

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

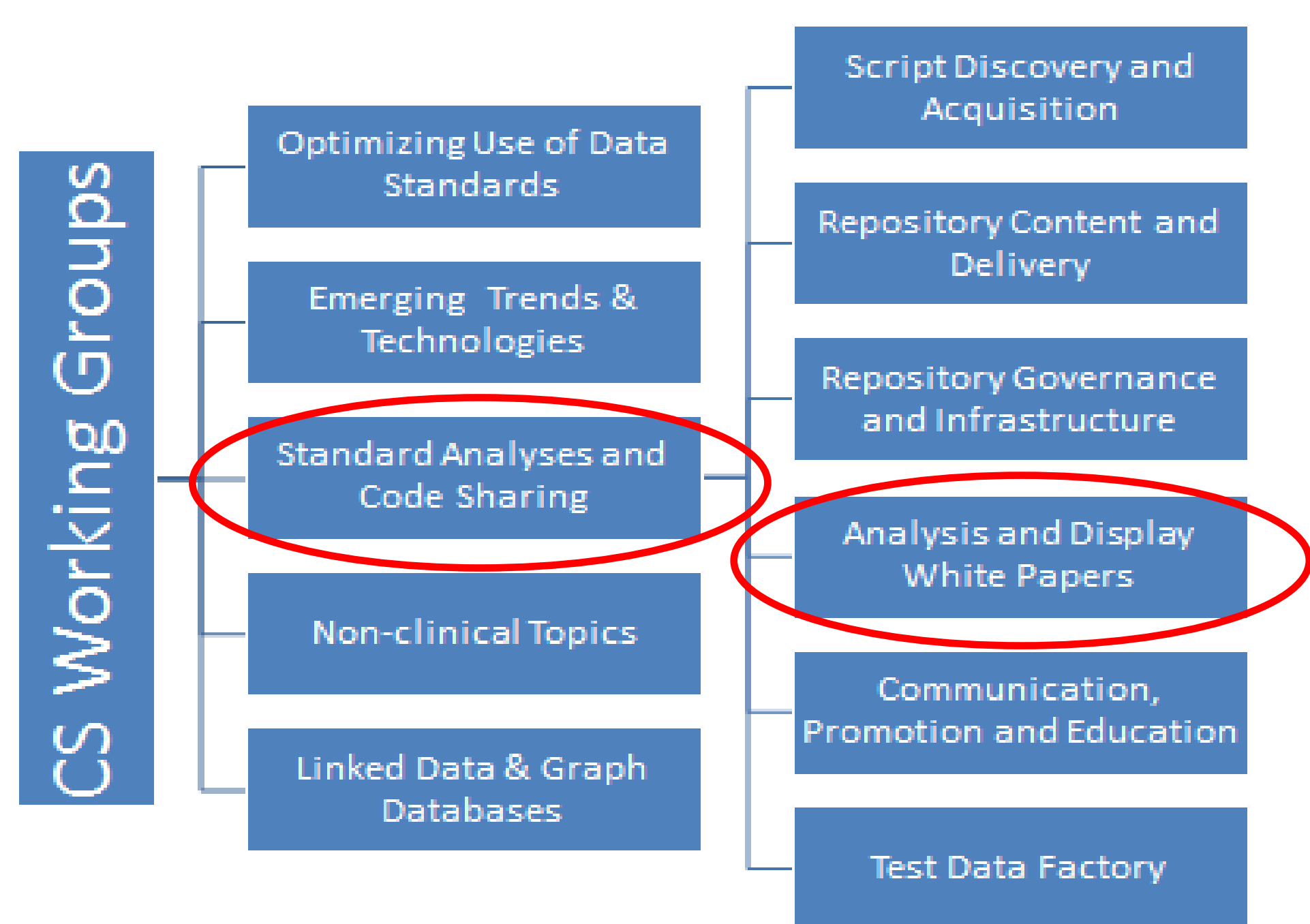
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## ABSTRACT

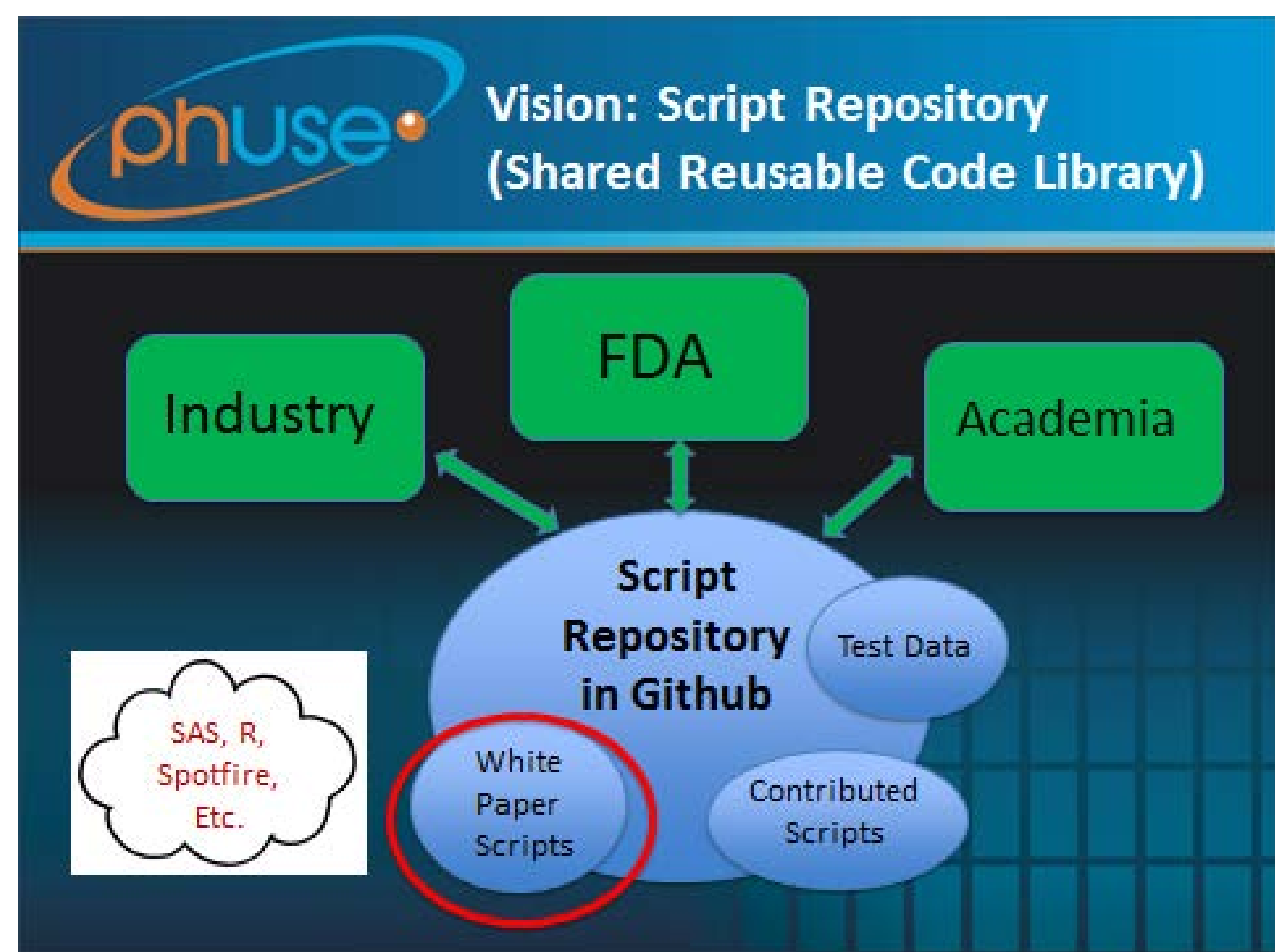
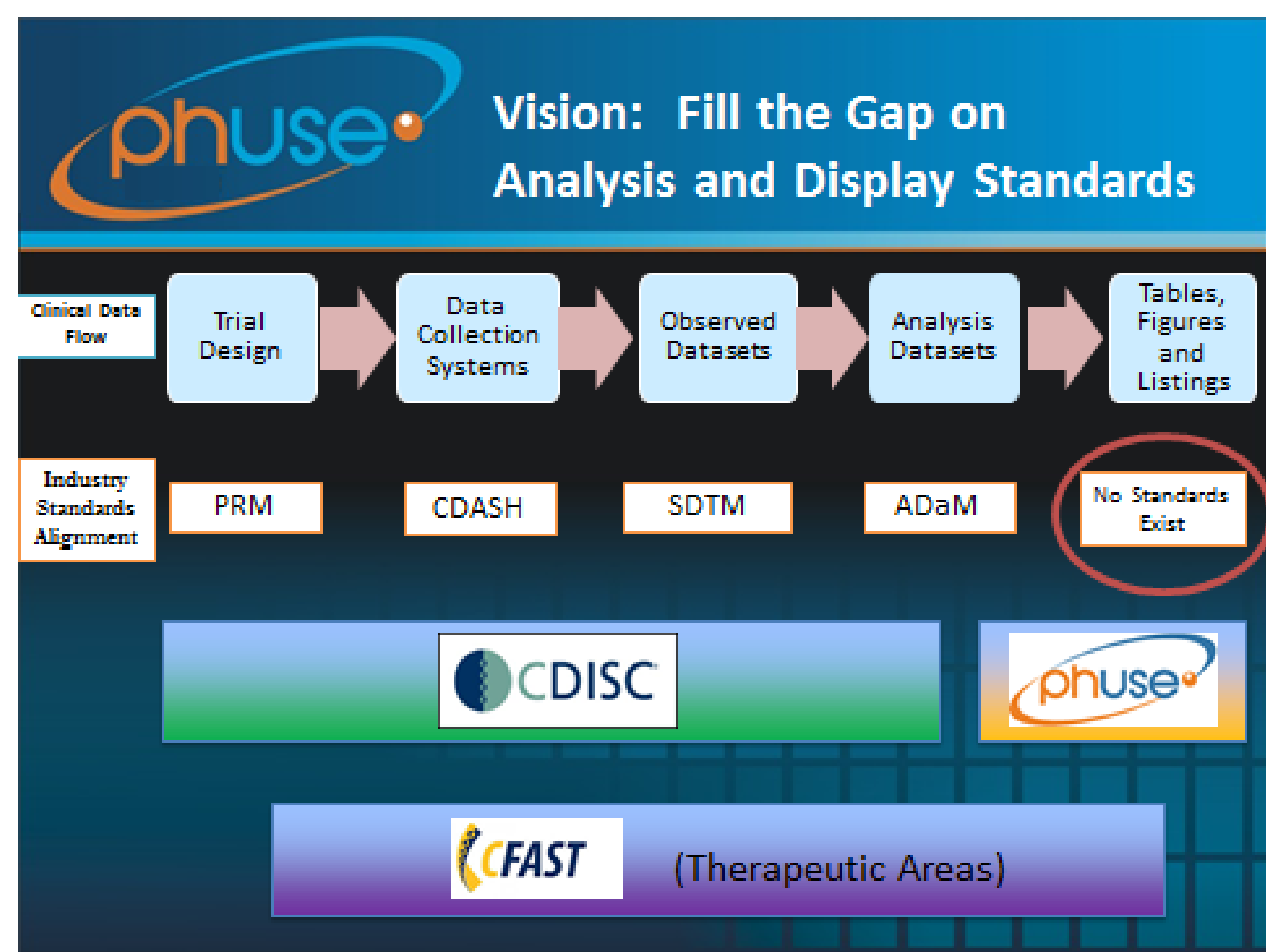
The “Analysis and Display White Papers” project team, which is part of the “Standard Analyses and Code Sharing” Computational Science (CS) Working Group, is providing recommendations for analyses, tables, figures, and listings for data that are common across therapeutic areas (laboratory measurements, 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. The latest white paper to be published covers analyses and displays for adverse events. 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 all medical researchers to utilize the recommendations, and we encourage all symposium participants to advertise this effort to their respective organizations!

## THE BIG PICTURE



## WHITE PAPERS OVERVIEW

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



Abbreviations: ADaM = Analysis Data Model; ADW = Analysis and Display White Papers (Project Team); 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; TEAE = Treatment Emergent Adverse Event; TFLs = Tables, Figures, and Listings

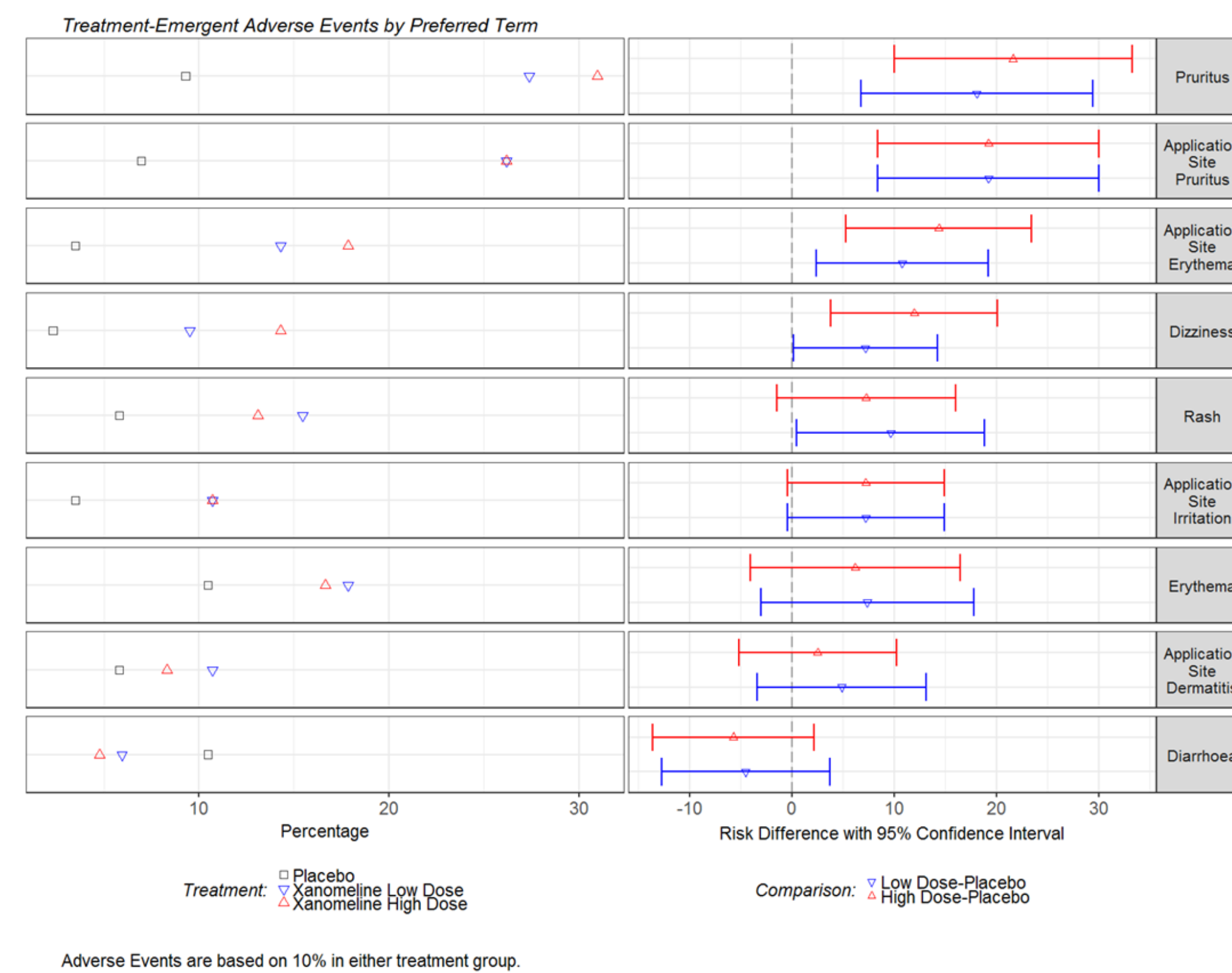
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## Adverse Event White Paper Highlights

- Recommended TFLs for CSRs and Integrated Submission Documents
- Discussion on p-values and confidence intervals
- Guiding Principles for inclusion/exclusion of TEAEs after stopping medication
- Recommends adding the study-size adjusted percentage to integrated tables

**NEW!**

## SAMPLE FIGURE



## HOW TO FIND WHITE PAPERS

- Go to [www.phuse.eu](http://www.phuse.eu)
- Click on Working Groups
- Click on CS Deliverables Catalog

## Script Repository

- Go to [www.phusewiki.org](http://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!**