

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

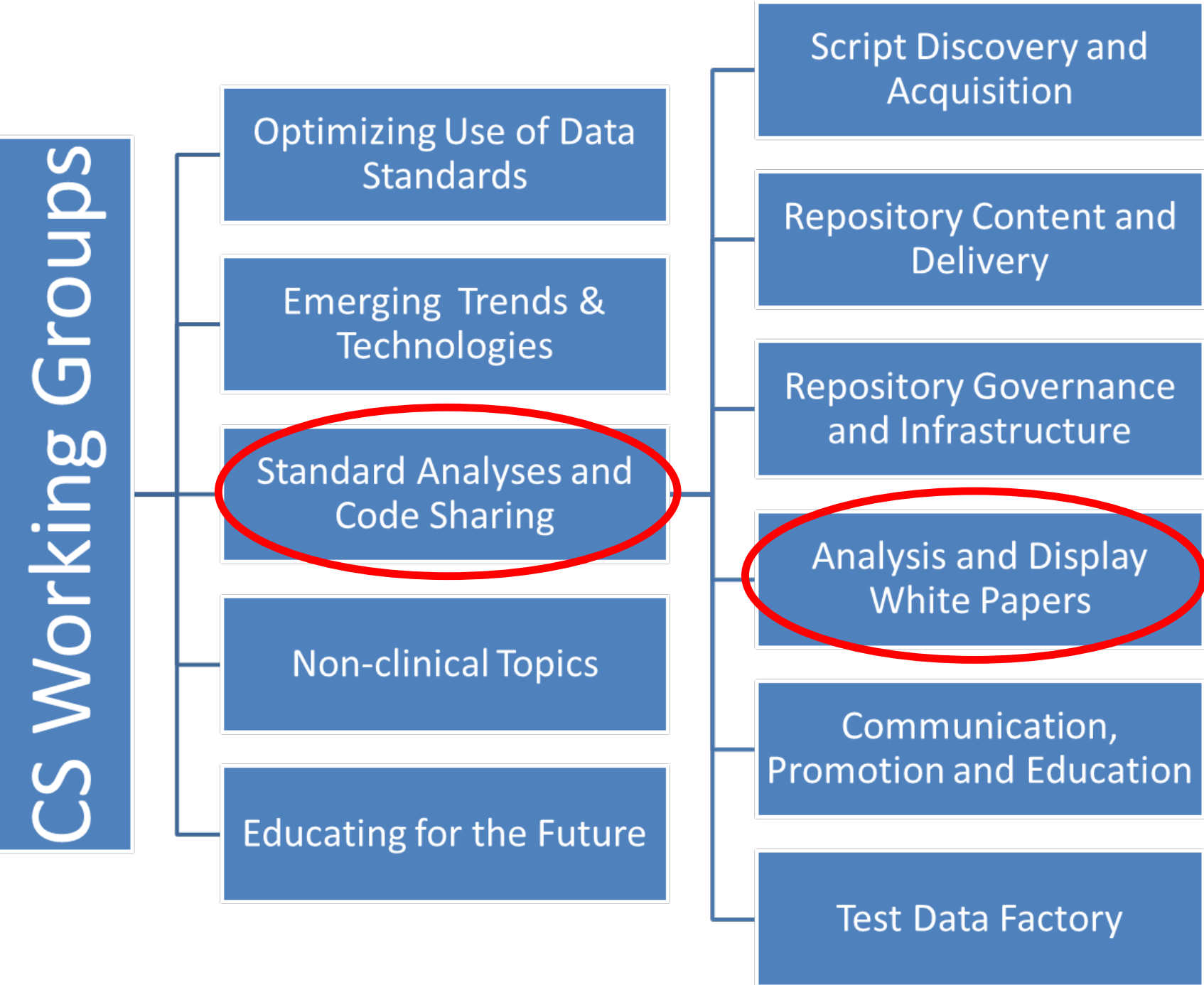
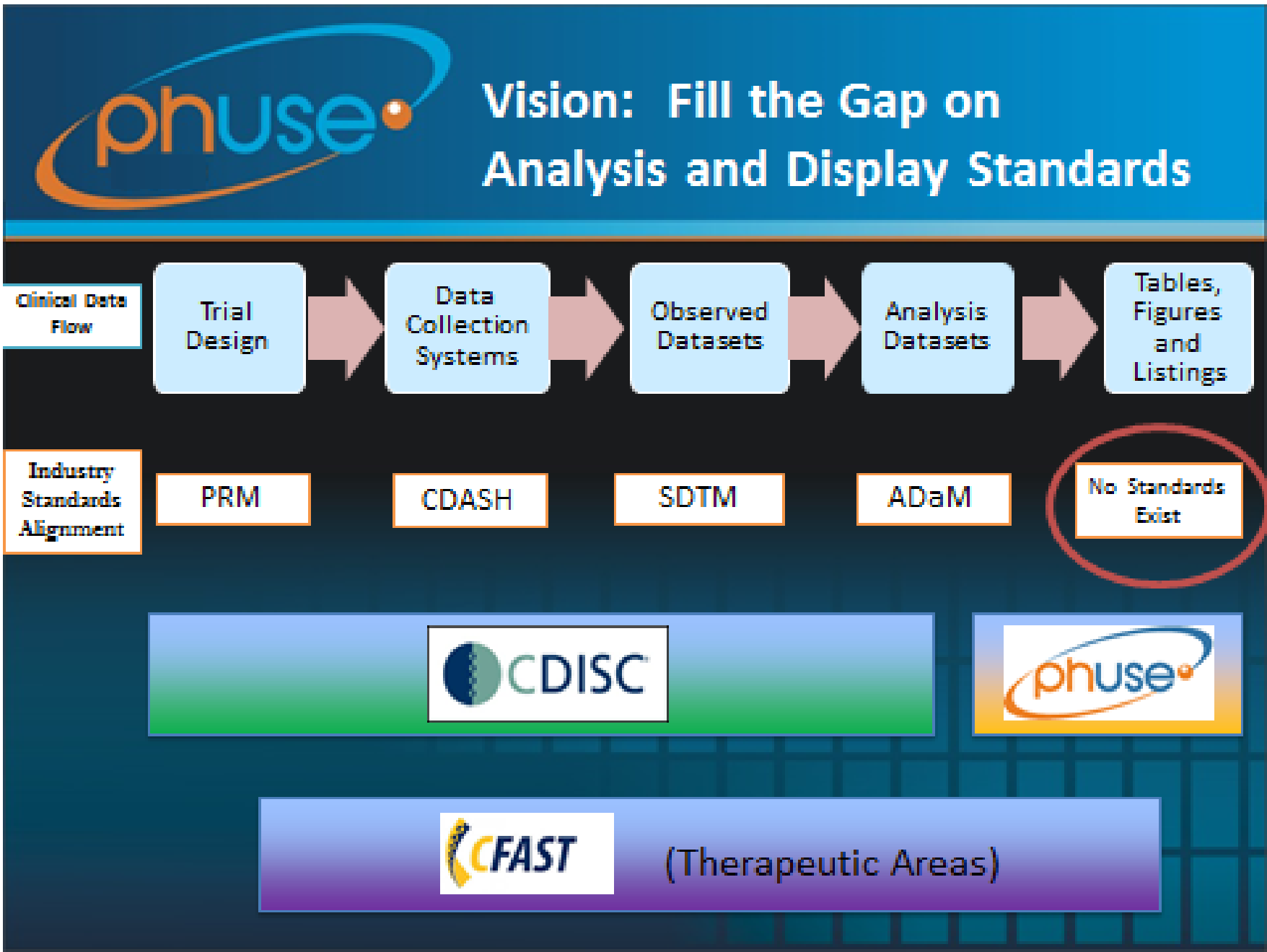
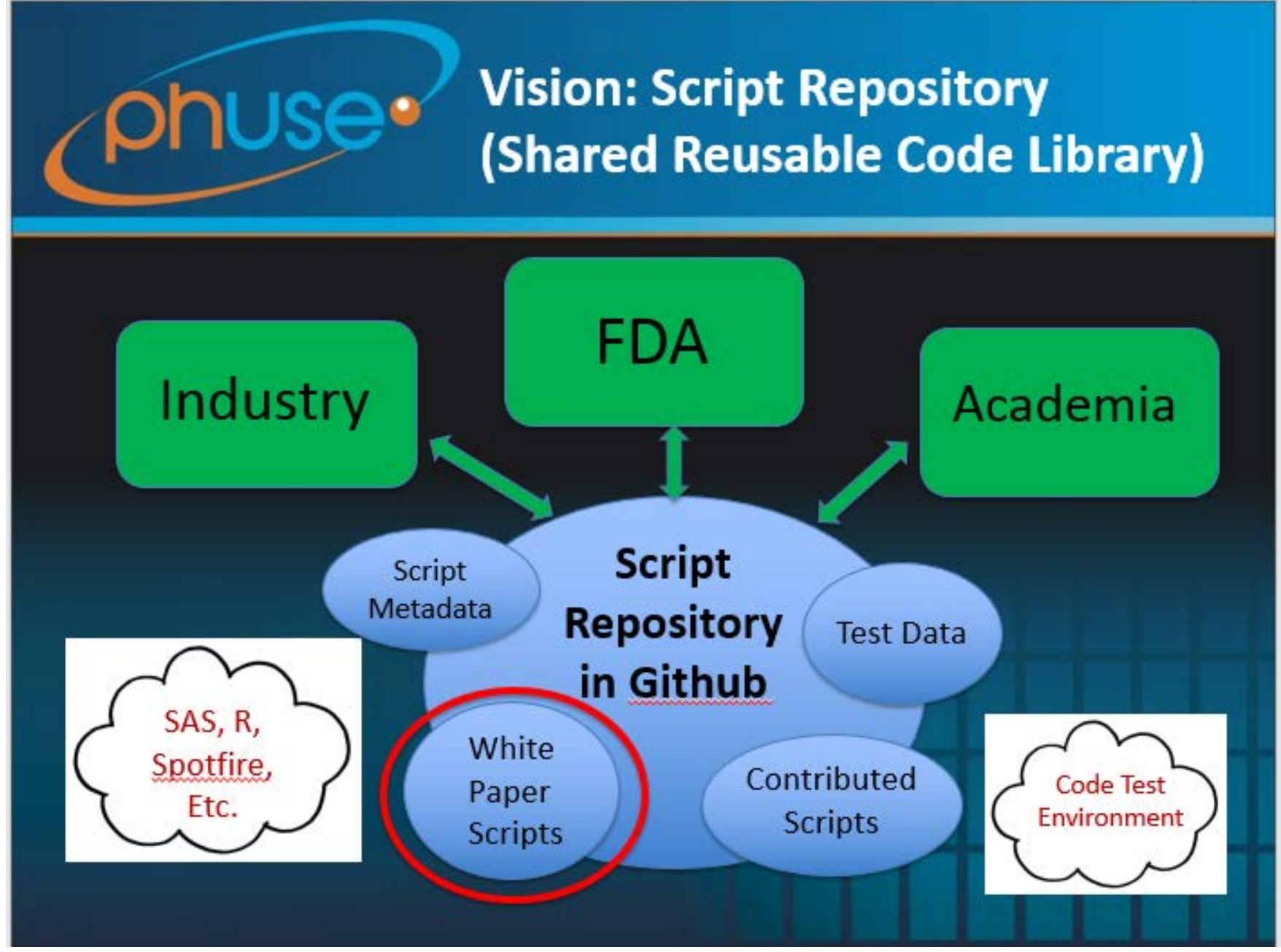
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ABSTRACT

The “Analysis and Display White Papers” project team, which is part of the “Standard Analyses and Code Sharing” Computational Science (CS) Working Group, is providing recommendations for analyses, tables, figures, and listings for data that are common across therapeutic areas (laboratory measurements, vital signs, electrocardiograms, adverse events, demographics, medications, disposition, hepatotoxicity, pharmacokinetics). Ten white papers are at various stages of development, including 6 that have been finalized. Updates to white papers are also in progress to incorporate shared learning and to conform to updated regulatory guidance. This project team provides an organized process for shared learning of improved methodologies (including visual analytics) that can lead to earlier safety signal detection, better characterization of the safety profile of compounds, and improved efficiency. This poster will provide an update of this effort. We encourage researchers to utilize the recommendations, and we encourage all participants to advertise this effort to their respective organizations.

THE BIG PICTURE



Abbreviations: ADaM = Analysis Data Model; ADW = Analysis and Display White Papers (Project Team); ATC = Anatomical Therapeutic Chemical; CDASH = Clinical Data Acquisition Standards Harmonization; CFAST = Coalition for Accelerating Standards and Therapies; CS = Computational Science; CSR = Clinical Study Report; PRM = Protocol Representation Model; SDTM = Study Data Tabulation Model; TFLs = Tables, Figures, and Listings

Disclaimer: The opinions expressed in this document are those of the authors and should not be construed to represent the opinions of the Pharmaceuticals User Software Exchange (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.

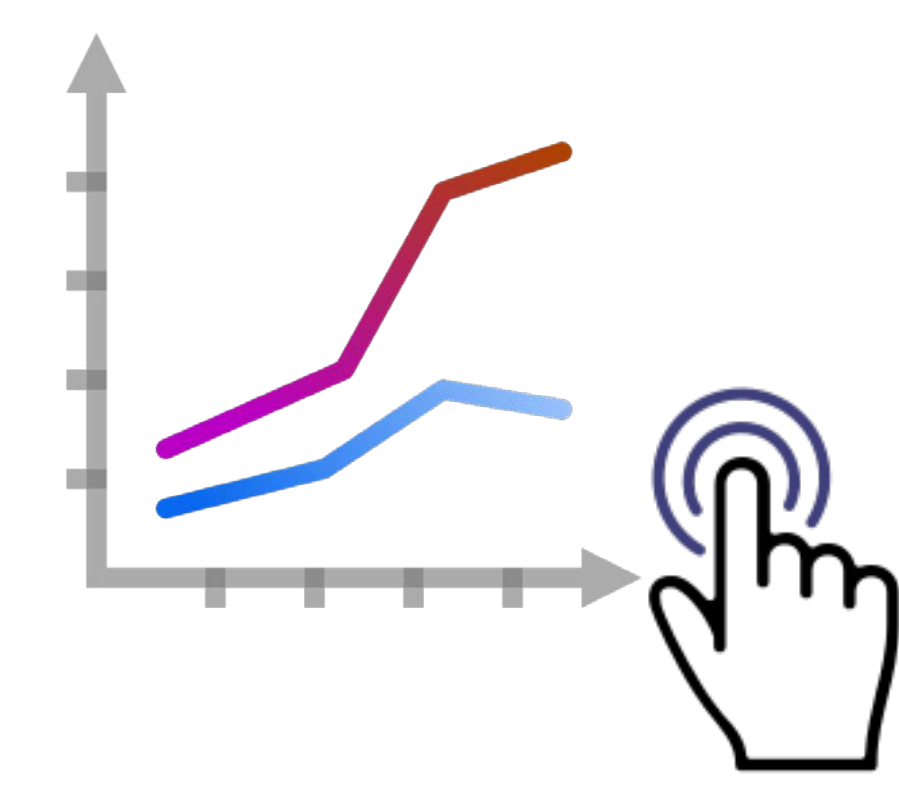
WHITE PAPERS OVERVIEW

	Version 1		Version 2	
	Public Review	Published	Public Review	Published
Vital Signs, Labs, ECG – Central Tendency		Oct 2013 ✓	Q3 2018	
Non-Compartmental PK		March 2014 ✓		
Demographics, Disposition, Medications		Oct 2014 ✓	Q4 2017 ✓	Q1 2018
Vital Signs, Labs, ECG – Outliers / Shifts		Sept 2015 ✓	Q3 2018	
QT/QTc Studies		March 2016 ✓		
Adverse Events		Feb 2017 ✓		
Treatment-Emergent Definitions	Q4 2018			
Hepatotoxicity	Q3 2018			
Questionnaires	Q4 2018			
Events of Special Interest	Q3 2018			

RECENT ACTIVITIES



Educational Video (Nov 2017) Topics in pooling data from multiple studies: Study-size adjusted percentages: why, when and what? (Link available from CS Deliverables Catalog)

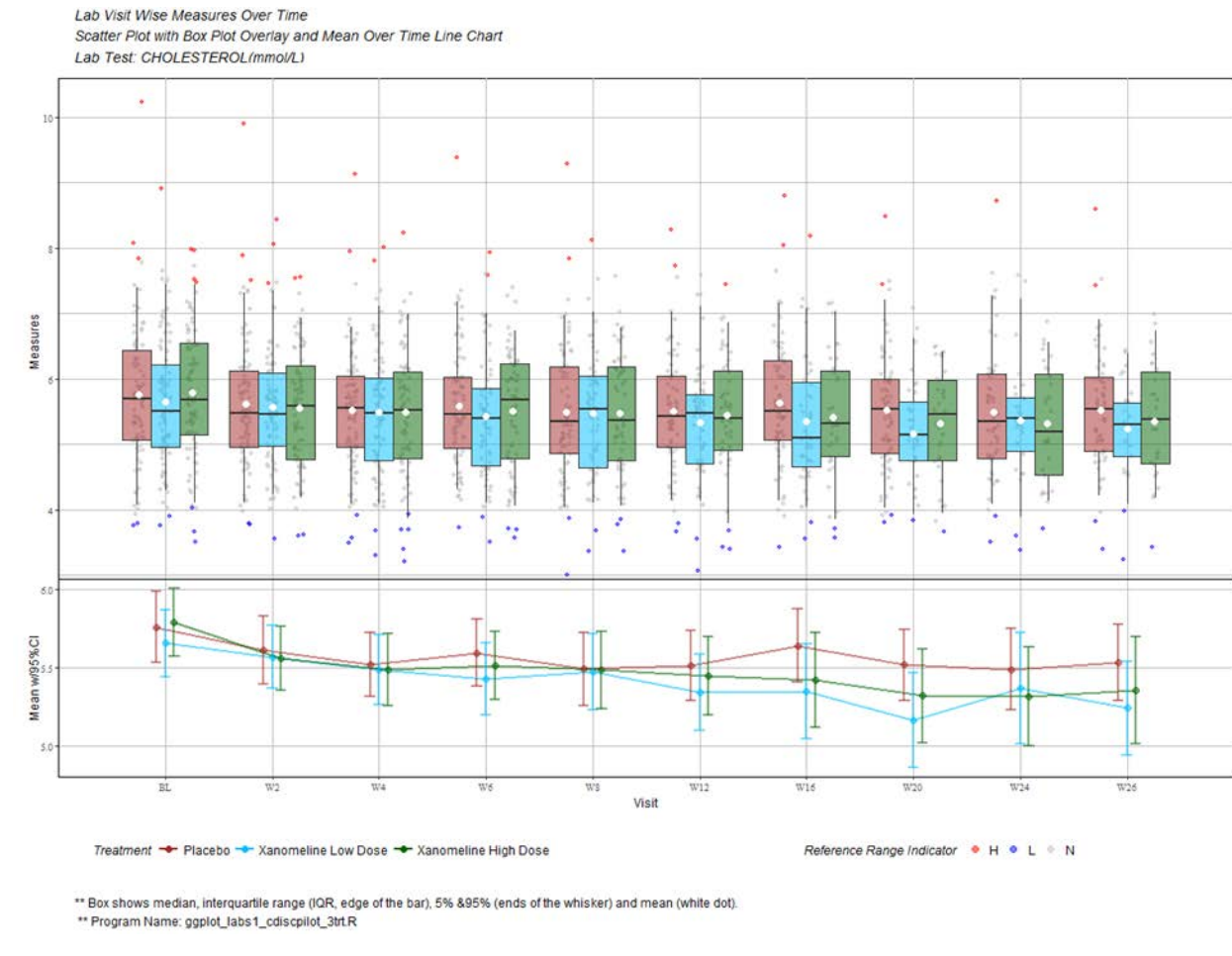


Interactive Visuals
Identify areas where interactive visuals can be leveraged (recommendations provided in recent white papers)

Medication Summary Tables
By Preferred Names?
By ATC coding?
By each ingredient?



Boxplot Variations
Which ones get the message across the best?
Which ones are easiest to understand?



HOW TO FIND WHITE PAPERS

- Go to www.phuse.eu
- Click on Working Groups
- Click on CS Deliverables Catalog



← CS Deliverables Catalog

Script Repository

- Go to www.phusewiki.org
- Click on CS Working Groups
- See links under Standard Analyses and Code Sharing



WE NEED YOU TO SOCIALIZE THE DELIVERABLES!

- Use the recommendations!
- Forward to any standards groups within your organization
- Include links to white papers in Statistical Analysis Plans
- ADVERTISE!