

Standard Analyses and Code Sharing

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Working Group Vision/Goals

- Leverage crowd-sourcing to improve the content and implementation of analyses for medical research, leading to better data interpretations and increased efficiency in the clinical drug development and review processes.
 - 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 that could benefit from crowd-sourcing (to reside in the repository).

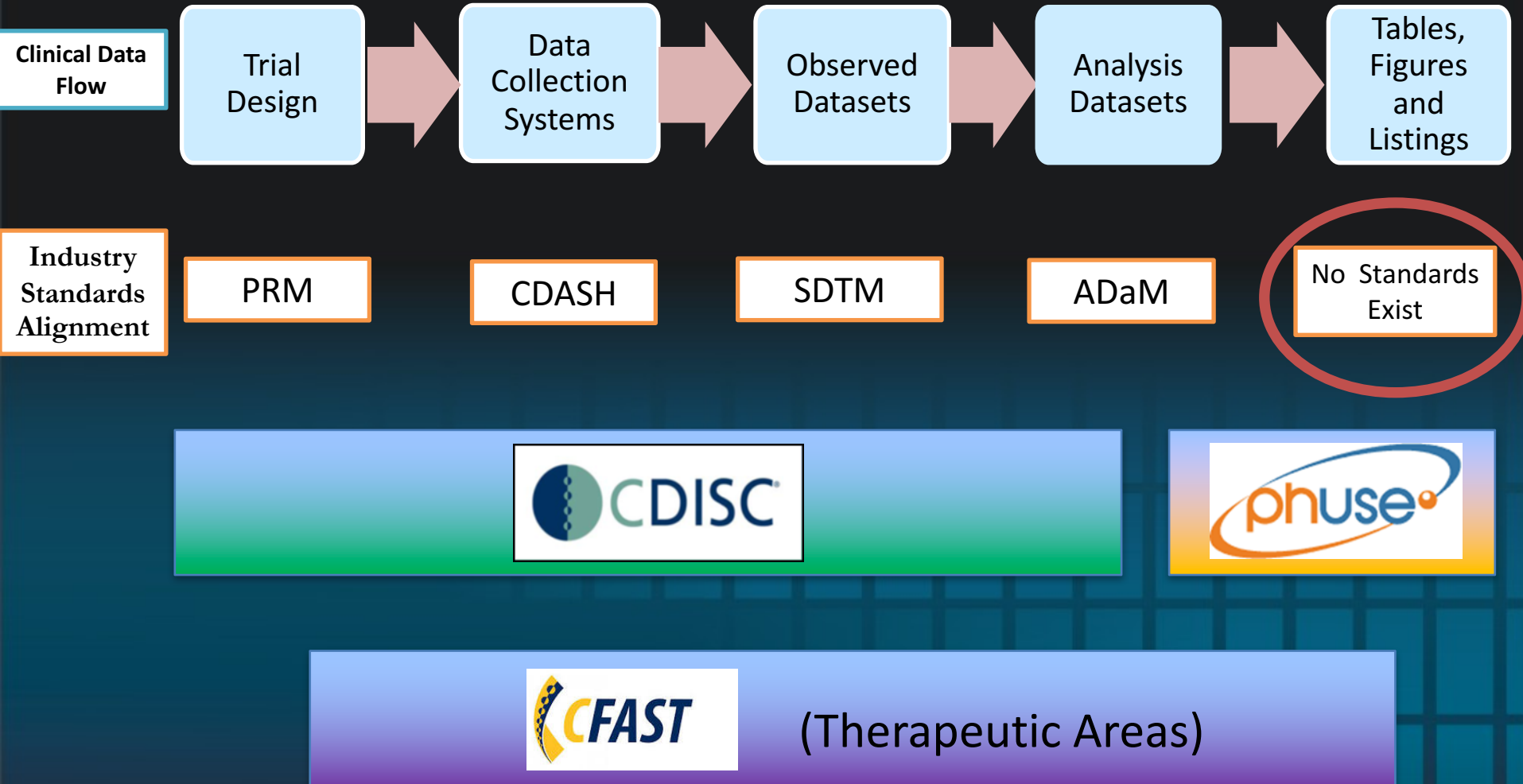


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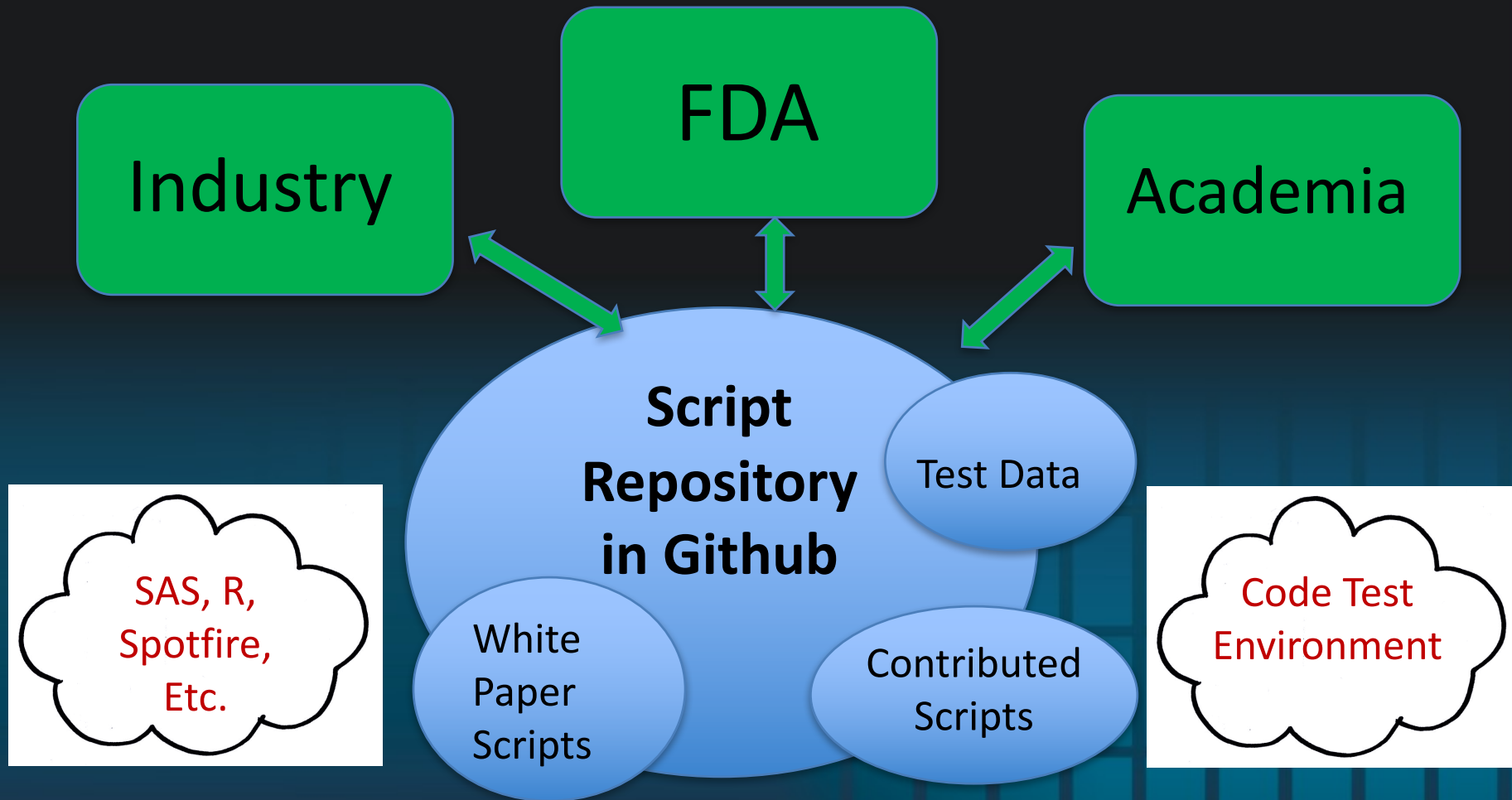


Vision: Fill the Gap on Analysis and Display Standards





Vision: Script Repository (Shared Reusable Code Library)





Focus Areas

- **Three Focus Areas, 6 active projects**

Script Repository
(4 projects)



Analyses and Display
White Papers
(ADW, Mary Nilsson)

Communication,
Promotion, Education
(CPE, Jared Slain and
Wendy Dobson)

Script Discovery and Acquisition (SDA,
Rebeka Revis, Alfredo Rojas)

Repository Content and Delivery (RCD,
Gustav Bernard, Andrew Miskell)

Repository Governance and
Infrastructure (RGI, Mike Carniello,
Hanming Tu)

Test Data Factory (TDF, Peter Schaefer)



Accomplishments: Repository

- Script Repository
 - MIT license chosen
 - <https://github.com/phuse-org/phuse-scripts/blob/master/LICENSE.md>
 - Qualification guidelines developed
 - http://www.phusewiki.org/wiki/index.php?title=WG5_Project_02#Qualification_Process
 - User-friendly front end developed
 - <https://github.com/phuse-org/phuse-scripts/wiki/Simple-Index>
 - Repository has been updated to have a place to store scripts developed by other groups



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Accomplishments: Scripts Contributed

- Scripts contributed by other groups
 - FDA: <https://github.com/phuse-org/phuse-scripts/wiki/JumpStart-Scripts>
 - Non-clinical: <https://github.com/phuse-org/phuse-scripts/tree/master/contributed/Nonclinical>
 - Data Handle: <https://github.com/phuse-org/phuse-scripts/tree/master/lang/SAS/datahandle>
 - Spotfire Templates: <https://github.com/phuse-org/phuse-scripts/tree/master/contributed/Spotfire>



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Accomplishments: Scripts Developed

- Scripts developed by volunteers
 - 6 Scriptathons (plus additional work by project members) resulting in several scripts at various stages
 - Focused on creating scripts associated with the displays in the white papers, starting with ADaM data
 - The specifications for the scripts include assumptions and required ADaM variables
 - Starting with CDISC pilot data
 - Scripts developed based on white paper
 - Central Tendency package Qualification Completed: 6 Recommended displays in CT White Paper



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Working Group Accomplishments

- 6 White Papers Finalized
 - Vital Signs, ECGs, Labs - Central Tendency (2013)
 - Non-Compartmental Pharmacokinetics (2014)
 - Demographics, Disposition, Medications (2014)
 - Vital Signs, ECGs, Labs – Outliers and Shifts (2015)
 - Thorough QT/QTc Studies (2016)
 - Adverse Events (2017)
- One additional white paper is almost final
 - Screen Shots of the Displays Created by JumpStart Programs

How to find final white papers: Go to www.phuse.eu, Click on Working Groups, Click on CS Deliverables Catalog



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Working Group Plans for CSS

- Github Workshop (Monday night)
 - Learn how to create and edit scripts in Github
 - Demo on JumpStart Scripts
 - Demo on a Spotfire interactive display package
- Discuss communication/education
- Discuss topics related to the repository
 - Identify priority test data sets
 - Define Script input format
 - Create Script test environment (STE)



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Working Group Plans for CSS

- Discuss plans for new white papers, plans for updating a couple existing white papers
 - AE white paper follow-up topics
 - Hepatotoxicity, Treatment-emergent definitions, labs/vitals/ECGs
- Joint meetings
 - Analysis and Display White Papers project team with
 - Best Practices for Data Collection Instructions project team
 - Data Visualizations project team



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Working Group Next Steps

- Continue work on Test Dataset Factory Project
 - To provide updated CDISC pilot test data for the script qualification effort and other projects.
 - Continue work on the Script Repository
 - To increase usability, quality, and acceptability of the code in the repository
 - To develop scripts based the recommendations from white papers
 - To continue reviewing scripts from FDA
 - Continue work on white papers
 - Hepatotoxicity (Working on Draft 1 for public review, Lead – Terry Walsh)
 - Questionnaire Data (Working on Draft 1, Lead – Karin LaPann)
 - Definitions for Treatment Emergence (Not yet started)
 - Events of Special Interest (Not started yet)
 - Update white paper on labs/vitals/ECGs
 - Update white paper on demographics/disposition/concom medications
 - Continue work on Communication/Promotion/Education
 - Develop training material
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Working Group Needs

- More project team members
- Increased participation in white paper reviews – Help recruit!
- Use/reference recommendations in existing final white papers!
 - Forward to any existing standards groups
 - Link to white papers from Statistical Analysis Plans
- Participate in re-usable code development
 - Write, Test, Qualify, Review, Improve
- Keep eyes open for existing scripts that need a public home
- Advertise! Advertise! Advertise!



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How to Participate

- Sign up for the PhUSE working group mailings
 - From phusewiki.org, click “Join a Working Group Now”
 - Standard Scripts Groups
 - CSS-WG-Standard-Scripts (Entire Working Group)
 - CSS-WG-Standard-Scripts-WhitePapers (White Paper Project Team)
 - CSS-WG-Standard-Scripts-Platform (Script Repository)
 - CSS-WG-SS-WhitePaperReviewers (Notified when a white paper is ready for review)
- See wiki pages for each of the projects (www.phusewiki.org)



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Important Links

- Working Group:
 - Main Page: http://www.phusewiki.org/wiki/index.php?title=Standard_Scripts
 - Projects:
 - [P01 - SDA](#): Script discovery and acquisition (Rebeka M Revis; Alfredo Rojas)
 - [P02 - RCD](#): Repository content and delivery (Gustav Bernard; Andrew Miskell; FDA Liaison: Mat Soukup)
 - [P03 - RGI](#): Repository governance and infrastructure: (Mike Carniello and Hanming Tu)
 - [P07 - CPE](#): Communication, Promotion and Education (Jared Slain and Wendy Dobson)
 - [P08 - ADW](#): Analysis and Display White papers (Mary Nilsson)
 - [P09 - TDF](#): Test Data Factory (Peter Schaefer)
- Repository:
 - Github: <https://github.com/phuse-org/phuse-scripts>
- Publications:
 - [Analyses and Displays of Central Tendency 10Oct2013](#)
 - [Analyses and Displays of PK 25Mar2014](#)
 - [Analyses and Displays of Demographics, Disposition, and Medications 07Oct2014](#)
 - [Analyses and Displays of Outliers/Shifts from Normal to Abnormal 10Sep2015](#)
 - [Analyses and Displays Associated with ThoroughQT/QTc Studies 11Mar2016](#)
 - [Analyses and Displays Associated with Adverse Events 03Feb2017](#)
- Index Pages:
 - Simple Index: <https://github.com/phuse-org/phuse-scripts/wiki/Simple-Index>.
 - Standard Index: <https://github.com/phuse-org/phuse-scripts/wiki/Standard-Script-Index>
 - Mirrored Index: http://www.phusewiki.org/wiki/index.php?title=Standard_Script_Index
 - FDA JumpStart: <https://github.com/phuse-org/phuse-scripts/wiki/JumpStart-Scripts>



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