



CDISC Italian User Network 2021

Virtual Event | 3 December 2021





Welcome & Intro

Silvia Faini & Angelo Tinazzi

CDISC EU Committe / Italian UN Representative



Grazie per aver reso possibile questo evento !!!



Attività IBIG



15 Dicembre
Virtual

PILLOLE DI STATISTICA - Parte II
Chi troppo vuole...Gestire la molteplicità

2022

PILLOLE DI STATISTICA

2022
Ottobre

IBIG Forum

Sito **IBIG**: WWW.BIOSTATISTICI.IT

Gruppo **IBIG** su Facebook



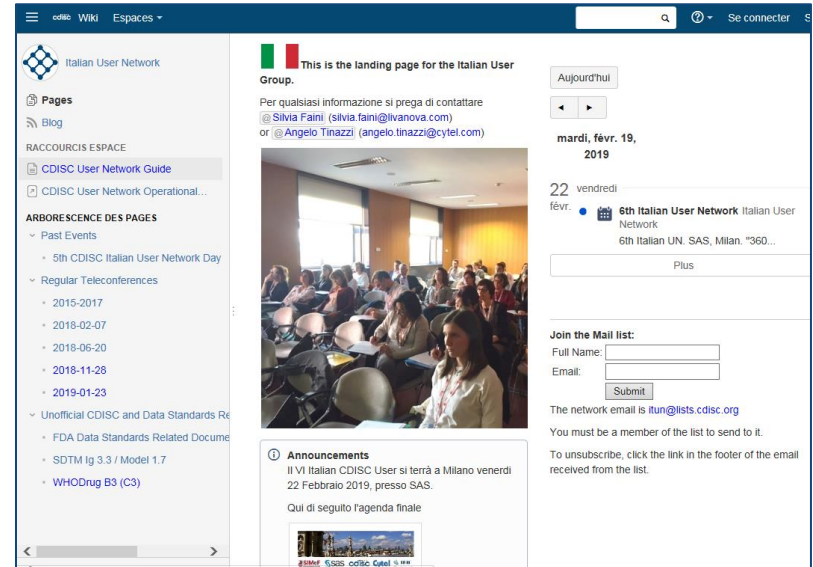
info@biostatistici.it (Mailing list - Proposte, suggerimenti, critiche, collaborazioni)

CDISC Italian UN – Un po' di Storia

Da CDISC

*CDISC User Networks discuss standards updates and developments, share implementation and learning experiences, participate in public review, and circulate feedback and new ideas to CDISC..... User Networks take place in Asia, Africa, Europe and North America with **face-to-face meetings in the respective countries** occurring on a periodic basis. CDISC offers each User Network access to our **online Wiki** to store presentations, documentation and updates*

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



The screenshot shows the landing page for the Italian User Network on the CDISC Wiki. The page features a navigation menu on the left with sections like 'Pages', 'Blog', 'RACCOURCIS ESPACE', and 'ARBORESCENCE DES PAGES'. The main content area includes a welcome message in Italian, contact information for Silvia Faini and Angelo Tinazzi, a photo of a meeting, and an announcement for the 7th Italian CDISC User meeting in Milan on February 22, 2019. There is also a 'Join the Mail list' form and a 'Plus' button.

CDISC Italian UN – Un po' di Storia (cont)

I. 2008

II. 2009

III. 2010

2014 BIAS workshop CDISC SDTM and ADaM: Moving from theory to practice

2015 CDISC DAY – ITALY

IV. 2016 – Data Standards e Loro Applicazione

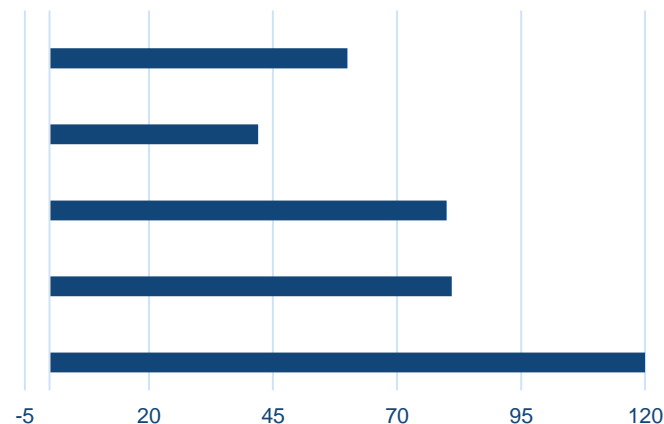
V. 2017 – Esempi Pratici di Implementazione dello standard CDISC ADaM

VI. 2019 - What's New a 360°

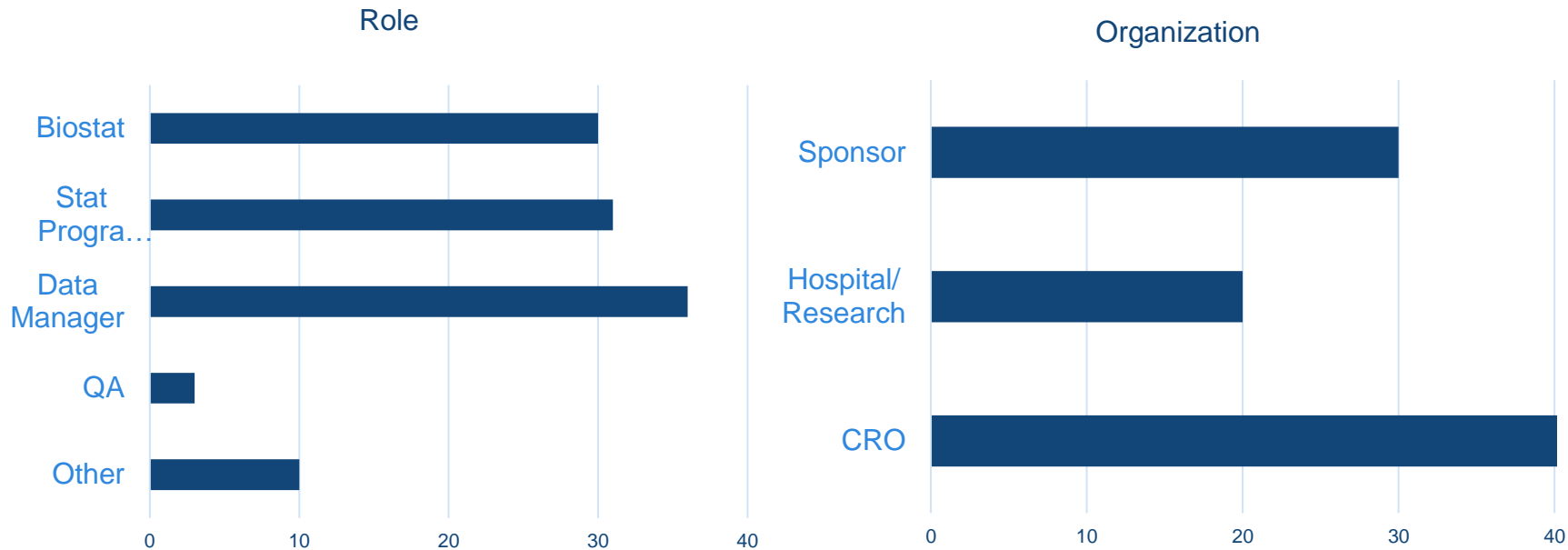
VII. 2020 – CDISC Standards Update

VIII. 2021 – Traceability (ma non solo)

Participants



VIII Italian CDISC User Network (Registered=120)





CDISC Italian UN – Un po' di Storia – Training (cont)

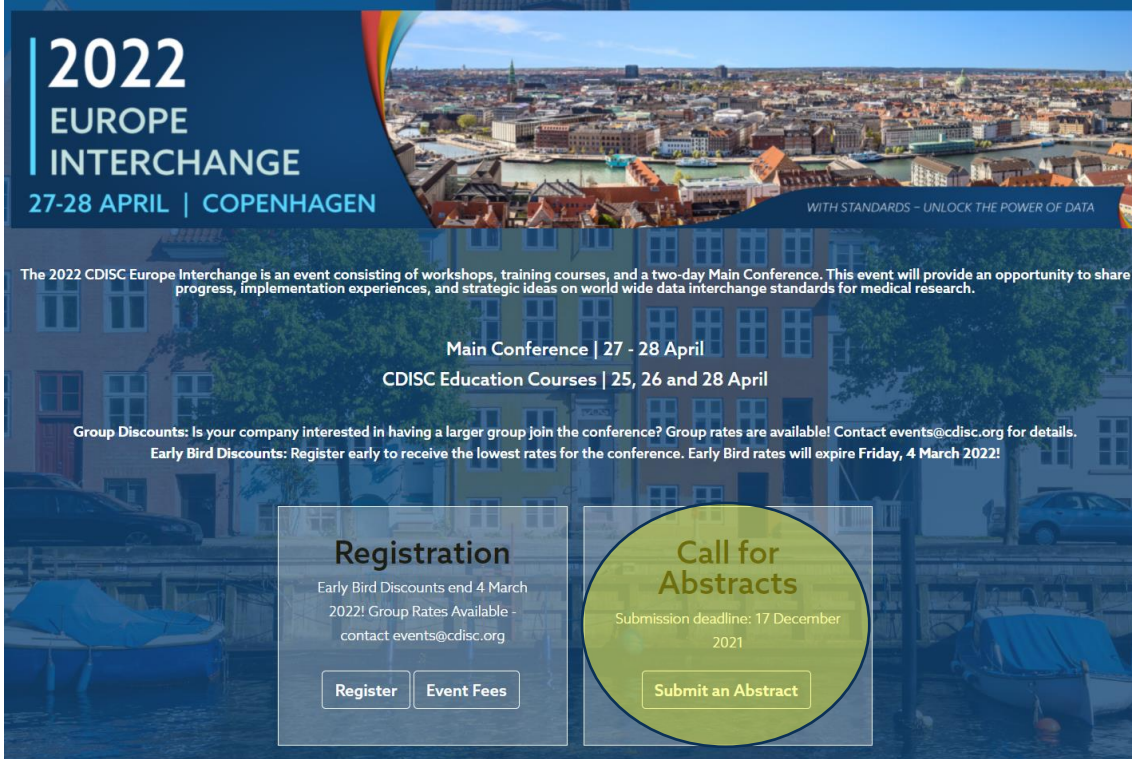
- I. 2020 CDISC-define-xml and submission-ready-documents – Ia Edizione
(27 Iscritti)
- II. 2021 CDISC-define-xml and submission-ready-documents – IIa Edizione
(11 Iscritti)

CDISC Italian UN – Come Funziona

- Silvia Faini (Cytel) e Angelo Tinazzi (Cytel) rappresentanti come membri del CDISC-EU Committee
- Condividere Esperienze
- TC Regolari almeno una per trimestre
- Un incontro F2F all'anno
- Partecipazione volontaria
 - mailing list gestita da angelo.tinazzi@cytel.com
 - CDISC Wiki Page

CDISC Events 2022

<https://www.cdisc.org/events/interchange/2022-europe-interchange>



2022
EUROPE
INTERCHANGE
27-28 APRIL | COPENHAGEN

WITH STANDARDS – UNLOCK THE POWER OF DATA

The 2022 CDISC Europe Interchange is an event consisting of workshops, training courses, and a two-day Main Conference. This event will provide an opportunity to share progress, implementation experiences, and strategic ideas on world wide data interchange standards for medical research.

Main Conference | 27 - 28 April
CDISC Education Courses | 25, 26 and 28 April

Group Discounts: Is your company interested in having a larger group join the conference? Group rates are available! Contact events@cdisc.org for details.
Early Bird Discounts: Register early to receive the lowest rates for the conference. Early Bird rates will expire Friday, 4 March 2022!

Registration
Early Bird Discounts end 4 March 2022! Group Rates Available - contact.events@cdisc.org

Call for Abstracts
Submission deadline: 17 December 2021

Register Event Fees Submit an Abstract

CDISC Standards Recent Update

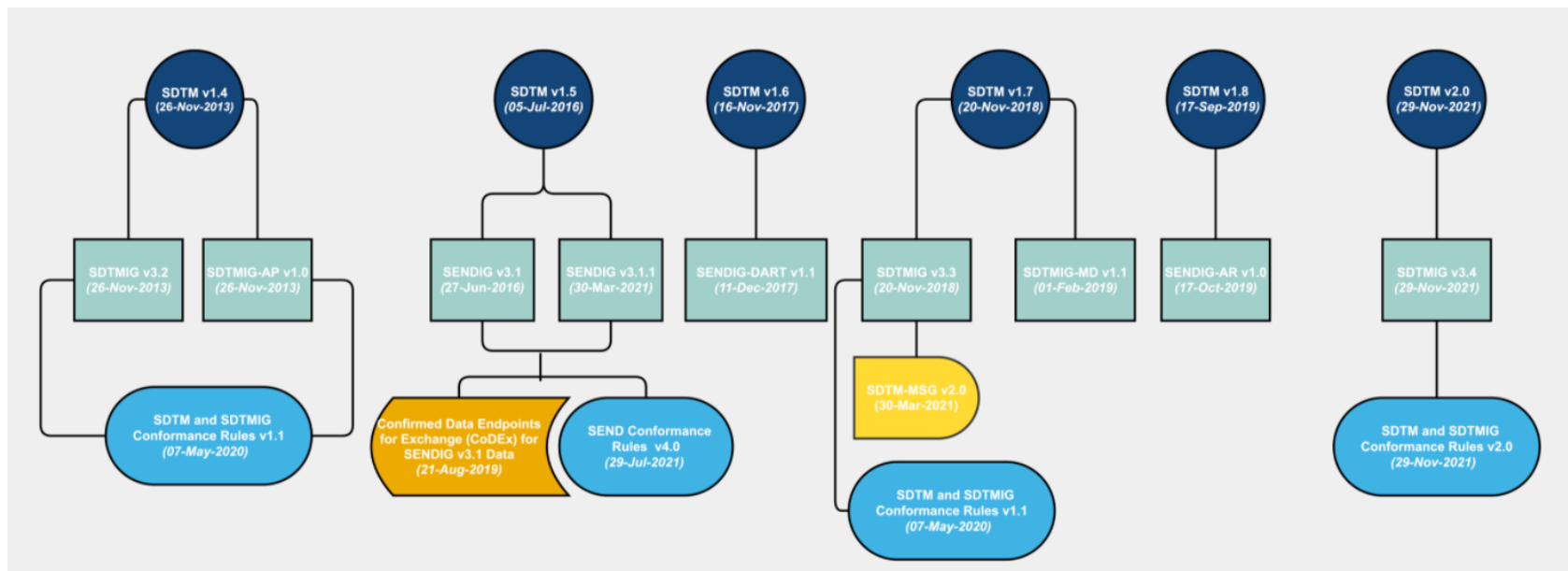
<https://www.cdisc.org/standards/publications>

- **Study Data Tabulation Model v2.0**
- **Study Data Tabulation Model Implementation Guide v3.4**
- **Conformance Rules for SDTM v2.0 and SDTMIG v3.4**
- **ADaMIG v1.3 Release Package**
 - ADaM Implementation Guide v1.3
 - ADaM Structure for Occurrence Data Implementation Guide v1.1
 - ADaM Implementation Guide for Non-compartmental Analysis Input Data v1.0**
 - ADaM Implementation Guide for Medical Devices v1.0**
 - ADaM Conformance Rules v4.0



CDISC Standards Recent Update (cont)

<https://www.cdisc.org/standards/foundational/sdtm>



CDISC Standards Recent Update (cont)

- **FHIR to CDISC Joint Mapping Implementation Guide v1.0 (Sep-2021)**
- New TAUGs
 - **COVID-19 Therapeutic Area User Guide v1.0 (Jul-2021)**
 - **Crohn's Disease Therapeutic Area User Guide v1.0 (Jul-2021)**
 - Diabetes Type 1 Therapeutic Area User Guide v1.0 - Exercise and Nutrition Modules (Jun-2021)
 - Controlled Terminology Relationships v1.0 for SDTM v1.4 and SDTMIG v3.2 (Jun-2021)
 - Diabetes Type 1 Therapeutic Area User Guide v2.0 - Pediatrics and Devices Modules (May-2021)
 - CDASH SAE Supplement v2.0 (Apr-2021)
 - Conformance Rules for Define-XML v2.1 (Mar-2021)
 - SEND IG 3.1.1 (Mar-2021)
 - SEND Conformance Rules v4.0 (Jul-2021)

CDISC Standards Recent Update (cont)

<https://www.cdisc.org/standards/in-development>

Foundational

For current versions of the standards, please visit the [Standards Home Page](#).

Standard ▲	Release Notes	Projected Publication
ADaM Examples of Traceability	Resolving Public Comments.	Q1 2022
ADaM Oncology Examples	In Development.	2022
Analysis Results Standard v1.0	In Development.	2022
Medical Devices Conformance Rules	In Development.	2022
Safety User Guide v1.0	In Development.	2022

CDISC Standards Recent Update (cont)

<https://www.cdisc.org/standards/in-development>

Therapeutic Areas

For current versions of the Therapeutic Area (TA) standards, please visit the [TA Home Page](#).

Therapeutic Area ▲	Release Notes	Projected Publication
Diabetes Type 1 Therapeutic Area User Guide - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes	Preparing for Publication	Q4 2021
Pediatrics User Guide v1.0	In Development.	2022
Rare Diseases Therapeutic Area User Guide	In Development.	Q1 2022
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	Preparing for Public Review.	2022

Agenda (1a Parte)

09:30 – 09:45 Benvenuti e Aggiornamento attività CDISC Italian User Network e dal mondo CDISC

Silvia Faini / Angelo Tinazzi (CDISC E3C IBiG)

09:45 – 10:15 Enabling traceability using the CDISC Dataset-XML Standard.

Jozef Aerts (XML4Pharma)

10:15 – 10:45 What's the Use of the Controlled Terminology?

Thierry Lambert (ADCLIN)

10:45 – 11:00 *Pausa*



Agenda (2a Parte)

11:00 – 11:30 A Governed Platform for collaboration, change management and versioning

Alberto Romanelli (SAS)

11:30 – 12:00 ADaM Traceability with Multiple Imputations

Silvia Faini (Cytel Inc)

12:00 – 12:30 ADaM Traceability in a Respiratory Trial


Paola Vaghi (Chiesi)

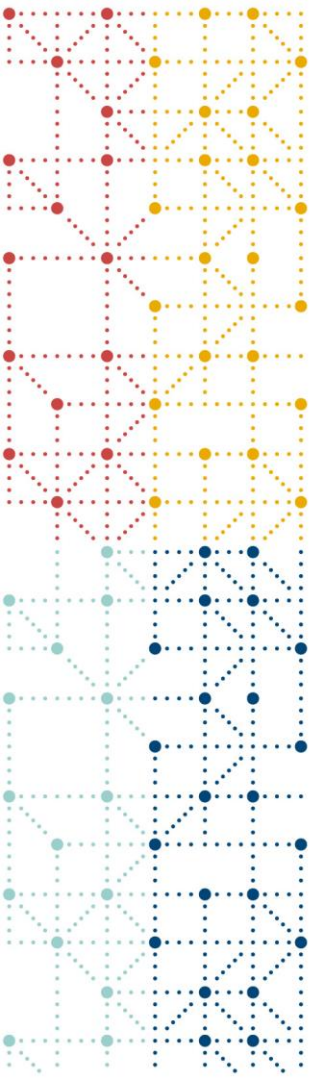
12:30 – 13:00 Doing good BIMO and News from the Data Submission Regulatory World

Angelo Tinazzi (Cytel Inc)

13:00 – 13:10 Final Q&A, Chiusura

Silvia Faini / Angelo Tinazzi (CDISC E3C IBiG)

- 
- **Certificato Partecipazione se partecipato a piu' 80% webinar**
 - **Questionario di gradimento da compilare alla fine dell'evento**
 - **Domande nella chat**



Thank You!

Silvia Faini

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Angelo Tinazzi

Angelo.tinazzi@cytel.com

