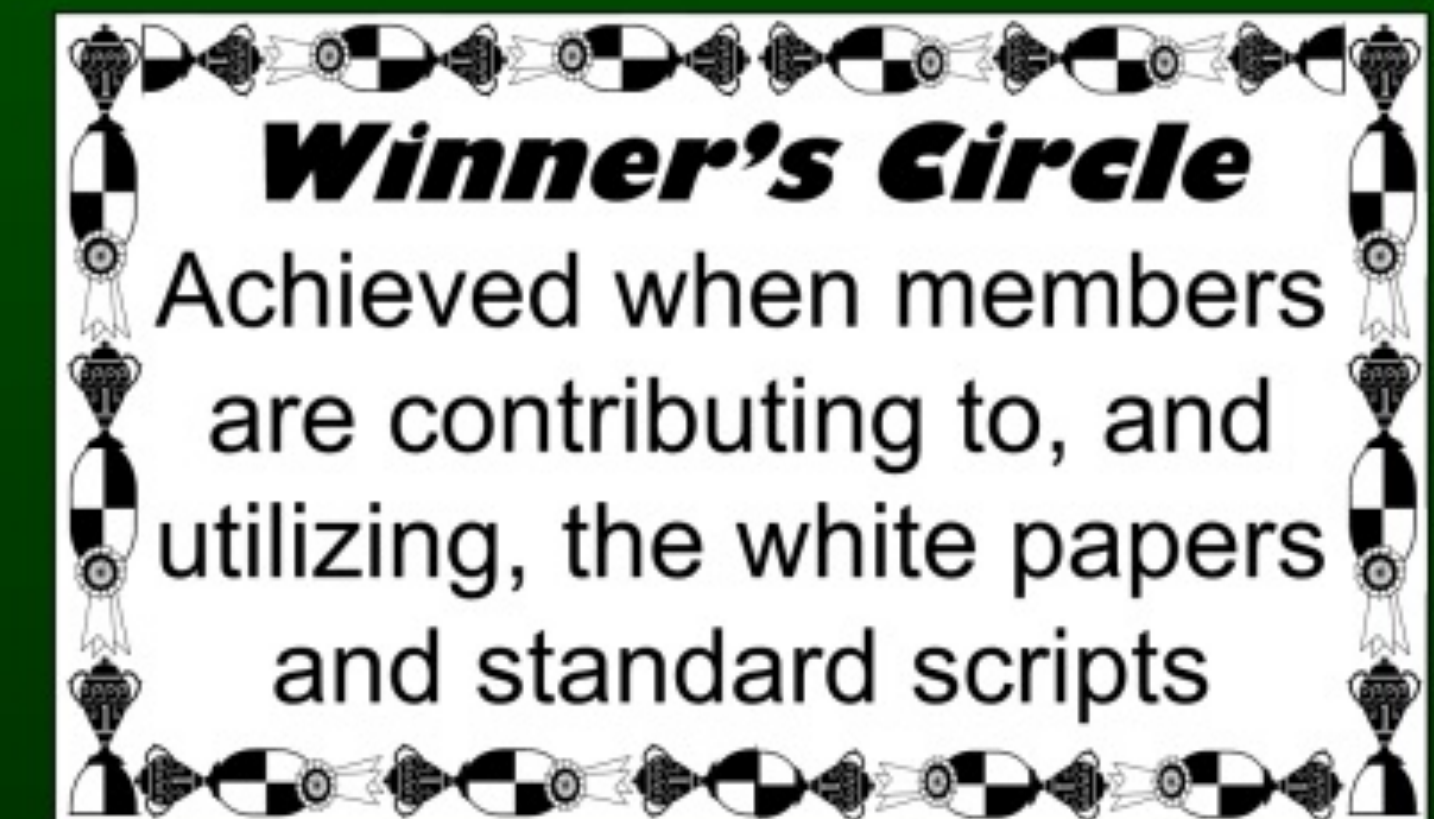




This poster shows the progress that this PhUSE Working Group has made toward our vision. That is to have a script repository containing shared code (in languages such as SAS and R) that can produce standard displays (e.g., tables, figures and listings) with the associated analysis.

Script Qualifying
2015

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Frank Senk³



Goal

- Establish a platform for the collaborative development of program code to be used as analytical tools for clinical trial research, reporting and analysis
- Includes recommendations for analyses, tables, figures and listings.
 - Process and guidelines
 - Data standards

Vision

- Reusable code used by all
- Validated Scripts
 - Good processes
 - Fills gap on analysis standards
 - Crowd sourced – continuously improved – shared learning
 - Industry
 - FDA
 - Academic



Platform

- Script library (Repository)
- Google cloud chosen
 - Dealt with legal issues
 - MIT license
 - Industry, FDA, Academic contributors Process guidelines
 - Qualification guidelines
 - User-friendly front-end
 - <http://code.phuse.com>

Current Leadership

Standard Scripts Projects Co-Leads
This group will identify potential standard scripts for data transformations and analyses across and/or within a therapeutic area and exploratory analysis.

- Mary Nilsson: mnilsson@lilly.com
- Hanming Tu: hanming.h.tu@accenture.com
- Stephen Wilson: Stephen.Wilson@fda.hhs.gov
- Mat Soukup: mat.soukup@fda.hhs.gov

PhUSE  **FDA**

Standard



Join Workgroups

Sign up for the PhUSE working group mailings:

- Goto phusewiki.org
- Click "Join a Working Group"
- See mailing list instructions
- Join "CSS-WG-Standard-Scripts"

Start interacting at:

- <https://code.google.com/p/phuse-scripts/>

Join Standard Script Group by sending an email to one of the repository maintainers

- See link under Script-athons



Script-athons

- Actively contribute code
- Qualify contributed code
- Google account required
- Standard Script Group
 - http://www.phusewiki.org/wiki/index.php?title=Standard_Scripts
- Script-athons held in conjunction with events:
 - Annual Conference
 - CSS, PhUSE SDEs

Script Development

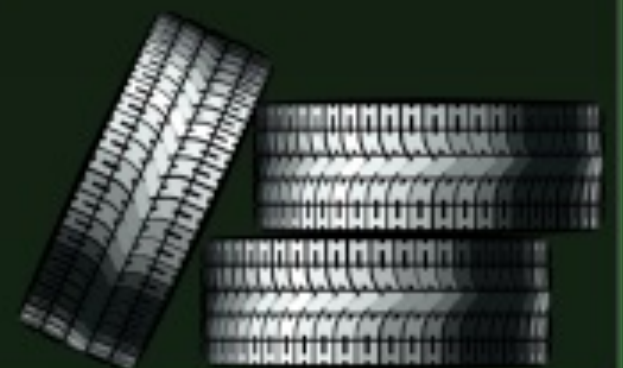
- Analytical tools for clinical trial research, reporting and analysis
- Outline in White Papers
 - Create code for tables, figures, listings
 - Consider SDTM & ADaM code
 - Look for other existing code
 - Follows process and qualification guidelines
 - Collaborative development



White Papers

Outline recommended analyses and displays for common TFLs

- Measures of central tendency
- Outliers or shifts from normal to abnormal
- Adverse events
- Demographics, Medications, Disposition
- Hepatotoxicity
- Non-Compartmental PK
- QT studies, Questionnaires, Events of Special Interest
- TOSNP and Narratives
- Combining studies for Integrated Analysis



First Scriptathon

2014

First White Paper Published

2013

Standard Scripts Kickoff

2012

Start

PhUSE CSS 2015
Join a PhUSE Working Group Today!

¹ MMS Holdings Inc.
² Eli Lilly and Company
³ AstraZeneca