

CDISC Italian User Network TC

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



Presented by Angelo Tinazzi (Cytel) Silvia Faini (Cytel)

22.02.2023

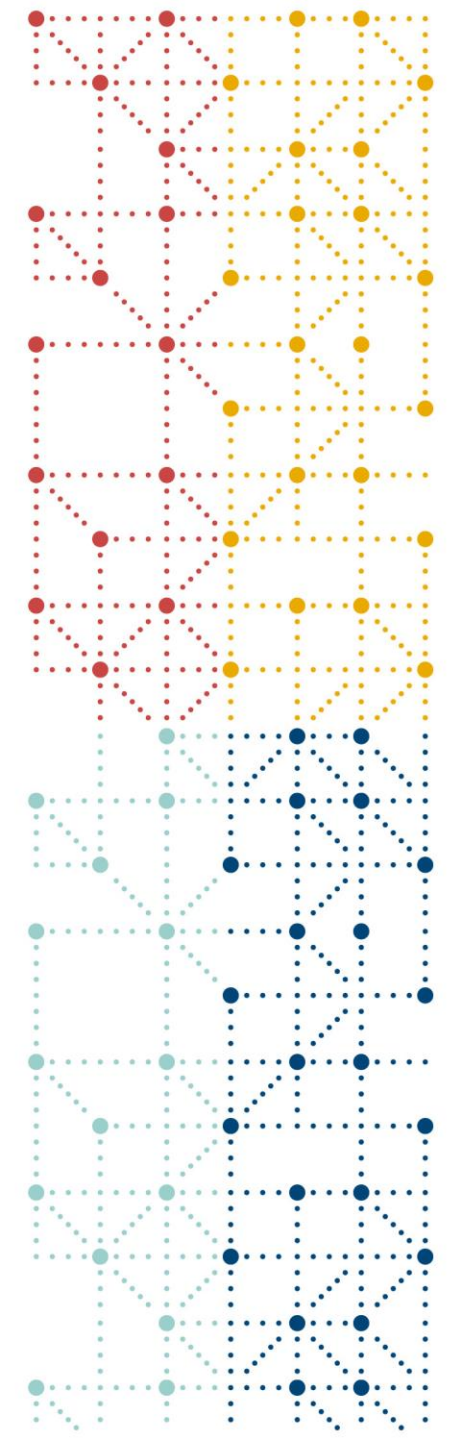




Agenda

1. CDISC EU Interchange
2. CDISC ITA Meeting
3. CDISC and Data Submission What's New
4. Other Topics and Q&A

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



CDISC EU Interchange



CDISC EU Interchange 2023

26-27 April 2023 – Copenhagen – Main Conference

24-25 April 2023 – Copenhagen – Trainings

Early bird discount until March 3rd

<https://www.cdisc.org/events/interchange/2023-europe-interchange>



CDISC EU Interchange 2023

Discounted Tickets

- 5 discounted passes
- Applicable to anyone from the Italian UN who have not attended a CDISC Interchange (virtual or in-person) over the past 3 years
- **US\$730** (\$858 after March 3rd)
- Email Angelo or Silvia if interested

EU CDISC Interchange 2023 - Agenda

26-27 April 2023 – Copenhagen – Main Conference

CDISC Foundational

- Special Handlings Required for Questionnaires, Ratings, and Scales
- Proposal for New ADaM Paired Variables: PARQUAL/PARTYPE
- Everything you Want to Know About CTUG, CT Relationships and Other Controlled Terminology topics
- Infant Safety Data (Associated Persons data) Collection in HIV Study
- **DHT Data Standard Subteam: A Path to Data Standardization of DHTs**
- Lessons Learned with the SENDIG-DART FDA Fit-For-Use Pilot

Biomedical Concepts

- The Development of CDISC Biomedical Concepts: Update and Next Steps
- Creating CORE Rules from Biomedical Concepts
- Extending Biomedical Concepts to Analysis

Governance

- To EC or not to EC, that is the Question
- The Joy (and Pain) of Implementing a Higher SDTM and SDTM IG Version - A Sponsor Story
- SDTM and define.xml Automation Made Easy
- Automate Harmonization of Study Metadata for Integrated define.xml
- Standardisation in a Fast Growing Environment; MDR, EDC and Other Abbreviations
- E2E clinical Development Standards - Taking us Beyond the Silos

Real World Data

- Leveraging on Real World Evidence (RWE) to Address Pitfalls in the Design and Conduct of Clinical Trials in Africa: Strategies for Optimizing Patient Recruitment and Retention.
- Heterogeneity in Data Sources: How to Deal with it?
- Creation of SDTM Datasets for a Real World Study Using Electronic Medical Records



<https://www.cdisc.org/events/interchange/2023-europe-interchange/program>

EU CDISC Interchange 2023 - Agenda

26-27 April 2023 – Copenhagen – Main Conference

Optimization Use Cases

- Can We Do It Better? Real-Time Validation of SDTM Mapping Is Superior to Double Programming
- All you Wanted to Know About Blood Pressure but Were Afraid to ask?
- Displaying the ODM-XML as a CRF Rendition Using a Style Sheet
- A Language-Orientated Approach to CDISC Metadata-Driven Automation

Core

- CORE Update
- Challenges of Creating CORE Rules
- Developing and Implementing CDISC CORE: a Data Manager's Testimonial
- How to Extend and Run CORE
- Tales from the Journey of a CORE Developer
- How we Achieved Real Time Validation by Integrating CORE into our Django (Python) Clinical Trial Platform
- How the new CDISC Open Rules Engine (CORE) can Improve the Speed and Quality of Dataset Deliverables in Clinical Trials
- Leveraging CORE for Real Time Validation – No More Endless Iterations

Secondary Use of CDISC

- Clinical Data Reuse: Opportunities and Challenges
- Automatic Defining ADaM for new Clinical Studies Using Machine Learning
- CDISC Paediatric User Guide: a Successful Academic Collaboration to Improve Paediatric Data Standards
- Challenges and Opportunities for CDISC at the Intersection of Observational and Intervention Research: the ECRAID-Base Experience with CDISC Implementation

Analysis Results Standard

- CDISC Analysis Results Logical Model: Background and Overview
- Coming together - a Journey in the Harmonisation and Modernisation of Clinical Analysis Standards
- Analysis Results Standards Guidelines and Implementation Using **R Shiny**



<https://www.cdisc.org/events/interchange/2023-europe-interchange/program>

EU CDISC Interchange 2023 - Agenda

26-27 April 2023 – Copenhagen – Main Conference

Submission/ Regulatory

- International Council on Harmonization (ICH) Progress Towards and Internationally Harmonized Clinical Electronic Structured Harmonized Protocol (CESharP)
- FDA-CTP and CDISC Project to Develop Tobacco Related Standards to Achieve Efficiencies for All Stakeholders
- Adapting and Evolving with OVRP Requirements
- Raising Awareness for Additional FDA Data Standards Submission Recommendations
- Balancing Quality and Efficiency - a Novo Nordisk Submission Example
- Ensuring That a Define-XML is Submission Ready
- The Journey of a 100 Million Records Submission
- FDA, EMA, PMDA presentations
 - PDUFA/EMA Updates: Data and Statistical Considerations when Submitting Analysis Data for DHT-Derived Endpoints
 - EMA Update on Data Submission in Europe
 - Other topics from EMA/FDA/PMDA to confirm

Digital Data Flow

- CDISCs Activities on DDF, Benefits for the Community and Looking Ahead
- Protocol **Optimization** with DDF
- Using DDF to Drive Clinical Data **Automation**
- **Automating** the Digital Data Flow with a Standards Foundation
- **Automating** Study Set-up with a Digital Data Flow

EU CDISC Interchange 2023 - Agenda

25 April 2023 – Copenhagen – Pre Conference Workshop

> TMF Workshop: About the Trial
Master File Reference Model
and More!

Workshops

9:00 AM-12:00 PM CET

> COSA Biomedical Concept &
OpenStudyBuilder Workshop

Workshops

9:00 AM-3:00 PM CET

> CORE Rules Development
Workshop

Workshops

12:30 PM-3:00 PM CET

<https://web.cvent.com/event/692520b3-5d88-48f1-b291-269010defffb/websitePage:645d57e4-75eb-4769-b2c0-f201a0bfc6ce>

EU CDISC Interchange 2023 - Agenda

24/25 April 2023 – Copenhagen – Trainings

April 24, 2023

> CDISC for Newcomers

Training Courses

> Define-XML

Training Courses

> CDASH Fundamentals and Implementation

Training Courses

> SEND Implementation

Training Courses

> SDTM Theory & Application

Training Courses

> SDTM Advanced

Training Courses

> ADaM Core Theory & Application

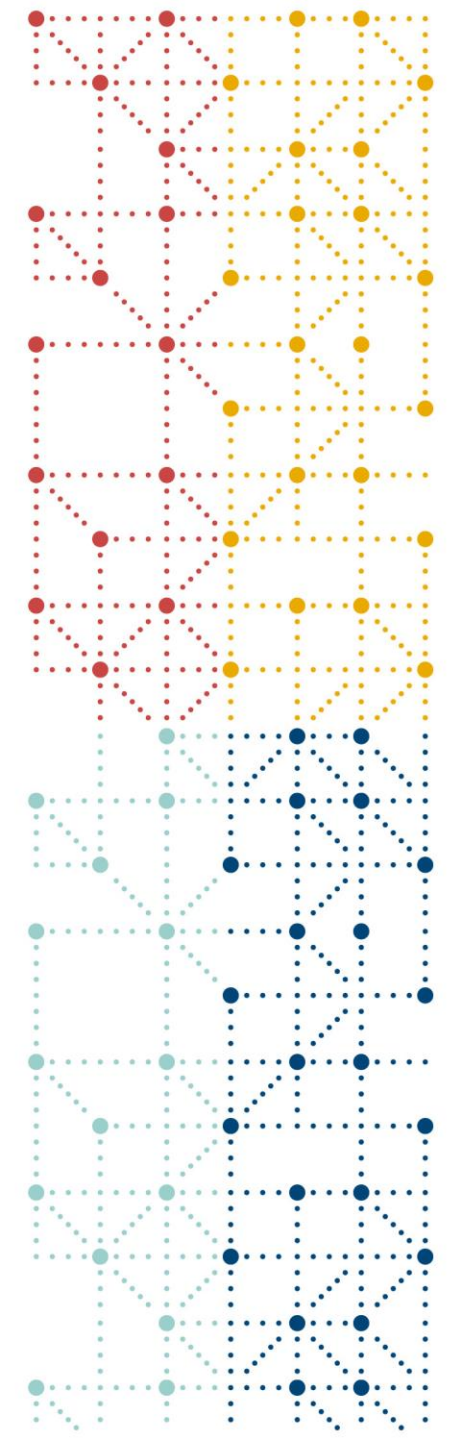
Training Courses

> ADaM Advanced

Training Courses



<https://web.cvent.com/event/692520b3-5d88-48f1-b291-269010defffb/websitePage:645d57e4-75eb-4769-b2c0-f201a0bfc6ce>



CDISC ITA Meeting

CDISC ITA Meeting

29 May 2023 (Monday) – Milan – SAS Institute



- Agenda to be confirmed
 - Submission experience e.g., ISS
 - Estimand PHUSE WG Preview (ADaM)
 - SAS
 -
- Any topic / real experience related to the application of CDISC standards and data submission in general



CDISC and Data Submission What's New



Standards publication

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

No Major Update since last meeting (December 2022)

Standards under public review

<https://www.cdisc.org/public-reviews>

Standard/Therapeutic Area	Comments Due
<p>QRS Supplements</p> <ul style="list-style-type: none">• Harvey-Bradshaw Index (HBI)• Kurtzke Functional Systems Scores (KFSS)• Modified Van Assche Index (MVAI)• Pain Relief (PR)• Patient Health Questionnaire - 9 (PHQ-9)	<p>7 March 2023</p>

<https://www.cdisc.org/standards/foundational/qrs>

Standards in development

<https://www.cdisc.org/standards/in-development> with projected publication in 2023

Standard	Release Notes
ADaM Metadata Submission Guidelines v1.0	Resolving Public Comments.
ADaM Oncology Examples	Resolving Public Comments.
ADaM popPK Implementation Guide v1.0	Resolving Public Comments.
Analysis Results Standard v1.0	In Development.
CDASHIG v2.3	In Development.
Conformance Rules for SDTMIG-Medical Devices v1.1	In Development.
Safety User Guide v1.0	In Development.
SDTM v2.1	In Development.
SDTMIG-Medical Devices v2.0 and Conformance Rules	In Development.
SENDIG v3.2	In Development.
SDTM for Observational Studies v1.0	In Development.
SENDIG-DART v1.2	Resolving Public Comments.
SENDIG-Genotoxicity v1.0	Resolving Public Comments.
Tobacco Implementation Guide v1.0	In Development.



Standards in development

<https://www.cdisc.org/standards/in-development> with projected publication in 2023

Standard	Release Notes
COVID-19 Therapeutic Area User Guide v2.0	In Development.
Pediatrics User Guide v1.0	Preparing for Publication (Q4 2022).
Rare Diseases Therapeutic Area User Guide	In Development.
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	Resolving Public Comments.

TAUG

Therapeutic Areas - Published User Guides

Therapeutic Area User Guides (TAUGs) extend the Foundational Standards to represent data that pertains to specific disease areas. TAUGs include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submissions.

Therapeutic Area	Guides Contain
Acute Kidney Injury	Terminology, SDTM, CDASH, ADaM
Alzheimer's	Terminology, SDTM
Asthma	Terminology, SDTM
Breast Cancer	Terminology, SDTM, CDASH, ADaM
Cardiovascular	Terminology, SDTM
CDAD	Terminology, SDTM
Colorectal Cancer	Terminology, SDTM, CDASH, ADaM
COPD	Terminology, SDTM, CDASH, ADaM
COVID-19	Terminology, SDTM, CDASH, ADaM
Diabetes	Terminology, SDTM, CDASH, ADaM
Diabetes Type 1 - Exercise and Nutrition	Terminology, SDTM, CDASH
Diabetes Type 1 - Pediatrics and Devices	Terminology, SDTM, CDASH, ADaM
Diabetic Kidney Disease	Terminology, SDTM, CDASH, ADaM
Duchenne Muscular Dystrophy	Terminology, SDTM

TAUG

<https://www.cdisc.org/kb/articles/taug-examples-sdtm-domains>

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CDISC Webinars and Events 2022/23



Upcoming Webinars

<https://www.cdisc.org/events/webinars/upcoming>

- QRS Office Hours – 28FEB23
- COSA Quarterly Spotlight - Q1 2023 – 28MAR23
- Genomics Findings Office Hours – 30MAR23
- TMF Reference Modal General Meeting – 23MAY23
- LB, MB & IS Domain Scope Changes for the SDTMIG v3.4 and Impact on Controlled Terminology – 22JUN23



Recent Past Webinars

<https://www.cdisc.org/events/webinars/members-only>

- CDISC Standards and Real-World Data – 21FEB23



{admiral} Hackathon Status

<https://www.cdisc.org/events/webinars/members-only>

- Pre{admiral} Hackathon Kickoff R for SAS Programmers – 17JAN23
- {admiral} Hackathon Kickoff – 26JAN23

Next and Last checking 23FEB23 (upcoming webinars)

{admiral} Hackathon Status

COSA Spotlight Webinar

Time: 11:00 AM – 12:30 PM Eastern US

Date: 28 Mar 2023

Join CDISC and Open-Source Developers from our Community
for our quarterly COSA webinar

{admiral} Hackathon Readout

Learn the results from last month's {admiral} Hackathon. The purpose of [ADaM in R Asset Library {admiral}](#) is to provide an open source, modularized toolbox that enables the pharmaceutical programming community to develop ADaM datasets in R. We'll share lessons learned, outcomes, and upshots about developing open-source R packages for clinical reporting purposes.

OAK - SDTM Automation: Call for Participants

OAK-SDTM Automation is a new initiative to develop an open-source, metadata-driven SDTM automation solution that enables users to automate SDTM datasets in R. We'll provide project overview (including vision and scope), describe the high-level roadmap, and show how you can volunteer to participate in this exciting project.

COSA Biomedical Concept & OpenStudyBuilder Workshop

Get a sneak peek to our upcoming workshop that will take place at the [CDISC Europe Interchange](#) in Copenhagen.

The workshop will dive into what Biomedical Concepts (BC) are, and how they can be applied within a MDR data standards repository and a SDR study definitions repository – illustrated within the OpenStudyBuilder (OSB) solution.



https://cdisc.zoom.us/webinar/register/WN_xeS2k7UGS2-1Q83PfYoNVg

The move to Open Source

Shifting to an Open-Source Backbone in Clinical Trials with Roche

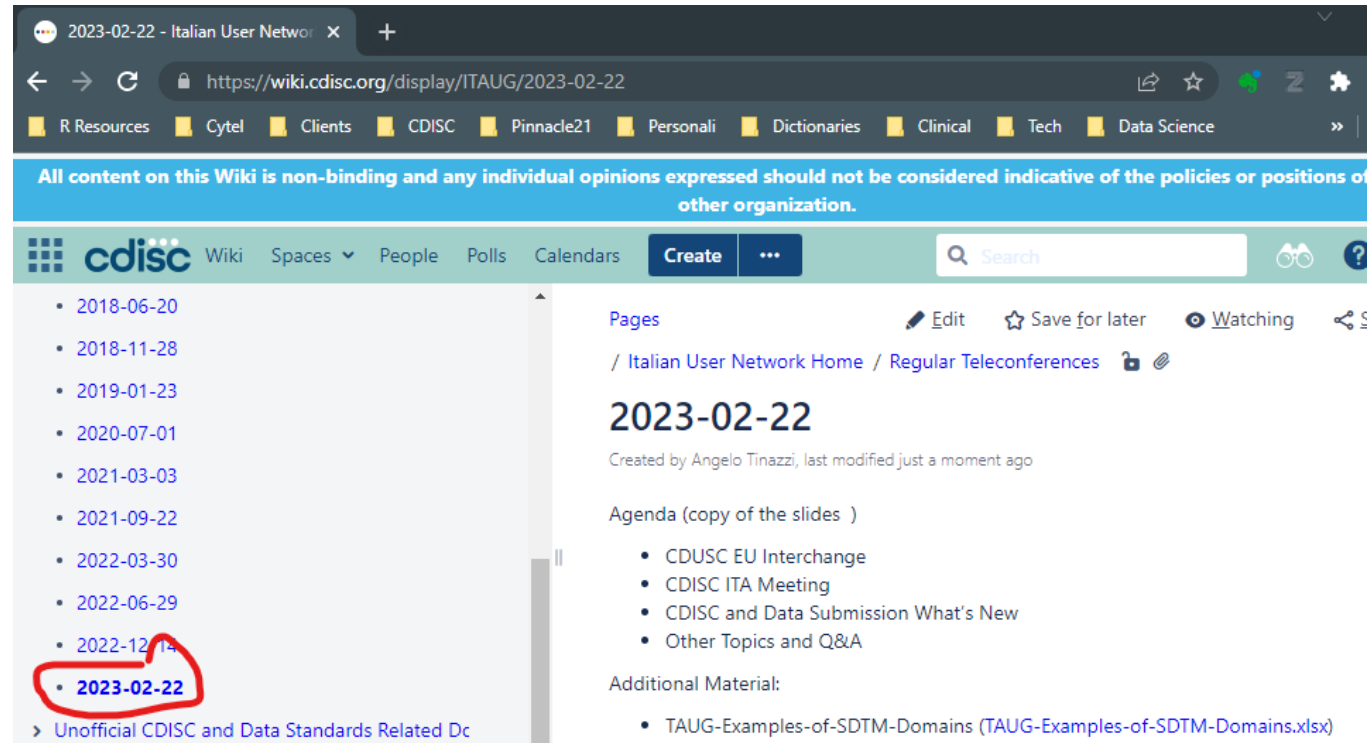


Posit PBC
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<https://www.youtube.com/watch?v=nqJsLSLd39A>

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



2023-02-22 - Italian User Network

<https://wiki.cdisc.org/display/ITAUG/2023-02-22>

R Resources Cytel Clients CDISC Pinnacle21 Personali Dictionaries Clinical Tech Data Science

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Agenda (copy of the slides)

- CDUSC EU Interchange
- CDISC ITA Meeting
- CDISC and Data Submission What's New
- Other Topics and Q&A

Additional Material:

- TAUG-Examples-of-SDTM-Domains (TAUG-Examples-of-SDTM-Domains.xlsx)

Thank You!

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