

CDISC Italian User Network TC

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



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

28.06.2023

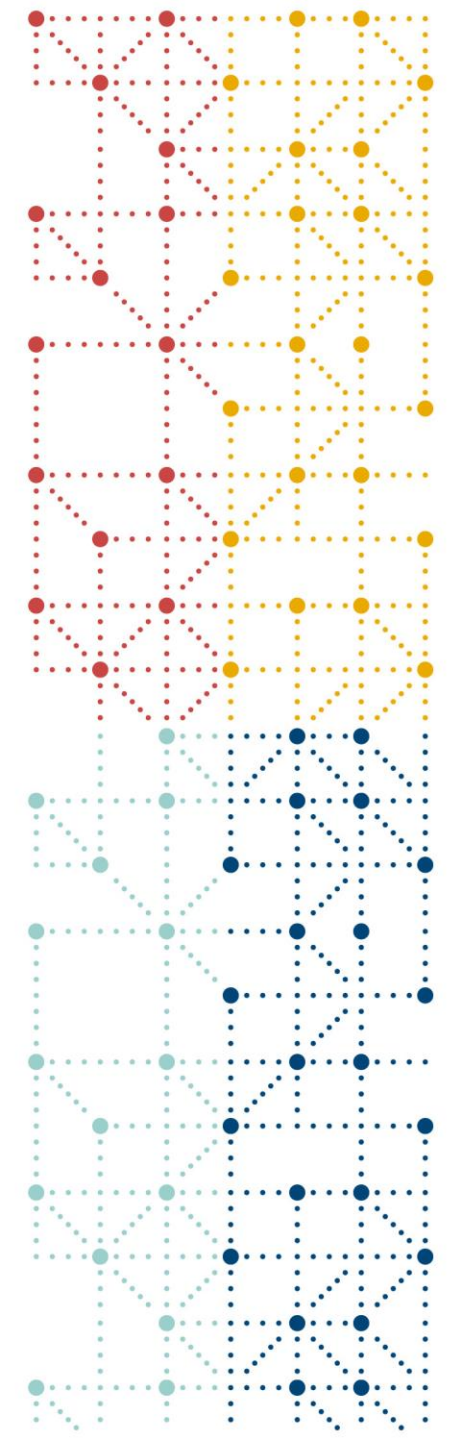




Agenda

1. CDISC Updates
2. CDISC CORE and 'Homemade CORE': Enhancing Data Check Operations, Davide Marinucci, Alira Health
3. CDISC 2023 Europe Interchange – Brief Summary, Federico Baratin, GSK
4. CDISC 2023 Europe Interchange – Antonio Gabriele, Opis Research
5. Other Topics and Q&A

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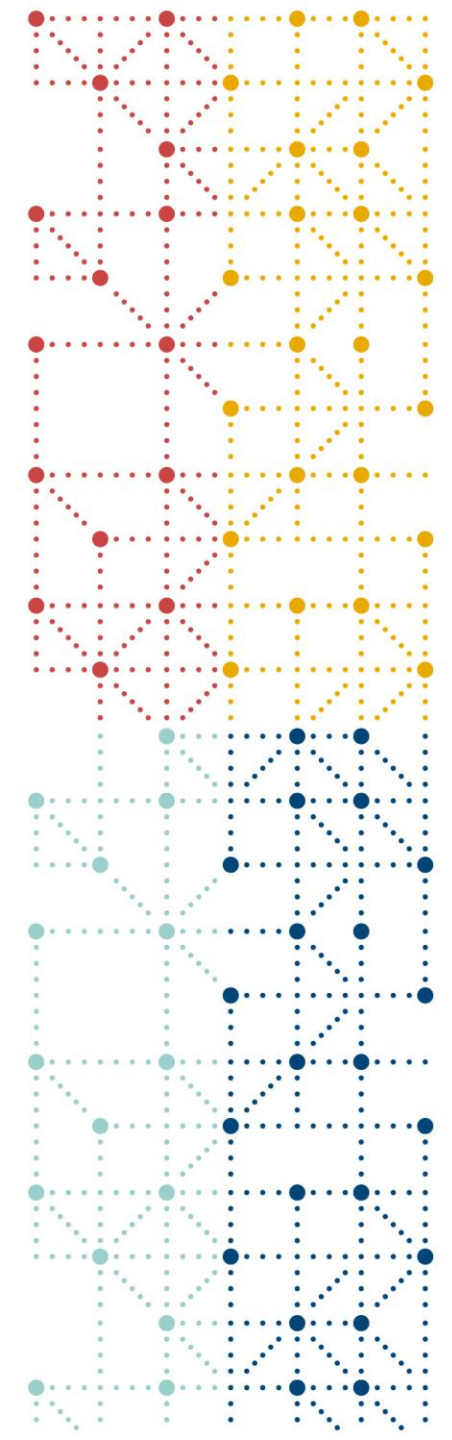
ITA CDISC UN Update



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Un grande **GRAZIE** e **BENVENUTO** a
Mauro Cortellini

Lead Data Manager in Chiesi Farmaceutici S.p.A.
Che si unisce a noi nel leading dell'Italian CDISC User Network



CDISC Standards Updates



Recently Published Standards

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

Standard	Published Date
Pediatrics User Guide v1.0	22 February 2023
ADaM Metadata Submission Guidelines v1.0	18 April 2023
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	6 June 2023



Recently Published Standards

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

- Pediatrics User Guide v1.0, created to provide guidance on:
 - data related to the pediatric subject of the study.
 - data related to family members of a pediatric subject of the study.
 - data specifically related to pregnancy and birth events.
 - the use of domains related to the conduct of a study (e.g., eligibility criteria and trial design).
 - a list of regularly used measures of interest for pediatric studies.



Recently Published Standards

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

- ADaM Metadata Submission Guidelines v1.0
→ provide guidance for preparing eCTD Module 5, this includes:
 - ADaM-MSG_v1.0.pdf
 - ADaM-MSG-Example-Submission-Package_1.zip
 - ADaM-MSG_ReadMe.pdf
- Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0 → sections also translated in Chinese



Standards under public review

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

Standard/Therapeutic Area	Comments Due
Controlled Terminology Package 55	21 July 2023
CDASH Model v1.3 and CDASHIG v2.3	17 July 2023
COVID-19 Therapeutic Area User Guide v2.0	27 June 2023
QRS Supplements to the SDTMIG	27 June 2023



CDISC Upcoming Webinars and CDISC Initiative



Upcoming Webinars

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

- COSA Quarterly Spotlight - Q2 2023 - 29JUN23
- Analysis Results Standards Hackathon Kick-off - 12JUL23
- Controlled Terminology Updates for Q2 2023 – 18JUL23
- QRS Office Hours – 29AUG23
- TMF Reference Model General Meeting - Q3 – 7SEP23
- COSA Quarterly Spotlight – Q3 2023 – 19SEP23



Analysis Results Standards Hackathon

- 12JUL-31AUG
- Hackathon Objective
- The Hackathon is an opportunity to collaborate with others from the CDISC Community to create open-source tools that operationalize the ARS Logical Model.
- Pre-Read
- We invite you to reference the paper "All You Need to Know about CDISC Analysis Result Standards," awarded Best Paper at PharmaSUG 2023. The paper will provide a solid foundation to gain insights and best practices on metadata creation, result ingestion, and display generation.



SDTM – OAK project

<https://www.cdisc.org/oak>

- OAK is an open-source community project to evolve software that uses agnostic transformation logic to enable mapping of CDASH to SDTM whose functionality will also generate raw synthetic data.
- Looking for Volunteer
Link to the volunteer form to engage in the project



EU CDISC Interchange 2023 Highlights



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GRAZIE a...
Davide Marinucci, Alira Health
Federico Baratin, GSK
Antonio Gabriele, OPIS Research



Thank You!

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The logo for CDISC, featuring the lowercase letters "cdisc" in a dark blue, sans-serif font. Above the letter "i" are three small circles: a red one, a yellow one, and a light blue one.