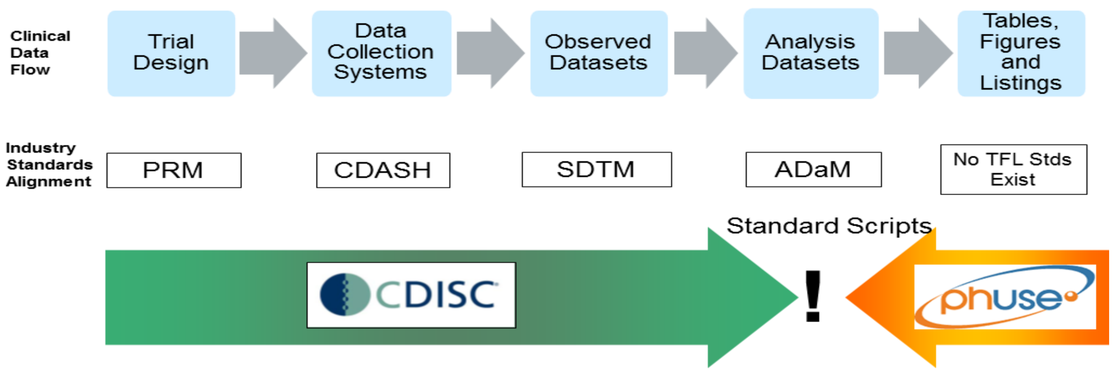
Collaborative Development of an Open Source Repository for Standardized Analysis Using Cloud Services

Hanming Tu, Accelerated R&D Services, Accenture ● Mike Carniello, Astellas Pharma ● Dirk Spruck, Accovion

Open Source Repository
Standardized Analysis

The objective of this poster is to describe the process, platform and progress of implementing an open source repository for the collaborative development of specialized programs to be used as analytical tools for clinical trial research, reporting, and analysis through cloud services.



Method:

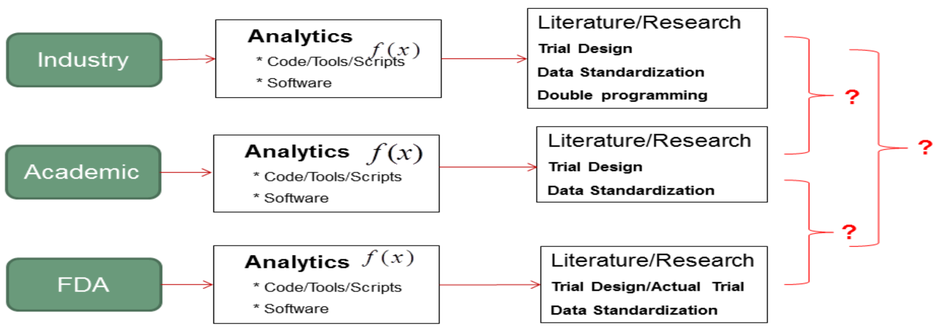
PhUSE formed a standard script working group in March 2012, consisting of members from FDA and Industry. A web-based open-source script repository has been created for collaborative development. A PhUSE Scriptathon event in March 2014 was used to test out the cloud implementation.

Collaboration
Key to Future Success

Determining Factors:

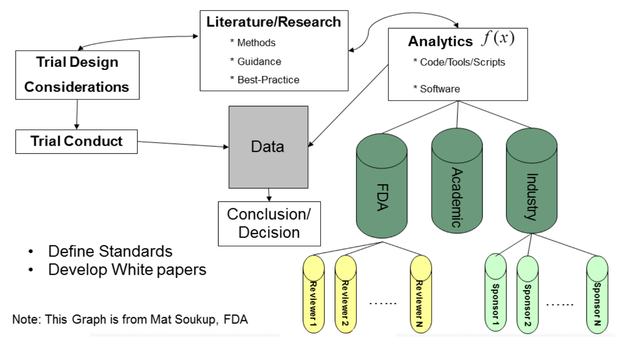
- Entrepreneurial Spirit
- Creativity and Innovation
- Cross-cultural Communications
- Interpersonal Skills
- Information Technology
- Open access
- Standardized process including documentation and metadata

Current work reality: industry, regulatory agencies, and academics work in silos

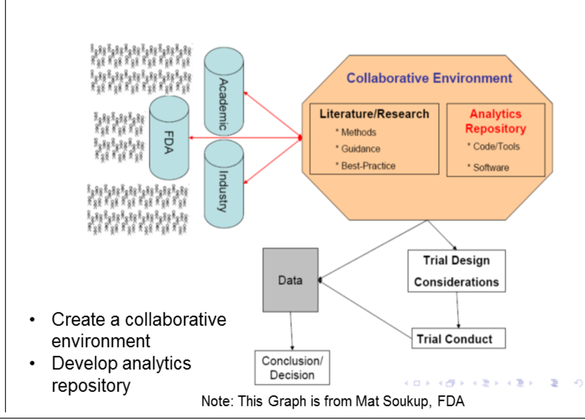


Collaboration
What is needed?

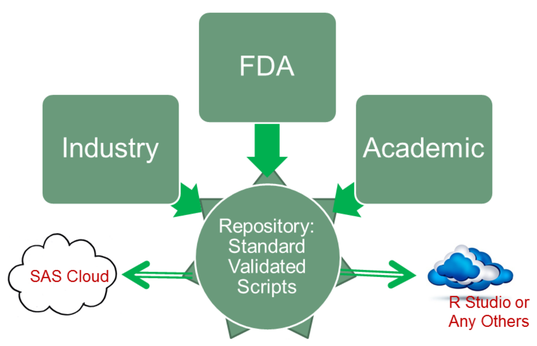
The development of commonly accessible tools and analysis standards is the first step to build a truly collaborative environment.



Building a collaborative environment and open repository is the foundation for successful and sustainable development of analysis scripts.



Cloud services make the collaboration easier and scalable



Results
PhUSE Standards Scripts Group

PhUSE CSS formed a „Standard Script for Analysis and Programming“ group

1. to create white papers outlining recommendations for safety analysis and reporting for clinical trial study reports and integrated safety-related submission documents
2. to establish a platform for sharing and developing standard scripts collaboratively and for implementing the recommendations through cloud services

Since March 2012, the group has accomplished the following tasks:

- Selected Google Code to host a standard script repository for development and storage of the Phuse Standard Scripts
- Established the basic structure and process for manging the repository
- White papers describing recommended anayses, tables, figures, and listings
- Sciptathon at PhUSE CSS 2014

PhUSE Scriptathon 2014
Event at PhUSE CSS

- Successful premiere on March 17, 2014
- 26 attendees / 15 coders from various organizations
- 13 Scripts developed (R and SAS)
- Volunteers for the remaining scripts
- Interested in organizing local and annual events

Accessing Scripts

Examples for execution of hosted R and SAS scripts

R:

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

SAS:

```
options source2 ;
filename code url "http://phuse-scripts.googlecode.com/svn/trunk/lang/SAS/report/test/src/summary.sas";
%include code;
```

Accessing Test Data in SAS

```
filename source url "http://phuse-scripts.googlecode.com/svn/trunk/scriptathon2014/data/adpc.xpt" ;
libname source xport ;
data work.adpc ;
set source.adpc ;
[...]
```

Verified Concepts

- Test data can be accessed remotely
- Scripts stored in the repository can be accessed by R and SAS systems in a cloud environment
- Developers can work collaboratively through the repository

Lesson Learned

- Export of scripts stored in the cloud system is difficult.
- It is very important to pre-define the file naming convention, coding template, and in-line comment recommendations.
- It is hard to have the same coding style in a company and even more difficult to do it cross companies

How can we maintain the openness of the tools that we use and at the same time guarantee the security of the data and the validity and correctness of the script?

The Scriptathon showed the possibility of leveraging secure cloud systems in R and/or SAS to use the open platform to develop scripts and utilize the validated scripts to process shared or secured data sources.

Conclusion

The goal of the standard script working group is to produce recommendations and establish a platform for the collaborative development of specialized programs to be used as analytical tools for clinical trial research, reporting, and analysis. This platform includes:

- Identification of areas that can benefit from a standard set of analyses
- Development of recommendations for analyses, tables and figures within a topic area
- Creation of a process and guidelines for documentation and management of scripts
- Incorporation of data standards whenever feasible

From more than two years of experience with the standards scripts group, we can conclude

- Google Code provides a scalable, reliable, and fast collaborative development environment for developing and sharing standard scripts and documents for data transformations and analyses.
- It is mutually beneficial to both the industry and the regulatory authorities if an open source repository is available for storing and developing standard scripts
- It is a good practice to use the white papers defining the cross-industry analysis and reports based on CDISC standards.
- The open source repository can be implemented through cloud services; this has been tested in the Scriptathon event.
- Coming to mutual agreed standards is a slow process

Work together openly and collaboratively, and we can achieve more than what we have hoped for!

Contact the authors for more information:

Hanming: hanming.h.tu@accenture.com
Mike: michael.carniello@astellas.com
Dirk: dirk.spruck@accovion.com

References

PhUSE home: http://phuse.eu/
PhUSE Wiki: www.phusewiki.org
PhUSE Standard Script Group: http://www.phusewiki.org/wiki/index.php?title=Standard_Scripts
PhUSE Repository: http://code.phuse.com
https://code.google.com/p/phuse-scripts/