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

<table>
<thead>
<tr>
<th>Standard/Therapeutic Area</th>
<th>Comments Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>SENDIG-GeneTox v1.0</td>
<td>6 February 2023</td>
</tr>
<tr>
<td>ODM v2.0</td>
<td>31 January 2023</td>
</tr>
<tr>
<td>SEND Tumor Combinations v1.0</td>
<td>16 January 2023</td>
</tr>
<tr>
<td>ADaM Population Pharmacokinetics (popPK) Implementation Guide</td>
<td>11 January 2023</td>
</tr>
</tbody>
</table>
### Standards in development

[https://www.cdisc.org/standards/in-development](https://www.cdisc.org/standards/in-development) with projected publication in 2023

<table>
<thead>
<tr>
<th>Standard</th>
<th>Release Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADaM Metadata Submission Guidelines v1.0</td>
<td>Resolving Public Comments.</td>
</tr>
<tr>
<td>ADaM Oncology Examples</td>
<td>Resolving Public Comments.</td>
</tr>
<tr>
<td>Analysis Results Standard v1.0</td>
<td>In Development.</td>
</tr>
<tr>
<td>CDASHIG v2.3</td>
<td>In Development.</td>
</tr>
<tr>
<td>Conformance Rules for SDTMIG-Medical Devices v1.1</td>
<td>In Development.</td>
</tr>
<tr>
<td>Safety User Guide v1.0</td>
<td>In Development.</td>
</tr>
<tr>
<td>SDTM v2.1</td>
<td>In Development.</td>
</tr>
<tr>
<td>SDTMIG-Medical Devices v2.0 and Conformance Rules</td>
<td>In Development.</td>
</tr>
<tr>
<td>SENDIG v3.2</td>
<td>In Development.</td>
</tr>
<tr>
<td>SENDIG-DART v1.2</td>
<td>Resolving Public Comments.</td>
</tr>
<tr>
<td>SENDIG-Dermal Ocular v1.0</td>
<td>In Development.</td>
</tr>
<tr>
<td>SENDIG-Genotoxicity v1.0</td>
<td>In Development.</td>
</tr>
<tr>
<td>Tobacco Implementation Guide v1.0</td>
<td>In Development.</td>
</tr>
</tbody>
</table>
Standards in development
https://www.cdisc.org/standards/in-development with projected publication in 2023

<table>
<thead>
<tr>
<th>Standard</th>
<th>Release Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Therapeutic Area User Guide v2.0</td>
<td>In Development.</td>
</tr>
<tr>
<td>Rare Diseases Therapeutic Area User Guide</td>
<td>In Development.</td>
</tr>
</tbody>
</table>
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

CDISC Library

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

Please create a cdisclID, 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
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 Guides (TAUGs), the Examples Collection can be a helpful resource for developers.
- **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 into your study design.

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. Keep an eye on the News and Updates section for new content. 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 of the page.

*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 assumes no liability for its use.*
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
UPDATE: Successful R-Based Package Submission with Shiny Component to FDA

https://github.com/R Consortium/submissions-pilot1-to-fda
https://github.com/R Consortium/submissions-pilot2-to-fda
https://rconsortium.shinyapps.io/submissions-pilot2
EMA launches pilot project on analysis of raw data from clinical trials

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 studies¹ 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)
Integrated Summary of Safety (ISS) is required by the US FDA.

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

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

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**

- 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**
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.
Conclusions

Regardless of which option you adopt for your next ISS/ISE, traceability and proper documentation are crucial.

The data integration option to adopt depends on the status and conformance, and variability of individual study datasets and in some cases on sponsor preference.

Document, document and document.....

Need for an Industry Standard

ADaM Data Structures for Integration Document → Status?

PhUSE Integrated Reviewer Guide for ADaM (iADRG) → Under Finalization

More......
Thank You!

Angelo Tinazzi
angelo.tinazzi@cytel.com

Silvia Faini
silvia.faini@cytel.com

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