

An Update on the Standard Analyses and Code Sharing Working Group

PhUSE SDE

14 April 2017

Mary Nilsson

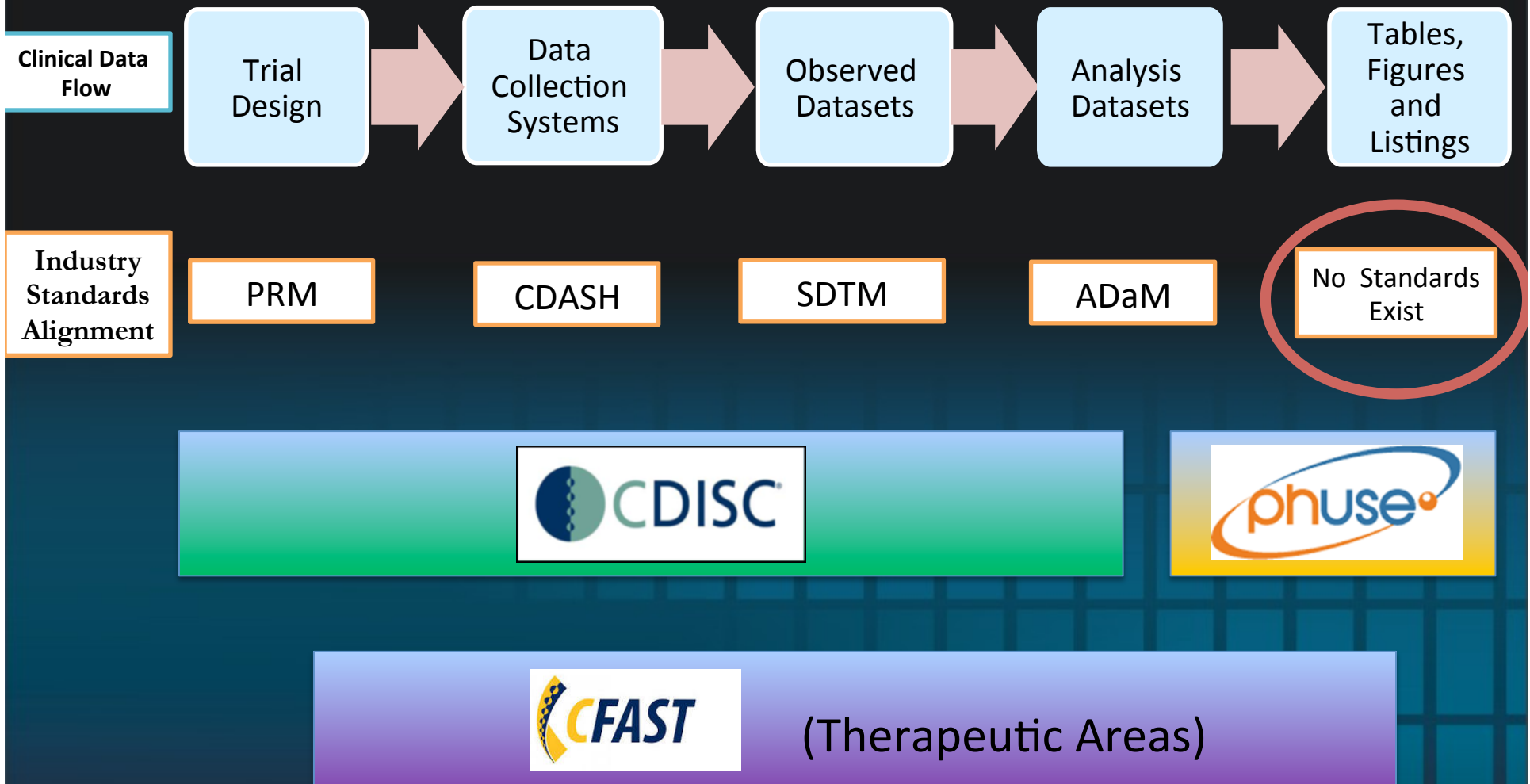


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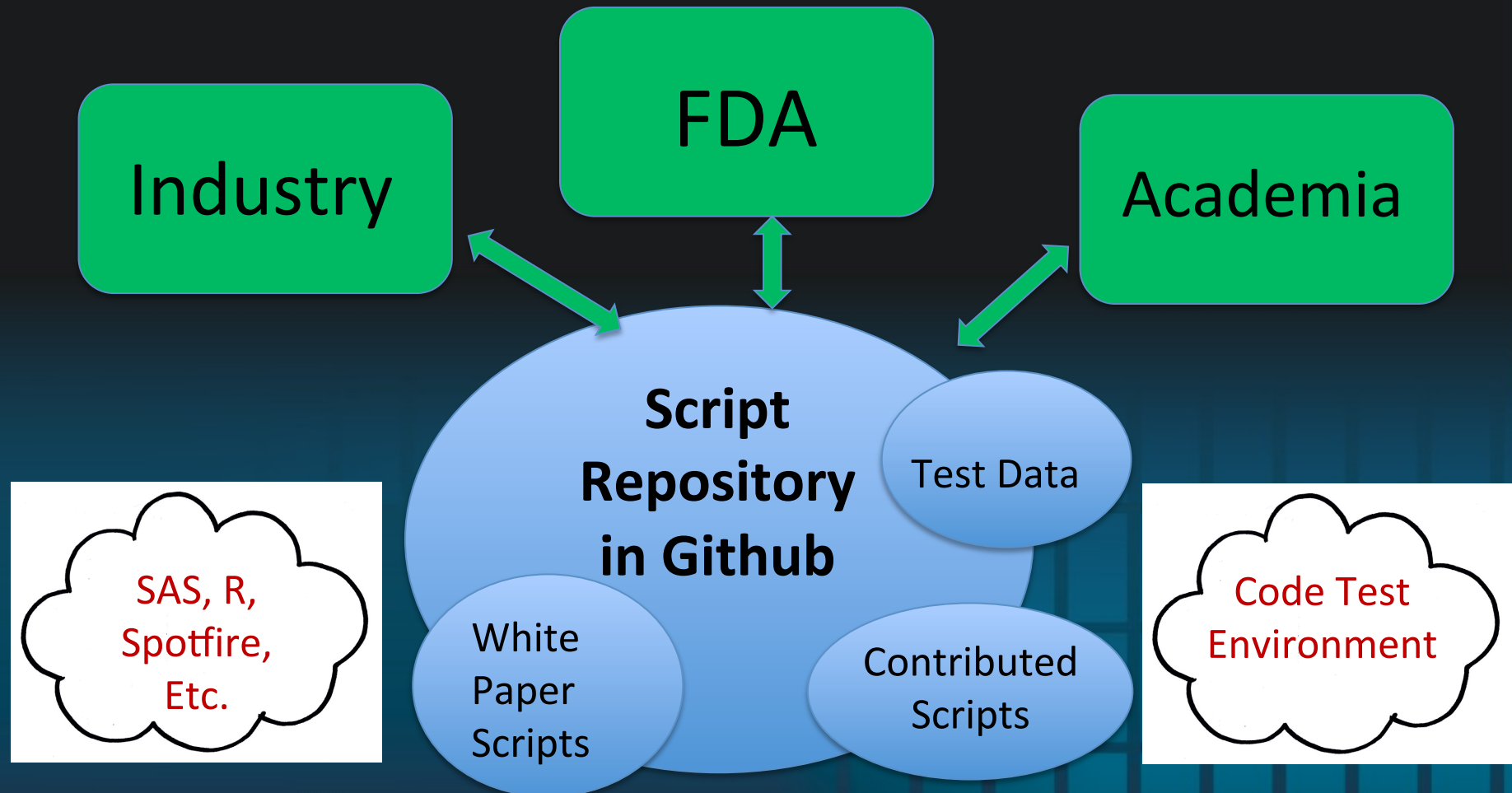


Vision: Fill the Gap on Analysis and Display Standards





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)

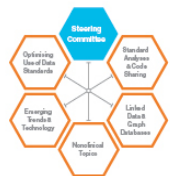
[Communication,
Promotion, Education](#)
(CPE, Jared Slain and
Wendy Dobson)

[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: Repository

- 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: Repository

- 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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Accomplishments: White Papers

- 7 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)
 - Screen Shots of the Displays Created by JumpStart Programs (2017)

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 Next Steps

- Continue work on Test Data Factory Project
 - Provide updated CDISC pilot test data
- Continue work on the Script Repository
 - Increase usability, quality, and acceptability of the code
 - Develop scripts based the recommendations from white papers
- Continue work on white papers
 - See next slide
- Continue work on communication, promotion, and education
 - Develop training material



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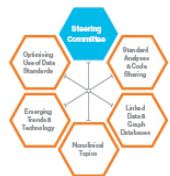


White Papers – Next Steps

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

Implementation at Lilly

- Analysis and display white papers inform internal standards
 - Treated “almost” as requirements
 - Starting to refer to white papers in Statistical Analysis Plans
- Contributed Spotfire templates to the repository
 - Interactive safety review tool using ADaM data
 - Working with the Working Group to see if crowd-sourcing will help continually enhance this tool for shared use
- Have not yet used any code from the repository



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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!

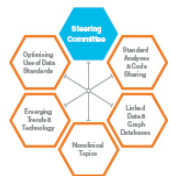


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How to Participate

- 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](#)
 - [Screenshots of Displays Created by JumpStart Programs 17March2017](#)
- 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>
 - Spotfire Templates: <https://github.com/phuse-org/phuse-scripts/tree/master/contributed/Spotfire>



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