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PP23 Filling in the Gaps: PHUSE/CDISC Collaboration

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ABSTRACT: Over the years, the Clinical Data Interchange Standards Consortium (CDISC) has developed many standards for the storage and exchange of data. PHUSE Working Groups have been formed to develop recommendations for analyses and displays of common data domains and best practices around the implementation of standards, as well as address other issues that arise during the conduct of clinical trials. Some of the Working Group project teams have opened up communication and direct collaboration with CDISC teams to ensure alignment with CDISC standards or develop CDISC data recommendations to facilitate implementation of any new analysis recommendations. This poster will provide a summary of some of these collaborations and indicate where additional volunteers are welcome.

History Highlights

- 1997 – CDISC founded (all volunteers)
- 2000 – CDISC incorporated as non-profit organization
- 2003 – SDTM 1.0 released
- 2004 – FDA/CDISC Pilot, FDA support for SDTM submissions
- 2009 – ADaMIG v1.0 released, second FDA/CDISC Pilot
- 2012 – FDASIA Act authorizes electronic submissions, PDUFA V specifically mentions CDISC as clinical data standard, first PHUSE CSS conference
- 2014 – Final FDA Binding Guidance on Standardized Study Data, PHUSE Standard Scripts Hackathons using pilot data
- 2015 – PHUSE De-Identification Standard for SDTMIG v3.2 issued
- 2016 – Requirement for submitting standardized study data begins on Dec 17
- 2018 – SDTMIG v3.3 published
- 2019 – PHUSE Test Data Factory updates CDISC Pilot data
- 2021 – FDA Study Data Technical Rejection Criteria issued, ADaMIG v1.3 published

Data Sharing

CDISC Pilot Data

- De-identified data from an actual submission
- Originally SDTMIG v3.1.2 and ADaMIG v1.0
- Made available by CDISC for use in PHUSE Standard Scripts Hackathons conducted at PHUSE EU Connect and PharmaSUG
- Updated by PHUSE Test Data Factory project team to SDTMIG v3.2 and ADaMIG v1.2
- Included in SDTM and ADaM Metadata Submission Guidelines

Hackathons

PHUSE Standard Scripts (2014)

- Started with PHUSE Analyses & Displays Associated with Measures of Central Tendency white paper
- SAS and R programs written to generate displays shown in the white paper

CDISC Dataset-JSON I (2022)

- Produced several open-source tools for converting between JSON and other dataset formats

CDISC Dataset-JSON II (2023)

- Short-term objective: show that Dataset-JSON can be used as drop-in alternative to XPT files in regulatory submissions
- Long-term objectives: add Dataset-JSON as an official data exchange format, remove XPT constraints from CDISC standards
- Pilot runs from Sep 1 to Oct 19

Analysis Results Standard (ARS) (2023)

- Goal: drive adoption of ARS, create open-source tools
- Hands-On Workshops planned for upcoming conferences

SDTM ADaM Implementation FAQ

- Under the Optimizing the Use of Data Standards Working Group
- Consists of members from CDISC SDS and ADaM teams
- Receives and answers questions related to:
 - Data Submission
 - SDTM/ADaM IG Nuances
 - Trial Design Domains
 - Validation/Conformance Rules
- Questions submitted via email to workinggroups@phuse.global
- Responses posted to PHUSE Advance Hub (<https://advance.phuse.global/display/WEL/SDTM+ADaM+Implementation+FAQ>)

Submit your questions!

ADaM Collaborations

FDA Medical Queries (FMQs)

- FDA-specified groupings of MedDRA preferred terms
- PHUSE AEGiS Project Team developing white paper including recommendations for implementing FMQs in safety assessments
- ADaM OCCDS sub-team developing recommendations for incorporating FMQ information in Adverse Event analysis datasets

ADaM Datasets to Support Integrated Lab Tables and Figures Sub-team

- New ADaM sub-team formed in June 2023
- Coordinating with PHUSE Safety Analytics Working Group, Analysis and Displays of Lab Data project team
- Develop examples of analysis datasets to support lab TFs included in *FDA Standard Safety Tables and Figures: Integrated Guide*

Estimands

- PHUSE Optimizing Use of Data Standards Working Group, Implementation of Estimands Using Data Standards project team includes ADaM team members
- Developing impact assessment of the estimands framework and recommendations/best practices for implementation
- ADaM sub-team to update standards to address intercurrent events and missing value imputation

Conclusion

- These are just some of the places where PHUSE and CDISC have collaborated over the years
- Get involved by:
 - Joining a PHUSE Working Group (send email to workinggroups@phuse.global)
 - Registering as a CDISC volunteer (fill out form at <https://www.cdisc.org/volunteer>)
 - Submitting questions to the SDTM ADaM FAQ

