

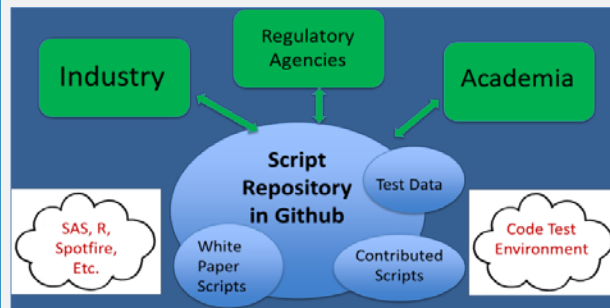
Standard Analyses and Displays for Common Data in Clinical Trials - The Journey Continues!

Nhi Beasley¹ and the PhUSE Analysis and Display White Papers Project Team

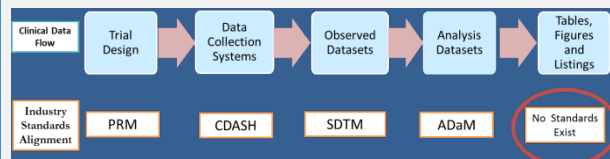
¹US Food and Drug Administration, White Oak, MD

Background and Objectives

- The PhUSE-Computational Science Standard Analyses and Code Sharing Working Group leverages industry-regulatory collaboration to:
 - Establish and maintain a publicly available repository for storing program code to be used as analytical tools for medical research
 - Where gaps exist, develop recommendations for analyses and displays in areas that could benefit from crowd-sourcing
 - Where gaps exist, develop code for recommended analyses and displays (to reside in the repository)



- The Analysis and Display White Papers Project seeks to develop recommendations and fill gaps in industry standards, specifically, for analysis and reporting of common clinical trial data in regulatory submissions



* PhUSE = Pharmaceuticals User Software Exchange; CS = Computational Science; PRM = Protocol Representation Model; CDASH = Clinical Data Acquisition Standards Harmonization; SDTM = Study Data Tabulation Model; ADaM = Analysis Data Model; SAP = Statistical Analysis Plan

White Papers Overview

	Version 1		Version 2	
	Public Review	Published	Public Review	Published
Vital Signs, Labs, ECG – Central Tendency		Oct 2013	✓ Q3 2018	🎯
Non-Compartmental PK		March 2014	✓	
Demographics, Disposition, Medications		Oct 2014	✓ Q4 2017	✓ Q1 2018
Vital Signs, Labs, ECG – Outliers / Shifts		Sept 2015	✓ Q3 2018	🎯
QT/QTc Studies		March 2016	✓	
Adverse Events		Feb 2017	✓	
Treatment-Emergent Definitions	Q4 2018	🎯		
Hepatotoxicity	Q3 2018	🎯		
Questionnaires	Q4 2018	🎯		
Events of Special Interest	Q3 2018	🎯		

Scope and Examples

- Recommended analyses and displays for individual studies and integrated summaries
- Sample SAP language
- Discussion on analytical and statistical topics such as:
 - P-values and confidence intervals
 - Events occurring after study drug discontinuation
 - Alternative methods when percentages are biased

For white papers ...

- Go to www.phuse.eu
- Click on Working Groups
- Click on CSS Deliverables

For scripts ...

- Go to www.phusewiki.org
- Click on CSS Working Groups
- See links under Standard Analyses and Code Sharing

To participate ...

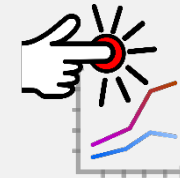
- Go to www.phuse.eu
- Click on "Join a Working Group Now"
- Follow instructions to select workstream

Recent Activities



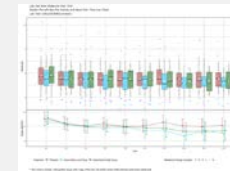
Educational Video (Nov 2017)

Topics in pooling data from multiple studies: Study-size adjusted percentages: why, when and what? (Link available from CS Deliverables Catalog)



Interactive Visuals

Identify areas where interactive visuals can be leveraged (recommendations provided in recent white papers)



Boxplot Variations

Which ones get the message across the best?
Which ones are easiest to understand?

To help ...

- Use the final white papers
- Include links to white papers in Statistical Analysis Plans
- Review upcoming white papers
- Advertise!

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