



Standard Scripts All-Hands meeting

August 27, 2015

- Facilitator: Hanming Tu
- PhUSE CS WG Overview – Mary Nilsson
- What is the Buzz? – Mat Soukup, FDA
- Projects
 - P01 - SDA: Script discovery and acquisition (Adrienne Bonwick and Aiyu Li)
 - P02 - RCD: Repository content and delivery (Dante Di Tommaso and Peter Schaefer)
 - Central tendency package: target – March 13, 2016
 - P03 - RGI: Repository governance and infrastructure: (Mike Carniello and Chris Butler)
 - P07 - CPE: Communication, Promotion and Education (Dirk Spruck)
 - P08 - ADW: Analysis and Display White papers (Mary Nilsson)
- Forward Looking - Steve Wilson, FDA



PhUSE Computational Science (CS) Working Group Overview

Mary Nilsson



CS Working Group Overview

- Development of Standard Scripts for Analysis and Programming
 - One of 5 Computational Science (CS) Working Groups (FDA/PhUSE collaboration)
 - Kick-off meeting was in 2012 (March 2012 CS Symposium)



Working Group Description

- 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 for documentation and management of scripts
 - Harness data standards whenever feasible

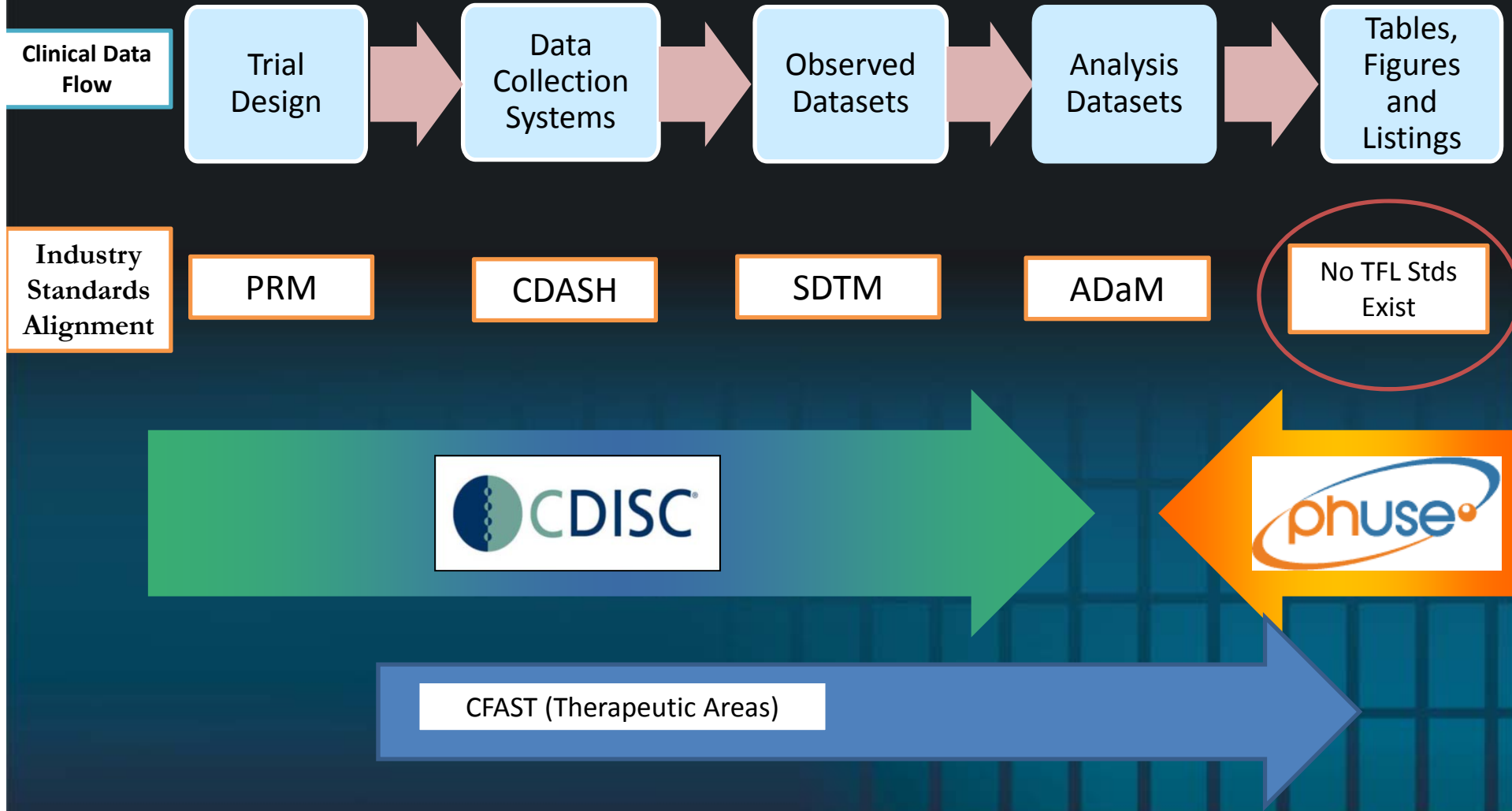


Working Group Leadership

- **Current Leadership**
 - Hanming Tu (Industry co-lead, Project Management)
 - Mary Nilsson (Industry co-lead, Steering Committee Liaison)
 - Steve Wilson (FDA Liaison)
 - Mat Soukup (FDA Liaison)
 - Adrienne Bonwick, Chris Butler, Mike Carniello, Aiyu Li, Mary Nilsson, Peter Schaefer, Dirk Spruck, Dante Di Tommaso (Project leaders)
 - Thank you to past project leaders!

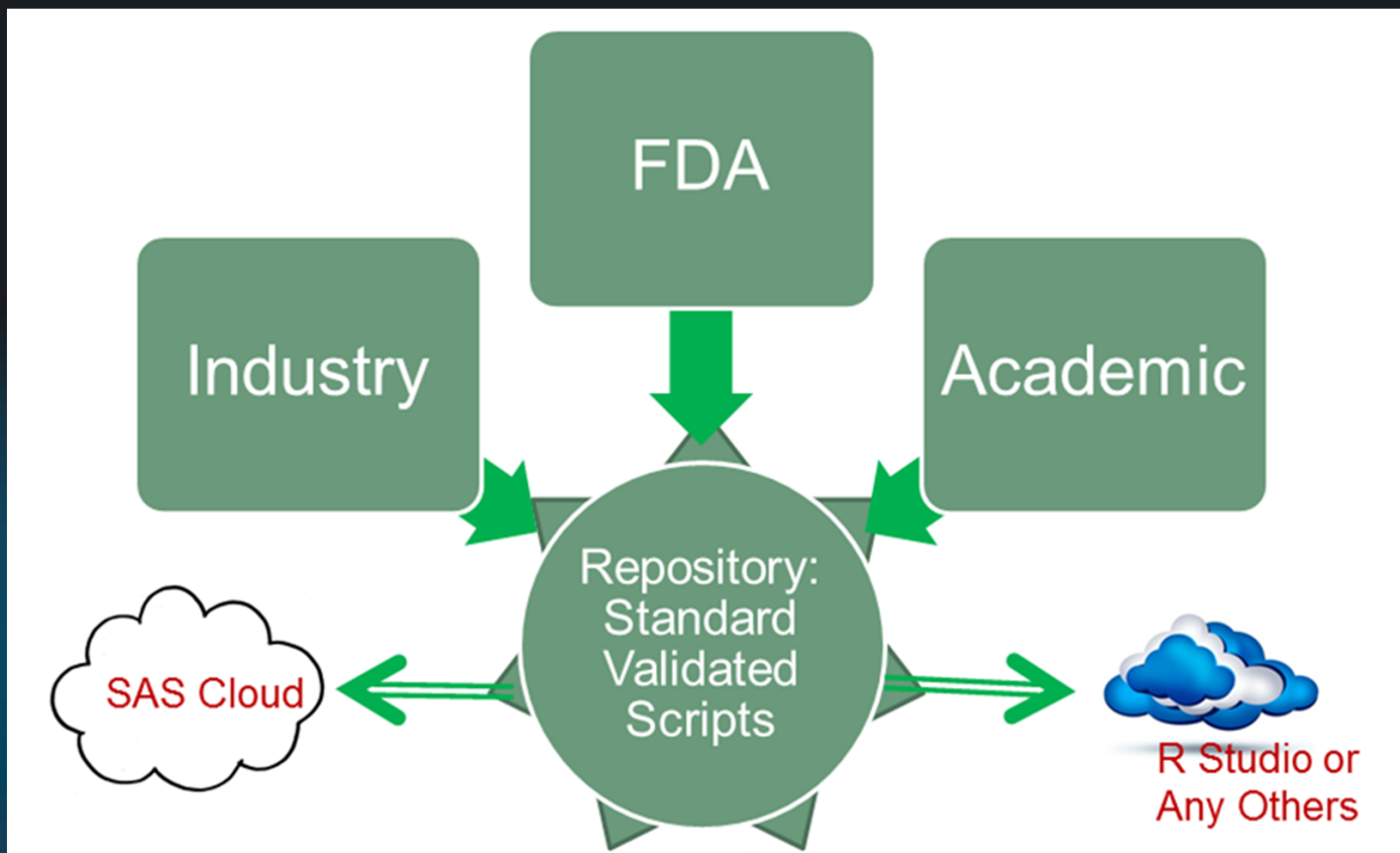


Vision: Fill the Gap on Analysis Standards





Vision: Shared Reusable Code Library (Script Repository)

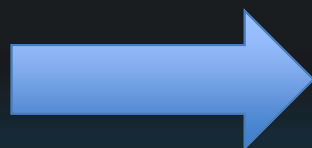




Focus Areas

- **Three Focus Areas, 5 active projects**

Script Repository
(3 projects)



Analyses and Display
White Papers
(ADW, 1 project)

Communication,
Promotion, Education
(CPE, 1 project)

Script Discovery and
Acquisition (SDA)

Repository Content and
Delivery (RCD)

Repository Governance
and Infrastructure
(RGI)



Accomplishments

- Script Repository has been created
 - Started in Google Code, now in GitHub
 - 4 Scriptathons
 - x scripts exist in the repository
 - MIT license chosen
 - Process guidelines developed
 - Qualification guidelines developed
 - User-friendly front end developed



Accomplishments

- 3 White Papers finalized
 - Vital Signs, ECGs, Labs - Central Tendency
 - *Finalized in October 2013*
 - Non-Compartmental Pharmacokinetics
 - *Finalized in March 2014*
 - Demographics, Disposition, and Medications
 - *Finalized October 2014*



What is the Buzz?

Mat Soukup, FDA



What's the Buzz?

- Concept presented at roundtable sessions
 - 2014 ASA Biopharm Statistics Workshop
 - 2015 DIA/FDA Statistics Forum
- Participants were primarily industry statisticians
- The Buzz?
 - Universally, this is a great Idea and concept!
 - Some question on how to get more involved



How do we Increase the Buzz?

- Working suite of scripts for CT white paper
 - Integrates the white paper and computational needs
 - Identification of a process for script creation/management
 - Understanding of the usability of GitHub
- Develop a Training module
- Advertise! Advertise! Advertise!



Benefits of Increasing the Buzz

- Move from a concept to a reality
 - Management buy-in can help provide resources
- Clear understanding of the various parts that need to be in place to make this work
 - Can identify where people can contribute
- Broader base of contributors/resources that can be utilized by the project leads



Project Updates



P01 - SDA: Script discovery and acquisition

Adrienne Bonwick and Aiyu Li



P01 - SDA: Script discovery and acquisition

- Three scripts provided by FDA
 - Demographics
 - Updated with instructions on how to use
 - Adverse events
 - Testing in progress
 - MedDRA at a glance
 - Testing in progress



P02 – RCD, Repository content and delivery

Dante Di Tommaso and Peter Schaefer



Update: P02 – RCD, Repository content and delivery 1 of 3

- Standard Script WG [Project 02 phusewiki site](#)
- Central Tendency package ([link to WG5 Project 08 White Paper](#))
 - ~10 participants and contributors
- Project Programming Guidelines ([link to phusewiki.org](#))
- Streamlined Qualification Process ([link to phusewiki.org](#))
 - Trello board to manage task backlog ([link to Trello board](#))
- Github script repository ([link to github project](#))
 - Specifications for Displays & Scripts ([link to CT Fig. 7.1 specs](#))
 - Test data creation, SDTM & ADaM ([link to github](#))



Update: P02 – RCD, Repository content and delivery 2 of 3

- Github script repository ([link to github project](#))
 - CT Fig. 7.1 scripts in SAS and R (links to github [SAS](#) and [R](#) scripts)
 - SAS and R: same results from same data (links to github [SAS](#) and [R](#) displays)
 - Test plan template ([link to github](#))
 - SAS test scripts in progress, some success
 - SAS test scripts [are in github](#)
 - Successful results [also stored in github](#)
- **CT Figure 7.1 is the basis for 8 of 9 CT displays**
 - White paper proposes 8 box plots, 1 scatter plot



Update: P02 – RCD, Repository content and delivery **3 of 3**

- Working Group Collaborations
 - Working with P03 to simplify github structure
 - Working with P08 to begin review of outputs
- Next steps, **opportunities to contribute**
 - Project 02 (RCD) phusewiki.org lists areas to contribute
 - see page: [Ways To Contribute & Why This Matters](#)
 - Specification, Coding, Testing, Review continue
 - PhUSE Scriptathon 2015 [plans in progress](#)
 - ["Box plot Challenge"](#) coming soon



**Project 03:
Repository Governance and Infrastructure
Project Team**

Chris Butler
Mike Carniello



Repository Governance and Infrastructure

- This project will establish the basic structure and management of the repository. In its first incarnation (2012-2015), Google Code was used for the repository. At the CSS 2015 Meeting (March), the decision was made to move to Github hosting (Google decided in early 2015 to shut down their public sharing site).



The goals of this project are to:

- Define and enforce folder structure and naming conventions
- Define and enforce existence of required metadata for each script
- Support the other projects in what they'd like to see in the repository



Project Plan

For the next CSS conference in 2016, our desire is to have a decided upon structure in place for placing scripts. Much of this input will be determined by our Validation working group.

We will be looking to garner more participation at the Scriptathon event. Additionally, a GitHub best practices session will be given at the conference to Scriptathon contributors.





Script Repository Front End

- <http://code.phuse.com>

This screenshot shows the GitHub interface for the 'phuse-org / phuse-scripts' repository. The main content is a 'Standard Script Index' page, which is a table listing various scripts. The table has four columns: Name, Title, Source, and Type. The table lists three entries: 'AE Scripts.zip', 'Demographics_20140516.zip', and 'MedDRA at a Glance Scripts.zip'. The page also includes navigation options like 'Edit' and 'New Page', and a sidebar with a 'Pages' section containing 'Home' and 'Standard Script Index'. There are also options to 'Clone this wiki locally' and 'Clone in Desktop'.

Name	Title	Source	Type
AE Scripts.zip	AE Analysis Panel	Contributed	table(AE)
Demographics_20140516.zip	Demographics Analysis Panel	Contributed	table(none)
MedDRA at a Glance Scripts.zip	MedDRA at a Glance Script Package	Contributed	table(None)



Current Topics

- Agreed on directory structure
- Not agreed on where to put data
- Not agreed on what to put in that index page
- Actions:
 - Make the new structure in Github and migrate content
 - Get agreement on data structure and index content
 - After that, update the Index page



P07 - CPE Communication, Promotion and Education

Dirk Spruck



Presenting Working Group Results

- 2015
 - PhUSE CSS & PharmaSUG Conference
 - PhUSE Annual Conference
(Scriptathon & update planned)
 - SCDM Annual Conference (update planned)
- Less Activities compared to 2014
 - Pending Consolidation and Qualification of PhUSE
Script Repository

- Development of Training Material
 - White Paper “Packages”
 - Webinars
 - Flyers
- Promote “Packages” and new White Papers
 - Conferences, Social Media
- Continuous Delivery of Progress Update
 - Please help spreading the word!



P08 - ADW: Analysis and Displays White Papers

Mary Nilsson



White Papers Project

- Finalized
 - Vital Signs, ECGs, Labs - Central Tendency
 - *Finalized in October 2013*
 - *Lead – Mary Nilsson*
 - Non-Compartmental Pharmacokinetics
 - *Finalized in March 2014*
 - *Lead - Francois Vandenhende*
 - Demographics, Disposition, and Medications
 - *Finalized October 2014*
 - *Lead – Simin Baygani*



White Papers Project

- Almost Final
 - Vital Signs, ECGs, Labs – Outliers/Shifts
 - Lead – Wei Wang
- In Progress
 - Adverse Events
 - Working on Draft 2 for broad review
 - Lead – Sheryl Treichel
 - Hepatotoxicity
 - Working on Draft 1 for broad review
 - Lead – Terry Walsh
 - TQT Studies
 - Draft 1 almost ready for broad review
 - Lead - Christos Stylianou
 - Questionnaire Data
 - Just starting
 - Lead - Karin LaPann





White Papers Project

- Planned
 - Events of Special Interest
 - Will likely start early next year
 - Lead – Wei Wang and Mary Nilsson
- Ideas
 - TOSNP and Narratives
 - Combining Studies for Integrated Analyses – Points to Consider
 - Multi-phase Studies – Points to Consider



White Papers Project

- Project Liaisons
 - CDISC ADaM – Karin LaPann and Nancy Brucken
 - White Papers to include ADaM specifications
 - Script Repository – Mercy Navarro
 - CFAST – Mary Nilsson
 - FDA – Nhi Beasley



White Papers Project

- Getting Involved
 - How to join the project team: Go to www.phusewiki.org. Under CSS Working Groups, you'll see a link to "Join a Working Group now". Follow the instructions. The analysis and display white papers project team is: CSS-WG-Standard-Scripts-WhitePapers
 - CSS-WG-SS-WhitePaperReviewers was created for those who do not want to join the project team but wants to be alerted when a white paper is ready for review or finalized



Forward Looking

Steve Wilson, FDA



Forward Looking: Purpose

This working group will identify potential standard scripts for data transformations and analyses across and/or within a therapeutic area and exploratory analysis. The goal will be to begin the process of standardizing analyses across the industry, but also include examples of what can be done with a standardized data set.

http://www.phusewiki.org/wiki/index.php?title=Standard_Scripts



Forward Looking: Opportunities

- Immediate
 - FDA/CDER (e.g., CDER/OCS, SDRG/ADRG)
 - CDISC – (e.g., MOU, Therapeutic Area Standards)
- Collaboration
 - Other PhUSE Working Groups
 - Regulatory Agencies
 - Industry
 - Healthcare
 - Academia
- Starting Small, but THINKING BIG



Forward Looking: Next Steps

- Establish the Development Environment
- Create a User-Friendly Interface
- Think about Science / Decisions
- Listen/Learn
- Educate
- Celebrate/describe/publicize “Success”
(i.e., Your Contributions)



Forward Looking: Volunteers





Interested In Learning More?

- Sign up for the PhUSE working group mailings
 - Go to www.listbox.com
 - Join this group: “CSS WG5: Developing Standard Scripts” (CSS-WG-Standard-Scripts@listbox.com)
- Sign up to be a contributor or committer in the script repository (Google account required)
 - Send an email to one of the repository maintainers to request to join the Google Code PhUSE/FDA script repository
 - Go to repository at <https://code.google.com/p/phuse-scripts/> and start interacting



Reference URLs

- PhUSE home: <http://phuse.eu/>
- PhUSE Wiki: www.phusewiki.org
- PhUSE Standard Script Group:
[http://www.phusewiki.org/wiki/index.php?title=Standard Scripts](http://www.phusewiki.org/wiki/index.php?title=Standard_Scripts)
- PhUSE Repository:
 - <http://code.phuse.com>
 - <https://github.com/phuse-org/phuse-scripts/wiki/Standard-Script-Index>
 - [http://www.phusewiki.org/wiki/index.php?title=Standard Script Index](http://www.phusewiki.org/wiki/index.php?title=Standard_Script_Index)

