

# 2021 US INTERCHANGE



With Standards – Science Will Prevail!



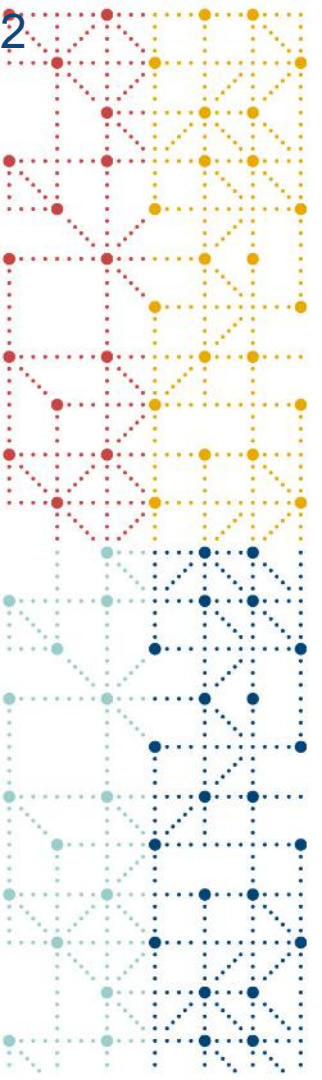
Conference | Trade Show

Live Event | 18-22 October

## Sneak Peek Webinar

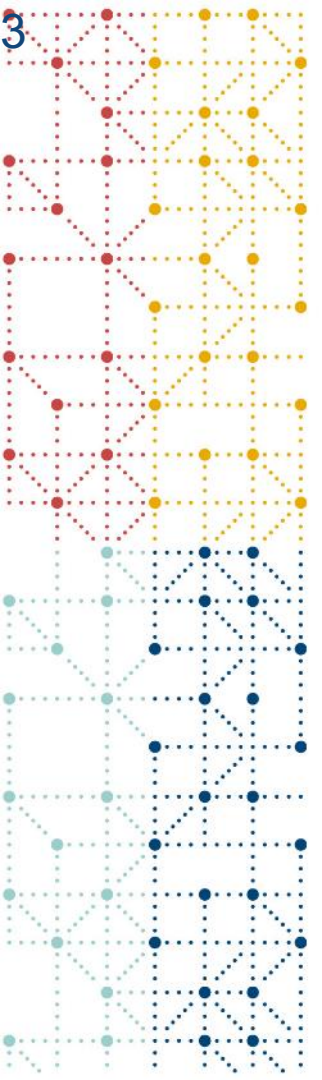
TUE 21 SEP

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**

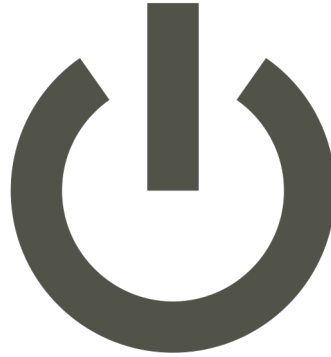


# Housekeeping



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 Thoenke, 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



# 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

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

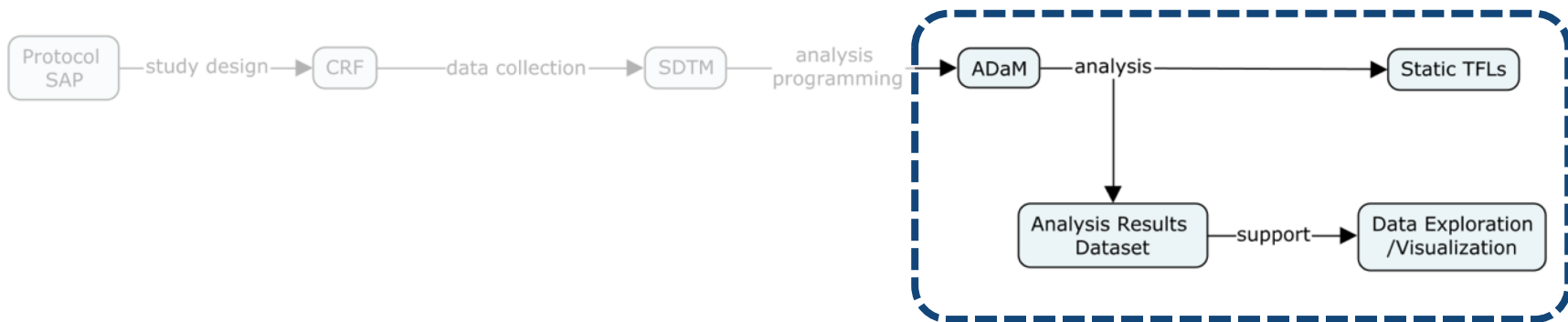
form (CRF) layout

```

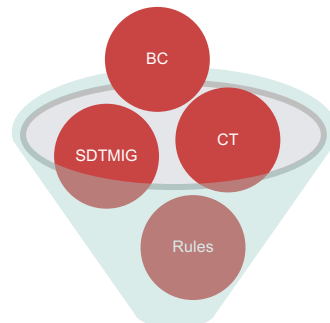
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  <Description>
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  </Description>
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  <ItemRef ItemOID="IT.AEONGO" Mandatory="No" OrderNumber="4"/>
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  <ItemRef ItemOID="IT.AEACN" Mandatory="No" OrderNumber="15"/>
  <ItemRef ItemOID="IT.AEACNOTH" Mandatory="No" OrderNumber="16"/>
  <ItemRef ItemOID="IT.AEOUT" Mandatory="No" OrderNumber="17"/>

```

# Analysis Results



# Behind the Scenes with CDISC Data Science



## Sources:

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

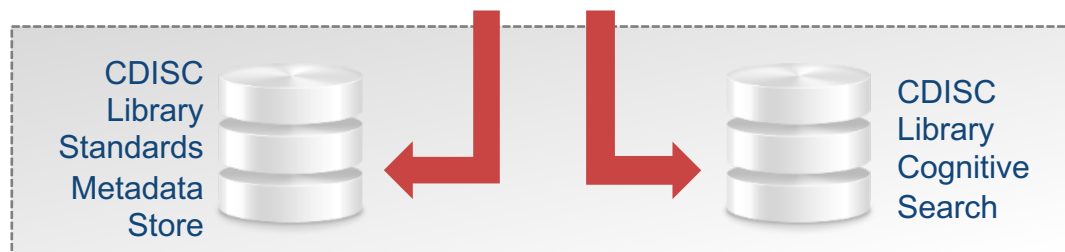
Spec Grabber / QC Checker / YAML Schema

**NEW**



Standards Pipeline

Standards JSON Documents





# 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



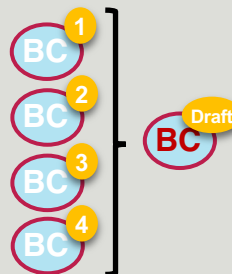
Test with single sponsor

## Multiple Sponsor Mining



Run with four sponsors

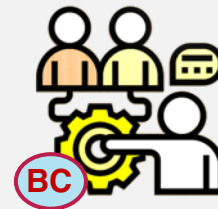
## Curate



For each BC we have 1 to 4 "answers"

Merge into a single 1<sup>st</sup> draft

## Release & Report

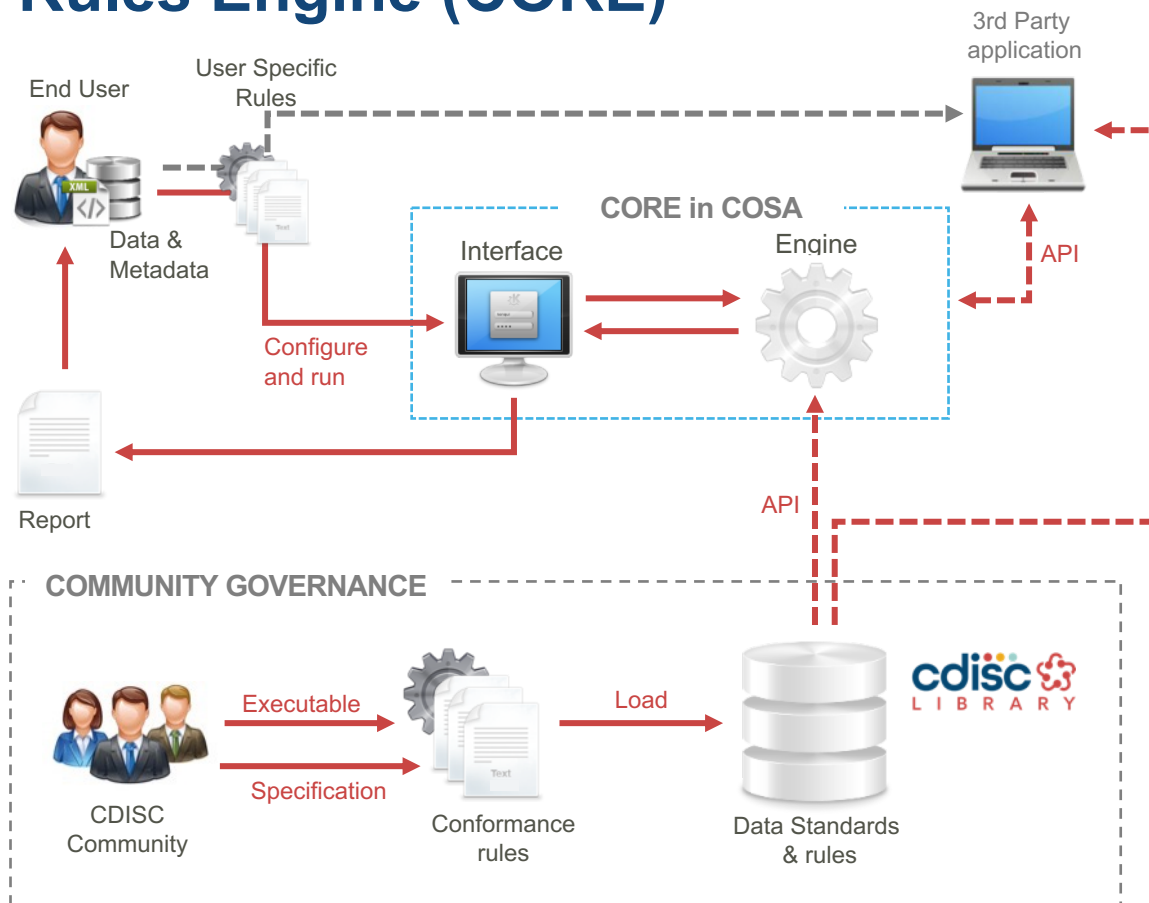


Share BCs with community and report on experience

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



# 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:

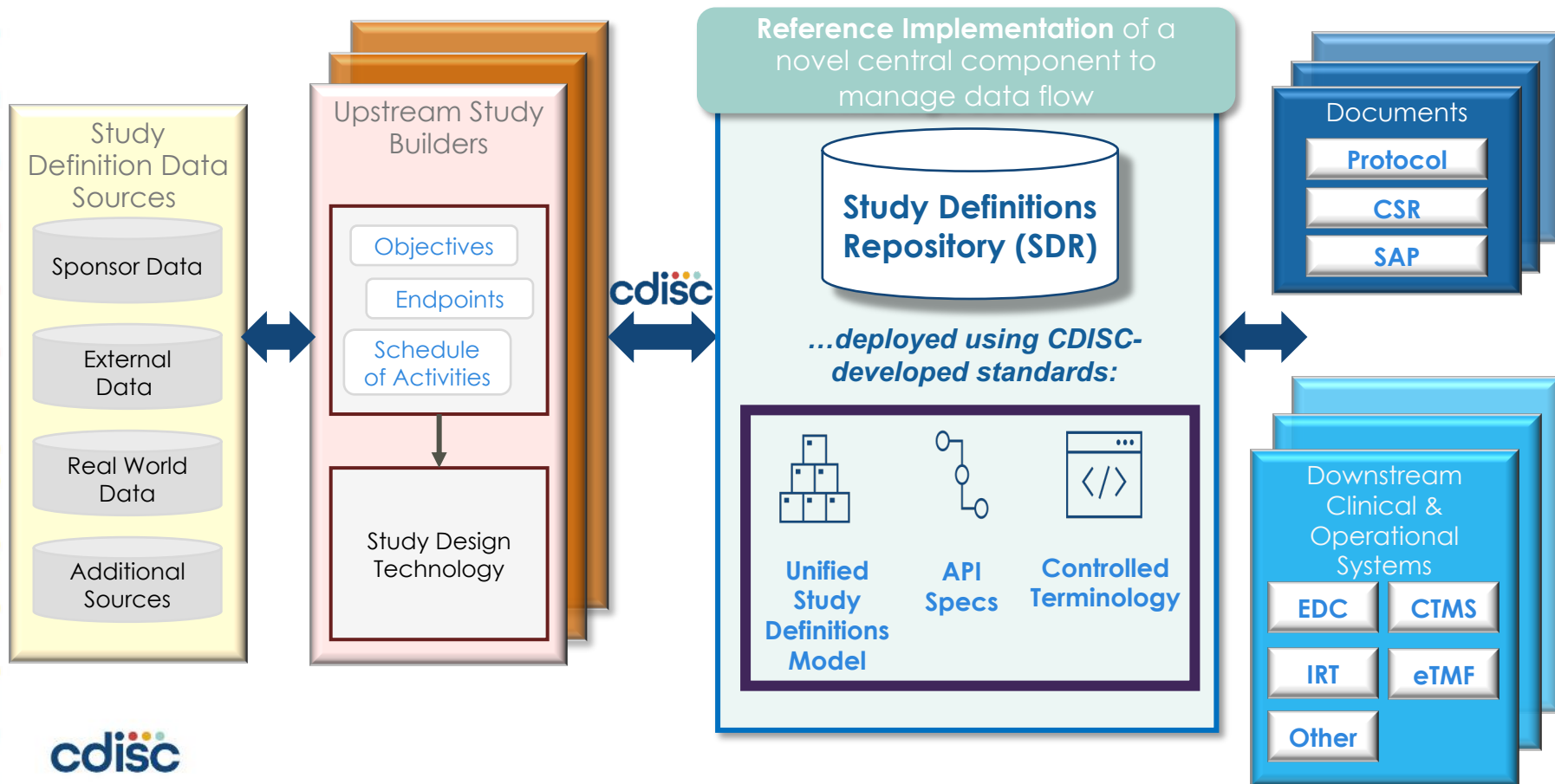
Engage with vendors and sponsors to pave the way for industry-wide transformation



#### Establish Self-Sustaining Governance:

Mobilize creation of a multi-stakeholder governance of the open-source solution and ongoing connection to standards

# Digital Data Flow

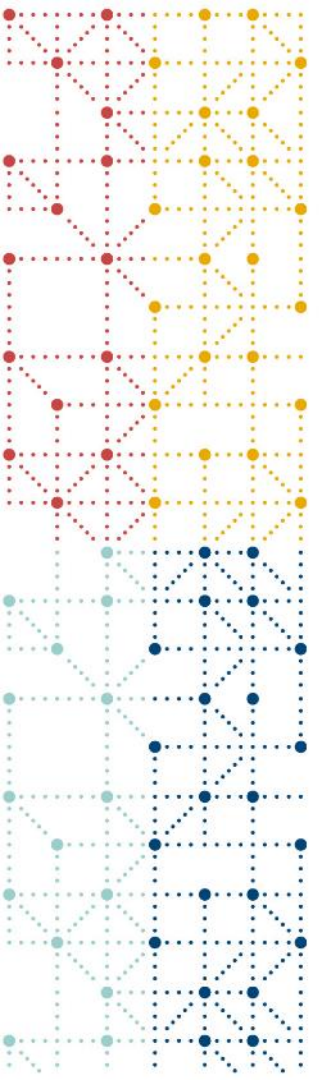


# Real World Data

CDISC ODM+Extensions Elements & Attributes						HL7 FHIR R4 Resources & Attributes						FHIR R4 snapshot 8/29/2019		
Source	Element	Element Body Contains	Element Contained	Element Body Container Item	Container Item Data Type	Element Attributes	Element Attribute Optionality	Element Attribute Format/Values	FHIR Definition Resource+Attribute	FHIR Request Resource+Attribute	Resource+Attribute	FHIR Additional or Referential Association	FHIR Mapping Comment	FHIR Link
ODM v1.3.2	StudyEventRef					OrderNumber	Optional	integer (Yes   No)		<Request> basedOn	<Event> basedOn	CarePlan basedOn	Associated to multiple re	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	StudyEventRef					Mandatory							No direct mapping identified.	
ODM v1.3.2	StudyEventRef					CollectionExceptionCode	Optional	oidref					No direct mapping identified.	
ODM v1.3.2	StudyEventDef	Description?, FormRef*, Alias*	Meta	MetaDataVersion					PlanDefinition.<multiple>			ActivityDefinition.<multiple>	Refer to individual element	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	StudyEventDef					OID		oid	PlanDefinition.identifier			ActivityDefinition.identifier; Questionnaire.identifier; ActivityDefinition.title; Questionnaire.title		<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	StudyEventDef					Name		text (Yes   No)	PlanDefinition.title					<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	StudyEventDef					Repeating		(Scheduled   Unscheduled   Common)	PlanDefinition.action.cardinalityBehavior					<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	StudyEventDef					Type	Optional	text	PlanDefinition.useContext			ActivityDefinition.useContext	Confirm mapping associated	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
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ODM v1.3.2	FormRef		StudyEventDef			FormOID		oidref				ActivityDefinition.identifier	Associated to multiple re	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	FormRef					OrderNumber	Optional	integer (Yes   No)					Associated to multiple re	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	FormRef					Mandatory							No direct mapping identified.	
ODM v1.3.2	FormRef					CollectionExceptionCode							No direct mapping identified.	
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ODM v1.3.2	FormDef					Name		text (Yes   No)	PlanDefinition.title					<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	FormDef					Repeating			PlanDefinition.action.cardinalityBehavior					<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	FormDef					FormOID		oidref	<Request>.<multiple>	<Event>.<multiple>	CarePlan.<multiple>	Refer to individual element	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>	
ODM v1.3.2	ItemGroupRef		FormDef			OrderNumber	Optional	integer (Yes   No)				ActivityDefinition.identifier	Associated to multiple re	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	ItemGroupRef					Mandatory			<Request> basedOn	<Event> basedOn	CarePlan basedOn	Associated to multiple re	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>	
ODM v1.3.2	ItemGroupRef					CollectionExceptionCode	Optional	oidref					No direct mapping identified.	
ODM v1.3.2	ItemGroupDef	Description?, ItemRef*, Alias*, def:Class, def:leaf	Meta	MetaDataVersion					PlanDefinition.<multiple>			ActivityDefinition.<multiple>	Refer to individual element	<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	ItemGroupDef					OID		oid	PlanDefinition.identifier			ActivityDefinition.identifier; Questionnaire.identifier; ActivityDefinition.title; Questionnaire.title		<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	ItemGroupDef					Name		text (Yes   No)	PlanDefinition.title					<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>
ODM v1.3.2	ItemGroupDef					Repeating			PlanDefinition.action.cardinalityBehavior					<a href="http://www.hl7.org/fhir/R4/plandefinition.html">http://www.hl7.org/fhir/R4/plandefinition.html</a>

ODM  
(and extensions)

FHIR  
(and extensions)



# Pathable Platform Tour

# 2021 US INTERCHANGE



With Standards – Science Will Prevail!

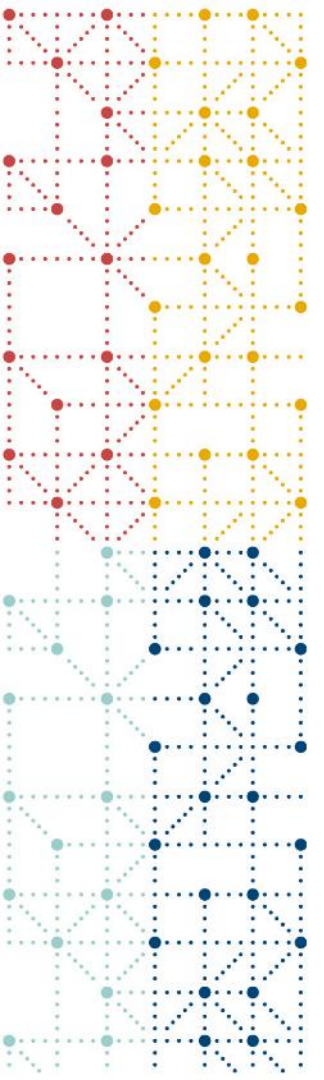


Conference | Trade Show

Live Event | 18-22 October

## 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
<b>TOTAL STACKABLE DISCOUNTS</b>	<b>\$432.00</b> (\$368.00 off regular admission)	<b>\$576.00</b> (\$224.00 off regular admission)	<b>\$720.00</b> (\$80.00 off regular admission)

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



# Registration Process

Is your company interested in having a larger group (10 or more people) join the conference? Group rates are available! Contact [events@cdisc.org](mailto:events@cdisc.org) for details.

### Registration

Membership and Group Rates available! Contact [events@cdisc.org](mailto:events@cdisc.org)

[Register](#) [Event Fees](#)

### Sponsor & Exhibitor Opportunities

Virtual Sponsor/Exhibitor Options Available

[Sign Up Here](#)

### Program

FULL Program Now Available!

[View Here](#)

### Sneak Peek Webinar

Get a sneak peek at the Interchange's big topics and an overview of the conference platform!

[Register now](#)

### Virtual Public Courses

Virtual courses covering ADaM, CDASH, SDTM, and more on 18, 19, and 22 OCT.

[Virtual Courses](#)

[Summary](#) [Fees](#) [Contact CDISC](#) [Register Now](#)



Live Stream | 20-21 October | Conference & Trade Show

October 20, 2021 – October 21, 2021  
9:00 AM-5:30 PM ET

[Register Now](#)  
[Already registered?](#)

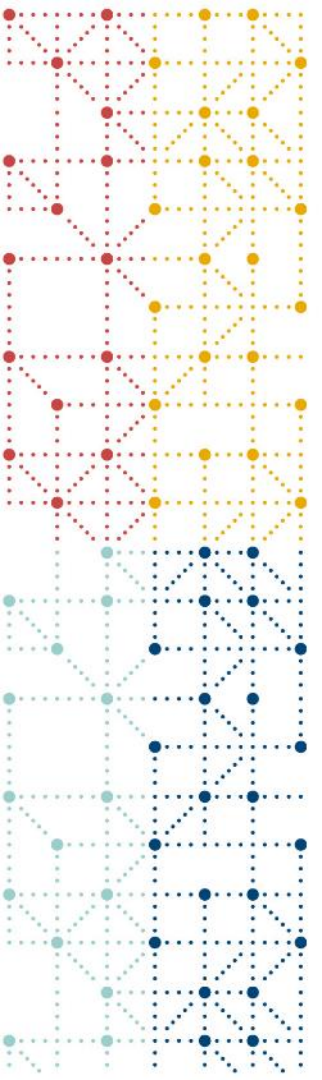
**Now A Virtual Event!**

The Virtual 2021 CDISC US Interchange will be held over two days, on 20 - 21 October.

The event will be held online. Those that register for the virtual conference will receive confirmation of their registration to the email address on file. Registrants will then receive an additional notification with details for accessing the virtual conference at a later date closer to the event.

CDISC will be using its highly-regarded Virtual Conference Platform during this event! Want to see more than one (or all) live presentations happening in multiple tracks at the same time? No problem! All video content will be available on-demand for attendees following the presentations (for a full year), so you don't have to miss a thing.

[CDISC Virtual Education Courses | 18 - 19 & 22 October \(Online\)](#)



## 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

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Early Bird Discounts end Friday, 17 September! Group rates available!  
Contact [events@cdisc.org](mailto:events@cdisc.org)

[Register](#) [Event Fees](#)

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[Virtual Courses](#)

## Sponsors

Ruby

Sponsorship opportunities are available for the Virtual 2021 CDISC US Interchange. Fill out the form below with your contact information and then select your preferred sponsorship package. Please make sure to click the "Submit Form" button once complete. You will then receive an electronic invoice from CDISC within five business days.

#### Virtual Conference Platform Sponsor/Exhibitor Features

##### Contact Information

Company/Organization \*

First Name \*

Last Name \*

Address \*

City/Town \*

State/Province \*

- Select -

ZIP/Postal Code \*

Country \*

- Select -

##### Sponsorship Packages

- ☐ Virtual Diamond | \$10,000
- ☐ Virtual Ruby | \$8,000
- ☐ Virtual Sapphire | \$5,000
- ☐ Virtual Exhibitor | \$2,000

##### Company Logo

Please submit a high-resolution (minimum 600px), up-to-date copy of your company's logo here. Ideally, the logo will be in vector format with a transparent background (i.e. no white or other color filling in the space around the logo and text).

[Choose File](#) no file selected

[Upload](#)

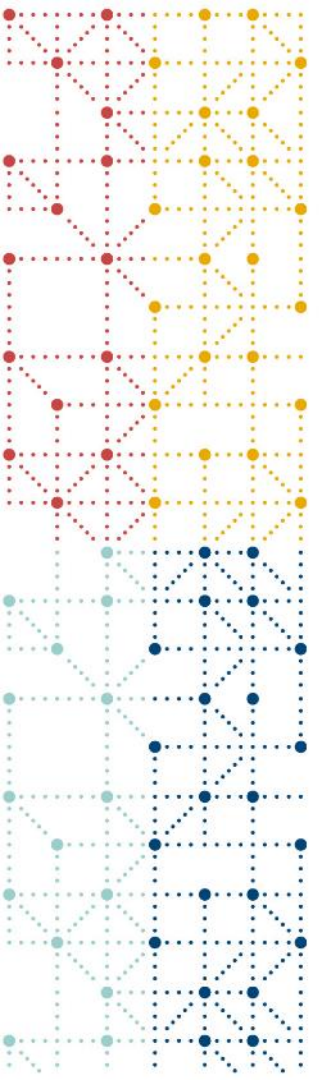
One file only.

100 MB limit.

Allowed types: jpg, png, ai, eps, svg, pdf.

##### Company Description

Please include a few sentences describing your company. This text will be used in our print and online materials.



# Networking Game

# 2021 US INTERCHANGE SCAVENGER HUNT GAME





A decorative vertical bar on the left side of the slide, featuring a white background with a grid of dots. The dots are connected by lines to form various geometric shapes, including squares and triangles. The colors of the dots and lines are red, yellow, and blue.

# Questions & Answers

# Audience Questions







## Upcoming Resources and Webinars

# New Virtual Training Methods

## Blended Learning from CDISC

Online Resources  
+ In-Person Instruction  
More Personalized Learning

Classes Starting Soon!



## CDISC Redefines Data Standards Training **NEW VIRTUAL CLASSROOM!**

- 100% Instructor Led
- Immediate Feedback
- Small Class Sizes
- Remote Convenience



- Information available at: [www.cdisc.org](http://www.cdisc.org)
- Register at: <https://learnstore.cdisc.org/>
- Contact us at: [training@cdisc.org](mailto:training@cdisc.org)



BLEND  
LEARNING



VIRTUAL  
TRAINING



CLASSROOM  
TRAINING



PRIVATE  
TRAINING



WEBINARS



WORKSHOPS

# 2022 Events



TOKYO, JAPAN

2022 JAPAN | June

CDISC STANDARDS - UNLOCK THE POWER OF DATA



AUSTIN, TX

2022 US | October

2022 EUROPE | April



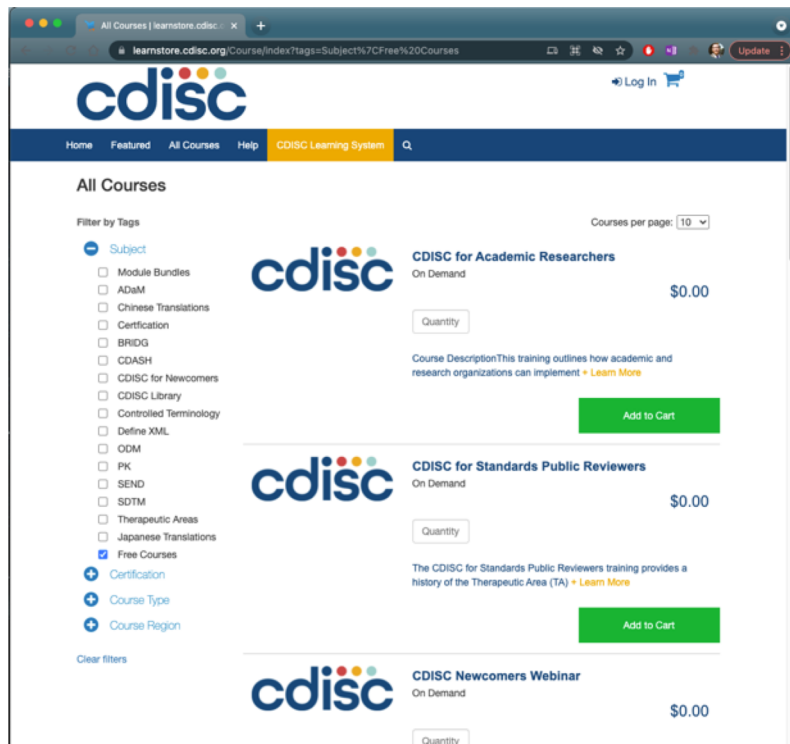
COPENHAGEN

2022 CHINA | August



BEIJING

# Free CDISC Courses



The screenshot shows the CDISC Learnstore website. The browser address bar displays [learnstore.cdisc.org/Course/index?tags=Subject%7CFree%20Courses](http://learnstore.cdisc.org/Course/index?tags=Subject%7CFree%20Courses). The website header includes the CDISC logo, a 'Log In' button, and a navigation bar with links to Home, Featured, All Courses, Help, and CDISC Learning System. The main content area is titled 'All Courses' and features a 'Filter by Tags' section on the left. Under the 'Subject' filter, the 'Free Courses' checkbox is selected. The main list displays three courses, all priced at \$0.00:

- CDISC for Academic Researchers** (On Demand): Includes a 'Quantity' input field and an 'Add to Cart' button.
- CDISC for Standards Public Reviewers** (On Demand): Includes a 'Quantity' input field and an 'Add to Cart' button.
- CDISC Newcomers Webinar** (On Demand): Includes a 'Quantity' input field.

Each course entry also includes a 'Course Description' and a 'Learn More' link.

[Http://learnstore.cdisc.org](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!



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