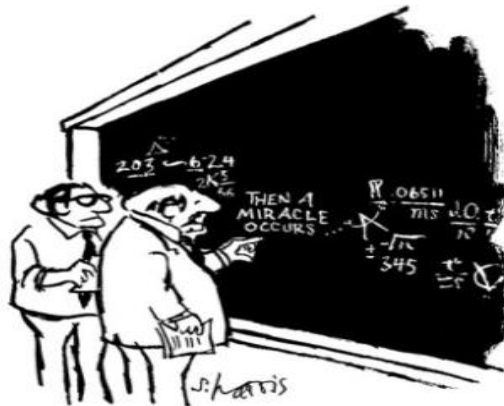


## STATISTICAL SOFTWARE

There are many statistical software packages available for end-users to conduct analyses. These prepackaged software platforms are often referred to as "black-box" in that the user chooses analyses from a menu after which a black-box of programming code conducts a statistical analysis and then spits out a summary of the results. Such software packages are efficient at processing basic statistical analyses of routine, repetitive study data. But problems arise when

- there is insufficient training on usage of the software
- there is insufficient statistical expertise to determine if the menu driven analysis options are appropriate for the current study design and collected data
- the most appropriate statistical analysis is beyond the scope of the software

Blind trust in these click-and-run packages is a growing concern in the scientific community. Access to powerful software allows scientists to derive answers without a thorough understanding of what the software is doing, is it doing it correctly and is it the most appropriate methodology.



"I think you should be more explicit here in step two."

Statistical methodology should not be driven by what's available in third party software or a copy and paste from the previous study protocol. Methodology in most black-box software is introductory level statistics designed to address routine/template study designs and common data attributes.

**BioSTAT Solution:** BioSTAT statisticians design an analysis plan specifically suited for each individual study then create single-use SAS® programs customized to each individual project and subject to our QC process SOP. Upon project completion, the programs are archived with the specific project material. This process allows us to adopt state of the art methodology and take advantage of the most current statistical and software technologies.