Titles and footnotes management from the TLF shell to the final outputs

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ABSTRACT

Currently, it is not unusual to have to produce several hundreds of Tables/Listings/Figures (TLF) for a statistical analysis and generally, the management of titles and footnotes is a manual process based on copy and paste of the titles/footnotes from the TLF shell to the SAS® programs.

Based on these observations and in order to decrease the risk of errors, the management of the titles and footnotes needed to be improved.

The main objectives were:
- Firstly, to increase the quality of deliverables,
- Secondly, to save time by decreasing the number of checks for outputs,
- Thirdly, to automate as much as possible the management of titles and footnotes during a statistical analysis.

To respond to these objectives, two tools were developed:
- “SAP reader”: VBA based tool
- “sas2outputs”: SAS macro

This paper details the implemented process and tools at Sanofi Pasteur in order to manage titles and footnotes from the TLF shell to the final outputs.

INTRODUCTION

These two tools have been developed in order to automate the inclusion of titles and footnotes into TLF outputs and to provide the ability to include those outputs directly into a rapport.

Moreover, using this process, all changes to outputs titles or footnotes are easily made. It is more efficient and easier for user than writes/pastes all titles and footnotes TLF per TFL in the SAS program. Also it reduces time spending on both programming and validating titles and footnotes.
1. PROCESS

The implemented process to manage titles and footnotes is a six step procedure:

**STEPS**

<table>
<thead>
<tr>
<th></th>
<th>PROCESS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TLFs shell Creation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Input: Standard Tables shell for safety Standard Tables shell for immunoo</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Output: TLFs shell document (Word Document)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Using of the « SAP reader » application</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Input: TLFs shell document</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Output: Headfoot.sas (SAS Program)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Headfoot.sas execution</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Input: None</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Output: Headfoot.sas7bdat</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Headfoot.sas7bdat created</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>SAS2output using</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Input: See SAS2OUTPUT paragraph</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Output: Final outputs with Titles &amp; footnotes</td>
<td></td>
</tr>
</tbody>
</table>

Fig01: Titles and footnotes management during a statistical analysis
2. SAP READER APPLICATION

Sapreader application is a tool developed in VBA, the objective of this tool is to scroll through the TLFs shell written by the Statistician and agreed by the clinical team in order to collect titles and footnotes. This application is based on styles defined for titles and footnotes inside the TLFs shell. The Sapreader application writes a SAS program where all titles and footnotes of the selected TLFs shell are automatically written.

This SAS program creates the final database headfoot which contains the titles and footnotes for each output to be produced.

2.1. REQUIREMENTS

1. Two styles need to be correctly applied: (due to the application)
   - Title should have the “style_title”
   - Footnotes should have the “style_footnote”

2. Each output needs to have its own associated title and footnotes (Due to the application)
3. The max. length of titles and footnotes needs to be less than 200 characters (due to internal decision)
4. Nine is the max. number of footnotes (due to internal decision).

Remarks:
Special characters need to be managed carefully. It’s strongly recommended to ensure that all characters are correctly displayed with SAS.
E.g.: the special character “≥” is not recognized in SAS, it is necessary to replace it by >= in the title and/or footnote.

2.2. USE

The use of SAP reader application is a three step procedure:

1. TLF shell Selection
   In this step the user has the possibility to select the TLF shell

2. Writing of the SAS program with titles and footnotes collected
   The application collects all titles and footnotes for all outputs presented in the document selected in the 1st step.
   During this phase, some checks are automatically done and they are mainly focused on the length of the title length and of the footnote. If some are more than 200 characters the application produces an execution report indicating which titles and/or footnotes are too long. The third step is not allowed if the execution report is not empty.

3. Saving of the SAS program
   If the first 2 steps are successfully executed, the user has the possibility to save the generated program.

3. HEADFOOT DATASET:

The headfoot dataset is the result of the execution of the program created by SAP reader application.

The structure of this dataset is described hereunder:

<table>
<thead>
<tr>
<th>Variable</th>
<th>Length</th>
<th>Label</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBJLABEL</td>
<td>200</td>
<td>Output Title</td>
</tr>
<tr>
<td>FT1</td>
<td>200</td>
<td>1st footnote</td>
</tr>
<tr>
<td>FT2</td>
<td>200</td>
<td>2nd footnote</td>
</tr>
<tr>
<td>FT3</td>
<td>200</td>
<td>3rd footnote</td>
</tr>
<tr>
<td>..</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OBJNO</td>
<td>200</td>
<td>Numbering inserted in the title</td>
</tr>
<tr>
<td>TABLENO</td>
<td>200</td>
<td>Output Name</td>
</tr>
<tr>
<td>TABLEID</td>
<td>200</td>
<td>Output reference</td>
</tr>
</tbody>
</table>

This dataset is used by the sas2output macro to populate title and footnotes in the created output.
PhUSE 2008

LINKS BETWEEN HEADFOOT DATASET AND THE FINAL OUTPUT

1: Information stored in the Headfoot dataset

<table>
<thead>
<tr>
<th>OBJLABEL</th>
<th>ft1</th>
<th>ft2</th>
<th>tableno</th>
<th>tableid</th>
<th>objno</th>
<th>ft3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects Distribution per Center and per Age Group - All Included Subjects</td>
<td>Center #1: XXXXXXXX</td>
<td>Center #2: XXXXXXXX</td>
<td>C9_001</td>
<td>C9_001</td>
<td>Table 9.1</td>
<td></td>
</tr>
</tbody>
</table>

2: Rules

For the Tableid="C9_001" the output will have the following characteristics:

<table>
<thead>
<tr>
<th>N°</th>
<th>Items</th>
<th>Rules</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Title</td>
<td>Concatenation between OBJNO and OBJLABEL</td>
<td>Table 9.1 : Subject distribution per Center and per Age Group – All Included Subjects</td>
</tr>
<tr>
<td>2</td>
<td>Footnotes:</td>
<td>FT1</td>
<td>Center #1: XXXXXXXX</td>
</tr>
<tr>
<td></td>
<td></td>
<td>FT2</td>
<td>Center #2: XXXXXXXX</td>
</tr>
<tr>
<td>3</td>
<td>Name of the output:</td>
<td>Tableno</td>
<td>C9_001</td>
</tr>
</tbody>
</table>

3: Produced output

- **Output's numbering:** Variable Objno from the headfoot dataset
- **Output's name:** Variable Tableid from the headfoot dataset
- **Output's title:** Variable Objlabel from the headfoot dataset
- **Output's footnotes:** Variables Ft1 and Ft2 from the headfoot dataset
- **Footnote automatically inserted by Sas2output macro**
4. SAS2OUTPUT MACRO

SAS2OUTPUT is a macro developed in SAS. The aim of this macro is to produce the outputs.

4.1. SAS2OUTPUT PARAMETERS

The macro is composed of several parameters:
- Parameters relating to the title and footnotes management
- Parameters relating to general characteristics for the output: paper orientation, paper format…
- Parameters relative to others information required on the output: study' name, program's name.

%SAS2output ( 

<table>
<thead>
<tr>
<th>Nº</th>
<th>Parameters</th>
<th>Comments</th>
<th>Possible values</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>_OutID=</td>
<td>reference in Headfoot dataset -</td>
<td>Can be empty if HdFtdata=&quot;&quot;</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>_RefData=</td>
<td>Dataset references - dataset(s) accessed in the program</td>
<td>Optional</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>_study=</td>
<td>Study Code</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>_Pgmname=</td>
<td>Program name</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>_AFile=</td>
<td>File localisation+name (without extension)</td>
<td>Mandatory</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>_AOrientation=</td>
<td>Paper Orientation</td>
<td>PORT or LAND</td>
<td>Mandatory</td>
</tr>
<tr>
<td>8</td>
<td>_AOutput=</td>
<td>Output format + font size</td>
<td>RTF10 or RTF9 or RTF8 or PDF10 or PDF9 or PDF8</td>
<td>Mandatory</td>
</tr>
<tr>
<td>9</td>
<td>_APaper=</td>
<td>Paper format</td>
<td>A4 or LETTER</td>
<td>Mandatory</td>
</tr>
<tr>
<td>10</td>
<td>_AObjL=</td>
<td>Title of the output (should be &lt; to 200 characters)</td>
<td>Must be empty if user uses a Headfoot dataset</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>_ALC1=</td>
<td>1st comment of the output (should be &lt; to 200 characters)</td>
<td>Must be empty if user uses a Headfood dataset</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>_ALC2=</td>
<td>2nd comment of the output (should be &lt; to 200 characters)</td>
<td>Must be empty if user uses a Headfood dataset</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>ALC3=</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>ALC4=</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>ALC5=</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>ALC6=</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>ALC7=</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>ALC8=</td>
<td>...</td>
<td>...</td>
<td></td>
</tr>
</tbody>
</table>

Colors code:

<table>
<thead>
<tr>
<th>Color</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Parameters involved in the title/footnote management with the headfoot dataset</td>
</tr>
<tr>
<td></td>
<td>Parameters involved in the footnote built by the SAS2OUTPUT macro</td>
</tr>
<tr>
<td></td>
<td>Parameters involved in the saving of the final output</td>
</tr>
<tr>
<td></td>
<td>Parameters involved in the selection of the template</td>
</tr>
<tr>
<td></td>
<td>Parameters involved in the manual process to manage title and footnotes</td>
</tr>
</tbody>
</table>
In function of the values fill-in in the following SAS2OUTPUT parameters:

_AOrient=
_AOutput=
_APaper=

One of those templates defined below is used:

<table>
<thead>
<tr>
<th>Template name</th>
<th>Type</th>
<th>Orientation</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTF_A4_10_PORT</td>
<td>RTF</td>
<td>PORTRAIT</td>
<td>10</td>
</tr>
<tr>
<td>RTF_A4_9_PORT</td>
<td>RTF</td>
<td>PORTRAIT</td>
<td>9</td>
</tr>
<tr>
<td>RTF_A4_8_PORT</td>
<td>RTF</td>
<td>PORTRAIT</td>
<td>8</td>
</tr>
<tr>
<td>RTF_A4_10_LAND</td>
<td>RTF</td>
<td>LANDSCAPE</td>
<td>10</td>
</tr>
<tr>
<td>RTF_A4_9_LAND</td>
<td>RTF</td>
<td>LANDSCAPE</td>
<td>9</td>
</tr>
<tr>
<td>RTF_A4_8_LAND</td>
<td>RTF</td>
<td>LANDSCAPE</td>
<td>8</td>
</tr>
<tr>
<td>PDF_A4_10_PORT</td>
<td>PDF</td>
<td>PORTRAIT</td>
<td>10</td>
</tr>
<tr>
<td>PDF_A4_9_PORT</td>
<td>PDF</td>
<td>PORTRAIT</td>
<td>9</td>
</tr>
<tr>
<td>PDF_A4_8_PORT</td>
<td>PDF</td>
<td>PORTRAIT</td>
<td>8</td>
</tr>
<tr>
<td>PDF_A4_10_LAND</td>
<td>PDF</td>
<td>LANDSCAPE</td>
<td>10</td>
</tr>
<tr>
<td>PDF_A4_9_LAND</td>
<td>PDF</td>
<td>LANDSCAPE</td>
<td>9</td>
</tr>
<tr>
<td>PDF_A4_8_LAND</td>
<td>PDF</td>
<td>LANDSCAPE</td>
<td>8</td>
</tr>
</tbody>
</table>

4.2. PROGRAM STRUCTURE WITH SAS2OUTPUT MACRO

<Program Start>
Program Header

Libname definition

Calculations/ data preparation for reporting
SAS2OUTPUT macro call

Proc report/ tabulate / Gplot

ODS _all_ close;
<Program End>
4.3. SAS2OUTPUT MACRO CALL EXAMPLE

%Sas2output (  
   _HdFtdata="dataset.headfoot",  
   _OutId="C9_001",  
   _Study="STUDY1",  
   _Pgmname="table1.sas",  
   _AFile="C:\PHUSE\",  
   _AOrient="LAND",  
   _APaper="A4",  
   _AOutput="PDF9",  
   _AObjTp="TABLE",  
   _AObjL="",  
   _ALC1="",  
   _ALC2="",  
   _ALC3="",  
   _ALC4="",  
   _ALC5="",  
   _ALC6="",  
   _ALC7="",  
   _ALC8=""  
);  

CONCLUSION

The process and tools presented in this paper provide a simple, efficient and flexible way to manage titles/footnotes from the TLF shell to the final output.

This automation of the process allows us to decrease:

- the risk of typing errors
- the time for the programming and the validation

Future enhancements will be implemented in at least in the SAP reader application with the CVS file creation in addition to the Headfoot.sas program.

This CVS file would have several uses:

- raw material for the “README file” requested by CBER.
- Tracking sheet for the programming validation

CONTACT INFORMATION

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APPENDIX 1

SAP READER INTERFACE

Execution of the application:
Writing of the SAS program with
titles and footnotes collected

Saving of the SAS program

Execution report indicating hot titles
and/or footnotes with more than 200
characters
APPENDIX 2
EXAMPLE OF TEMPLATE DEFINITION

**Proc Template:**
```
Define Style Styles.RTF_A4_10_PORT;
Parent = Styles.Rtf;
Replace Table From Output /
   Rules = All
   Frame = Box
   Cellpadding = 2pt
   Cellspacing = 0.75pt
   Borderwidth = 0.75pt
   Bordercolor=Color_list('fg')
;
Replace Body from Document /
   Topmargin=3.0cm
   Bottommargin=4.3cm
   Leftmargin=2.8cm
   Rightmargin=1.5cm
;
Replace Fonts /
   'TitleFont2' = ("Times New Roman", 10.1pt)
   'TitleFont' = ("Times New Roman", 10.1pt)
   'StrongFont' = ("Times New Roman", 10.1pt)
   'EmphasisFont' = ("Times New Roman", 10.1pt)
   'FixedEmphasisFont' = ("Courier New", 10.1pt)
   'FixedStrongFont' = ("Courier New", 10.1pt)
   'FixedHeadingFont' = ("Courier New", 10.1pt)
   'FixedFont' = ("Courier New", 10.1pt)
   'headingEmphasisFont' = ("Times New Roman", 10.1pt)
   'headingFont' = ("Times New Roman", 10.1pt)
   'docFont' = ("Times New Roman", 10.1pt)
;
Replace Color_list /
   'link' = blue
   'bgH' = cxA0A0A0
   'fg' = black
   'bg' = _undef_
;
Replace Colors /
   'headerfgemph' = color_list('fg')
   'headerbgemph' = color_list('bg')
   'headerfgstrong' = color_list('fg')
   'headerbgstrong' = color_list('bg')
   'headerfg' = color_list('fg')
   'headerbg' = color_list('bg')
   'datafgemph' = color_list('fg')
   'databgcolor' = color_list('bg')
   'datafgstrong' = color_list('fg')
   'databgstrong' = color_list('bg')
   'datafg' = color_list('fg')
   'databg' = color_list('bg')
   'batchbg' = color_list('bg')
   'batchfg' = color_list('fg')
   'tableborder' = color_list('fg')
   'tablebg' = color_list('bg')
   'notebg' = color_list('bg')
   'notefg' = color_list('fg')
   'bylinefg' = color_list('fg')
   'bylinebg' = color_list('bg')
```