Category: Investigator-Initiated Trials - Completed Project

Use of R-Scripts Can Help to Decrease Time and Improve Accuracy on Summary Tables for IND and Semi-Annual Reports

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1. Background

Robert H. Lurie Comprehensive Cancer Center (RHLCCC) is responsible for submitting roughly 50 annual investigational new drug (IND) reports to the FDA and 180 semi-annual reports (SARs) to the IRB. Creating these reports involves generating summary tables for All Adverse Events (AEs), Related AEs, and demographics. On average, these three tables take 142.4 minutes to complete for one IND report. SARs require only the demographics table averaging 11.6 minutes per report. There is variation in time required to complete each table due to differing Excel abilities within the team. Further, the process is error-prone because of the amount of manual work required. The RHLCCC spends roughly 153 hours a year on table creation for SARs and IND reports.

2. Goals

First aim: Reduce time to complete summary tables required for IND and SARs submissions
Second aim: Remove user error on summary tables for IND and SARs to improve accuracy

3. Solutions and Methods

Custom programmatic R-scripts were written to automatically calculate and complete each of the tables. R-scripts remove the manual work required, thus removing human error and reducing the time spent on the task. The R-scripts were integrated into our homegrown clinical trial management system utilizing a sandboxed environment on a remote server. This method was chosen to ensure the security and protection of patient data. Four Quality Assurance Monitors (QAMs) (n=4) responsible for SAR and IND reporting were timed on a standardized version of creating each table before and after R-script implementation. Their work was collected and compared with an answer key to check for accuracy.

4. Outcomes

There was a 91.3 percent reduction in incorrect calculations and typos after R-script implementation. A paired-samples t-test was conducted on the three tables to compare time to complete before and after R-script implementation. There was a significant difference in the time to complete the table for all AEs before (M=49.7 minutes, SD=12.4) and after R-script implementation (M=1.3, SD=0.2); $t(3)=7.8$, $p = 0.998$. There was also a significant difference in the time to complete the table for related AEs before (M=81.1, SD=11.1) and after R-script implementation (M=1.2, SD=0.1); $t(3)=14.7$, $p = 0.999$. Finally, there was also a significant difference in the time to complete the table for demographics before (M=11.6, SD=6.3) and after R-script implementation (M=2.6, SD=1.0); $t(3)=2.9$, $p = 0.970$. There was a 92.2 percent reduction in time spent on tables for IND and SARs reports.

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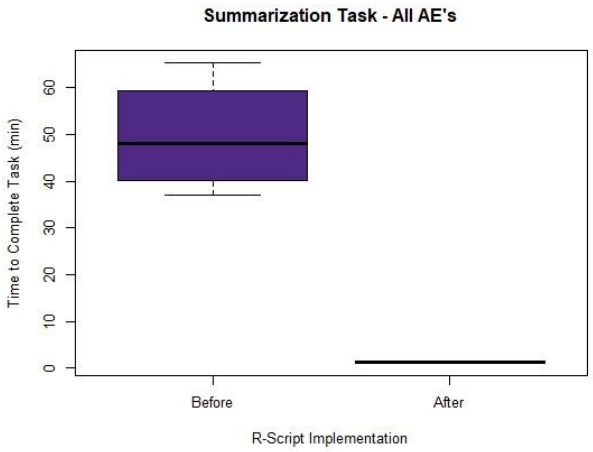
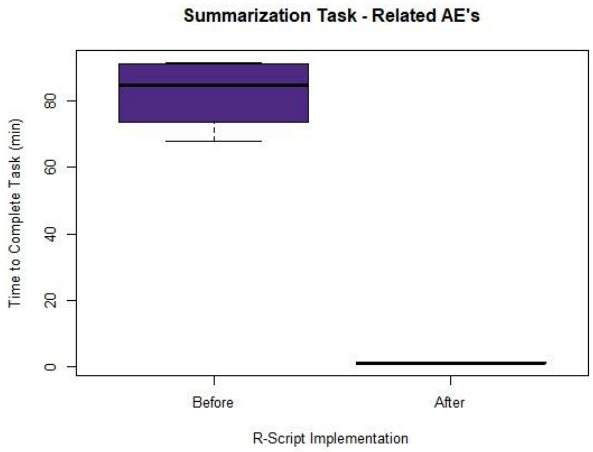
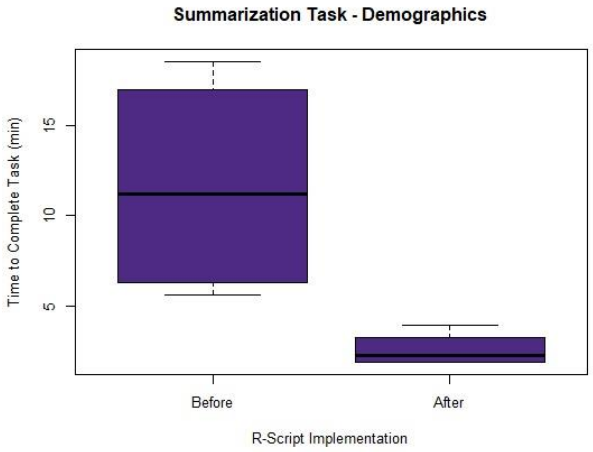
5. Lessons Learned

Overall, R-script implementation has reduced the total annual time spent on all these tables from 153 to 12 hours. Saving 141 hours allows more time for effective trial monitoring, auditing, and other process improvement. Further, accuracy and consistency are of the utmost importance when reporting to the FDA/IRB. User error was noted and reduced in multiple places while implementing this process. In the future, further improvement to the demographics R-script can eliminate copy and paste errors. To achieve this, the output will be updated to a format that matches our report templates. Ultimately, R-scripts can reduce time and error on any task that involves data summarization.

Figure:







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