CDISC Italian User Network TC

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29.06.2022

Agenda

1. CDISC and Data Submission What's New
2. CDISC 2022 EU Interchange Highlights
3. Other Topics and Q&A

https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home

CDISC e Data Submission What's New

Upcoming Webinars, Trainings, New Standards and Working Progress

Upcoming Webinars
https://www.cdisc.org/events/webinars/upcoming

COSA Spotlight Q2 2022

30 June 2022, 11am - 12:30pm EDT

REGISTER NOW!

Join open-source developers from the CDISC community as they showcase their free tools as part of the **CDISC Open Source Alliance (COSA)**. Learn how you can leverage these tools to facilitate the implementation of CDISC standards in your systems.

- **Admiral** – An open source, modularized toolbox that enables the pharmaceutical programming community to collaboratively develop ADaM datasets in R.
- **R4DSXML** – R package for import CDISC Dataset-XML and Define-XML as R data frame.

Plus, we'll share a sneak peak of what's coming to COSA in the third quarter.

We'll also introduce Dataset-JSON and provide details about an upcoming Dataset-JSON Hackathon. A data exchange standard for tabular datasets that uses the JSON format, Dataset-JSON is part of the ODM v2.0 draft standard and an enhancement to the Dataset-XML v1.0 specification. Dataset-JSON is designed to meet the requirements of the regulatory submission use case as well as other data exchange scenarios.

Developing Standards for Cell and Gene Therapy Product Monitoring

7 July 2022, 11am - 12pm

REGISTER NOW!

Join CDISC and **Embleema** as we share our plans to develop new standards for experimental assays and bioinformatics protocols to facilitate monitoring the activity of Cell and Gene Therapy Products (CGTP). Initial projects will focus on the following three areas:

- Protocols for experimental assays and bioinformatics pipelines for evidence generation and submission to the regulation bodies
- Provenance and privacy with relation to the patient CGTP datasets
- Longitudinal data linkage and patient engagement

The new standards are intended to create opportunities to accelerate drug development and regulatory approvals in personalized medicine and bring associated costs down.

Upcoming Webinars
https://www.cdisc.org/events/webinars/upcoming

QRS Office Hours

8 September 2022, 11am - 12:30pm EDT

REGISTER NOW!

Join us for QRS Office Hours, an open forum to ask our QRS Team questions about the development and implementation of **QRS Supplements and Terminology**. Examples include:

- Please explain the organization of the Controlled Terminology and Questionnaires, Ratings, and Scales pages on the CDISC website?
- What are the rules for determining if a supplement should be in the Disease Response and Clin Classification (RS) domain?
- What are our QRS naming rules for terminology?
- How do we determine FACT/FACIT synonyms and terminology?
- What is the status of representing logically skipped items in QRS?

Genomics Findings Office Hours

15 September 2022, 11am - 12:30pm EDT

REGISTER NOW!

Ask panelists your questions about the SDTM Genomics Findings (GF) Domain, which is a new domain from the latest release of SDTMIG, **version 3.4** . GF contains data related to the structure, function, evolution, mapping, and editing of subject and non-host organism genomic material of interest.

This webinar is a follow up to the recent **Introduction to the SDTM Genomics Findings (GF) Domain** (CDISC Members Only access). The panelists will respond to the questions they weren't able to and answer new questions as well.

There is a space on the webinar registration page to submit your questions in advance so that our panelists can prepare responses. Panelists will also receive questions during the webinar.

(Past) Webinars – Office Hours Serie
https://www.cdisc.org/events/webinars/public

ADaM June 22nd,2022
https://www.cdisc.org/events/webinar/adam-office-hours

CDASH May 25th,2022
https://www.cdisc.org/events/webinar/cdash-office-hours-1

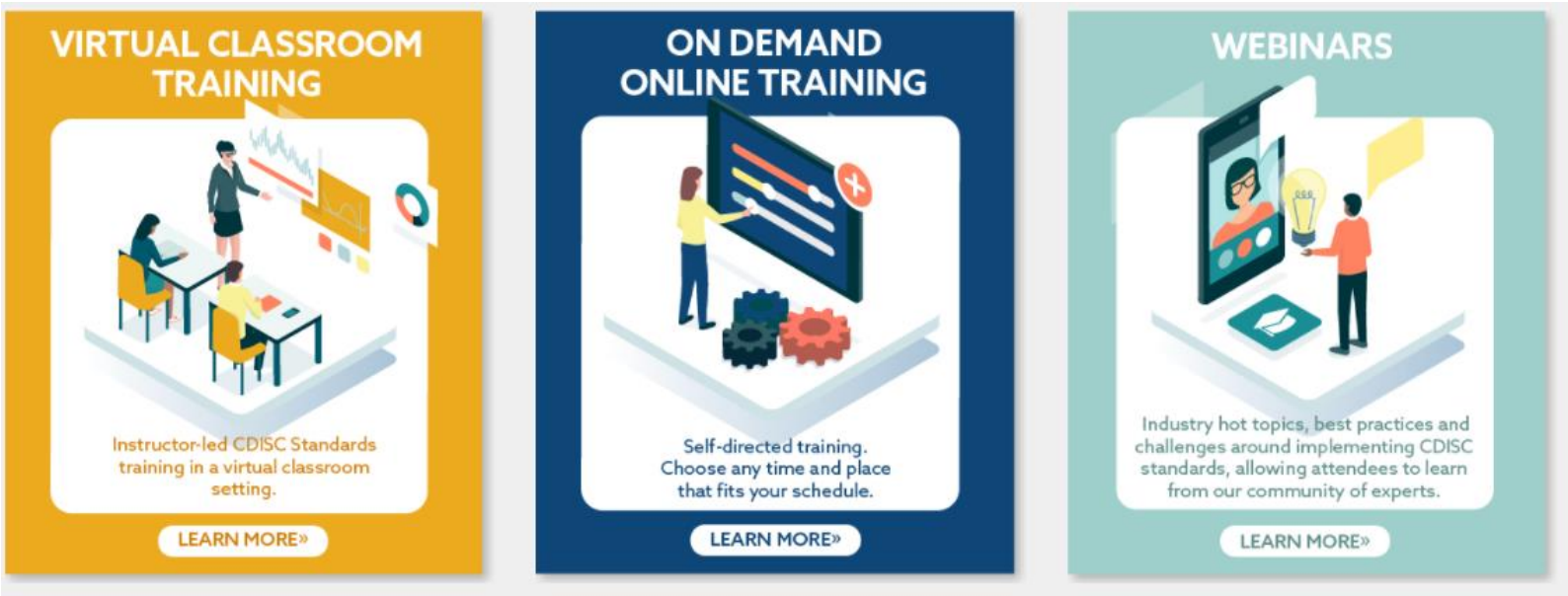
SDTM March 29th,2022
https://www.cdisc.org/events/webinar/sdtm-office-hours

define.xml February 17th,2022
https://www.cdisc.org/events/webinar/define-xml-office-hours

CDASH + eCRF Portals July 6th ,2021
https://www.cdisc.org/events/webinar/cdash-office-hours-ecrf-portal-update

Public Trainings

https://www.cdisc.org/education/public-training



- **UpcomingTraining**: https://learnstore.cdisc.org/Course/featuredCourse

CDISC Update

- Pubblicazioni Recenti:

ADaM Examples of Traceability – May 12, 2022

https://www.cdisc.org/standards/foundational/adam/adam-examples-traceability

The purpose of this document is to provide examples of traceability using **ADaM**. Please refer to **ADaM v2.1**, **ADaMIG v1.2** and the **ADaM OCCDS v1.0** for required background about ADaM and ADaM data structures.

The ADaMIG states: To assist review, ADaM datasets and metadata must clearly communicate how the ADaM datasets were created. The verification of derivations in an ADaM dataset requires having at hand the input data used to create the ADaM dataset. A CDISC-conformant submission includes both **SDTM** and ADaM datasets; therefore, it follows that the relationship between SDTM and ADaM must be clear. This requirement highlights the importance of traceability between the analyzed data (ADaM) and its input data (SDTM).

Traceability is built by clearly establishing the path between an element and its immediate predecessor. The full path is traced by going from one element to its predecessors, then on to their predecessors, and so on, back to the SDTM datasets, and ultimately to the data collection instrument.

CDISC Update

- Prossime pubblicazioni:

https://www.cdisc.org/standards/in-development

Standard	Release Notes	Projected Publication
√ ADaM Examples of Traceability	Preparing for Publication.	Q1 2022
→ ADaM Oncology Examples	In Development.	2022
ADaM popPK Implementation Guide v1.0	In Development.	Q4 2022
Conformance Rules for SDTMIG-Medical Devices v1.1	In Development.	Q4 2022
ODM v2.0	In Development.	2022

CDISC Update

Therapeutic Area

Therapeutic Area ▲	Release Notes	Projected Publication
COVID-19 Therapeutic Area User Guide v2.0	In Development.	2023
Pediatrics User Guide v1.0	Public Review runs through 25 July.	Q4 2022
Rare Diseases Therapeutic Area User Guide	In Development.	Q4 2022
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	Preparing for Public Review.	Q4 2022

Pinnacle21 Version 4.x
https://www.pinnacle21.com/downloads

Support for define.xml 2.1

Mandatory for FDA submission for studies started after March 15, 2023

Type vs Source

Type	Definition	Source (*)			
		Subject	Investigator	Vendor	Sponsor
Collected	Data that were actually observed or recorded by a person or received from an instrument.	ePro	CRF	Lab data, ECG	X
Derived	Data that is not directly collected, but is calculated by an algorithm or reproducible rule, which is dependent upon other data values.	X	X	Lab data, ECG	SDTM ADaM
Assigned	Data that is determined by individual judgment as provided by an evaluator other than the subject or investigator.	X	X	X	SDTM ADaM
Protocol	Data that is defined as part of the trial design preparation.	X	X	X	SDTM
Predecessor	Data that is copied from a variable in another dataset.	X	X	X	SDTM ADaM

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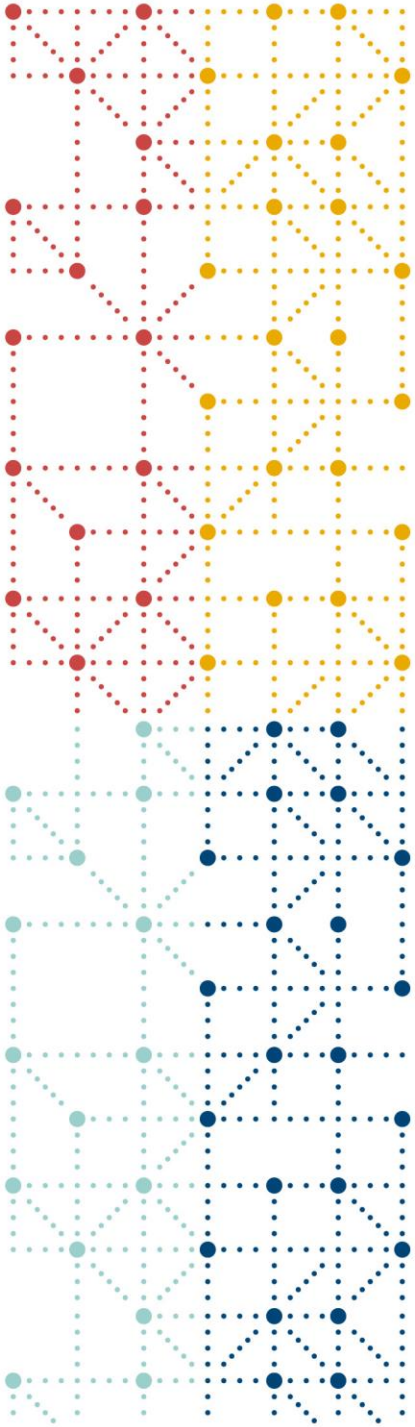
From "The Present and Future of Define-XML", Lex Jansen, PhilaSUG 2018



CDISC 2022 EU Interchange Highlights

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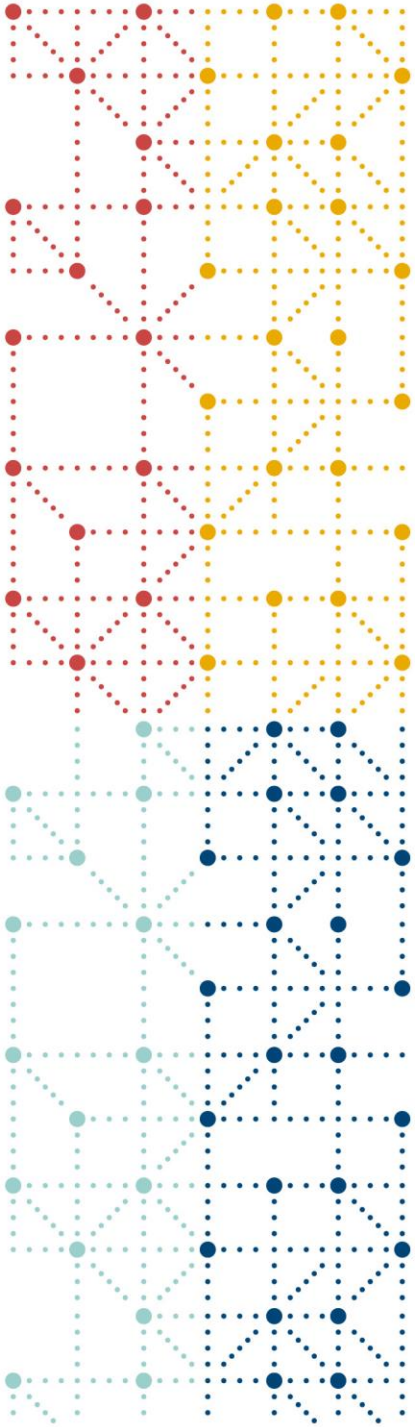
- CDISC 2022 EU Interchange Highlights – Mauro Cortellini (Chiesi Farmaceutici):
  - CDISC Open Source Alliance (COSA) - An Introduction - Katja Glaß, Katja Glaß Consulting
  - Update on DARWIN EU®, Andrej Segec, EMA

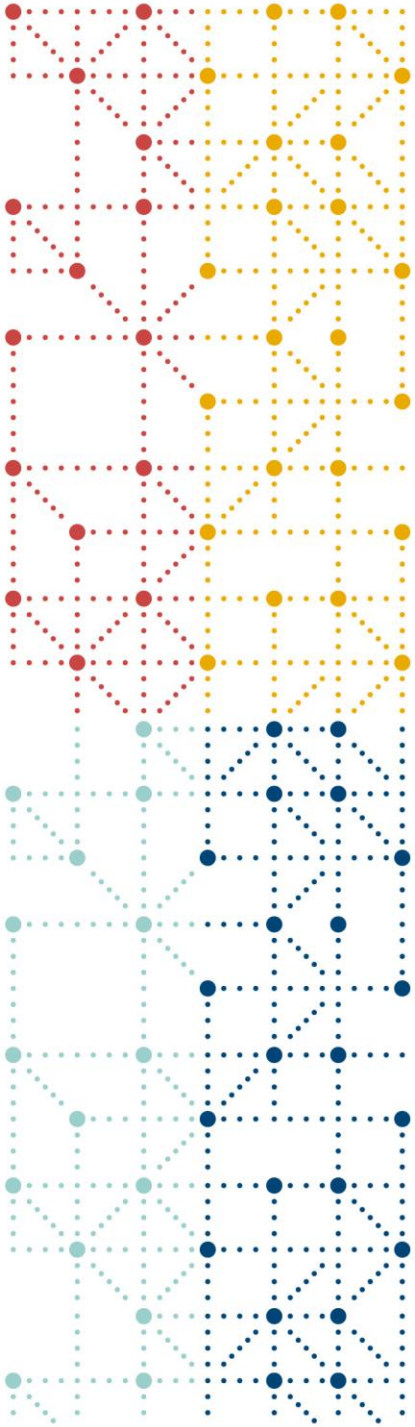
- CORE Demonstration, Nick De Donder (recorded session)

https://cdisceurope2022.pathable.co/meetings/virtual/LKPMoMWZnaH49mCQv (minute 39:53....27 minutes)

https://www.cdisc.org/events/webinar/**core-volunteer-onboarding-training-webinar**



Other Topics and Q&A



Thank You!

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