

Pre-Workshop Webinar for Digital Data Flow (DDF): Mastering USDM

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PHUSE EU Connect,
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USDM is a foundational aspect of TransCelerate's Digital Data Flow Initiative which aims to break the document paradigm

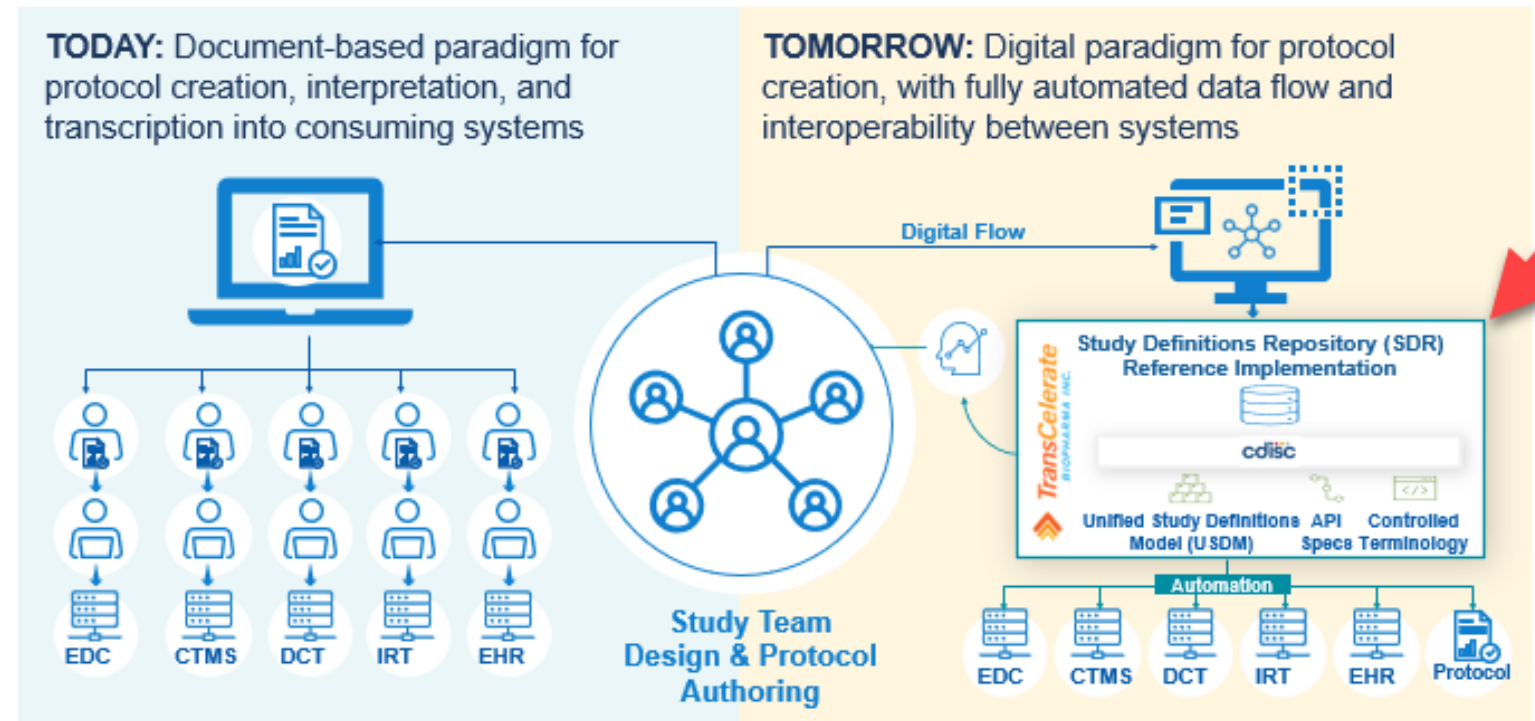
Documents to Data / Write Once, Read Many

Digital - standard representation of study protocol

- ✓ structured
- ✓ machine readable
- ✓ executable

Data Flow – industry-wide interoperability

- ✓ exchange of data
- ✓ non-cooperating organizations
- ✓ minimal effort



Eliminate non-value added activities, work smarter not harder
Enable automation of downstream study startup and conduct processes
Create foundation for study design analytics insights

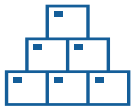
The DDF Initiative consists of two main technical solutions

The standards component of the DDF solution is provided by the USDM

DDF Technical Solutions



Unified Study Definitions Model (USDM) v2.0 – developed with CDISC; this is an industry standard for specifying and structuring study definitions (design & protocol information) in a digital, machine-readable format promulgated and maintained by CDISC.



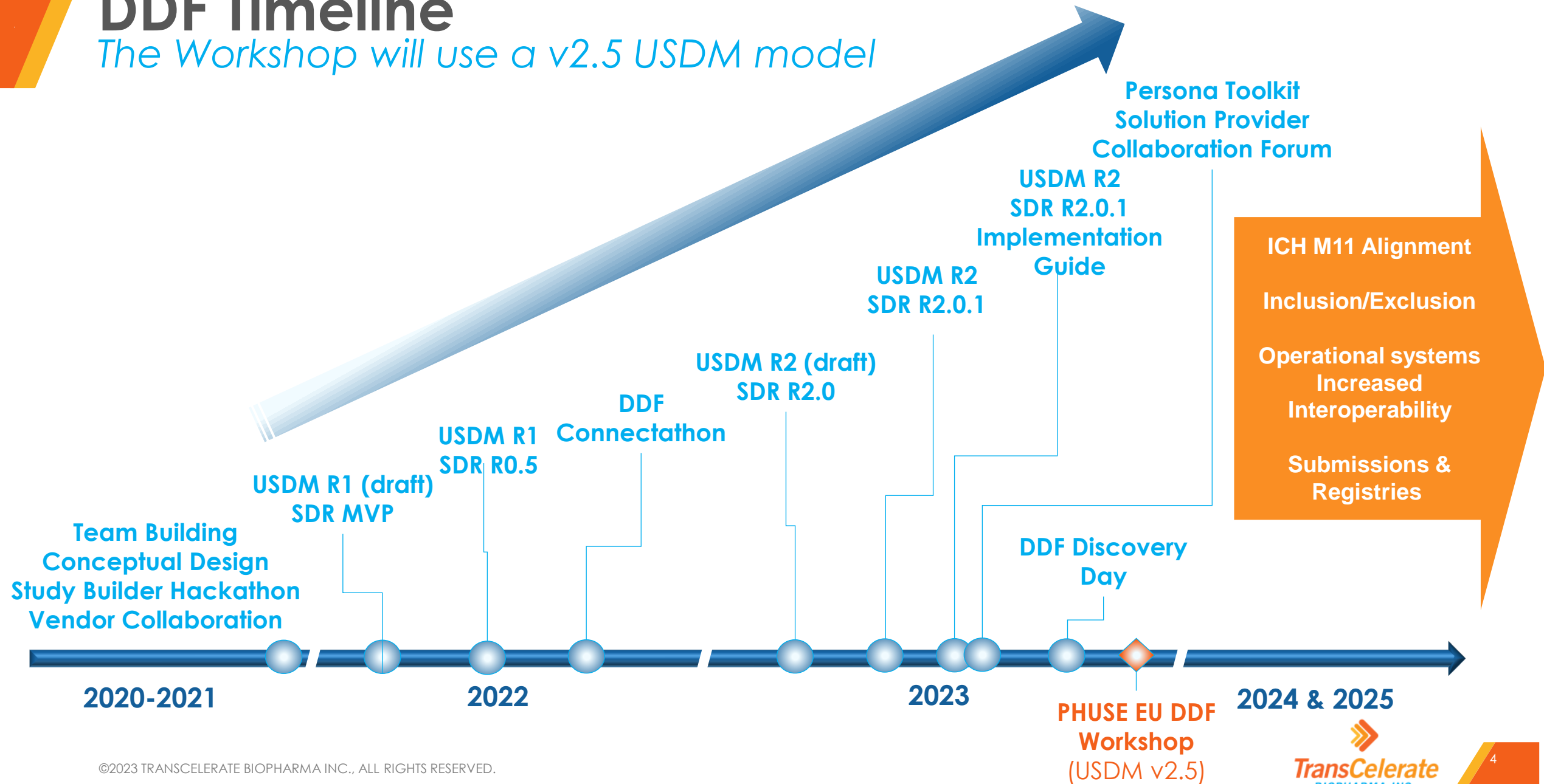
Study Definitions Repository (SDR) v2.0.1 – Type of repository that is conformant with USDM and acts as a functioning, example approach to store protocol information and connect other producing and consuming systems to achieve interoperability. Source code is available under an open-source license.

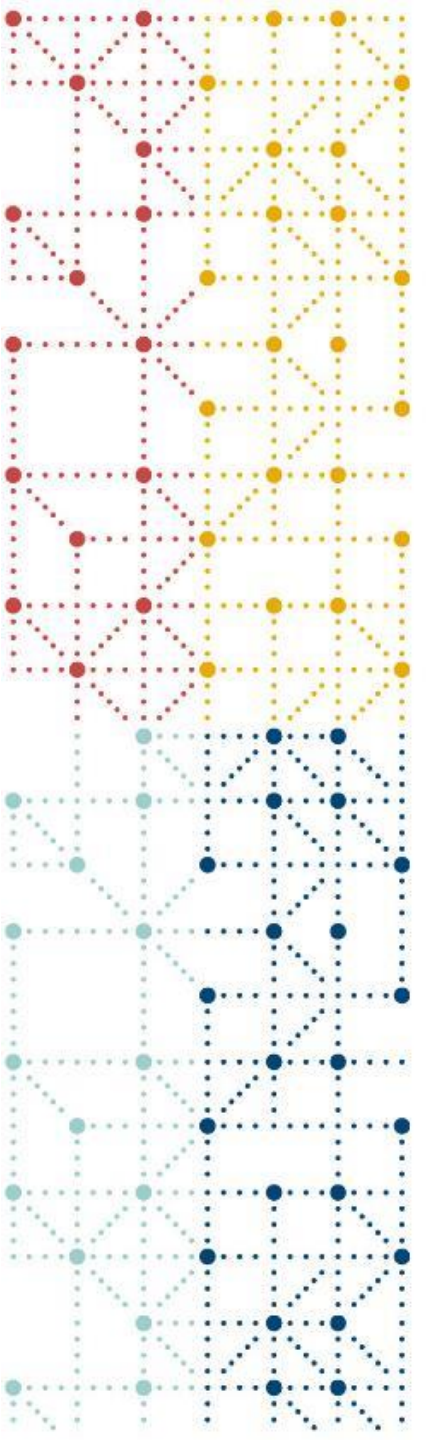


<https://transcelerate.github.io/ddf-home/>

DDF Timeline

The Workshop will use a v2.5 USDM model



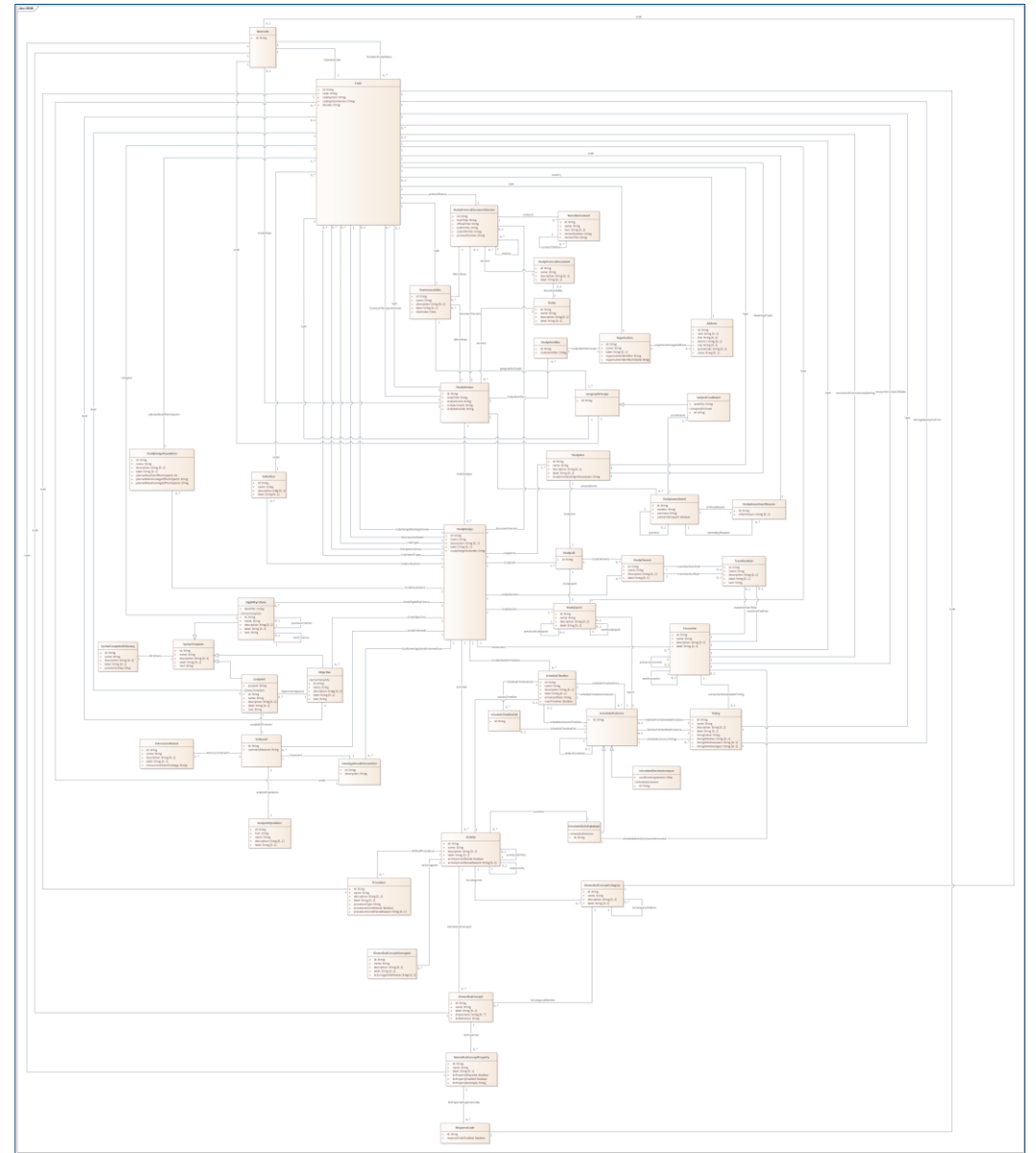


Agenda

1. Purpose
2. Focus Areas
3. Pre-reads
4. Tools
5. Protocol

Purpose

- Provide an understanding of the USDM model
- To do this we will use a MS Excel tool to “make it real”
- Not the purpose of this workshop to give you all the detail on using the MS Excel tool



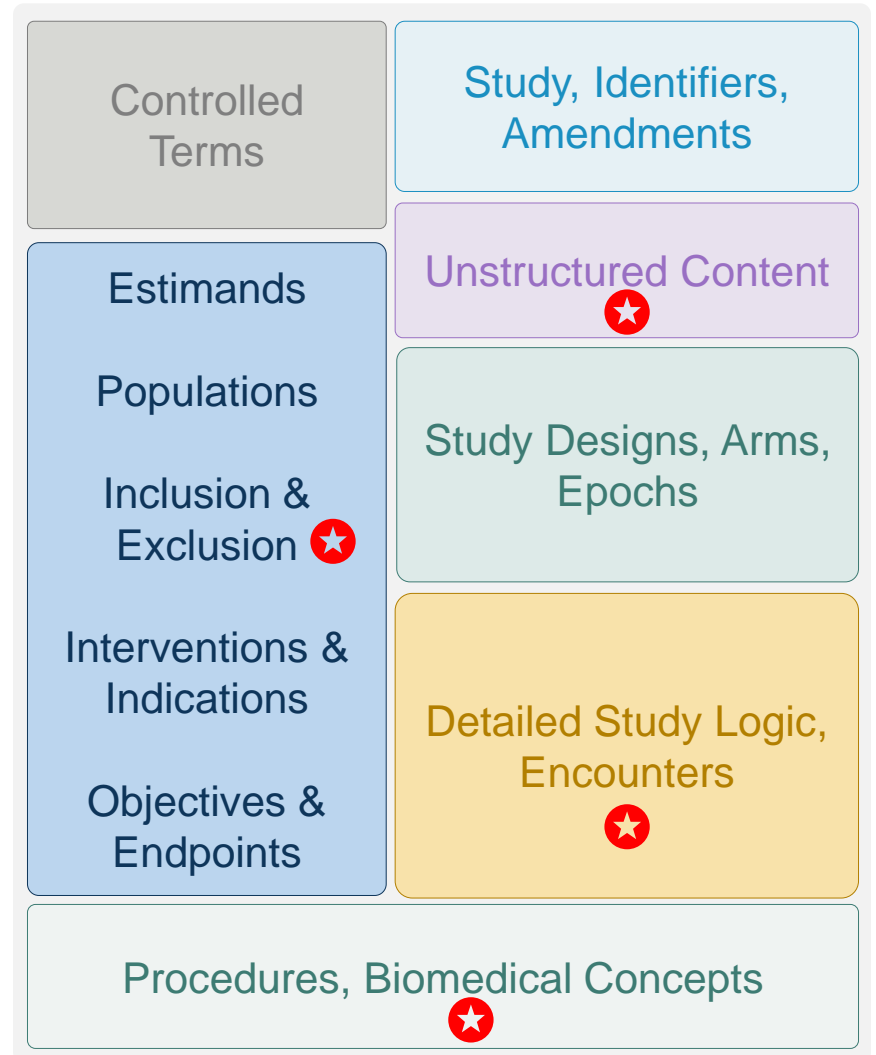
Focus Areas

Cannot cover every aspect in detail in an hour and a half. We will provide an overview and focus on some of the interesting aspects of the model

- Overview of model
- Inclusion / Exclusion Criteria
- SoA & Timelines
- Biomedical Concepts
- Footnotes
- Unstructured text & the ICH M11 document template
- Hands-on exercises & discussion

We will try and give you the most up-to-date information. We will be looking at release 2.5 of the USDM.

Remember this is “work in progress”.



Prereads

Materials to look at prior to the workshop if you wish to. **NOT** compulsory!

Item	Link	Notes
Model (UML)	https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/UML/USDM_UML.png	Release 2.5
Controlled Terminology (XLSX)	https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/CT/USDM_CT.xlsx	Release 2.5
Implementation Guide (PDF)	https://github.com/cdisc-org/DDF-RA/blob/main/Deliverables/IG/USDM-IG.pdf	Work in progress
Informative Diagram (PNG)	https://github.com/cdisc-org/DDF-RA/blob/main/Documents/DDF%20USDM%20Model%20Informative.png	Release 2.5
Miro Board (Web)	https://miro.com/app/board/uXjVPI5X2AY=/	P: CDISC-DDF-SME Currently as per release 2.0 Will be updated in the coming week to release 2.5

Tools For The Workshop

- Laptop!
- Tools on Laptop
 - MS Excel
 - Text editor (e.g. VS Code)
- Web tools
 - USDM Web Tool
 - Web Text/JSON Comparison



Web Tools

No need to install any tools on your laptop other than MS Excel

Item	Link	Notes
Excel To JSON Tool	https://usdm-service.fly.dev/	Currently supports release 2.3. Will be updated to release 2.5 this coming week U: PHUSE P: learning_usdm
Excel to JSON Tool readme	https://github.com/data4knowledge/usdm	Will be updated prior to the workshop (to release 2.5)
Excel to JSON Tool Infographic	https://github.com/data4knowledge/usdm/blob/main/docs/sheets.png	Will be updated prior to the workshop (to release 2.5)
JSON Comparison	https://www.textcompare.org/json/	Useful to see changes in the resulting JSON outputs



Excel to JSON Utility

USDM Excel to JSON Utility STATUS 

Excel File List (i)

A list of files held within the system for which a converted USDM JSON file can be downloaded.

File List.

workshop.xlsx, dated 2023-10-26   

Upload New Excel File

CLICK TO UPLOAD NEW FILE

Delete file

Download error file

Download JSON file

Example Protocol

- We will use the CDISC Pilot Study Protocol for the workshop
- This was donated by Eli Lilly many years ago
- It has served CDISC well
- Download from here
 - https://github.com/cdisc-org/DDF-RA/blob/main/Documents/Examples/CDISC_Pilot/CDISC_Pilot_Study.pdf

The information contained in this clinical study protocol is
Copyright © 2006 Eli Lilly and Company.

Xanomeline (LY246708)

Protocol H2Q-MC-LZZT(c)

**Safety and Efficacy of the Xanomeline
Transdermal Therapeutic System (TTS) in Patients
with Mild to Moderate Alzheimer's Disease**

Next Steps: Summary

Prior to the workshop, be sure to complete the following

- ❑ Download the workshop materials from the dedicated [CDISC Wiki page](#)
- ❑ If you run into issues: arrive early! The workshop team will be available in the room starting at 14:00 to help resolve any issues
- ❑ Team will be available for approx. 1 hour following formal session conclusion to work through any specific examples or questions you want to bring

For More Info: Scan QR Code to explore the DDF GitHub



<https://transcelerate.github.io/ddf-home/>