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 !!!
15 Dicembre  
PILLOLE DI STATISTICA - Parte II
Virtual  
Chi troppo vuole...Gestire la molteplicità

2022  
PILLOLE DI STATISTICA

2022  
IBIG Forum
Ottobre

Sito IBIG: www.biostatistici.it
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
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)
VIII Italian CDISC User Network (Registered=120)

**Role**
- Biostat
- Stat Progra...
- Data Manager
- QA
- Other

**Organization**
- Sponsor
- Hospital/Research
- CRO
CDISC Italian UN – Un po’ di Storia – Training (cont)

I. 2020 CDISC-define-xml and submission-ready-documents – la 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
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.

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<tr>
<th>Standard</th>
<th>Release Notes</th>
<th>Projected Publication</th>
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<td>ADaM Examples of Traceability</td>
<td>Resolving Public Comments.</td>
<td>Q1 2022</td>
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<td>ADaM Oncology Examples</td>
<td>In Development.</td>
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<td>Analysis Results Standard v1.0</td>
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<td>Medical Devices Conformance Rules</td>
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<td>Safety User Guide v1.0</td>
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## 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](https://www.cdisc.org/standards/in-development).

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<th>Therapeutic Area</th>
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<tr>
<td>Diabetes Type 1 Therapeutic Area User Guide - Screening, Staging and Monitoring of Pre-clinical Type 1 Diabetes</td>
<td>Preparing for Publication</td>
<td>Q4 2021</td>
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<td>Pediatrics User Guide v1.0</td>
<td>In Development.</td>
<td>2022</td>
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<tr>
<td>Rare Diseases Therapeutic Area User Guide</td>
<td>In Development.</td>
<td>Q1 2022</td>
</tr>
<tr>
<td>Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0</td>
<td>Preparing for Public Review.</td>
<td>2022</td>
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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
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<th>Time</th>
<th>Session</th>
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- **13:00 – 13:10:** Final Q&A, Chiusura by Silvia Faini / Angelo Tinazzi (CDISC E3C IBiG)
• Certificato Partecipazione se partecipato a più’ 80% webinar
• Questionario di gradimento da compilare alla fine dell’evento
• Domande nella chat
Thank You!

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