

PP07: Plunging into Pools: Dive into a Comparative Analysis of Pooled TLFs with R

Sophie Khan, skhan94@its.njn.com, J&J Innovative Medicine, High Wycombe, UK

As we delve into the realm of innovative programming methodologies beyond SAS, we venture into the ever-evolving landscape of R programming. R emerges as a versatile tool, offering efficiency in data analysis and visualization, opening new avenues of exploration and discovery in the pharmaceutical industry.

Abstract

Background: As an integral component of the submission dossier for a drug, a Safety Clinical Summary (SCS) pooling reporting effort encompassing multiple Immunology studies was conducted, tailored specifically for submission to the FDA.

Methods: This poster outlines a systematic method for importing RTF documents and processing them for integration into dataframes, extracting conditional R code from an Excel document corresponding to each pooled TLF, employing the 'compare_df' package for dataframe comparisons, and exporting the outcomes as HTML outputs for comprehensive review.

Results: A comprehensive array of HTML outputs for each pooled TLF for review to make informed decisions.

Objective

The primary objective is to conduct a comprehensive and efficient comparative analysis, scrutinizing each pooled TLF against its respective individual study TLFs whenever feasible.

Figure 1. Display of the RTF documents of a pooled TLF and its individual study TLFs, and the plan to split the data ready to compare outlined

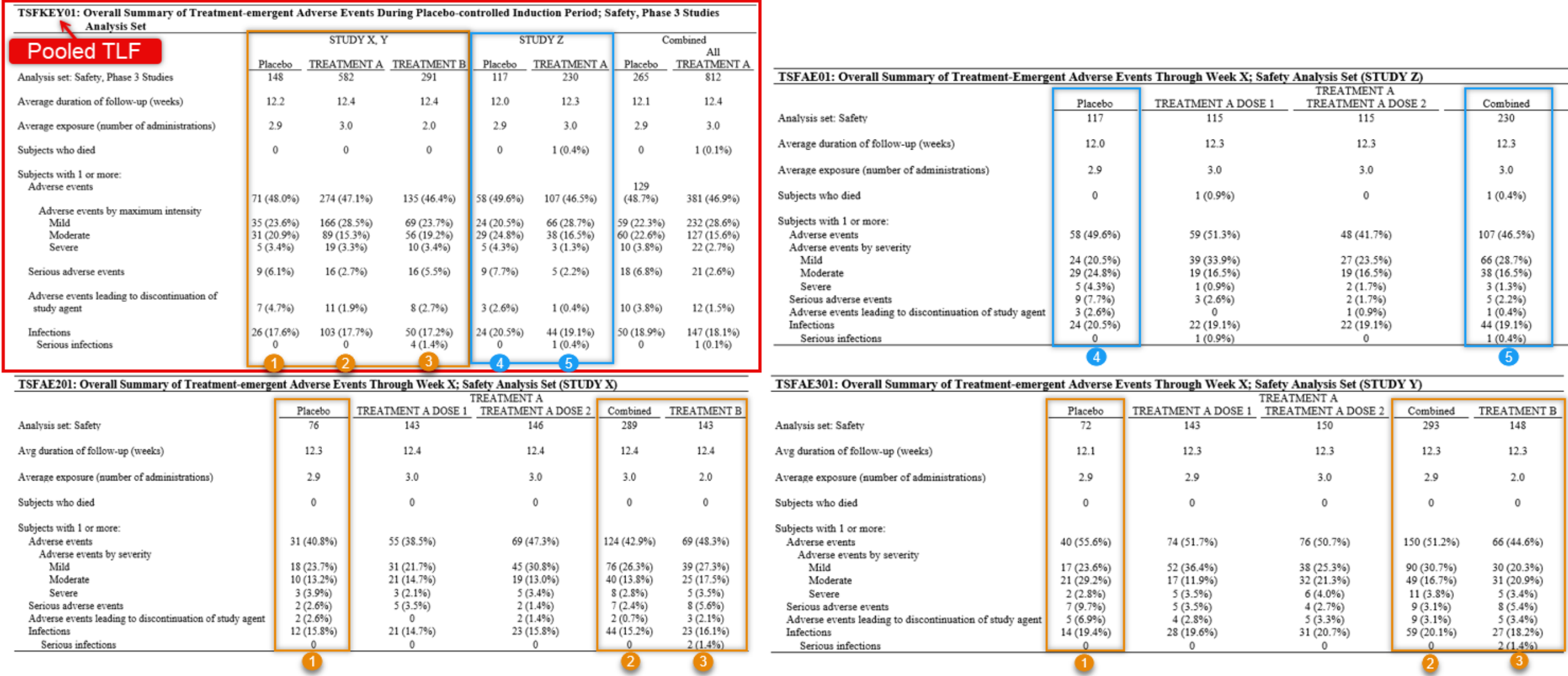


Figure 2. Display of the Excel document containing R coding to extract for each pooled TLF

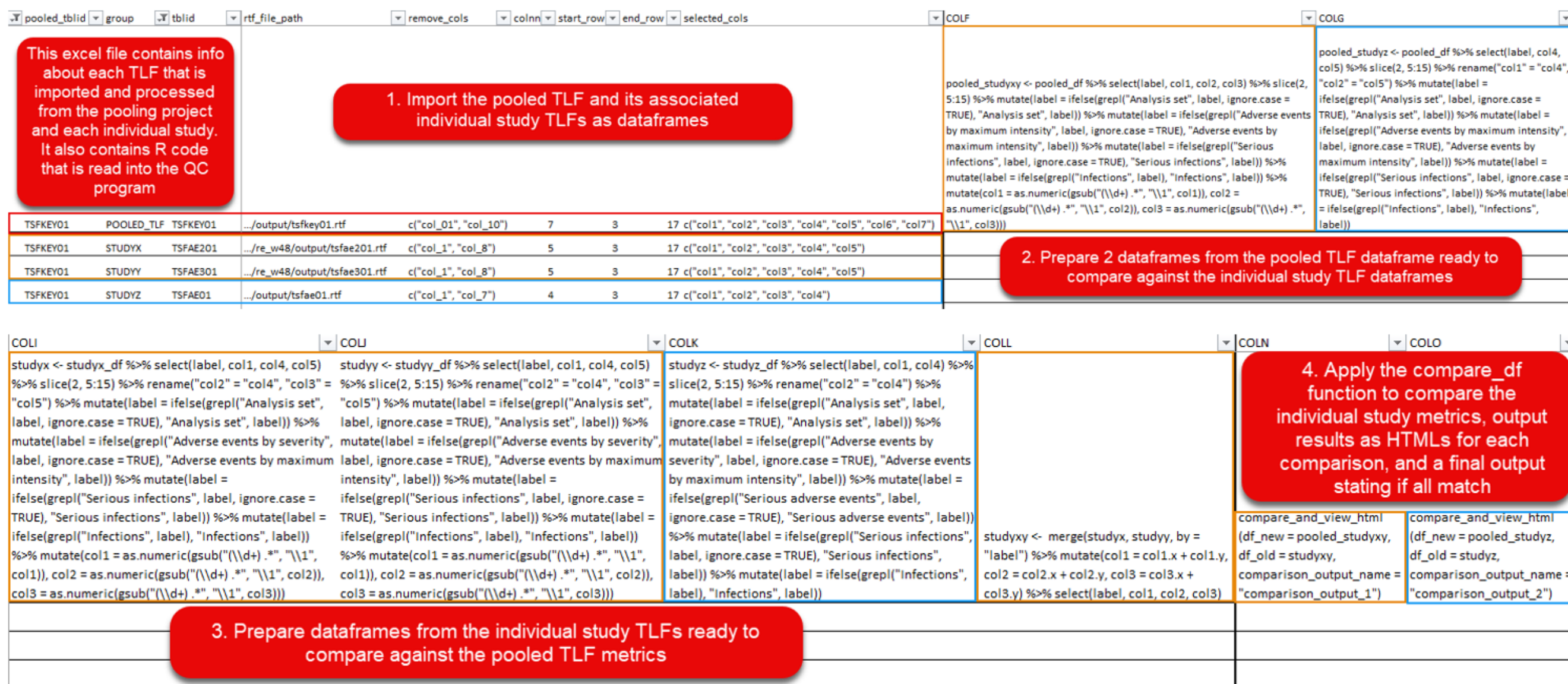


Figure 3. Display of the QC process involved, and the R functions used throughout

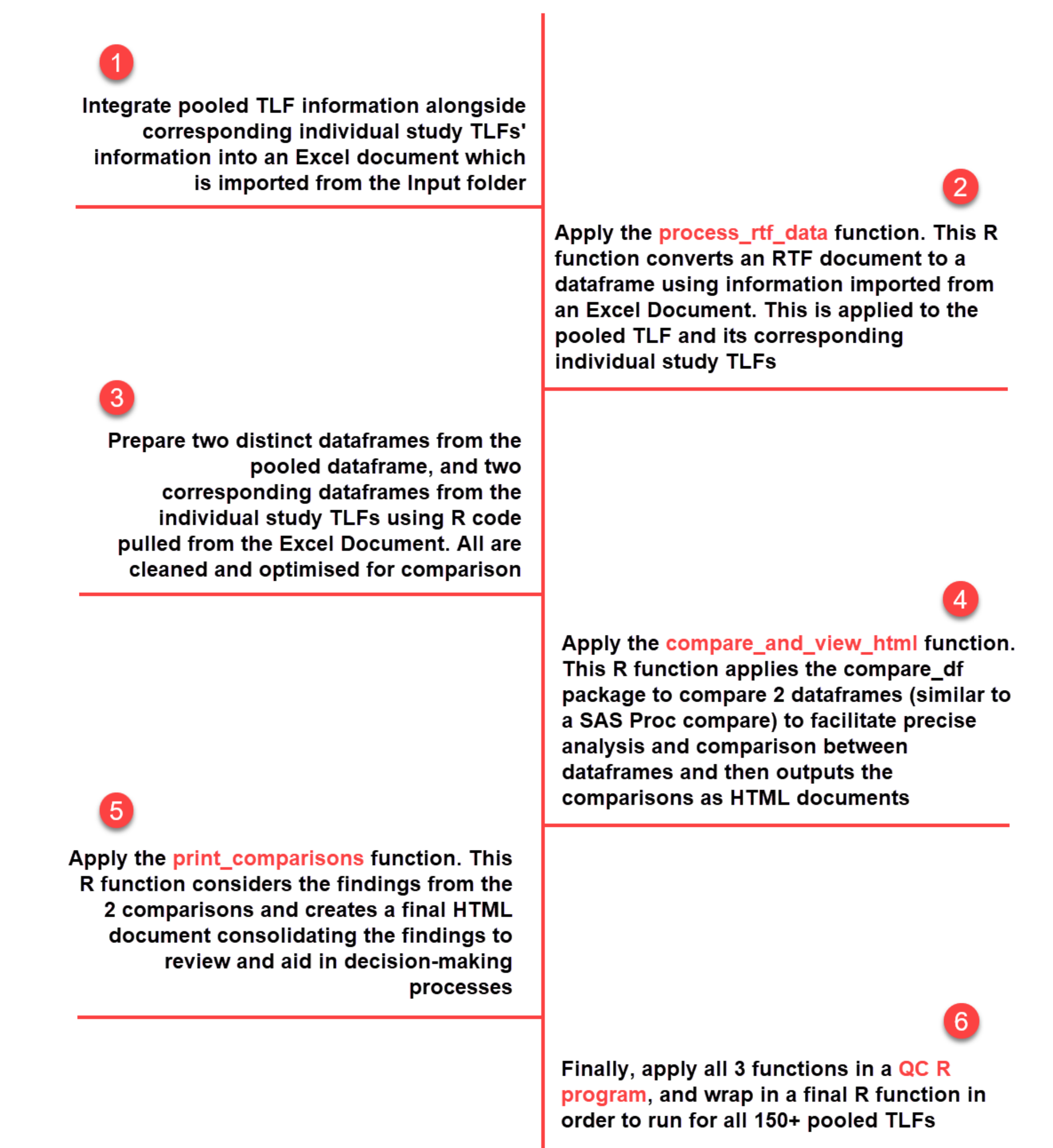


Figure 4. Display of the QC R program as it is run for a pooled TLF

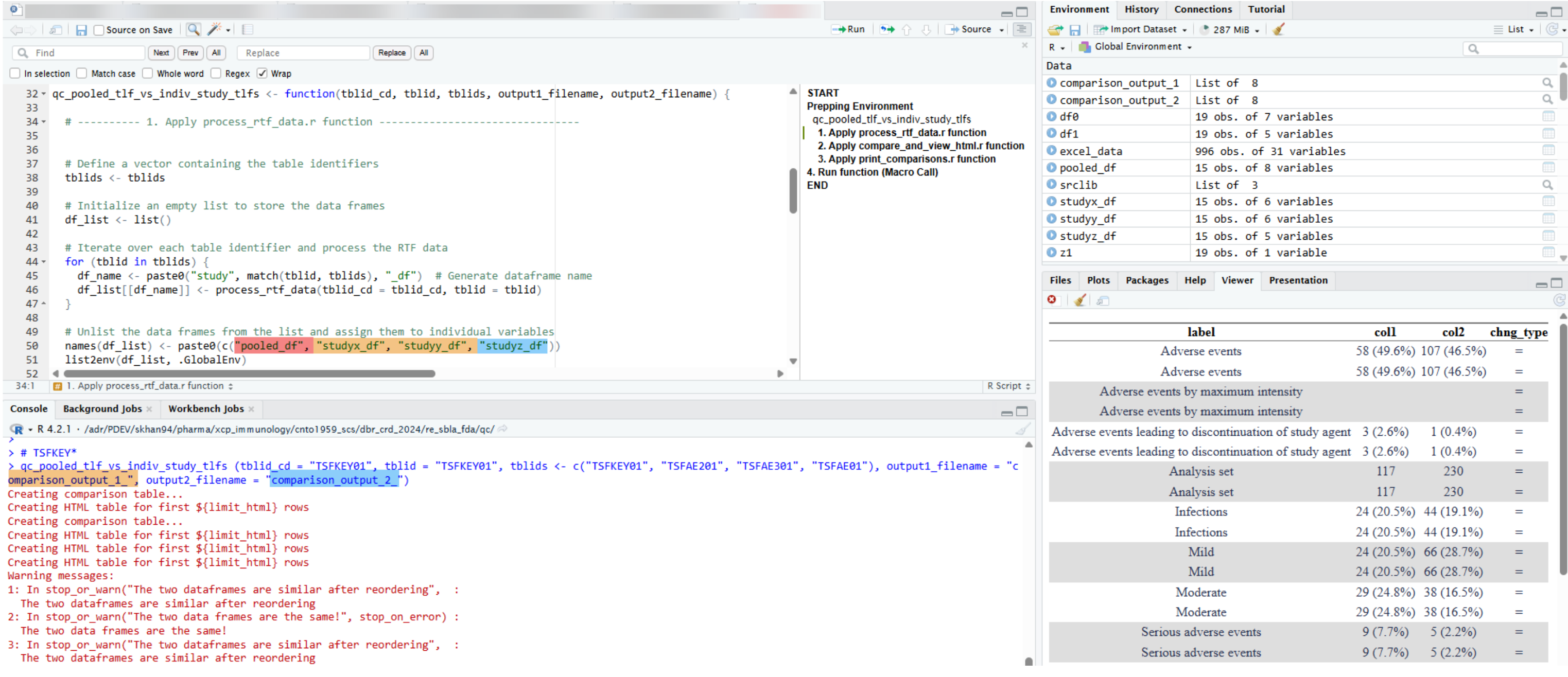
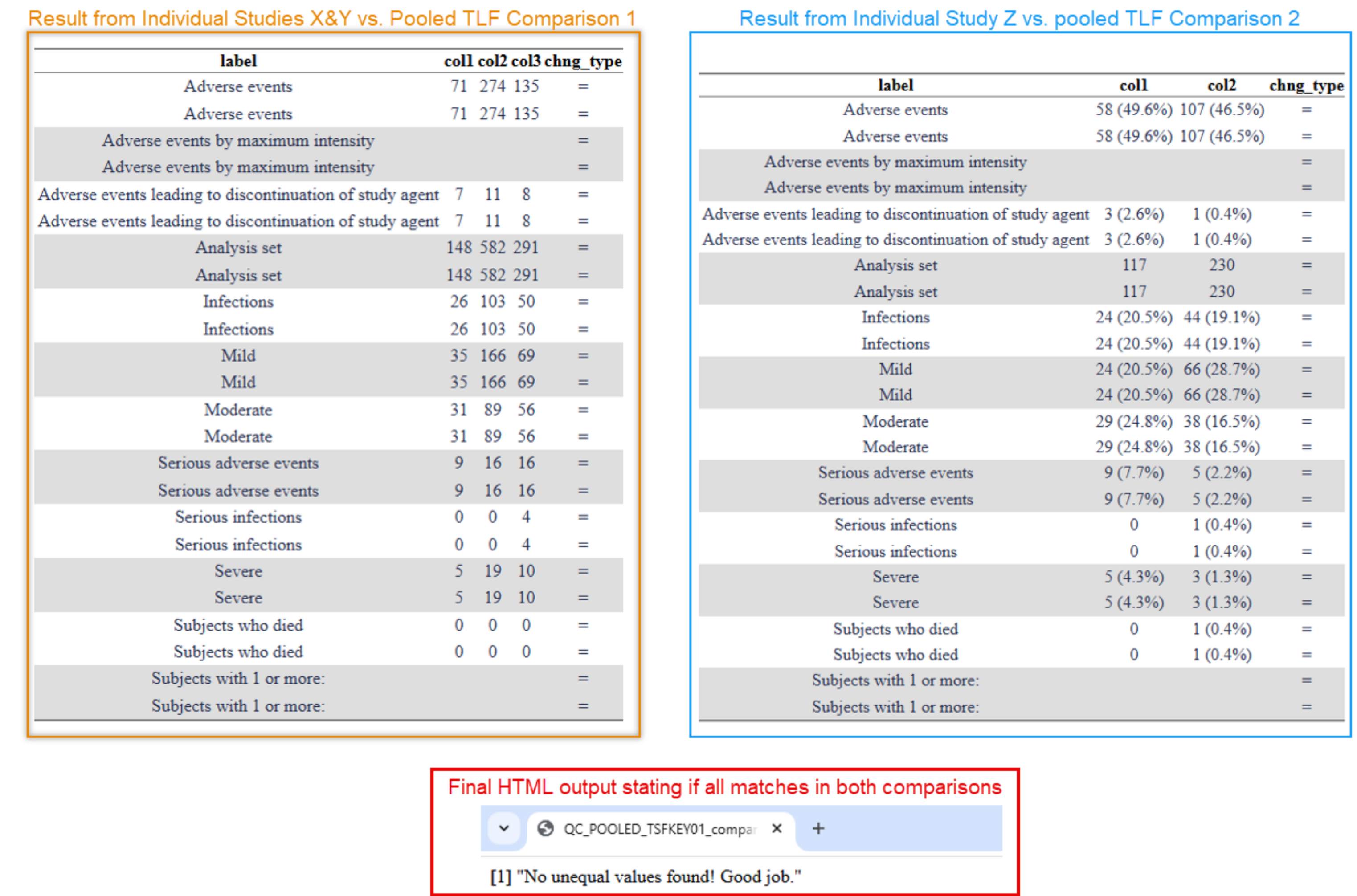


Figure 5. Display of the HTML outputs showing a visual of the comparisons and its final evaluation



Results & discussion

Based on the arrangement of the TLF layout, the pooled TLF underwent a segmentation process into distinct studies X & Y, and Study Z components. Subsequently, comparisons were conducted against the respective individual study TLFs, merging data from study X & Y, and study Z. Application of the 'compare_df' function to their corresponding dataframes revealed identical matches in both comparisons. The culmination of these findings is in a final HTML document, presenting the observed final evaluation (Figure 5).

Conclusion

Incorporating the power of R, this program represents an original approach towards the quality assessment of examining pooled TLFs against their individual study TLFs, offering a streamlined option that significantly reduces time and effort. This tool optimizes workflow efficiency, ultimately advancing the pace of decision-making processes within the pharmaceutical industry.

Recommendations for enhancing the examination of pooled TLFs against their corresponding individual study counterparts include the implementation of a comprehensive summary document aggregating final evaluations from each pooled TLF. Additionally, refinement of the R coding to enhance efficiency to optimize this process further as we continue to consider other tools in the pharmaceutical industry.