PP18 PHUSE Standard Analysis and Code Sharing Working Group Update Jane Marrer Merck & Co Inc

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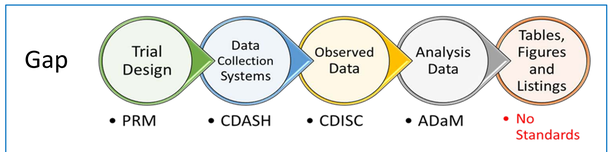
Abstract

- This poster will provide an update on the efforts of the 6 project teams in the Standard Analysis and Code Sharing Working Group.
- The PHUSE Standard Analyses and Code Sharing Working Group provides recommendations for analyses, tables, figures, and listings for data that are common across therapeutic areas
- Online platform called PHUSE Education (education.phuse.eu) for sharing code using GitHub: Contains a wealth of scripts that have been written by PHUSE members or developed and donated by the FDA and other organizations.
  - Crowd-sourcing code development will enable consistent interpretation of methods and substantial savings in resourcing across the industry.

Analysis and Display White Papers

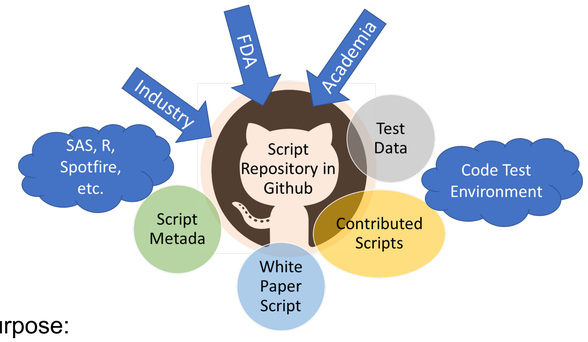


Purpose: Development of white papers that provide recommended tables, figures and listings for clinical trial study reports and submission documents

Accomplishments: Safety Analytics Workshop: CSS June,2019
- AEs, Labs, Disposition, Medications

	Version 1		Version 2	
	Review	Publish (ed)	Review	Publish (ed)
Vital Signs, Labs, ECG – Central Tendency		Oct 2013 ✓		
Non-Compartmental PK		Mar 2014 ✓		
Demographics, Disposition, Medications		Oct 2014 ✓	Q4 2017 ✓	Q1 2018 ✓
Vital Signs, Labs, ECG – Outliers / Shifts		Sep 2015 ✓		
QT/QTc Studies		Mar2016 ✓		
Adverse Events		Feb 2017 ✓		
General Output Tips and Considerations (Karin)	Q1 2020	Q2 2020		
Treatment-Emergent Definitions (Survey Results)	Q2 2020	Q3 2020		
Labs (Wei)	Q3 2020	Q1 2021		
Hepatotoxicity (Terry)	Q3 2020	Q1 2021		
Questionnaires (Karin)	Q3 2020	Q1 2021		
Listings	Q3 2020	Q4 2020		
Safety Topics of Interest (Brenda)	Q3 2020	Q4 2020		
Vital Signs	Q3 2021	Q4 2021		
ECG's	Q3 2021	Q4 2021		
Treatment-Emergent Definitions (Recommendations on Definition)	Q3 2021	Q1 2022		
Interactive Displays for Clinical Safety Data (Wei)	Q4 2021	Q1 2022		

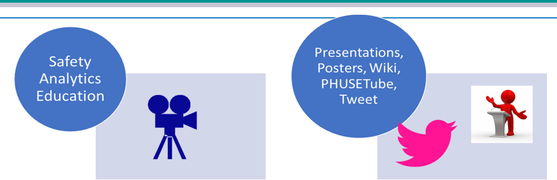
Code Sharing (Repository)



Purpose:
- Establish and maintain collaboration platform leveraging crowd-sourcing to improve content and implementation of analyses
- Lead to better data interpretations and increased efficiency in clinical drug development and review processes
- Collaboratively build shared tools and reusable code library

Accomplishments
- 03-Oct-2019 Script Repository in Github created
- Qualification guidelines created
- Scripts from other groups have been contributed
  - FDA, Non-clinical, Data handling, Sp… emplates, etc.
- White paper showing the displays created from the FDA-contributed scripts
- Script metadata for sharing white paper: published on Jan 13, 2019
- Scripts from within the project have been created
  - Tables and figures from the 2013 labs/vitals/ECGs white paper
- An R Shiny tool to create simplified TS Domain:

Communication, Promotion, and Education



Purpose: The Communications Plan conceptualizes efficient ways to communicate the Working Groups progress and results
- Relies on the acceptance, input, feedback and further development from/by the user community.
- Defines target groups, timing, communication channels and the presentation
- Ensures success of the Standard Analyses & Code Sharing Working Group

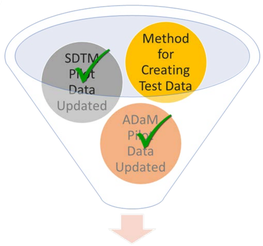
Best Practices for Quality Control and Validation

Purpose: Author a white paper describing the best approach for the QC and validation process
- GAP: there are no industry standards or guidelines on the best way to QC and validate programs used for analysis and reporting.
- Pharmaceutical companies and CROs follow quality control processes to identify errors in their analysis programs to ensure high quality, however the process varies throughout the pharmaceutical industry.

Accomplishments and Future Plans: White paper released for industry and FDA review Nov 2019. Target final release of paper in 1Q2020

Test Dataset Factory

- Purpose: Provide test data formatted in SDTM and ADaM to support systematic and comprehensive testing
  - Update the CDISC Pilot Data to meet newer standards
  - Mechanism to create customized SDTM or ADaM databases
- Achievement:
  - Updated TDF Package based on the CDISC pilot has been released
- Next steps: Design mechanism to create custom databases:
  1. Ongoing: Define scope for custom databases: domains, variables, etc
  2. Ongoing: Create a user-configuration input form
  3. Ongoing: SAS and R code to create custom databases



GPP in Macro Development

- Purpose: Create a guideline for creating well-structured and precisely documented macro code that will be easy to read and maintain over time
- Macros provide an effective way to automate and reuse code in a standard and consistent manner across SAS programs.
  - Ability to reuse code means that the use of GPP is particularly important in macro code
- There is a need to develop a consensus and document good programming practices specifically for macro programming.

Recruiting new members! Contact wendy@phuse.eu to get involved!