Digital Data Flow Phase 4 Public Information Webinar

TUE 2 JUL
11:00AM – 12:00PM US ET
Today’s Agenda

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

You will remain on mute
Submit questions at any time via the Questions tool on your Zoom app
Housekeeping

Audio Issues?

First, close and restart your Zoom App
Second, check your local internet connection strength
Webinar Recording

A recording of this webinar and a PDF of the slides will be available in the Public Webinar Archive on the CDISC website.
Digital Data Flow Phase 4 Public Information Webinar

TUE 2 JUL
11:00AM – 12:00PM US ET
Questions & Answers
Will it be possible to use USDM data elements to pre-populate data in TMF document templates?
ICH M11 template, specifications, and guidance are planned to be implemented in November 2025. Is TransCelerate planning to have its CPT aligned with ICH M11, including technical specifications that will allow DDF and integration with PRISM, by November 2025?

DDF and USDM development is aligning directly with M11 technical specifications as they emerge so there is no dependency on the TransCelerate CPT.
For those currently using the TransCelerate CPT, I am wondering if/when that template will have capabilities that allow DDF and integration with PRISM?
Question to Dave: In your planned US workshop you just mentioned, will the protocol data be entered via Excel template (like in Berlin) or via OpenStudyBuilder?

DAVE IH: We will use the Excel but also have some new “toys”. OSB can only export in USD, does not use it internally and also does not store the entire protocol document.
(probably for Dave):
Between the two extremes of 100% document-based and 100% data-based, where would you put ICH M11 as far as you can tell?

DAVE IH: Dangerous question :) Depends on how you measure it obviously, but I would say as a rough guide 30% - 40% area.
Audience Questions
Upcoming Events
# Upcoming Webinars

<table>
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<tr>
<th>Date</th>
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<td>TUE 2 JULY</td>
<td>Digital Data Flow Project Phase 4 Informational Webinar</td>
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<td>TUE 16 JULY</td>
<td>Level Up Your Clinical Data Skills with CDISC Education</td>
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<td>TUE 17 SEP</td>
<td>TMF Reference Model General Meeting – Q3</td>
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<td>TUE 24 SEP</td>
<td>CDISC Open Source Alliance Quarterly Spotlight – Q3</td>
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### CDISC Education Training Courses

- Information available at: [www.cdisc.org](http://www.cdisc.org)
- Register at: [https://learnstore.cdisc.org/](https://learnstore.cdisc.org/)
- Contact us at: [training@cdisc.org](mailto:training@cdisc.org)

#### Course Listings

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<th>Location</th>
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<td>Shanghai</td>
<td>Shanghai, China</td>
<td>28-29 August 2024</td>
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<tr>
<td>Scottsdale</td>
<td>Scottsdale, Arizona</td>
<td>21-25 October 2024</td>
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<tr>
<td>Seoul</td>
<td>Seoul</td>
<td>11-15 November 2023</td>
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<td>Virtual Event</td>
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#### Other Options

- CDISC Newcomers Virtual
- TMF Virtual / On-Demand
- CT Virtual / On-Demand
- SEND Virtual / On-Demand
- CDASH Virtual / On-Demand
- SDTM Virtual / On-Demand
- ADaM Virtual / On-Demand
- ODM Virtual / On-Demand
- Define-XML Virtual / On-Demand
- Tobacco Implementation Guide (TIG) On-Demand
- "Coming Soon" LHEA On-Demand

#### Additional Resources

- TAUGs & Free Trainings
- CDISC Certifications
- Miscellaneous / Other

**Contact Information**

- [www.cdisc.org](http://www.cdisc.org)
- [https://learnstore.cdisc.org/](https://learnstore.cdisc.org/)
- [training@cdisc.org](mailto:training@cdisc.org)
Free CDISC Courses

Courses tagged with "Free"

SDTM Module 1: Introduction

The CDISC standards, process, participants and an Introduction to the Study Data Tabulation Model and its documentation set.

Module-Level Learning Outcomes:
- explain the purpose of the CDISC Standards and SDTM
- locate and access the documentation for the current versions of SDTM-related documents

Language: English | Duration: 00:36:34 | CEUs: 0.1

TAUG Module 1: Overview of Therapeutic Area User Guides

Therapeutic Area User Guide, Module 1 provides an overview of the structure of Therapeutic Area User Guides. It describes concept maps and metadata, shows the relationship between foundational concepts and TAUGs, and also discusses how to review draft TA User Guides.

Module-Level Learning Outcomes:
- describe the CFAST organization, stakeholders, and high level TA standards development process
- describe deliverables for each development process stage
- discuss the development of concept models/maps and how they are used
- use the concept metadata structures
- explain the Therapeutic Area User Guides (TAU User Guides) and where the concepts fit into the existing CDISC models
- apply best practices for reviewing and contributing feedback on TA User Guides during public review periods

Language: English | Duration: 02:10:14 | CEUs: 0.2

Http://learnstore.cdisc.org
Upcoming 2024 Interchanges

- **2024 CDISC + TMF Europe Interchange**
  - **Location:** Berlin, Germany
  - **Main Conference:** 24-25 April 2024

- **2024 Japan Interchange**
  - **Location:** Tokyo, Japan
  - **Main Conference:** 12-13 June 2024

- **2024 China Interchange**
  - **Location:** Shanghai, China
  - **Main Conference:** 30-31 August

- **2024 CDISC + TMF US Interchange**
  - **Location:** Scottsdale, Arizona
  - **Main Conference:** 23-24 October

- **2024 Korea Interchange**
  - **Location:** Seoul, South Korea
  - **Main Conference:** 12-13 November

Visit [https://www.cdisc.org/events](https://www.cdisc.org/events) for more information!
## Sponsor a 2024 Interchange!

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<th>RUBY (3 AVAILABLE)</th>
<th>DIAMOND (2 AVAILABLE)</th>
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### 2023 Interchange Attendee Snapshot

- **Pharmaceutical**: 24.0%
- **CRO**: 21.0%
- **Technology Service Provider**: 11.0%
- **Biotech**: 15.0%
- **Academia**: 4.0%
- **Consulting**: 6.0%
- **Healthcare**: 8.0%
- **Other**: 11.0%
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
CDISC MEMBERSHIP

Become a Member!
Join nearly 500 member organizations that contribute to bringing clarity to data.

Already a Member?
Thank you! It is our members’ support which enables us to develop standards, keeping it free and accessible to all.

Email: membership@cdisc.org
Thank you!

Contact the Events inbox: events@cdisc.org

Contact Education inbox: training@cdisc.org

Contact Bernard directly: bklinke@cdisc.org