

# CDISC Italian User Network TC

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



Presented by Angelo Tinazzi (Cytel) Silvia Faini (Cytel)

14.12.2022





# Agenda

1. CDISC and Data Submission What's New
2. CDISC Webinars and Events 2022/23
3. Access to CDISC Library
4. CDISC Knowledge Base
5. Data Submission Regulatory Update
6. PHUSE 2022 EU Connect Highlights
7. Other Topics and Q&A

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



## CDISC and Data Submission What's New



# Standards publication

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

All publications available from the most recent backward.

In 2023 only “ADaM Examples of Traceability”



# Standards under public review

<https://www.cdisc.org/public-reviews>

<b>Standard/Therapeutic Area</b>	<b>Comments Due</b>
SENDIG-GeneTox v1.0	6 February 2023
ODM v2.0	31 January 2023
SEND Tumor Combinations v1.0	16 January 2023
ADaM Population Pharmacokinetics (popPK) Implementation Guide	11 January 2023



# Standards in development

<https://www.cdisc.org/standards/in-development> with projected publication in 2023

Standard	Release Notes
ADaM Metadata Submission Guidelines v1.0	Resolving Public Comments.
ADaM Oncology Examples	Resolving Public Comments.
Analysis Results Standard v1.0	In Development.
CDASHIG v2.3	In Development.
Conformance Rules for SDTMIG-Medical Devices v1.1	In Development.
Safety User Guide v1.0	In Development.
SDTM v2.1	In Development.
SDTMIG-Medical Devices v2.0 and Conformance Rules	In Development.
SENDIG v3.2	In Development.
SENDIG-DART v1.2	Resolving Public Comments.
SENDIG-Dermal Ocular v1.0	In Development.
SENDIG-Genotoxicity v1.0	In Development.
Tobacco Implementation Guide v1.0	In Development.



# Standards in development

<https://www.cdisc.org/standards/in-development> with projected publication in 2023

Standard	Release Notes
COVID-19 Therapeutic Area User Guide v2.0	In Development.
Pediatrics User Guide v1.0	Preparing for Publication (Q4 2022).
Rare Diseases Therapeutic Area User Guide	In Development.
Traditional Chinese Medicine - Acupuncture Therapeutic Area User Guide v1.0	Resolving Public Comments.



# CDISC Webinars and Events 2022/23





# EU CDISC Interchange 2023

**26-27 April 2023 – Copenhagen – Main Conference**

**Call for abstract open until January 6th**

- Novelty in Clinical Trials and CDISC Standards
  - How modernization of clinical trials is impacting CDISC standards: experience from decentralized trials, master protocols, etc.
  - World-wide events impact on CDISC standards: e.g., how interim Covid guidelines have impacted and how they have been integrated/confirmed by CDISC and/or regulatory agencies
  - Social evolution can impact clinical trials conduct and standards: share experience or initiative related to this (e.g., diversity inclusion)
- Real World Data / Evidence
- CDISC in Academic Research
- Unlocking the Power of Historic R&D Data and Opportunities in Clinical Data Sharing
- Conformance Rules and Validation, Including CDISC Open Rules Engine (CORE)
- Global Regulatory Submissions
- Standards Governance, MDR and CDISC 360 - User Experiences
- Artificial Intelligence (AI) and Impact of CDISC Standards on Business Optimization
- CDISC Foundational Standards



# EU CDISC Interchange 2023

**26-27 April 2023 – Copenhagen – Main Conference**

- Early bird discount until March 3rd
- Discounted rate for group of 10+ people
- Call for abstract open until January 6th
- Special passes to User Group participants → ITA CDISC  
UN included, stay tuned!



# Upcoming Webinars

<https://www.cdisc.org/events/webinars/upcoming>

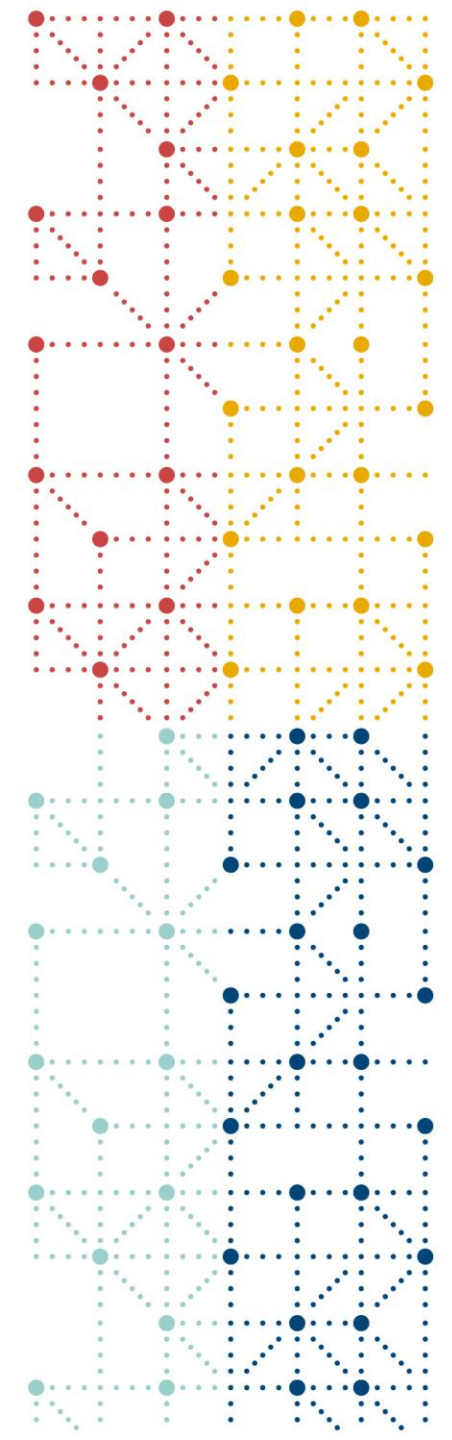
- Controlled Terminology Updates for Q4 2022 – 20DEC22
- ODM v2.0 Public Review Webinar – 12JAN23
- {admiral} Hackathon – R package to create ADaM
  - 17JAN23: Introduction to R for SAS Programmers Workshop
  - 26JAN23: Admiral Hackathon Kickoff
  - 1-28FEB23: Admiral Hackathon
- QRS Office Hours – 28FEB23
- Genomics Findings Office Hours – 30MAR23



## Recent Past Webinars

<https://www.cdisc.org/events/webinars/public>

- TFL Designer Virtual Workshop – Part I 13SEP22 and Part II 06OCT22
- COSA Spotlight for Q3 2022 – 29SEP22
- TMF Reference Model General Meeting – 13OCT22
- CORE Volunteer Onboarding Training Webinars



## Access to CDISC Library

# Access to the CDISC Library

Home / CDISC Library

## CDISC Library

Overview Available Content **Access** FAQs Product Inquiry

CDISC Library is available to **all employees** of our **Member Organizations** as well as non-members.

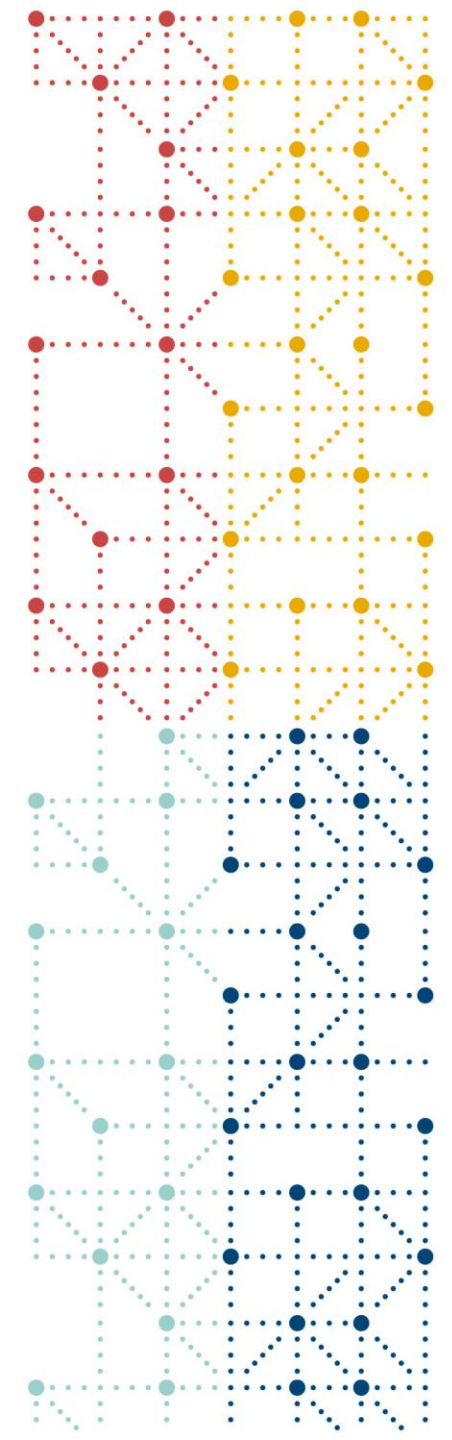
Please **create a cdiscID**, which allows Single Sign-On to CDISC Library, our website, CORE, and the CDISC Learning System.

One set of credentials allows you to download our standards from our website, leverage standards metadata via CDISC Library, run conformance checks on sample CDISC datasets with CORE, and access trainings in our Learning System.

<https://library.cdisc.org/browser/#/>

"Yes you can access the SAS Library from SAS", CDISC-Eu Interchange 2021

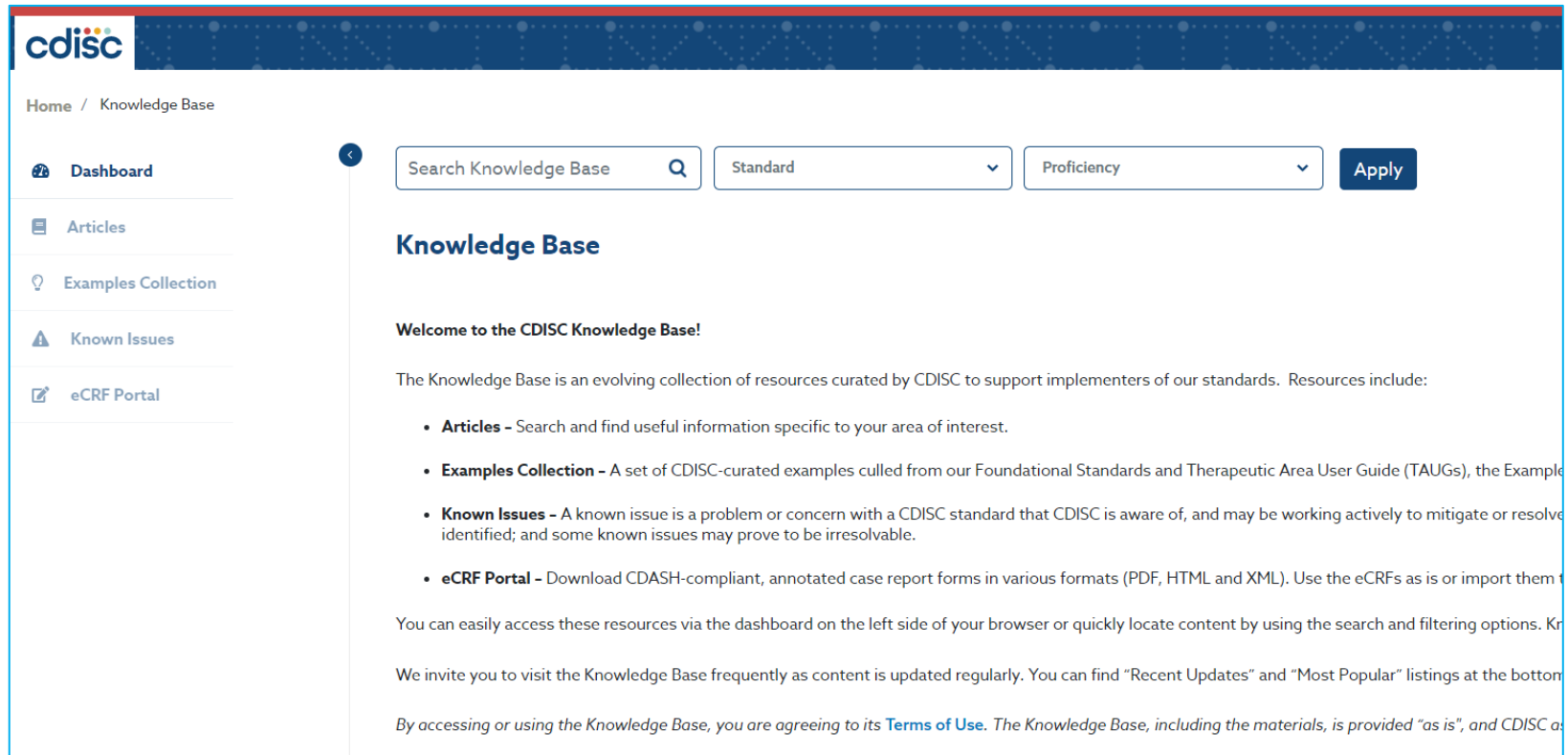




# CDISC Knowledge Base

# CDISC Knowledge Base

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



The screenshot shows the CDISC Knowledge Base website. At the top left is the CDISC logo. Below it is a breadcrumb trail: Home / Knowledge Base. A left-hand navigation menu contains links for Dashboard, Articles, Examples Collection, Known Issues, and eCRF Portal. The main content area features a search bar labeled 'Search Knowledge Base' with a magnifying glass icon, and two dropdown menus for 'Standard' and 'Proficiency', followed by an 'Apply' button. Below the search filters is the heading 'Knowledge Base' and a sub-heading 'Welcome to the CDISC Knowledge Base!'. The main text explains that the Knowledge Base is an evolving collection of resources curated by CDISC to support implementers of their standards. It lists three resource types: Articles, Examples Collection, and eCRF Portal. The text concludes with an invitation to visit frequently and a disclaimer about the Terms of Use.

cdisc

Home / Knowledge Base

Dashboard

Articles

Examples Collection

Known Issues

eCRF Portal

Search Knowledge Base

Standard

Proficiency

Apply

## Knowledge Base

### Welcome to the CDISC Knowledge Base!

The Knowledge Base is an evolving collection of resources curated by CDISC to support implementers of our standards. Resources include:

- **Articles** - Search and find useful information specific to your area of interest.
- **Examples Collection** - A set of CDISC-curated examples culled from our Foundational Standards and Therapeutic Area User Guide (TAUGs), the Example
- **Known Issues** - A known issue is a problem or concern with a CDISC standard that CDISC is aware of, and may be working actively to mitigate or resolve identified; and some known issues may prove to be irresolvable.
- **eCRF Portal** - Download CDASH-compliant, annotated case report forms in various formats (PDF, HTML and XML). Use the eCRFs as is or import them t

You can easily access these resources via the dashboard on the left side of your browser or quickly locate content by using the search and filtering options. Kr

We invite you to visit the Knowledge Base frequently as content is updated regularly. You can find "Recent Updates" and "Most Popular" listings at the bottom

*By accessing or using the Knowledge Base, you are agreeing to its [Terms of Use](#). The Knowledge Base, including the materials, is provided "as is", and CDISC a*





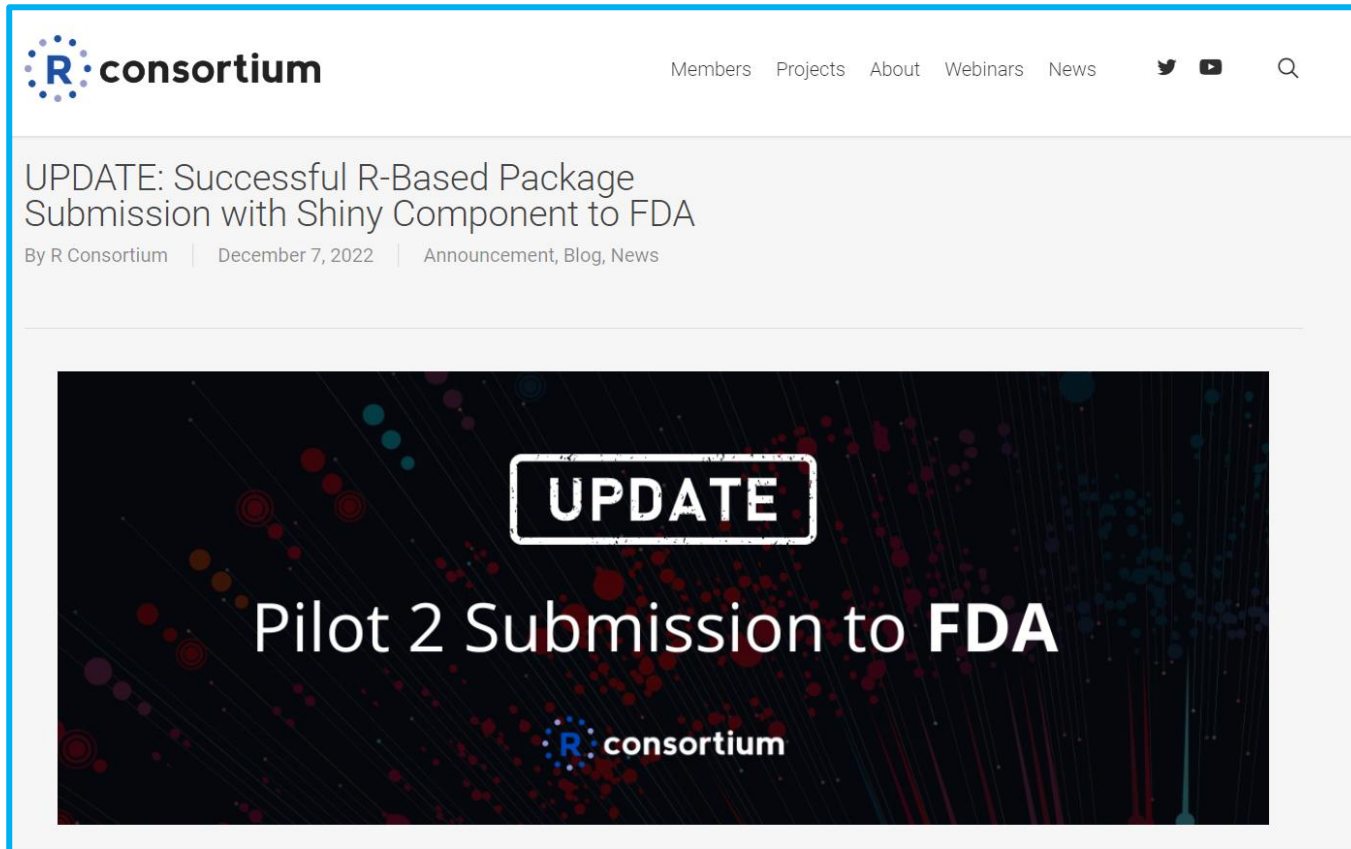
# Data Submission Regulatory Update






# Data Submission Regulatory Update

- «FDA Study Data Technical Conformance Guide v5.0 October 2022» **NO MAJOR UPDATE**
- From «FDA Data Stds Catalog\_8.01.2022 (v8.2)», Studies started after March 15, 2023 should use:
  - SDTM Ig 3.3
  - Define.xml 2.1
  - Any ADaM Ig(s), 1.1, 1.2, 1.3

# Data Submission Regulatory Update



The screenshot shows the R Consortium website header with navigation links for Members, Projects, About, Webinars, and News, along with social media icons for Twitter and YouTube, and a search icon. The main content area features a large black banner with the text 'UPDATE' in a white box, followed by 'Pilot 2 Submission to FDA' in large white font, and the R Consortium logo at the bottom. The background of the banner is dark with colorful dots and lines.

**R consortium** Members Projects About Webinars News   

UPDATE: Successful R-Based Package Submission with Shiny Component to FDA

By R Consortium | December 7, 2022 | Announcement, Blog, News

**UPDATE**

Pilot 2 Submission to **FDA**

**R consortium**

<https://github.com/RConsortium/submissions-pilot1-to-fda>

<https://github.com/RConsortium/submissions-pilot2-to-fda>

<https://rconsortium.shinyapps.io/submissions-pilot2>

# Data Submission Regulatory Update



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## EMA launches pilot project on analysis of raw data from clinical trials [← Share](#)

News 12/07/2022

EMA has launched a pilot project to assess whether the analysis of 'raw data' from clinical trials by regulatory authorities improves the evaluation of marketing authorisation applications (MAAs) for new medicines as well as post-authorisation applications and to explore the practical aspects of the submission and analysis of such data.

Raw data constitutes individual patient data from clinical studies<sup>1</sup> in electronic structured format that is directly accessible for analysis and visualisation. Examples of raw data include records of original observations and measurements of clinical study participants, such as clinical laboratory results, imaging data, and patient medical charts. Currently, the European medicines regulatory system does not routinely require the



# PHUSE 2022 EU Connect Highlights



# PHUSE 2022 EU Connect Highlights

- Several Presentations on use of R
- Summary to be provided .....
- Highlights from Angelo Presentation “The Integration Dilemma”  
(<https://www.cytel.com/blog/reintegration-dilemma>)

# PHUSE 2022 EU Connect Highlights

“The Integration Dilemma”, A. Tinazzi – PHUSE EU 2022



**Integrated Summary of Safety (ISS)** is required by the US FDA



This is a **detailed integrated analysis** of all relevant data **from individual studies**



The aim is to provide a **more robust safety profile** across different populations



**Integrated Summary of Efficacy (ISE)** might be also needed



With ISS, and ISE, **a single database is formed by pooling** the results of all concerned studies

# PHUSE 2022 EU Connect Highlights

“The Integration Dilemma”, A. Tinazzi – PHUSE EU 2022

## Data Integration - Things to take care with Data Integration

Integration Strategies in Support of ISS/ISE Submissions – PHUSE White Paper 2020

2020

Fri. 26 Mar. 2021

Expert Answers to Community Questions” PHUSE webinar Friday March 26th, 2021

- Subjects participating to **more than one study**
- **Medical dictionaries up-versioning** e.g., MedDRA
- **Terminology alignment** used by different studies for major items and when applicable and possible e.g., CDISC-CT, Visit Naming Conventions
- **Standard Unit Conversion** e.g., labs
- **Data Filtering** e.g., not all laboratory parameters need to be integrated
- **CDISC Conformance**



# PHUSE 2022 EU Connect Highlights

“The Integration Dilemma”, A. Tinazzi – PHUSE EU 2022

## Data Integration - Things to take care with Data Integration

- **ADaM Integration (iADaM)** is required to support all ISS (and ISE) analysis
- The question: **what should be the source of iADaM?**
- 3 options are provided in the PHUSE White Paper
  - **Integrate from SDTM(s)**
  - **Integrate from ADaM(s)**
  - **Create an intermediate iSDTM from which iADaM is derived**
- In all three scenario, integration from **both legacy, either raw data or analysis datasets, and CDISC datasets**, is allowed

Integration Strategies in Support of ISS/ISE Submissions – PHUSE White Paper 2020

2020

Fri. 26 Mar. 2021

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# PHUSE 2022 EU Connect Highlights

“The Integration Dilemma”, A. Tinazzi – PHUSE EU 2022

## Conclusions



[ADaM Data Structures for Integration Document](#) → Status?

[PhUSE Integrated Reviewer Guide for ADaM \(iADRG\)](#) → Under Finalization

More.....

All content on this Wiki is non-binding and any individual opinions expressed should not be considered indicative of the policies or positions of CDISC or any other organization

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Pages / Italian User Network Home  
/ Regular Teleconferences

## 2022-12-14

Created by Angelo Tinazzi, last modified just a moment ago

Agenda (copy of the slides)

- CDISC and Data Submission What's New
- CDISC Webinars and Events 2022/23
- Access to CDISC Library
- CDISC Knowledge Base
- Data Submission Regulatory Update
- PHUSE 2022 EU Connect Highlights
- Other Topics and Q&A

Additional Material:

- FDA Technical Study Data Conformance Guidance - October 2022 (3 - StudyDataTechnicalConformanceGuide\_v5.0\_Oct\_2022\_Final\_0.pdf)
- "ADaM Traceability" (ADaM\_Traceability\_Examples\_v1.0.pdf)
- "Yes you can access the SAS Library from SAS" (CDISC-2021-Europe-YesYouCanAccessCDISCLibraryFromSAS-Tinazzi-Paper.pdf) - Presentation from CDISC EU 2021
- "The Integration Dilemma", Angelo Tinazzi (PAP\_S109.pdf) - Presentation from PHUSE EU 2022

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Calendars

SPACE SHORTCUTS

- CDISC User Network Guide
- CDISC User Network Operational Procedure (COP-011)

PAGE TREE

- > Admin
- > Past Events
- > Regular Teleconferences
  - 2015-2017
  - 2018-02-07
  - 2018-06-20
  - 2018-11-28
  - 2019-01-23
  - 2020-07-01
  - 2021-03-03
  - 2021-09-22
  - 2022-03-30
  - 2022-06-29
  - **2022-12-14**

# Thank You!

Angelo Tinazzi

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

Silvia Faini

[silvia.faini@cytel.com](mailto:silvia.faini@cytel.com)

