DDF (Digital Data Flow) - Project Information and Call for Volunteers

Presenters: Christine Connolly, CDISC Senior Project Manager, Dave Evans, CDISC President & CEO, John Owen, CDISC Head of Partnership & Development
Panelists: Alison Luckman, TransCelerate co-Product Owner/Lead for the DDF Delivery/Build Team
Peter Van Reusel, CDISC Chief Standards Officer

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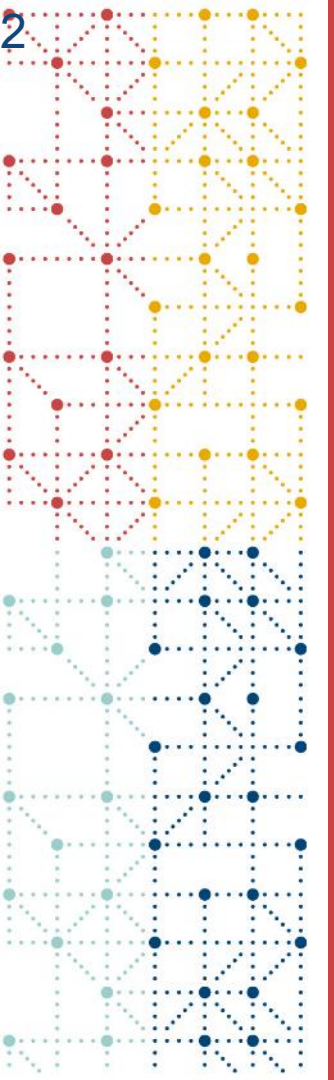
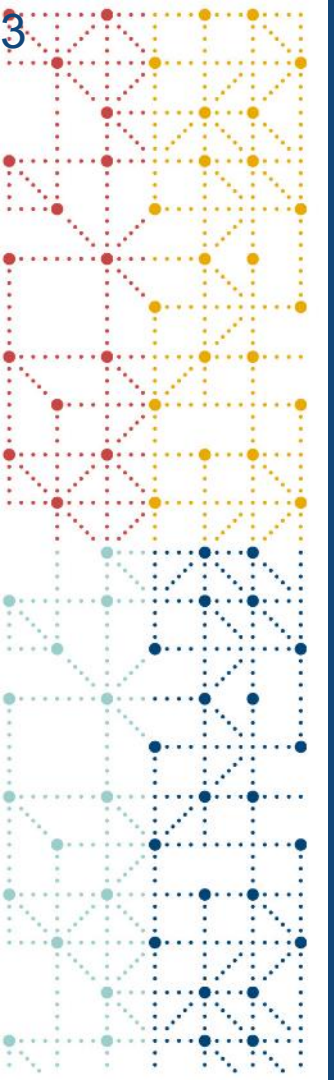
TUE 5 OCT
11:00AM-12:30PM ET



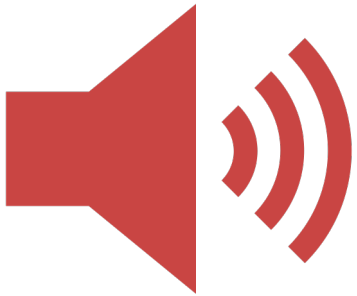
Today’s Agenda

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



Housekeeping

Housekeeping

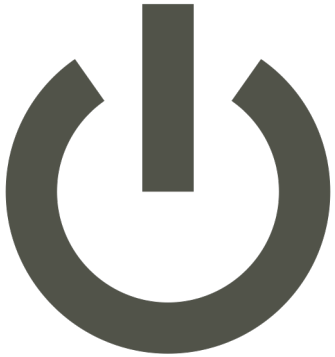


You will remain on **mute**

Housekeeping

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

Housekeeping



Audio issues?

Shut down & restart GTW app

Housekeeping

A recording of this webinar and the slides will be available in the **Webinar Archive** section of CDISC website, and on the DDF pages.

Today's Presenters and Panelists

- **Presenters**:
  - Christine Connolly, CDISC Senior Project Manager
  - Dave Evans, CDISC President & CEO
  - John Owen, CDISC Head of Partnership & Development
- **Panelists**:
  - Alison Luckman, TransCelerate co-Product Owner/Lead for the DDF Delivery/Build Team
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TUE 5 OCT
11:00AM-12:30PM ET

Digital Data Flow (DDF) Project Scoping Overview and Call for Volunteers

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

Panelists: Alison Luckman, TransCelerate co-Product Owner/Lead for the DDF Delivery/Build Team

Peter Van Reusel, CDISC Chief Standards Officer

5th October 2021

1. **Webinar Introduction**
2. Introduction to DDF
3. CDISC Involvement in the DDF project
4. Results of the scoping phase
5. Ongoing development work
6. Call for volunteers
7. Q&A

Why is CDISC partnering with TransCelerate on DDF?

CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

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Why is CDISC partnering with TransCelerate on DDF?

CDISC has always been an evolving transformational standards organization for information used in clinical research and regulatory submission.

CDISC Data Standards Lifecycle

Automation requires:

- *Standard Machine-executable content for Useability*
- *Standard Technology Interfaces for Integration for Accessibility*
- *Standard Verification and Conformance Rules for Integrity*
- *Standard Trial Design Specifications for Total Automation of the Digital Data Flow*

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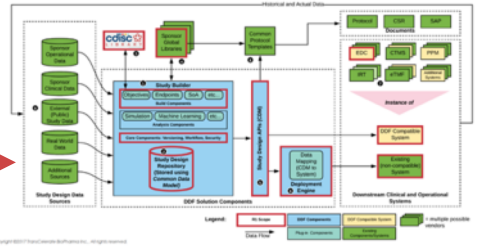
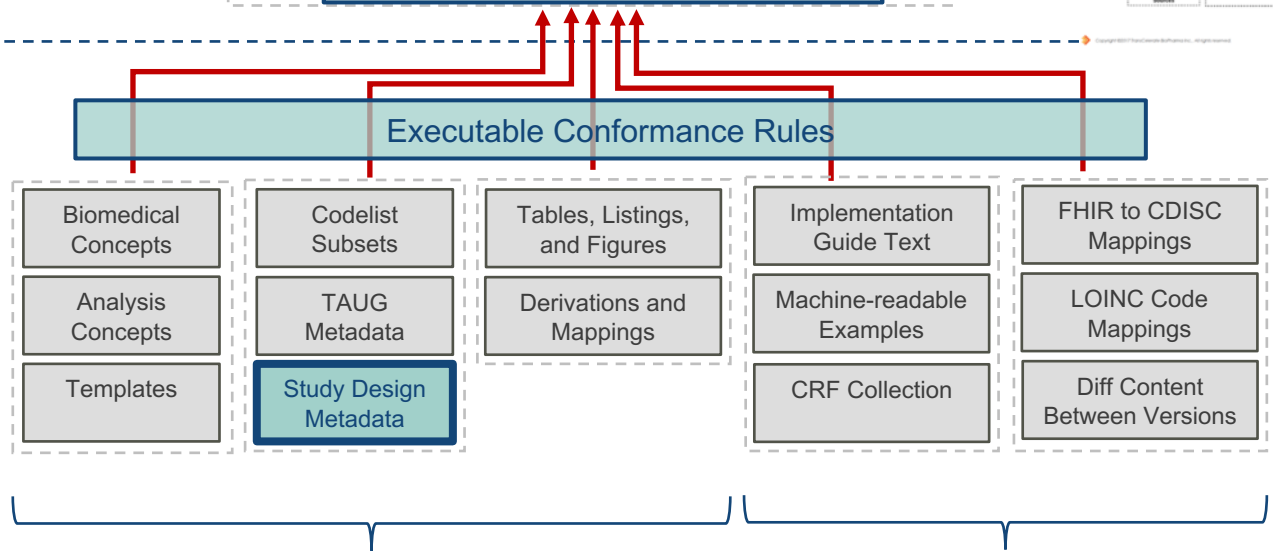
CDISC Library

Connect with Digital Data Processes through Open-API

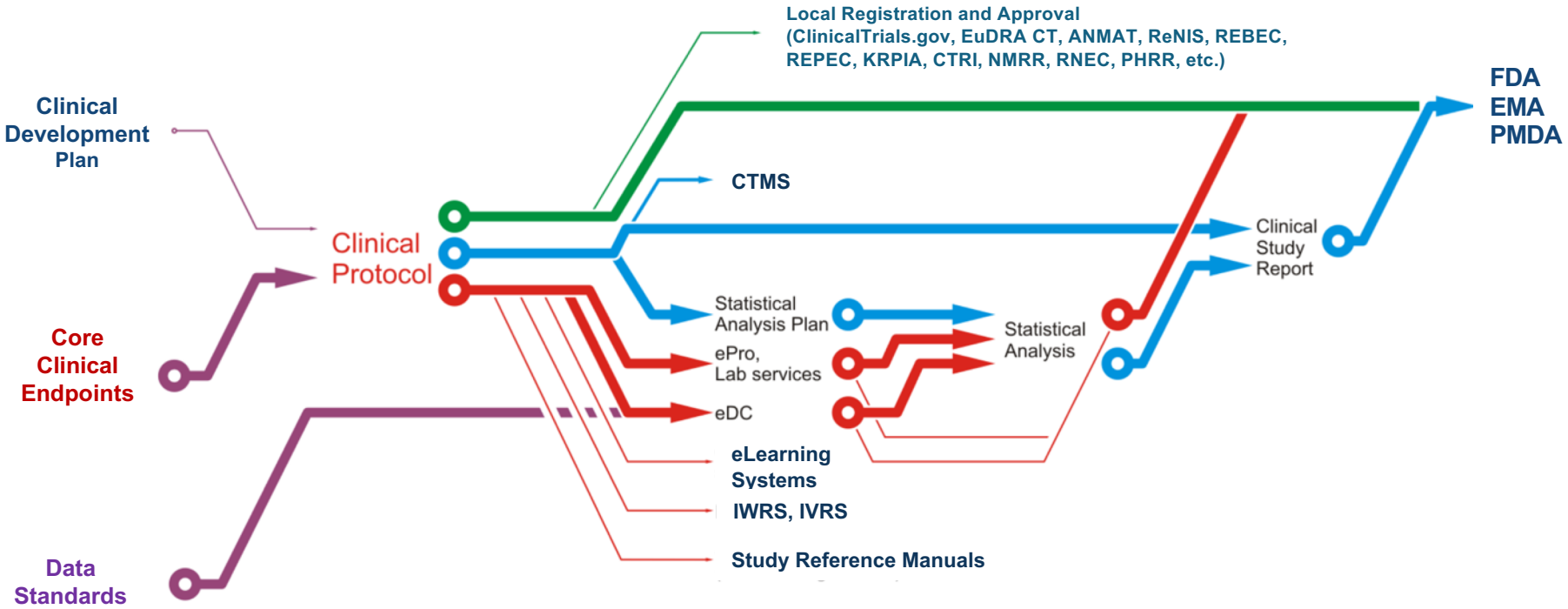




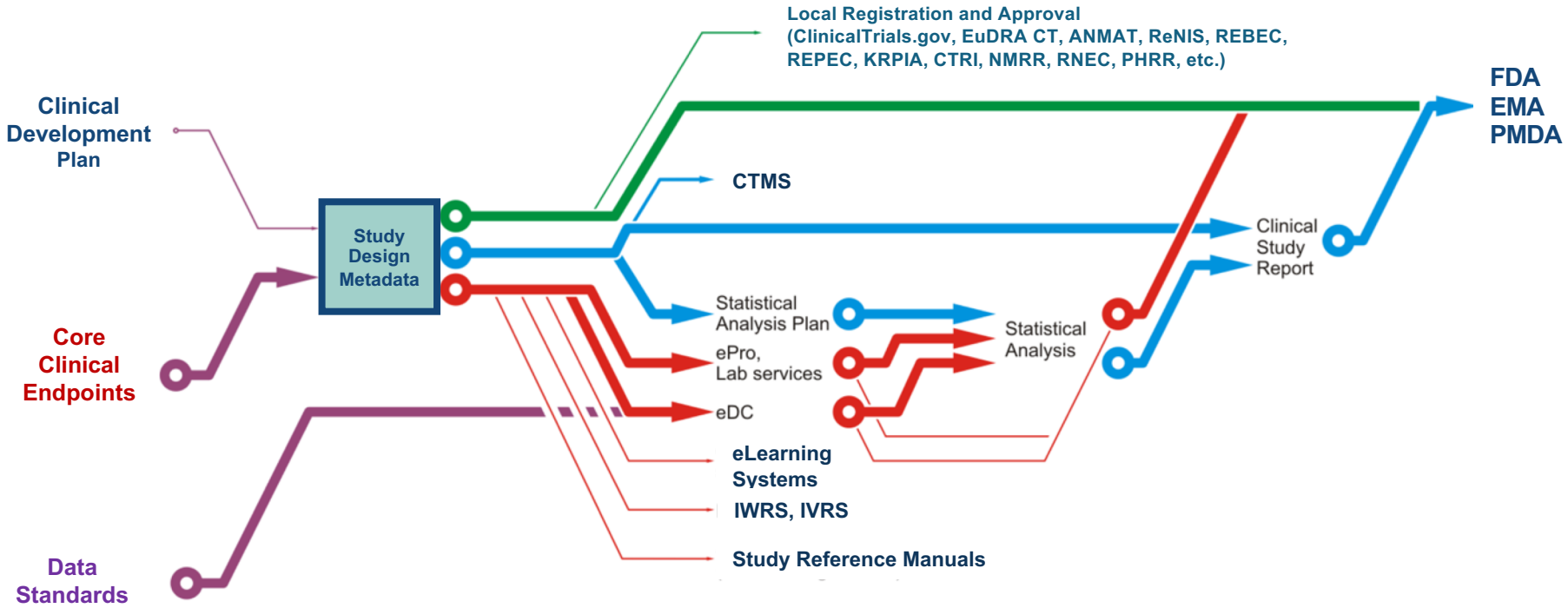
CDISC Standards

Informative Content

The Clinical Trial Information Flow



The Clinical Trial Information Flow



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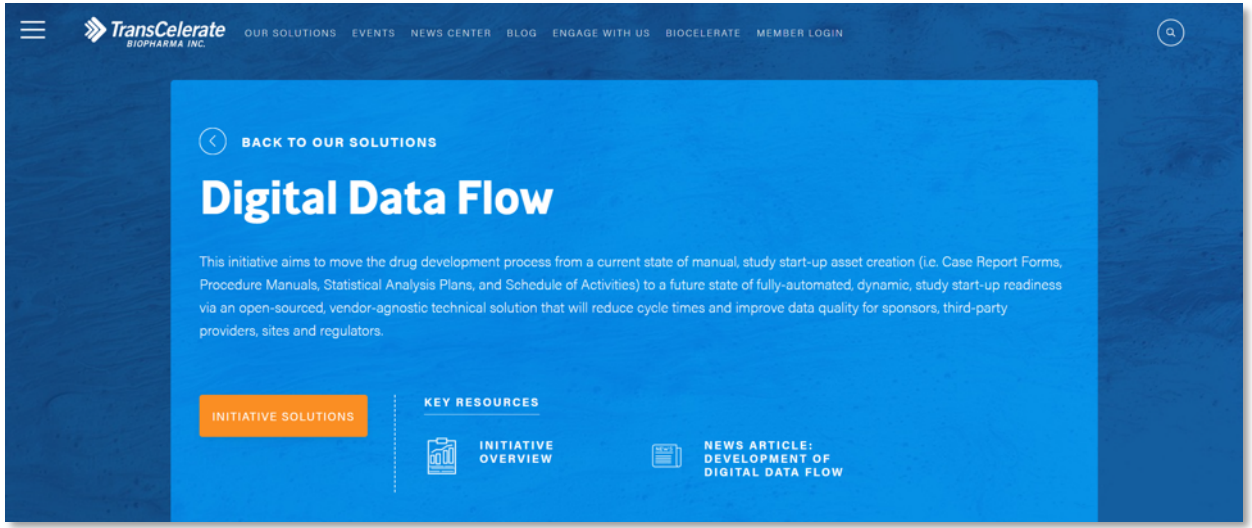
TransCelerate Digital Data Flow (DDF) Solution

This initiative aims to:

- Move the drug development process from a current state of manual, study start-up asset creation (i.e. Case Report Forms, Procedure Manuals, Statistical Analysis Plans, and Schedule of Activities)
- To a future state of fully-automated, dynamic, study start-up readiness
- Via an open-sourced, vendor-agnostic technical solution
- That will reduce cycle times and improve data quality for sponsors, third-party providers, sites and regulators

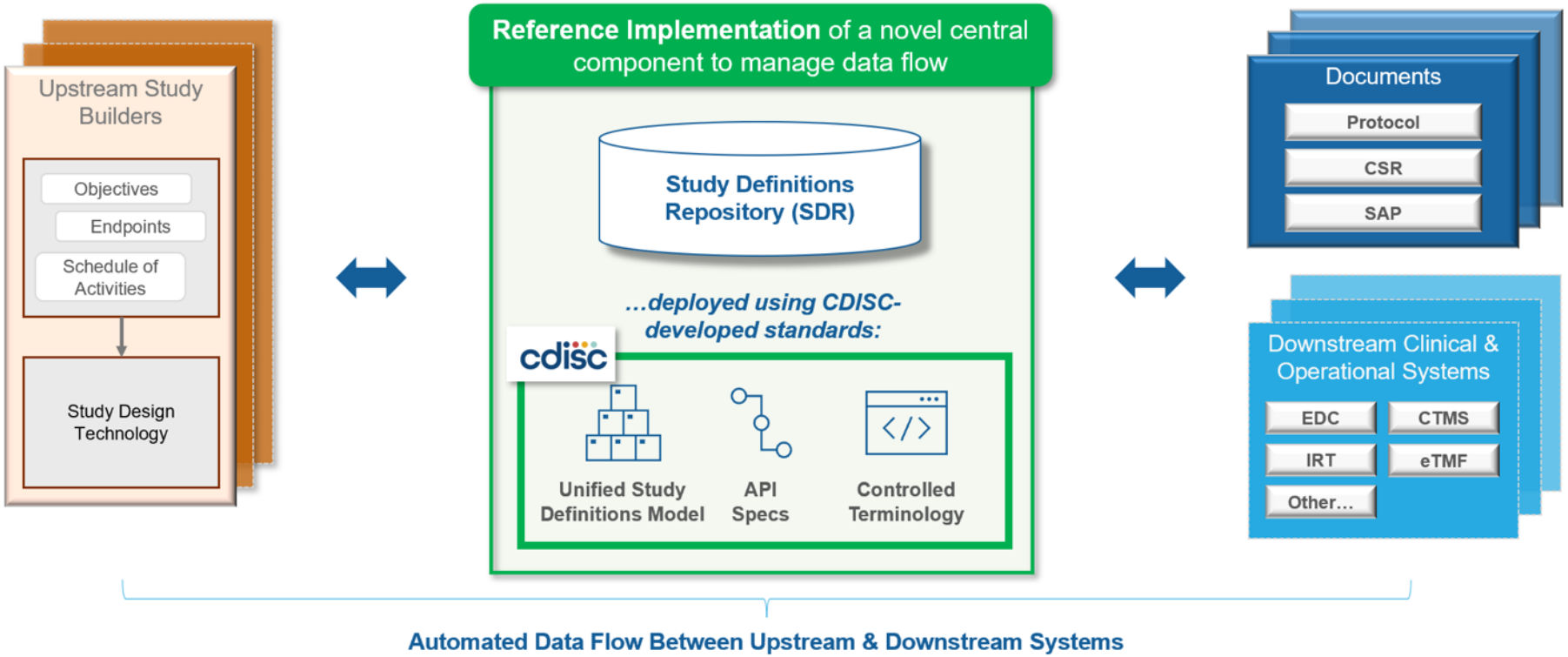
TransCelerate DDF Information

Please visit the TransCelerate DDF Webpage for more information

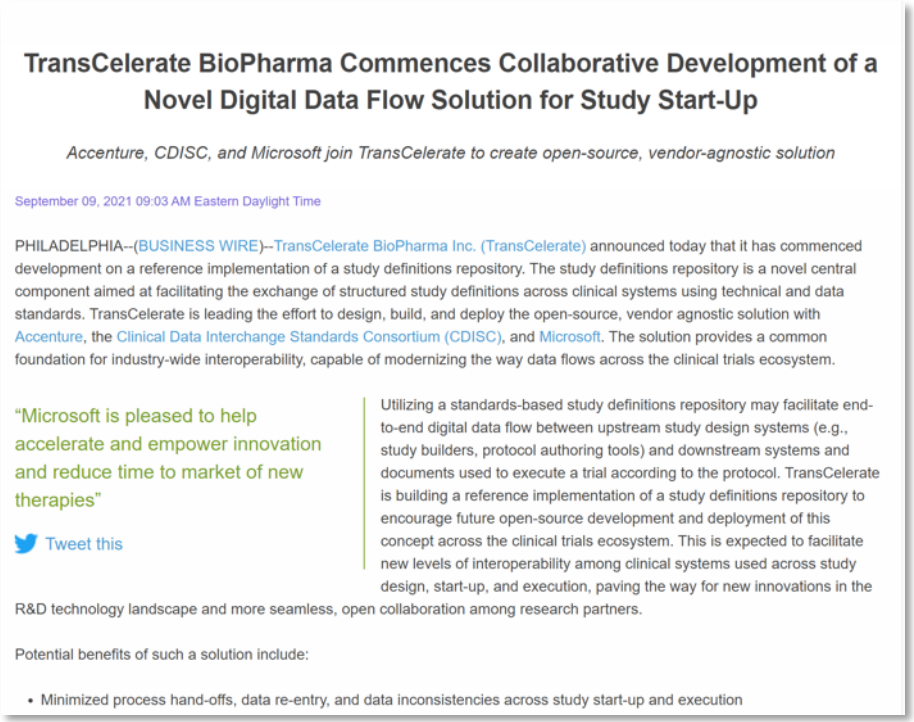


https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/

DDF is building “middleware” to connect systems, not to replace them



TransCelerate DDF Press Release



TransCelerate BioPharma Commences Collaborative Development of a Novel Digital Data Flow Solution for Study Start-Up

Accenture, CDISC, and Microsoft join TransCelerate to create open-source, vendor-agnostic solution

September 09, 2021 09:03 AM Eastern Daylight Time

PHILADELPHIA--(BUSINESS WIRE)--TransCelerate BioPharma Inc. (TransCelerate) announced today that it has commenced development on a reference implementation of a study definitions repository. The study definitions repository is a novel central component aimed at facilitating the exchange of structured study definitions across clinical systems using technical and data standards. TransCelerate is leading the effort to design, build, and deploy the open-source, vendor agnostic solution with Accenture, the Clinical Data Interchange Standards Consortium (CDISC), and Microsoft. The solution provides a common foundation for industry-wide interoperability, capable of modernizing the way data flows across the clinical trials ecosystem.

"Microsoft is pleased to help accelerate and empower innovation and reduce time to market of new therapies"

Tweet this

Utilizing a standards-based study definitions repository may facilitate end-to-end digital data flow between upstream study design systems (e.g., study builders, protocol authoring tools) and downstream systems and documents used to execute a trial according to the protocol. TransCelerate is building a reference implementation of a study definitions repository to encourage future open-source development and deployment of this concept across the clinical trials ecosystem. This is expected to facilitate new levels of interoperability among clinical systems used across study design, start-up, and execution, paving the way for new innovations in the R&D technology landscape and more seamless, open collaboration among research partners.

Potential benefits of such a solution include:

- Minimized process hand-offs, data re-entry, and data inconsistencies across study start-up and execution

https://www.businesswire.com/news/home/20210909005612/en/TransCelerate-BioPharma-Commences-Collaborative-Development-of-a-Novel-Digital-Data-Flow-Solution-for-Study-Start-Up

1. Webinar Introduction
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DDF Initiative – CDISC Involvement

TransCelerate has partnered with CDISC in support of this vision and will:

- Develop standards and reference architecture for a study definitions repository to be built by a lead vendor.
- Maintain developed standards and reference architecture utilized by the Digital Data Flow solution.

A reference architecture generally includes common architecture principles, patterns, building blocks, and standards. A reference architecture in the field of software architecture provides a template solution for an architecture for a domain.

- With reference architecture and standards, any vendor can build a study definitions repository using different technologies, etc.

CDISC Study Definition Repository RA Deliverables

Unified Study Definitions Model (USDM) Class Diagram

Application Programming Interface (API) Specification

CDISC Controlled Terminology

Reference Architecture Conformance Tests

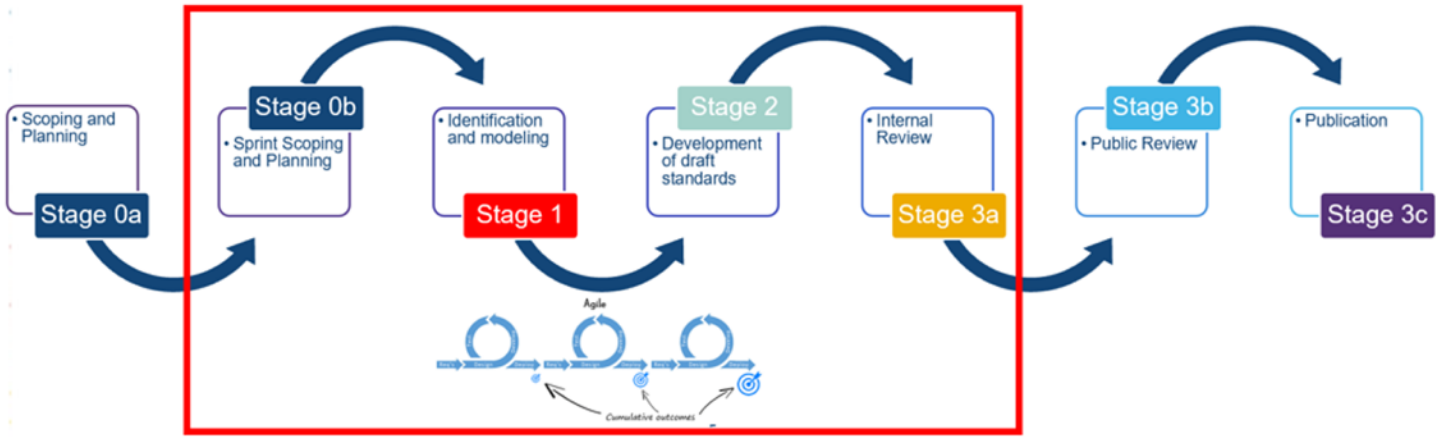
CDISC Deliverables

Essential User Stories

Architecture Principles

*Minimal Viable Product

The Process for MVP



Parts of Stage 0b – 3a take place in each sprint.

- After Stage 0a, the sprints begin and a small scoping effort happens as part of the planning for each sprint
- A review step happens at the end of the sprint.

Timelines for the MVP*

Stage 0	Scoping and Planning
Stage 1/2	Identification/Modeling of Concepts Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review 3 - Publication

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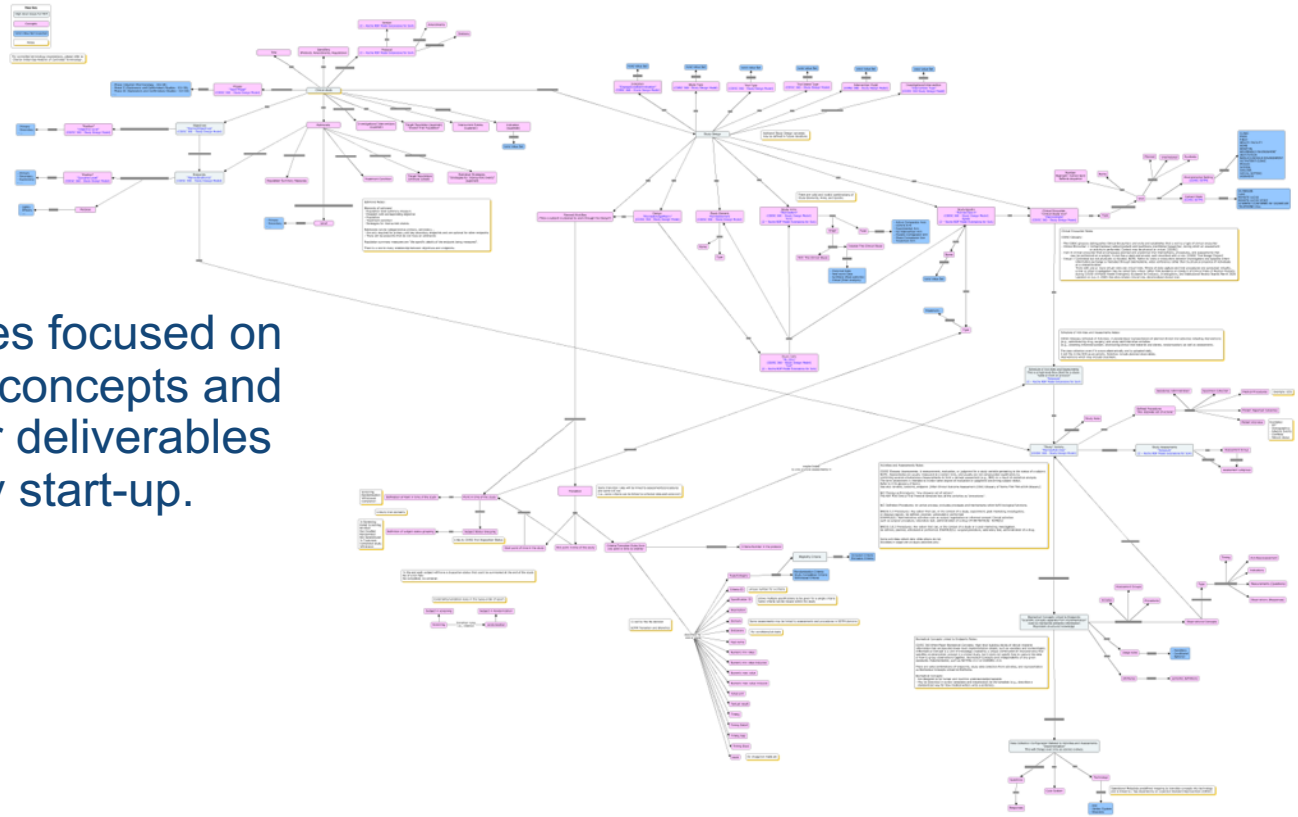
Scoping for Reference Architecture (RA)



Scoping activities focused on identification of concepts and relationships for deliverables to support study start-up.

Scoping for Reference Architecture (RA)

At a minimum, scoping was required to include the following concepts:

- Objectives and endpoints
- High level study design
- Eligibility criteria
- Schedule of activities and assessments
- Activities and assessments
- Biomedical concepts linked to endpoints
- Data collection configuration related to activities and assessments

RA Scoping Results

Scoping resulted in inclusion of general **clinical study** concepts; including but not limited to:

Titles	Phase	Investigational Interventions	Trial Type
Identifiers	Objectives	Target Populations	Trial Intent Type
Protocol	End points	Indications	Intervention Model

RA Scoping Results

Scoping resulted in inclusion of high-level **study design** concepts; including but not limited to:

- Study Elements
- Study Epochs
- Clinical Encounters
- Study Arms
- Study Cells

RA Scoping Results

Scoping resulted in inclusion of **planned workflow** concepts; including but not limited to:

Types/Categories; e.g.
- Eligibility
- Randomization
- Study Completion
- Study Withdrawal

Transitions

Criteria

Start Points in Time

End Points in Time

RA Scoping Results

Scoping resulted in inclusion of **activity and assessment** concepts; including but not limited to:

- Schedule
- Substance Administration
- Reported Outcomes
- Groupings
- Specimen Collection
- Patient Interviews
- Data Collection
- Medical Procedures

RA Scoping Results

Scoping resulted in inclusion of concepts to describe **biomedical concepts**; including but not limited to:

- Activities
- Procedures
- Usage Rules
- Assessment Groups
- Observational Concepts
- Semantic Definitions

RA Scoping Results

Scoping resulted in inclusion of concepts to describe **data collection**; including but not limited to:

- Questions
- Code System
- Answers
- Technology

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5. **Ongoing development work**
6. Call for volunteers
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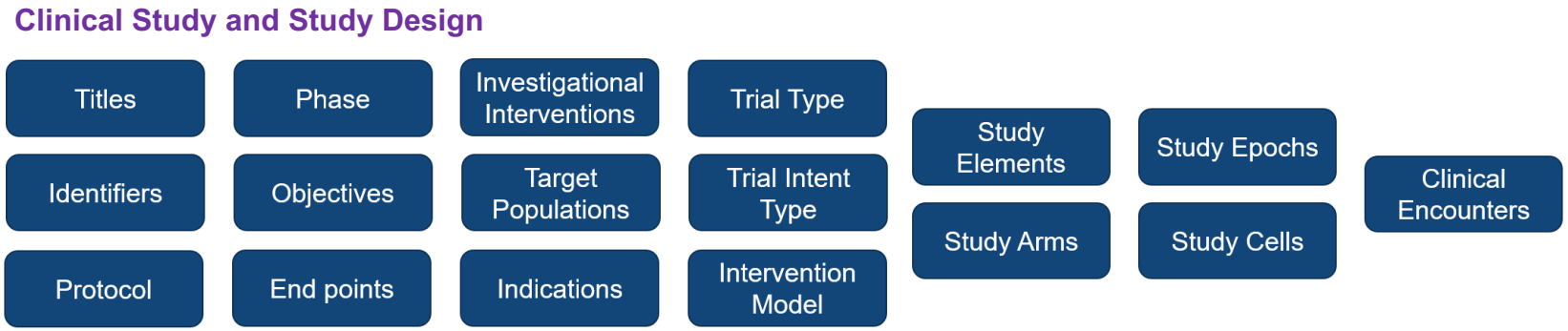
Ongoing Development Work

Development work has started with current focus on scoped concepts:

- Likely applicable to any to-be defined RI requirements
- Already defined in mature CDISC and/or industry standards
- Which are dependencies for development of content related to protocol *Schedule of Activities and Assessments*.



Ongoing Development Work

Deliverables currently in development are:

- Unified Study Definition Model (USDM) Class Diagram
- CDISC Controlled Terminology
- Application Programming Interface (API) Specification

Reference Architecture Conformance Tests will be be developed later in project timelines based on near final deliverables.

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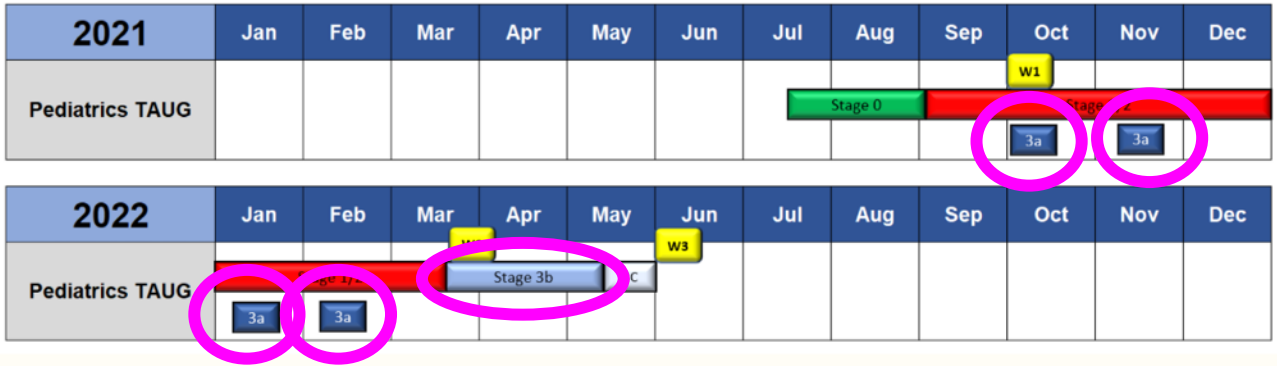
Why Volunteer?

- Opportunities are available to become part of the CDISC DDF team
- At a minimum, opportunities to review the draft standards through the development process and public review
  - Other opportunities are available depending on time availability, please complete the volunteer with a description of your interest in the project



Stage 0	Scoping and Planning
Stage 1/2	Identification/Modeling of Concepts Standards Development
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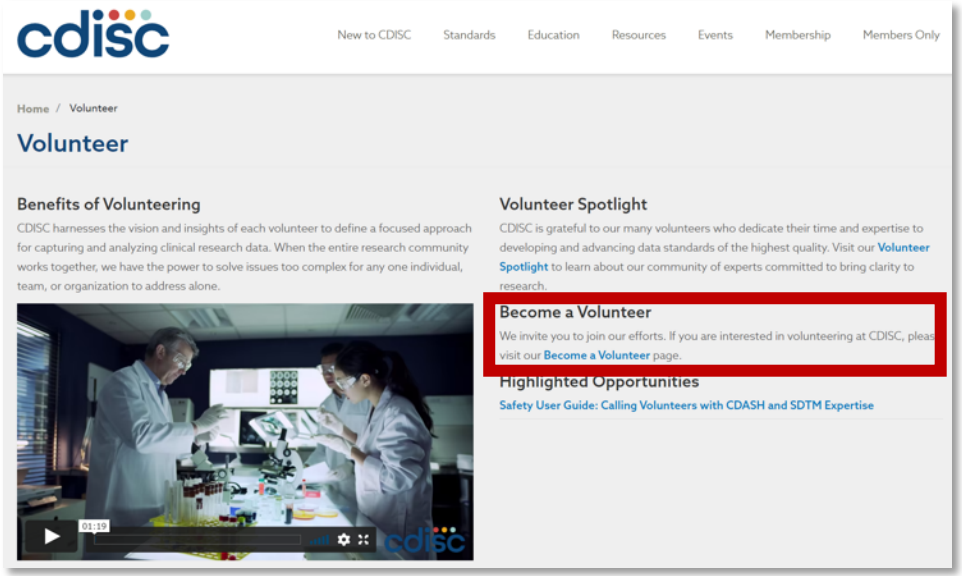
W	Public Webinars 1 - Scoping Results 2 - Public Review 3 - Publication

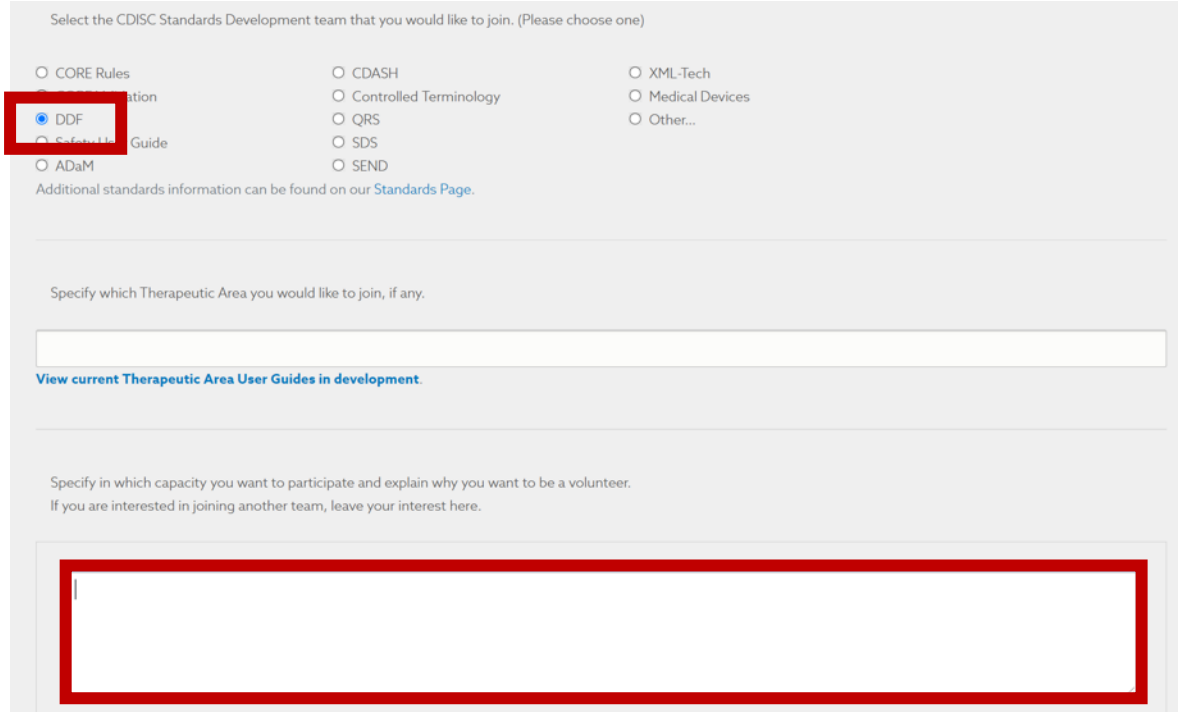
How to volunteer

- Create a free cdisc.org account (https://www.cdisc.org/user/registration)
  - Only required if you don't have a cdisc.org account
- Navigate to the volunteers section of the website (https://www.cdisc.org/volunteer)



How to volunteer

- Review the following video and documents and complete the form



Q&A

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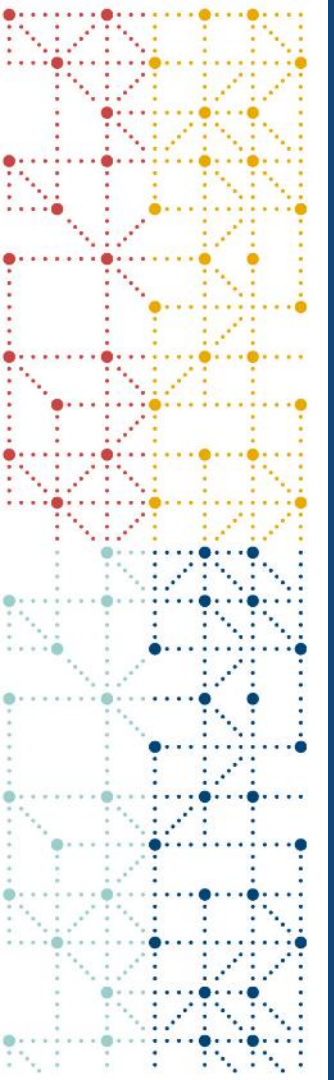
Thank You



Questions & Answers

Audience Questions

How will contents of the individual elements within the USDM be authored/reviewed/approved? (e.g. Endpoints, or Inclusion Criteria)

Audience Questions

Where does this fit into the current CDISC standards landscape?

Audience Questions

Will this impact the foundational standards (CDASH, SDTM, ADaM)?

Audience Questions

I work with CDISC foundational standards, but am unfamiliar with deliverables for this project apart from controlled terminology, can I still get involved?

Audience Questions

Do I have to be a CDISC member to volunteer?

Audience Questions

Is the USDM using an existing or new standard?

Audience Questions

Are you also using the terminology developed by the CDISC Protocol Entities team? We have developed more than 350 terms to support protocol development, with more terms in the wings.

Audience Questions

What are the volunteer activities you're looking for besides review?

+

What is the time commitment for volunteers?

Audience Questions

Is it expected that volunteers for DDF should have any specific technology/programming skills as well?

Audience Questions

When I signed up for volunteering at CDISC, I had initially picked ADAM as the interest area. Can I change it to DDF for participating in this?

Audience Questions

What is the relationship of the Unified Study Definition Model (USDM) to the BRIDG model?

Audience Questions

What kind of technology recommendations is the effort going to publish? Is there a concern that any technology recommendation will bias towards one implementation or another and ultimately hurt the ability to innovate?

Audience Questions

Will CDISC develop and publish a formal model for biomedical concepts as part of this project?

Audience Questions

Does the scope of CDISC DDF also cover development of biomedical taxonomies and ontologies as well?

Audience Questions

Do you plan to develop TA USDM?

Audience Questions

What is the plan to ensure that the study definition will encompass all study designs, including oncology and immunology?

Audience Questions

Has the Open Source License been picked? There are a couple of open source licenses that make corporate oversight extremely uncomfortable.

Audience Questions

Where can we find the Standard CRFs developed for different domains within Transcelerate portal, can we have access to view them if we are registered in Transcelerate?

Audience Questions

Interoperability is the ultimate goal. Is the integration of clinical studies with Electronic Health Records (EHRs) is planned in the future with enhanced data exchange security?

Audience Questions

Is there any specific link to check on what is actually happening or any standards available as a part of Transcelerate?

Audience Questions

Are you all using the PRM in any way?

Audience Questions

What about something like RESTFUL versus GraphQL? That selection has particular implementation implications.

Audience Questions

Will the model or the reference implementation be tested through some form of connectathon?

Audience Questions

Is this project linked to the CDISC 360 initiative? What are the connections?

Audience Questions

Would you consider or promote another round of an Hackathon - such as the TransCelerate DDF hackathon which ran two years back now?

Audience Questions

Is this project for clinical data only or will it include nonclinical studies?

Audience Questions

Is the USDM intended for RCTs only, or are you considering observational studies within the initial, or later, scope?

Audience Questions

Would this project deliver a standard protocol template which can be machine readable?

Upcoming Learning Opportunities

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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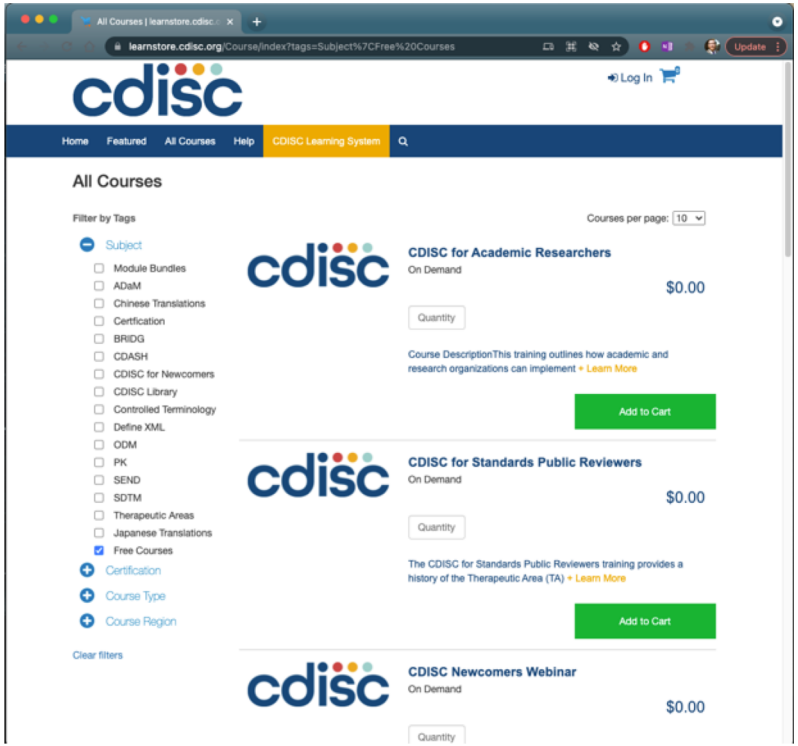
Free CDISC Courses



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2021 US INTERCHANGE
With Standards – Science Will Prevail!
VIRTUAL EVENT!
Live Stream | 20-21 October
Conference & Trade Show


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2021 CHINA INTERCHANGE
With Standards – Science Will Prevail!
LIVE EVENT!
Beijing | 19-20 November
Conference | Trade Show

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

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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