2021 US INTERCHANGE

With Standards – Science Will Prevail!

Conference | Trade Show

Live Event | 18-22 October

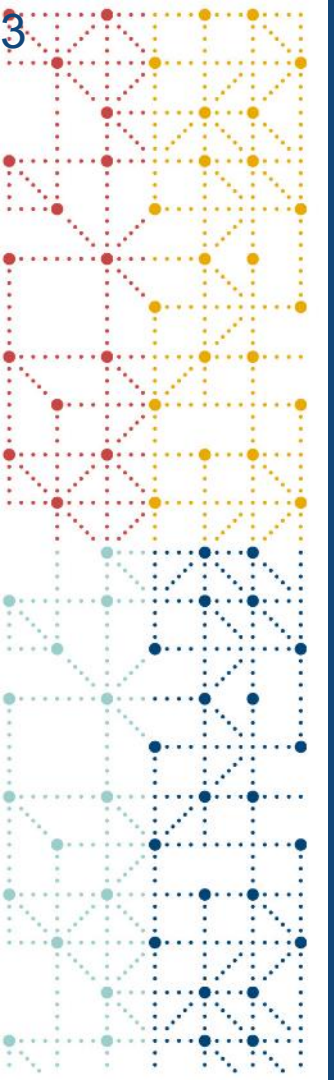
cdisc

Sneak Peek Webinar

TUE 21 SEP
10:00AM-10:45AM ET

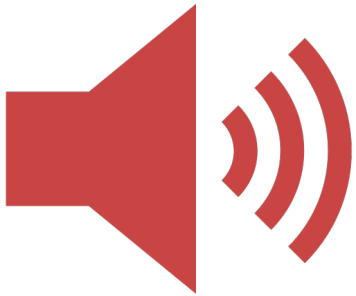
Today's Agenda

1. Housekeeping
2. Speaker Introductions
3. Regulatory + Plenary Details
4. CORE + COSA Project Presentation Details
5. Pathable Platform Overview
6. Q&A
7. Upcoming Learning Opportunities & Events



Housekeeping

Housekeeping

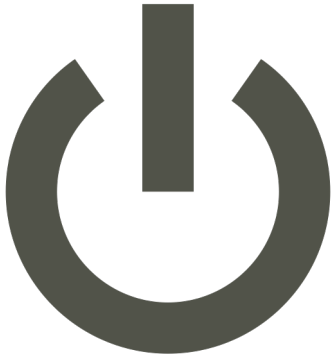


You will remain on **mute**

Housekeeping

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

Housekeeping



Audio issues?

Shut down & restart Zoom app

Housekeeping

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

Today's Presenters

- Sam Hume, Vice President, Data Science, CDISC
- Bernard Klinke, Virtual Experience Manager, CDISC
- Amy Palmer, Head of Standards Development, CDISC
- Andrea Vadakin Rao, Sr. Director, Membership and Events, CDISC

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Regulatory and Plenary Sessions

Amy Palmer
Head of Standards Development
CDISC

Opening Plenary

Keynote Presentation: The Post Covid "wild west" of DCTs, and technology - is there a place for standards?

- Dr. Isaac R. Rodriguez-Chavez, Ph.D., M.H.S., M.S., Senior Vice President for Scientific & Clinical Affairs, ICON plc
- Kent Thoelke, Chief Innovation Officer, ICON plc

Interchange Highlights – Data Standards

- Questionnaires, Ratings and Scales
  - FDA Participation
- COVID-19
  - Global Public Health
- ADaM
  - 2 full sessions
- CDISC Fundamentals
  - Overview of SDTM v2.0
  - Laboratory data
  - Biospecimens and precision medicine
- Analysis Results Standard
  - Full session on CDISC's newest standard

Regulatory Session and Closing Plenary

- **Closing Keynote Presentation: Facilitating the Development of COVID-19 Vaccines**
  - Dr. Peter Marks, Director, Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration

- EMA, FDA, and PMDA presentations
- Regulatory Roundtable Discussion

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Sneak Peek: Special Projects

Sam Hume
VP, Data Science
CDISC

CDISC Open Source Alliance (COSA)

Mission: The CDISC Open Source Alliance supports, promotes, and sometimes sponsors open source and free software development projects that create tools for implementing or developing CDISC standards to drive innovation in the CDISC community.

- Directory for open-source projects
- Conference sessions & webinars
- Hackathons & workshops
- Sandbox environment & test data
- Community building
- Information exchange
- Open-source best practices
- Licensing guidance

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Email cosa@cdisc.org for more information

Implementing 360: Projects

STANDARDS DEVELOPMENT

1. Complete E2E Foundational Standards

- **Project:** eCRF Portal
- **Project:** Analysis Results Standard
- **Project:** Safety User Guide

2. Enrich Foundational Standards

- **Project:** Mining Define.xml's

STANDARDS DELIVERY

3. Extend CDISC Library Model

- **Project:** Model concepts
- **Project:** Add QRS content

4. Collaborate with Industry

- **Project:** Use mining Define.xml project as prototype for collaborative curation process

eCRF Portal Project

t form (CRF) layout

Form AE - Adverse Events			
1 AE - Adverse Events			
1.1	Were any adverse events experienced?	[N] No [Y] Yes	***AEYN***
1.2	What is the adverse event term?		***AETERM***
1.3	Start Date (DD-MMM-YYYY)		***AESTDAT***
1.4	Ongoing (as of [the study-specific time point or period])	[N] No [Y] Yes	
1.5	End Date (DD-MMM-YYYY)		
1.6	Severity	[MILD] M [MODERATE] [SEVERE]	

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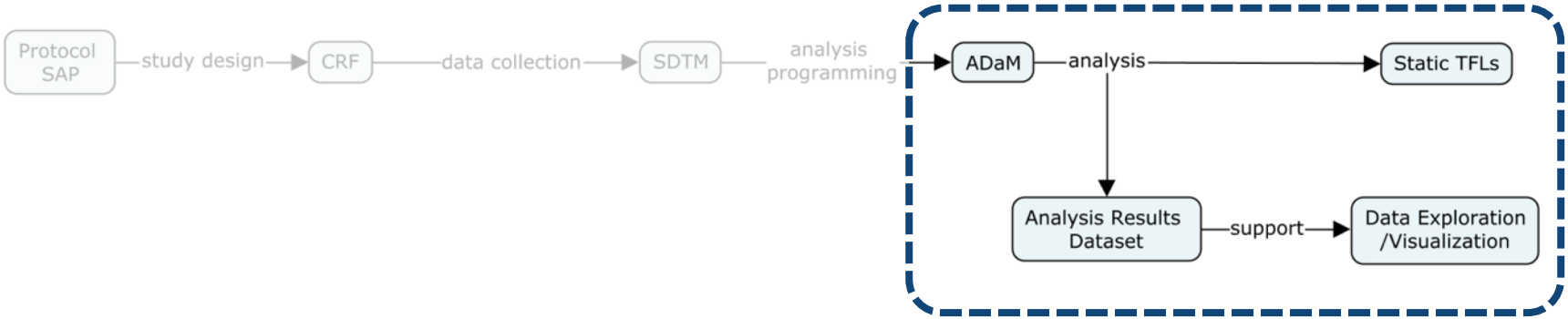
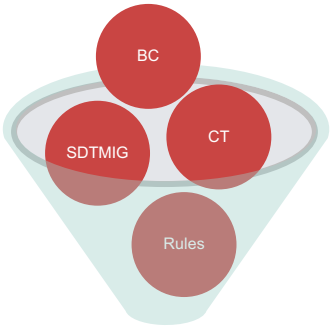
Analysis Results



Behind the Scenes with CDISC Data Science



Sources:

- CDISC Wiki
- YAML Editor
- NCI EVS FTP Site
- ODM or Define-XML

Spec Grabber / QC Checker / YAML Schema

NEW

Standards Pipeline

Standards JSON Documents

CDISC Library Standards Metadata Store

CDISC Library Cognitive Search

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cdisc LIBRARY

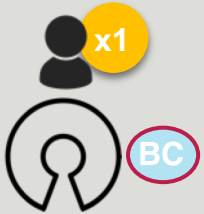
Biomedical Concepts and Define-XML Mining

Develop

Develop the app based on existing work to speed progress.

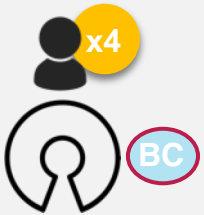
Allow for audit of what is stored to assure Sponsors no data preserved other than metadata

One Sponsor Test



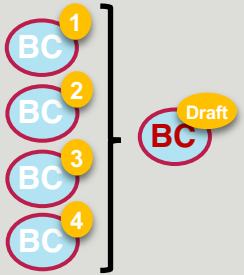
Test with single sponsor

Multiple Sponsor Mining



Run with four sponsors

Curate



For each BC we have 1 to 4 ”answers”

Merge into a single 1st draft

Release & Report

Share BCs with community and report on experience

A3 can host within community version to allow people to become familiar

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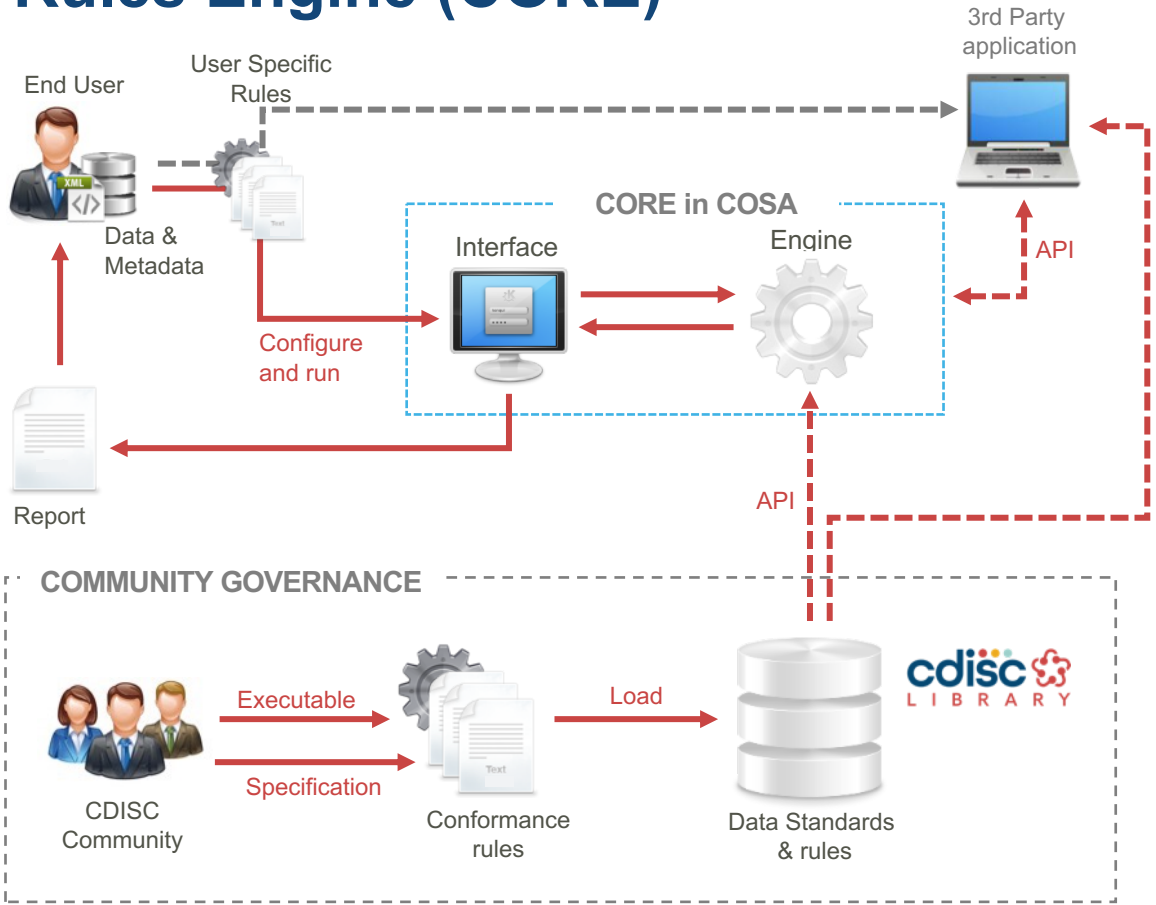
CDISC Open Rules Engine (CORE)



Digital Data Flow

Digital Data Flow

Catalyze industry-level transformation enabling vendor-agnostic, digital exchange of study definition information by collaborating with technology providers and standards bodies to create a sustainable open-source solution

Project Life Cycle Phase:

Last Update: May 2021

Benefits:

- Accelerate study startup & execution
- Increase automation while reducing manual hand-offs and transcription
- Increase flexibility of system architecture enabling increased interoperability
- Enable collaboration among parties, including vendors, leading to innovation
- Wide accessibility via open-source
- Ability of solution to evolve while maintaining dynamic alignment to standards

Pathway to Solution:

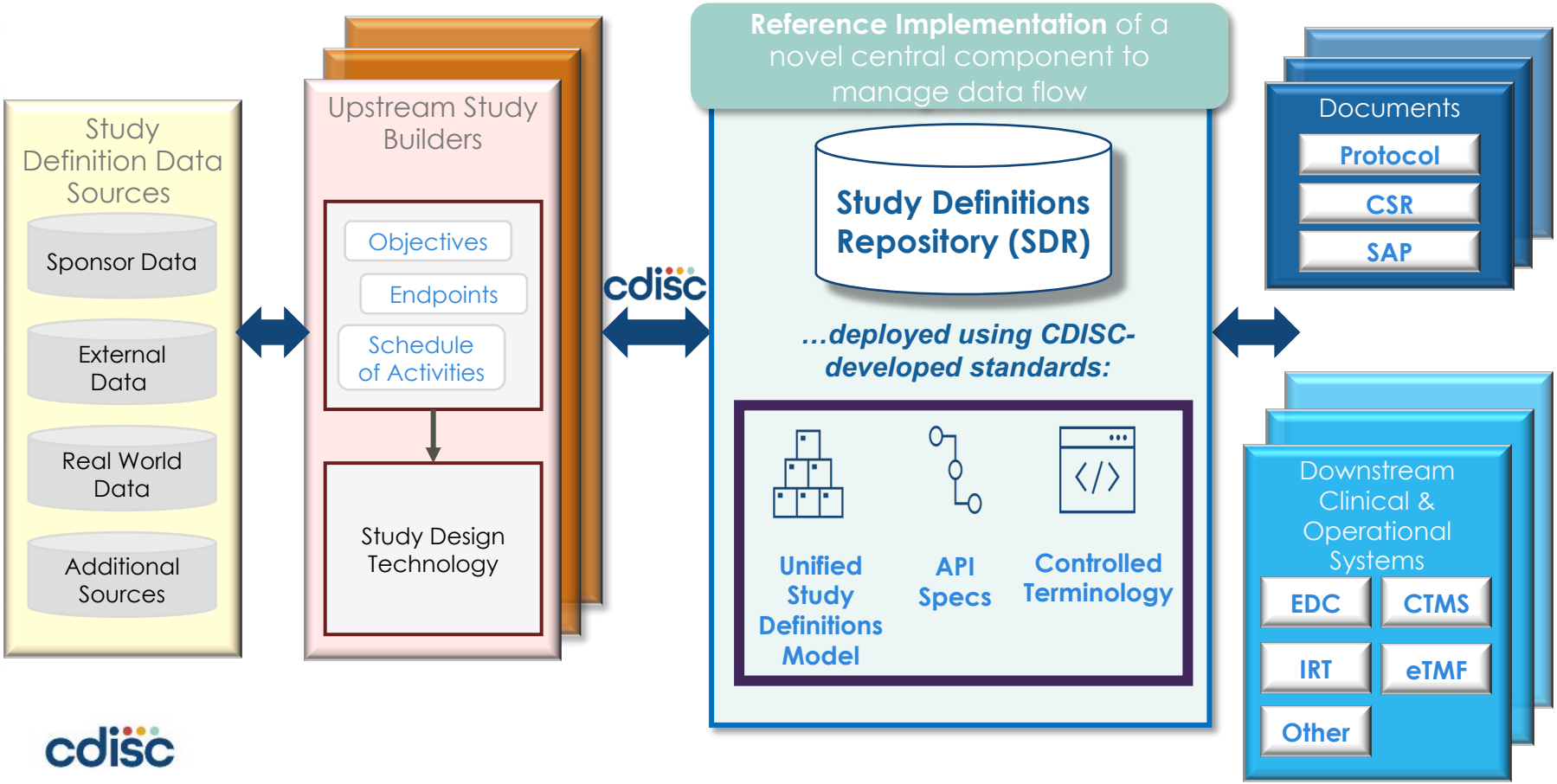
Develop the Study Design Repository Reference Implementation:
Collaborate with technology vendors on a viable functioning environment showcasing standards, capabilities and connectivity with the clinical systems infrastructure

Develop Unified Study Definition Standards:
Standards Setting Organizations (SSOs) to develop the data standards and API standards core to the SDR

Prepare the Ecosystem for Transformational Change:
Engage with vendors and sponsors to pave the way for industry-wide transformation

Establish Self-Sustaining Governance:
Mobilize creation of a multi-stakeholder governance of the open-source solution and ongoing connection to standards

Digital Data Flow



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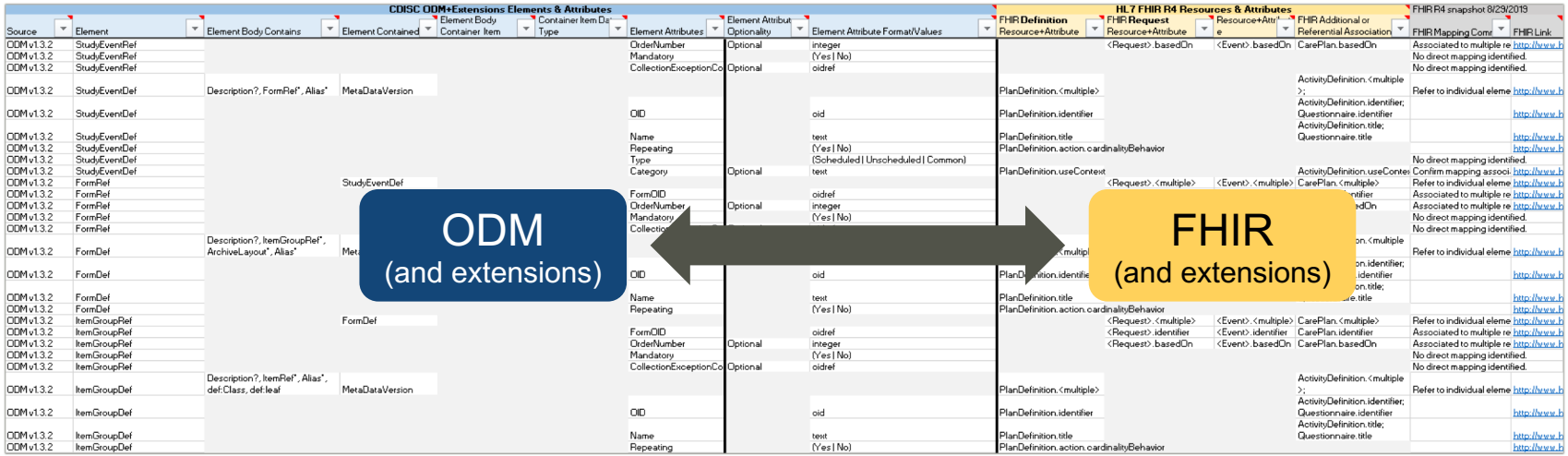
Real World Data



Pathable Platform Tour

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Registration, Sponsoring, and Exhibiting

Andrea Vadakin Rao
Sr. Director, Membership & Events
CDISC

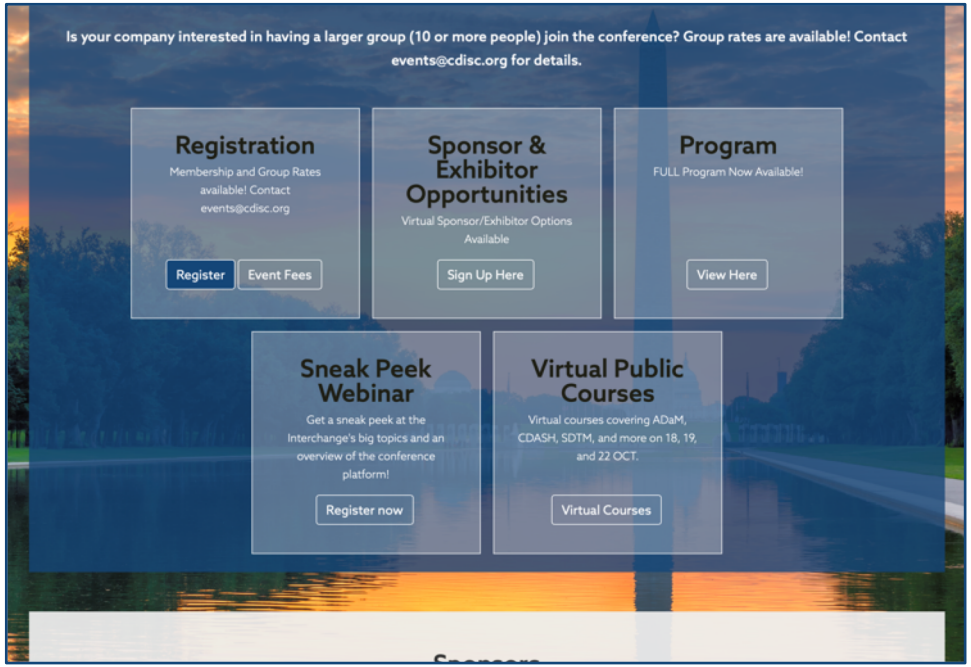
Registering for the Event

Event Fees & Discounts

Virtual Conference Fees			
Discount	**Platinum Members**	**Gold Members**	**Non-Members**
Membership Discount (40% for Platinum, 20% for Gold)	$480	$640	$800
+ Group Discount (10% off for 10+ people)	$432	$576	$720
TOTAL STACKABLE DISCOUNTS	**$432.00** *($368.00 off regular admission)*	**$576.00** *($224.00 off regular admission)*	**$720.00** *($80.00 off regular admission)*

Additional rates for non-profit organizations, government agencies, and students available!

Registration Process

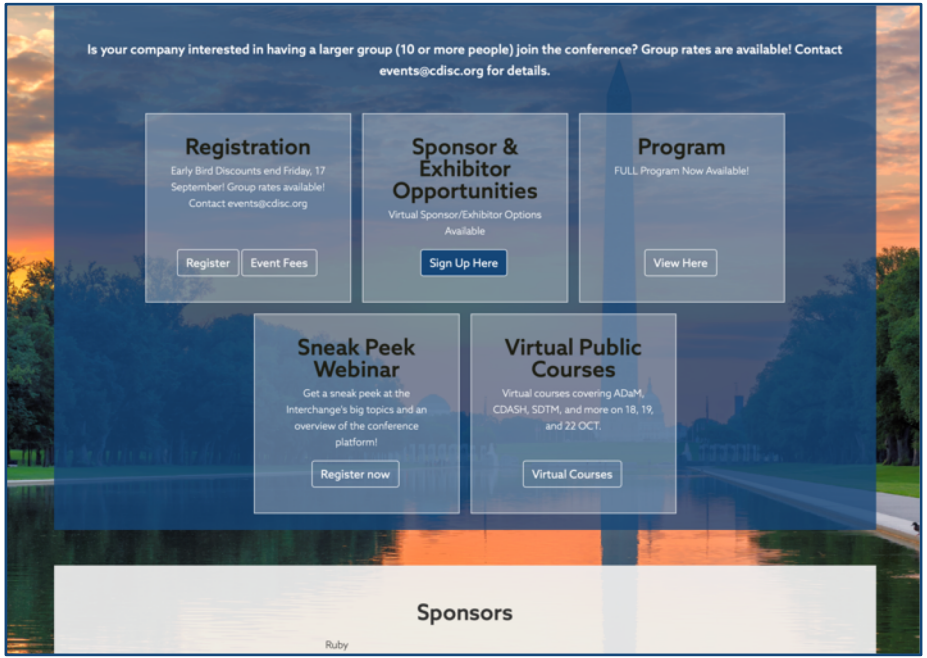


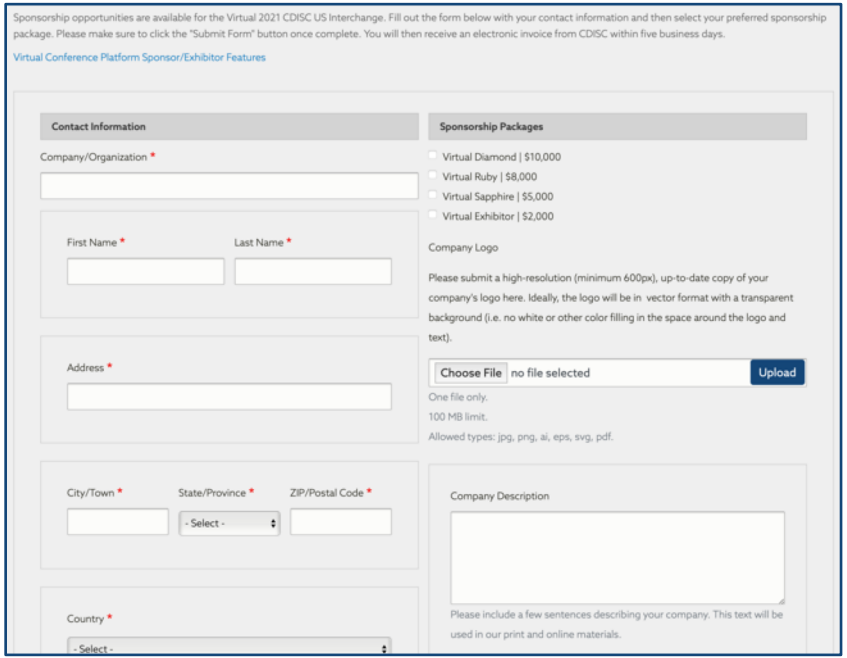
Sponsoring / Exhibiting

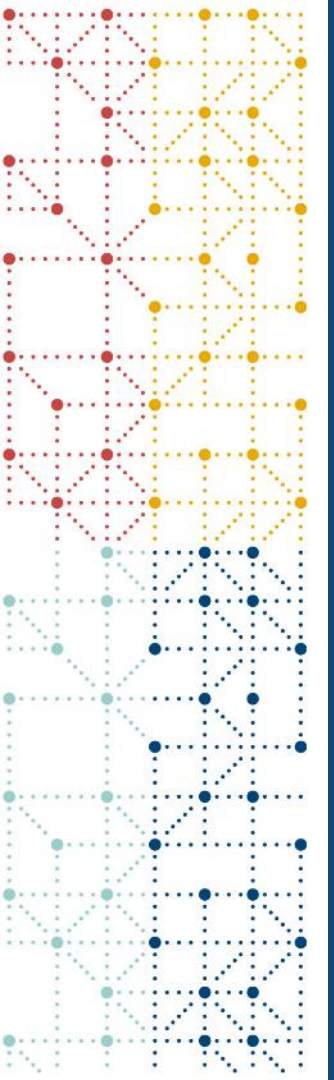
Sponsorship & Exhibitor Benefits

Benefits	Virtual Diamond $10,000	Virtual Ruby $8,000	Virtual Sapphire $5,000	Virtual Exhibitor $2,000
Whole App Virtual Platform Sponsorship	X			
30-Second Advert during Breaks & Lunches	X			
Choice of Session Sponsorship	X			
Sponsored Communication with Attendees	X	X		
Complimentary Product Demonstration	X	X		
1-Page Advert during Breaks and Lunches	X	X		
Inclusion on Platform Sponsorship Page	X	X	X	
Virtual Exhibitor Booth	X	X	X	X
Full Conference Passes	4	3	2	2
Lead Generation + Visitor List	X	X	X	X
Company Branding during Breaks and Lunches	X	X	X	
Company Logo on CDISC Website	X	X	X	
Recognition in CDISC eBlast	X	X	X	

Signing Up to Sponsor / Exhibit

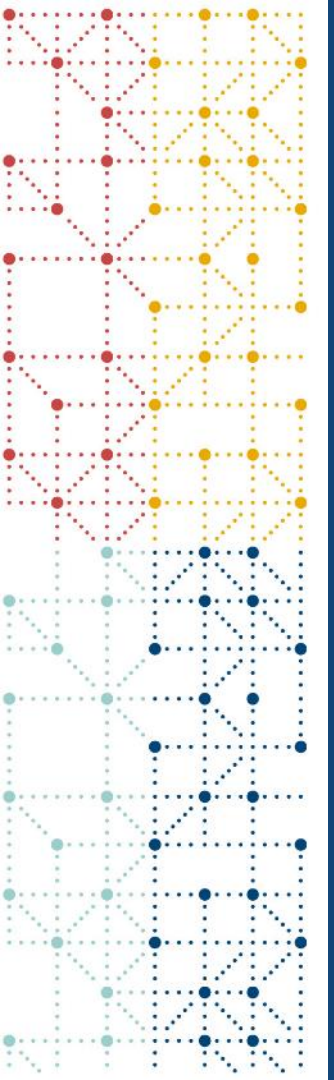






Networking Game

2021 US INTERCHANGE SCAVENGER HUNT GAME



Questions & Answers

Audience Questions

Upcoming Resources and Webinars

New Virtual Training Methods

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

BLENDED LEARNING | VIRTUAL TRAINING | CLASSROOM TRAINING | PRIVATE TRAINING | WEBINARS | WORKSHOPS

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2022 Events

TOKYO , JAPAN

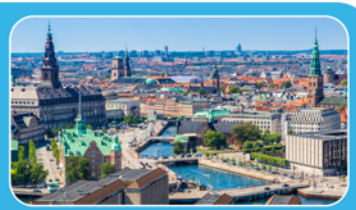
2022 JAPAN | June

CDISC STANDARDS - UNLOCK THE POWER OF DATA

AUSTIN, TX

2022 US | October

2022 EUROPE | April

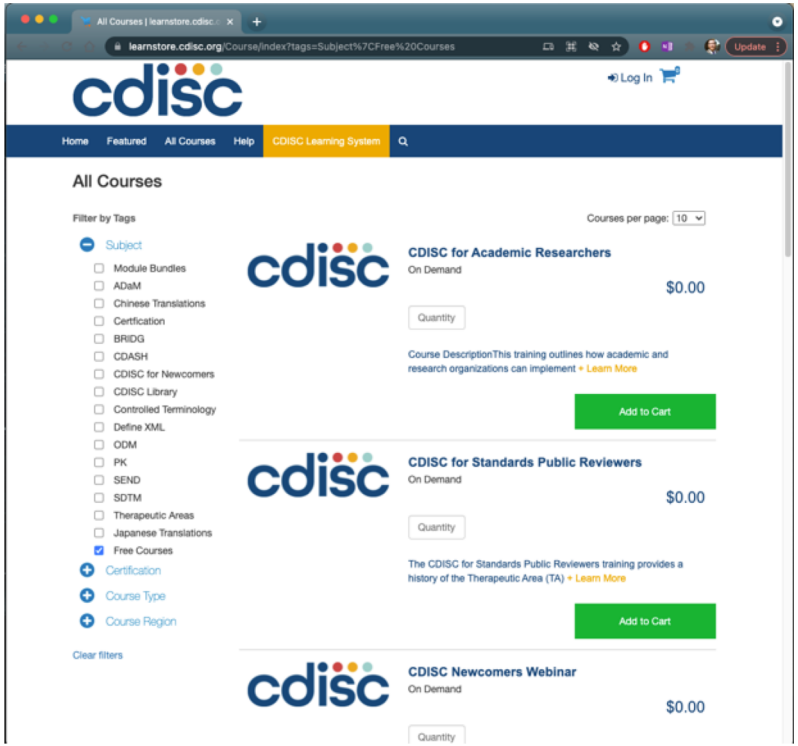


COPENHAGEN

2022 CHINA | August

BEIJING

Free CDISC Courses



Http://learnstore.cdisc.org

Select “Free Courses” in the SUBJECT filter

Upcoming Webinars

Controlled Terminology Updates for Q3 2021

30 September 2021, 11am - 12:30pm EDT

REGISTER NOW!

This quarterly webinar series addresses the latest Controlled Terminology release package as well as content currently in Public Review. Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets.

Panelist(s)

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, Enterprise Vocabulary Services, National Cancer Institute

Language

English

Digital Data Flow: Project Information and Call for Volunteers

5 October 2021, 11am - 12:30pm EDT

REGISTER NOW!

CDISC, in collaboration with TransCelerate's Digital Data Flow Project, is developing a reference architecture, which will serve as a standard model for the development of a Study Definitions Repository. The Repository is a novel central component aimed at facilitating the exchange of structured study definitions across clinical systems using technical and data standards.

Deliverables will include a logical data model, supporting Controlled Terminology, API specifications and related conformance tests.

Join us as we share project progress and how to get involved.

Read the press release announcing the project.

Panelist(s)

Dave Evans, CDISC President & CEO
John Owen, CDISC Head of Partnership & Development
Christine Connolly, CDISC Senior Project Manager

Language

English

Upcoming Webinars

CDISC Open Source Alliance (COSA) Spotlight

18 November 2021, 11am - 12:30pm EST

REGISTER NOW!

To drive innovative approaches to standards-based automation, CDISC has initiated the CDISC Open-Source Alliance (COSA), which supports, promotes, and sometimes sponsors open-source software projects that create tools for implementing or developing CDISC standards.

Join us to learn the basics of how you can leverage the first COSA-approved tools to facilitate the implementation of CDISC standards in your systems.

- TFL Designer
- Visual Define-XML Editor
- Odmlib

We will also share how open-source developers can learn to apply for inclusion in the COSA Directory.

Panelist(s)

Sam Hume, VP Data Science, CDISC
Dmitry Kolosov, Expert Statistical Programmer, Parexel
Bhavin Busa, VP of Clinical Data Services & Operations, Vita Data Sciences

Language

English

Controlled Terminology Updates for Q4 2021

21 December 2021, 11am - 12:30pm EST

REGISTER NOW!

This quarterly webinar series addresses the latest Controlled Terminology release package as well as content currently in Public Review. Controlled Terminology is the set of codelists and valid values used with data items within CDISC-defined datasets. Controlled Terminology provides the values required for submission to FDA and PMDA in CDISC-compliant datasets.

Panelist(s)

Dr. Erin Muhlbradt, Clinical/Biomedical Information Specialist, Enterprise Vocabulary Services, National Cancer Institute

Language

English

https://www.cdisc.org/events/webinar

Thank you!

Contact the Events inbox:
events@cdisc.org

Contact Education inbox:
training@cdisc.org

Contact Bernard directly:
bklinke@cdisc.org