Optimizing the Use of Data Standards CSS Summary

PhUSE Webinar
26 April 2017

Co-Leads: Susan Kenny (Maximum Likelihood)
Jane Lozano (Eli Lilly)

Best Practices for Data Collection Instructions

Project Lead: Todd Bazin - Biogen

- This project team, in partnership with CDISC, will create a white paper documenting challenges and gaps with the CDASH CRF completion as well as recommendations for a future version of CDASH.
  - Standard Analysis and Code Sharing WG leads provided an overview of their current work and the limitations encountered when working to compile standard analysis and re-usable scripts due to the variability in how data is collected
  - Additional discussions around this project followed at both the CSS and CDISC IntraChange which highlighted both the many challenges with standardizing collection practices and also the opportunities/benefits of doing so.

Best Practices for Metadata Documentation (Define-XML document vs. reviewer's guide)

Project Lead: Sandy VanPelt Nguyen - Pfizer

- This project is aimed at looking at use of the reviewer's guide in conjunction with the Define-XML document. The team plans on delivering a white paper this year.
  - We did not meet at this year's CSS, but did find some additional folks interested in joining the group.
  - Sandy will be setting up meetings to get back to work on the white paper with a goal of finishing the paper this year.
  - The poster "Sorting Out the Paperwork" won an award at the CSS

Data Reviewer's Guide in XML

Project Lead: Mike Hamidi - Merck

- This project team will develop the Data Reviewer's Guide (i.e., SDRG and ADRG) in an XML format for regulatory submissions.
  - Provided DRG in XML overview to attendees to ensure awareness, obtain interest and discuss the possibilities of the project.
  - Conducted an FAQ session in order to obtain feedback from implementers across multiple organizations.
  - Explained the importance of a machine readable DRG. Further extrapolated the necessity of cross-document interoperability (e.g., Define-XML document).
  - Recruitment of technical experts in the area of style sheet, schema and XML development.

Define-XML v2.0 Completion Guidelines & Stylesheet Recommendations

Completion Guidelines (CG) Project Leads: Marcelina Hungria - DIcore Group
Prafulla Girase - Biogen

- Deliverable: *Completion Guidelines* document, focusing on best practices for content and granularity.
  - Examples of how to populate challenging metadata items under a few relevant scenarios
- Estimated completion for Phase 1: 3Q2017
  - ~17 active members from Pharma/Biotech Sponsors, Consulting companies, CDISC Teams and FDA
- In Scope:
  - Phase 1: SDTM/ADaM/SEND Phase 2: ARM
  - Coordination with CDISC Teams (Define-XML, MSG, SDTMIG, SENDIG, ADaMIG) and other PhUSE Teams
    - Securing appropriate CDISC teams representation to support/lead CG discussions
    - Avoiding redundancy with other teams deliverables, specially Define-XML and MSG
- Out of Scope:
  - A comprehensive metadata definition for any given study
  - A data model for representing metadata
  - Operational implementation guidelines
  - Technical guidance/reference on how to develop software to create a Define-XML document

Define-XML v2.0 Completion Guidelines & Stylesheet Recommendations

Stylesheet Project Leads: Dmitry Kolosov- PAREXEL
Lex Jansen - SAS

- Deliverables of the Stylesheet Recommendations project team:

  Phase 1: Development of a Define-XML v2.x stylesheet for regulatory submissions

  – Phase 1 scope in addition to the stylesheet development:
    - Documentation of the stylesheet – explanation on how parameters and stylesheets can be utilized, process for HTML creation, and the list of tested browsers.
    - Test XMLs – XML files which implement different aspects of the Define-XML v2.0 standard to test a stylesheet functionality.

  Phase 2: Demonstrate other uses of a stylesheet

Legacy Data Conversion Plan & Report

Project Lead: Jane Lozano – Eli Lilly

- This project team is working on a standardized approach to the development of a single document to address conversions from non-standardized data (i.e. legacy) to standardized data (SEND, SDTM, ADAM).
  - The scope was agreed at the CSS in that the cSDRG and ADRG will contain a new section for the Legacy Data Conversion Plan & Report
  - The definition of legacy includes data that was created in SDTM v1.1/IG 3.1.1
  - Met with the nonclinical group and determined that the definition of legacy is not the same for them
    - Nonclinical to provide this project team their definition
  - Sub-groups formed to update the existing Completion Guidelines and Example Documents

SDTM ADaM Implementation FAQ

Project Leads: Bhavin Bhusa – Softworld Life Sciences
Mat Bryant – inVentiv Health Clinical

- This project focuses on understanding standards implementation nuances that exist across available SDTM and ADaM versions.
  - Progress made by the sub-groups:
    - Team completed review of questions and drafted responses within 4 of the sub-groups
    - Team is currently recruiting leads for the following sub-groups:
      - Therapeutic Area Specific
      - Legacy SDTM Mapping
  - Project will have sessions at the PhUSE EU CSS in June.
  - Format exists to submit questions, but technology needs to be improved to make this more visible and have a Google form tied to the Wiki.
  - Team is ready to publish the current questions and answers on the Wiki after CSS Steering Committee review.

Study Data Standardization Plan

Project Lead: Jane Lozano – Eli Lilly

- This project team has developed the deliverables that sponsors can use now and are available on the Wiki.
  - Met with CBER to discuss their version of the SDSP
    - The team agreed to add an appendix to the SDSP
  - Completion Guidelines and Example Documents will be updated to reflect a CBER example
  - FDA provided comments from the FR Notice for Intent to Review
    - The template was updated based on the comments
    - There are additional comments that FDA is reviewing
  - The most current version of the template is on the Wiki (with the Updated 28March2017 appendage in the name)
    - The original template is still on the Wiki

Possible New Projects

- PMDA/FDA Submissions
  - Possible white paper on differences between FDA and PMDA in regards to submissions.
    - PhUSE is looking at the JPMA User Aide for ADRG
- When data is integrated a version of the SDRG or ADRG is created, but they are single-study focused and not multiple-study focused
  - Legacy Data Conversion Plan & Report could be included if study data is up-versioned within an integration
- Implementing the WHO Drug B3 Format - Best Practices for Integrated Databases

How to Find Out More & Get Involved

- PhUSE Website:
  - http://www.phuse.eu/
- Project activity and deliverables are on the PhUSE Wiki:
  - Optimizing the Use of Data Standards
- Questions? Contact Us!
  - Susan Kenny – susankenny@maxlikelihood.com
  - Jane Lozano - j.a.Lozano@lilly.com

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