

Standard Analyses and Displays for Common Data in Clinical Trials: The Journey Continues

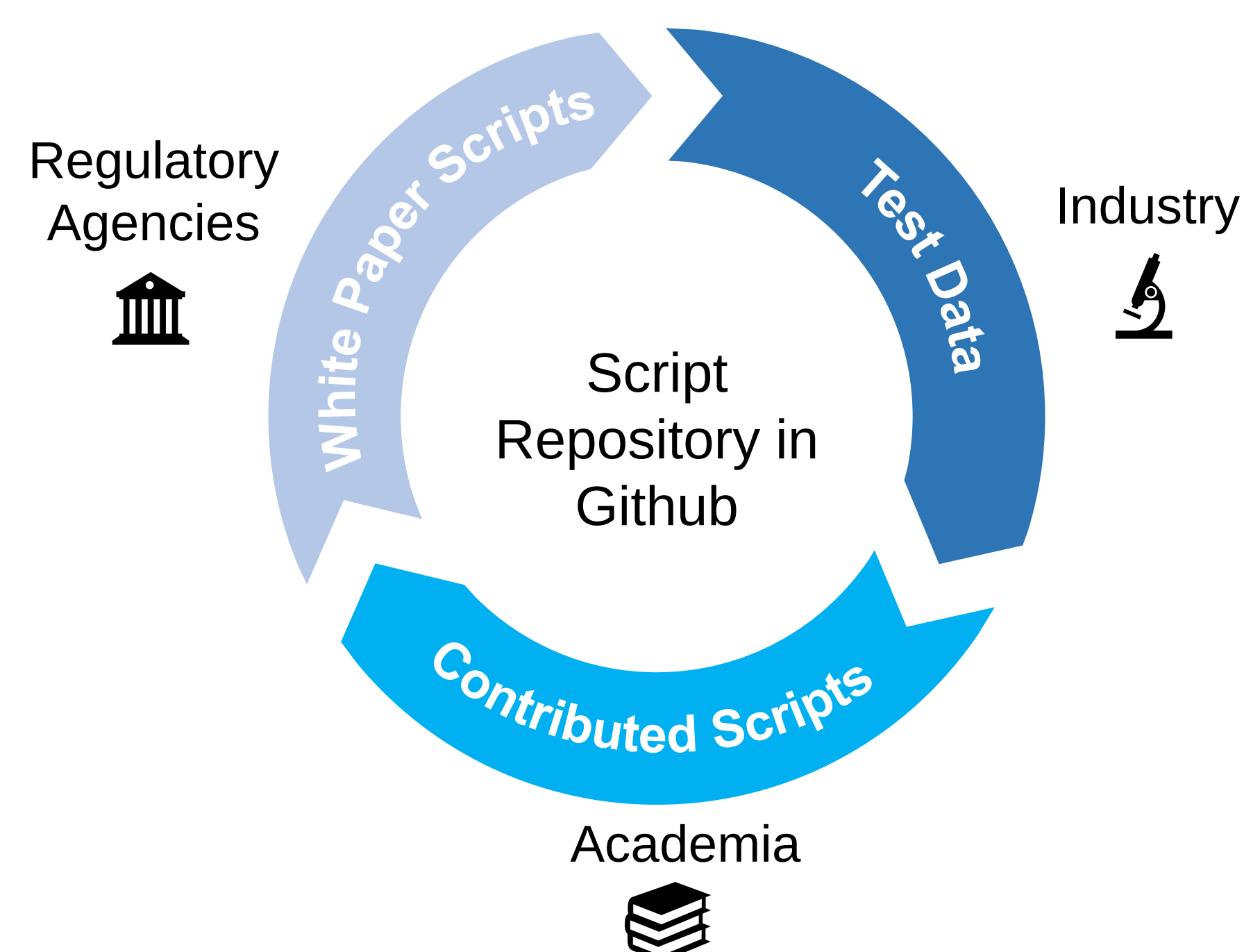
Nhi Beasley¹ and the PhUSE Analysis and Display White Papers Project Team

¹US Food and Drug Administration, White Oak, MD

Background & Objectives

The Pharmaceuticals User Software Exchange (PhUSE) Computational Science Standard Analyses and Code Sharing Working Group leverages industry-regulatory collaboration to:

- Establish and maintain a publicly available repository for storing program code to be used as analytical tools for medical research
- Where gaps exist, develop recommendations for analyses and displays in areas that could benefit from crowd-sourcing
- Where gaps exist, develop code for recommended analyses and displays (to reside in the repository)

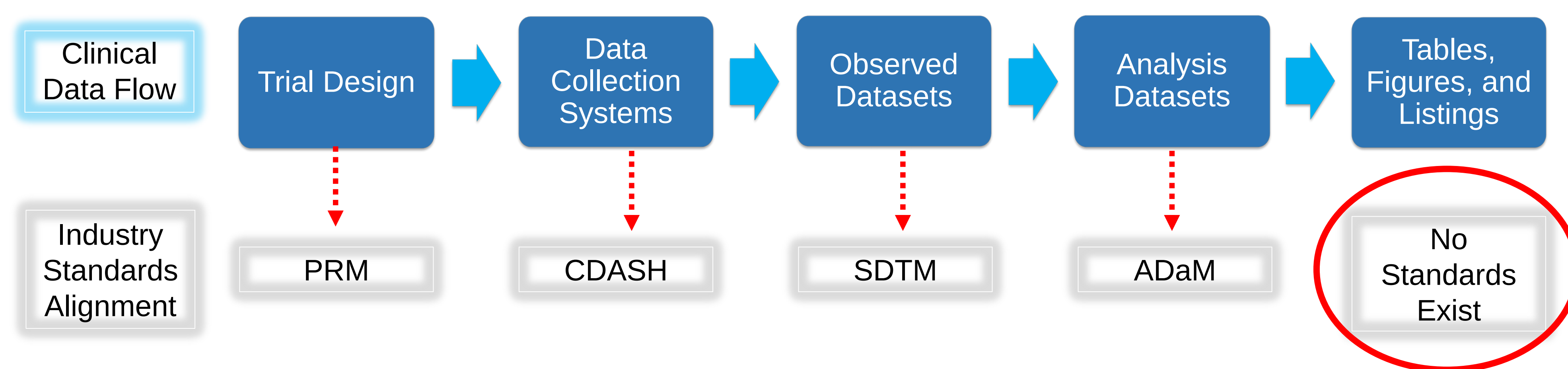


For White Papers:

1. Go to www.phuse.eu
2. Click on Working Groups
3. See CSS Deliverables

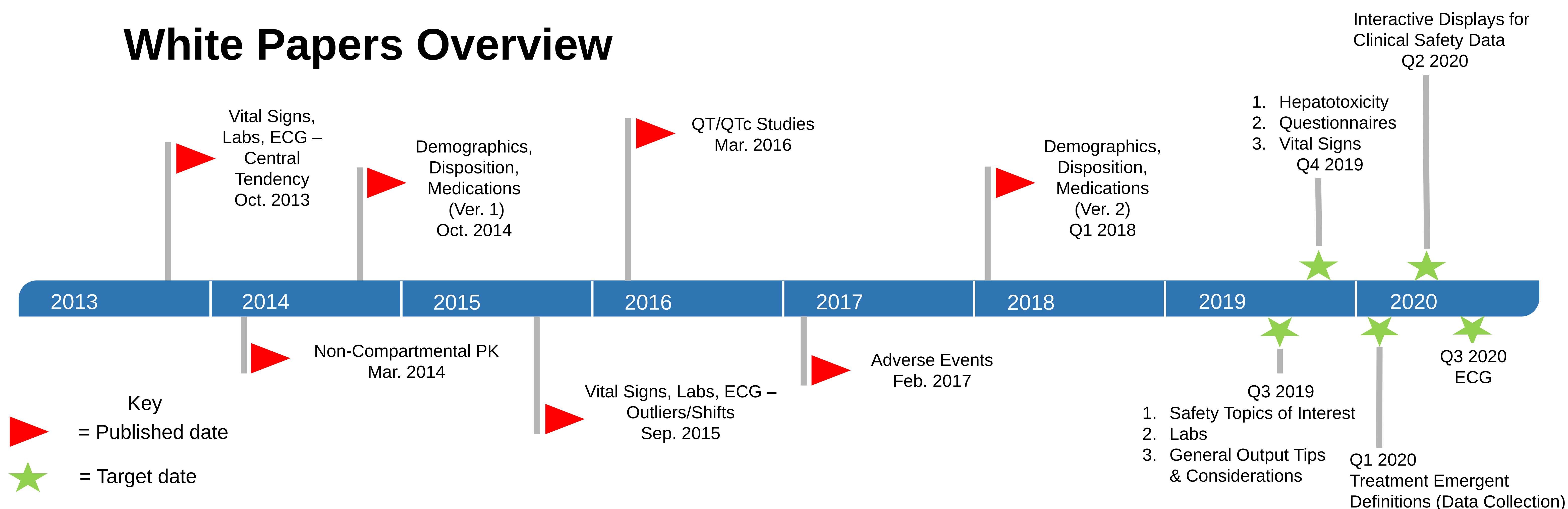
For Scripts:

1. Go to www.phusewiki.org
2. Click on CSS Working Groups
3. See Standard Analyses and Code Sharing



The Analysis and Display White Papers Project seeks to develop recommendations and fill gaps in industry standards for analysis and reporting of common clinical trial data in regulatory submissions.

White Papers Overview



Scope & Examples

- Recommended analyses and displays for individual studies and integrated summaries
- Sample SAP language
- Discussion on analytical and statistical topics such as:
 - P-values and confidence intervals
 - Events occurring after study drug discontinuation
 - Alternative methods when percentages are biased

Recent Activities

Safety Analytics Workshop

Highlight tables, figures, and listings that facilitate review

Interactive Visuals

Identify areas where interactive visuals can be leveraged

Displays that identify labs requiring further investigation

Which ones get the message across the best?

Which ones are easiest to understand?

Getting Involved

1. Use the final white papers
2. Include links to the white papers in SAPs
3. Review upcoming white papers
4. Raise Awareness

Participate! See www.phusewiki.org for projects. Sign up for a project: workinggroups@phuse.eu Contact any project lead

Disclaimer: The opinions expressed in this document are those of the authors and should not be construed to represent the opinions of the PhUSE members' respective companies or organizations, or FDA's views or policies. The content in this document should not be interpreted as a data standard and/or information required by regulatory authorities.

*PhUSE = Pharmaceuticals User Software Exchange; CS = Computational Science; PRM = Protocol Representation Model; CDASH = Clinical Data Acquisition Standards Harmonization; SDTM = Study Data Tabulation Model; ADaM = Analysis Data Model; SAP = Statistical Analysis Plan