Welcome and news from CDISC

Silvia Faini and Angelo Tinazzi – E3C Member, ITA CDISC UN
1. Welcome
2. CDISC updates
3. ITA CDISC User Network
Benvenuti! Welcome!

- 7th Italian CDISC User Network Annual Meeting

  Milan 28th February 2020 ➔ Virtual 7th October 2020

- Agenda 90% confirmed
  - Italians and non-Italians speakers

- 95 attendees
Grazie! Thank you!

• Supported by SIMeF

• Sponsored by Cytel

• Empowered and encouraged by CDISC
VII Italian UN was also define-xml and submission ready documents workshop with 26 attendee from 16 different companies.

Funzione

- Data Manager
- Biostatistics
- Programmer
- Other (specific)

Tipo azienda

- Pharma
- CFO
- University
- Consultant
- Hospital
- Centre di Ricerca
- Other (specific)

Anni Esperienza

- 0-3
- 4-6
- 6-10
- >10

Esperienza CDISC e documentazione

- CDASH
- SDTM
- Adeli
- define-ml
- Reviewer Guide
- Other (specific)

Esperienza Data Submission

- FDA
- EMA
- PHDA
- Other (specific)
### IBIG Activities – 2020 Virtual Forum

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
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<tbody>
<tr>
<td>2 October</td>
<td>Quantitative Decision Making (QDM) in the Clinical Drug Development</td>
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<tr>
<td>9 October</td>
<td>SAS, R, Python – Differences, Similarities and Potentialities of Widely Used Stats Software</td>
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<td>16 October</td>
<td>Clinical Trial Management during the COVID-19 Pandemic – Guidelines and Practical Impacts</td>
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<td>23 October</td>
<td>Taxonomy of Subgroup-related Analyses and Issues in Clinical Trials</td>
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<tr>
<td>30 October</td>
<td>Data Visualization for a Better Communication with Non-Stats People</td>
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https://www.simef.it/index.php?option=com_eventbooking&view=event&id=548&catid=7&Itemid=386&lang=it
CDISC website restyling

- CDISC standards section has been recently restyled, e.g. SDTM foundational standard
  
  https://www.cdisc.org/standards/foundational/sdtm

- Description
- Version
- Education
- Knowledge Base
- Public Review
- Archive
CDISC website restyling
CDISC website restyling

SDTM

Description Versions Education Knowledge Base Public Review Arch

SDTM Courses
Private, Public, Virtual Classroom
SDTM Advanced Topics
SDTM Changes and Updates
SDTM Theory and Application for Medical Devices

Online
New Events Domains in SDTMIG v3.2
New Interventions Domains in SDTMIG v3.2

SDTM

Description Versions Education Knowledge Base Public Review Arch

Public Review - SDTM
Study Data Tabulation Model Metadata Submission Guidelines v2.0
Comments Due by: 20 November 2020

SDTM

Description Versions Education Knowledge Base Public Review Archive

Articles
A Short History of CDISC and SAS Transport Files
Assessing Causality
CDISC-Annotated CRF Repository in Japanese
Changing Event Severity
Concept Maps for a Finding with Increasing Levels of Detail
Concept Maps for Adverse Events with Increasing Levels of Detail
Concept Maps for Subject Administration with Increasing Levels of Detail

Examples
Breakdown of
Diabetes History
End-Stage Renal Disease
Glomerular Filtration Rate
Glomerular Filtration Rate
Hypoglycemia
Hypoglycemia

SDTM
CDISC guidelines

• In April 2020 «Interim User Guide - COVID-19»

• CDISC standards in development section
  • Public Reviews https://www.cdisc.org/public-reviews
    • Study Data Tabulation Model Metadata Submission Guidelines v2.0
  • In Development https://www.cdisc.org/standards/in-development
  • RWD project https://www.cdisc.org/standards/real-world-data
  • CDISC 360 project https://www.cdisc.org/cdisc-360 → In November Hands-on Workshop at PHUSE EU Connect 2020
CDISC events

CDISC moved to virtual all the events until Jun 2021

- 2020 US Interchange 7-8 Oct 9:00 AM-5:30 PM ET
- **2021 CDISC TechniCon 3 Feb** (Europe time zone)
  - [https://www.cdisc.org/form/2021-technicon-call-for-abstracts](https://www.cdisc.org/form/2021-technicon-call-for-abstracts) → close this Friday
- **28 - 29 Apr 2021 Europe Interchange** (Virtual Event)
  - The call for abstracts will open 9 Oct 2020
  - From “Third Quarter 2020 Newsletter” E3C update
- 10 - 11 Jun 2021 Japan Interchange (Virtual Event)
- 6 - 7 Aug 2021 China Interchange (Beijing, China)
CDISC webinars

• TUE, 13 OCT 2020, Controlled Terminology Updates for Q4*
• THU, 15 OCT 2020, Type 1 Diabetes Pediatrics and Devices Publication
• TUE 20 OCT 2020, Linking Data in SDTM*
• THU, 22 OCT 2020, Introducing the Next Generation CDISC Library
  11:00 AM - 12:30 PM Eastern Standard Time → 5:00 PM - 6:30 PM CEST

• TUE, 27 OCT 2020, Introducing the Analysis Results Standard: Project Start Up and Call for Volunteers
  11:00 AM - 12:30 PM Eastern Standard Time → 4:00 PM - 5:30 PM CET

* These should be public, the others only for CDISC members.
CDISC public trainings

• Virtual Classroom Training
  • [https://www.cdisc.org/education/virtual-classroom-training](https://www.cdisc.org/education/virtual-classroom-training)
  • Week 1: 26-30 October 2020
  • Week 2: 2-6 November 2020

• Public Training in Frankfurt, 23-27 November 2020
  • CDASH Implementation, SDTM Theory and Application, SDTM Changes & Updates, Define-XML, ADaM Primer, ADaM Theory and Application
ITA CDISC User Network

- Check our news on CDISC quarterly newsletter
- Check and contribute to CDISC Wiki space
  https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home

- One full day annual meeting
- Teleconferences during the year (mailing list)

- Volunteers
ITA CDISC User Network - Volunteers

• «Sharing is caring» principle
• Volunteers are the engine of ITA CDISC UN
• How can you contribute?
  • Propose topics for next TCs/events
  • Prepare a presentation to share during TCs/events
  • Basic or advanced levels are all welcomed
  • Do not be shy, any contribution is valuable!

• To all past, present and future volunteers:
  Thank you! We always need you!
Enjoy the VII Italian CDISC UN Day

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