



Digital Data Flow (DDF) Project – Phase 2 Public Review Webinar

Presented by

John Owen, Head PMO, CDISC

Dave Iberson-Hurst, DDF Technical Product Owner, CDISC

Berber Snoeijer, Janssen Pharmaceuticals

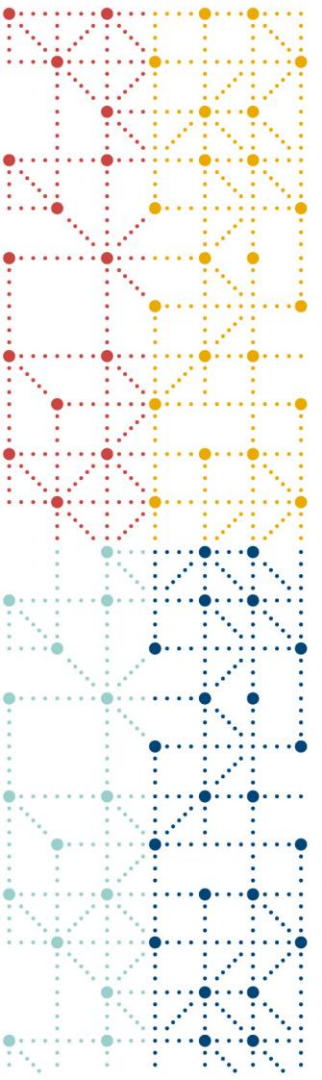
19th April 2023





Agenda

1. TransCelerate Introduction to DDF (Berber)
2. CDISC Project Introduction and Status (John)
3. Overview of the USDM v2.0 (Dave)
4. Public Review Information (John)



TransCelerate Introduction to DDF

Berber Snoeijer



Digital Data Flow (DDF)

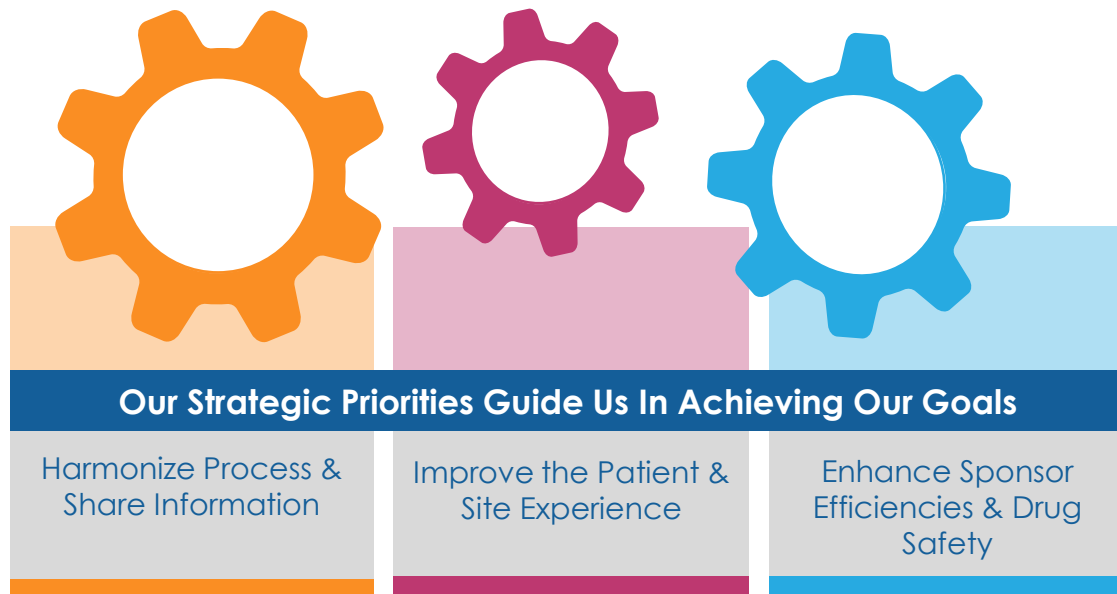
Enabling Digital Transformation in Clinical Study Start-up

CDISC Phase 2 Webinar
20 April 2023

Presenter: Berber Snoeijer, Janssen Pharmaceuticals
Member of TransCelerate DDF Project

TransCelerate – A Catalyst for Collaboration

We are a not-for-profit entity created to foster collaboration. Our mission is to collaborate across the global biopharmaceutical R&D community on solutions designed to drive the efficient, effective, and high-quality delivery of new medicines.

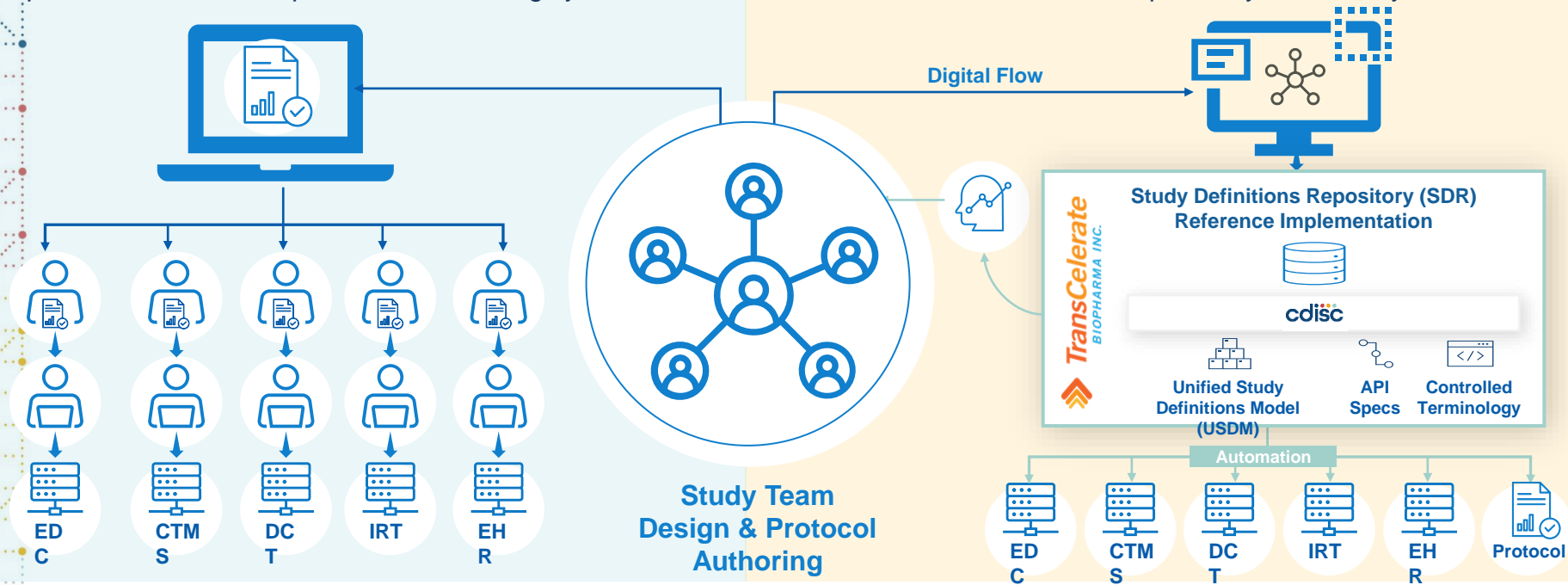


TransCelerate Digital Data Flow (DDF) Ambition

Write Once, Read Many

TODAY: Document-based paradigm for protocol creation, interpretation, and transcription into consuming systems

TOMORROW: Digital paradigm for protocol creation, with fully automated data flow and interoperability between systems



The DDF Initiative has a unique collaborative delivery approach

TransCelerate works in collaboration with industry stakeholders, such as **Clinical Data Interchange Standards Consortium (CDISC)**, to development and delivery an open-source, vendor-agnostic solution.



This collaboration aims to provide a universally available foundation for industry-wide interoperability, capable of modernizing data flows across the clinical trials ecosystem.

Input from technology solution providers across multiple system types will be incorporated into development



Open Source

Developed in open collaborative environment the Study Definitions Repository (SDR) reference implementation (RI), which is available via open-source license.



Vendor Agnostic

Neutral and unbiased solution, enabling connections of many upstream and downstream systems.



Agile Development

Incremental development of usable solutions with cross-functional teams from TransCelerate, vendors, and Standards Setting Organizations.



Dynamic Alignment to Standards

Enable broad input into CDISC standards; and governance of technical standards (APIs) & Reference Implementation (RI) enabling dynamic implementation of standards

Release 2 is now available

Staggered release schedule enables broad public input & review of the new data model, supporting understanding and adoption within sponsor & vendor community

R2 Milestones

March 31

DRAFT V2.0 of CDISC USDM
(Data Model)
+
Release 2.0.0 of the SDR
incorporating the draft standards

April-May

CDISC USDM
Public
Review
Period

June/July

FINAL V2.0 of CDISC USDM
(Data Model)
+
Release 2.0.1 of the SDR
incorporating the final
standards

MVP vs. Release 2 Comparison

Richer data model supporting more complex designs, SoA and automated CRF selection

CDISC Data Model

- Basic structure for specifying a study in digital format
- Sponsors & vendors can use a CRF link to specify which forms to use in EDC. *Specific items within forms not routinely available.*

Study Definitions Repository (SDR)

- Consume digitized study specification from an upstream source (e.g., study builder)
- Store, view and search study concepts
- Downstream EDC systems may pull study specification to aid in set-up

Connectivity with Other Initiatives

- n/a

MVP

- Sponsors can fully specify a digitized Schedule of Activities (SoA) for a study
- Sponsors & vendors can reliably demo, test and run pilot projects using a variety of complex study designs
- EDC vendors can identify appropriate CRFs for data collection to enable automated, faster configuration

- Downstream vendors can readily consume the SoA from the SDR
- Sponsor system admins can perform a visual check that SoA data received from an upstream system displays an accurate, human-readable SoA table
- Opportunity to aggregate robust historical protocol information to support analytics to drive smart design and assess risk

- With a future release of the CPT, users will be able to import study information directly from an SDR into the human-readable document template

Latest Release

How to Get Started with DDF?



Scan QR Code for
Open-Source Code



Explore CDISC DDF Standards

<https://www.cdisc.org/ddf>



CONTACT US!



Additional Information

DDF Connectathon Event: Fall 2022



258

Participants

123

Organizations

15

Projects Submitted

- 28 Clinical Solution Vendors
- 36 Sponsors
- 18 Consulting Organizations
- 16 General Technology Firms
- 14 CROs
- 11 Academic Organizations

- Automated flow of study design from study builder tool to downstream EDC
- Schedule of Activities optimization
- Protocol submissions to government registries
- Match eligibility criteria to site systems for patient screening



Scan for Videos

Learn More: Reference URL Links

Contact Us: <https://www.transceleratebiopharmainc.com/assets/digital-data-flow-feedback-form/>

DDF GitHub: SDR RI Open-Source Code

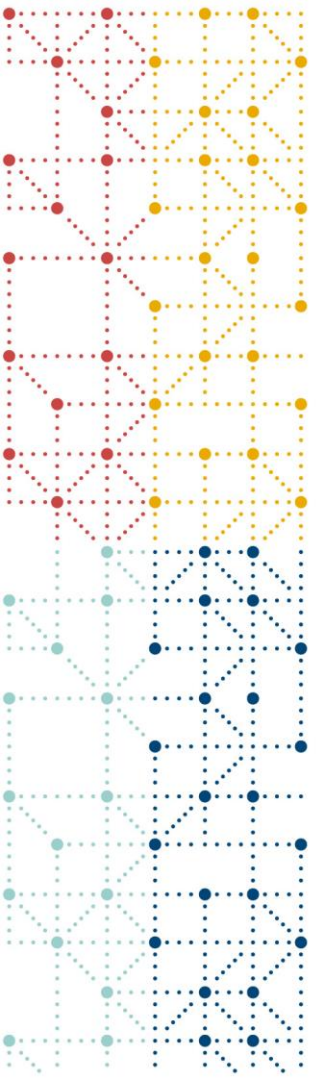
<https://transcelerate.github.io/ddf-home/sdr-ri-codebase-access.html>

TransCelerate Digital Data Flow Project
BIOPHARMA INC.

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

cdisc Digital Data Flow: <https://www.cdisc.org/ddf>

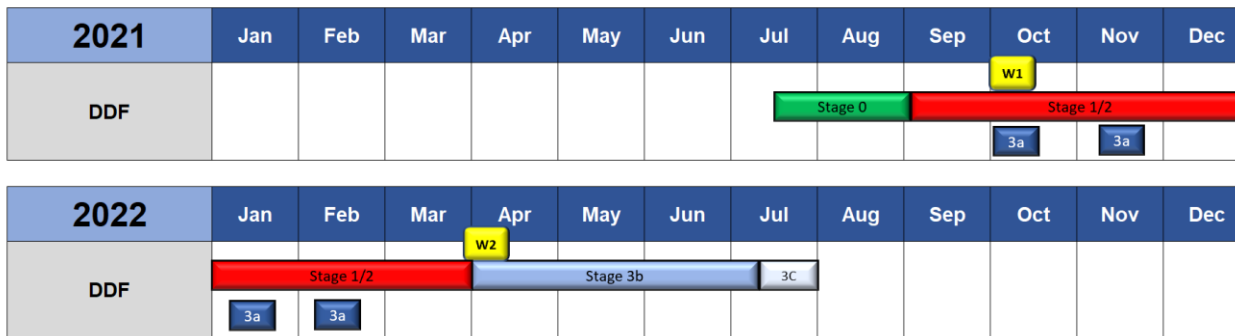
cdisc



Project Introduction and Status

John Owen

Timelines – Phase 1



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



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[USDM RA v1.0 \(Provisional\)](#)

[Digital Data Flow v1.0 Public Review Comments](#)

<https://www.cdisc.org/ddf>



Timelines – Phase 2





DDF Phase 2 Standards Strategy

- The primary goal of this phase of the project is enablement of EDC automation for sponsor adoption
- Secondary goals were additional updates to the model to enable greater population of study set-up elements, including selected structured eCPT data elements

CDISC Study Definition Repository RA Deliverables



Unified Study Definitions Model (USDM) Class Diagram



Application Programming Interface (API) Specification



CDISC Controlled Terminology



USDM Implementation Guide



USDM IG



Unified Study Definitions Model Implementation Guide (USDM-IG)

Version 1.0 (Draft)

Prepared by the
DDF Team

Notes to Readers

- This is the draft version 1.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v1.0). It is intended for internal review only and is not a final version.
- This version of the Unified Study Definitions Model Implementation Guide (USDM-IG v1.0) aligns with the Unified Study Definitions Model (USDM-v2.0)

Revision History

Date	Version
2023-03-08	1.0 Draft

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 - 3.1 Relationship to Other CDISC Standards
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Overview of Development Areas for DDF2

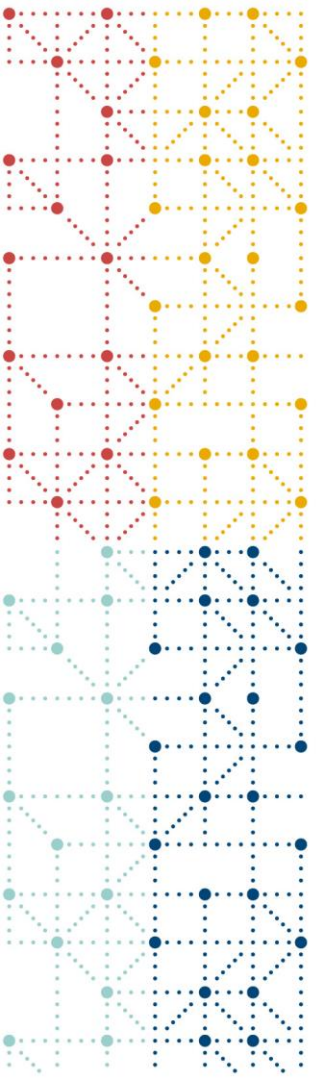
Enhancements/bug fixes from DDF1 Updates

Updates to accommodate Biomedical Concepts (EDC build)

Updates for Common Protocol Template use case

Updates for more complex studies

Updates from Connectathon feedback



Overview of the USDM Model v2.0

Dave Ibersen-Hurst

Technical Walkthrough

Technical walkthrough will be undertaken using a Miro board. Link will be pasted in the webinar chat. A PDF of the board will also be made available.

Link: <https://miro.com/app/board/uXjVPI5X2AY=/>

Password: CDISC-DDF-SME

Digital Data Flow Last Updated: 19th April 2023

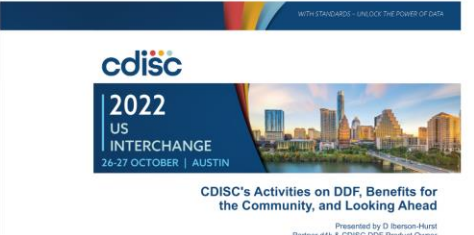
This initiative aims to move the drug development process from a current state of manual, study start-up asset creation (i.e. Case Report Forms, Procedure Manuals, Statistical Analysis Plans, and Schedule of Activities) to a future state of fully automated, dynamic, study start-up readiness via an open-sourced,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

Links

- Transcelerate Digital Data Flow page
 - <https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/>
- CDISC DDF Page
 - <https://www.cdisc.org/ddf>
- CDISC Github
 - <https://github.com/cdisc-org/DDF-RA>

Main Elements

- Reference Architecture (CDISC)
 - Unified Study Definitions Model (USDM)
 - Controlled Terminology (CT)
 - Application Programming Interface (API)
 - Implementation Guide (IG)
- Reference Implementation (Accenture), the Study Definitions Repository (SDR)



CDISC's Activities on DDF, Benefits for the Community, and Looking Ahead

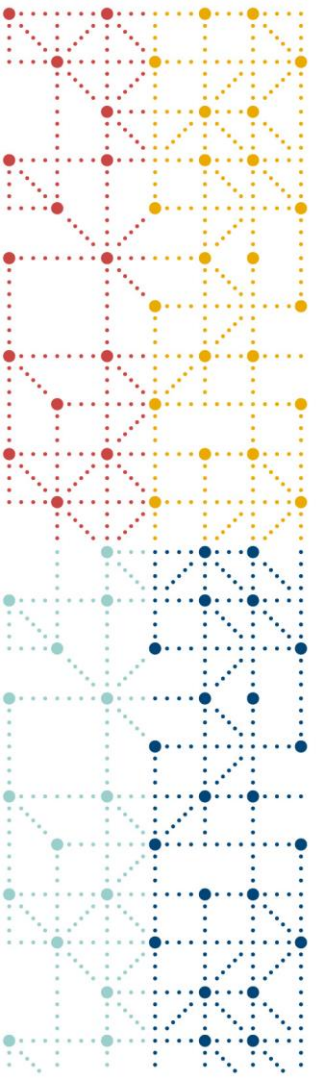
Presented by D. Benson-Hunt
Partner d4k & CDISC DDF Product Owner

Project Background (see slide deck above)

- Phase 1 -> USDM V1
- Phase 2 -> USDM V2
- **Entering Public Review, April 2023**

MIRO Board Status

- Used for technical run throughs
- Staging zone for Implementation Guide content
- **Status: Informational. Updated regularly**



Public Review Information

John Owen

Public Review Information



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SDTM

SDTMIG

ADaM

QRS

Medical Devices

Genomics

Data Exchange

CTR-XML

Dataset-XML

Define-XML

LAB

ODM-XML

RDF

SDM-XML

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Controlled Terminology

NSV Registry

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Alphabetical

By Disease Area

Published User Guides

Standards

Publications

In Development

Public Reviews

Standards in Development

CDISC 360

CORE

CDISC Biomedical Concepts

Digital Data Flow

CDISC Library

CDISC Library

Real World Data

FHIR-CDISC

Vaccine Administration



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By Disease Area

Published User Guides

Standards

Publications

In Development

Public Reviews

Standards in Development

CDISC Library

CDISC Library

Real World Data

FHIR-CDISC

Vaccine Administration

Public Reviews

Standard/Therapeutic Area	Comments Due
Digital Data Flow - Phase 2	18 May 2023
QRS Supplements to the SDTMIG	16 May 2023
QRS Supplement to the ADaMIG	4 May 2023
Controlled Terminology Package 54	21 April 2023



<https://www.cdisc.org/>

Public Review Information



Digital Data Flow Phase 2 Public Review

CDISC invites you to provide comments on v2.0 of the Unified Study Definitions Model (USDM).

[Provide Comments](#)

CDISC, in continued collaboration with [TransCelerate's Digital Data Flow Project](#), has updated the USDM 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.

The focus of Digital Data Flow (DDF) Phase 2 is:

- Facilitating eCRF automation with the implementation of [Biomedical Concepts](#) into the model.
- Enabling the model to handle more complex study designs including the representation of complex timing, branching and cycles.
- Adding protocol elements to help demonstrate population of structured USDM data elements to a protocol template.

Deliverables will include a logical data model, supporting Controlled Terminology, API specifications and a corresponding Implementation Guide.

Public Review Information

Digital Data Flow - Phase 2

Comments Due By
18 May 2023

Webinar
[Digital Data Flow Project Phase 2 Public Review](#)

CDISC invites you to submit comments on the draft v2.0 of the Unified Study Definitions Model (USDM) during Public Review.

CDISC, in continued collaboration with [TransCelerate's Digital Data Flow Project](#), has updated the USDM 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.

The focus of DDF Phase 2 is:

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- Adding protocol elements to help demonstrate population of structured USDM data elements to a protocol template.

Deliverables include a logical data model, supporting Controlled Terminology, API specifications, and an associated Implementation Guide.

To Provide Comments:

- [View the USDM v2.0 draft and Instructions for Reviewers.](#)

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.

Public review is a key quality step in our Standards Development Process. CDISC relies on your input to ensure neutral, consensus-based data standards are developed and adopted by a diverse global community interested in improving research processes and quality for the benefit of all.

Thank you for contributing your time and expertise.

Public Review Dashboard

Public Review Dates
Final Review Start: Tuesday, 10/18/2023
Final Review End: Tuesday, 10/18/2023
Comments received after 10/18/2023 may not be addressed during the public review period but will be deferred to the next version of the USDM.
To direct any questions to [CDISC-Data](mailto:CDISC-Data@cdisc.org) (CDISC-Data@cdisc.org)

Location of Materials for Public Review
CDISC team has used OneDrive to store the deliverables for this project. However for ease of use please download the following zip file to access the UML, API and CT deliverables.
UML v2.0 - Draft for Public Review.zip
Link to the WHO version of the USDM Implementation Guide is here
Implementation Guide USDM v1.0 v1.0
Throughout the development process we have been using a visual representation to aid understanding of the UML model. The two files below represent the model at the end phase 1.0.
• 2023-07-04 CDISC Model Home USDM v1.0.simg
• 2023-04-10 CDISC Model Screen v1.0.simg

Public Review Webinar
To sign up to the 2023 Public Review Webinar to find out more information about the Public Review Version of the USDM. A recording of the webinar will be available here.

Internal Review USDM Deep Dive
Stephan-Mueller hosted a recorded USDM Deep Dive for Internal Review on Tuesday, 10/18/2023.
Please access the recording here
Introductory slide deck here
One with Q&A here
Link to the **DDF Micro Board** used in the deep dive (password = CDISC-DDF-DIVE)
* Note that this is a live board - please refer to the slide on updates on the front page
* Please feel free to add notes to this board if you need additional explanation - Any comments related to the model should however be added as a JIRA issue

Instructions for Public Review
1. It is recommended to familiarize yourself with the Digital Data Flow project by reading resources from: TransCelerate's Digital Data Flow Project and CDISC's Digital Data Flow Information.
a. If readers are new to Digital Data Flow it is recommended to watch the video presentation on the TransCelerate DDF video library.
b. Of particular interest will be the video on the USDM Overview.
2. Download the Review Materials zip file from the link above.
a. The CT, API and UML deliverables can be found in the following directory of the zip file => USDM v2.0 - Draft for Internal Review.zip\DDF-BA-1.1.0\Deliverables
b. Navigate to each directory to see the deliverables.
c. API has both xml and json formats.
d. The CT is in excel format. There is a CT file and also a change log that lists all of the CT changes since version 1.0 was released last August.
e. The UML is in json Enterprise Architect .img (picture file) and json (JSON) format as well as a change log from version 1.0 released last August.
f. To locate the Implementation Guide viewer contains a PDF of the WHO version of the USDM v1.0 as well as a folder of CDISC examples of study designs in USDM format.
3. Use the link above to navigate to the USDM Implementation Guide version on the WHO.
4. Please read information on Instructions for Reviewers and also How to Read this Document for additional information on performing the review of the USDM Implementation Guide.
5. Perform your review.
6. Email your review comments into JIRA - See instructions below.

Public Review Issue Summary
Views an overview of Public Review Comments that have been received.
Comments: Status
Showing 8 of 8 statistics
in 0:00

See below for a detailed list of Public Review Comments
Click here for more detail on Internal Review Comments that have been received. If the same comment has already been made you may want to add a comment to the JIRA ticket to add your comments here to see a list of Internal Review Comments.

Instructions to create a JIRA comment for the USDM Implementation Guide
As the USDM Implementation Guide has been developed in the CDISC WHO and therefore JIRA comments can be made directly in the WHO.
Please see the instructions for Reviewers section of the USDM v2.0

Instructions to create a JIRA comment for the UML, CT and API Deliverables
Step 1 - Open JIRA | Step 2 - Create Ticket | Step 3 - Review Your Tickets | Step 4 - Making Comments on Issues | Q&A
• Navigate to the CDISC JIRA Project
• Click the **CREATE** button

Public Review Commenting Dates

Location of Materials

Supporting Materials – Public Review Webinar/Deep Dive

Instructions for Reviewers

How to provide comments

[Public Review Dashboard](#)

Internal Review Materials

DDF-RA-1.11.0.zip

- Deliverables
- documents
- HowTos
- images
- .gitignore
- CODE_OF_CONDUCT.md
- CONTRIBUTING.md
- LICENSE
- README.md

API

CT

IG

UML

USDM_API.json

USDM_API.yaml

USDM_CT.xlsx

USDM_CT_Changes.xlsx

examples

readme.txt

USDM IG.pdf

UML_DELTA_1-0_1-9.csv

UML_DELTA_1-9_1-11.csv

USDM_UML.eapx

USDM_UML.png

USDM_UML.xmi

USDM Examples

cycles_1.json

cycles_1.png

cycles_1.xlsx

profile_1.json

profile_1.png

profile_1.xlsx

Roche Phase 3 NCT04320615.json

Roche Phase 3 NCT04320615.png

Roche Phase 3 NCT04320615.xlsx

simple_1.json

simple_1.png

simple_1.xlsx

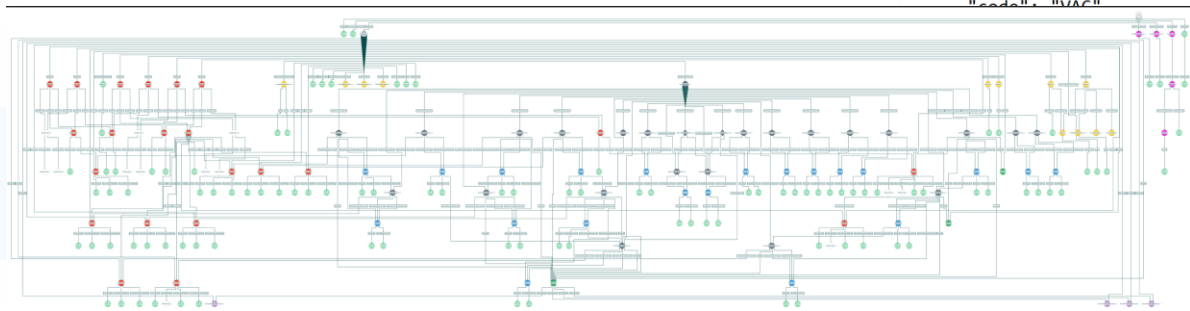
simple_2.json

simple_2.png

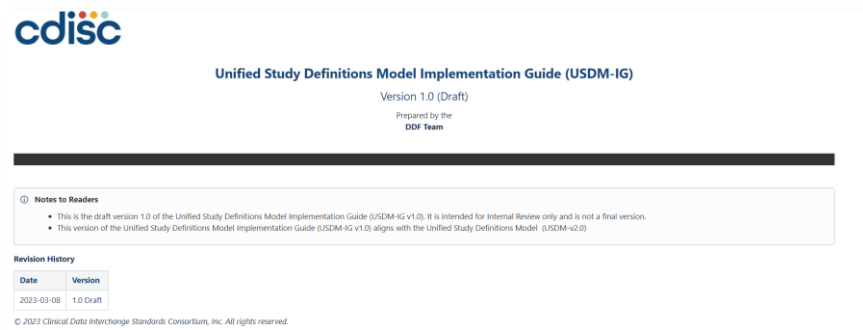
simple_2.xlsx

studyTitle	Cycles Test 1				
studyVersion	1				
studyType	Interventional Study				
studyPhase	C15602				
studyAcronym	CYCLES 1				
studyRationale	A cycles test				
businessTherapeuticAreas	SPONSOR: VAC=Vacines Group				
briefTitle	officialTitle	publicTitle	scientificTitle	protocolVersion	pr
Something Brief	Something Very Official	Something Public	Somehign Clever	1	
Something Brief	Something Very Official	Something Public	Somehign Clever But New	1	

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    "standardCode": {
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      "code": "C15602",
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      "codeSystemVersion": "2022-12-16",
      "decode": "Phase III Trial"
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  },
  "businessTherapeuticAreas": [
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      "code": "VAC"
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    {
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      "code": "VAC"
    },
    {
      "codeId": "Code_5",
      "code": "VAC"
    },
    {
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    },
    {
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      "code": "VAC"
    },
    {
      "codeId": "Code_20",
      "code": "VAC"
    }
  ]
}
```



USDM IG – WIKI Version



The screenshot shows the top portion of a web page for the 'Unified Study Definitions Model Implementation Guide (USDM-IG)'. It features the CDISC logo in the top left. The main title is 'Unified Study Definitions Model Implementation Guide (USDM-IG)', followed by 'Version 1.0 (Draft)' and 'Prepared by the DDF Team'. Below this is a 'Notes to Readers' section with two bullet points: 'This is the draft version 1.0 of the Unified Study Definitions Model Implementation Guide (USDM-IG v1.0). It is intended for Internal Review only and is not a final version.' and 'This version of the Unified Study Definitions Model Implementation Guide (USDM-IG v1.0) aligns with the Unified Study Definitions Model (USDM-v2.0)'. A 'Revision History' table is also visible, showing a single entry for '2023-03-08' and '1.0 Draft'. At the bottom of the screenshot, there is a copyright notice: '© 2023 Clinical Data Interchange Standards Consortium, Inc. All rights reserved.'

<https://wiki.cdisc.org/display/USDMIGv1/USDM+Implementation+Guide+%28USDM-IG%29+v1.0>

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6 USDM API

7 EXAMPLES

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- Appendix B: Glossary and Abbreviations
- Appendix C: Revision History
- Appendix D: Representations and Warranties, Limitations of Liability, and Disclaimers

Next Steps

- **Tuesday 18th April 2023**
 - Public Review Commenting Starts
- **Thursday 20th April 2023**
 - DDF Public Review webinar
- **Thursday 18th May 2023**
 - Public Review Commenting Ends
- **Friday 30th June 2023**
 - Anticipated Release Date



2023

EUROPE
INTERCHANGE
COPENHAGEN



Session 7: Track B- Digital Data Flow

14:00 - 16:00
Stijn Rogiers, argenX
Ballonsalen + Blomstersalen

27 April 2023

14:00 - 14:30

CDISCs Activities on DDF, Benefits for the Community and Looking Ahead

Dave Ibersen-Hurst, CDISC

14:30 - 14:50

Protocol Optimization with DDF

Siddarth Shah, ZS Associates

14:50 - 15:10

Using DDF to Drive Clinical Data Automation

Suman Kumar, Deloitte

15:10 - 15:30

Automating the Digital Data Flow with a Standards Foundation

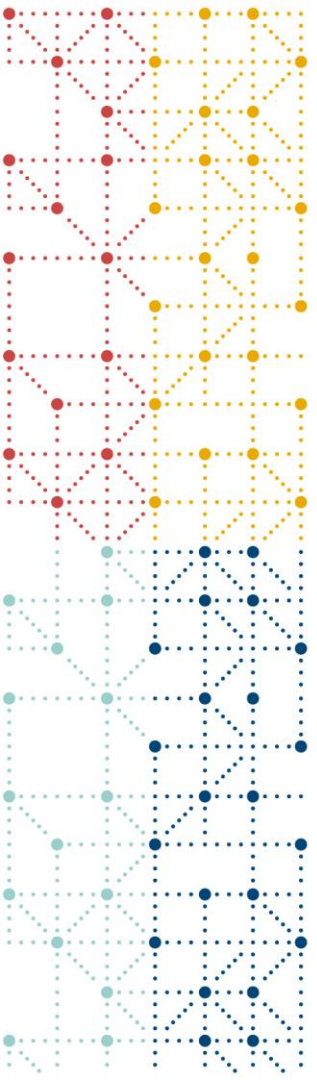
Jason Konn, eClinical Solutions

15:30 - 16:00

Panel Discussion

- Dave Ibersen-Hurst, CDISC
- Siddarth Shah, ZS
- Suman Kumar, Deloitte
- Jason Konn, eClinical Solutions





Thank You

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