

Automation of Review Process

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ABSTRACT

Statistical outputs for clinical study report are produced as separate tables, listings and figures (TLFs) in the form of Rich Text Format (RTF). The output review process usually involves a huge amount of TLFs and all kinds of comments back-and-forth. It becomes more and more challenging to track the status of each comment from individual reviewers; very often a few important comments are left unattended or overlooked until very late stage.

This paper presents a few useful SAS macros to streamline the review process in a well-controlled way: Firstly, a SAS macro is developed to combine all outputs in RTF format into a single RTF file for different reviewers to comment. The names of the original RTF files are kept on the header of each page of the combined file for later reference. Secondly, reviewers can use the MS Word "Review" feature and put comments freely on each page as necessary. Lastly, another SAS macro is developed to extract all comments from each page of the combined file into a well formatted Excel spreadsheet. The spreadsheet contains separate columns for each applicable field (i.e., the comment itself, reviewer's name, page number, and the RTF file name). This information is useful to identify the stakeholder and locate the corresponding table, listing or graph for any given comment, as well as to track the status of each individual comment. This innovative approach greatly improves the communication among stakeholders, and significantly optimizes the statistical review process.

INTRODUCTION

Visual Basic for Applications (VBA) is the programming language that provides automation capabilities in Microsoft office applications. SAS provides users the capability to create a VBA script to run by using "put line". The integration of SAS and VBA can expedite statistical outputs review process. Usually prior to final delivery, statistical outputs undergo a review process which involves a huge amount of TLFs and all kinds of comments back-and-forth. A question arises from the review process: how can we use VBA to facilitate the review process in a timely and well-controlled way? With the modification of a well-developed SAS macro, all TLF outputs can be combined into one single RTF file with the original individual RTF file name on the header. Thus, taking advantage of the relative strengths of VBA to deal with the Microsoft Word, we developed a VBA script to extract all comments and changes from the reviewed file.

This paper presents an example of integrating VBA and SAS to automate review process, which can be served as a starting point to get benefits from both VBA and SAS for SAS programmers in the pharmaceutical industry.

DISCUSSION

Firstly, a SAS macro was developed to combine all outputs in RTF format into a single RTF file for reviewers to comment (the original RTF file name is kept on the header of each page of the combined file for later reference). The macro was modified to insert the original RTF file name on the header. See below for the key part of the code.

```
do rtfcode=
    '\sect\sectd',
    %if %upcase(&output_name_show)=Y %then
    '{\header \pard\plain
\li0\ri0\widctlpar\aspalpha\aspnum\faauto\adjustright\rin0\lin0\itap0\
fs20\lang1033\langfe1033',
    '\cgrid \langnp1033\langfenp1033\qr\cf2{||strip(fname)||'}\par}',;
    '{\footer \pard\plain \qc
\li0\ri0\widctlpar\aspalpha\aspnum\faauto\adjustright\rin0\lin0\itap0\
fs20\lang1033\langfe1033',
    '\cgrid \langnp1033\langfenp1033{\field{\*\fldinst {PAGE
\r1}}{\fldrslt {\lang1024\langfe1024\noproof}}}'/,
    '{\field{\*\fldinst{NUMPAGES}}{\fldrslt
{\lang1024\langfe1024\noproof }}}\par}',
    '{\bkmkstart '||"&bkmkpref"
||strip(put(ford,best.))
||'}{\bkmkend '
||"&bkmkpref"
||strip(put(ford,best.))
||}'
;
    output rtf;
end;
```

Using the sample call as shown below we can combine all outputs in RTF format into a single RTF file (Figure 1) for reviewers to comment.

```
%comb0rtf(
    inpath=C:\test-area\test6
    ,inpath_graph=C:\test-area\test6\graph
    ,outpath= C:\test-area\test6\combined
    ,outfile=%str(Combined test)
    ,inlist=ALL
    ,file_title=%str(Combined CSR PharmaSUG 2019)
    ,output_name_show=Y
    ,debug=N
);
```

Combined CSR PharmaSUG 2019

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Subjects With Adverse Events
(Incidence $\geq 10\%$ in One or More Treatment Groups)

| | TREATMENT 1 | | TREATMENT 2 | | Total | |
|--|-------------|---------------|-------------|---------------|------------|---------------|
| | n | (%) | n | (%) | n | (%) |
| Subjects in population | 365 | | 363 | | 728 | |
| with one or more adverse events | 330 | (90.4) | 330 | (90.9) | 660 | (90.7) |
| with no adverse events | 35 | (9.6) | 33 | (9.1) | 68 | (9.3) |
| Gastrointestinal disorders | 150 | (41.1) | 143 | (39.4) | 293 | (40.2) |
| Diarrhoea | 59 | (16.2) | 47 | (12.9) | 106 | (14.6) |
| Nausea | 39 | (10.7) | 34 | (9.4) | 73 | (10.0) |
| General disorders and administration site | 62 | (17.0) | 72 | (19.8) | 134 | (18.4) |

Figure 1. Screen print of a sample combined file.

Secondly, a reviewer can use the MS Word “Review” feature and put comments freely on each page as necessary. As shown in Figure 2, comments and changes were made in a sample page

Subjects With Adverse Events
(Incidence $\geq 10\%$ in One or More Treatment Groups)
Weeks 0-96; Base Study (Double Blind)

| | TREATMENT 1 | | TREATMENT 2 | | Total | |
|---|-------------|---------------|-------------|---------------|------------|---------------|
| | n | (%) | n | (%) | n | (%) |
| Subjects in population | 365 | | 363 | | 728 | |
| with one or more adverse events | 330 | (90.4) | 330 | (90.9) | 660 | (90.7) |
| with no adverse events | 35 | (9.6) | 33 | (9.1) | 68 | (9.3) |
| Gastrointestinal disorders | 150 | (41.1) | 143 | (39.4) | 293 | (40.2) |
| Diarrhoea | 59 | (16.2) | 47 | (12.9) | 106 | (14.6) |
| Nausea | 39 | (10.7) | 34 | (9.4) | 73 | (10.0) |
| General disorders and administration site conditions | 62 | (17.0) | 72 | (19.8) | 134 | (18.4) |
| Infections and infestations | 222 | (60.8) | 209 | (57.6) | 431 | (59.2) |
| Nasopharyngitis | 44 | (12.1) | 49 | (13.5) | 93 | (12.8) |
| Upper respiratory tract infection | 40 | (11.0) | 30 | (8.3) | 70 | (9.6) |
| Injury, poisoning and procedural conditions | 44 | (12.1) | 33 | (9.1) | 77 | (10.6) |

Zhao, Shunbing
Check the number

Zhao, Shunbing
Check specific AE

Figure 2. Screen print of a sample page with comments and changes.

Lastly, another SAS macro was developed to extract all comments on each page of the combined file into a well formatted Excel spreadsheet. The key part of the macro is shown below.

```

%macro extract0comment(
    in_path= /*Path to the folder containing RTF file.*/
    ,out_path=/*Path to the folder outputing excel comment file. */
    ,rtf_file= /*RTF file name.*/
    ,excel_file= /*excel file name.*/
    ,display_flag=N /*Not open excel file if N, otherwise will open
excel file.*/
)
)

...

* Generate VBA Script;
data _null_;
...
put line $varying1024. len;
line = "    Set myRange = objDoc.Comments(i).Scope";
len = length(line);
put line $varying1024. len;
line = "    j = myRange.Information(2)";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 1).Formula =
objDoc.Comments(i).Index";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 2).Formula =
objDoc.Comments(i).Reference.Information(1)";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 3).Formula =
objDoc.Sections(j).Headers(1).Range.Text";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 4).Formula =
objDoc.Comments(i).Scope";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 5).Formula =
objDoc.Comments(i).Range";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 6).Formula =
objDoc.Comments(i).Author";
len = length(line);
put line $varying1024. len;
line = "    .Cells(i + HeadingRow, 7).Formula =
FormatDateTime(objDoc.Comments(i).Date, 2) ";
len = length(line);
put line $varying1024. len;
line = "    .Columns.AutoFit ";
len = length(line);
put line $varying1024. len;

```

```

line = "    Next";
len = length(line);
...
run;

* Executing Script;
data _null_;
    rc = system("""&workdir\_extract.vbs""");
    put "NOTE-Exit code after executing VBScript: " rc;
    CALL SYMPUT('rc', strip(put(rc, best.)));
run;
...
%mend extract0comment;

```

With this macro, all comments and changes can be extracted into an Excel spreadsheet. In this spreadsheet, there are separate columns for each applicable field (i.e., the comment itself, reviewer's name, page number, and the RTF file name). The corresponding table, listing or graph can be located for a given comment and the status of each individual comment can be tracked with the help of the extracted information. Figure 3 shows one example of the output of this macro in details.

| A | B | C | D | E | F | G |
|----------------|------|------------------------|--|--|----------------|------------|
| No. Comment | Page | Output File Name | Scope | Comment | Reviewer | Date |
| 1 | 2 | ae0counts010pct0base | 68 (9.3) | Check the number | Zhao, Shunbing | 11/19/2018 |
| 2 | 2 | ae0counts010pct0base | Upper respiratory tract infection | Check specific AE | Zhao, Shunbing | 11/19/2018 |
| 3 | 4 | ae0counts05pct0base | incidence criterion in the report title, after rounding. | Align the footnote | Zhao, Shunbing | 11/19/2018 |
| 4 | 10 | ae0counts0anal0base | Miettinen & Nurminen method | Check the method citation | Zhao, Shunbing | 11/19/2018 |
| Line of Change | Page | Output File Name | Type of change | Change | Reviewer | Date |
| 18 | 2 | ae0counts010pct0base | Inserted | | Zhao, Shunbing | 11/19/2018 |
| 22 | 2 | ae0counts010pct0base | Inserted | | Zhao, Shunbing | 11/19/2018 |
| 4 | 12 | ae0counts0discon0base | Deleted | (Double Blind) | Zhao, Shunbing | 11/19/2018 |
| 3 | 14 | ae0counts0overall0base | Inserted | Base Study (Double Blind) | Zhao, Shunbing | 11/19/2018 |
| 25 | 58 | ae0counts0ser0base | Inserted | Every subject is counted a single time for each applicable row and column. | Zhao, Shunbing | 11/19/2018 |

Figure 3. Screen print of a sample output.

CONCLUSION

This innovative approach presented in this paper greatly improves the communication among stakeholders, and significantly optimizes statistical review process. As SAS programmers, we can greatly improve our efficiency and accuracy in analysis and reporting activities while integrating with VBA.

REFERENCES

A Simple SAS Utility to Combine Existing RTF Tables/Figures and Create a Multi-level Bookmark Hierarchy and a Hyperlinked TOC. Lulang Larry Xie, PharmaSUG 2019

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