



CDISC Italian User Network 2020
Milan, Italy | 7 October 2020

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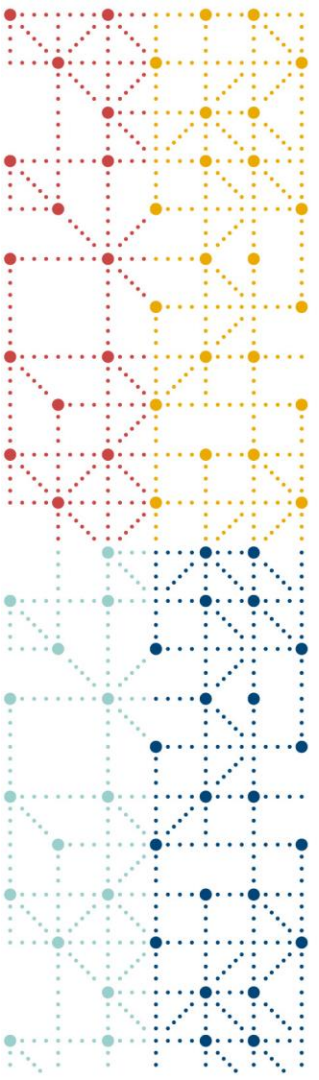


Welcome and news from CDISC

Silvia Faini and Angelo Tinazzi – E3C Member, ITA CDISC UN



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1. Welcome
2. CDISC updates
3. ITA CDISC User Network

Benvenuti! Welcome!

- 7th Italian CDISC User Network Annual Meeting

Milan 28th - 29th July 2020 → **Virtual 7th October 2020**

Cancelled

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



Grazie! Thank you!

• Supported by



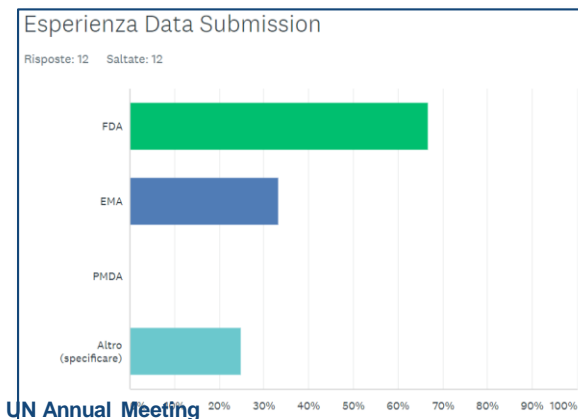
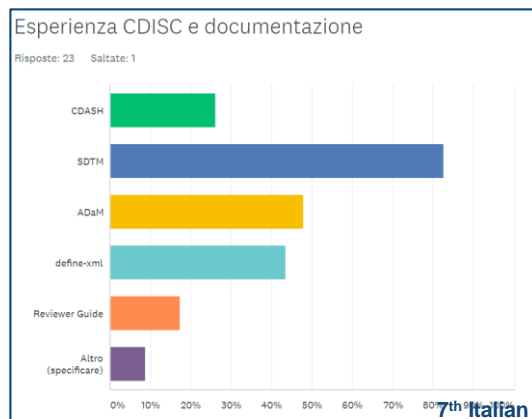
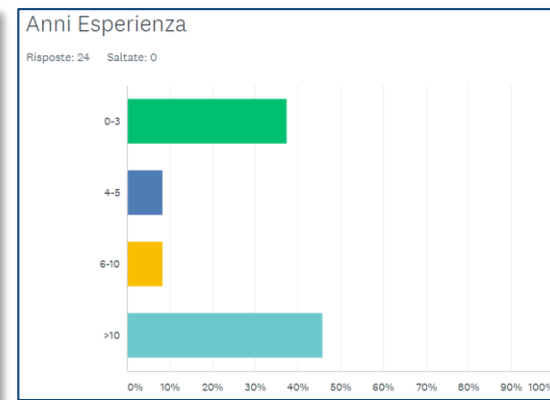
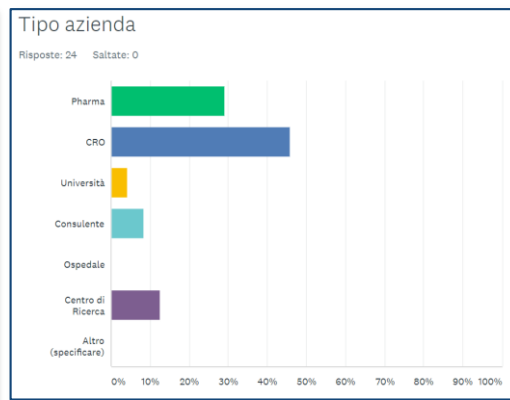
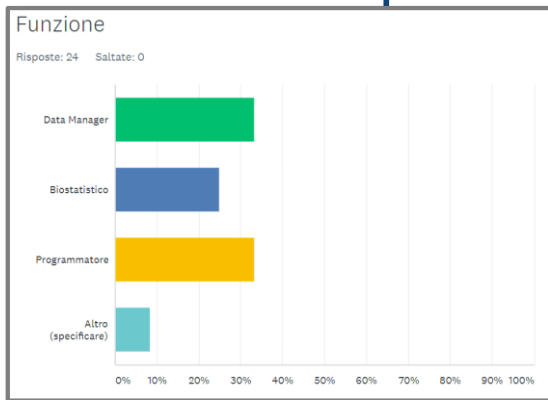
• Sponsored by



• Empowered and encouraged by



VII Italian UN was also **define-xml** and **submission ready documents** workshop with 26 attendee from 16 different companies



IBIG Activities – 2020 Virtual Forum

Date	Topic
2 October	Quantitative Decision Making (QDM) in the Clinical Drug Development
9 October	SAS, R, Python – Differences, Similarities and Potentialities of Widely Used Stats Software
16 October	Clinical Trial Management during the COVID-19 Pandemic – Guidelines and Practical Impacts
23 October	Taxonomy of Subgroup-related Analyses and Issues in Clinical Trials
30 October	Data Visualization for a Better Communication with Non-Stats People

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



A screenshot of the CDISC website showing the SDTM page. The CDISC logo is at the top left, and 'New to CDISC' and 'Standards' are at the top right. The breadcrumb trail is 'Home / Standards / Foundational / SDTM'. The main heading is 'SDTM'. Below it is a navigation menu with links: 'Description', 'Versions', 'Education', 'Knowledge Base', 'Public Review', and 'Archive'. The 'Description' link is highlighted with a red box and a red arrow. Below the navigation menu is a paragraph of text: 'SDTM provides a standard for organizing and formatting data to streamline processes in collection, management, and aggregation and warehousing; fosters mining and reuse; facilitates sharing; helps perform due diligence and other im'.

CDISC website restyling

Home / Standards / Foundational / SDTM

SDTM

Description Versions Education Knowledge Base Public Review Archive

Version	Related
SDTM v1.8 17 September 2019	SENDIG-Animal Rule v1.0
SDTM v1.7 20 November 2018	SDTMIG v3.3 SDTMIG for Medical Devices v1.1 Conformance Rules v1.1 for SDTMIG v3.2 and v3.3

CDISC website restyling

Home / Standards / Foundational / SDTM

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](#)

Home / Standards / Foundational / SDTM

SDTM

Description Versions Education Knowledge Base **Public Review** Archive

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

Home / Standards / Foundational / SDTM

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 Substance Administration with Increasing Levels of Detail](#)

Examples

[Breakdown of](#)

[Diabetes Histo](#)

[End-Stage Re](#)

[Glomerular Fil](#)

[Glomerular Fil](#)

[Hypoglycemic](#)

[Hypoglycemic](#)

Home / Standards / Foundational / SDTM

SDTM

Description Versions Education Knowledge Base Public Review **Archive**

[SDTM v1.3](#)

[SDTM v1.2](#)

[SDTM v1.1](#)

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> → 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
<https://www.cdisc.org/newsletter/issue/third-quarter-2020/cdisc-eu-interchange-2021>
- 10 - 11 Jun 2021 Japan Interchange (Virtual Event)
- 6 - 7 Aug 2021 China Interchange (Beijing, China)
- 18 - 22 Oct 2021 US Interchange (Washington, DC)

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>
 - 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)

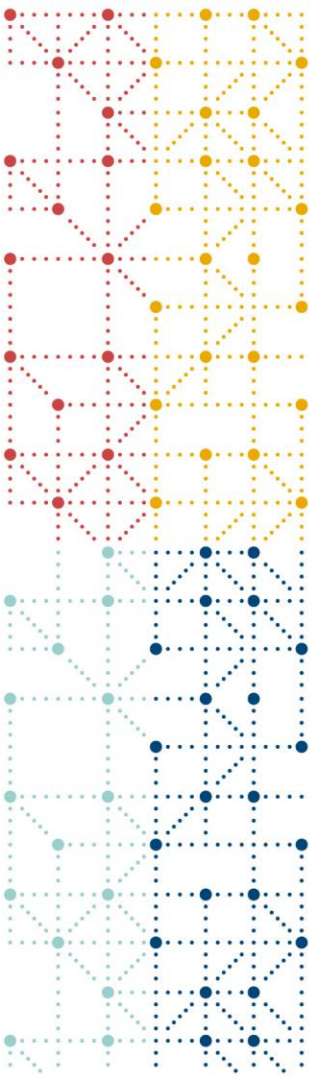


- Volunteers

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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