A Quick Way to Cross Check Listing Outputs

Shunbing Zhao, Jeff Xia, Merck & Co., Inc., Rahway, NJ, USA

ABSTRACT

Very often, listings are required to support summary reports in clinical trials. Normally these listings are in RTF format, and each one could be tens or hundreds of pages in length. Since a single study could involve dozens of listings, it becomes very challenging to detect potential issues in the process of generating listing, or cross-check between the summary report and the corresponding listing.

This paper presents a convenient way to find out how many subjects are included in each listing, which is a good indicator for cross-checking against summary reports. A macro was developed to go through each listing and produce an overall report, which includes a comprehensive summary tab with information, i.e., file name, title of the listing, number of subjects in that listing; it also includes a separate tab for each listing to display the list of involved subjects. Additionally, a hyperlink is built in the file name in the summary tab so that a reviewer can navigate to corresponding list of subjects, and dig further if any discrepancy occurs.

INTRODUCTION

SAS programmers usually deliver CSR table/listing/graph in RTF format. They are reviewed to identify potential data issues and inconsistencies among them. Many listings are generated to support summary reports. Considering each listing could be tens or hundreds of pages, it is tedious and challenging for a reviewer to cross-check between the summary report and the corresponding listing.

This paper presents a programmatic way to check how many subjects in each listing are under a certain folder. All listings are summarized into an Excel file with a file name, a title of the listing, and number of subjects in that listing. Thus, a reviewer can cross-check against corresponding summary reports.

DISCUSSION

When facing lots of listings in RTF format it is needed to load them into SAS. Thus, we can count distinct subjects using a regular expression pattern and extract title and file name of individual listings. Additionally, we cross-check subject ID with DM domain. The code (key part) below can perform this task programmatically.

Firstly, we load all RTF files from a folder. Then using regular expression pattern, we are able to extract subject id and compare them with DM domain.

```
/*load all RTF files from a folder*/
  %readfilesindir(inpath=&inpath,outset=outtable,sect_ord=1,s_title=Ta
bles and Listings);
  data rtffiles;
    set outtable;
  run;
…
    /*usubjid dummy pattern*/
    pattern1 = prxparse("/\d{6,}/");
    retain title sect1_ pattern1;
…
      if find(rtfcode,'\intbl')>0 and prxmatch(pattern1, rtfcode) >0
then do;
        call prxsubstr(pattern1,rtfcode,position,length);
        subjid=substr(rtfcode,position,length);
        output rtf;
      end;
  end;

…
```

Furthermore, we generate an overall report which includes a comprehensive summary tab with
information, i.e., file name, title of the listing, number of subjects in that listing; it also includes a
separate tab for each listing to display the list of involved subjects. Additionally, a hyperlink is built in the
file name of the summary tab. See below for the key part of the code.

```
…
proc format;
   value $urlfmt
   %do i=1 %to &tot;
    "&&f&i"="#&&f_&i!A1"
   %end;
    ;
run;
ods excel file = "&outpath.&slash.&outfile..xlsx"   style=printer;
  ods excel   options (sheet_name = "Summary"
                  zoom = '100'
                orientation='landscape'
                pages_fitheight = '100'
                center_horizontal = 'yes'
                center_vertical = 'no'
                start_at="A1");
 proc report data = summary
                              style(header)={font_weight=bold
font_size=10pt just=center protectspecialchars=off borderstyle=solid
bordercolor=black}
                              style(column)={borderstyle=solid
bordercolor=black};
            column fname title num;
            define fname /display style(column)={url=$urlfmt. }
'File Name';
```

```
                define title /display 'Listing Title';
                define num /display 'Number of Subject';
run;
```
…

After calling the macro (Figure 1), a comprehensive Excel file is created as shown in Figure 2 so that a reviewer can cross-check between the summary report and the corresponding listing and navigate to corresponding list of subjects, and dig further if any discrepancy occurs.

```
%count0listing0subject(
        inpath=%str(C:\Users\test-area\test\outtable)
      ,outpath=%str(C:\Users\test-area\test\)
      ,outfile=test1
      ,inlist=all
)
```

Figure 1. Screen print of a sample call.

File Name	Listing Title	Number of Subject
ae0list0death048wk	Listing of Subjects With Adverse Events Resulting in Death	2
ae0list0death0all	Listing of Subjects With Adverse Events Resulting in Death All Data Available	2
ae0list0death0all0ps	Listing of Subjects With Adverse Events Resulting in Death All Data Available (Including Post-Study)	4
ae0list0discon048wk	Listing of Subjects With Adverse Events Resulting in Discontinuation	34
ae0list0discon0all	Listing of Subjects With Adverse Events Resulting in Discontinuation All Data Available	34
ae0list0serious048wk	Listing of Subjects With Serious Adverse Events	34
ae0list0serious0all	Listing of Subjects With Serious Adverse Events All Data Available	40
ae0list0si0immune	Listing of Subjects With Adverse Events - Immune Reconstitution Syndrome	6
ae0list0si0overdose	Listing of Subjects With Adverse Events - Report of ECI of Overdose without Adverse Effect	4

| ◄ ► | **Summary** | ae0list0death048wk | ae0list0death0all | ae0list0death0all0ps | ae0list0discon048wk | ae0list … ⊕ |

Figure 2. Screen print of a sample output.

CONCLUSION

This paper presents a convenient way to facilitate a reviewer to cross-check listings and further warrant clinical analysis report.

ACKNOWLEDGMENTS

The authors would like to thank Cynthia He for her great support and valuable input to this paper.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Name: Shunbing Zhao
Enterprise: Merck & Co., Inc.
Address: 126 E. Lincoln Avenue

City, State ZIP: Rahway, NJ 07065-4607
Work Phone: 732-594-3976
Fax:
E-mail: shunbing.zhao@merck.com
Web: www.merck.com

Name: Jeff Xia
Enterprise: Merck & Co., Inc.
Address: 126 E. Lincoln Avenue
City, State ZIP: Rahway, NJ 07065-4607
Work Phone: 732-594-6439
Fax:
E-mail: jeff.xia@merck.com
Web: www.merck.com