotlight – Q3	

 <p>In-Person Trainings SHANGHAI, CHINA 28-29 August 2024</p> <p>Shanghai</p>	 <p>In-Person Trainings SCOTTSDALE, ARIZONA 21-25 October 2024</p> <p>Scottsdale</p>	 <p>In-Person Trainings SEOUL, KOREA 11, 14, 15 November 2024</p> <p>Seoul</p>	 <p>SEPTEMBER EUROPE VIRTUAL TRAINING EVENT</p> <p>Virtual Event</p>	 <p>CDISC Newcomers Virtual</p>
--	---	---	--	--

 <p>TMF Virtual / On-Demand</p>	 <p>CT Virtual / On-Demand</p>	 <p>SEND Virtual / On-Demand</p>	 <p>CDASH Virtual / On-Demand</p>	 <p>SDTM Virtual / On-Demand</p>
--	---	---	--	--

 <p>ADaM Virtual / On-Demand</p>	 <p>ODM Virtual / On-Demand</p>	 <p>Define-XML Virtual / On- Demand</p>	 <p>Tobacco Implementation Guide (TIG) On- Demand</p>	 <p>*Coming Soon* LHEA On- Demand</p>
---	--	--	--	---

 <p>TAUGS & Free Trainings</p> <p>TAUGS & Free Trainings</p>	 <p>CDISC Certifications</p> <p>CDISC Certifications</p>	 <p>Additional Trainings</p> <p>Miscellaneous/ Other</p>
---	---	---

CDISC Education Training Courses

- Information available at: www.cdisc.org
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: training@cdisc.org



BLEND
ED LEAR
NING



VIRTUA
L TRAIN
ING



CLAS
SROOM
TRAIN
ING



PRIV
ATE TR
AINING



WEBI
NARS



WORK
SHOPS

Free CDISC Courses

Dashboard / CDISC Learning Management System / Tags / Free



Free

Add "Free" to my interests Flag as inappropriate Edit this tag

Courses tagged with "Free"



SDTM Module 1: Introduction

The CDISC standards, process, participants and an introduction to the Study Data Tabulation Model and its documentation set.

Module-Level Learning Outcomes:

- explain the purpose of the CDISC Standards and SDTM
- locate and access the documentation for the current versions of SDTM-related documents

Language: English | **Duration:** 00:36:34 | **CEUs:** 0.1

Category: SDTM



TAUG Module 1: Overview of Therapeutic Area User Guides

Therapeutic Area User Guide, Module 1 provides an overview of the structure of Therapeutic Area User Guides. It describes concept maps and metadata, shows the relationship between foundational Guides, and also discusses how to review draft TA User Guides.

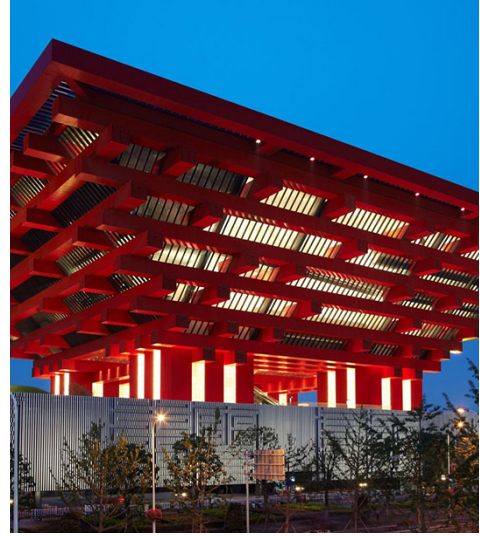
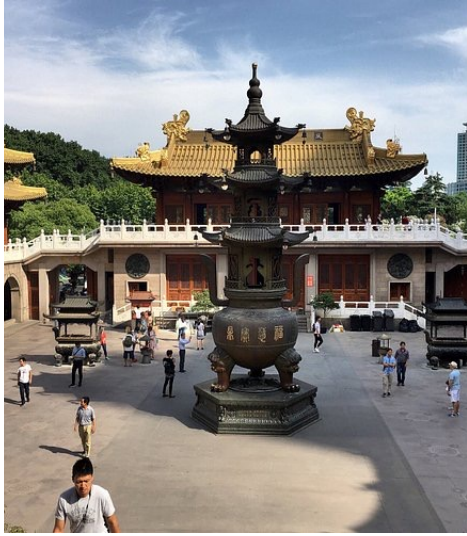
Module-Level Learning Outcomes:

- describe the CFAST organization, stakeholders, and high level TA standards development process
- describe deliverables for each development process stage
- discuss the development of concept models/maps and how they are used
- use the concept metadata structures
- explain the Therapeutic Area User Guides (TA User Guides) and where the concepts fit into the existing CDISC models
- apply best practices for reviewing and contributing feedback on TA User Guides during public review periods

Language: English | **Duration:** 02:10:14 | **CEUs:** 0.2



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



2024 CDISC China Interchange

Shanghai, China
30– 31 August 2024

<https://www.cdisc.org/events/interchange/2024-china-interchange>





2024 CDISC + TMF US Interchange

*Scottsdale, Arizona
23 - 24 October 2024*

<https://www.cdisc.org/events/interchange/2024-cdisc-us-tmf-interchange>

Upcoming 2024 Interchanges



2024 CDISC + TMF Europe Interchange

Location:
Berlin, Germany

Main Conference:
24-25 April 2024



2024 Japan Interchange

Location:
Tokyo, Japan

Main Conference:
12-13 June 2024



2024 China Interchange

Location:
Shanghai, China

Main Conference:
30-31 August



2024 CDISC + TMF US Interchange

Location:
Scottsdale,
Arizona

Main Conference:
23-24 October



2024 Korea Interchange

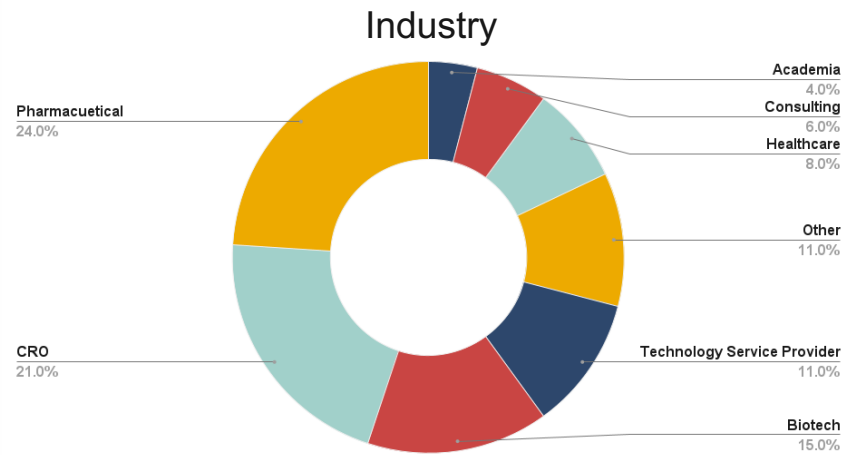
Location:
Seoul, South
Korea

Main Conference:
12-13 November



Sponsor a 2024 Interchange!

	EMERALD (5 AVAILABLE)	SAPPHIRE (4 AVAILABLE)	RUBY (3 AVAILABLE)	DIAMOND (2 AVAILABLE)
EVENT PARTICIPATION				
Exhibitor Booth(s)	0	1	1	2
Conference Passes	1	2	4	6
Thank You During Open Plenary	X	X	X	X
Sponsored Sessions			1	2
Additional Registrant Discount*		5% REGISTRATION DISCOUNT	7% REGISTRATION DISCOUNT	10% REGISTRATION DISCOUNT
VISIBILITY AND BRANDING				
Logo on CDISC Website	X	X	X	X
Logo on Agenda	X	X	X	X
Your Logo on Rotating Slides	X	X	X	X
Branded Sponsor Signage	X	X	X	X
1 Page Flyer at Registration**	X	X	X	X
Percentage Off Additional À-la-carte Sponsorship Items			10%	15%
MARKETING & COMMUNICATIONS				
Logo in Email Communications	X	X	X	X
Logo on Mobile App	X	X	X	X
Mobile App Push Notifications		1	2	3
Featured Sponsor on Mobile App		X	X	X
1/2 Page Ad in Program				X
Company Promotion on Rotating Slides				X
NETWORKING				
Basic Attendee List	X	X	X	X
Attendee Marketing List***			X	X
PRICE (USD)	\$6,000	\$12,000	\$18,000	\$24,000



2023 Interchange Attendee Snapshot



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



Members Only

Thank you for being a CDISC Member.

We hope you take advantage of the resources in the Members Only area to help you make the most of the standards.

<p>Industry Job Board</p> <p>Need CDISC expertise?</p> <p>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.</p>	<p>Member Online Training Credit</p> <p>Each CDISC member organization receives credit annually based on membership level to apply to our online training.</p>	<p>CDISC Library</p> <p>The authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.</p>
<p>CDISC Library Archives</p> <p>Download CDISC Standards and Controlled Terminology in multiple formats, including Diff files.</p> <p>CDISC LIBRARY ARCHIVES WILL BE RETIRED AT THE END OF 2022.</p>	<p>Webinars</p> <p>Learn from CDISC experts with our Members. Only mini-training sessions and public webinars, archived to access at your convenience.</p>	<p>Interchange Presentations</p> <p>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.</p>

NEW MEMBERSHIP RATES (US\$) - Effective 1 January 2022			
Total Number of Employees in Organization	GOLD Member Annual Fee	PLATINUM Member Annual Fee	First Year PLATINUM Member One-Time Contribution
1-19	\$1,690	\$4,500	Annual fee + \$4,500
20-99	\$4,500	\$7,315	Annual fee + \$7,315
100-999	\$9,570	\$11,820	Annual fee + \$11,820
1,000-9,999	\$24,200	\$27,015	Annual fee + \$27,015
10,000-24,999	\$32,640	\$36,580	Annual fee + \$36,580
25,000-49,999	\$39,395	\$47,270	Annual fee + \$47,270
50,000 +	\$55,445	\$65,280	Annual fee + \$65,280

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