



**CDISC Italian User Network 2019**  
Milan, Italy | 22 February 2019

**cdisc**



## Welcome & Intro

Silvia Faini & Angelo Tinazzi

CDISC EU Committe / Italian UN Representative

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Grazie per aver reso possibile questo evento !!!



# Grazie per aver reso possibile questo evento !!!



Cristina



Stefano



Peter



Massimiliano



Gabriele



Fabio



Paola



Stijin

# Grazie per aver reso possibile questo evento !!!



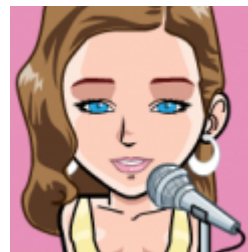
Tina



Fabrizio



Gaetano



Sabrina

# Attività IBIG



22 marzo  
Milano

***CORSO***  
**Statistica in Oncologia per non statistici:  
Concetti e metodi per studi epidemiologici e clinici**

10 maggio  
Torino

***WORKSHOP***  
**Italian Bayesian Day**

22 maggio  
Milano

***WORKSHOP***  
**Come ci adattiamo agli studi adattivi**

# Attività IBIG



**10 luglio**  
**Milano**

***CORSO***  
**Corso Avanzato di R**

**9 ottobre**  
**Milano**

***Tutorial***

- Sample size calculation
- SAS – CDISC practical applications

**10-11 ottobre**  
**Milano**

***IBIG FORUM***  
**Randomization & Blinding in CTs – Key features,  
historical and new issues, recent solutions**

Sito IBIG: [WWW.BIOSTATISTICI.IT](http://WWW.BIOSTATISTICI.IT)

Gruppo IBIG su Facebook

[info@biostatistici.it](mailto: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>

Italian User Network

This is the landing page for the Italian User Group.

Per qualsiasi informazione si prega di contattare  
@Silvia Faini (silvia.faini@ilvanova.com)  
or @Angelo Tinazzi (angelo.tinazzi@cyltel.com)

Aujourd'hui

mardi, févr. 19, 2019

22 vendredi

févr. 6th Italian User Network Italian User Network  
6th Italian UN, SAS, Milan, "360...

Plus

Join the Mail list:

Full Name:

Email:

The network email is [itun@lists.cdisc.org](mailto:itun@lists.cdisc.org)  
You must be a member of the list to send to it.

To unsubscribe, click the link in the footer of the email received from the list.

Announcements

Il VI Italian CDISC User si terrà a Milano venerdì 22 Febbraio 2019, presso SAS.

Qui di seguito l'agenda finale





# 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

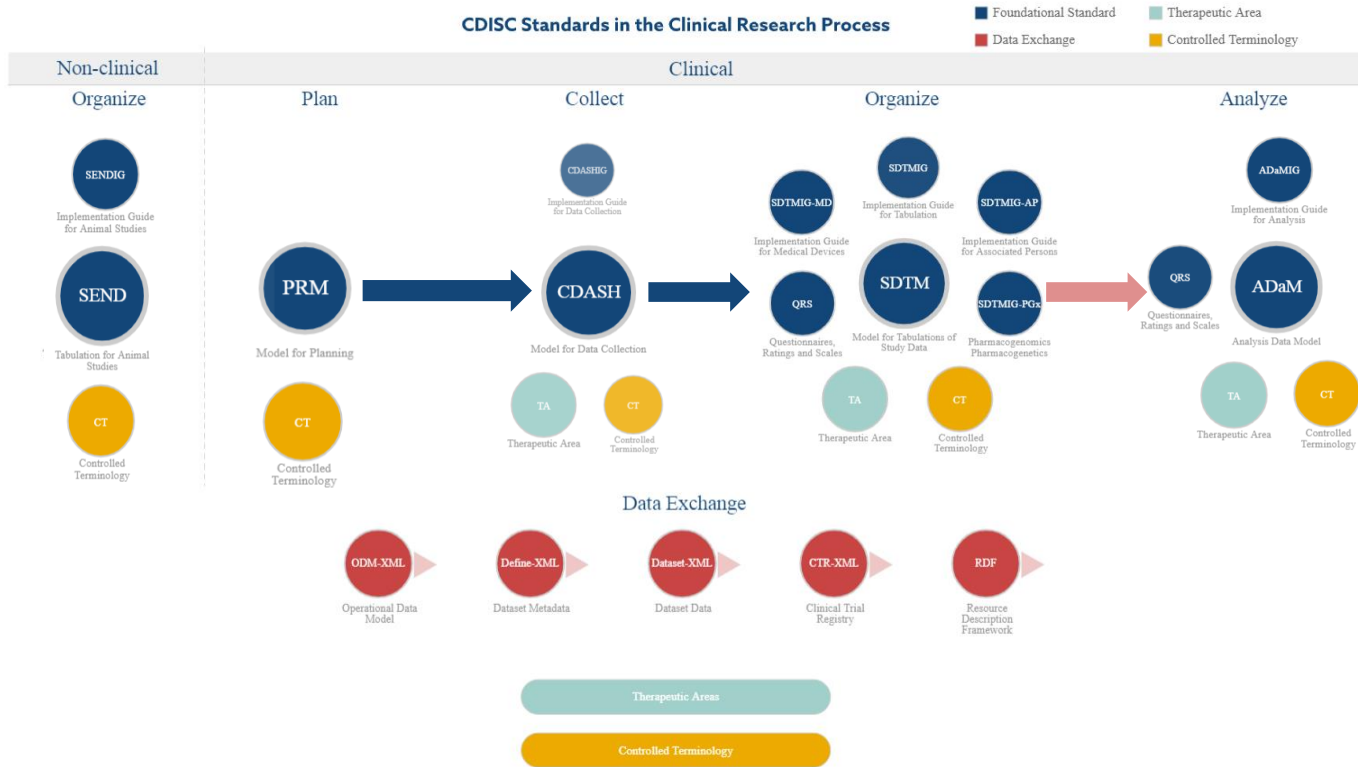
**VI. 2019 - What's New a 360°**

# CDISC Italian UN – Come Funziona

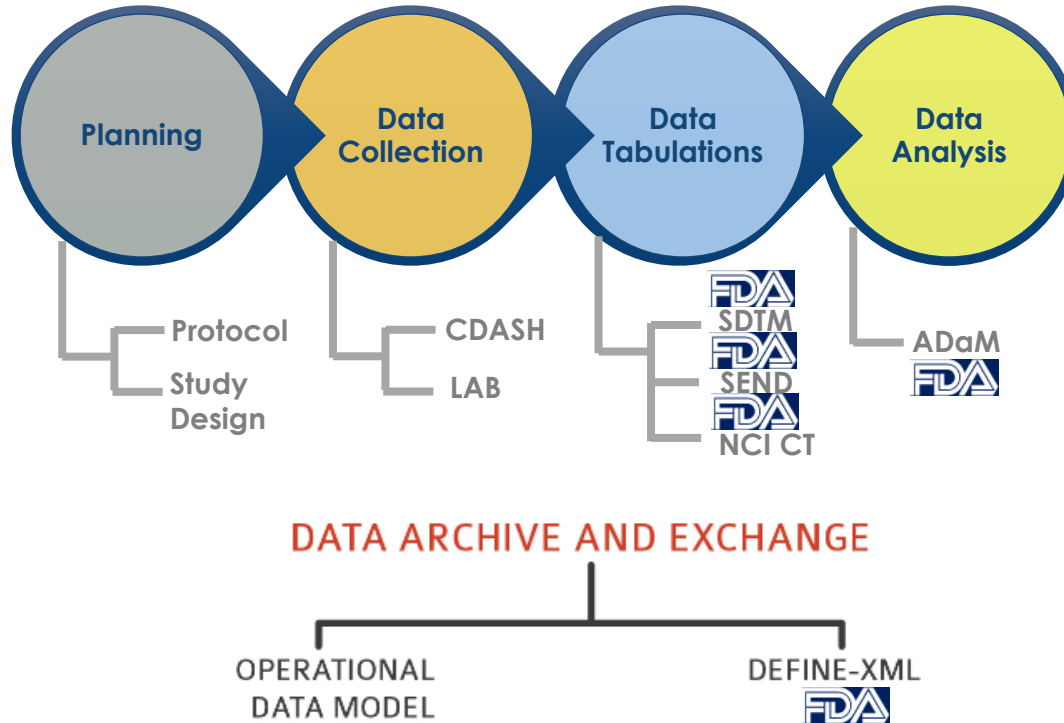
- Silvia Faini (Livanova) e Angelo Tinazzi (Cytel) rappresentanti come membri del CDISC-EU Committee
- Condividere Esperienze
- TC Regolari
- Un incontro F2F all'anno
- Partecipazione volontaria
  - mailing list gestita da [angelo.tinazzi@cytel.com](mailto:angelo.tinazzi@cytel.com)
  - Gruppo LinkedIn
  - CDISC Wiki Page
- Piu' « governance »?

# What's New a 360°

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



# What's New a 360°



# What's New a 360°

## Non dimenticatevi del CDISC Glossary!!!!

### CDISC CDISC Glossary, 2018-12-21

Source: NCI EVS Terminology Resources website: <http://www.cancer.gov/cancertopics/cancerlibrary/terminologyresources/cdisc>

NCI Code	CDISC Submission Value	Codelist Name	CDISC Definition	Codelist Extensible
C67497	<a href="#">CDISC Glossary</a>	CDISC Glossary	The terminology of the Clinical Data Interchange Standards Consortium (CDISC) glossary.	NA

### +700 Termini

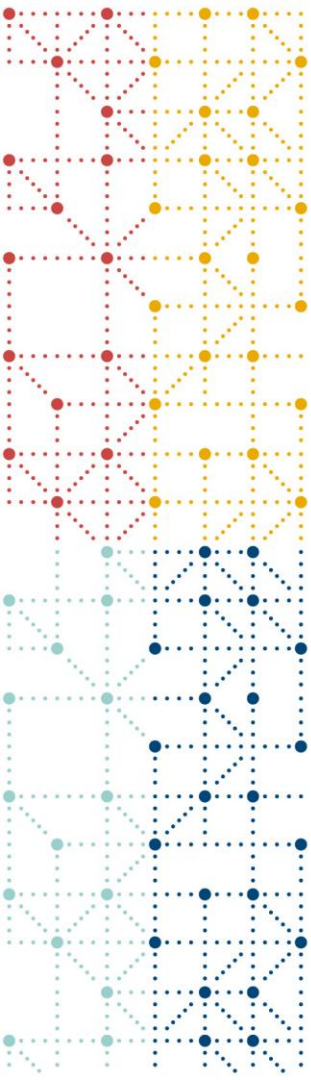
C70793	C67497	sponsor	An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. NOTE: If there is also a secondary sponsor, the responsible entity would be considered the primary sponsor. A corporation or agency whose employees conduct the investigation is considered a sponsor and the employees are considered investigators. [After ICH E6, WHO, 21 CFR 50.3 (e), and after IDMP] See also secondary sponsor.	Clinical Study Sponsor
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# Agenda (Mattino)

<b>10:00 – 10:30</b>	Benvenuti Aggiornamento attività CDISC Italian User Network	<b>SAS, IBIG e CDISC E3C</b>
<b>10:30 – 11:10</b>	CDISC 360 Project Introduction	<b>Peter Van Reusel (CDISC CSO)</b>
<b>11:10 – 11:30</b>	CDASH 2.0	<b>Cristina Rossi (Menarini)</b>
<b>11:30 – 12:05</b>	SDTM Ig 3.3	<b>Fabio Montanaro (Latis)</b>
<b>12:05 – 12:30</b>	Clinical Trial – AI Value Cases	<b>Massimiliano Cea (SAS)</b>
<b>12:30 – 13:30</b>	<i>Pranzo</i>	

# Agenda (Pomeriggio)

13:30 – 14:05	ADaM 1.2 e altro da ADaM Team	<b>Paola Vaghi (Chiesi)</b>
14:05 – 14.40	Define 2.1 / ARM / e altri WG PhUSE sul tema	<b>Silvia Faini (Livanova)</b>
14:40 – 15:00	<i>Pausa Caffè</i>	
15:00 – 15:40	Standards Management & Study Metadata Management	<b>Stijn Rogiers (SAS)</b>
15:40 – 16:10	Use Case: Real Case in Vaccine sull'implementazione dei dati da e-diary in CDISC format	<b>Gabriele Filippo Di Domenico / Stefano Lombardi (GSK)</b>
16:10 – 16:40	Therapeutic Area User Guidance Update	<b>Angelo Tinazzi (Cytel Inc)</b>
16:40 – 17:00	<b>Novità Mondo Regolatorio, Final Q&amp;A e Chiusura</b>	<b>CDISC E3C</b>



# Thank You!

Silvia Faini

[Ilvia.fiani@livanova.com](mailto:Ilvia.fiani@livanova.com)

Angelo Tinazzi

[Angelo.tinazzi@cytel.com](mailto:Angelo.tinazzi@cytel.com)

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