



PHUSE

Insight into the growing use of R, Shiny and Python

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Introduction

The use of Python and R in clinical reporting has not been the most popular despite its recent growth over the past few years and its practical use still seems to be hindered by SAS and other several factors, despite these bottlenecks, though, Python and R programming are creating its own niche in the pharmaceutical industry.

There have been many papers/presentations demonstrating the power of R in supporting innovative statistical methodologies and advanced visualization.

Which One to Choose



R Studio
Shiny

SAS

Minitab

Python



The FDA Approach

FDA policy regarding software used to prepare submissions for drug approvals with clinical trials: Sponsors may use R in their submissions.

The FDA does not endorse or require any particular software to be used for clinical trial submissions, and there are no regulations that restrict the use of open-source software (including R) at the FDA. Nonetheless, any software (R included) used to prepare data analysis from clinical trials must comply with the various FDA regulations and guidances.

The R Foundation helpfully provides a guidance document for the use of R in regulated clinical trial environments, which provides details of the specific FDA regulations and how R complies with them.

FDA Views on R

- All results from data should be reproducible independent of software used.
- In submissions, FDA reviewers would like to know: which R functions were accessed; how they were accessed; and that the results are accurate, reliable and consistent.
- The FDA has used R for its own reports. (Interesting side-note: as a government agency, its reports must be Section 508 compliant, one part of which demands that reports be accessible to readers with limited color vision)

SAS and Python

Big advantage of Python is that plenty of Python libraries to implement various analysis and it can be a “one stop shop” for programming.

Although SAS® is one of the powerful analytical tool in clinical study, Python will expand reporting activity such as data aggregation and visualization in addition to SAS.

SASPy is the new ticket to Python for SAS programmers. It is known as Python Package library to the SAS system and enables to start SAS session in Python. This means Python can support the activities from SAS data handling to reporting.

The Industry conception

Despite some mistaken conceptions in the pharmaceutical industry, SAS is **not** required to be used for clinical trials.

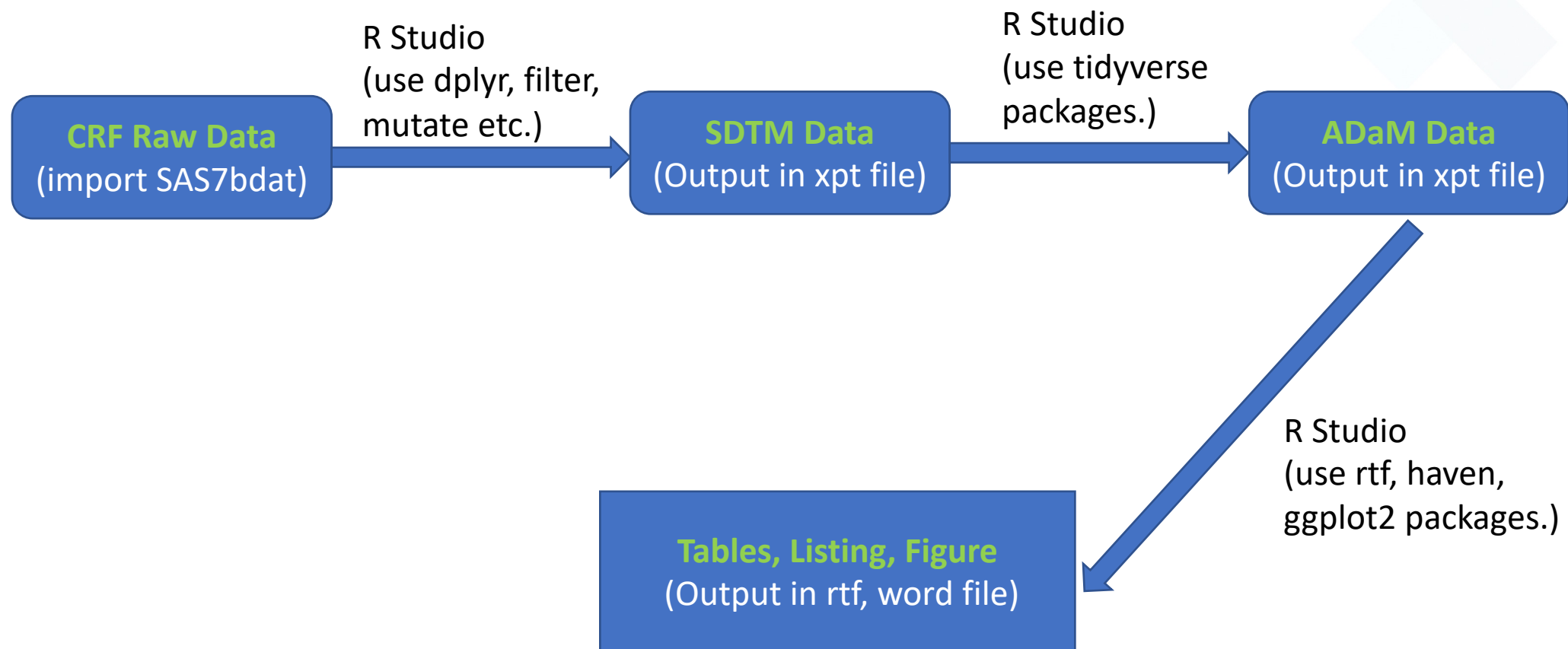
The origin of this fallacy is probably related to the fact that data must be submitted in the XPT "transport format" (which was originally created by SAS). This data format is now an open standard: XPT files can be read into R with the standard `read.xport` function and exported from R with the `write.xport` function

Clinical Reporting in R

One of the main goals of analyzing clinical data is to produce a report. The R Project has, of course, all the tools you need to perform the statistical analysis, calculate the tables of results, and present conclusions graphically.

The “rreport” package for R. It's designed to produce statistical reports for clinical trials and is especially useful for producing interim reports for data monitoring committees (DMCs). You can use it to create a complete report document, fully automating the process of generating tables from your R analyses

R Steps



Comparison Table: SAS, R, and Python

Criterion	SAS	R	Python
Cost	Paid	Free	Free
Learning	Difficult	Easy	Easy
Data Manipulation	High	High	High
Analytic Modelling	High	High	Medium
Graphical capability	Low	High	Medium
Text Processing	Low	Medium	High
Big Data	Medium	Low	Medium
Common usages	High	High	Medium
Job Scenario	High	Medium	Low
Customer support	High	Low	Medium
Advancements in tool	High	Low	Medium

Source: [SAS vs R vs Python | 13 Most Wonderful Comparisons To Know \(educba.com\)](#)



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Advantages and Challenges of Using R/Python

• Advantages

- Cost
- Ease of Use
- Community
- Packages
- Web Application (R Shiny)

• Challenges

- Support
- Hardware Needs, RAM
- Packages of Various Quality
- Packages
- Reproducibility (not just R but all versions of packages)

Summary

- SAS has been a staple in the industry for decades
- Opensource tools have come along way and provide alternative, lower-cost options to SAS but with their own strengths
- Validation remains a key to ensure that outputs are aligned with specifications
- Controls are necessary for ensuring that opensource options are “controlled” and assured of producing consistent results
- Need to reexamine requirements for providing source code to regulatory agencies against more detailed specifications
- Programmers/statisticians now have a larger selection of tools to be able to leverage the strengths of each