

Get involved with the FDA/PhUSE Script Repository

On behalf of the Development of Standard Scripts for Analysis and Programming FDA/PhUSE Working Group: **Lina Ulkjær Jørgensen. Novo Nordisk A/S**



Kick off in March 2012

Introduction:

In March 2012 at a PhUSE/FDA symposium, a project was launched to set up an open source script repository to hold and to share programs that would be useful in medical research. The steering committee is now:

- Hanming Tu(Project Manager)
- Scott Getzin(Steering Committee Liaison)
- Steve Wilson(FDA co-lead)
- Mat Soukup (FDA co-lead)
- Mary Nilsson(Industry co-lead)

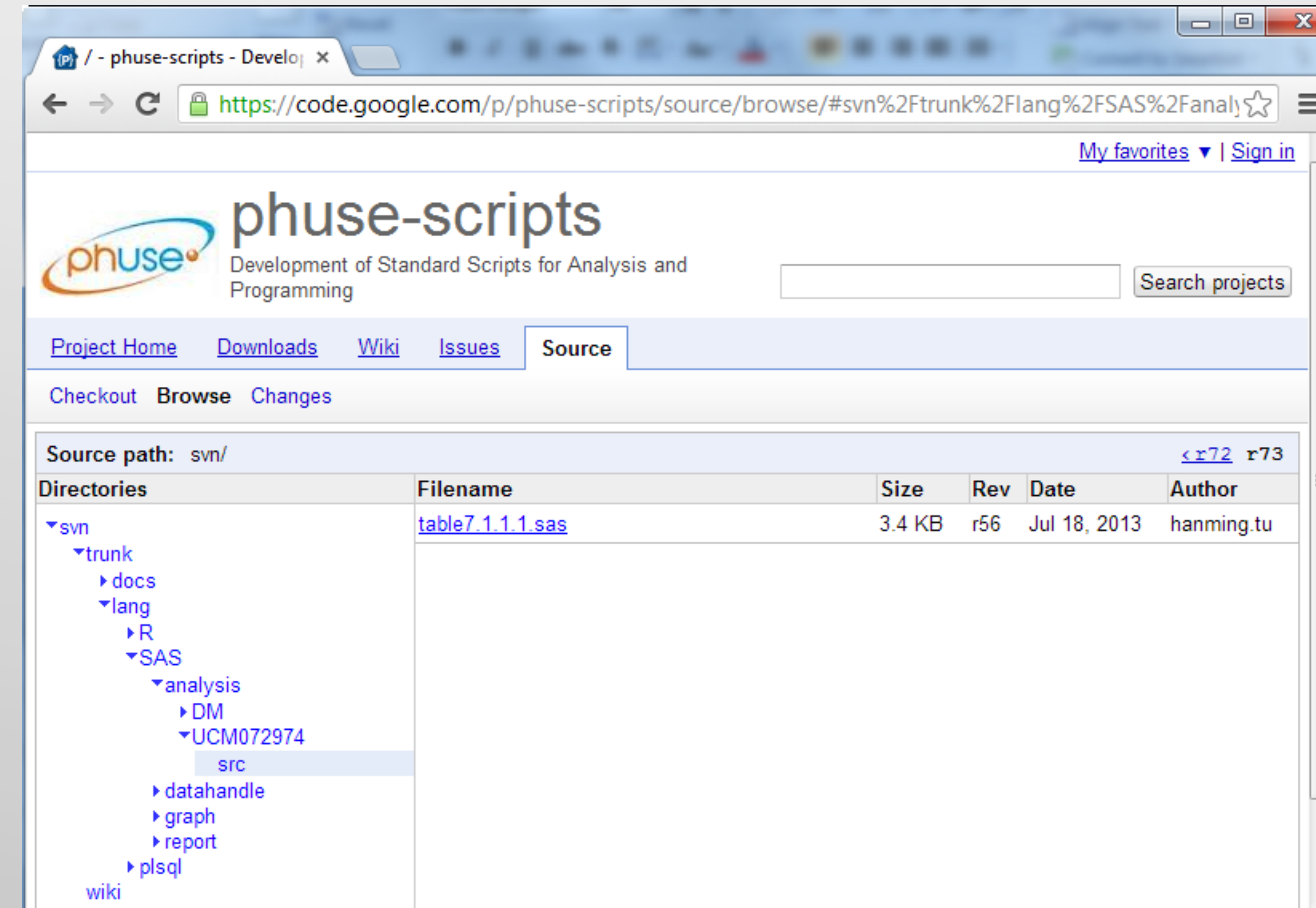
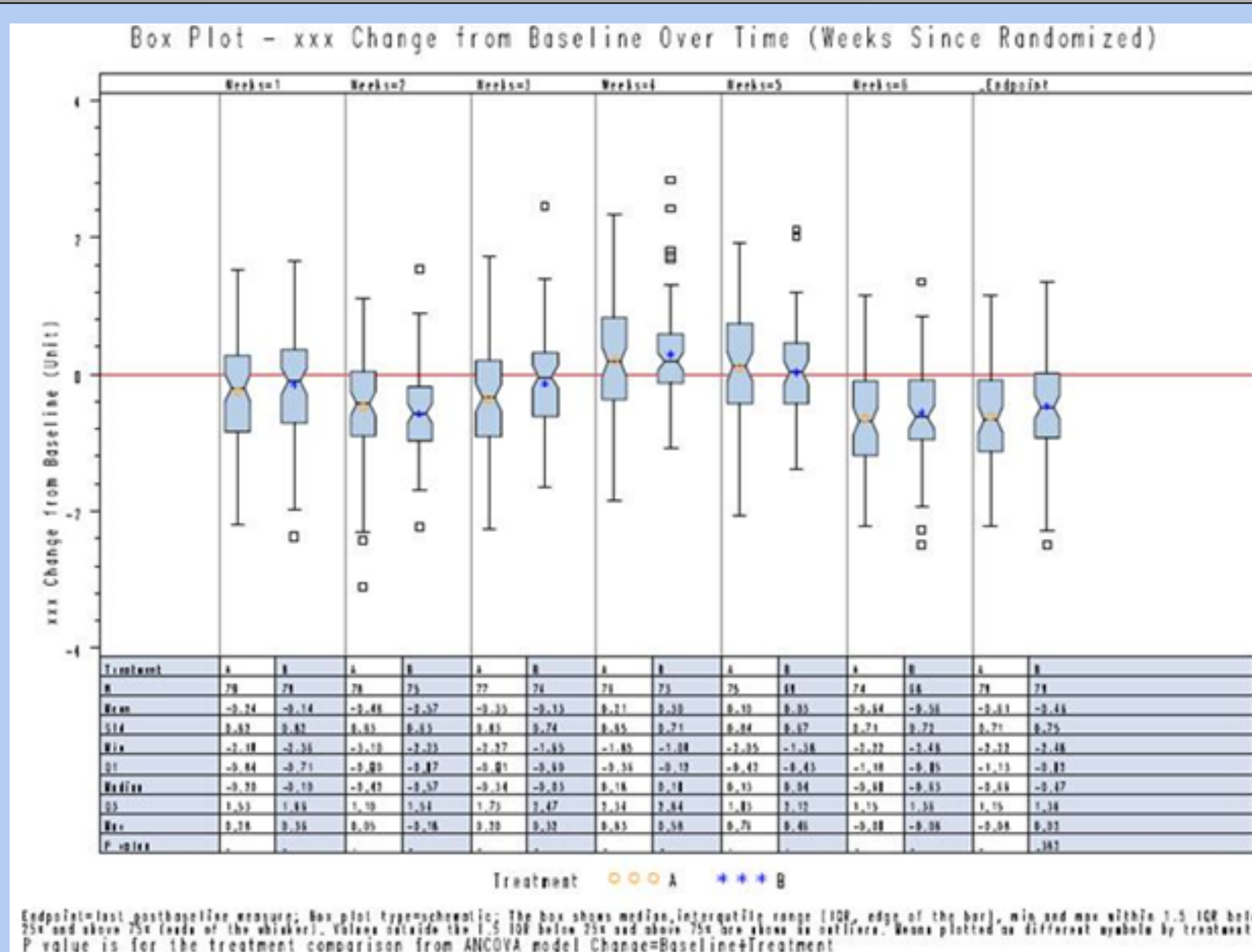
White paper:

The first white paper is now complete:

The first white paper is now complete and publicly available!

Analyses and Displays Associated with Measures of Central Tendency

- Focus on Vital Sign, Electrocardiogram, and Laboratory Analyte Measurements in Phase 2-4 Clinical Trials and Integrated Submission Documents



Technology platform developed by:
Mike Carniello(Takeda), Ian Fleming (D-Wise), Sam Tamioka (Sunovian), Hanming Tu (Accenture)

This is done !!!

All scripts in Google Code

MIT license chosen

Process guidelines developed

Code identified to access datasets and to execute SAS and R scripts that are R hosted in repository

Code tested in both R and SAS cloud-based environments

It's your turn to press the button

Please help us fill the repository.

If you have useful code that you have authored, donate it, thanks.

Ask for a guideline

Or find the guide here:

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

We now have the following 8 project groups:

- 1.Look for existing scripts and store them in the repository
- 2.Define qualification steps and Metadata for scripts in the repository
- 3.Maintain and enhance platform (repository) for sharing scripts
- 4.Legal ownership and issues in open source repository
- 5.Create templates for documenting scripts and coding practices
- 6.Refine process for creating and editing scripts in Google Code
- 7.Implement and further develop communication plan for standard scripts
- 8.Create white papers providing recommended display and analysis including Table, List and Figure shells



What's in pipeline:

FDA script TOC into repository

Code-a-thon in March 2014 (create code to support white papers)

More White papers

More and more scripts in repository

More members in project groups

More programming language in repository.

More information: phusewiki.org

