PP18

Reducing Duplicated Effort on Standard Analyses through Collaboration - Roadmap for Standard Analyses and Code Sharing Working Group

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ABSTRACT

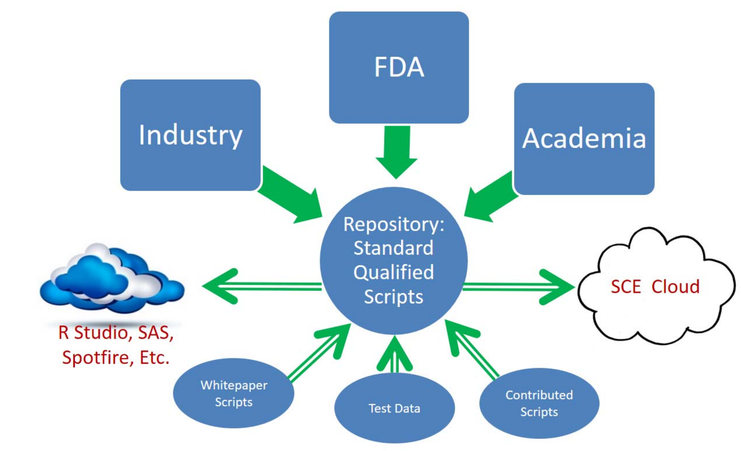
The main goal for the Standard Analyses and Code Sharing Working Group is to "leverage crowd-sourcing to improve the content and implementation of analyses for medical research, leading to better data interpretations and increased efficiency in the clinical drug development and review processes". This poster will provide an update on the recent progress in the following three areas: 1) a GitHub code repository including an established qualification processes; 2) published white papers with recommendations for analysis and reporting; 3) inclusion of scripts from FDA and other resources. The main goals for the coming years are 1) to increase usability, quality, and acceptability of the code in the repository; 2) to continue the creation and maintenance of white papers on recommendations on analyses, including mock figures, tables, and listings; 3) to develop scripts based on the recommendations from white papers; 4) to provide test data for the script qualification effort and beyond our working group through a newly established Test Data Factory project. In order to make it easy for the industry, academia and regulatory to adopt and use the repository, a framework has to be set up, and a toolkit has to be built based on the repository. This pivotal effort requires more dedicated resources and a commitment by the stakeholders. This poster will show the roadmap of how we will further achieve these goals.

WORKING GROUP VISION

Two issues in the industry

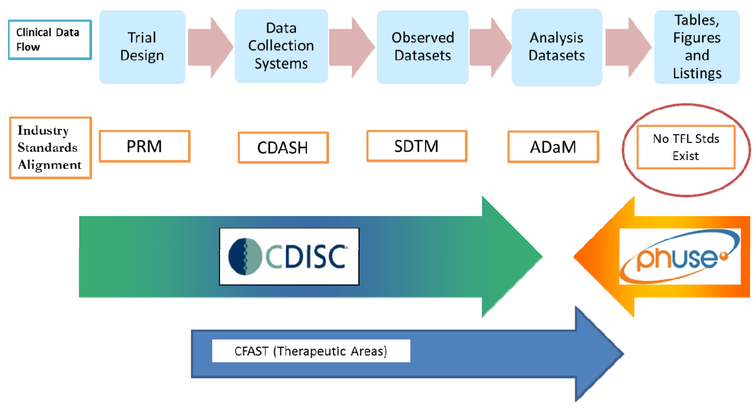
- Silo development in analysis and programming
- Duplicated effort on the same analysis and programming

The Vision: Establish a platform for the collaborative development of program code to be used as analytical tools for clinical trial research, reporting, and analysis



The Goals:

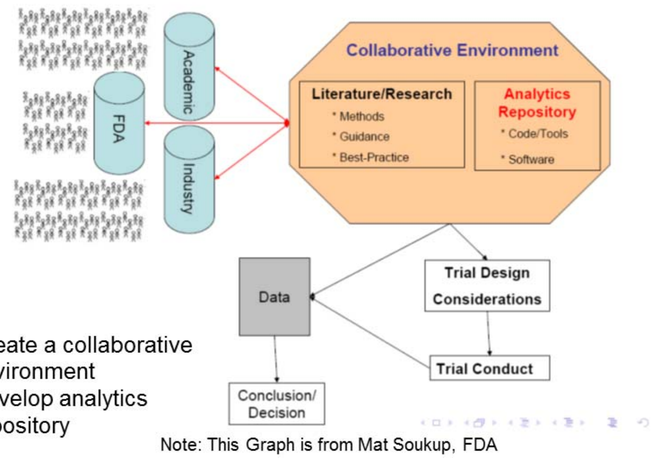
- Create **white papers** outlining recommendations and best practices for safety analysis and reporting for clinical trial study reports and integrated safety-related submission documents
- Establish a **platform** for sharing and developing standard scripts collaboratively and for implementing the recommendations through cloud services.



ROADMAP FOR COLLABORATION

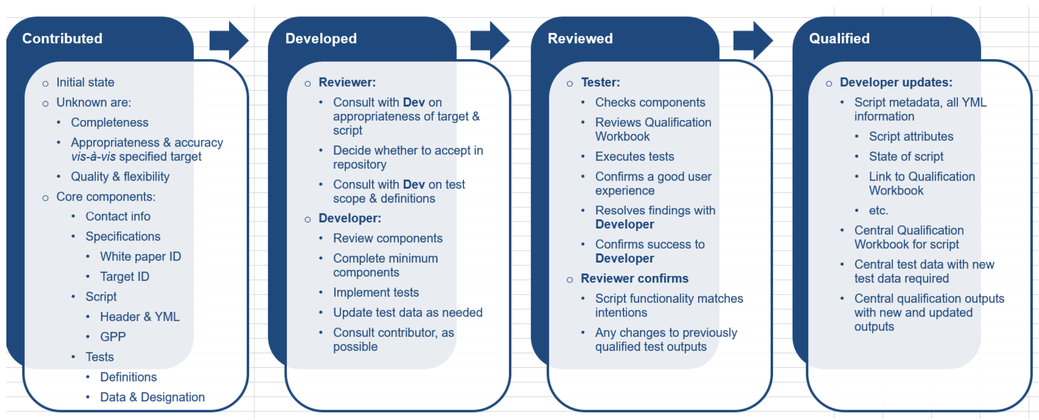
Create a collaborative environment

- Current work reality: industry, regulatory agencies, and academics work in silos
- The development of commonly accessible tools and analysis and reporting 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.
- The cloud services make the collaboration easier and scalable.



Note: This Graph is from Mat Soukup, FDA

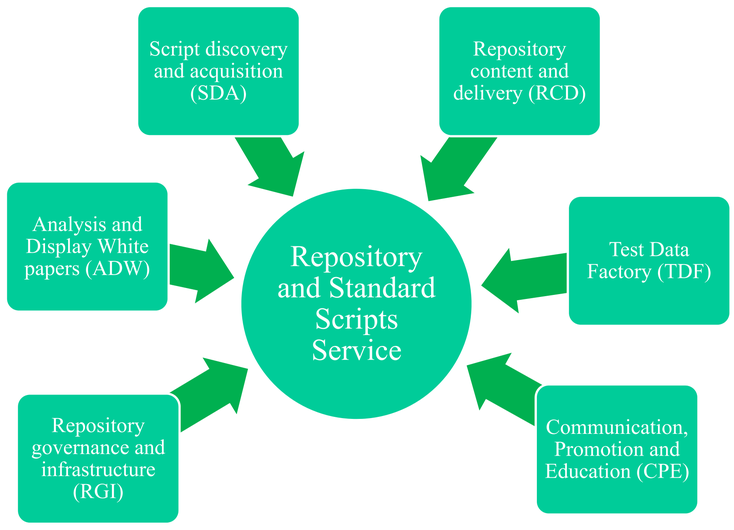
Follow a qualification process



- **Contributed**: A script is at contributed stage when it is received from any source in the community and initially stored in the repository.
- **Developed**: A script is under development when at least one developer agrees to make progress with the script.
- **Reviewed**: A script is under review when at least one volunteer has agreed to review the script.
- **Qualified**: A script is qualified when it has passed review and all the required documentation is done.

Develop voluntary teams and projects

- Open source repository such as Github provides a scalable, reliable, and fast collaborative environment.
- It is mutually beneficial to industry, academia and regulatory authorities to use shared and open source repository for storing and developing standard scripts and known test data sets.
- Leverage the content of the white papers defining the cross-industry analysis and reports based on CDISC standards such SDTM and ADaM.
- If possible, implement the open source repository through cloud services.
- Implement and conduct the qualification process for each script stored in the repository to test the accessibility, usability and functionality.



Build Standard Script Service

One Service: Provide a service to assist in qualifying and cataloging the scripts and to easily access and execute the scripts in a statistical computing environment.

Two Objectives:

- Fill the gap between the data standards and data presentation (TFL)
- Assist in the qualification process for the tools in the repository.

Three Benefits:

- Reduce the redundancy in developing analysis scripts for common data presentations;
- Shorten the time for reviewing the statistical analysis;
- Build common statistical computing environment for testing and reviewing data through integrated and metadata based services in the industry.

Standard Script Service - share, access and execute scripts in the cloud

Abbreviations:
ADaM = Analysis Data Model; ADW = Analysis and Display White Papers (Project Team); CDASH = Clinical Data Acquisition Standards Harmonization; CS = Computational Science; PRM = Protocol Representation Model; SDTM = Study Data Tabulation Model; TEAE = Treatment Emergent Adverse Event; TFL = Tables, Figures, and Listings