



FDA/PhUSE 
Computational Science Symposium

March 18th – 19th 2013

Silver Spring Civic Center | Silver Spring, Maryland, USA



Development of Standard Scripts for Analysis and Programming

18 March 2013



Outline



- Working Group Description
- Summary of Accomplishments
- Summary of Next Steps



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 tables and figures
 - Developing a process and guidelines for documentation and management of scripts
 - Harness data standards whenever feasible



Working Group Description

- 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)



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 Tables, Figures, and Listings
 - For common measurements (e.g., safety)
 - One white paper is nearing completion; 5 others planned



Google Code

- Google Code provides a free collaborative development environment for open source projects.
- Project hosting on Google Code provides the tools necessary for engineers to work together to build, and maintain open source software.
- Each project comes with its own member controls, Subversion/Mercurial/Git repository, issue tracker, wiki pages, and downloads section.

PhUSE Script Repository

The image is a collage of four screenshots related to the PhUSE Script Repository:

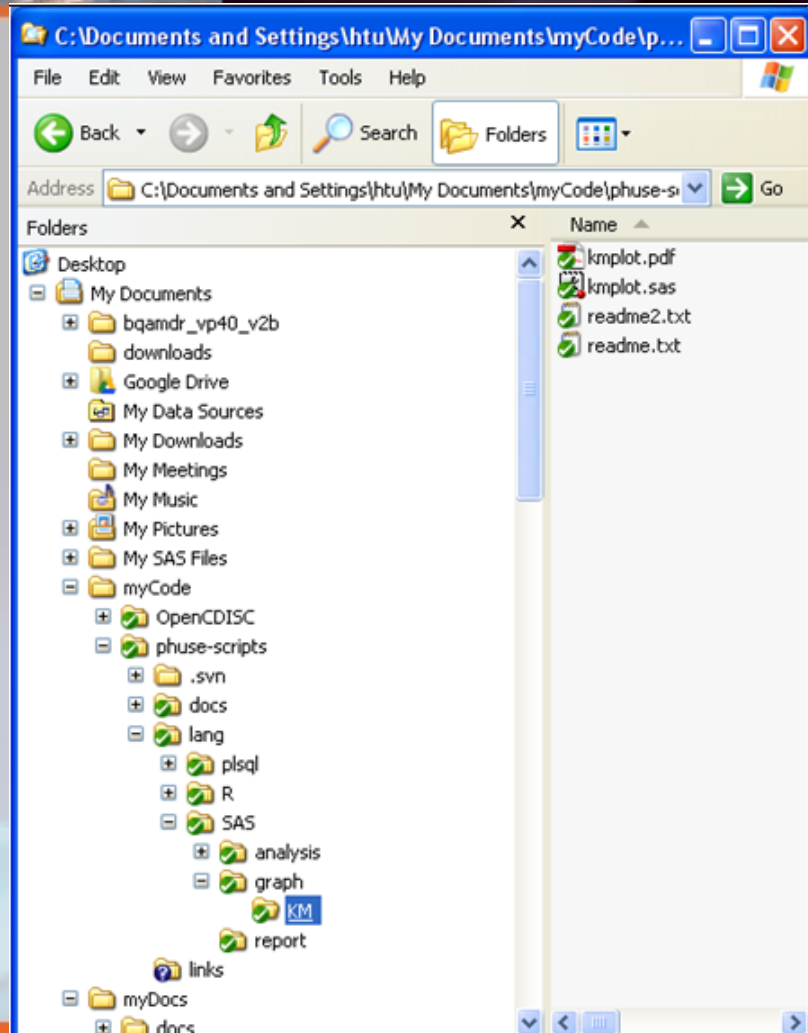
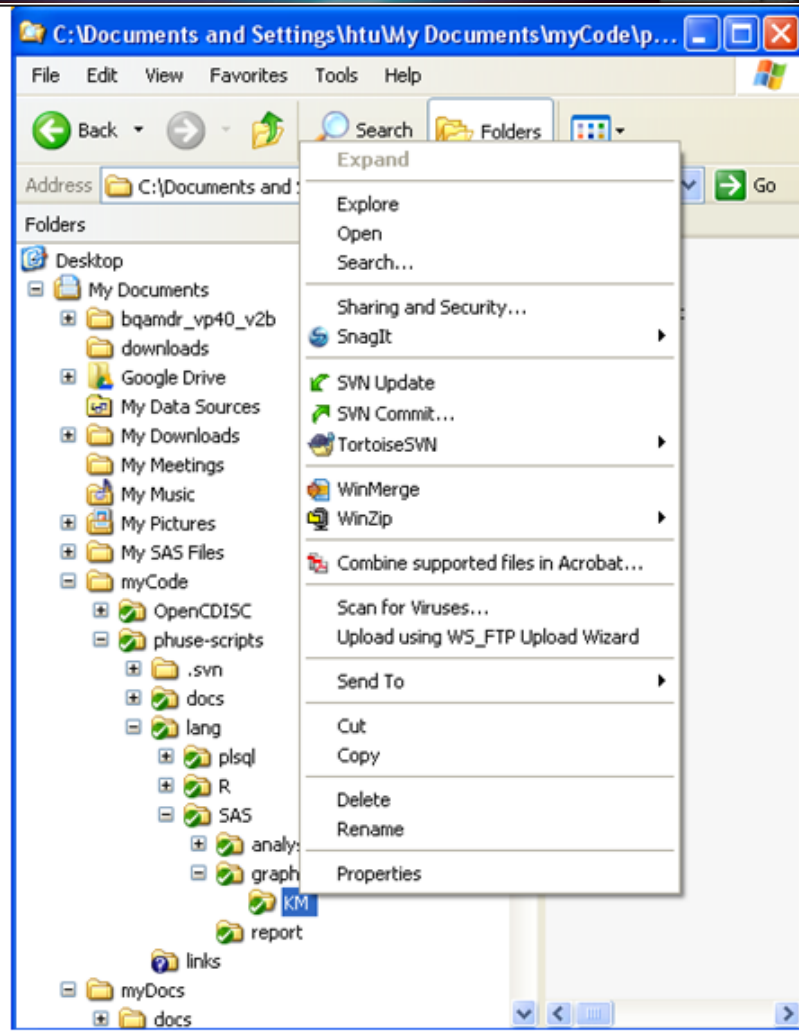
- Top Left:** The PhUSE logo and the text "phuse-scripts Development of Standard Scripts for Analysis and Reporting". Below this are navigation links: "Project Home", "Downloads", "Wiki", "Issues", and "Source". There are also buttons for "Checkout", "Browse", and "Changes".
- Bottom Left:** A screenshot of a web browser showing the "Source" page for the "report" directory. It displays a tree view of directories: "svn" (trunk, docs, lang, R), "analysis" (DM, graph, report), "SAS" (analysis, DM, datahandle, graph, report), "plsql", and "wiki".
- Top Right:** A screenshot of a Windows Explorer window showing the "Documents library" for the "report" directory. It lists files: "doevents.sas" (0 KB) and "summary.sas" (84 KB). Both were modified on 2/20/2013 at 3:31 PM.
- Bottom Right:** A screenshot of the TortoiseSVN "Log Messages" window for the path "C:\Users\Sally PC\Documents\PhuseWork\lang\SAS\report". It shows a table of revisions with columns: Revision, Actions, Author, Date, and Message. The message for revision 44 states: "This is a SAS macro designed to create tables of event counts (e.g. adverse events/concomitant medications) in clinical trials." Below the table are checkboxes for "Show only affected paths", "Stop on copy/rename", and "Include merged revisions".



Roles In the Repository

- **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.

Tools for the Repository

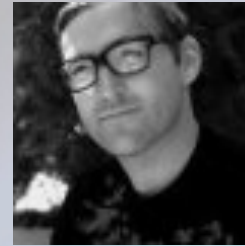


Team Member Recognition

- Mike Carniello - Takaeda



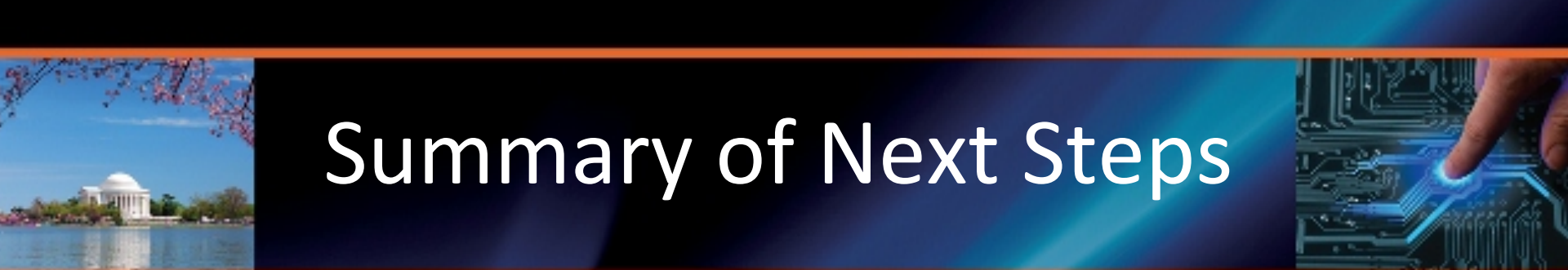
- Ian Fleming – D-Wise



- Sam Tamioka - Sunovian

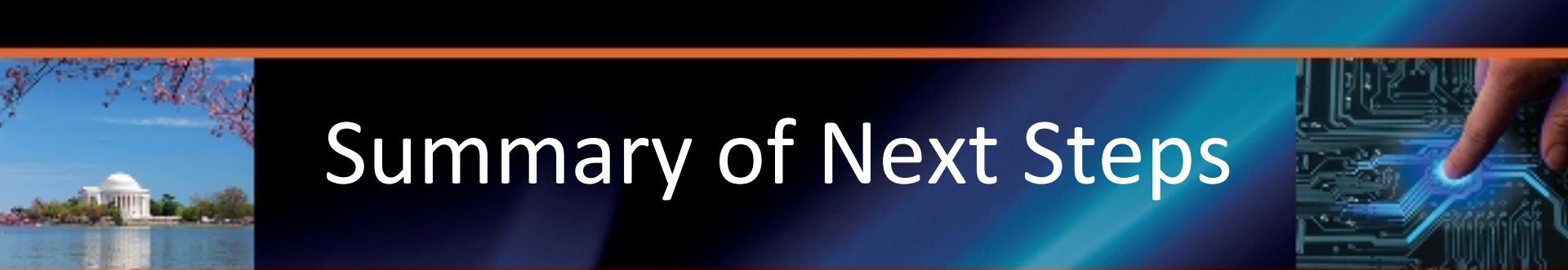


Evaluated 3 technology platforms for the repository based on requirements developed in March 2012, performed 'proof of concept' tests, evaluated UI tools and developed self-training materials for the Wiki.



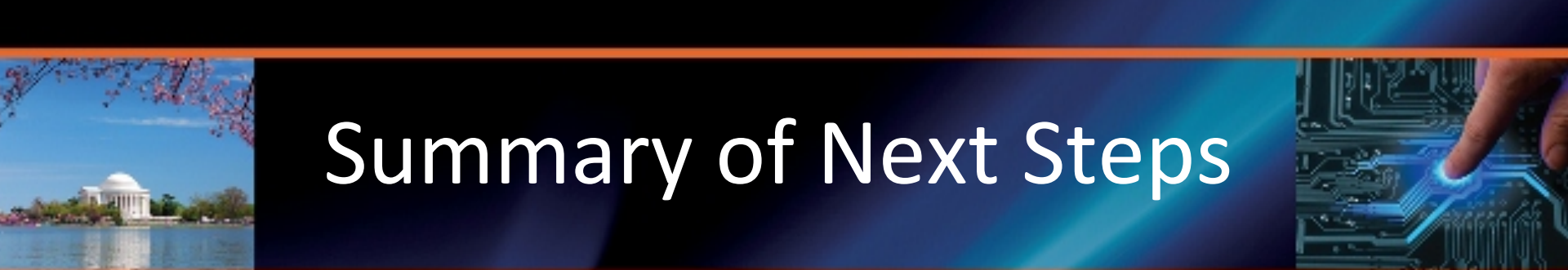
Summary of Next Steps

- Get more scripts in the Script Repository
 - Networking
 - Broad Communications
- Address any remaining validation, legal, process issues
- Finalize first white paper
 - Goal to finalize within a couple of months
- Begin work on the remaining white papers
 - Looking for more active participants
 - Goal to be final or near-final by next year



Summary of Next Steps

- The work has now been divided into 8 projects
 - P01: Look for existing scripts and store them in the repository (Kevin Kane)
 - P02: Define validation steps for scripts in the repository (Lina Jørgensen)
 - P03: Maintain and enhance platform (repository) for sharing scripts (Hanming Tu)
 - P04: Legal ownership and issues in open source repository (Kevin Kane/Sally Cassells)



Summary of Next Steps

- 8 projects (cont'd)
 - 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)