



Computational Science Symposium

March 16th - 18th 2014

Silver Spring Civic Center | Silver Spring, Maryland, USA



Optimizing Data Standards Working Group

Meeting Summary

2014-04-18



Optimizing Data Standards



- **Meeting Summary**

- Break out sessions for each working group
 - Traceability and Data Flow
 - ADaM Data Reviewer's Guide
 - Best Practices (New: Multiple Sub-Projects Identified)
- Identified new project to be initiated following this meeting:
 - Study Data Standardization Plan (SDSP)



Optimizing Data Standards Active Projects



Traceability and
Data Flow

ADaM Data
Reviewer's
Guide

Best Practices

Study Data
Standardization
Plan



ODS Projects



Traceability and Data Flow

- Leaders: Paul Bukowiec, Sandra Minjoe, Tanja Petrowitsch, Natalie Reynolds
- This project will discuss and define traceability considerations and best practices for study level dataset and integrated datasets conversion for a variety of different data flow scenarios.



ODS Projects



Traceability and Data Flow

- Meeting Accomplishments:
 - Developed first draft of **Study Level Traceability** white paper
 - Noted specific traceability details to be added to current **Basic Linear Data Flow** white paper
 - Determined the need to develop a template for the **Legacy Data Conversion Plan** (*mentioned in the new draft FDA Study Data Technical Conformance Guide*)



ODS Projects



Traceability and Data Flow

- Next Steps:
 - Scoped 4 tasks, assigned leads and members
 1. Update **Basic Linear Data Flow** white paper
 2. Finalize **Study Level Traceability** white paper
 3. Develop **Integration Level Traceability** white paper
 4. Develop **Legacy Data Conversion Plan Template**
 - Developed draft timelines and meeting plans



ODS Projects



Analysis Data Reviewer's Guide (ADRG)

- Leaders: Susan Kenny, Gail Stoner
- Development of an ADRG template and instructions for industry to consider that will enable consistent and usable ADaM documentation in submissions.



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Analysis Data Reviewer's Guide (ADRG)

- Accomplished at Meeting
 - Completed final review of Template
 - Completed final review of Completion Guideline
 - Presented poster and expect to receive additional comments. Comments due by MARCH 28.
 - Began review of one ADRG example
- By April 30:
 - Complete review and updates to 2 examples
 - Finalize **ALL** documents (template, guidelines, samples)
 - Post all materials to PhUSE Wiki



ODS Projects



Best Practices for Standards Implementation (NEW)

- Leaders: Mike Molter, Lisa Lyons
- Goal of the Project is to develop a set of recommendations for best practices in optimizing the data standards. Short, single topic best practice recommendations available on the Wiki.
- Each topic will be ~3-5 months duration for delivery of the recommendation.
- Each best practice will have a sub-team (with leadership) under the Best Practices leadership to address each topic.



- What: **Lab Unit Standardization**
- Leader: Mat Bryant
- Description: Challenges of defining an industry wide standard unit (e.g. --STRESU).
Also to include...
 - LB SDTM domain, 50-100 tests,
 - Dimension representation of standard units (e.g. mg vs Mg)
 - Need an EU member – Contact Mat



- What: **EPOCH/VISITNUM Assignments**
- Leader: Natalia Smeljenski
- Description: Challenges of defining, deriving, and implementing assignment of values of these variables at a subject level



- What: **Multiple Imputation Data Sets**
- Leader: Robert Woolson
- Description: Addresses the use of stepwise multiple imputation data sets
- Note: This topic will be addressed within the CDISC ADaM team.



Data Optimization: Best Practices



- What: **USUBJID Assignment**
- Leaders: Monica Mattson, Mark Sullivan
- Description: Assignment of values to USUBJID to ensure uniqueness across an application and within study.



Data Optimization: Best Practices



- **Future Best Practices Topics Identified**
 - Programming Documentation
 - Reference Range Standardization
 - Unit Standardization Beyond Labs
 - Trial Design Setup
 - Treatment Emergent Flags
 - ARM/ARMCD assignment and standard implementation
 - Others welcome – Will be a place to identify new topics on Best Practices Wiki



ODS Project



- **Study Data Standardization Plan (SDSP)**
 - New Project Starting in 2014
 - Goal of the Project is to develop a Template to be made available for Industry to Use.
 - Template Model will follow a similar development as the SDTM and ADaM Reviewer's Guide
 - Initial Leads: Jane Lozano, Jim Johnson
 - 16 people (Industry and FDA) have indicated interest to participate.
 - Teleconference and Initial Meeting will be in April 2014
 - Initial Goal is to have a Template Available by PhUSE Meeting (October 2014)



ODS Project



- **Study Data Standardization Plan (SDSP) (Cont'D)**
 - Initial discussion of the SDSP indicates that the template may address:
 - Non-clinical (SEND) data – Will reach out to Non-Clinical team for representation on SDSP team
 - Should consider including endpoints relevant to the data standardization.
 - Template should be organic and grow with the program as new information is developed with the CDP.
 - SDSP may be an Appendix (Attachment) to the Clinical Development Plan



Optimizing Data Standards



Thank You