



Digital Data Flow (DDF) Project Public Review

Dave Evans, CDISC President & CEO

Dave Iberson-Hurst, CDISC DDF Technical Product Owner

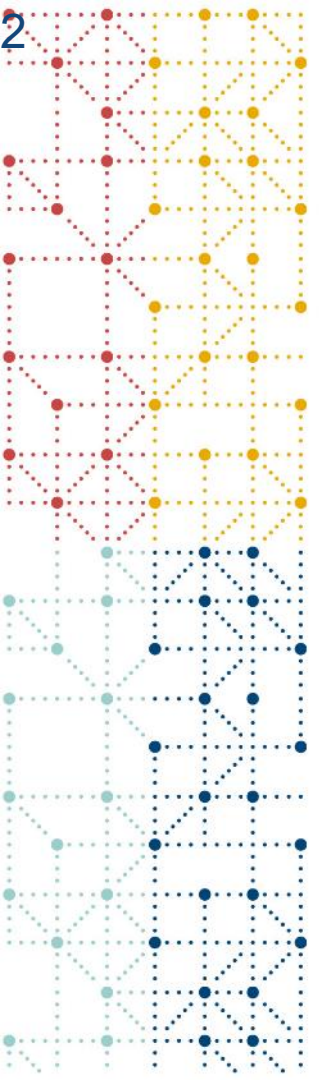
Alison Luckman, TransCelerate co-Product Owner/Lead for the DDF Delivery/Build Team

John Owen, CDISC Head PMO



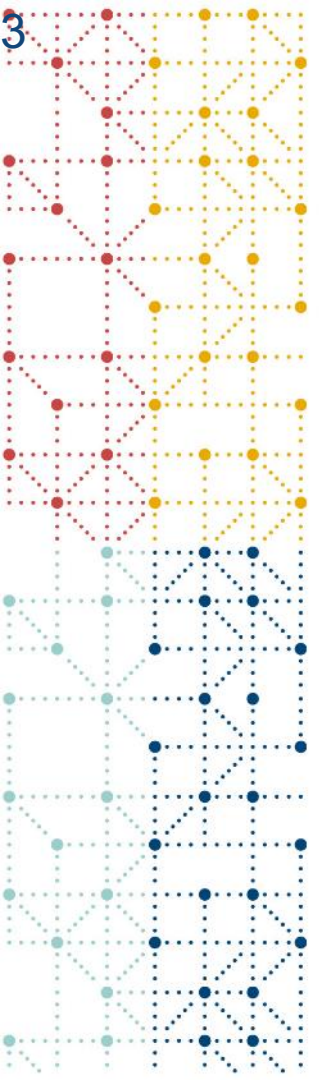
TUE 22 MAR 2022

11:00AM-12:30PM ET



Today's Agenda

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



Housekeeping

Housekeeping



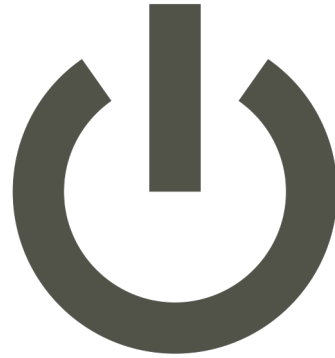
You will remain on **mute**

Housekeeping



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

Housekeeping



Audio issues?

Shut down & restart GoToWebinar app

Housekeeping



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



Today's Presenters

Dave Evans

President & CEO
CDISC

Dave Ibersen-Hurst

DDF Technical Product Owner
CDISC

Alison Luckman

co-Product Owner/Lead for the
DDF Delivery/Build Team
TransCelerate

John Owen

Head PMO
CDISC



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Digital Data Flow (DDF) Project Public Review Webinar

Presenters:

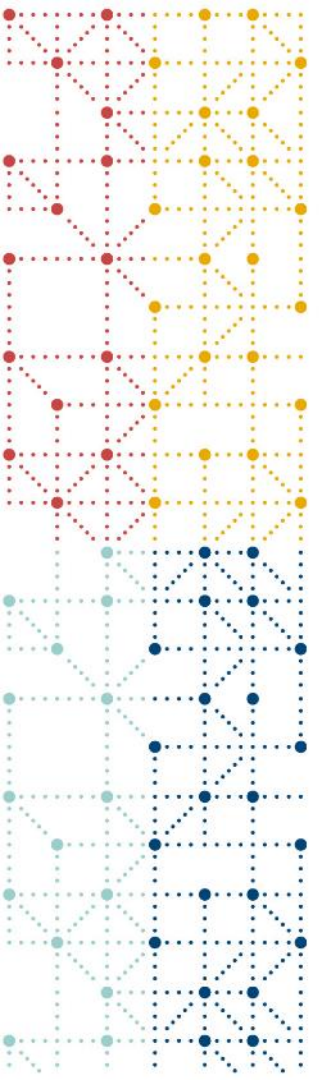
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- 1. Webinar Introduction**
2. TransCelerate and DDF
3. CDISC DDF standards for public review
4. Public Review Process
5. Q&A

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.

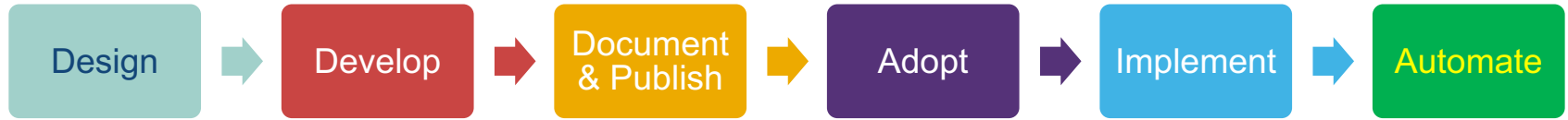
CDISC Data Standards Lifecycle



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CDISC Data Standards Lifecycle



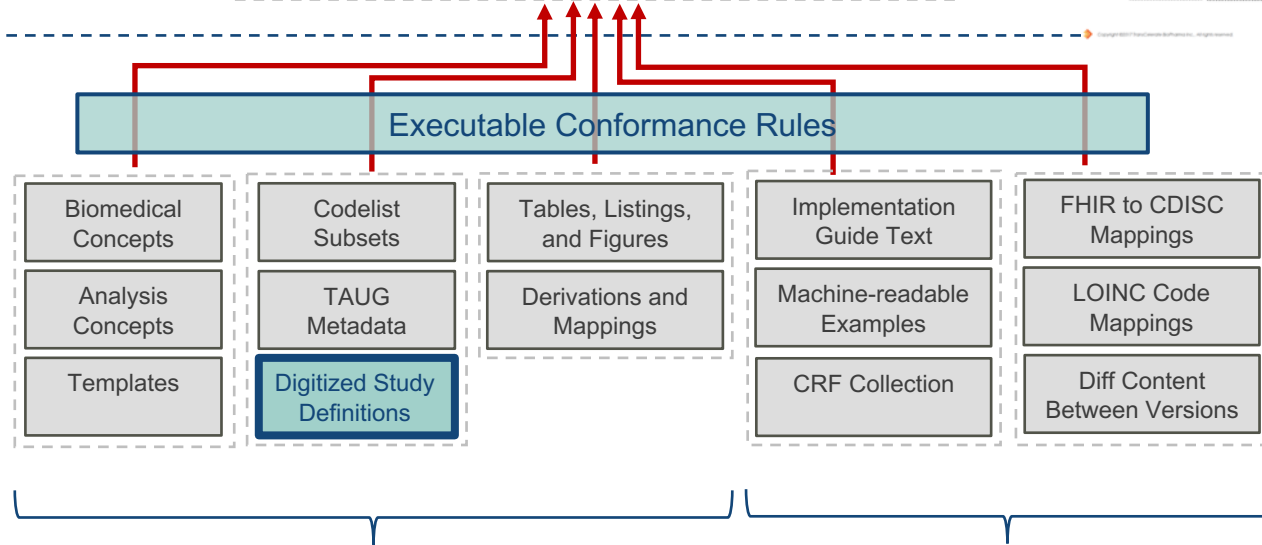
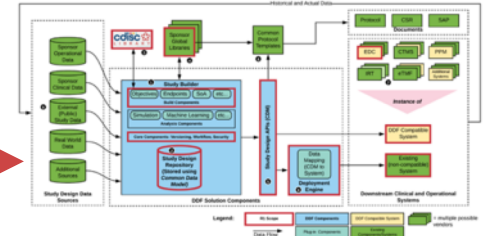
Automation requires:

- *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*

CDISC Library



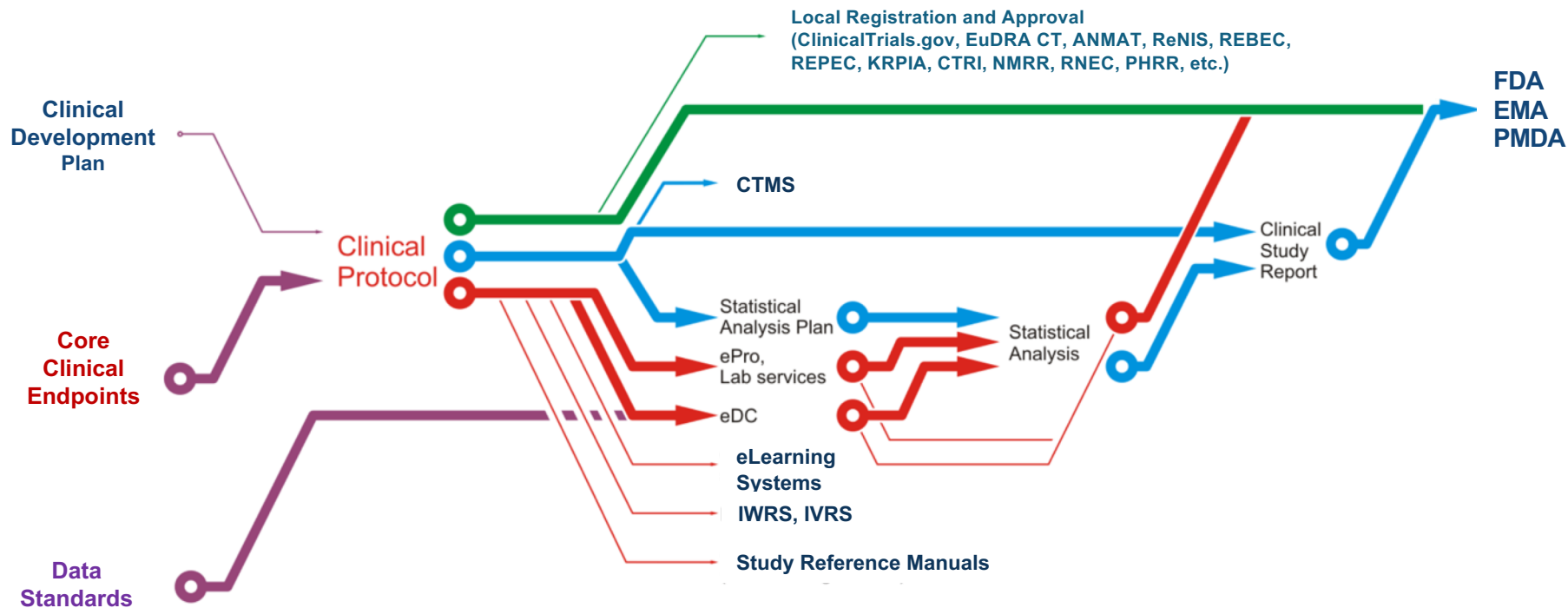
Connect with Digital Data Processes through Open-API



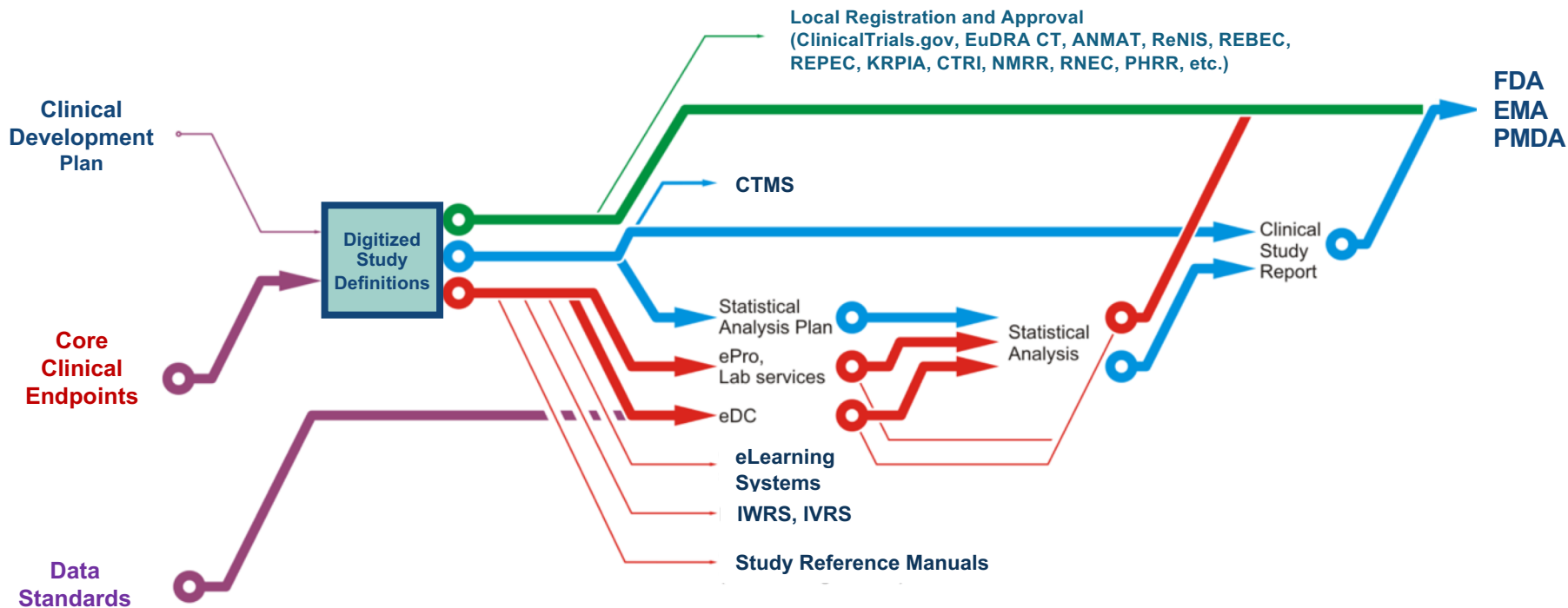
CDISC Standards

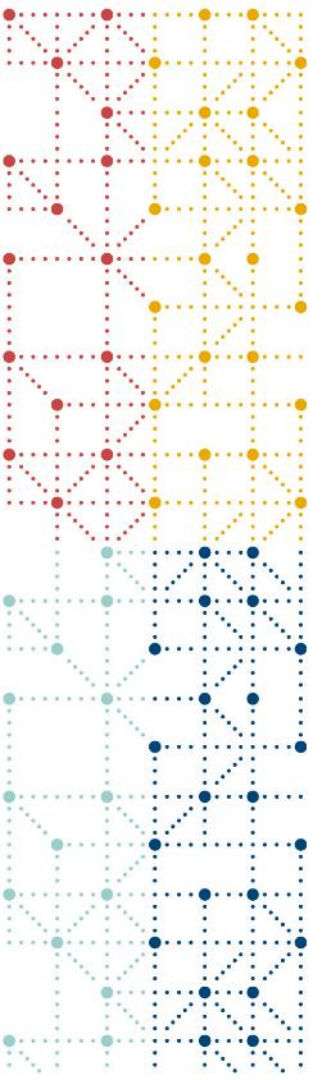
Informative Content

The Clinical Trial Information Flow



The Clinical Trial Information Flow





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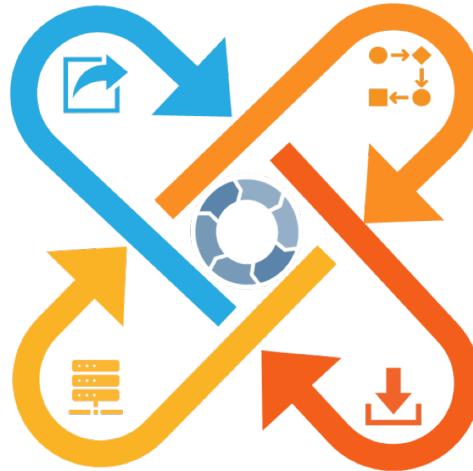
The Digital Data Flow Initiative (DDF) aims to catalyze digital transformation; breaking the document paradigm to enable seamless flow of the data within:

Digitized Protocols

Enabling the use of technologies that identify and assemble study elements allows industry to move to digital protocols

Advanced Analytics

Better enabling the use of advanced analytics such as Artificial Intelligence and Machine Learning to improve study designs



Connectivity of Data and Processes

Enabling traceability, automated flow of content to key clinical documents, and automation to clinical & operational systems (e.g.. EDC, CTMS)

Open and Flexible Solution

Developing a dynamic, fully automated solution that is vendor agnostic, open and flexible

Development principles to enable broad collaboration, stakeholder input, and sustainability



Open Source



Vendor Agnostic



Agile Development



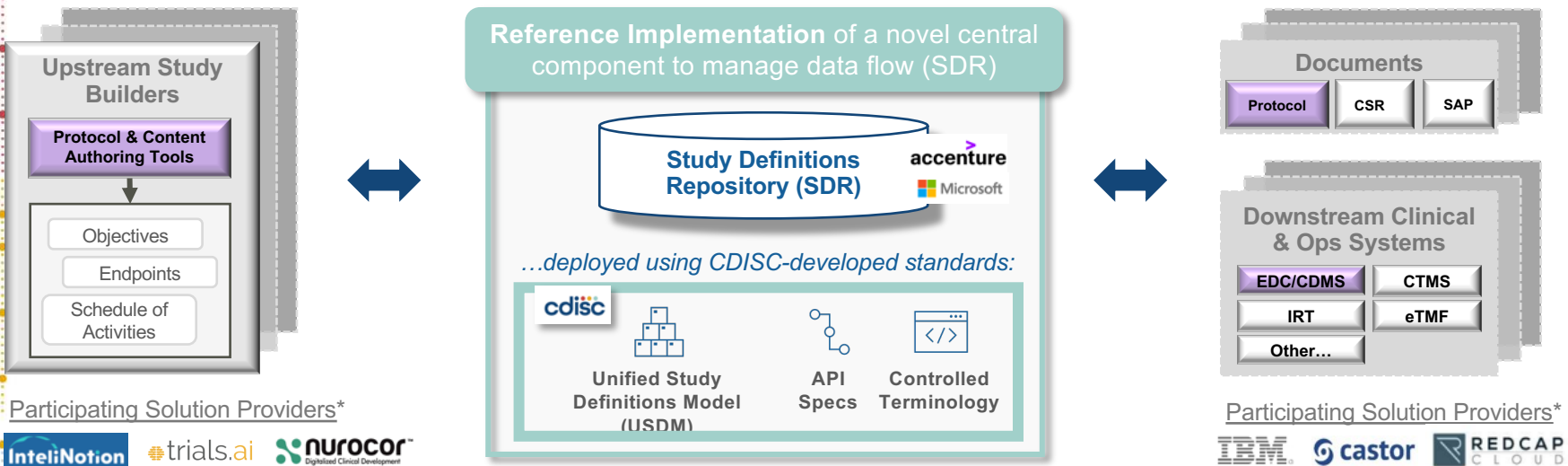
Dynamic Alignment to Standards

Minimum Viable Product (MVP) development underway

The MVP release will focus on enabling flow of study definitions data from study builders to Study Definitions Repositories (SDR) to Electronic Data Capture (EDC)/CDMS

System or Tool of Focus for MVP

Potential Future System of Focus



* Solution Providers above have volunteered to participate in MVP development in anticipation of making use of DDF solutions in the future. Additional Solution Providers may volunteer in coming weeks/months. TransCelerate does not endorse nor recommend specific vendors or commercial products.

Enabling DDF – Where are we on the DDF journey?

2022 >>

Deliver MVP

Pilot, Learn/Adapt & Continue Development

◆ MVP Release
(Q2)

◆ Public
Connectathon
(Q2/Q3)

Study Builder & EDC
Vendor Design
Collaboration



Digitized Protocol



Limited EDC Integration



*Initial discussions and alignment
between technical solution teams (RA/RI
for USDM, SDR) and Study Builders,
EDC vendors to collaborate on SDR
design compatibility to receive and send
data*

coisc

*Digitizing a portion of the study data
elements included in the Common
Protocol Template significantly facilitates
for automated Protocol Document
enablement*

*Digitizing a portion of the study data
elements enables partial automated EDC
build*

Engaging with DDF

•What's Coming?

• DDF GitHub Launch for Open-source (OS) Collaboration

Launch of DDF GitHub site to foster, develop, and maintain an open-source community of active DDF project contributors. GitHub repository will be the central destination for OS material & future collaboration.

• DDF Connectathon

Planned Connectathon event in 2022 will encourage demonstrations of use/connectivity to the Study Definitions Repository & CDISC standards by anyone in the vendor community.

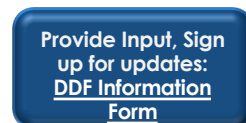
Resources to Learn More
(Click on any of icons/links below.)



TransCelerate DDF
Solutions Webpage



FAQ: Digital Data
Flow



DDF Information
Form



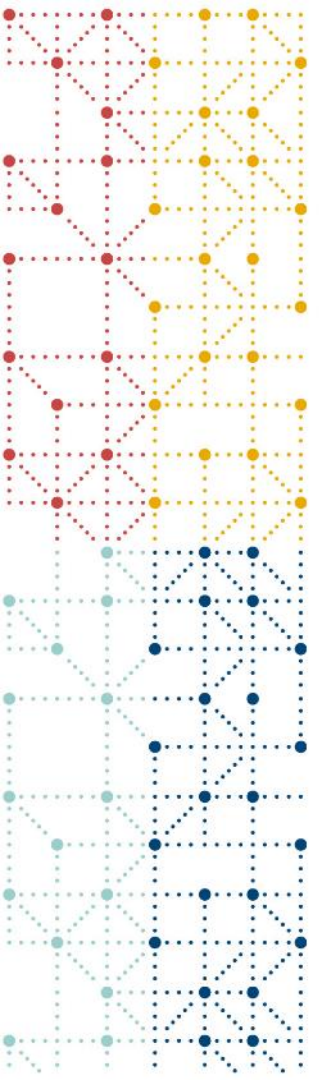
Overview:
Digital Data
Flow



DDF Public
Webinars



DDF Launch:
Press Release



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CDISC Study Definition Repository RA Deliverables



Unified Study Definitions Model (USDM) Class Diagram

The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)



Application Programming Interface (API) Specification

The API definition (normative) in JSON and HTML forms



CDISC Controlled Terminology

The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.



Reference Architecture Conformance Tests

Provided by the functionality provided by tools such as SwaggerHub and Postman



Essential Users Stories

The User Stories. PDF document



Architecture Principles

The architectural principles developed by the project. PDF Document



Supporting Materials

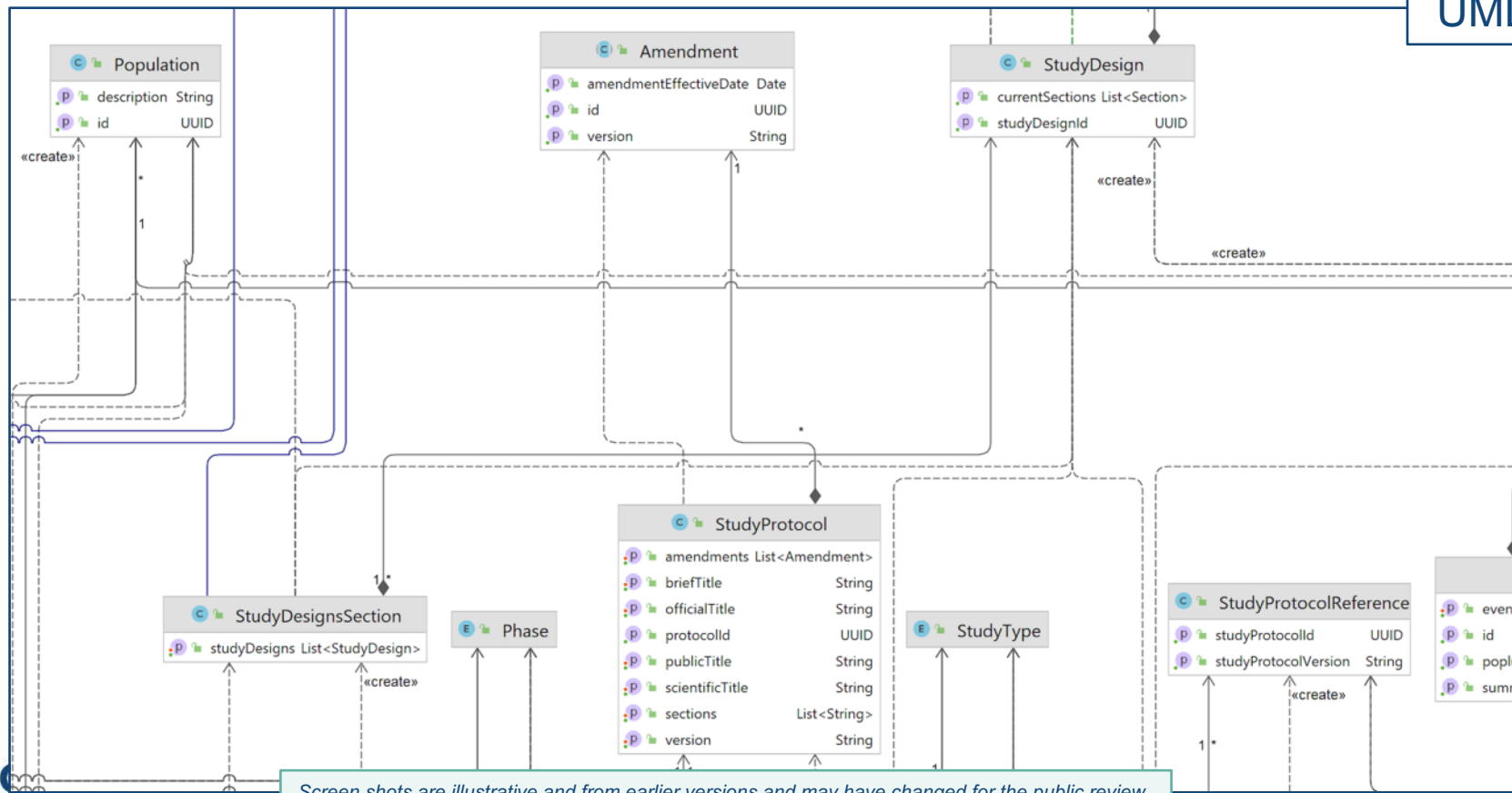
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Unified Study Definitions Model (USDM) Class Diagram

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UML

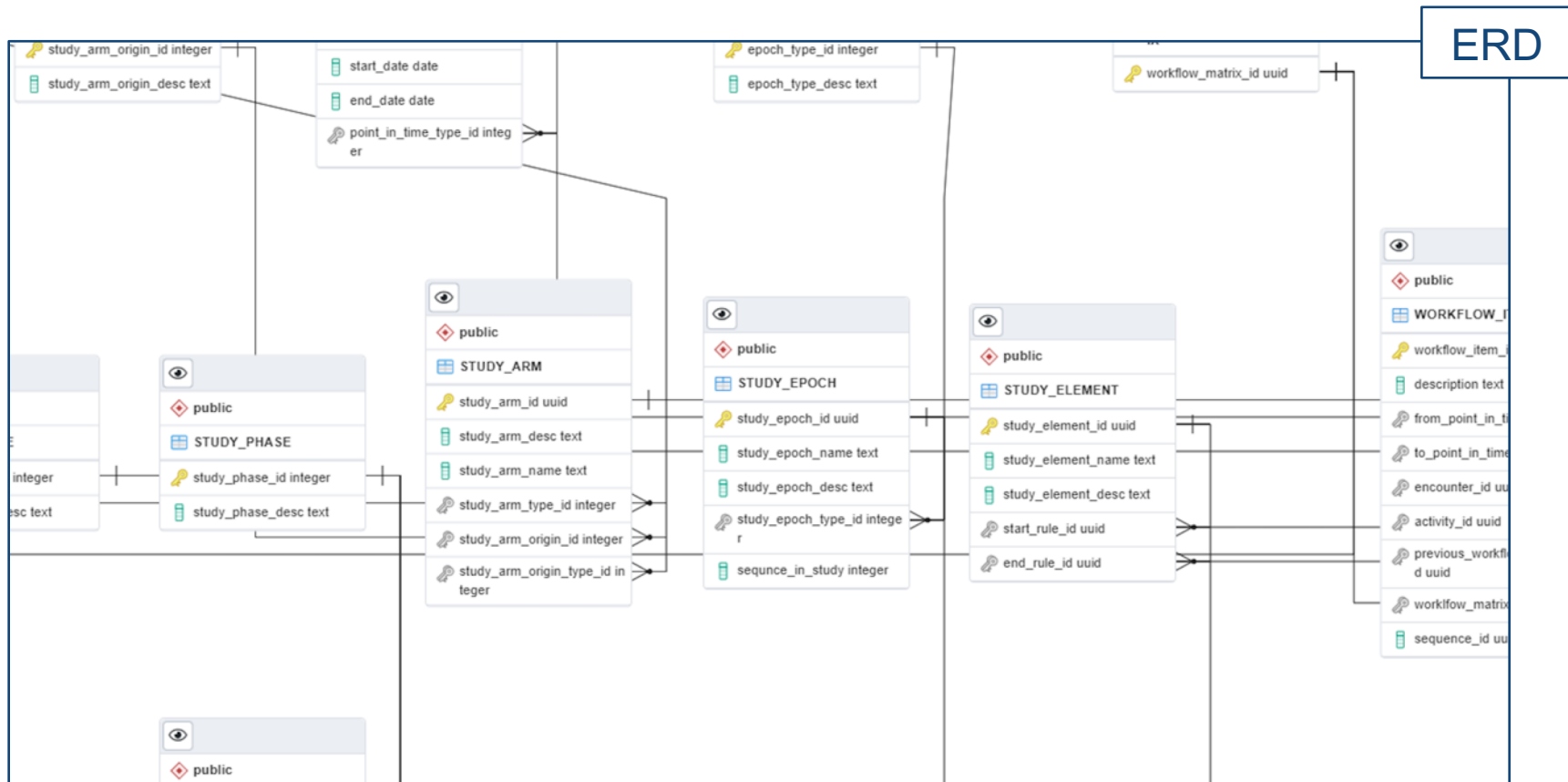


Screen shots are illustrative and from earlier versions and may have changed for the public review



Unified Study Definitions Model (USDM) Class Diagram

The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)



ERD



Unified Study Definitions Model (USDM) Class Diagram

The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)

SQL DD

```
-- This script was generated by a beta version of the ERD tool
-- Please log an issue at https://redmine.postgresql.org/projects/USDM
BEGIN;

CREATE TABLE IF NOT EXISTS public."STUDY"
(
    study_id uuid NOT NULL,
    study_title text NOT NULL,
    study_version text NOT NULL,
    study_tag text,
    study_type_id integer NOT NULL,
    study_phase_id integer NOT NULL,
    study_status text NOT NULL,
    study_protocol_id uuid,
    study_protocol_version text,
    CONSTRAINT pk_study_id PRIMARY KEY (study_id)
);

CREATE TABLE IF NOT EXISTS public."STUDY_TYPE"
(
    study_type_id integer NOT NULL,
    study_type_desc text NOT NULL,
    PRIMARY KEY (study_type_id)
);

CREATE TABLE IF NOT EXISTS public."STUDY_PHASE"
(
    study_phase_id integer NOT NULL,
    study_phase_desc text NOT NULL,
    CONSTRAINT pk_study_phase_id PRIMARY KEY (study_phase_id)
);

CREATE TABLE IF NOT EXISTS public."STUDY_IDENTIFIER"
(
    study_identifier_id uuid NOT NULL,
    org_code text NOT NULL,
    study_identifier_type_id integer NOT NULL,
    study_identifier_name text,
    study_id uuid,
    PRIMARY KEY (study_identifier_id)
);
```

JSON

```
{
  "studyTitle": "Study Number One",
  "studyType": "INTERVENTIONAL",
  "studyPhase": "PHASE_1_TRIAL",
  "studyStatus": "this is a study status",
  "studyIdentifiers": [
    {
      "id": "f1aae4a0-2ddf-44cc-9f65-f3077f3f5939",
      "orgCode": "2.16.840.1.113883.3.1077",
      "name": "ClinicalTrials.gov",
      "idType": "REGISTRY_STUDY"
    },
    {
      "id": "74bab1ed-9439-4467-83a3-284727e0b0e9",
      "orgCode": "2.16.840.1.113883.3.1077",
      "name": "ClinicalTrials.gov",
      "idType": "SPONSOR_ID"
    }
  ],
  "studyProtocolReferences": [
    {
      "studyProtocolId": "a5709f39-dcf1-40a0-bd40-5164a96e07b8",
      "studyProtocolVersion": "1.0"
    }
  ],
  "studyVersion": "1.0",
  "studyTag": null,
  "studyId": "8bf37e48-cbf0-49f5-a113-4c5a15b2cd90",
  "currentSections": [
    {
      "id": "bd8e986a-d7cd-4289-bc14-f05e05e3342f",
      "sectionType": "STUDY_INDICATIONS",
      "studyIndications": [
        {
          "id": "f192251c-a732-44b5-b63a-6f3b99bd7c99",
          "description": "Alzheimer's disease",
          "coding": [
            {
              "code": "26929004",
              "codeSystem": "SNOMED-CT",
              "codeSystemVersion": "4.0.6.4",
              "decode": "Alzheimer's disease (disorder)"
            }
          ]
        }
      ]
    }
  ]
},
```



Application Programming Interface (API) Specification

The API definition (normative) in JSON and HTML forms

JSON

GET /studydefinitionrepository/v1/studyhistory

Get history of all studies (get.studydesignrepository.history)

Get history of all studies

Return type

[inline_response_200_1](#)

Example data

Content-Type: application/json

```
{
  "study" : [ {
    "studyVersion" : [ 1, 1 ],
    "studyId" : "e3e84e94-927e-42da-9625-e4f18bc4b7a4",
    "studyTitle" : "Example study title"
  }, {
    "studyVersion" : [ 1, 1 ],
    "studyId" : "e3e84e94-927e-42da-9625-e4f18bc4b7a4",
    "studyTitle" : "Example study title"
  } ]
}
```

Produces

This API call produces the following media types according to the Accept request header; the media type will be converted to the following media type.

- application/json

Responses

200

OK [inline_response_200_1](#)

HTML

```
{
  "openapi": "3.0.0",
  "info": {
    "title": "Simple API for DDF",
    "description": "This is a sample API for the DDF project - including sectioning (Acc",
    "license": {
      "name": "MIT",
      "url": "https://opensource.org/licenses/MIT"
    },
    "version": "1.2.6"
  },
  "servers": [
    {
      "url": "https://virtserver.swaggerhub.com/CDISC1/DDF/1.2.6",
      "description": "SwaggerHub API Auto Mocking"
    }
  ],
  "paths": {
    "/studydefinitionrepository/v1/{study}": {
      "get": {
        "tags": [
          "default"
        ],
        "summary": "Get study build sections",
        "description": "Get Study Build Sections",
        "operationId": "get.studydesignrepository.sections",
        "parameters": [
          {
            "name": "study",
            "in": "path",
            "description": "Study Builder Study",
            "required": true,
            "style": "simple",
            "explode": false,
            "schema": {
              "type": "string",
              "example": "ACME001"
            }
          }
        ]
      }
    }
  }
}
```

This Set

Default

- [GET /studydefinitionrepository/v1/studyhistory](#)
- [GET /studydefinitionrepository/v1/{study}/sectionhistory](#)
- [GET /studydefinitionrepository/v1/{study}](#)
- [GET /studydefinitionrepository/v1/{study}/studydesign/{s](#)
- [GET /studydefinitionrepository/v1/{study}/studyprotocols](#)
- [POST /studydefinitionrepository/v1](#)
- [POST /studydefinitionrepository/v1/{study}/studyprotocol](#)

Ignore!

Hidden

- [POST /studydefinitionrepository/v1/components](#)
- [DELETE /studydefinitionrepository/v1/{study}/studyassessmentgroup/{assessmentgroupId}](#)
- [DELETE /studydefinitionrepository/v1/{study}/biomedicalconcepts/{biomedicalConceptId}](#)





CDISC Controlled Terminology

The controlled terminology (normative) developed for the project. Provided in an Excel format so as to be easily searched and filtered.

Row #	UML Class Name	UML Item Name	Role	NCIC-code	CT Item Preferred Name	Synonym(s)	Definition	Has Value List
1	STUDY	STUDY	Entity	C15206	Clinical Study		A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials (also called interventional studies) and observational studies. [http://ClinicalTrials.gov/CDISC_Glossary]	N
2	STUDY	study_title	Attribute	C49802	Study Title	Trial Title; Official Study Title; Study Title	The sponsor-defined name of the clinical study.	N
3	STUDY	study_version	Attribute	C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	N
4	STUDY	study_status	Attribute	CNEW	Protocol Status		A condition of the protocol at a point in time with respect to its state of readiness for implementation.	Y (CNEW Protocol Status Response)
5	STUDY	study_protocol_version	Attribute	C93490	Study Protocol Version		A plan at a particular point in time for a formal investigation to assess the utility, impact, pharmacological, physiological, and/or psychological effects of a particular treatment, procedure, drug, device, biologic, food product, cosmetic, care plan, or subject characteristic. (BRIDG)	N
6	STUDY_TYPE	STUDY_TYPE	Entity	C142175	Study Type	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	N
7	STUDY_TYPE	study_type_desc	Attribute	C142175	Study Type Classification	Study Type; Study Type Classification	The nature of the investigation for which study information is being collected. (After clinicaltrials.gov)	Y (C99077 STYPE)
8	STUDY_PHASE	STUDY_PHASE	Entity	C48281	Trial Phase	Trial Phase; Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	N
9	STUDY_PHASE	study_phase_desc	Attribute	C48281	Trial Phase Classification	Trial Phase; Trial Phase Classification	A step in the clinical research and development of a therapy from initial clinical trials to post-approval studies. NOTE: Clinical trials are generally categorized into four (sometimes five) phases. A therapeutic intervention may be evaluated in two or more phases simultaneously in different trials, and some trials may overlap two different phases. [21 CFR section 312.21; After ICH Topic E8 NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS, CPMP/ICH/291/95 March 1998]	Y (C66737 TPHASE)
10	STUDY_IDENTIFIER	STUDY_IDENTIFIER	Entity	C83082	Study Identifier		A sequence of characters used to identify, name, or characterize the study.	N
11	STUDY_IDENTIFIER	org_code	Attribute	CNEW	Study Identifier Organization Code		A coded value specifying the organization that creates and/or assigns the study identifier.	N
12	STUDY_IDENTIFIER	study_identifier_name	Attribute	CNEW	Study Identifier Name		The literal identifier (i.e., distinctive designation) of the sequence of characters used to identify, name, or characterize the study.	N



User Stories

Dave Iberson-Hurst, 21st March 2022

Changes

- 25th January 2022 – Initial draft
- 31st January 2022 – Updates after informal review
- 14th February 2022 – Updates after initial Transclerate (TCB) review. Includes better alignment with TCB terminology. Also the Essential User Stories and those raised as JIRA tickets have been incorporated such they can viewed in context.
- 21st March 2022 – Updates after further review.

Purpose

This note presents a set of user stories for the Digital Data Flow Project based on the essential user stories produced by the project to date. The presented user stories try and respond to comments raised on the essential user stories such as the following JIRA ticket.

However the users of the USDM are the upstream and downstream systems and not directly the users of those systems. So search and add/remove functions like described in user story L1 to L5 are not directly applicable to the USDM and RA. However, the data structure must make it possible for the upstream system to provide this functionality. So a logical data structure and API requests are in scope. Can the user stories be adjusted to reflect this?



Architecture Principles

The architectural principles developed by the project. PDF Document

PDF

Architecture Principles

Description of the Deliverable for the Development Phase

The architecture principles aim to help implementers understand how to create conformant solution architectures through the implementation of the DDF Study Definition Reference Architecture (RA). They inform solution architects of the approach expected by the RA stakeholders to ensure consistency across Study Definition implementations and to ensure alignment with the business and technology objectives. Architecture principles define the fundamental assumptions regarding the RA and aid in developing a framework for decision making by solution architects implementing the RA.

Summary of work to be performed during scoping

A framework for the architecture principles was developed during the scoping period.

CDISC Study Definition Repository RA Deliverables



Unified Study Definitions Model (USDM) Class Diagram

The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative)



Application Programming Interface (API) Specification

The API definition (normative) in JSON and HTML forms



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Reference Architecture Conformance Tests

Provided by the functionality provided by tools such as SwaggerHub and Postman



Essential Users Stories

The User Stories. PDF document



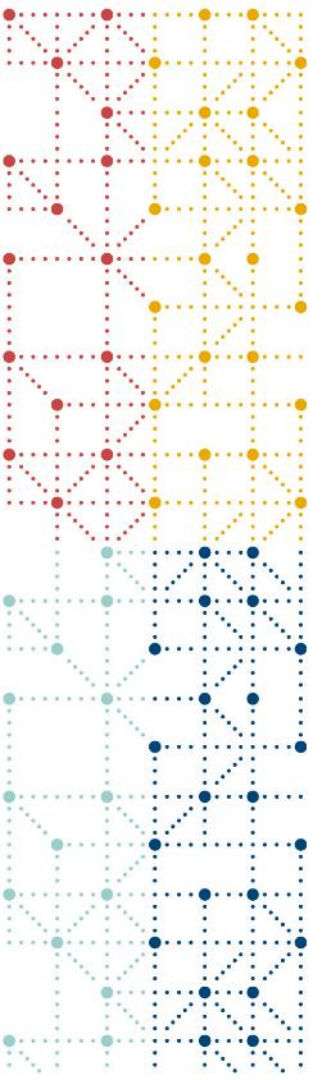
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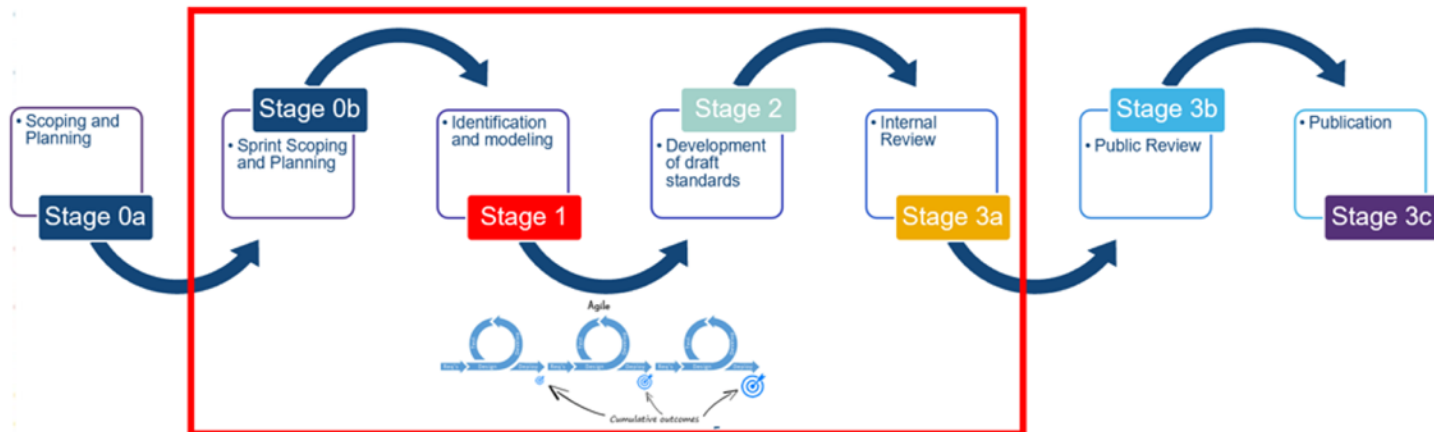
Supporting Materials

A set of informational materials in PDF format to help understand the deliverables being reviewed. PDF documents or references.



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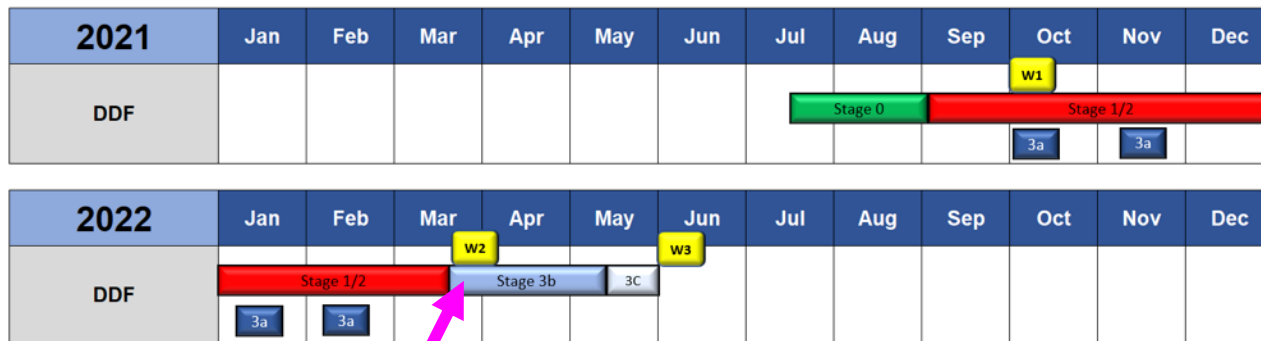
The Process for MVP



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



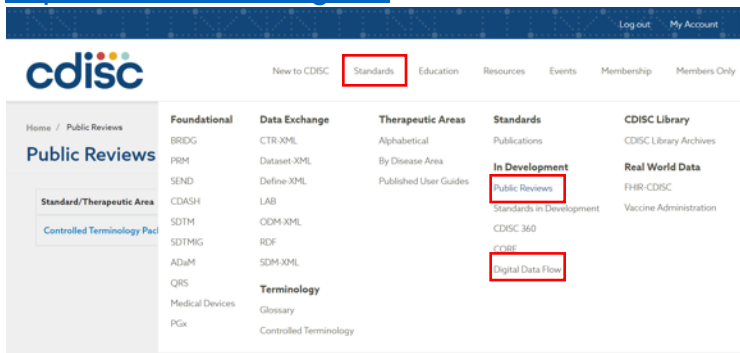


Public Review Timetable

- **Tuesday 22nd March 2022** – DDF Public Review Webinar
- **Tuesday 29th March 2022** – DDF Materials sent out for review – Start of 30-day public review
- **Monday 4th April 2022** – 10:00-11:00 US Eastern Time - DDF Public Review Workshop – open invite (details on the DDF Public Review Webinar Page)
- **Friday 29th April 2022** – DDF Public Review Commenting Period ends

Public Review Materials

- Email will be sent from CDISC Communications
- Public Review information will also be available from the Public Review section of the CDISC website
 - <https://www.cdisc.org/public-reviews>
 - <https://www.cdisc.org/ddf>



- Links will direct reviewers to the DDF Public Review Dashboard

DDF Public Review Dashboard

DDF Public Review Dashboard

Created by John Owen, last modified just a moment ago

The CDISC standards Development Process



The DDF Standards are now entering the public review commenting period after completing the standards development and internal review phases.

The purpose of the Public Review is to develop widespread consensus for the proposed standard by allowing for broad comment by the general public. Anyone interested may review and submit comments which must be reviewed and addressed by teams before proceeding to publication (CDISC-COP-00).

- Additional information on the overall aims of the DDF project can be found on the [TransCelerate DDF Website](#)
- Additional information is available in the [TransCelerate press release](#) about the DDF project

Public Review Timelines

The Public Review commenting period will be open for 30-days.

Public Review Commenting Start Date - (E) 29 Mar 2022

Public Review Commenting End Date - (E) 29 Apr 2022

Public Review Webinar

A recording of the Public Review Webinar from 22nd March 2022 can be found [here < insert link >](#). It is recommended that you watch this recording to gain a deeper understanding of the materials that are being sent for Public Review. The [slide deck < insert link >](#) used in the webinar is also available.

Webinar Summary

Topic	Presenter	Timing
Webinar introduction	Dave Evans	
TransCelerate and DDF	Allison Luckman	
CDISC DDF standards for public review	Dave Ibersen-Hurst	
Public Review Process	John Owen	
Q&A	All	

What should you review?

- ▲ Please be aware that some of the deliverables that are being developed may be out of your skill set.
- The DDF review team is made up of experts in all the areas that the deliverables cover.
- We appreciate any comments that you can provide that you feel you can provide input on.

Deliverable	CDISC Standard	What would people Review	Files Available for Public Review	Files
Unified Study Definitions Model (USDM) Class Diagram	Yes	The UML class diagram (normative) as well as SQL Data Dictionary, Entity Relationship Diagram and example JSON output (informative) <div style="border: 1px solid gray; padding: 5px; margin-top: 5px;">Need some info on UML? If you are unfamiliar with UML, Section 5.6 of the BRDGG Users Guide might be used as a model for a 'Basics of UML' guide for DDF</div>	PDF export from Enterprise Architect	
API Specification	Yes	The API definition.	JSON and HTML formats	
Controlled Terminology	Yes	The controlled terminology (normative) developed for the project.	Excel format for ease of searching and filtering.	DDF Controlled Terminology_Public Review_FINAL.xlsx
Essential User Stories	No	The User Stories.	PDF Document	
Architecture Principles	No	The architectural principles developed by the project.	PDF Document	DDF CDISC RA GGG - Architecture_Principles - 2021-02-23.pdf
Supporting Materials	No	A set of informational materials in PDF format to help understand the deliverables being reviewed.	PDF documents or references.	

Using the DDF JIRA project for commenting

- All Public Review comments should be entered into the [DDF JIRA Project](#), as JIRA tickets.
 - You will need to log in or register for the CDISC Wiki to provide comments.
 - Register for the Wiki. If you already have an account on Wiki or JIRA, our issue-tracking system, simply log in to your account. Wiki and JIRA use the same login credentials. CDISC Wiki is a different login from [www.cdisc.org](#).
- ▶ [Click here to expand instructions for entering JIRA comments](#)

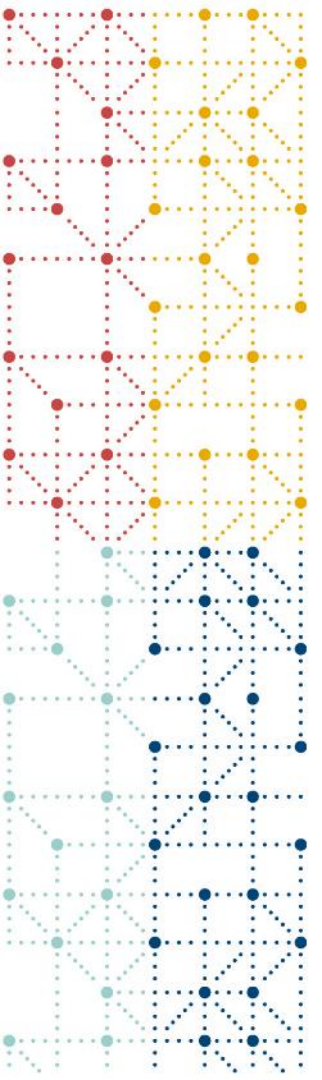
Introduction

Timelines

Webinar

Materials

Commenting



Questions & Answers

Audience Questions



Do I need to become a CDISC volunteer to take part in the public review?

Audience Questions

Will you send out a list of resolutions to public review comments?



Audience Questions



What study types will you cover in the DDF initiative?

Audience Questions

Will the DDF model also enable automation of disclosure of study protocols/results to CT.gov, EU CTR CTIS portal, etc?



Audience Questions



Is there a concern that any technology recommendation will show a bias towards a particular implementation and ultimately hurt the ability to innovate?

Audience Questions

Is there a standard
computable study protocol
schema for study builder,
study repository and
downstream application
RWD use?



Audience Questions



Is the open source license planned to be permissive or copy left?

Audience Questions

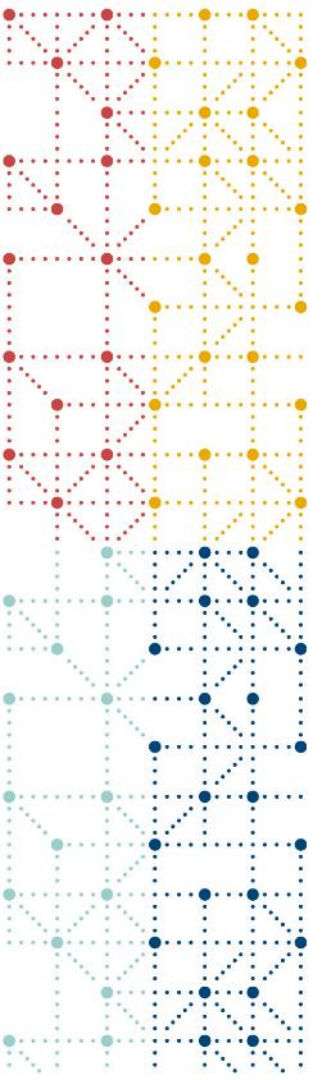
Can you elaborate on the public connectathon?



Audience Questions



One of the slides mentioned Biomedical Concepts as a CDISC standard. Is that currently an approved standard and how does it integrate with USDM?



Upcoming Learning Opportunities

April - May

2022



Europe Interchange Trainings

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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CLASSROOM
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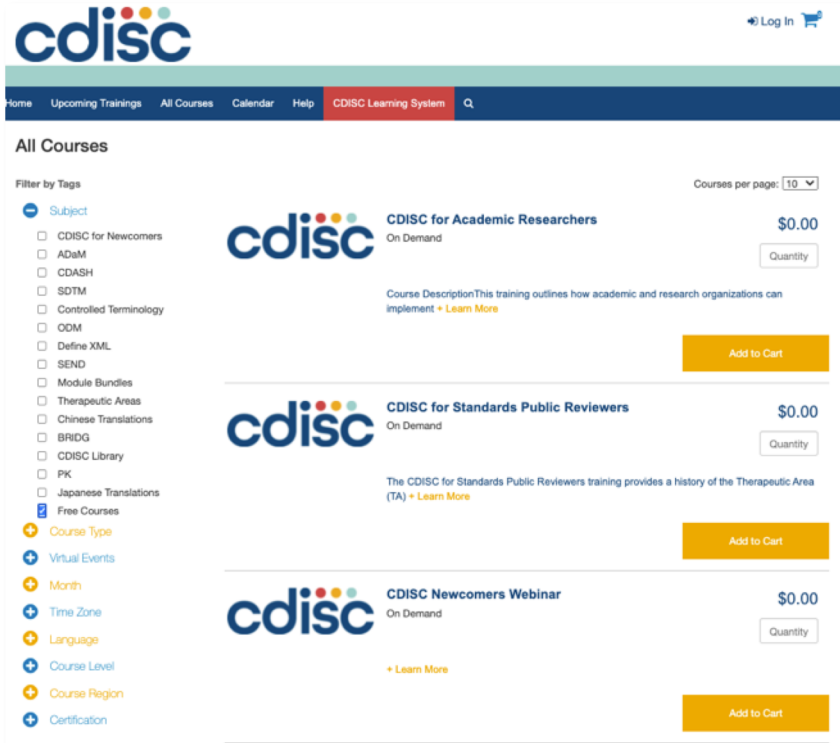


WEBINARS



WORKSHOPS

Free CDISC Courses



The screenshot shows the CDISC Learning System website. The top navigation bar includes links for Home, Upcoming Trainings, All Courses, Calendar, Help, and CDISC Learning System. The main content area is titled "All Courses" and features a "Filter by Tags" sidebar on the left. The sidebar lists various filters such as Subject, Course Type, Virtual Events, Month, Time Zone, Language, Course Level, Course Region, and Certification. The main content area displays three course listings, each with the CDISC logo, course title, price (\$0.00), and an "Add to Cart" button. The courses are: "CDISC for Academic Researchers", "CDISC for Standards Public Reviewers", and "CDISC Newcomers Webinar".

cdisc Log In

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

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
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- Certification

cdisc **CDISC for Academic Researchers** \$0.00
On Demand
Quantity
Course Description This training outlines how academic and research organizations can implement + Learn More
Add to Cart

cdisc **CDISC for Standards Public Reviewers** \$0.00
On Demand
Quantity
The CDISC for Standards Public Reviewers training provides a history of the Therapeutic Area (TA) + Learn More
Add to Cart

cdisc **CDISC Newcomers Webinar** \$0.00
On Demand
Quantity
+ Learn More
Add to Cart

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



**2022 EUROPE INTERCHANGE
CDISC VIRTUAL CONFERENCE**

27-28 APRIL



**2022 JAPAN INTERCHANGE
CDISC VIRTUAL CONFERENCE**

13-14 JUNE

COSA OpenStudyBuilder Workshop

Friday, April 29th

Register for FREE!

**Register on the Europe Interchange registration page –
no requirement to register for the main conference.**

The OpenStudyBuilder is an open-source project for clinical study specification. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.



2022 CHINA INTERCHANGE

29 - 30 JULY | BEIJING



WITH STANDARDS – UNLOCK THE POWER OF DATA



2022 US INTERCHANGE

26-27 OCTOBER | AUSTIN, TX



WITH STANDARDS – UNLOCK THE POWER OF DATA

Upcoming Webinars

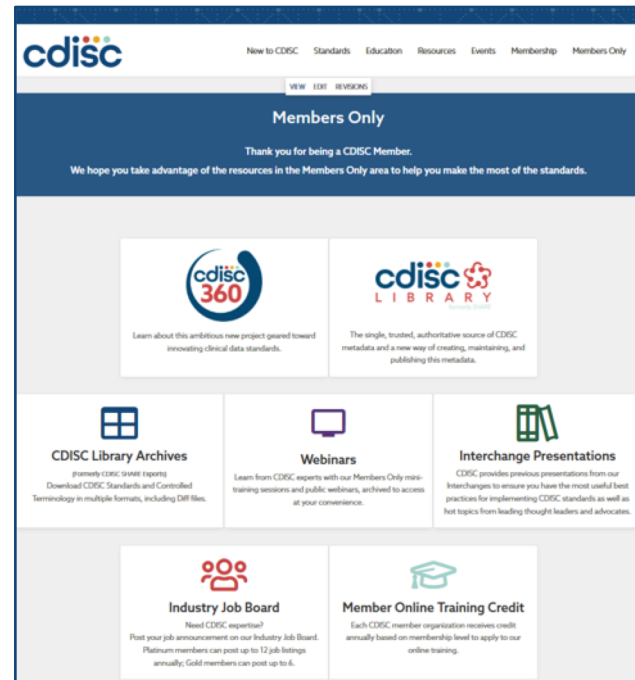
Date	Webinars
24 March	Introduction to the SDTM Genomics Finding (GF) Domain
29 March	SDTM Office Hours
31 March	CDISC Open Source Alliance (COSA) Spotlight
5 April	Controlled Terminology Updates for Q1 – P49 Publication / P50 Public Review
19 April	QRS Office Hours
28 June	Controlled Terminology Updates for Q2 – P50 Publication / P51 Public Review

Ideas or suggestions for webinar topics?
Any topics you would love to see us cover?

Let us know via our topic suggestion form:

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' button. 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 reworking clinical data standards.
- cdisc LIBRARY**: The single, trusted, authoritative source of CDISC metadata and a new way of creating, maintaining, and publishing this metadata.
- CDISC Library Archives**: formerly CDISC Grant Reports. Download CDISC Standards and Controlled Terminology in multiple formats, including DDF files.
- Webinars**: Learn from CDISC experts with our Members Only mini-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.

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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!



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events@cdisc.org



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bklinke@cdisc.org