

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
- “sas2ouputs”: 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:

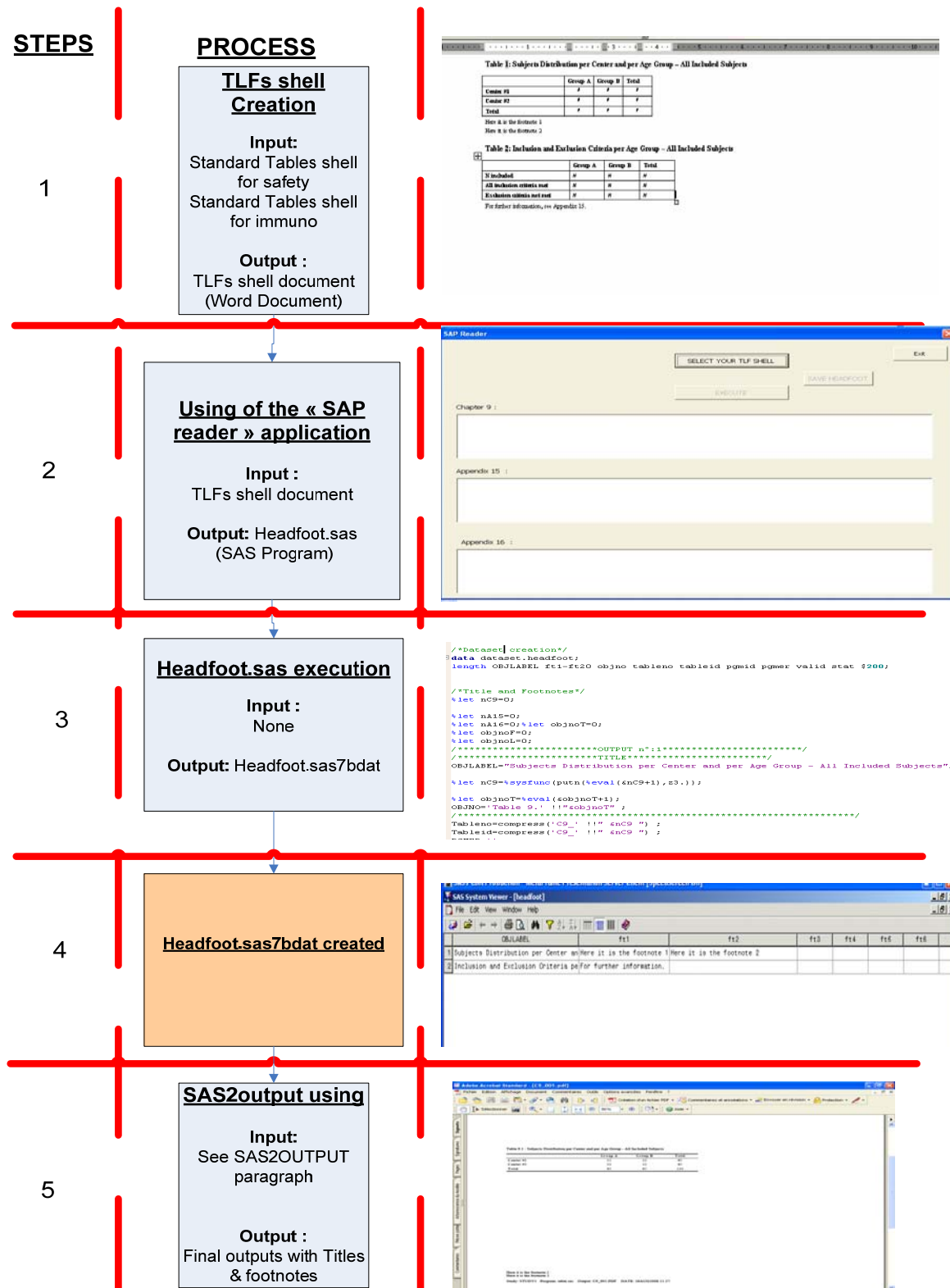


Fig01: Titles and footnotes management during a statistical analysis

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 define 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:

Variable	Length	Label
OBJLABEL	200	Output Title
FT1	200	1 st footnote
FT2	200	2 nd footnote
FT3	200	3 rd footnote
....		
OBJNO	200	Numbering inserted in the title
TABLEN0	200	Output Name
TABLEID	200	Output reference

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

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LINKS BETWEEN HEADFOOT DATASET AND THE FINAL OUTPUT

1: Information stored in the Headfoot dataset

	OBJLABEL	ft1	ft2	tableno	tableid	objno	ft3
1	Subjects Distribution per Center and per Age Group - All Included Subjects	Center #1: XXXXXXXXX	Center #2: XXXXXXXXX	C9_001	C9_001	Table 9.1	

2: Rules

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

N°	Items	Rules	Value
1	Title	Concatenation between: OBJNO and OBJLABEL	Table 9.1 : Subject distribution per Center and per Age Group – All Included Subjects
2	Footnotes:	FT1	Center #1: XXXXXXXXX
		FT2	Center #2: XXXXXXXXX
3	Name of the output:	Tableno	C9_001

3: Produced output

The screenshot shows the Adobe Acrobat Standard interface with the file "C9_001.pdf" open. The main content area displays a table titled "Table 9.1 : Subjects Distribution per Center and per Age Group - All Included Subjects". The table has four columns: "Center #1", "Center #2", "Group A", "Group B", and "Total". The data rows are: "Center #1" (32, 33, 65), "Center #2" (33, 32, 65), and "Total" (65, 65, 130). Below the table, there are two footnotes: "Here is the footnote 1" and "Here is the footnote 2". At the bottom of the page, there is a footer line: "Study: STUDY1 Program: table.sas Output: C9_001.PDF DATE: 28AUG2008 11:27".

Annotations explaining the mapping from the headfoot dataset to the output elements:

- Output's numbering:** Variable **Objno** from the headfoot dataset. This points to the "C9_001" in the file name.
- Output's name:** Variable **Tableid** from the headfoot dataset. This points to the "C9_001" in the file name.
- Output's title:** Variable **Objlabel** from the headfoot dataset. This points to the table title "Table 9.1 : Subjects Distribution per Center and per Age Group - All Included Subjects".
- Output's footnotes:** Variables **Ft1** and **Ft2** from the headfoot dataset. This points to the two footnotes below the table.
- Footnote automatically inserted by Sas2output macro:** This points to the footer line "Study: STUDY1 Program: table.sas Output: C9_001.PDF DATE: 28AUG2008 11:27".

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 (

N°	Parameters	Comments	Possible values	Status
2	_OutID=	reference in Headfoot dataset -		Can be empty if HdFtdata=""
3	_RefData=	Dataset references - dataset(s) accessed in the program		Optional
4	_study=	Study Code		Mandatory
5	_Pgmname=	Program name		Mandatory
6	_AFile=	File localisation+name (without extension)		Mandatory
7	_AOrient=	Paper Orientation	PORT or LAND	Mandatory
8	_AOutput=	Output format + font size	RTF10 or RTF9 or RTF8 or PDF10 or PDF9 or PDF8	Mandatory
9	APaper=	Paper format	A4 or LETTER	Mandatory
10	_AObjL=	Title of the output (should be < to 200 characters)		Must be empty if user uses a Headfoot dataset
11	_ALC1=	1 st comment of the output (should be < to 200 characters)		Must be empty if user uses a Headfoot dataset
12	_ALC2=	2 nd comment of the output (should be < to 200 characters)		Must be empty if user uses a Headfoot dataset
13	_ALC3=	...		...
14	_ALC4=	...		...
15	_ALC5=	.		
16	_ALC6=			
17	_ALC7=			
18	_ALC8=			

Colors code:

Color	Explanation
	Parameters involved in the title/footnote management with the headfoot dataset
	Parameters involved in the footnote built by the SAS2OUTPUT macro
	Parameters involved in the saving of the final output
	Parameters involved in the selection of the template
	Parameters involved in the manual process to manage title and footnotes

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In function of the values fill-in in the following SAS2OUTPUT parameters:

_AOrient=
_AOutput=
APaper=

One of those templates defined below is used

	Template name	Type	Orientation	Size
1	RTF_A4_10_PORT	RTF	PORTRAIT	10
2	RTF_A4_9_PORT	RTF	PORTRAIT	9
3	RTF_A4_8_PORT	RTF	PORTRAIT	8
4	RTF_A4_10 LAND	RTF	LANDSCAPE	10
5	RTF_A4_9 LAND	RTF	LANDSCAPE	9
6	RTF_A4_8 LAND	RTF	LANDSCAPE	8
7	PDF_A4_10_PORT	PDF	PORTRAIT	10
8	PDF_A4_9_PORT	PDF	PORTRAIT	9
9	PDF_A4_8_PORT	PDF	PORTRAIT	8
10	PDF_A4_10 LAND	PDF	LANDSCAPE	10
11	PDF_A4_9 LAND	PDF	LANDSCAPE	9
12	PDF_A4_8 LAND	PDF	LANDSCAPE	8

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

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

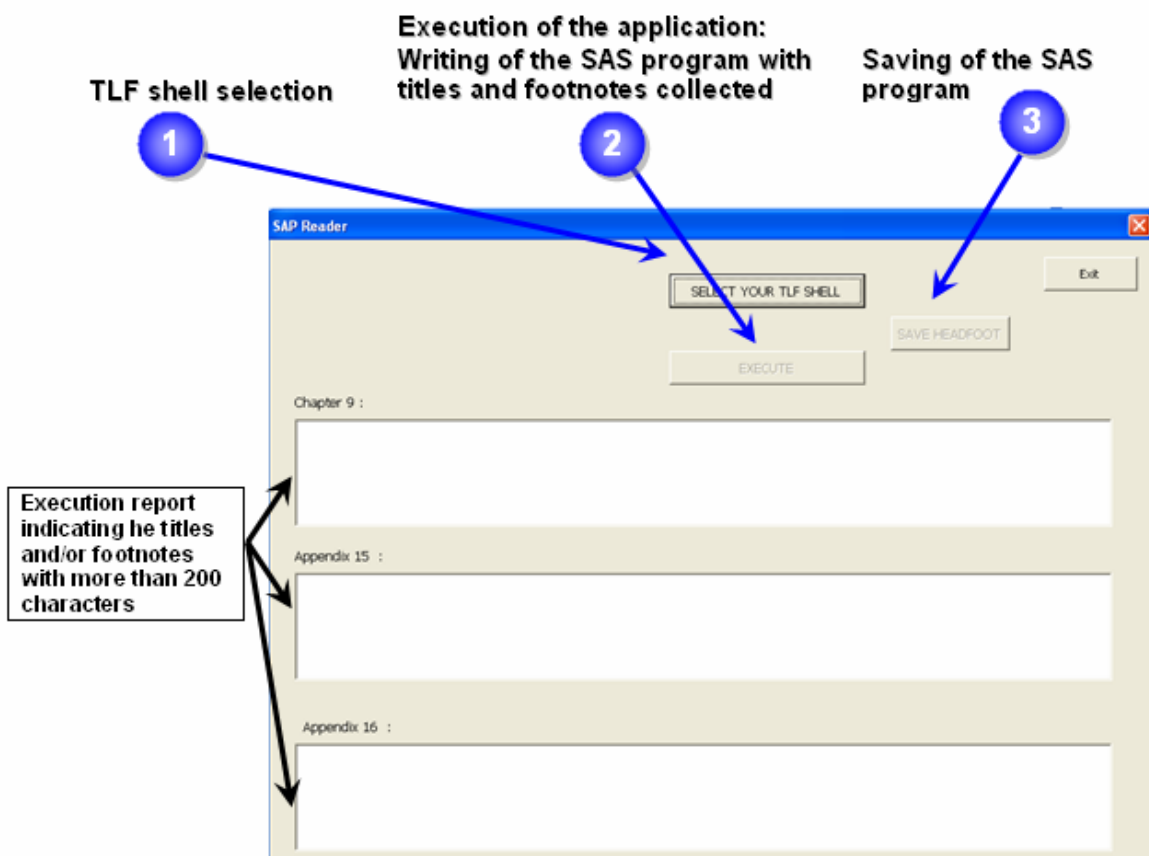
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APPENDIX 1

SAP READER INTERFACE



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)
    'BatchFixedFont' = ("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')
    'databgemph' = 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')
    'notefg' = color_list('fg')
    'notebg' = color_list('bg')
    'bylinefg' = color_list('fg')
    'bylinebg' = color_list('bg')

```

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```
'captionfg' = color_list('fg')
'captionbg' = color_list('bg')
'proctitlefg' = color_list('fg')
'proctitlebg' = color_list('bg')
'titlefg' = color_list('fg')
'titlebg' = color_list('bg')
'systitlefg' = color_list('fg')
'systitlebg' = color_list('bg')
'Conentryfg' = color_list('fg')
'Confolderfg' = color_list('fg')
'Contitlefg' = color_list('fg')
'link2' = color_list('link')
'link1' = color_list('link')
'contentfg' = color_list('fg')
'contentbg' = color_list('bg')
'docfg' = color_list('fg')
'docbg' = color_list('bg')
;
End;
Run;
```