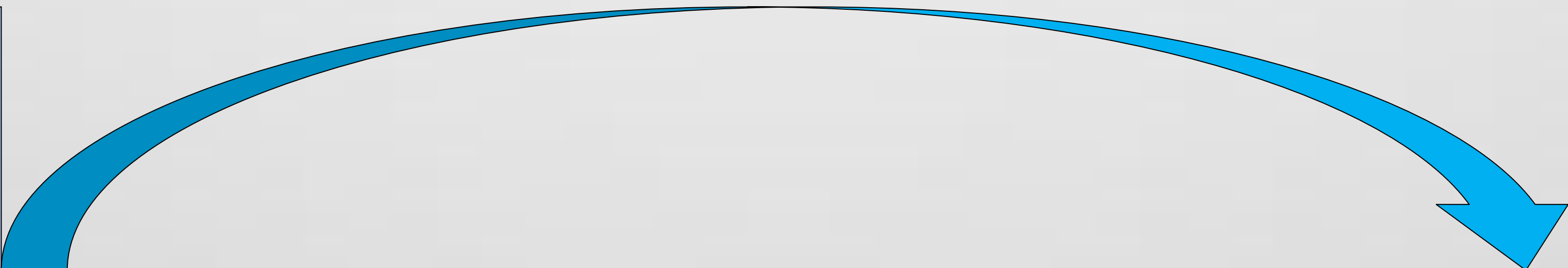


PhUSE CSS White Paper on Analyses and Displays Associated with Demographics, Disposition, and Medications

On behalf of the Development of Standard Scripts for Analysis and Programming,
PhUSE Computational Science Symposium (CSS) Working Group:
Simin K Baygani, Eli Lilly and Lina Ulkjær Jørgensen. Novo Nordisk A/S



From
White
paper



To Google
code



History:

In March 2012 at a PhUSE symposium, a project was launched to set up an open source script repository to hold and to share programs that would be useful in medical research. The Computational Science Symposium (CSS) Development of Standard Scripts for Analysis and Programming Working Group is leading an effort to create several white papers providing recommended analyses and displays for common measurements, and has developed a Script Repository as a place to store shared code.

The working group leaders now are:

- Hanming Tu (Project Manager)
- Steve Wilson (FDA Liaison)
- Mat Soukup (FDA Liaison)
- Mary Nilsson (Industry co-lead)

White paper:

Demographics, subject disposition, and medications are commonly collected and summarized across clinical trials and across therapeutic areas. Why not have common approaches to analysis, reporting, and even scripts/source to produce them?

Templates for TFL's

Demographic Summary				
Demographic/Parameter	Treatment A (N=XXX)	Treatment B (N=XXX)	Total (N=XXX)	P-value*
Sex n (%)				
n%	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
F	XX (XX.X)	XX (XX.X)	XX (XX.X)	
M	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Age (yrs)				
n%	XX	XX	XX	
Mean	XX.X	XX.X	XX.X	X.XXX
Std.Dev.	XX.X	XX.X	XX.X	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX, XX	XX, XX	XX, XX	
Min, Max	XX, XX	XX, XX	XX, XX	
Age categories n (%)				
n%	XX	XX	XX	
< 65	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
>= 65 and < 75	XX (XX.X)	XX (XX.X)	XX (XX.X)	
>= 75 and < 85	XX (XX.X)	XX (XX.X)	XX (XX.X)	
>= 85	XX (XX.X)	XX (XX.X)	XX (XX.X)	
>= 65	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
>= 75	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Race n (%)				
n%	XX	XX	XX	
AMERICAN INDIAN OR ALASKA NATIVE	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
ASIAN	XX (XX.X)	XX (XX.X)	XX (XX.X)	
BLACK OR AFRICAN AMERICAN	XX (XX.X)	XX (XX.X)	XX (XX.X)	
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	XX (XX.X)	XX (XX.X)	XX (XX.X)	
WHITE	XX (XX.X)	XX (XX.X)	XX (XX.X)	
MULTIPLE	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Ethnicity n (%)				
n%	XX	XX	XX	
HISPANIC OR LATINO	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
NOT HISPANIC OR LATINO	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Weight (kg)				
n%	XX	XX	XX	
Mean	XX.X	XX.X	XX.X	X.XXX
Std.Dev.	XX.X	XX.X	XX.X	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX, XX	XX, XX	XX, XX	
Min, Max	XX, XX	XX, XX	XX, XX	
Country n (%)				
n%	XX	XX	XX	
Country 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Country 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	
Country n	XX (XX.X)	XX (XX.X)	XX (XX.X)	

Disposition Table				
	Treatment A (N=XXX)	Treatment B (N=XXX)	Total (N=XXX)	P-values*
Subject Disposition	n (%)	n (%)	n (%)	
Completed	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Death or Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Death	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Adverse Event	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Lack of Efficacy-Related Reasons	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Lack of Efficacy	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Progressive Disease	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Disease Relapse	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Other Reasons	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Lost to Follow-up	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Non-compliance with Study Drug	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Pregnancy	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Protocol Violation	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Physician Decision	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Withdrawal by Subject	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Withdrawal by Parent/Guardian	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Recovery	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Technical Problems	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX
Other	XX (XX.X)	XX (XX.X)	XX (XX.X)	X.XXX

Abbreviations: N = total number of subjects; n = number of subjects in the specified category
% = Percentage of patient
* = Fisher's exact test when comparing 2 treatment groups

Concomitant Medication				
Enrolled / Randomized Population Study period Study Name				
	Treatment A (N = XXX) n (%)	Treatment B (N = XXX) n (%)	Total (N = XXX) n (%)	P-values*
Concomitant Medication				
Patients with >=1 Concomitant Therapy	XXX	XXX	XXXX	.XXX
Concomitant Med 1	XX (XX.X)	XX (XX.X)	XX (XX.X)	.XXX
Concomitant Med 2	XX (XX.X)	XX (XX.X)	XX (XX.X)	.XXX
ETC				.XXX
* = Number of patient % = Percentage of patients * = Fisher's exact test when comparing 2 treatment groups				
Program Location: program name Output Location: output name Data Set Location: data set name				

Help us and give
feedback

What are your main
challenges working with
**Demographics, Disposition
and Medication?**

Share with us a good graph you
often use for these topics.

More information:
phusewiki.org

Please contact:
Simin K Baygani:
baygani_simin_k@lilly.com

Overview White papers:

1. Analyses and Displays Associated with Measures of Central Tendency – With a Focus on Vitals, ECGs, and Labs in Phase 2-4 Clinical Trials and Integrated Submission Documents. (Final)
2. Analyses and Displays Associated with Outliers or Shifts from Normal to Abnormal – With a Focus on Vitals, ECGs, and Labs in Phase 2-4 Clinical Trials and Integrated Submission Documents. (Initial draft sent for *team review*)
3. Analyses and Displays Associated with Adverse Events and Deaths – With a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents
4. Analyses and Displays Associated with Demographics, Medications, and Disposition – With a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents (Initial draft sent for *team review*)
5. Analyses and Displays Associated with Hepatotoxicity – With a Focus on Phase 2-4 Clinical Trials and Integrated Submission Documents
6. Analyses and Displays Associated to Pharmacokinetics – with a focus on clinical trials (Initial draft sent for *team review*)