

IX CDISC Italian User Network

Milan May 12th , 2023





2023

IX ITALIAN
CDISC USER NETWORK

MILAN, 12 MAY 2023



Welcome & Intro

Silvia Faini & Angelo Tinazzi
CDISC EU Committee / CDISC Italian UN Representative

Thank You!!!





Wifi pw

lumbering-stag

SAS Survey



Marian Survey

1 question, multiple answers, 1 choice

- PollEv.com/marianmitroi554
- **‘In a randomized trial some patients took rescue medication or discontinued the study. What scenario will lead to the treatment effect estimate that was investigated? The objective was to show Superiority of treatment over placebo.’**
- You can respond once
- Anonymous (skip filling your name in)
- Will help to illustrate the need for E9(R1)



Once upon a time the Covid Pandemic ... Back to “Live”



Probably the first conference impacted by the pandemic

--EPCHGI="Y"



L'EMERGENZA SANITARIA

February 25, 2020

Coronavirus Lombardia, 68 nuovi casi e tre morti. Il prefetto di Lodi: «Non allargheremo la zona rossa»

Sono passati da 15 a 35 i check point nel Lodigiano. Fontana: «È una situazione senz'altro difficile, ma non così tanto pericolosa: il virus è molto aggressivo nella diffusione ma molto meno nelle conseguenze»

di Redazione Milano online



Once upon a time the Covid Pandemic ... Back to “Live”

From: Angelo Tinazzi <Angelo.Tinazzi@cytel.com>

Sent: 25. februar 2020 06:40

To: Stijn Rogiers <stijn.rogiers@sas.com>; Andrea Rauch <andrea.rauch@boehringer-ingenelheim.com>; SJTK (Sujit Khune) <sjtk@novonordisk.com>; Simon Lundberg <eanna.kiely@clinbuild.com>; Johannes Ulander <ju@s-cubed.dk>; Malathi Hari (MHR@larixcro.com) <MHR@larixcro.com>; Jörg Dillert (joerg.dillert@oracle.com) (joerg.dillert@oracle.com) <joerg.dillert@oracle.com>; Jörg Dillert (joerg.dillert@oracle.com) (joerg.dillert@oracle.com) <joerg.dillert@oracle.com>; Andrea Vadakin (avadakin@cdisc.org) <avadakin@cdisc.org>

Subject: CDISC Italian UN - Cancelled

Hi,

This is to inform you the Italian CDISC UN planned for this Friday in Milan has been cancelled due to the recent issue with the Corona virus in the Northern regions of Italy. This is very sad because as I mentioned last Friday we did our record with 80 registered people. We will try to re-schedule as soon as possible probably end-of-May.

Also all companies in Italy are inviting their employees to not travel unless business critical. This is for the time being only for this week, but it might be extended. I really hope this is not just the start of a general issue in Europe that could potentially impact the CDISC-EU as well (cross fingers)

Kind Regards
Angelo

Once upon a time the Covid Pandemic ... Back to “Live”

 **Silvia Faini** • You
Principal Statistical Programmer at Cytel
3yr • 

I always use LinkedIn for working purpose, but as long as I have several foreign people in my network I would like to spread an Italian initiative (draw a rainbow with a message of hope [#tuttoandrabene](#) see picture) all over EU and more... all the world is facing Covid-19, all of us are invited to stay at home, but at the same time to stay united, trusting our doctors, nurses... trusting in people! [#tuttoandrabene](#) [#everythingwillbealright](#)



  43 2 reposts

 Like  Comment  Repost  Send

Once upon a time the Covid Pandemic ... Back to “Live” No more virtual conferences

CDISC-EU 2020



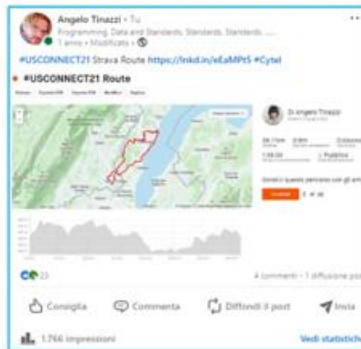
CDISC-EU 2021



PHUSE-EU 2020



PHUSE-US 2021



PHUSE-EU 2021



Once upon a time the Covid Pandemic ... Back to “Live”

No more virtual conferences

CDISC-EU 2020

Angelo Tinazzi • Tu
Programming, Data and Standards, Standards, Standards, ...
2 anni • 🌐

The virus has locked down our societies, but life goes on and while I'm getting prepared for my speech for the #CDISC EU Interchange virtual conference next Wednesday, my girls are taking care of our Sunday (Italian) lunch with meat Ravioli. Registrations to the CDISC event, and not to the lunch, will remain open until Tuesday night. #cytel

64 13 commenti • 2 diffusioni post

Consiglia Commenta Diffondi il post Invia

4.796 impressioni Vedi statistiche

- **4796+3055** Views
- **64+56** Likes
- **2** re-post
- **13+8** Comments

Jozef Aerts • 1*
2 anni ...
Passionate about standards in clinical research and healthcare, and thei...
Can I get both ravioli and the presentation? The latter will presumably still need to wait a few days ...

Anthony Chow • 1*
2 anni ...
#00B #FuelUp Career geek specializes in data standards, data modelin...
Recipe in the slide deck, please?

Consiglia 1 | Rispondi - 1 risposta

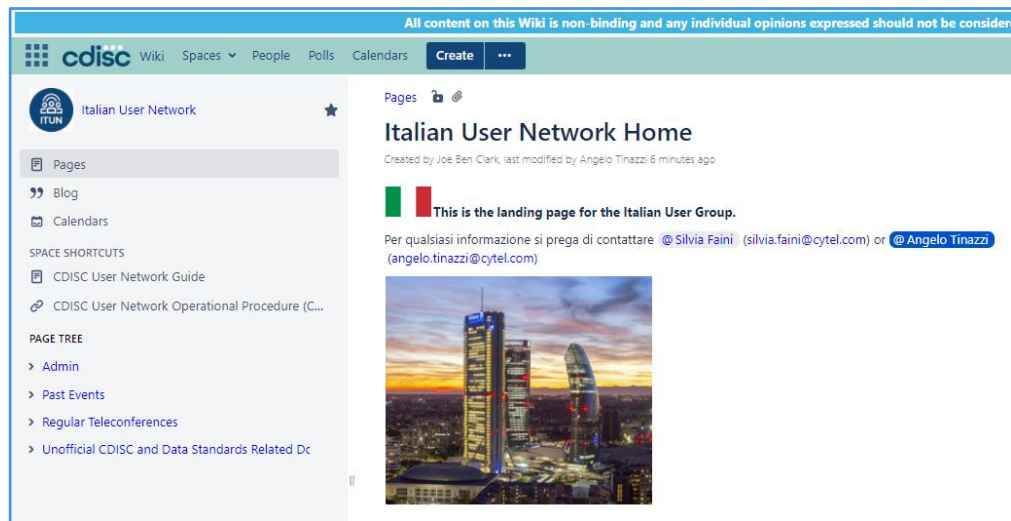
Angelo Tinazzi Autore
2 anni ...
Programming, Data and Standards, Standards, Standards, ...
I need to convince my wife :-)) I found so far a good one but just for the filling <https://www.foodandwine.com/recipes/meat-ravioli>

Consiglia | Rispondi

CDISC Italian User Network

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>



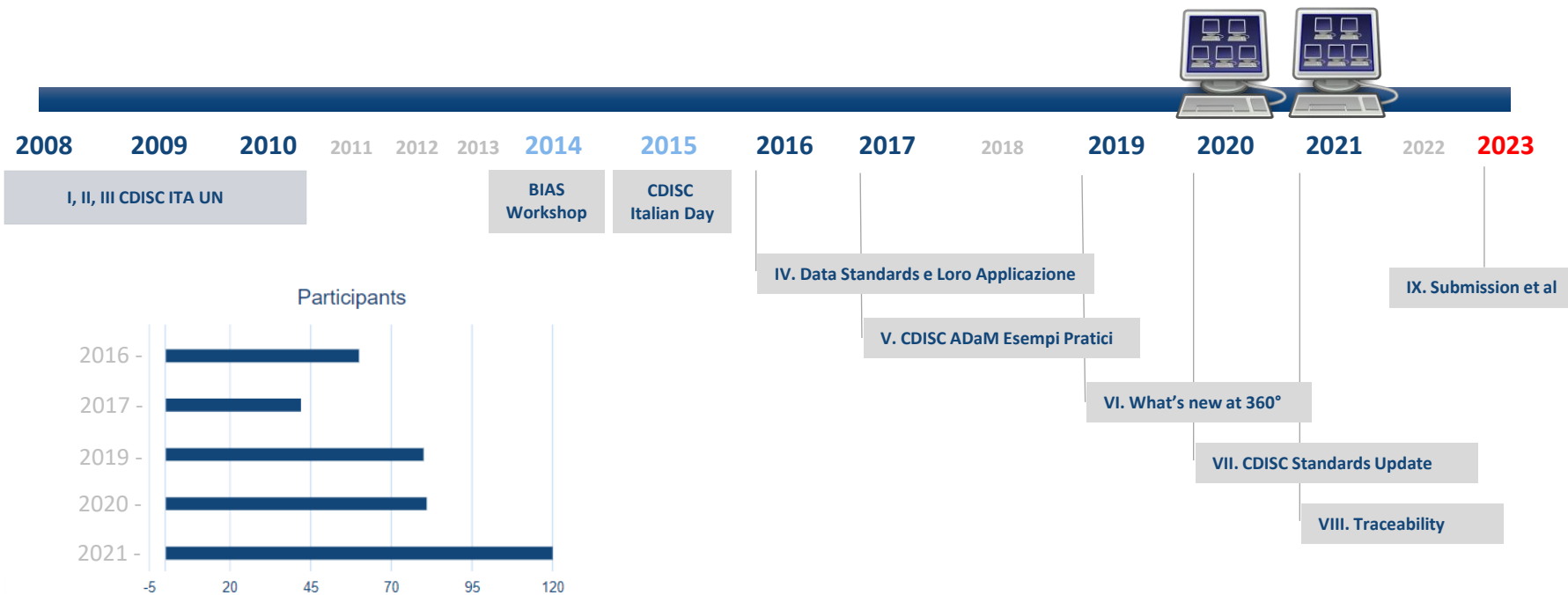
The screenshot shows the CDISC Wiki interface for the Italian User Network. The page title is "Italian User Network Home". It includes a navigation menu on the left with options like Pages, Blog, Calendars, and a Page Tree. The main content area features a header with the CDISC logo and the text "This is the landing page for the Italian User Group." Below this, there is contact information for Silvia Faini and Angelo Tinazzi, and a photograph of a modern city skyline at sunset.



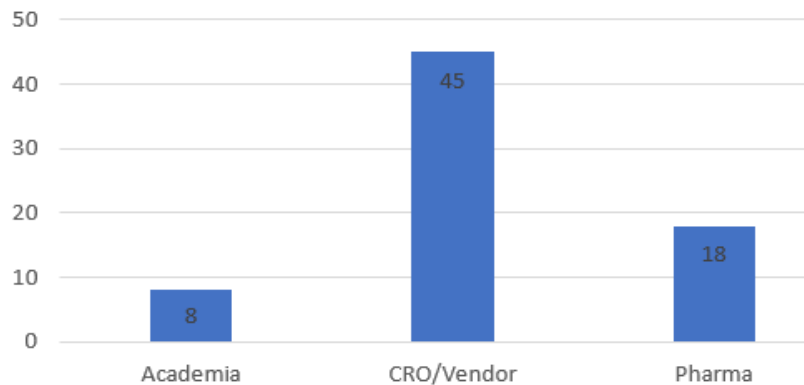
CDISC Italian User Network

- 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

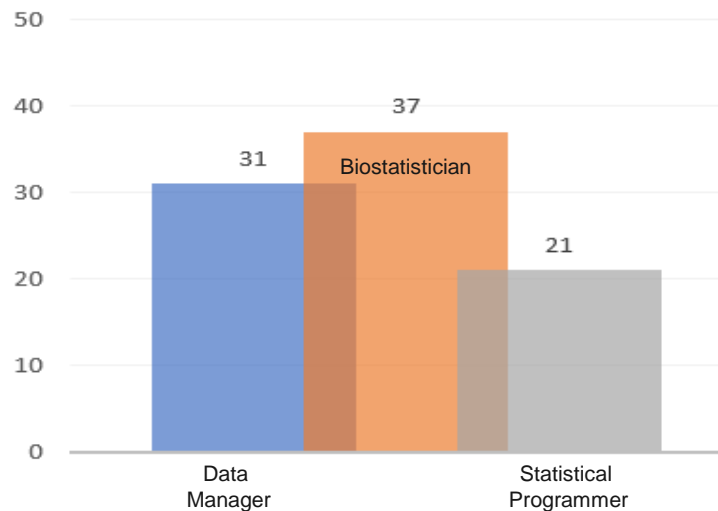
CDISC Italian UN History



Attendees



72



- **Italian Bayesian Day** l'8 settembre a Roma
- **IBIG Forum** a Milano dall'9 al 11 ottobre

Soon available at www.simef.it

SAS Pharma Masterclass 2023

An intensive course, dedicated to **Pharma sector** and data analysis with SAS through theoretical and practical lessons. Lessons will be held by SAS specialists and Cytel, one of the main providers of statistical software and advanced analytics for clinical trial design and execution.

The main goal of the masterclass is to provide the basics of **SAS Programming, data management and analysis, Statistics, Data Mining and Machine Learning models and Open Sources integration**, concluding with the SAS Programming certification exam.

Theoretical topics will also be followed by **practical lessons with use cases** on Pharma data. The **fundamentals of clinical trials** will be provided, followed by an **introduction to CDISC standards**, the current regulatory data standard that has to be used when clinical trial data is part of the application for medical approval, e.g. for drugs, medical devices, etc.

The creation and use of clinical standard datasets to support the analysis of clinical trial data will be the key part of use cases that will be completed by students. In particular, the **creation of analysis datasets in CDISC ADaM format** (the CDISC standard for dataset analysis), **aggregating and "transforming" SDTM datasets** (the CDISC format for representing collected clinical trial data), according to the rules defined in a Statistical Analysis Plan (SAP) sample that will be part of the training material.

15 DAYS / 8 WEEKS (twice a week)
27 Sept - 22 Nov 2023

LIVE WEB SESSIONS
(recorded)

Data Preparation
& Data Import
Management
(SAS 9 Platform)

Days 1-5

Analytics
Data Visualization
& Reporting

Days 6-10

SAS Viya

Days 11-15

WHAT YOU'LL LEARN

Develop skills on SAS programming, manipulate and summarize data using SAS procedures, create SAS programs that are reusable and dynamic using macros, process SAS data using Structured Query Language (SQL).

Create and use clinical standard datasets to support the analysis of clinical trial data. Work on SAS analytics and analysis relevant to Pharma industry.

Create high quality presentation reports and graphs. Get hands-on experience with SAS Viya evolutions and key benefits.

Work on SAS integration with open source.

Take part in practical exercises to analyze and work on examples and critical issues that may occur in day to day operations and activities.

Have the opportunity to gain a SAS Certification through an official SAS Exam.

Get more information or apply at formazione@ita.sas.com

- 1a Edizione
- 20 partecipanti, in Italiano
- 2a Edizione, dal 27 Settembre
- Esteso a EMA

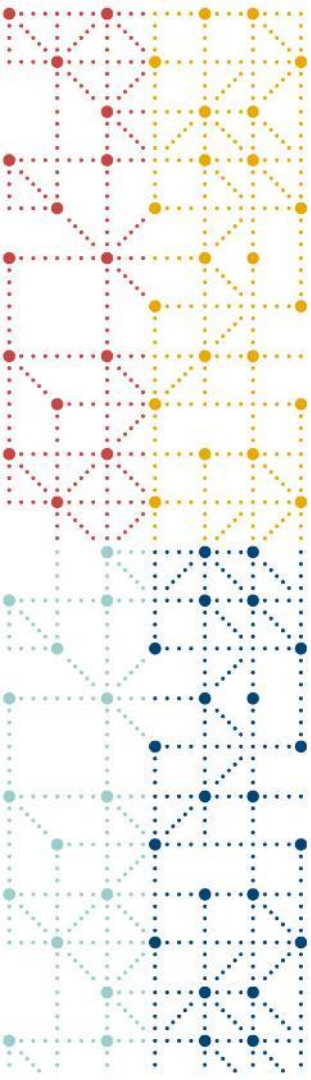
https://www.sas.com/it_it/news/leading-art-innovation/education-future/tinazzi-brazzolotto-analytics-life-science.html

Agenda

10:00	Benvenuti e Aggiornamento CDISC Italian UN SAS, IBIG, CDISC E3C
10:15	CDISC Key initiatives for 2023 and beyond Peter Van Reusel, CDISC
10:45	Introduction to ISS/ISE Florence Le Maulf, Cytel
11:15	ISS/ISE and CDISC Angelo Tinazzi, Cytel
11:45	The value of Real-World Evidence in Clinical Trials Stefano Patarnello e Marta Cicchetti, Gemelli Digital Medicine/Healthcare and SAS
12:15	Pranzo

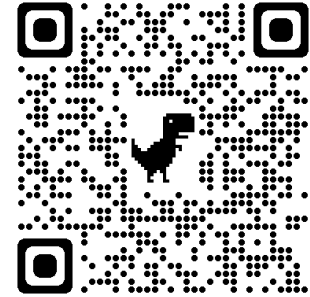
Agenda

13:30	E9(R1) Estimand Framework & CDISC Marian Mitroiu, Biogen
14:00	APIs through SAS, Endless possibilities Davide Marinucci, Alira Health
14:30	Pausa Caffè
14:50	A successful journey through FDA review - Sharing experience in a Vaccine Submission Gabriele Filippo Di Domenico, GSK
15:20	China submission preparation: lost in translation Rebecca Moretti e Glauco Cappellini, Chiesi
15:50	Clinical Studies Visualization & Analysis Marta Cicchetti, SAS
16:20	Chiusura e Novità Mondo CDISC / Final Q&A CDISC E3C



Enjoy the IX CDISC Italian UN!

Silvia Faini & Angelo Tinazzi
CDISC E3C / CDISC Italian Coordinator



IX CDISC ITALIAN USER NETWORK– Milan May 12th, 2023 | #CDISCEU #ClearDataClearImpact