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
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"
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.rogers@sas.com>; Andrea Rauch <andrea.rauch@boehringer-ingelheim.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); Andeva 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 #everythingwillbeallright
Once upon a time the Covid Pandemic ... Back to “Live”
No more virtual conferences

IX CDISC ITALIAN USER NETWORK – Milan May 12th, 2023 | #CDISCEU #ClearDataClearImpact
Once upon a time the Covid Pandemic ... Back to “Live”
No more virtual conferences

CDISC-EU 2020

- 4796+3055 Views
- 64+56 Likes
- 2 re-post
- 13+8 Comments
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](https://wiki.cdisc.org/display/ITAUG/Italian+User+Network+Home)
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
Attendees

- Academia: 8
- CRO/Vendor: 45
- Pharma: 18

72 Attendees

IX CDISC ITALIAN USER NETWORK – Milan May 12th, 2023 | #CDISCEU #ClearDataClearImpact
▪ **Italian Bayesian Day** l’8 settembre a Roma
▪ **IBIG Forum** a Milano dall’9 al 11 ottobre

Soon available at [www.simef.it](http://www.simef.it)
1a Edizione

20 partecipanti, in Italiano

2a Edizione, dal 27 Settembre

Esteso a EMA

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00</td>
<td>Benvenuti e Aggiornamento CDISC Italian UN SAS, IBIG, CDISC E3C</td>
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<tr>
<td>10:15</td>
<td>CDISC Key initiatives for 2023 and beyond</td>
<td>Peter Van Reusel, CDISC</td>
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<td>10:45</td>
<td>Introduction to ISS/ISE</td>
<td>Florence Le Maulf, Cytel</td>
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<tr>
<td>11:15</td>
<td>ISS/ISE and CDISC</td>
<td>Angelo Tinazzi, Cytel</td>
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<tr>
<td>11:45</td>
<td>The value of Real-World Evidence in Clinical Trials</td>
<td>Stefano Patarnello e Marta Cicchetti, Gemelli Digital Medicine/Healthcare and SAS</td>
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<tr>
<td>12:15</td>
<td>Pranzo</td>
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<tr>
<td>Time</td>
<td>Session Title</td>
<td>Speaker(s)</td>
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<tr>
<td>13:30</td>
<td>E9(R1) Estimand Framework &amp; CDISC</td>
<td>Marian Mitroiu, Biogen</td>
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<td>14:00</td>
<td>APIs through SAS, Endless possibilities</td>
<td>Davide Marinucci, Alira Health</td>
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<td>14:30</td>
<td>Pausa Caffè</td>
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<td>14:50</td>
<td>A successful journey through FDA review - Sharing experience in a Vaccine</td>
<td>Filippo Di Domenico, GSK</td>
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<td>15:20</td>
<td>China submission preparation: lost in translation</td>
<td>Rebecca Moretti e Glauco Cappellini, Chiesi</td>
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<td>15:50</td>
<td>Clinical Studies Visualization &amp; Analysis</td>
<td>Marta Cicchetti, SAS</td>
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<td>16:20</td>
<td>Chiusura e Novità Mondo CDISC / Final Q&amp;A</td>
<td>CDISC E3C</td>
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Enjoy the IX CDISC Italian UN!

Silvia Faini & Angelo Tinazzi
CDISC E3C / CDISC Italian Coordinator