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
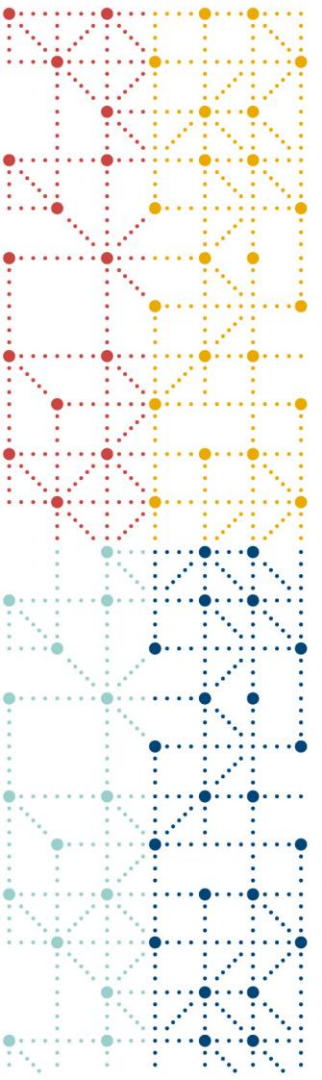
Berber Snoeijer, Janssen Pharmaceuticals

19th April 2023

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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

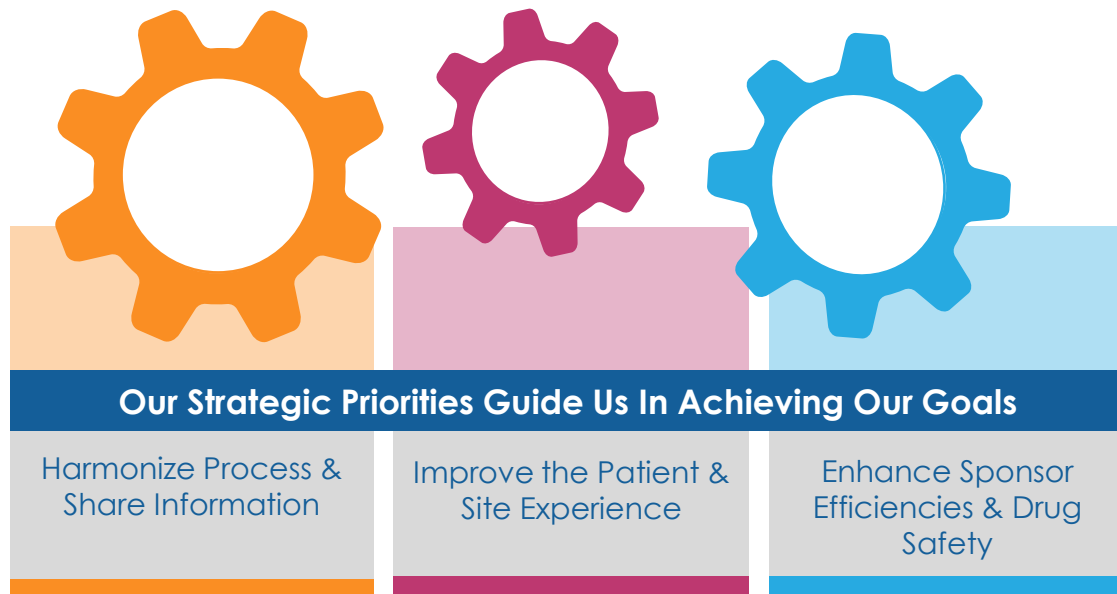Berber Snoeijer

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.
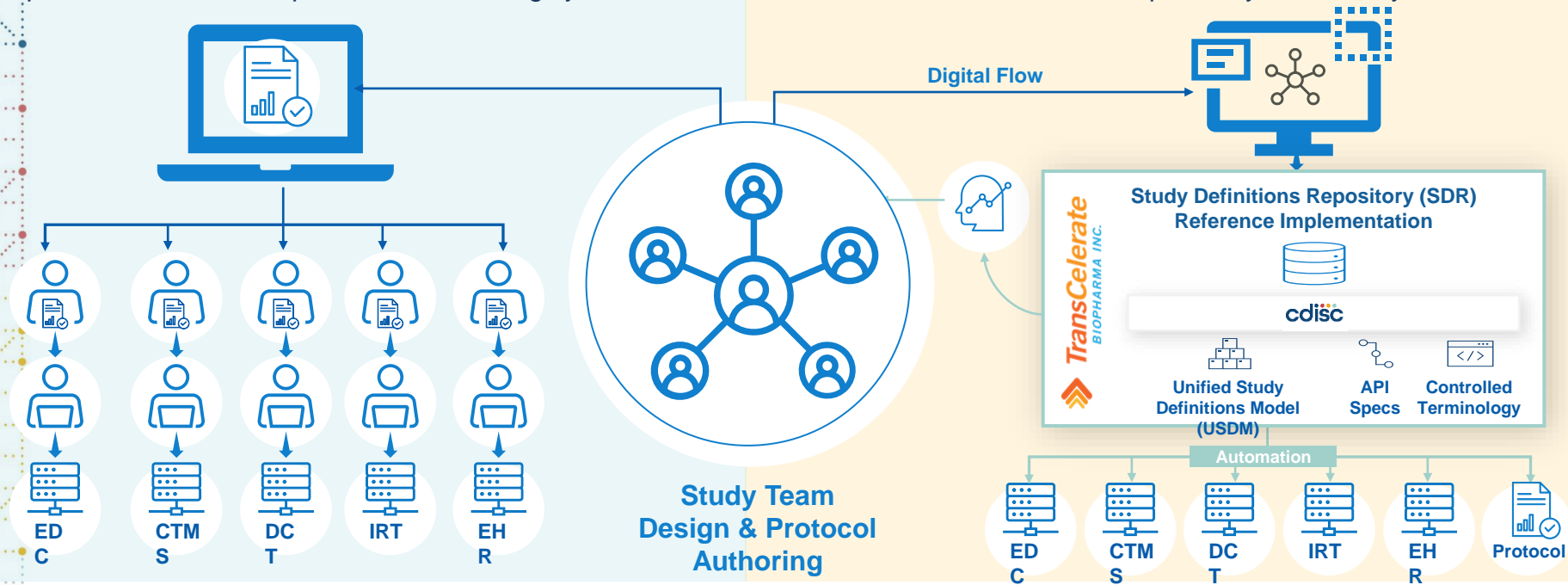

Our Strategic Priorities Guide Us In Achieving Our Goals

Harmonize Process & Share Information	Improve the Patient & Site Experience	Enhance Sponsor Efficiencies & Drug Safety

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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

Digital Flow

EDC
CTMS
DCT
IRT
EHR

Study Team
Design & Protocol
Authoring

Study Definitions Repository (SDR)
Reference Implementation

TransCelerate
BIOPHARMA INC.

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Unified Study
Definitions Model
(USDM)

API
Specs

Controlled
Terminology

Automation

EDC
CTMS
DCT
IRT
EHR
Protocol

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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.

TransCelerate
BIOPHARMA INC.

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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

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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	April-May	June/July
DRAFT V2.0 of CDISC USDM (Data Model) **+** **Release 2.0.0 of the SDR incorporating the <u>draft</u> standards**	**CDISC USDM Public Review Period**	**FINAL V2.0 of CDISC USDM (Data Model)** **+** **Release 2.0.1 of the SDR incorporating the <u>final</u> standards**

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MVP vs. Release 2 Comparison
Richer data model supporting more complex designs, *SoA and automated CRF selection*

	CDISC Data Model	**Study Definitions Repository (SDR)**	**Connectivity with Other Initiatives**
MVP	• 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.*	• 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	• n/a
Latest Release	• 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

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How to Get Started with DDF?

Scan QR Code for Open-Source Code

GitHub

Explore CDISC DDF Standards
https://www.cdisc.org/ddf

CONTACT US!

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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

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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 BIOPHARMA INC. Digital Data Flow Project

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

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

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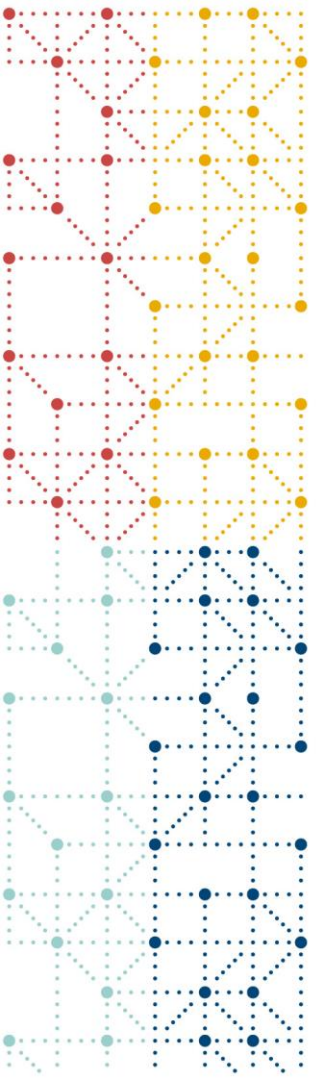
Project Introduction and Status

John Owen

Timelines – Phase 1

2021	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DDF								Stage 0		Stage 1/2		
										3a	3a	

W1 (Oct)

2022	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DDF	Stage 1/2			Stage 3b			3C					
	3a	3a										

W2 (Apr)
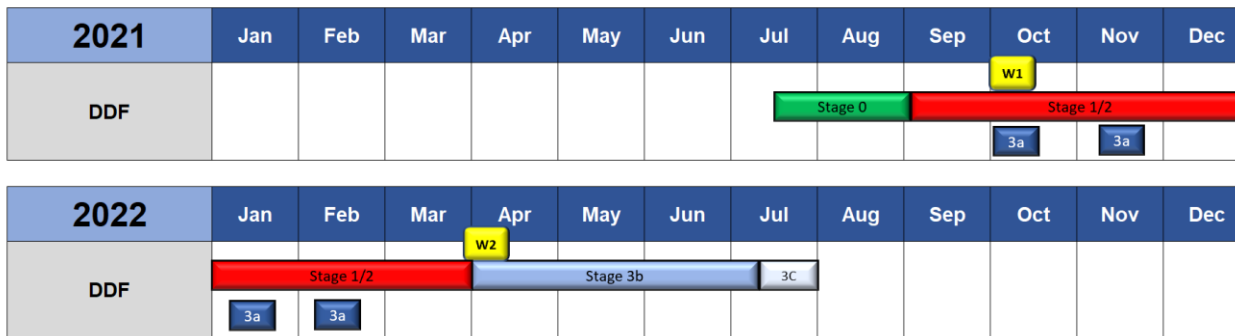
Stage 0	Scoping and Planning
Stage 1/2	Identification/Modeling of Concepts Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review

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New to CDISC   Standards   Education   Resources   Events   Membership   Members Only

Home / Digital Data Flow

Digital Data Flow

Overview   Participate   Webinar   Release Information   Files   FAQ   Contact Us

USDM RA v1.0 (Provisional)
Digital Data Flow v1.0 Public Review Comments

https://www.cdisc.org/ddf

Timelines – Phase 2

Year 1	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11
Month (2022)	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun

DDF2

W1 - Scoping Results Public Webinar
W2 - Public Review Webinar

W1

W2

Discovery and Preparation Involvement

Scoping and Planning Sprint

Modeling and Development Sprints

Internal Review Fix Sprints

CDISC Internal

Public Review Period

Public Review Fix Sprints

Finalization and publication activities

"Code" Complete

"Code" Freeze

https://www.cdisc.org/ddf

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

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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

CONTENTS

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
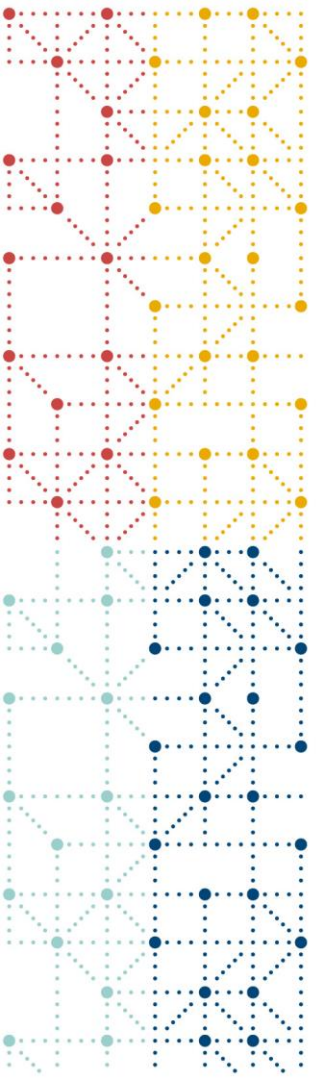
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Overview of the USDM Model v2.0

Dave Iberson-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/uXjVPl5X2AY=/
Password: CDISC-DDF-SME

Public Review Information

John Owen

Public Review Information

https://www.cdisc.org/

Public Review Information

https://www.cdisc.org/

Public Review Information

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:

- 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 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.

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Public Review Dashboard

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
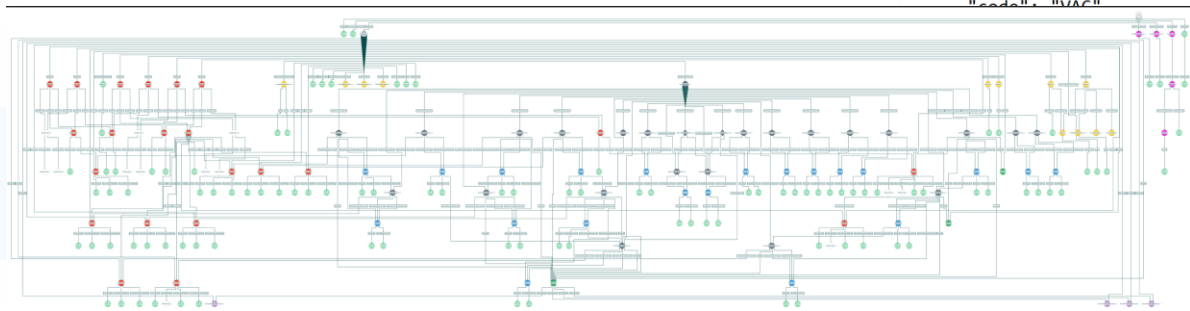- simple_1.json
- simple_1.png
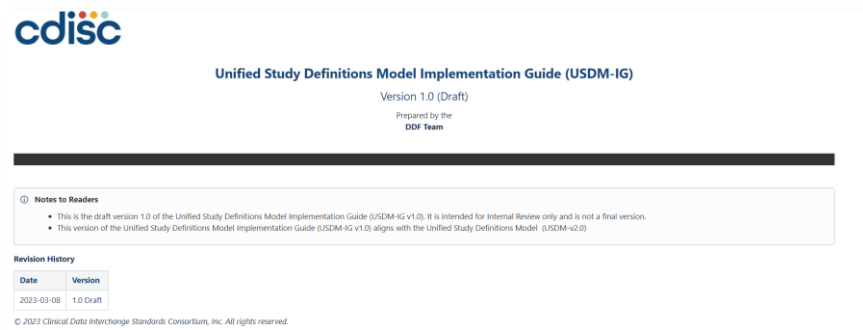- simple_1.xlsx
- simple_2.json
- simple_2.png
- simple_2.xlsx

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	pro
Something Brief	Something Very Official	Something Public	Somethign Clever	1	
Something Brief	Something Very Official	Something Public	Somethign Clever But New	1	

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    "decode": "Interventional Study"
  },
  "studyPhase": {
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    "standardCode": {
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      "code": "C15602",
      "codeSystem": "http://www.cdisc.org",
      "codeSystemVersion": "2022-12-16",
      "decode": "Phase III Trial"
    },
    "standardCodeAliases": []
  },
  "businessTherapeuticAreas": [
    {
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      "code": "VAC",
      ...12",
      ...up"
```

USDM IG – WIKI Version

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

CONTENTS

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

Year 1	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11
Month (2022)	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun

DDF2
W1 - Scoping Results Public Webinar
W2 - Public Review Webinar

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2023 EUROPEAN INTERCHANGE — COPENHAGEN

27 April 2023

Session 7: Track B- Digital Data Flow
14:00 - 16:00
Stijn Rogiers, argenX
Ballonsalen + Blomstersalen

14:00 - 14:30

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

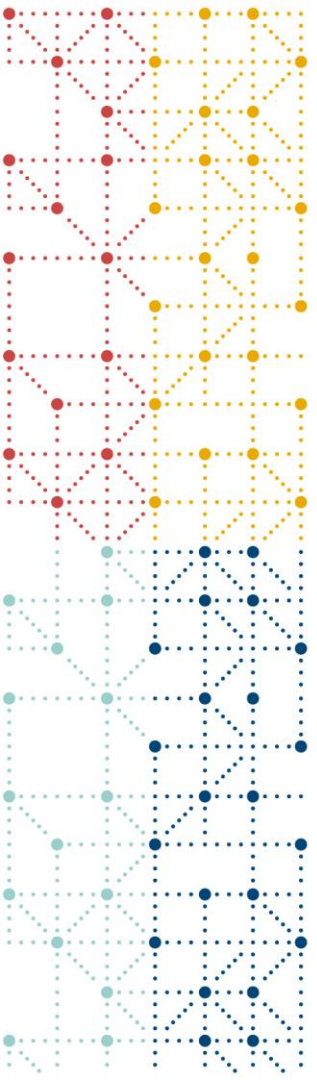**Automating the Digital Data Flow with a Standards Foundation**
Jason Konn, eClinical Solutions

15:30 - 16:00

Panel Discussion

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

Thank You

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