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

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

<table>
<thead>
<tr>
<th>Standard</th>
<th>Published Date</th>
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<tbody>
<tr>
<td>Pediatrics User Guide v1.0</td>
<td>22 February 2023</td>
</tr>
<tr>
<td>ADaM Metadata Submission Guidelines v1.0</td>
<td>18 April 2023</td>
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<tr>
<td>Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0</td>
<td>6 June 2023</td>
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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](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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<tbody>
<tr>
<td>Controlled Terminology Package 55</td>
<td>21 July 2023</td>
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<tr>
<td>CDASH Model v1.3 and CDASHIG v2.3</td>
<td>17 July 2023</td>
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<tr>
<td>COVID-19 Therapeutic Area User Guide v2.0</td>
<td>27 June 2023</td>
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<tr>
<td>QRS Supplements to the SDTMIG</td>
<td>27 June 2023</td>
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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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