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

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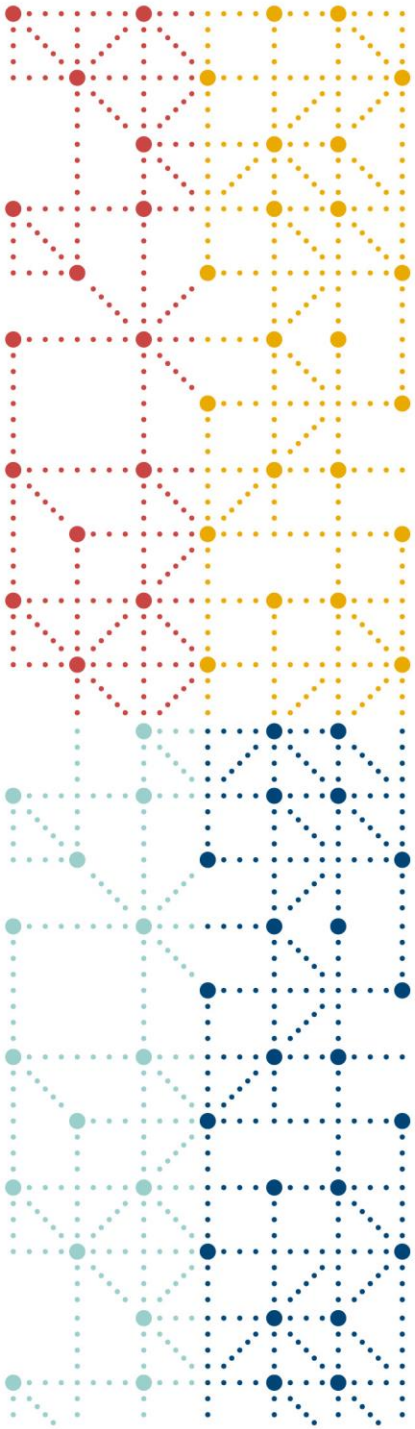


CDISC and Data Submission What's New

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

Standard/Therapeutic Area	Comments Due
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

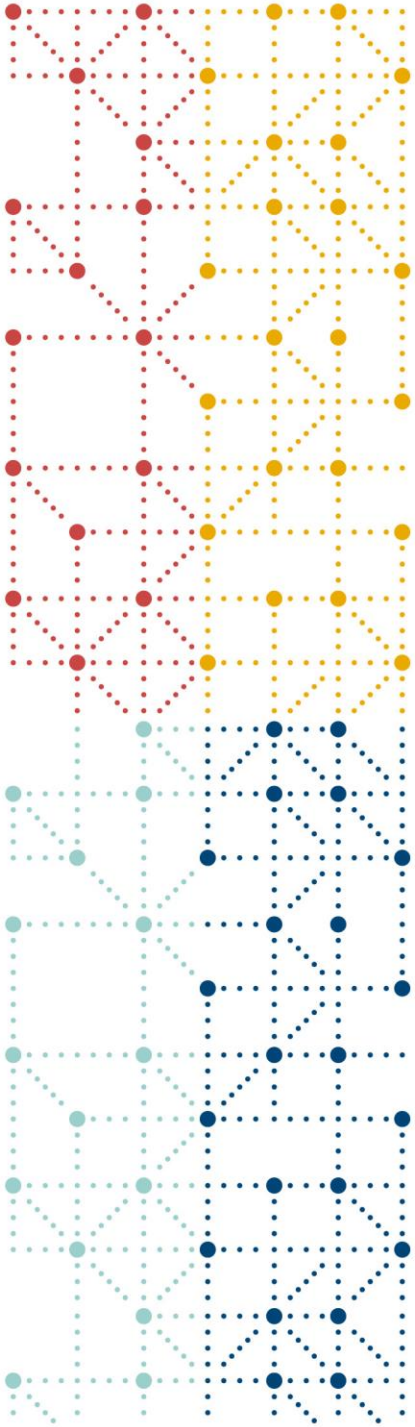
https://www.cdisc.org/standards/in-development with projected publication in 2023

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

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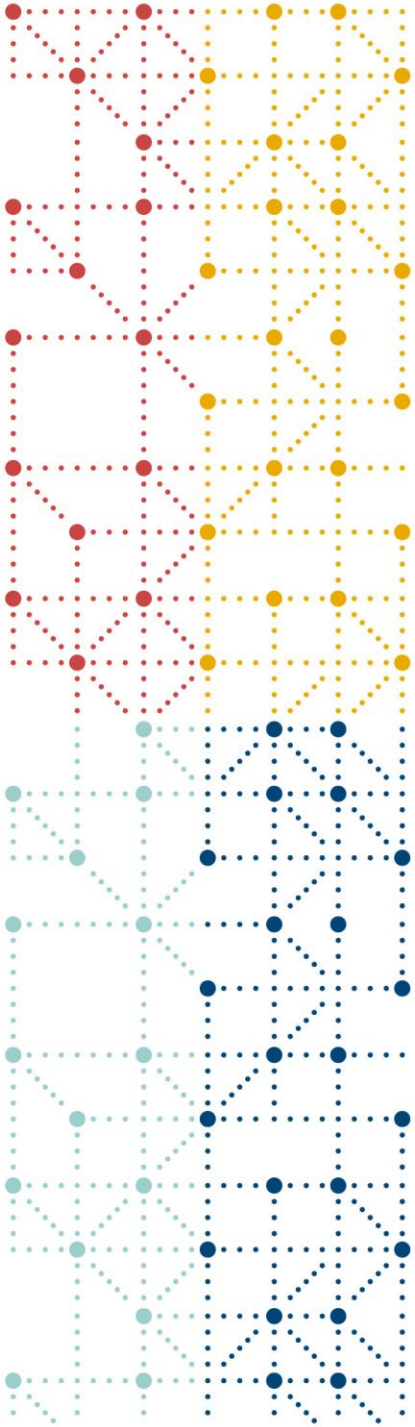
Recent Past Webinars

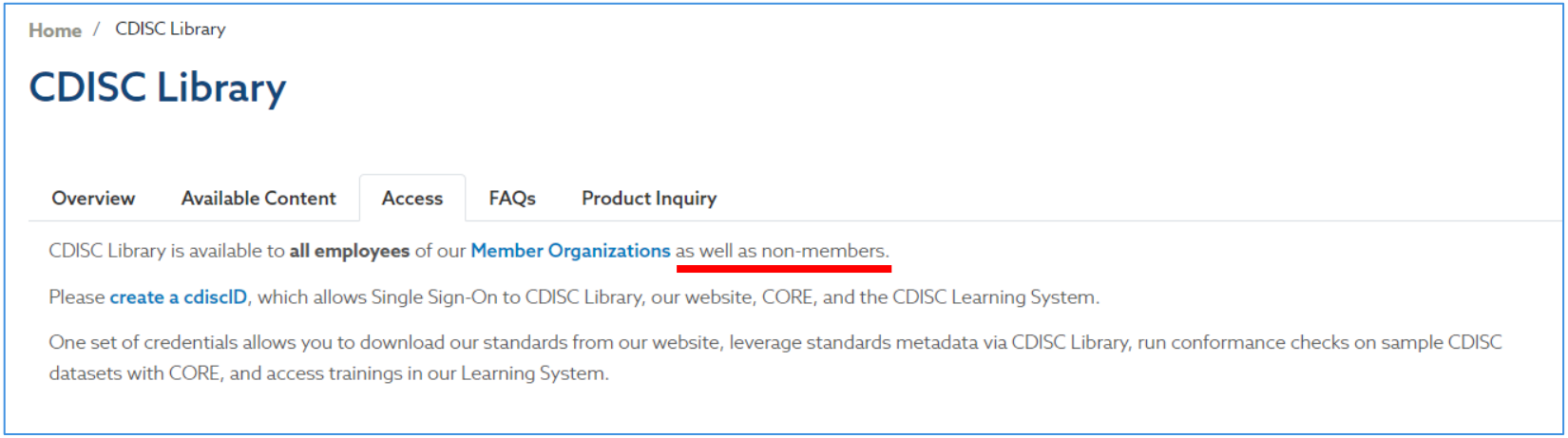
https://www.cdisc.org/events/webinars/public

- 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



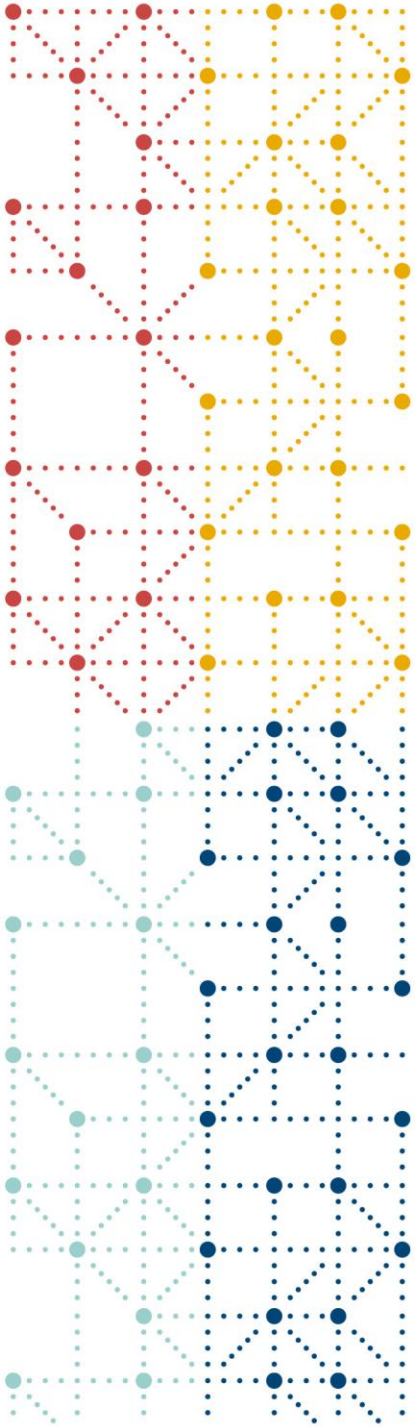
Access to CDISC Library

Access to the CDISC Library



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

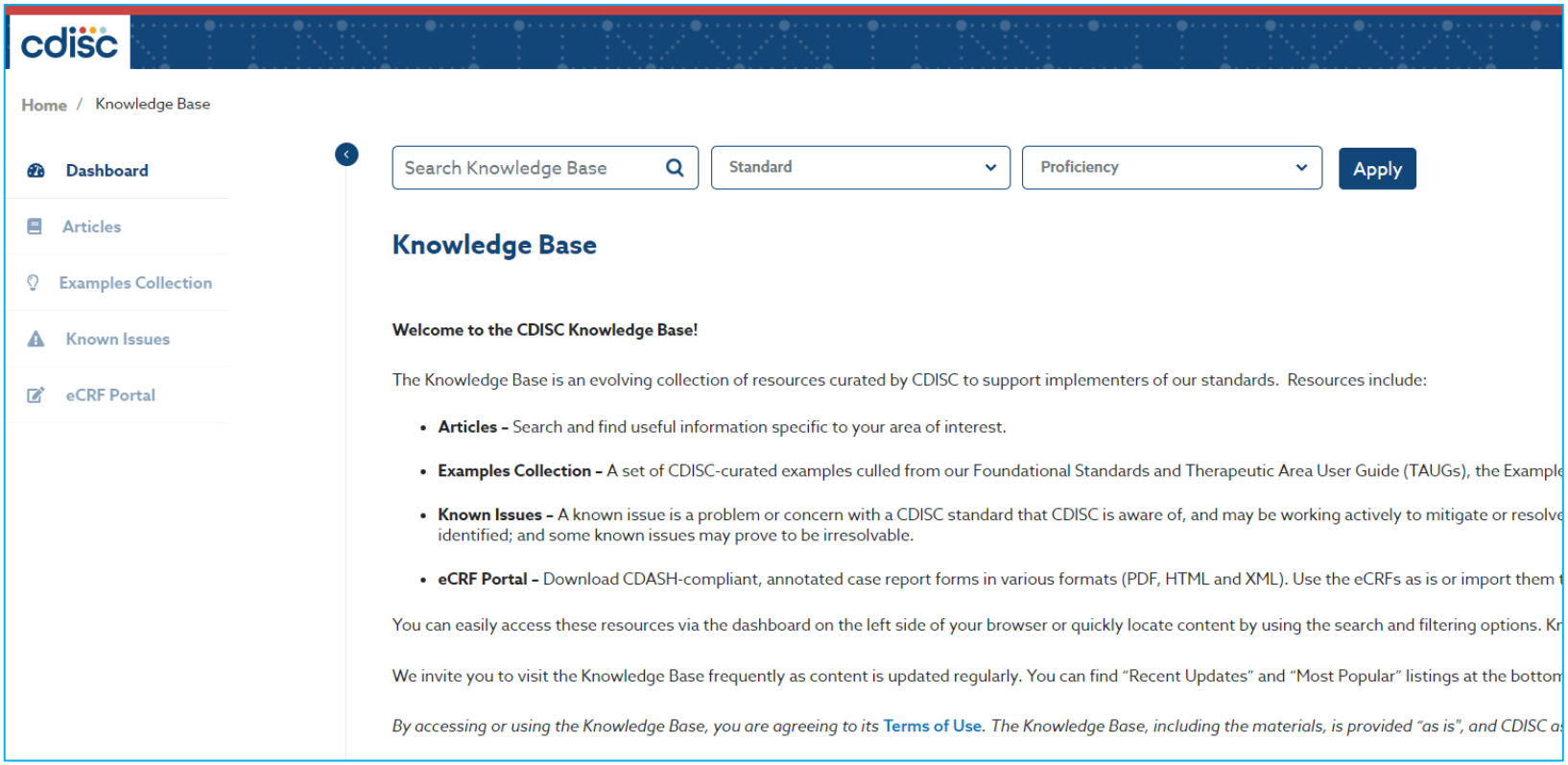
"Yes you can access the SAS Library from SAS“, CDISC-Eu Interchange 2021



CDISC Knowledge Base

CDISC Knowledge Base

https://www.cdisc.org/kb



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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

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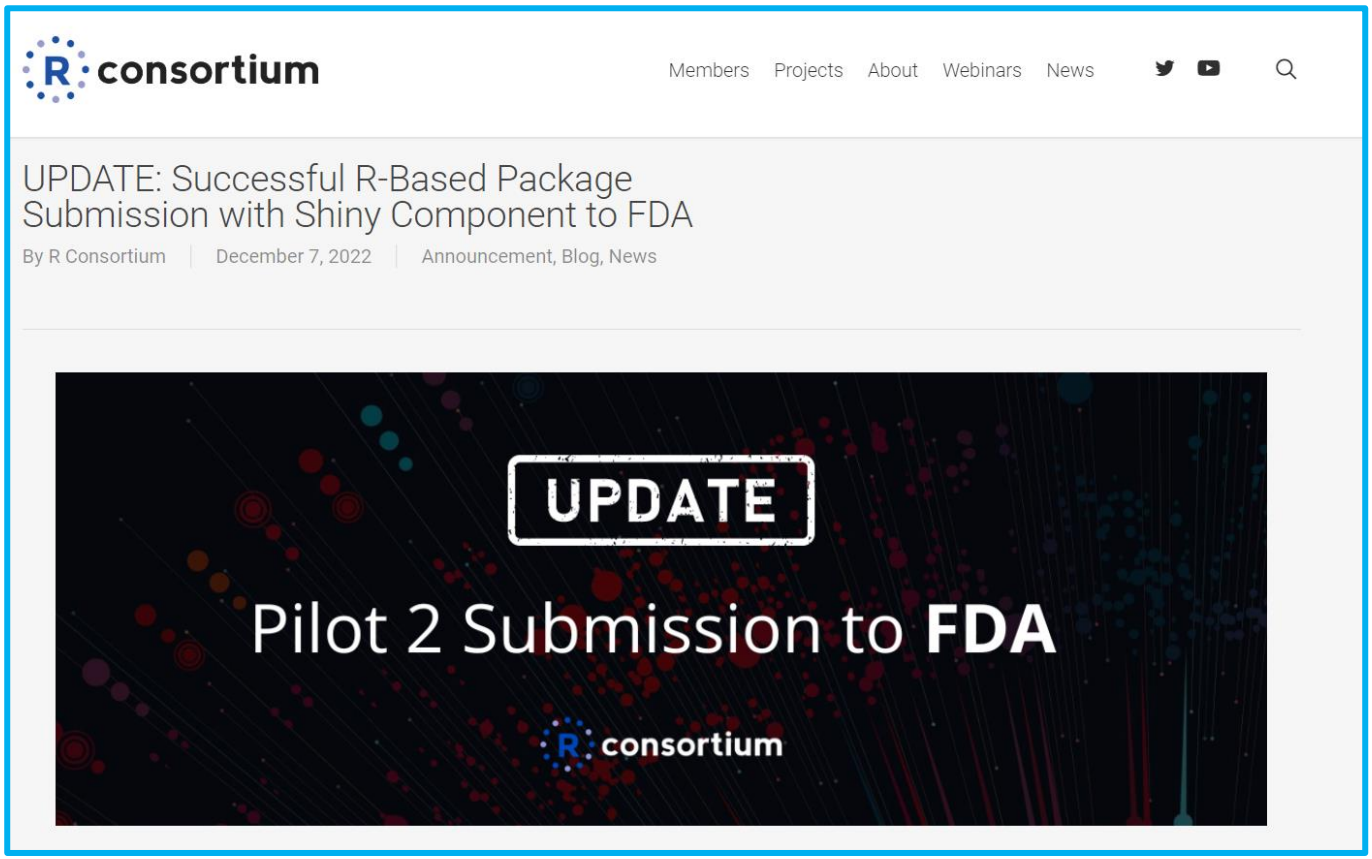
Data Submission Regulatory Update



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

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

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

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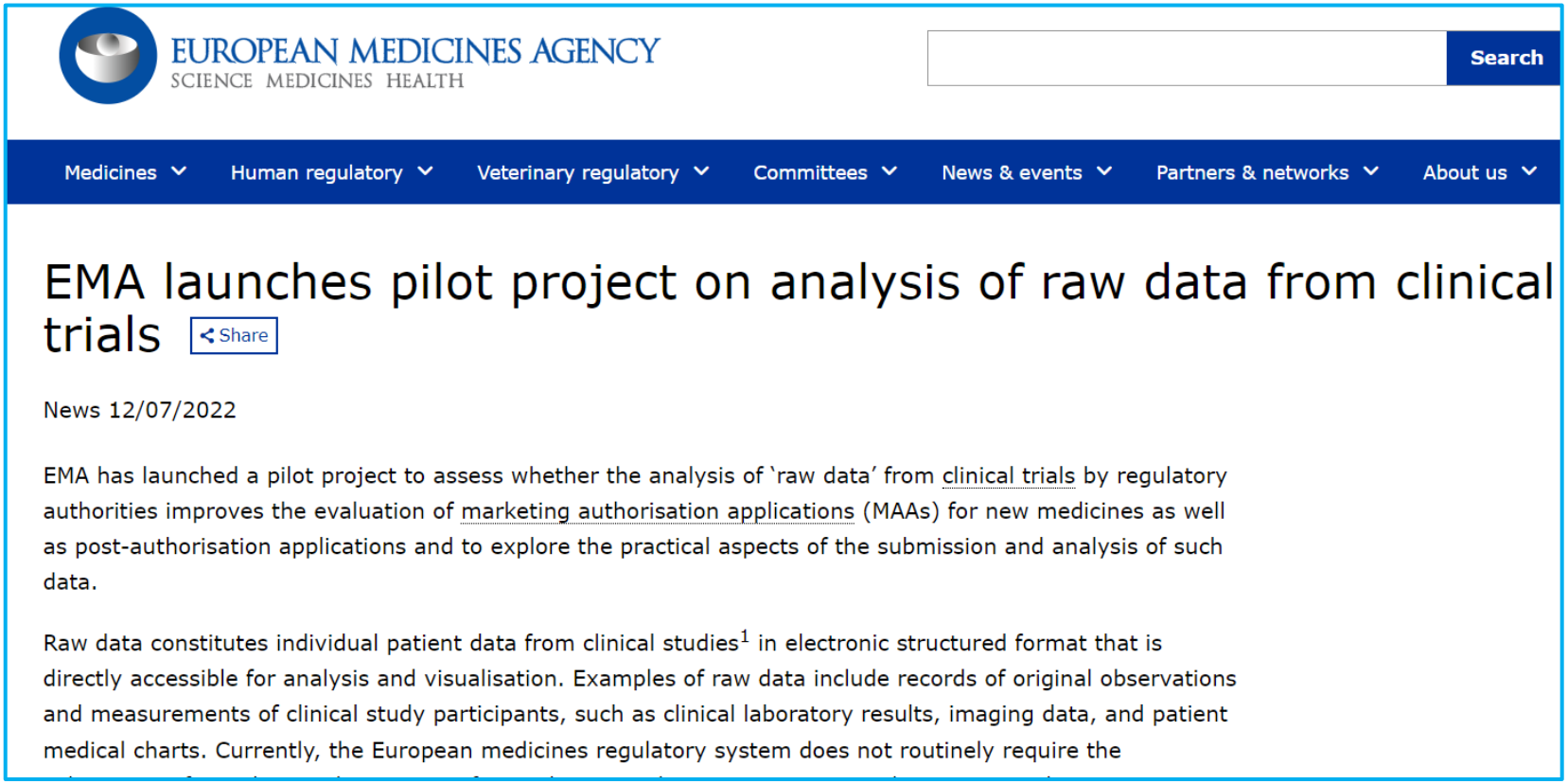
Data Submission Regulatory Update



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EMA launches pilot project on analysis of raw data from clinical trials

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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[1] 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

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PHUSE 2022 EU Connect Highlights

"The Integration Dilemma", A. Tinazzi – PHUSE EU 2022

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

- 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**

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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

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.....

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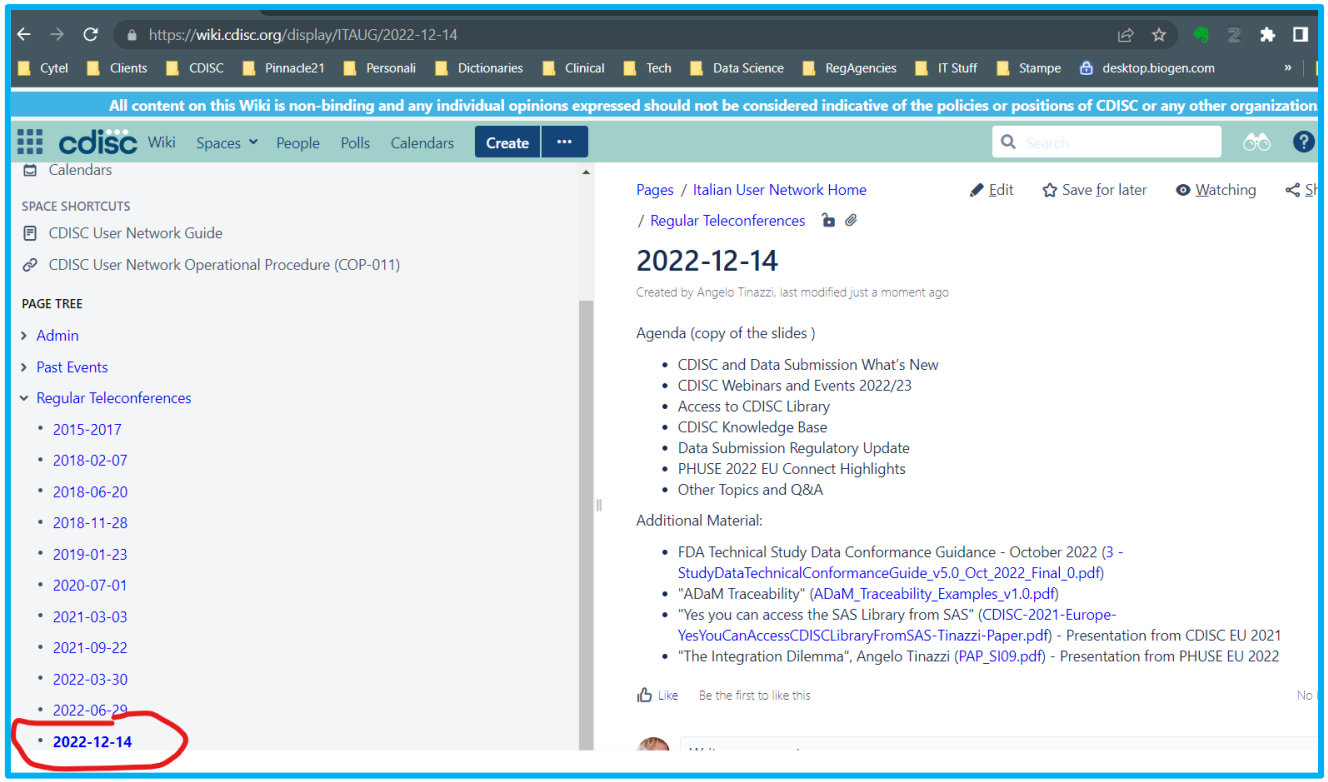

Thank You!

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