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Dynamic Titles and Footnotes Tool in a Clinical Study Report

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Introduction

Title and footnotes are integral parts of Tables, Figures or Listings (TFLs) in Clinical Study Reports (CSRs) for regulatory purposes. In any standard reporting process, the titles and footnotes are created or typed in a requirement document such as Statistical Analyses Plan (SAP). The originally typed titles and footnotes in the SAP do not need to be retyped (or hardcoded) in each SAS program that generate the TFLs, instead they can be dynamically captured from the SAP and automatically placed into the corresponding TFLs. This methodology will preclude adding any typing errors or duplicate typing of titles and footnotes in the TFLs. Furthermore, it eliminates the need of program modification due to any changes in the title and footnotes. Even after a program is archived in a production environment it takes only to rerun it without revalidation to replace the new titles and footnotes in the TFLs.

PROCESS STEPS

First, a good, consistent working SAP (or other file which includes titles and footnotes for all TFLs) is prepared, so that an automated tool such as a MS Word macro could be used to extract the text of titles and footnotes and convert them into an excel spreadsheet. The following SAS code reads in title and footnote excel spreadsheet file into a SAS data:

```
proc import datafile="your title and footnote file"
   Out=titfoot dbms=excel2000 replace;
   Getname=yes; sheet="sheet1";
run;
```

Then use a SAS program to make any necessary changes to create a SAS data set of titles and footnotes named say "titfoot". Another excel file containing linesize information for each TFL is read and merged with the SAS data set titfoot. The long titles and footnotes are needed to be split into short lines according to the report linesize. The titles and footnotes are customized, for example, to replace (N=XXX) in title with (N=&TOTPAT) and populate the total number of patient number macro variable TOTPAT that will be resolved in the report title during program execution.

Next a SAS macro is used to assign all titles and footnotes into macro variables. A macro variable OUTNAME is defined to include all output names from report program. For example %LET OUTNAME= SMEFFA11# SMEFFA12# SMEFFA13# SMEFFA14#;

The macro code found in the appendix will put all titles and footnotes into the macro variables _title and _footnote

Finally, these macro variables are used to include the title and footnote into TFLs.

CODE

```
%macro gettf(tablst);

%global _tabnum _ftabnum;
%let _tabnum=%scan(&outname,&tablst,'#');
%global _title _footnote;

* sas program vextfl that identifies open SAS files, we try to get program name
and put it into footnote;
 proc sql;
   create table vextfl as
```

```
   select *
   from sashelp.vextfl;
quit;

* 1. delete autoexec.sas and autoexec.log from list;
* 2. create macro variable that contains path and program name;
data _null;
   length xp $30;
   set vextfl;
   if index(upcase(xpath),".SAS") ^= 0;
   if index(upcase(xpath),'AUTOEXEC') then delete;
   xp=reverse(scan(reverse(xpath),1,'\'));
   call symput('_runsas',trim(xp));
run;

*this is to make sure that when no footnote is present, at least the time stamp
is still shown;
data _null_;
length _ footnote $100;
_ footnote ="{\line} Program: &_runsas Version: &sysdate &systime
\brdrt\brdrs\brdrw12\ ";
call symput('_footnote',_ footnote);
run;

data _null_;
 call symput('_fileid',translate("&_tabnum",'_','.'));
run;

*Get the title and footnote subset for the table;
data a;
 set alltitft (where=(upcase(tabnum)="%upcase(&_tabnum)"));
 call symput('_ftabnum',left(trim(ftabnum)));
run;

*put title and footnote into macro variable;
data _null_;
 set a end=end;
length lstr $32767;
retain lstr;
by tabnum type notsorted;
 if first.type then do;
   if upcase(type)=:'T' then
lstr=left(right("&_ftabnum"))||'{\line}'||trim(text);
   else if upcase(type)=:'F' then lstr=trim(text);
end;
else lstr=trim(lstr)||'{\line}'||trim(text);
 if last.type and upcase(type)=:'T' then
   call symput('_title',trim(lstr)||'{\line} ##~~## \brdrb\brdrs\brdrw12
{\line}');
else if last.type and upcase(type)=:'F' then
   call symput('_ footnote ',trim(lstr)||'{\line}'||"&_ footnote ");
run;
%mend;
```


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