

RECORD: software tool for streamlining documentation and enhancing communication of modeling analyses

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Introduction

Timely and clear communication of modeling analysis results is essential for a pharmacometrician to achieve meaningful impact in any R&D project. However, compiling these results into a formal report often presents significant challenges:

- Lack of readily available standardized templates to initiate report writing;
- Strict formatting requirements when working with custom-provided templates;
- Resource-intensive and error-prone (re-) integration of outputs into the report;
- Object numbering and cross-references can frequently get broken during editing.

Aim

We developed an R-based tool for **RE**porting and **CO**munication in drug R&D (**RECORD**) aimed at streamlining the preparation of reports through an easy-to-use user interface (UI) that supports custom templates and allows automatization and reproducibility in the handling of the objects (figures and tables) in a document.

Methods

- The **RECORD** tool was developed in R Statistics software (version 4.2.2) as a UI application using shiny package (version 1.7.4).
- XML parser was created based on the xml2 (version 1.3.3) library and allows recognition of the structure of XML-type files, including .docx and .pptx.
- Parsing procedure is complemented by compilation of a human-readable control file with relative paths to sources of figures and tables.
- Object insertion, deletion, and replacement were implemented using custom wrapper functions built on the officer package (version 0.6.2).

Conclusions

In this work, we have created an R-based software tool designed to automate the parsing and modification of MS Word .docx files and increase the efficiency of modeling report compilation and editing. The **RECORD** tool optimizes the routine aspects of pharmacometric report preparation, by providing a library of templates and enabling dynamic updates while maintaining proper formatting, object numbering, and cross-referencing

Results

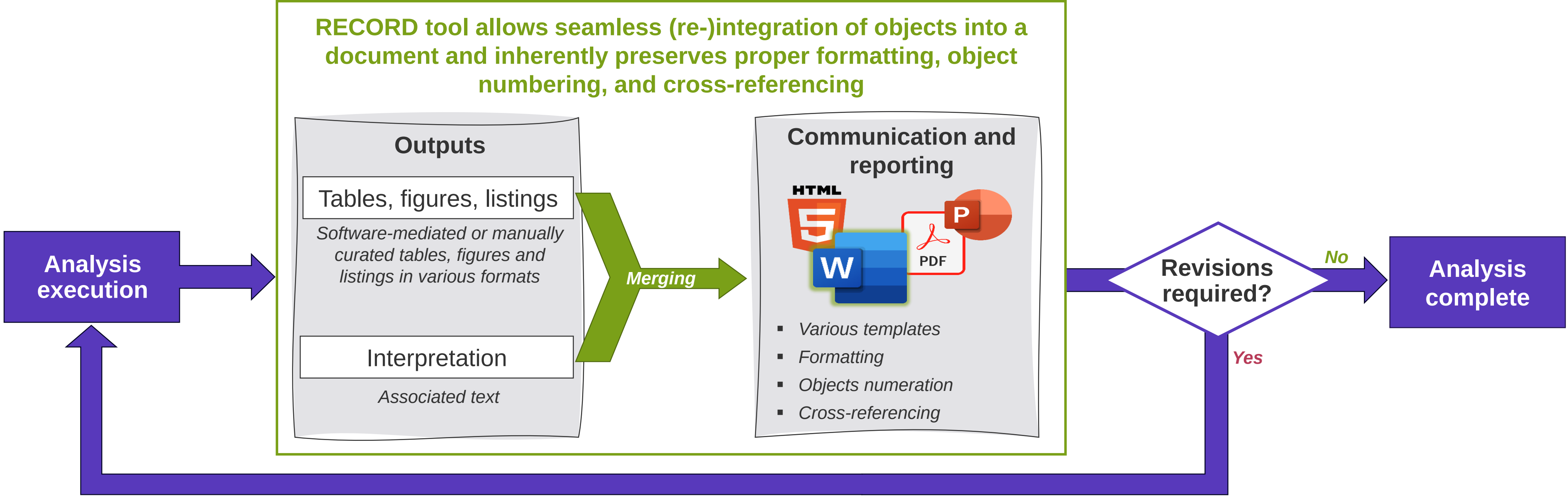


FIGURE 1. Integration of the RECORD tool into the pharmacometric analysis workflow. The tool assists with communication and reporting tasks by automating the compilation of report after outputs are updated and providing a template library to get started.

The **RECORD** tool is developed to streamline the integration of analysis results into an MS Word .docx report and tackles the core challenges of report generation (**Figure 1**). The tool is easy to use and flexible to account for various modeling reporting tasks and can be applied in any type of pharmacometrics workflow. **Figure 2** illustrates essential functionality available within the UI of the application. **RECORD** is equipped with a library of templates (**1**) tailored for various types of modeling analyses, such as population PK and PK/PD reports, exposure-response reports, QSP and others, compiled in accordance with FDA guidelines and current best practices within the industry [1-3]. It is also possible to upload a custom template (**2**) through the “Import” button. Once a user uploads a .docx file into the interface, the software parses its structure, returning the hierarchy of headers along with the corresponding objects located in each section. Each object is labeled with a caption and is automatically assigned a running number, facilitating easy cross-referencing of figures and tables throughout the text. An object can be removed, or a new one can be added (**3**) using dedicated buttons associated with headers and individual objects. Moreover, an object can be linked with a source file (.jpg, .png, .tiff – for figures; .csv, .xls, .xlsx – for tables) which will then be inserted into the report under the appropriate caption. For the convenience of a user, there is a “Set project directory” button that allows user to select the root folder of the modeling analysis project, where all outputs are located (**4**). With a single click (**5**), all objects linked with a source can be updated with their latest versions across the whole document. The tool stores relative paths to these objects in a control file (**5**), which can be visually reviewed and manually adjusted if needed.

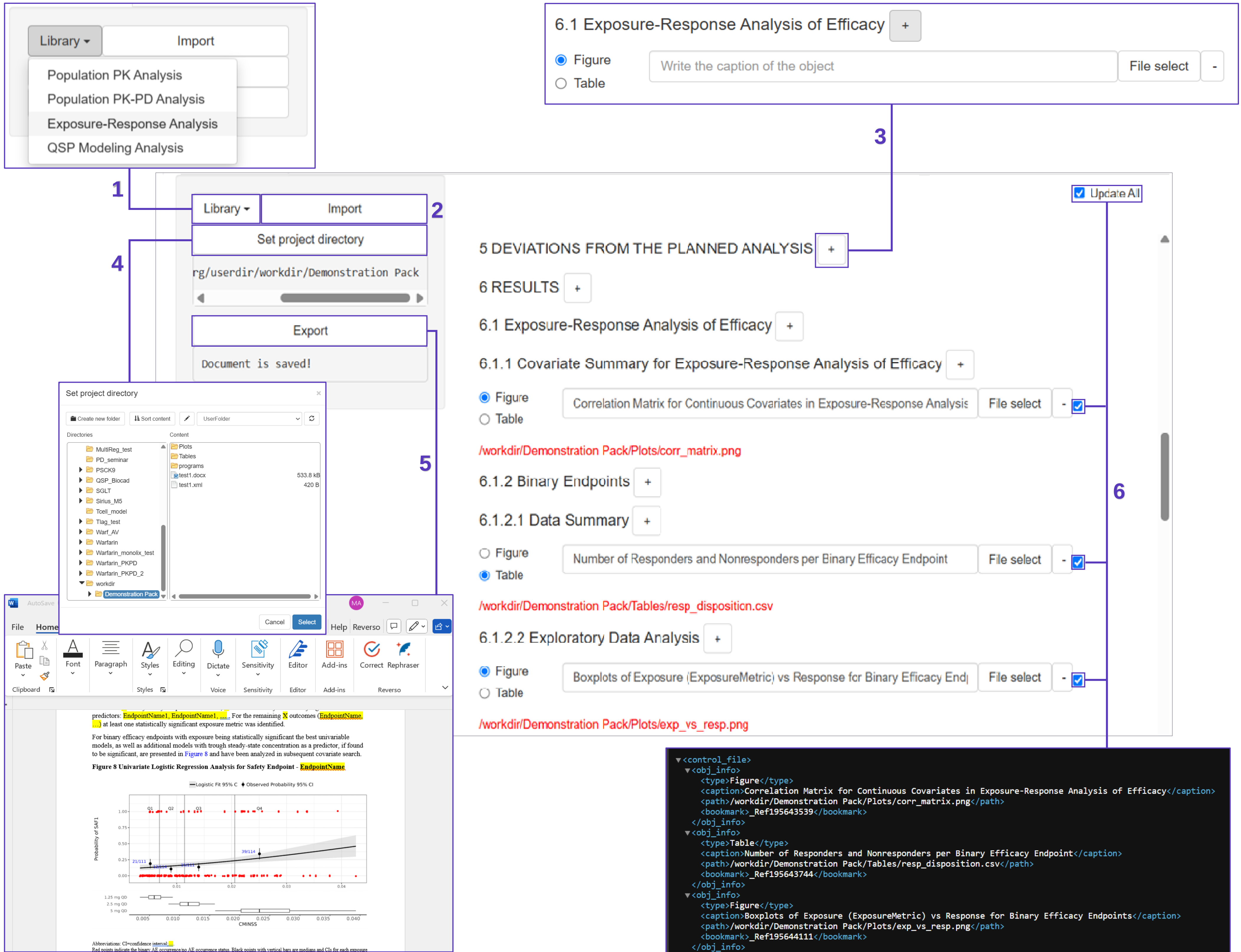


FIGURE 2. Illustration of RECORD functionality, composed of screenshots of the application elements.

References

[1] L. Brum, Guidance for Industry, Clinical Pharmacology (2022).
[2] FDA Guidance for Industry, Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications (2003).
[3] ICH Harmonized Guideline M15, General Principles for Model-Informed Drug Development (2024).

