Multi-center Clinical trials reporting with R

Scott Gillespie[1], Courtney McCracken[1], Dane Van Domelen[2], Traci Leong[2*]

1. Emory University School of Medicine
2. Emory University School of Public Health
*Contact author: tleong@emory.edu

Reporting in clinical trials is a requirement from both local and funding source agencies. Regular reporting also aids the study team in evaluating enrollment rates and patient eligibility characteristics. For multi-center clinical trials, there is often a need for reports to be sent to the study team and enrolling sites to monitor each institution's contribution to enrollment. Regular reporting can become a time burden without an automated system. We will evaluate several methods of clinical trials reporting and will demonstrate the computing speed differences as well as the output for each method. We will also consider the amount of manual time required to implement each method.

Results from a critical care clinical trial [1] will be shown using methods incorporating the packages **tab** [2] and **xtable** [3]. In conjunction with the xtable package, we will use **Sweave** [4] to produce high quality summary tables in Latex. The method requiring xtable allows for the greatest flexibility, but requires that the user first summarize the data, then manually fit the output to a matrix prior to obtaining the Latex output from the **xtable** function. An alternative to this approach utilizes the **tab** package in RStudio. Here, the user simply specifies the data as either continuous or discrete, indicates any specific levels to summarize by, and runs the appropriate command. These results can be easily copied and pasted into Microsoft Word for general and quick reporting.

Both **tab** and **xtable** methods are reasonable approaches to displaying data summaries and results. The **xtable** method would be best utilized for presenting publication quality tables and output; whereas, the **tab** approach could be best used for monthly summary reports to be presented to study teams and enrolling sites in clinical trials.

References

[1] Rigby MR, Leong, T, Preissig C, et al. (2014). Introducing a protocol to control hyperglycemia in pediatric critical illness: Associations of hyperglycemia, glycemic control and hypoglycemia. In SCCM 2014, Society of Critical Care Medicine (San Francisco, CA).

[2] Van Domelen DR. (2014). tab: Functions for creating summary tables for statistical reports.. R package version 1.0. http://CRAN.R-project.org/package=tab

[3] Dahl DB. (2013). xtable: Export tables to LaTeX or HTML. R package version 1.7-1. http://CRAN.R-project.org/package=xtable

[4] Leisch F. (2002).Sweave: Dynamic Generation of Statistical Reports Using Literate Data Analysis Physica Verlag, Heidelberg. ISBN 3-7908-1517-9.

[5] R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/.