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](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

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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! 9:00 AM-12:00 PM CET
Workshops

▶ COSA Biomedical Concept & OpenStudyBuilder Workshop 9:00 AM-3:00 PM CET
Workshops

▶ CORE Rules Development Workshop 12:30 PM-3:00 PM CET
Workshops

https://web.cvent.com/event/692520b3-5d88-48f1-b291-269010defffb/websitePage:645d57e4-75eb-4769-b2c0-f201a0bfc6ce
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-b291-269010defff8/websitePage:645d57e4-75eb-4769-b2c0-f201a0bfc6ce
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
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

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<thead>
<tr>
<th>Standard/Therapeutic Area</th>
<th>Comments Due</th>
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<td>QRS Supplements</td>
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<td>• Harvey-Bradshaw Index (HBI)</td>
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<td>• Kurtzke Functional Systems Scores (KFSS)</td>
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<td>• Modified Van Assche Index (MVAI)</td>
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<td>• Pain Relief (PR)</td>
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https://www.cdisc.org/standards/foundational/qrs
Standards in development

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

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<thead>
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<th>Standard</th>
<th>Release Notes</th>
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<td>ADaM Oncology Examples</td>
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<td><strong>ADaM popPK Implementation Guide v1.0</strong></td>
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<td>SENDIG-Genotoxicity v1.0</td>
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Standards in development

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<td>Rare Diseases Therapeutic Area User Guide</td>
<td>In Development.</td>
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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.

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<thead>
<tr>
<th>Therapeutic Area</th>
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[https://www.cdisc.org/standards/therapeutic-areas/published-user-guides](https://www.cdisc.org/standards/therapeutic-areas/published-user-guides)
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[Link to CDISC Knowledge Base Article: https://www.cdisc.org/kb/articles/taug-examples-sdtm-domains]
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

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

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