# 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

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# 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

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# 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 OVRR 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
  - PDUFAVII 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

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

# EU CDISC Interchange 2023 - Agenda

## 25 April 2023 – Copenhagen – Pre Conference Workshop

| | |
|---|---|
| > TMF Workshop: About the Trial Master File Reference Model and More!<br>Workshops | 9:00 AM-12:00 PM CET |
| > COSA Biomedical Concept & OpenStudyBuilder Workshop<br>Workshops | 9:00 AM-3:00 PM CET |
| > CORE Rules Development Workshop<br>Workshops | 12:30 PM-3:00 PM CET |

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

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# 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

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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

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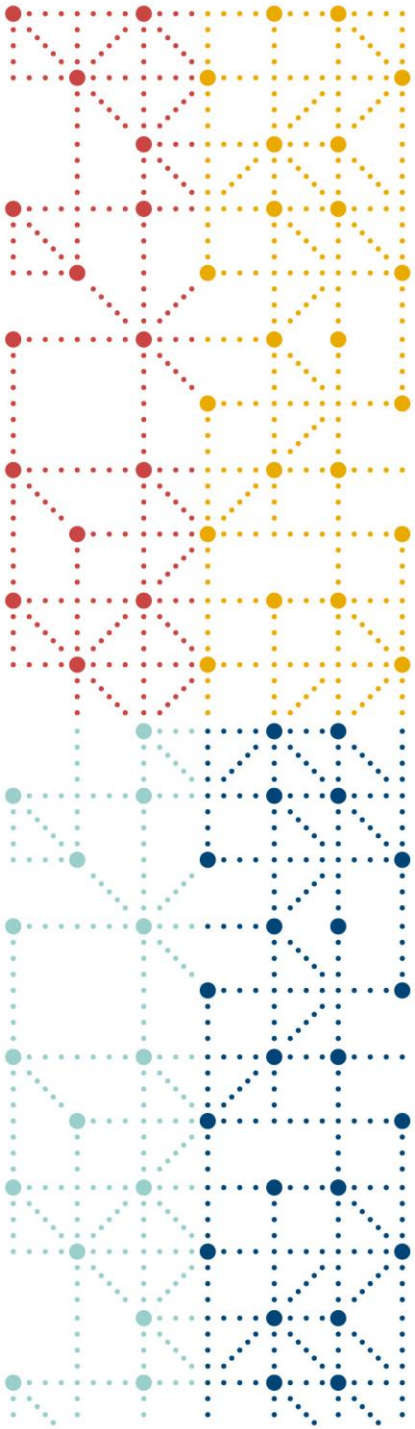


# CDISC and Data Submission What's New

# 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 |
|---|---|
| QRS Supplements<br>• Harvey-Bradshaw Index (HBI)<br>• Kurtzke Functional Systems Scores (KFSS)<br>• Modified Van Assche Index (MVAI)<br>• Pain Relief (PR)<br>• Patient Health Questionnaire - 9 (PHQ-9) | 7 March 2023 |

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

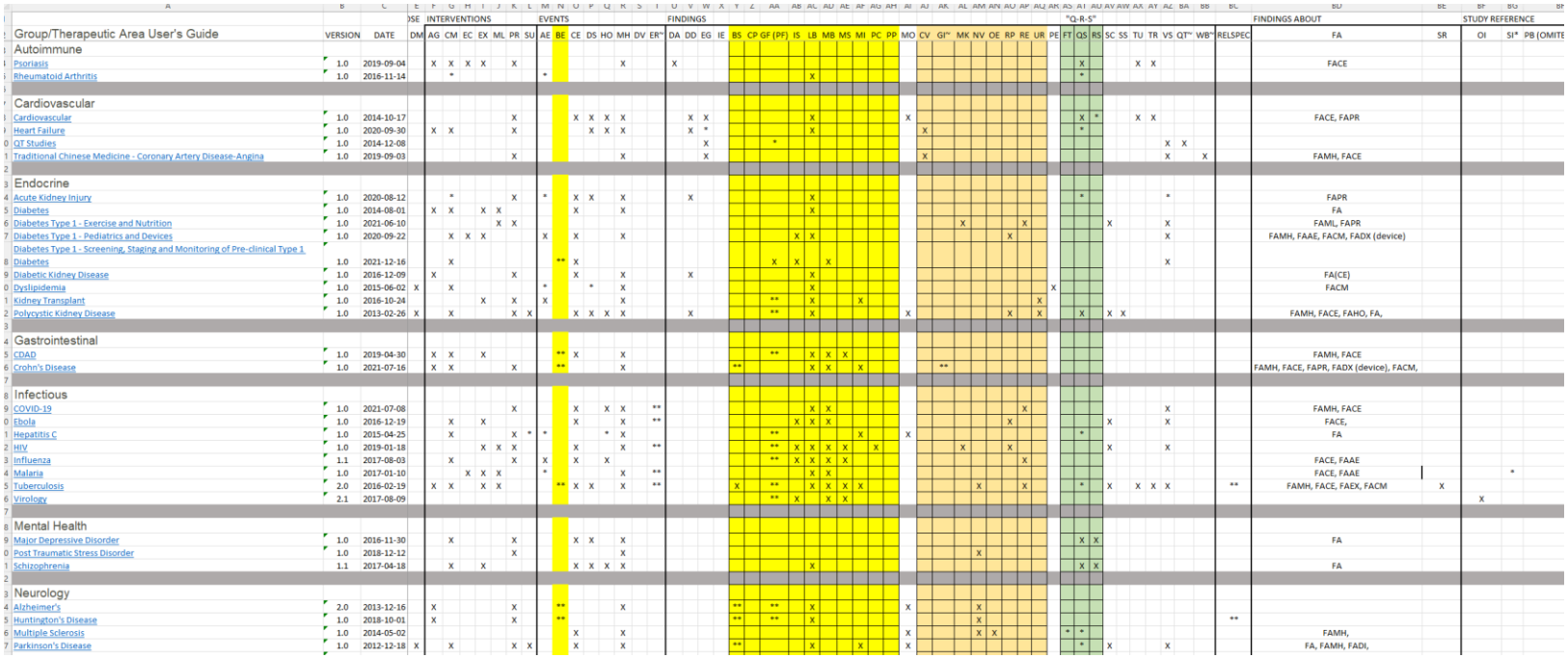
Therapeutic Area User Guides (TAUGs) extend the Foundational Standards to represent data that pertains to specific disease areas. TAUGs include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submissions.

| 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 |

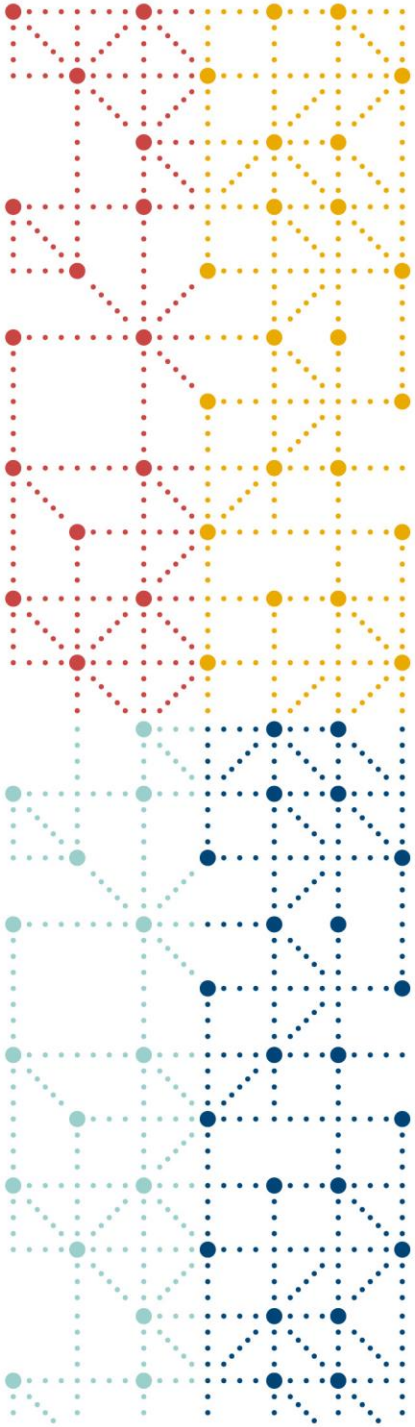
https://www.cdisc.org/standards/therapeutic-areas/published-user-guides

# TAUG

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



| Group/Therapeutic Area User's Guide | VERSION | DATE | DM | AG | CM | EC | EX | ML | PR | SU | AE | BE | CE | DS | HO | MH | DV | ER** | DA | DD | EG | IE | BS | CP | GF | (PF) | IS | LB | MB | MS | MI | PC | PP | MO | CV | GI** | MK | NV | OE | RP | RE | UR | PE | FT | QS | RS | SC | SS | TU | TR | VS | QT** | WB** | RELSPEC | FA | SR | OI | SI* | PB (OMITE |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Autoimmune | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Psoriasis | 1.0 | 2019-09-04 | | X | X | X | X | | X | | | | | | | X | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | FACE | | | | |
| Rheumatoid Arthritis | 1.0 | 2016-11-14 | | | * | | | | | | * | | | | | | | | | | | | | | | | X | | | | | | | | | | | | | | | | | | | * | | | | | | | | | | | | |
| Cardiovascular | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cardiovascular | 1.0 | 2014-10-17 | | | | | | | X | | | | X | X | X | X | | | X | X | | | | | | | X | | | | | | | | X | | | | | | | | | | X | * | | X | X | | | | | | | | | |
| Heart Failure | 1.0 | 2020-09-30 | | X | X | | | | X | | | | X | | X | X | | | X | * | | | | | | | X | | | | | | | | X | | | | | | | | | | * | | | | | | | | | | | | |
| QT Studies | 1.0 | 2014-12-08 | | | | | | | | | | | | | | | | | | X | | | | | | * | | | | | | | | | | | | | | | | | | | | | | | | | X | X | | | | |
| Traditional Chinese Medicine - Coronary Artery Disease-Angina | 1.0 | 2019-09-03 | | | | | | | X | | | | | | | X | | | | X | | | | | | | | | | | | | | | X | | | | | | | | | | | | | | | | | X | | X | | FAMH, FACE | | | | |
| Endocrine | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acute Kidney Injury | 1.0 | 2020-08-12 | | | * | | | | X | | * | | X | X | | X | | | | X | | | | | | | | X | | | | | | | | | | | | | | | | | * | | | | | | | | * | | | FAPR | | | | |
| Diabetes | 1.0 | 2014-08-01 | | X | X | | X | X | | | | | X | | | X | | | | | | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | FA | | | | |
| Diabetes Type 1 - Exercise and Nutrition | 1.0 | 2021-06-10 | | | | | | X | X | | | | | | | | | | | | | | | | | | | | X | | | | | | | | X | | | | | X | | | | | | X | | | | | | | FAML, FAPR | | | | |
| Diabetes Type 1 - Pediatrics and Devices | 1.0 | 2020-09-22 | | | X | X | X | | | | X | | X | | | X | | | | | | | | | | | | X | X | | | | | | | | | | | | X | | | | | | | | | | | | | | | FAMH, FAAE, FACM, FADX (device) | | | | |
| Diabetes Type 1 - Screening, Staging and Monitoring of Pre-clinical Type 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Diabetes | 1.0 | 2021-12-16 | | | X | | | | | | | ** | X | | | | | | | | | | | X | | X | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Diabetic Kidney Disease | 1.0 | 2016-12-09 | | X | | | | | X | | | | X | | | X | | | | X | | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | FA(CE) | | | | |
| Dyslipidemia | 1.0 | 2015-06-02 | X | | X | | | | | | * | | | * | | X | | | | | | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | FACM | | | | |
| Kidney Transplant | 1.0 | 2016-10-24 | | | | | X | | X | | X | | | | | X | | | | | | | | | | | | ** | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Polycystic Kidney Disease | 1.0 | 2013-02-26 | X | | X | | | | X | X | | | X | X | X | X | | | | X | | | | | | | | ** | | X | | | | | X | | | | | | | | | | | | | | | | | | | | | FAMH, FACE, FAHO, FA, | | | | |
| Gastrointestinal | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CDAD | 1.0 | 2019-04-30 | | X | X | | X | | | | | ** | X | | | X | | | | | | | | | | | | ** | | X | X | X | | | | | | | | | | | | | | | | | | | | | | | | | FAMH, FACE | | | | |
| Crohn's Disease | 1.0 | 2021-07-16 | | X | X | | | | X | | | ** | | | | X | | | | | | | ** | | | | | | X | X | | X | | | | ** | | | | | | | | | | | | | | | | | | | | FAMH, FACE, FAPR, FADX (device), FACM, | | | | |
| Infectious | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| COVID-19 | 1.0 | 2021-07-08 | | | | | | | X | | | | X | | X | X | | ** | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | FAMH, FACE | | | | |
| Ebola | 1.0 | 2016-12-19 | | | X | | X | | | | | | X | | | X | | ** | | | | | | | | | X | X | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | FACE, | | | | |
| Hepatitis C | 1.0 | 2015-04-25 | | | X | | | | X | * | * | | | | * | X | | | | | | | | | | ** | | | | | X | | | X | | | | | | | | | | | | | | | | | | | | | FA | | | | |
| HIV | 1.0 | 2019-01-18 | | | | | X | X | X | | | | X | | | X | | ** | | | | | | | | ** | X | X | X | X | | X | | | | X | | | X | | | | | | | | | | | | | | | | | | | |
| Influenza | 1.1 | 2017-08-03 | | | X | | | | X | | X | | X | | X | | | | | | | | | | | ** | X | X | X | X | | | | | | | | | | X | | | | | | | | | | | | | | | | FACE, FAAE | | | | |
| Malaria | 1.0 | 2017-01-10 | | | | X | X | X | | | * | | | | | X | | ** | | | | | | | | | | X | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | FACE, FAAE | | | * | |
| Tuberculosis | 2.0 | 2016-02-19 | | X | X | | X | X | | | | ** | X | X | | X | | ** | | | | | X | | | ** | | X | X | X | X | | | | | | | | | | | | | | | | | | | | | | | | | | FAMH, FACE, FAEX, FACM | X | | | |
| Virology | 2.1 | 2017-08-09 | | | | | | | | | | | | | | | | | | | | | | | | | ** | | X | | X | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | X | | |
| Mental Health | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Major Depressive Disorder | 1.0 | 2016-11-30 | | | X | | | | X | | | | X | X | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | FA | | | | |
| Post Traumatic Stress Disorder | 1.0 | 2018-12-12 | | | | | | | X | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | X | | | | | | | | | | | | | | | | |
| Schizophrenia | 1.1 | 2017-04-18 | | | X | | X | | | | | | X | X | X | X | | | | | | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | FA | | | | |
| Neurology | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Alzheimer's | 2.0 | 2013-12-16 | | X | | | | | X | | | ** | | | | X | | | ** | ** | | | | | | | | X | | | | | | | X | | | | X | | | | | | | | | | | | | | | | | | | | |
| Huntington's Disease | 1.0 | 2018-10-01 | | X | | | | | X | | | ** | | | | X | | | ** | ** | | | | | | | | X | | | | | | | | | | X | | | | | | | | | | | | | | | | | ** | | | |
| Multiple Sclerosis | 1.0 | 2014-05-02 | | | | | | | | | | | X | | | X | | | | | | | | | | | | | | | | | | | X | | | X | X | | | | | * | * | | | | | | | | | | | FAMH, | | | | |
| Parkinson's Disease | 1.0 | 2012-12-18 | X | | X | | | | X | X | | | X | | | X | | | | ** | | | | | | | | X | | | | | | | X | | | | | | | | | | * | | X | | | | X | | | | FA, FAMH, FADI, | | | | |



# 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)

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# {admiral} Hackathon Status

**COSA Spolight 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.

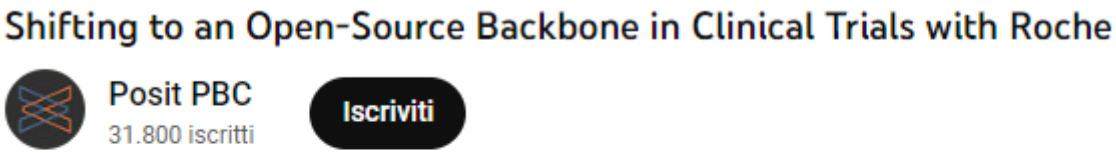
**COSA Biomedical Concept & OpenStudyBuilder Workshop**

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




https://www.youtube.com/watch?v=nqJsLSLd39A

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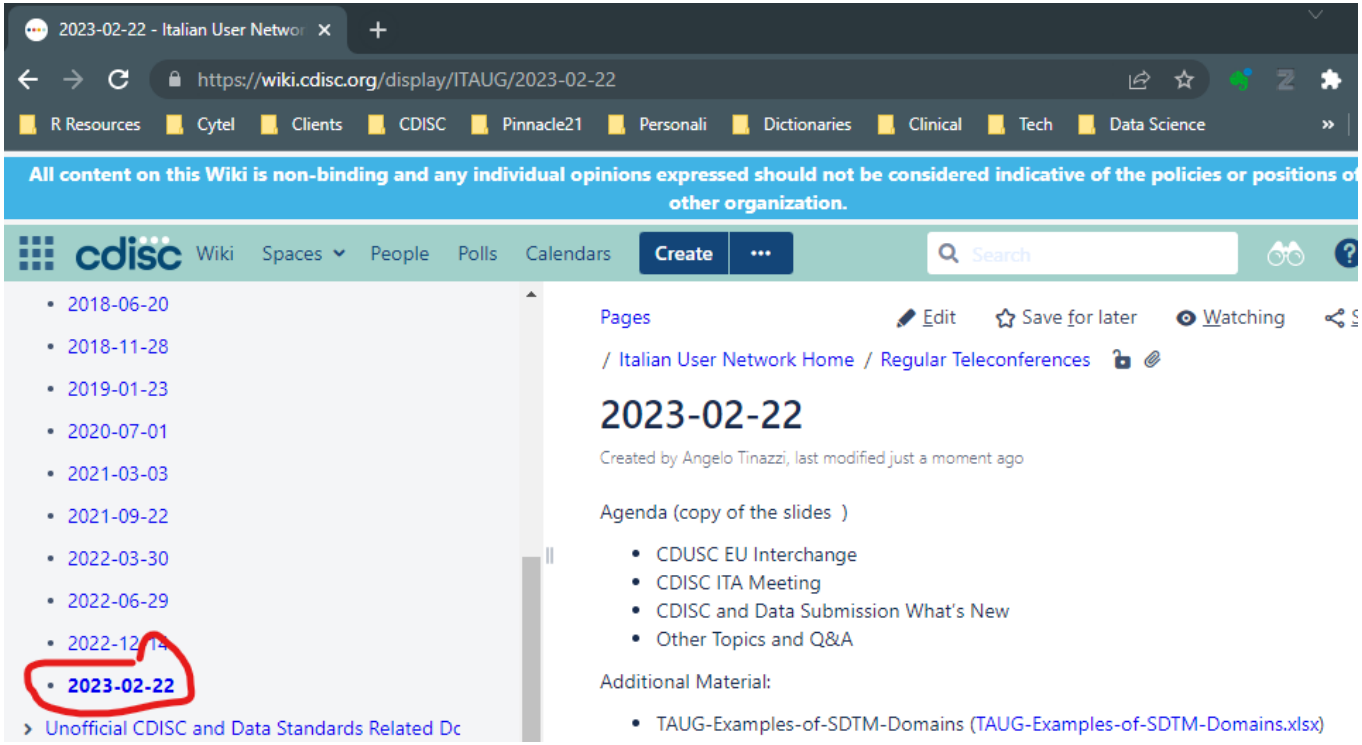
https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home




# Thank You!

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Silvia Faini

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