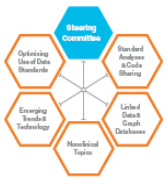
An Update on the Optimizing the Use of Data Standards Working Group

PhUSE SDE

14 April 2017

Jane Lozano



Computational Science Working Groups

Background

- The *Optimizing Use of Data Standards WG* is tasked with identifying specific gaps that prevent FDA and industry from optimizing the use of data standards and then improving industry practices so as to increase efficiencies
- The WG oversees projects that close the gaps, which includes providing document templates identified in FDA guidance

Working Group Deliverables

Completed Projects

- Study Data Reviewer's Guides:
  - nSDRG
  - cSDRG
  - ADRG

- Standardizing Data Within the Site Selection Process
  - Gap analysis finished and provided to FDA/CDISC

Working Group Deliverables

White Papers

- Traceability: Current State Analysis (2013)
- Preliminary Recommendations for Traceability Documentation using Define-XML 2.0 (2013)
- Traceability: Best Practices for Linear Data Flow (2014)
- Study Level Traceability in a Non Linear Data Flow (2014)

Working Group Deliverables

Active Projects

- Best Practices for Data Collection Instructions
- Best Practices for Metadata Documentation (define xml vs. reviewer's guide)
- Data Reviewer's Guide in XML
- Define v2.0 Implementation & Style Sheet Recommendations
- Legacy Data Conversion Plan & Report
- SDTM ADaM Implementation FAQ
- Study Data Standardization Plan

Best Practices for Data Collection Instructions

Project Lead: Todd Bazin - Biogen

- This project team will create a white paper documenting challenges and gaps with the CDASH CRF completion as well as recommendations for a future version of CDASH. The white paper will be provided to CDISC for their consideration. The project team will initially focus on the following domains:
  - Adverse Events
  - Medical History
  - Concomitant Medications
  - Pregnancy
  - Reasons for Treatment and Study Discontinuation

Best Practices for Metadata Documentation (define xml 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. The team is generating best practices and lessons learned for handling some of the gray/ subjective areas within the reviewer's guides as well as where there is overlap between the two documents. The team plans on delivering a white paper this year.
- Look for the poster "Sorting Out the Paperwork" on the PhUSE site (http://www.phuse.eu/css-2017-presentations-posters)

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. Additional goals are to identify and develop style sheets, elements and semantics capability. This project team will also assess a more cohesive cross-documentation data exchange between the define.xml and data reviewer's guide as an XML format. The project intends to use the existing Analysis Data Reviewer's Guide (ADRG) and Study Data Reviewers Guide (SDRG) as its basis.

Define v2.0 Implementation & Style Sheet Recommendations

- This project addresses documenting the best practices in the implementation of the define v2.0 and the existing style sheet.
- There are 2 separate project teams:
  - Implementation and Style Sheet Recommendations
  - Style Sheet Recommendations

Implementation Project Leads*: Marcelina Hungria – DIcore Group

*** Co-Lead - Open**

- Deliverable of the Define-XML 2.0 Implementation project team is a "Completion Guidelines" document, focusing on best practices for content and granularity.

Define v2.0 Implementation & Style Sheet Recommendations

Style Sheet Project Leads: Dmitry Kolosov- Parexel
Lex Jansen - SAS

- Deliverables of the Style Sheet Recommendations project team:

  1) Development of a Define-XML v2 stylesheet for regulatory submissions, by reviewing and updating the existing CDISC stylesheet.

  2) Demonstrate other uses of a stylesheet, and utilizing libraries and frameworks to make the display more interactive.

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 goals of the team are to provide a template, completion guidelines (with a decision tree showing when to create a LDCP), and some examples that may be utilized by sponsors to develop the LDCP.
- The decision tree is completed. The team is now working on the template creation.

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.
- The deliverables include:
  - A process through which users can submit questions and see previously answered questions – PhUSE collaboration space Teamwork area
  - A Wiki, where users can go for FAQs for helpful implementation information

Sub-Teams	
SDTM ADaM IG Nuances	Legacy SDTM Mapping
Validation/Conformance Rules	Trial Design Domains
Data Submissions (SDTM & ADaM)	

Study Data Standardization Plan

Project Lead: Jane Lozano – Eli Lilly

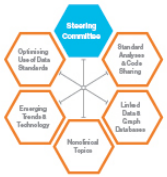
- Deliverables are available on the PhUSE Wiki:
  - Template
  - Sponsor Implementation Guide
  - Completion Guidelines
  - Example Documents (Asthma & Oncology)
- FDA FR Notice for Intent to Review period ended in January. Comments were shared with the project team during the CSS.
- This project team also met with CBER colleagues and an appendix has been added to the SDSP.
- Deliverables will be finalized once all FDA comments are received.

Lilly Involvement

- Reviewer's Guides are created when a study locks or closer to submission
  - The working group has received the JPMA User Aid for the ADRG and will be working with PhUSE to understand the differences
- The SDSP has been created and submitted to FDA
  - FDA has responded
- Lilly employees are active in PhUSE projects

How to Participate

- Sign up for the PhUSE working group mailings
  - From phusewiki.org, click “Join a Working Group Now”
  - Optimizing the Use of Data Standards
- See wiki pages for each of the projects (www.phusewiki.org)
- Learn about the projects at the working group link:
  - http://www.phusewiki.org/wiki/index.php?title=Optimizing_the_Use_of_Data_Standards



Computational Science Working Groups

phuse

The premier community for people working in the biometric area

phuse.eu
@PhUSETwitta
/PhUSE
phusewiki.org