111

Challenges in the Implementation of R as a Small-sized Company

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The adoption of open-source tools, particularly R, has seen a significant rise in the pharmaceutical industry. A notable milestone was achieved in 2023 when the FDA accepted an entire R-based submission. Regulators are encouraging such submissions to experiment evaluation of analyses based on open-source tools. For small-sized companies, the implementation of R is a significant challenge due to limited available resources compared to larger companies. Particularly related to training, validation, reproducibility, and quality control.

To integrate R into our operational activities, we have established a set of standardized procedures. These include a list of trusted R packages and detailed guidelines on the use of R and programming practices, with git employed as a versioning tool. Quality control is maintained through an internal package that includes a suite of unit tests, ensuring the reliability of our analyses. Additionally, local Docker containers are utilized to manage versions of R and packages, which guarantees the reproducibility of our analyses.

Our implementation of R is almost free (using local resources) and has enabled us to perform more innovative statistical analyses. This has allowed us to broaden our services and better meet client demands. It is crucial to carefully manage teams and implementation, weighing the pros and cons of R, and staying informed about best practices. We have established basic tools and procedures that provide a solid foundation to prepare for the evolving context of R in the pharmaceutical industry.