



FDA/PhUSE CSS Working Group: Open Code Repository

Hanming Tu
PhUSE Standard Script Group
Project Manager

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

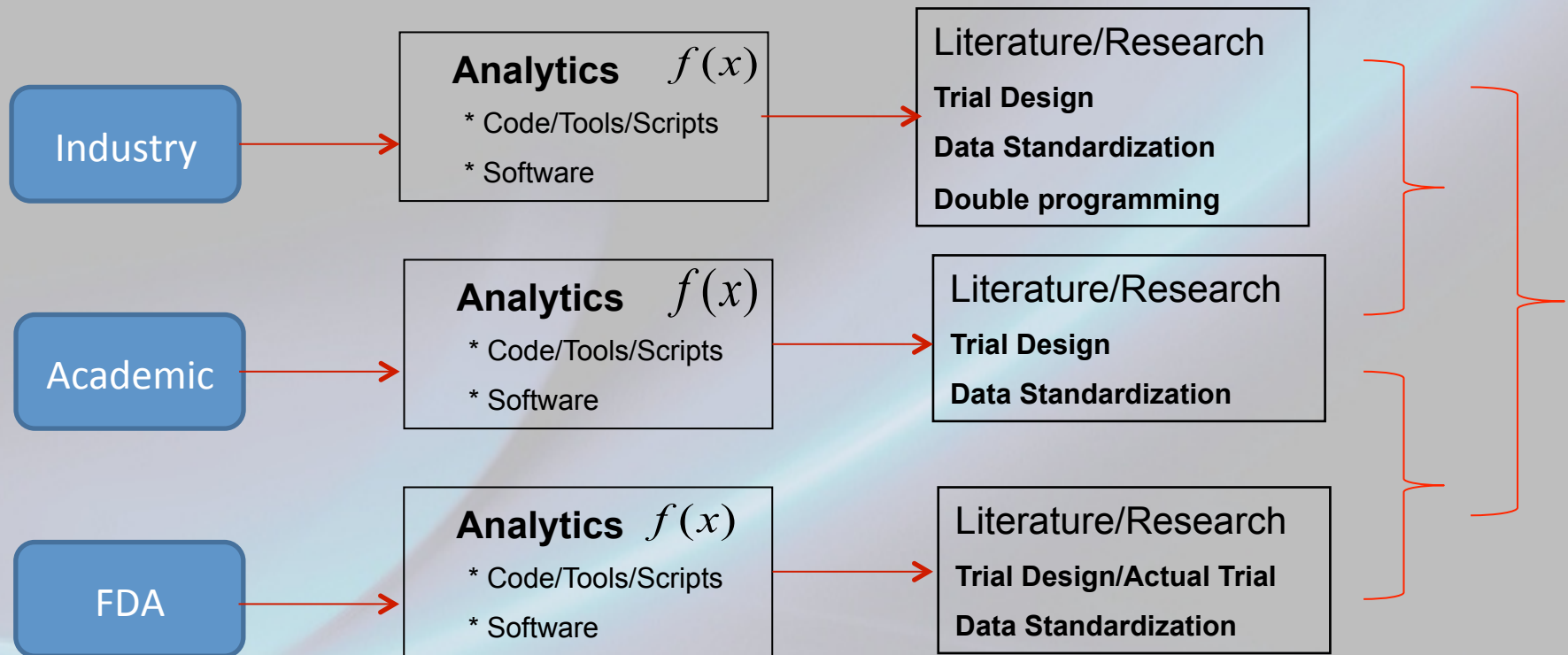


Agenda

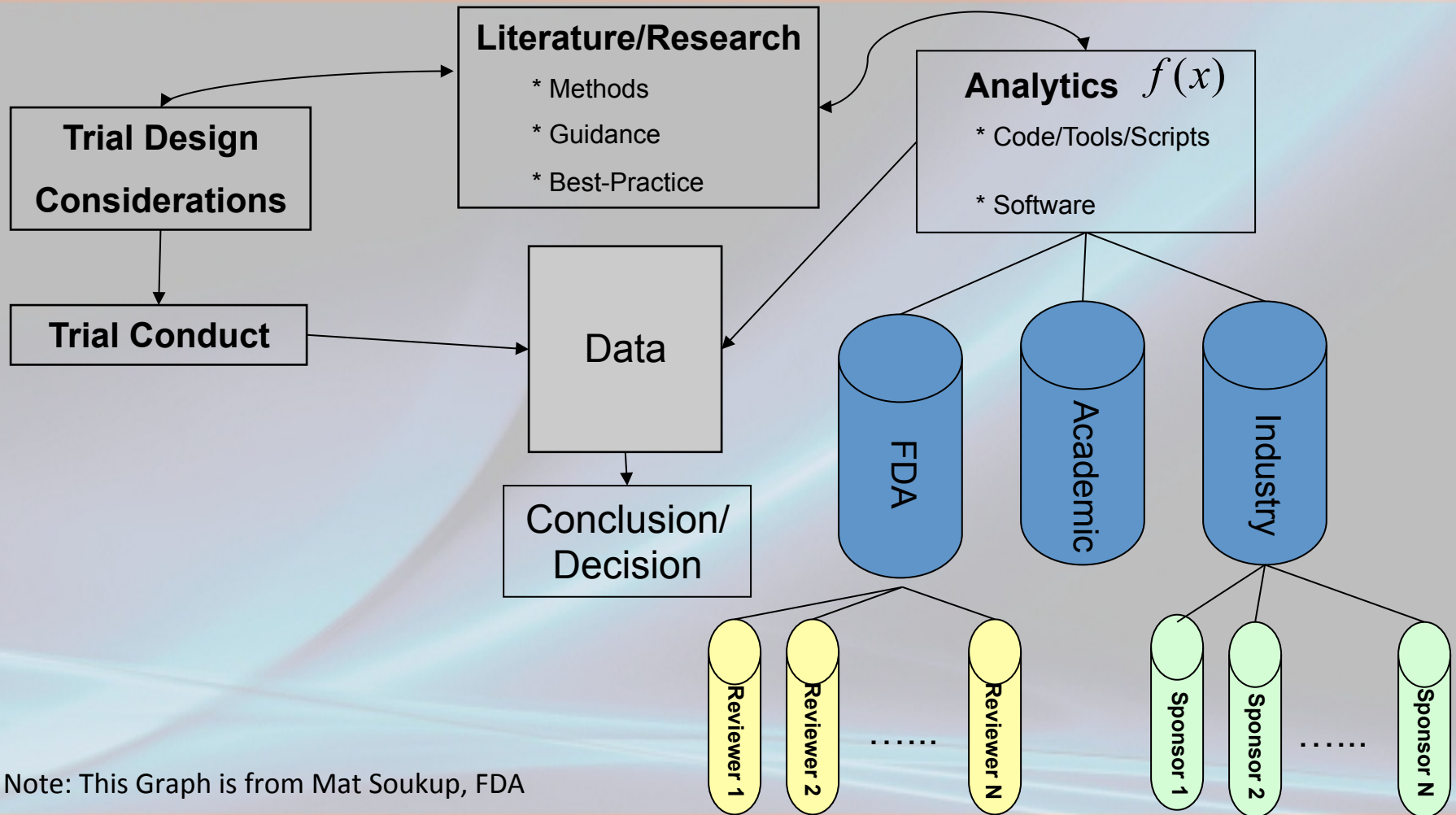


- Why We Need the Open Source Repository
- Intro to the Standard Script Group
- Review Open Source Repository
- Current and Future Events

In a Silo World

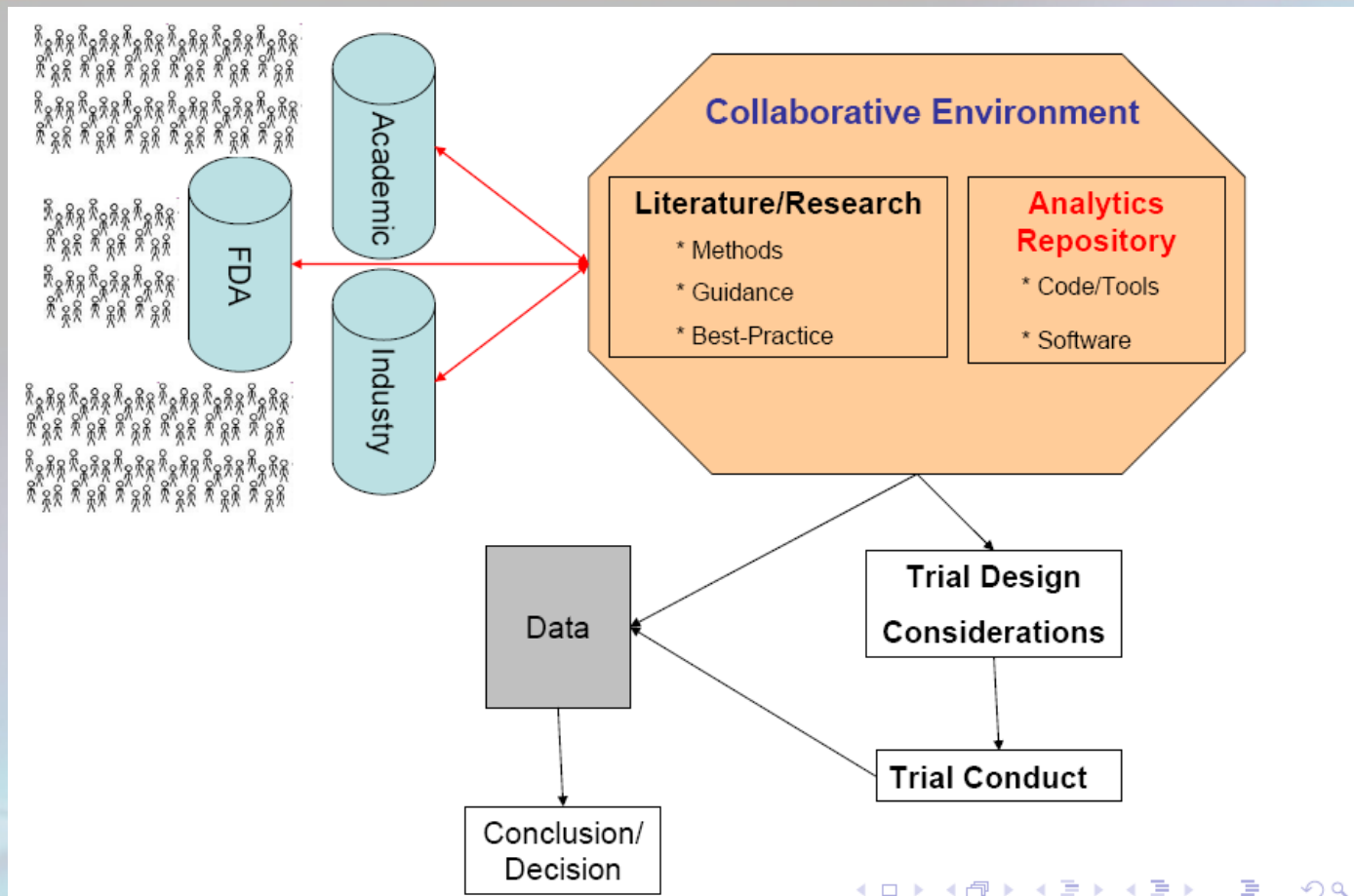


Moving Away from Silos



Note: This Graph is from Mat Soukup, FDA

Towards Collaboration



Note: This Graph is from Mat Soukup, FDA



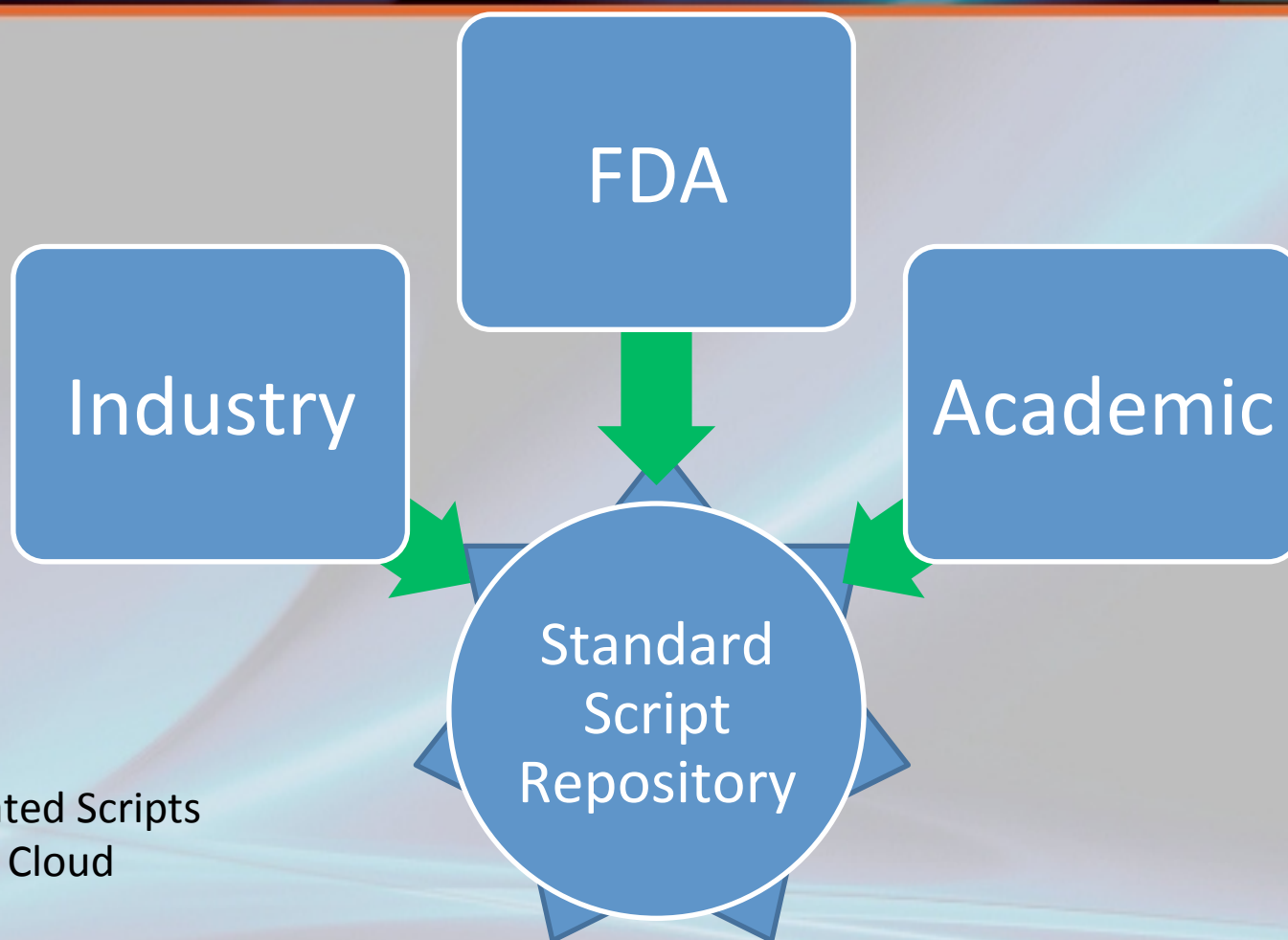
Not TOO Long Ago Vision

Three Areas that Need to be Addressed

1. Development of platform that caters to collaboration
2. Need for a process and guidelines for registering and maintaining scripts
3. Standards analyses across the industry

Formed the basis of the discussion at the 2012 FDA/PhUSE Meeting

Future Vision



- * Validated Scripts
- * In the Cloud



Standard Script Group Formed

- **Development of Standard Scripts for Analysis and Programming Group was formed during 2012 FDA/CSS PhUSE March 2012 meeting**
- **Leadership**
 - Hanming Tu (Project Management)
 - Scott Getzin (Steering Committee Liaison)
 - Steve Wilson (FDA co-lead)
 - Mat Soukup (FDA co-lead)
 - Mary Nilsson (Industry co-lead)



Working Group Description

- Goal: Establish a platform for the collaborative development of specialized program code to be used as analytical tools for the clinical trial research, reporting, and analysis. This includes:
 - Identification of areas that can benefit from a standard set of analyses
 - Within a topic area, includes recommendations for analyses, tables and figures
 - Developing a process and guidelines for documentation and management of scripts
 - Harness data standards whenever feasible



Two Focus Areas

- **Initially three sub-groups**
 - Sub Group 1: works on developing and prioritizing lists of analysis scripts to be developed
 - Sub Group 2: works on process for developing, validating and documenting scripts
 - Sub Group 3: works on technology platform to support script development, testing and documentation.
- **Two Focus Areas:**
 - White Paper Development: standards, formats, etc.
 - Repository Platform: platform, process, development, access, validation, etc.



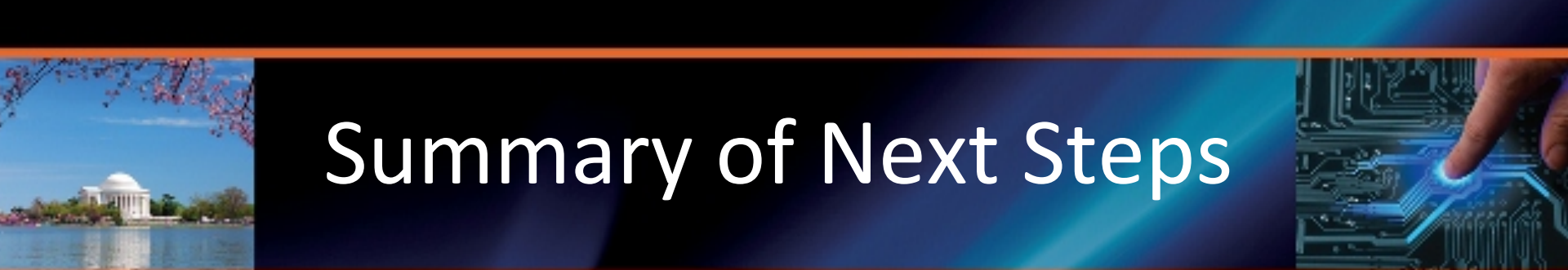
Eight Projects

- [P01](#): Look for existing scripts and store them in the repository (Kevin Kane)
- [P02](#): Define qualification steps and Metadata for scripts in the repository (Jack Averill/Lina Jørgensen)
- [P03](#): Maintain and enhance platform (repository) for sharing scripts (Mike Carniello/Hanming Tu)
- [P04](#): Legal ownership and issues in open source repository (Kevin Kane/Sally Cassells)
- [P05](#): Create templates for documenting scripts and coding practices (Jean-Marc Ferran)
- [P06](#): Refine process for creating and editing scripts in Google Code (Kevin Kane)
- [P07](#): Implement and further develop communication plan for standard scripts (Dirk Spruck)
- [P08](#): Create white papers providing recommended display and analysis including Table, List and Figure shells (Mary Nilsson)



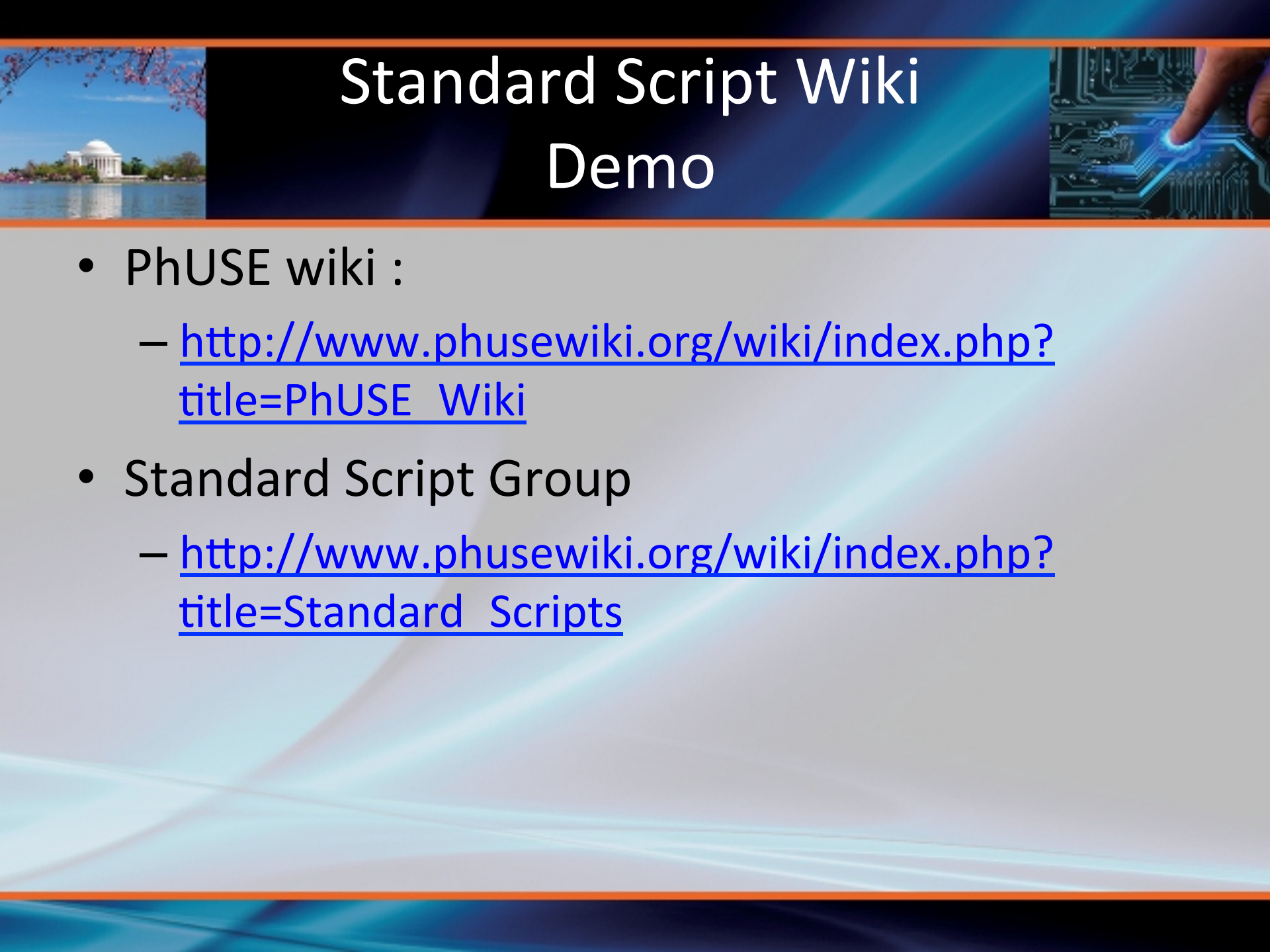
Accomplishments

- Script Repository has been created
 - Google Code chosen
 - Some scripts exist on repository
 - Call for additional scripts issued last month
 - MIT license chosen
 - Process guidelines developed
- White Papers Describing Recommended Analyses, Tables, Figures, and Listings
 - For common measurements (e.g., safety)
 - One white paper is nearing completion; 5 others planned



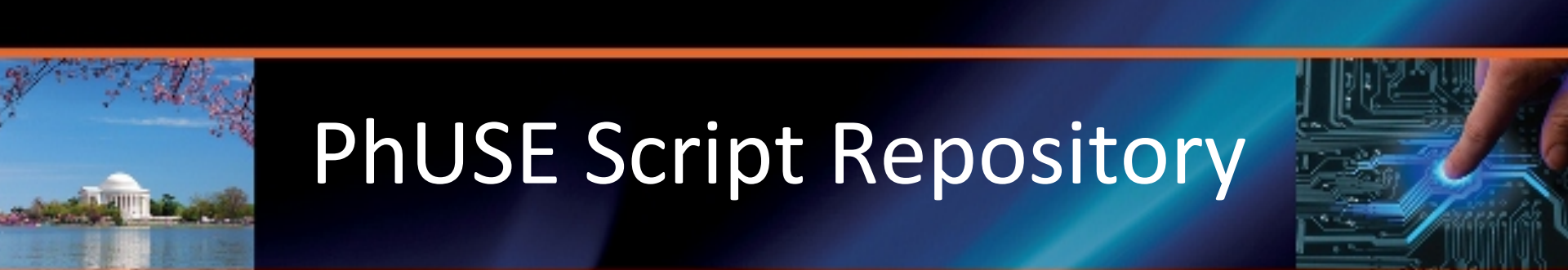
Summary of Next Steps

- Get more scripts in the Script Repository
 - Networking
 - Broad Communications
- Address any remaining validation, legal, process issues
- Finalize first white paper
 - Goal to finalize by **October 4**
- Begin work on the remaining white papers
 - Looking for more active participants
 - Goal to be final or near-final by **March 2014**



Standard Script Wiki Demo

- PhUSE wiki :
 - http://www.phusewiki.org/wiki/index.php?title=PhUSE_Wiki
- Standard Script Group
 - http://www.phusewiki.org/wiki/index.php?title=Standard_Scripts



PhUSE Script Repository

- This project 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.
- This will be an interactive session using online wiki to create and add input that can be shared openly between industry and regulatory.

PhUSE Script Repository

The image is a collage of three screenshots related to the PhUSE script repository.

Top Left: PhUSE Scripts Website
The website header shows the PhUSE logo and the text "phuse-scripts Development of Standard Scripts for Analysis and Reporting". Navigation links include "Project Home", "Downloads", "Wiki", "Issues", and "Source". Below these are links for "Checkout", "Browse", and "Changes". The "Source" section shows the "svn/" path and a directory tree:

- svn
 - trunk
 - docs
 - lang
 - R
 - analysis
 - DM
 - graph
 - report
 - SAS
 - analysis
 - DM
 - datahandle
 - graph
 - KM
 - report
 - plsql
 - wiki

Top Right: Windows Explorer
The Explorer window shows the "report" folder in the path "Libraries > Documents > My Documents > PhuseWork > lang > SAS > report". The "Documents library" pane shows a table of files:

Name	Date modified	Type	Size
doevents.sas	2/20/2013 3:31 PM	SAS File	0 KB
summary.sas	2/20/2013 3:31 PM	SAS File	84 KB

Bottom: TortoiseSVN Log Messages
The "Log Messages - TortoiseSVN" window shows the log for the path "C:\Users\Sally PC\Documents\PhuseWork\lang\SAS\report". The log entry for revision 44 is:

Revision	Author	Date	Message
44		2/13/2013	This is a SAS macro designed to create tables of event counts (e.g. adverse events/concomitant medications) in clinical trials.

PhUSE Script Repository

- Interface: Project Home

[hanming.tu@gmail.com](#) ▼ | [My favorites](#) ▼ | [Profile](#) | [Sign out](#)

 **phuse-scripts**
Development of Standard Scripts for Analysis and Programming

[Project Home](#) | [Downloads](#) | [Wiki](#) | [Issues](#) | [Source](#) | [Administer](#)

[Summary](#) | [People](#)

Tip: Project owners, see our [Getting Started](#) guide for steps to configure your project.

Project Information

 +4 including [Kevin](#)

 Starred by 3 users
[Project feeds](#)

Code license
[MIT License](#)

Labels
[PhUse](#), [Scripts](#), [Academic](#),
[R](#), [SAS](#), [PLSQL](#), [FDA](#)

 **Members**
[hanming.tu](#)
[6 committers](#)

This project 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. This will be an interactive session using online wiki to create and add input that can be shared openly between industry and regulatory.

PhUSE Script Repository

- Interface: Download

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[Administer](#)

New download

Search

Current downloads



for

Search

1 - 4 of 4

	Filename ▼	Summary + Labels ▼	Uploaded ▼	ReleaseDate ▼	Size ▼	DownloadCount ▼	...
☆	sl_gs_output.sas	Output helper code for demographics.sas	Oct 24	Oct 24	32.5 KB	7	
☆	Master.sas	Helper file used by demographics.sas	Oct 24	Oct 24	22.7 KB	4	
☆	data_checks.sas	Error checking code used by demographics.sas	Oct 24	Oct 24	10.0 KB	8	
☆	demographics.sas	Demographics Code from FDA	Oct 24	Oct 24	36.7 KB	12	

1 - 4 of 4

PhUSE Script Repository

- Interface: Wiki

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Development of Standard Scripts for Analysis and Programming

Search projects

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New page

Search

Current pages



for

Search

1 - 1 of 1

PageName ▼	Summary + Labels ▼	Changed ▼	ChangedBy ▼	...
★ ReadMeFirst	This page is designed to serve as the Welcome page for this Google Code site.	Dec 19	hanming.tu	

1 - 1 of 1

[Terms](#) - [Privacy](#) - [Project Hosting Help](#)

Powered by [Google Project Hosting](#)

PhUSE Script Repository

- Interface: Source

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phuse-scripts

Development of Standard Scripts for Analysis and Programming

[Project Home](#) [Downloads](#) [Wiki](#) [Issues](#) **Source** [Administer](#)

Checkout [Browse](#) [Changes](#) [Request code review](#)

How-to: Explore this project's source code by clicking the "Browse" and "Changes" links above.

Command-line access

If you plan to make changes, use this command to check out the code as yourself using HTTPS:

```
# Project members authenticate over HTTPS to allow committing changes.  
svn checkout https://phuse-scripts.googlecode.com/svn/trunk/ phuse-scripts --username hanming.tu@gmail.com
```

When prompted, enter your generated [googlecode.com password](#).

Use this command to anonymously check out the latest project source code:

```
# Non-members may check out a read-only working copy anonymously over HTTP.  
svn checkout http://phuse-scripts.googlecode.com/svn/trunk/ phuse-scripts-read-only
```

PhUSE Script Repository

- Folder Structure

```
./trunk/{type}/{lang}/{cat}/{prg|sub-cat}/
```

where

{type}	- docs lang etc
{lang}	- SAS R plsql SPSS JAVA C perl etc
{cat}	- report graph ...
{prg}	- program name; for large program with multiple source files, it can have the following sub-folders:
./baks	- backups of milestone versions
./data	- testing data
./docs	- stores the documents for the requirements, proposed solutions, etc.
./src	- stores the source programs
./result	- expected output result
./valid	- validation process and steps

trunk

```
./docs - documents for describing a procedure, report, program or anything related to the repository.  
./lang - languages such as SAS, R, PL/SQL, etc  
    ./SAS  
    ./R  
    ./plsql  
    ./SPSS  
    ./JAVA  
    ./C  
    ./perl  
    ./etc  
./etc
```

PhUSE Script Repository

- Folder Hierarchy



phuse-scripts
Development of Standard Scripts for Analysis and Programming

[Project Home](#) [Downloads](#) [Wiki](#) [Issues](#) **Source** [Administer](#)

[Checkout](#) **Browse** [Changes](#) [Request code review](#)

Source path: `svn/` [<r20](#) [r21](#)

Directories	Filename	Size	Rev	Date	Author
▼ svn ▼ trunk - docs ▼ lang ▼ R ▼ analysis - DM ▼ graph - KM - report ► SAS ► plsql - wiki	No files in the selected directory. Select a subdirectory, if one exists, or another directory from the tree on the left.				
Create or upload a new file					

Your project is using approximately 22.2 MB out of 4096 MB total quota.
You can [reset this repository](#) so that `svnsync` can be used to upload existing code history.

PhUSE Script Repository

- Folder Hierarchy



phuse-scripts

Development of Standard Scripts for Analysis and Programming

Search projects

[Project Home](#) [Downloads](#) [Wiki](#) [Issues](#) **Source** [Administer](#)

[Checkout](#) **Browse** [Changes](#)

Search Trunk

[Request code review](#)

Source path: svn/

[< r20](#) [r21](#)

	Filename	Size	Rev	Date	Author
docs	Master.sas	22.7 KB	r1	Nov 5, 2012	hanming.tu
▼ lang	age_analysis.sas	866 bytes	r1	Nov 5, 2012	hanming.tu
▶ R	agegroup_analysis.sas	903 bytes	r1	Nov 5, 2012	hanming.tu
▼ SAS	create_adsl.sas	1.7 KB	r1	Nov 5, 2012	hanming.tu
▼ analysis	data_checks.sas	10.0 KB	r1	Nov 5, 2012	hanming.tu
▼ DM	demographics.sas	36.7 KB	r1	Nov 5, 2012	hanming.tu
baks	err_output.sas	8.6 KB	r1	Nov 5, 2012	hanming.tu
data	race_analysis.sas	850 bytes	r1	Nov 5, 2012	hanming.tu
docs	sl_gs_output.sas	32.5 KB	r1	Nov 5, 2012	hanming.tu
result					
src					
valid					
▼ graph					
KM					
report					

Your project is using approximately 22.2 MB out of 4096 MB total quota.

You can [reset this repository](#) so that svnsync can be used to upload existing code history.



PhUSE Script Repository – Roles and Contribution

- **Require:** Google Account email address. Each person must have already created a Google Account with that email address.
- **Project owners:** may make any change to this project.
- **Project committers:** may work in the project, but may not reconfigure it. In FDA/PhUSE project, a committer shall take some duties in the repository and shall take ownership for at least one script and shall guide and recruit developers to develop the script and document milestones of the script advancements.
- **Project contributors:** start with the same permissions as non-members, but their role in the project is visible. A contributor shall take at least one duty in the repository and may participate at development of a script.
- Additional permissions can be granted to committers and contributors on the project's people sub-tab.

Role: Owner

Role: Owner [Hide permissions](#)

Standard permissions

☒ View	View downloads, wiki pages, and issues
☒ Commit	Commit source code changes (including wiki)
☒ CreateDownload	Create a new download
☒ EditDownload	Edit attributes of a download
☒ DeleteDownload	Delete a download
☒ EditWiki	Create, edit, and delete wiki pages via web UI
☒ AddWikiComment	Add a comment to a wiki page, if enabled in the project
☒ CreateIssue	Enter a new issue
☒ AddIssueComment	Add a comment to an issue
☒ EditIssue	Edit the attributes of an issue
☒ DeleteIssue	Delete/undelete an issue
☒ ViewPrivateArtifact	View issues labeled private
☒ DeleteAny	Delete comments by anyone
☒ EditAnyDuties	Edit anyone's duties

Custom permissions

Duties:

Role: Committer

Role: Committer [Hide permissions](#)

Standard permissions

- | | |
|---|---|
| ☒ View | View downloads, wiki pages, and issues |
| ☒ Commit | Commit source code changes (including wiki) |
| ☒ CreateDownload | Create a new download |
| ☒ EditDownload | Edit attributes of a download |
| ☒ DeleteDownload | Delete a download |
| ☒ EditWiki | Create, edit, and delete wiki pages via web UI |
| ☒ AddWikiComment | Add a comment to a wiki page, if enabled in the project |
| ☒ CreateIssue | Enter a new issue |
| ☒ AddIssueComment | Add a comment to an issue |
| ☒ EditIssue | Edit the attributes of an issue |
| ☐ DeleteIssue | Delete/undelete an issue |
| ☒ ViewPrivateArtifact | View issues labeled private |
| ☐ DeleteAny | Delete comments by anyone |
| ☐ EditAnyDuties | Edit anyone's duties |

Custom permissions

Duties:

Role: Contributor

Role: Contributor [Hide permissions](#)

Standard permissions

- | | |
|---|---|
| ☒ View | View downloads, wiki pages, and issues |
| ☐ Commit | Commit source code changes (including wiki) |
| ☐ CreateDownload | Create a new download |
| ☐ EditDownload | Edit attributes of a download |
| ☐ DeleteDownload | Delete a download |
| ☒ EditWiki | Create, edit, and delete wiki pages via web UI |
| ☒ AddWikiComment | Add a comment to a wiki page, if enabled in the project |
| ☒ CreateIssue | Enter a new issue |
| ☒ AddIssueComment | Add a comment to an issue |
| ☐ EditIssue | Edit the attributes of an issue |
| ☐ DeleteIssue | Delete/undelete an issue |
| ☐ ViewPrivateArtifact | View issues labeled private |
| ☐ DeleteAny | Delete comments by anyone |
| ☐ EditAnyDuties | Edit anyone's duties |

Custom permissions

Duties: Document our development process and help new members



PhUSE Script Repository – Tools and Access



- **Browser:** you can perform the following tasks with a browser:
 - Browse the repository and review committed changes
 - Create or upload a new file
 - Edit an existing file
- **Subversion:** This repository may be accessed using many different client programs and plug-ins.
- TortoiseSVN:



Current and Future Events

- The 1st White paper for final approval:
 - http://www.phusewiki.org/wiki/images/a/a4/FDA_PhUSE_WhitePaper_CentralTendency_ForApproval_20Sept2013.docx
- Code-athon at FDA/PhUSE Computational Science Symposium 2014 :
 - http://www.phusewiki.org/wiki/index.php?title=Codeathon_2014_proposal
 - Time: March 17~18, 2014
 - Who: the first 20 people who sign up as part of the meeting registration process



Access Scripts in the Repository

- How to execute SAS and R scripts which are hosted in the Code Repository
- R example: To execute the R script in your R environment, execute:

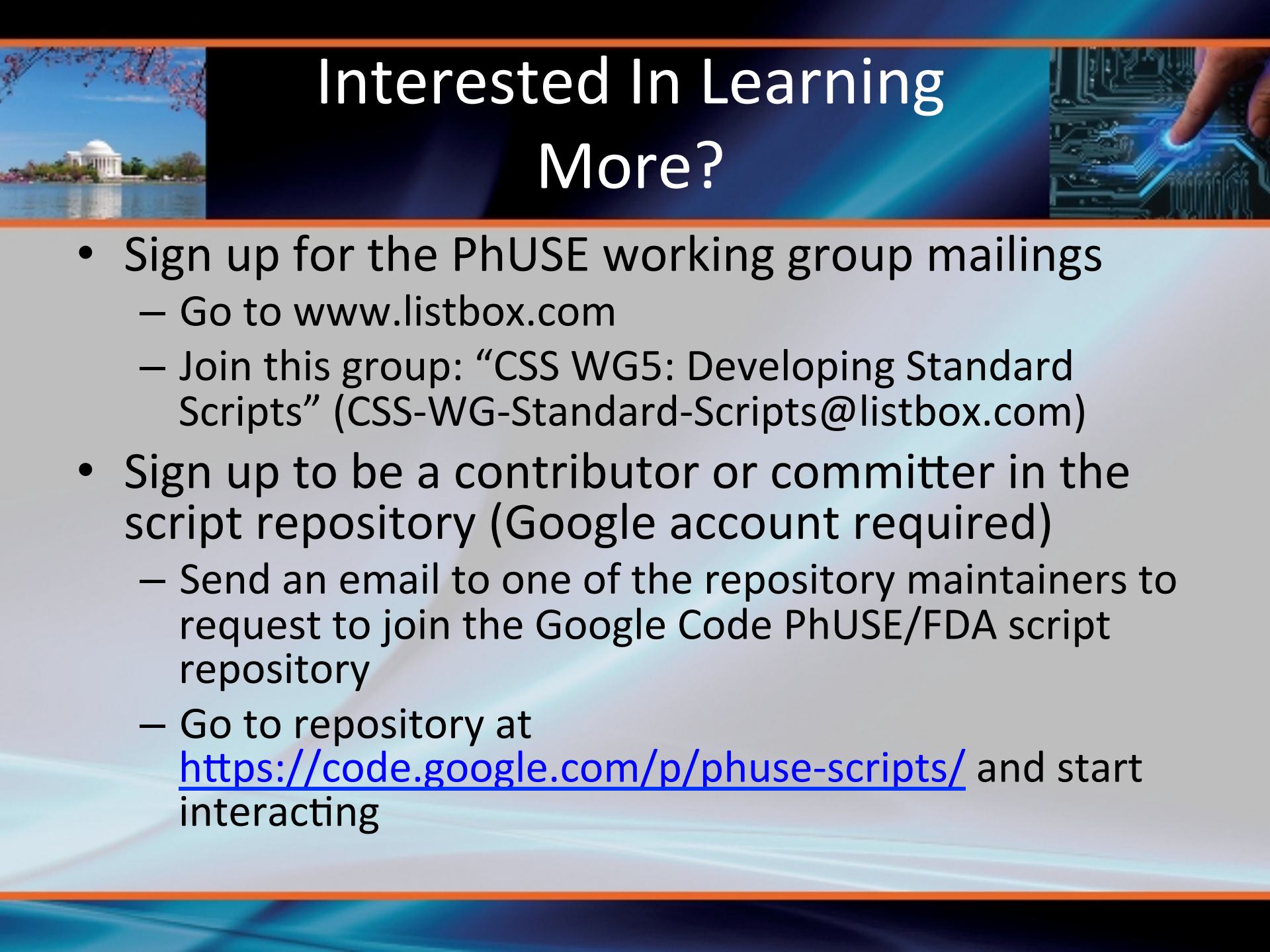
```
source("http://phuse-scripts.googlecode.com/svn/trunk/lang/R/report/test/src/adsl.R",echo=T)
```

- SAS example: To execute the SAS script in your SAS environment, execute:

```
options source2 ;
```

```
filename code url "http://phuse-scripts.googlecode.com/svn/trunk/lang/SAS/report/test/src/  
summary.sas" ;
```

```
%include code ;
```



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



Q&A

