

Automating the Production of Clinical Trial Data Tables

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ABSTRACT

Preparation of clinical trials semi-annual data reports used to be a time-consuming and error-prone task of transferring numbers from computer printouts into reader friendly formats. We stopped this repetitive transcribing and checking by using SAS® and WordPerfect® together for rapid and accurate preparation of publication quality tables.

For each table the first step is to design a skeleton form in WordPerfect. Next a SAS program is written to put data for the table into an ASCII delimited text file. The third step is to execute the SAS program and to merge the data into the form in WordPerfect and thus create the final report table.

Once the form is designed and the SAS program written, the update of the table can be accomplished easily by repeating step three above. Also, when several tables are required, this method can be automated by creating WordPerfect macros to perform the merges and to combine the tables into the final report.

INTRODUCTION

The NHLBI/VA Cooperative Study on the "Trial to Evaluate the Effect of Digitalis on Mortality in Heart Failure"¹ Data Monitoring and Safety Board Report includes 86 tables. The report was prepared semiannually for five years. A way was needed to move information from SAS outputs into publication quality tables without spending hours transferring and checking numbers and doing it all again in six months. We used SAS and WordPerfect to produce the necessary report tables with a minimum of manual intervention. Examples of report tables and of the data and WordPerfect macros that produced them will be displayed.

INFORMATION

The first step is to determine what information is to appear in the table. Design the table in WordPerfect as a merge form file (see Figure 1). Decide on title

lines, contents and placement of columns and rows, and labeling. The form file will be a combination of text and merge codes. The text entries will remain constant. Put the merge code FIELD in each location where text and/or numeric data will be inserted from the merge data file. These fields are consecutively numbered. Information can be merged into titles, headers and footers as well as table cells. The merge data file is an ASCII file created in SAS.

The macro RENUMBER can be used to number the fields. Put the tilde symbol "~" in the document where you want a merge field code. The macro will insert the field codes numbered appropriately. It can also be used to renumber the fields if the table is changed.

Renumber Macro

```
//Description: RENUMBER renumber all fields
PosDocVeryTop
```

```
SearchString ("[MRG: FIELD]")
ReplaceString ("~")
ReplaceForward (Extended!)
```

```
PosDocVeryTop ()
```

```
ForNext(LP;1;3;1)
  ForNext(num; 0; 9; 1)
    PosDocTop
    ReplaceConfirm(No!)
    SearchString("~"+num)
    ReplaceString("~")
    ReplaceForward(Extended!)
```

```
  Endfor
```

```
Endfor
```

```
PosDocVeryTop ()
```

```
ASSIGN(NUM; "0")
```

```
LABEL (Begin@)
  ASSIGN(NUM; NUM+1)
  OnNotFound(labelb)
  SearchString ("~")
  SearchNext (Extended!)
  SelectMode (Off!)
  MergeCode (Field!; NUM)
```

```
GO(Begin@)
```

Table 4 a						
Continuous Variables - Randomized Patients - Telephone Data						
Ejection Fraction ≤ 45						
Variable	Placebo		Active		Total	
Age (Mean, S.D.)	FIELD(1)	FIELD(2)	FIELD(3)	FIELD(4)	FIELD(5)	FIELD(6)
<u>N. %</u>						
< 60	FIELD(7)	FIELD(8)	FIELD(9)	FIELD(10)	FIELD(11)	FIELD(12)
60 - 70	FIELD(13)	FIELD(14)	FIELD(15)	FIELD(16)	FIELD(17)	FIELD(18)
71 - 80	FIELD(19)	FIELD(20)	FIELD(21)	FIELD(22)	FIELD(23)	FIELD(24)
> 80	FIELD(25)	FIELD(26)	FIELD(27)	FIELD(28)	FIELD(29)	FIELD(30)
Ejection Fraction Percent (Mean, S.D.)	FIELD(31)	FIELD(32)	FIELD(33)	FIELD(34)	FIELD(35)	FIELD(36)
<u>N. %</u>						
36 - 45	FIELD(37)	FIELD(38)	FIELD(39)	FIELD(40)	FIELD(41)	FIELD(42)
25 - 35	FIELD(43)	FIELD(44)	FIELD(45)	FIELD(46)	FIELD(47)	FIELD(48)
< 25	FIELD(49)	FIELD(50)	FIELD(51)	FIELD(52)	FIELD(53)	FIELD(54)

Figure 1. WordPerfect Form File

LABEL(labelb)

PosDocVeryTop
 SearchString ("~")
 ReplaceString ("")
 ReplaceForward (Extended!)
 beep
 PosDocVeryTop

ASCII DELIMITED TEXT FILE

The information that will be merged into the table must be put into an ASCII delimited text file, the data file. This file may contain text as well as frequencies, means, p values, etc. The data values can come from various sources such as DATA step processing, PROC FREQ, PROC MEANS, and PROC GLM. Some procedures have output data sets available; the printed output can also be read.

Entries must be placed in the file in the same order as the field numbers in the form file. This is done with SAS PUT statements. The delimiters can be any characters you choose. (WordPerfect uses a comma as the default field delimiter and [CR][LF] as the default record delimiter.) We use the asterisk and the equal sign to separate fields and records.

If you plan to use the merge command from the menu

or merge bar there must be a record delimiter after the last record. If you plan to merge the table using a WordPerfect macro omit the record delimiter after the last record. For both methods separate multiple records with delimiters. The example is for use with a macro.

Sample data file:

```
63.5*10.8*63.4*11.0*63.5*10.9*
1106*32.5*1081*31.8*2187*32.2*
1366*40.1*1410*41.5*2776*40.8*
806*23.7*767*22.6*1573*23.1*
125*3.7*139*4.1*264*3.9*
28.4*8.9*28.6*8.8*28.5*8.8*
804*23.6*834*24.6*1638*24.1*
1469*43.2*1436*42.3*2905*42.7*
1130*33.2*1127*33.2*2257*33.2*
```

WORDPERFECT TABLE

The study table (see Figure 2), containing the desired information in the desired format, is achieved by merging the ASCII data file into the WordPerfect form file using the WordPerfect Merge command. Whenever the study data change, a new data file can be prepared and merged into the form file . . . yielding a relatively quick and painless revised study table.

Table 4 a						
Continuous Variables - Randomized Patients - Telephone Data						
Ejection Fraction < 45						
Variable	Placebo		Active		Total	
Age (Mean, S.D.)	63.5	10.8	63.4	11.0	63.5	10.9
N, %						
< 60	1106	32.5	1081	31.8	2187	32.2
60 - 70	1366	40.1	1410	41.5	2776	40.8
71 - 80	806	23.7	767	22.6	1574	23.1
> 80	125	3.7	139	4.1	264	3.9
Ejection Fraction Percent (Mean, S.D.)	28.4	8.9	28.6	8.9	28.5	8.9
N, %						
36 - 45	804	23.6	834	24.5	1638	24.1
25 - 35	1469	43.2	1436	42.3	2905	42.7
< 25	1130	33.2	1127	33.2	2257	33.2

Figure 2. WordPerfect Table

TABLE MACRO

We use WordPerfect macros to automate the merging process. For each table a macro is written containing all the statements required to produce the finished version of the table from a form file and a data file. The WordPerfect macro merges the form with the data and saves the resulting table as a WordPerfect document.

Table Macro

```
// RANDOM1
Application (A1; "WordPerfect"; Default; "US")

// names of merge form file, data file, merged
// document
vForm:="D:\P995\RPT\FORM\RANDOM1.FRM"
vData:="H:\P995\RPT\RANDOM1.DAT"
vTable:="D:\P995\RPT\TABLES\RANDOM1.WPD"

// Data file
ImportSetFileName (vData)
ImportSetSource (ASCII!)
ImportSetDestination (MergeData!)

// Field Delimiter - macro uses * as the field delimiter
ImportSetAsciiFieldDelimiter ("*")
```

```
// Record Delimiter - macro uses = as the record delimiter
ImportSetAsciiRecordDelimiter ("=")
```

```
// Hard returns are removed from the data file before
// merging into the form file
ImportSetAsciiStrip (StripChars: "[SRt][HRt]")
```

```
// text strings are surrounded by ""
ImportSetAsciiEncap (EncapsulationChar: "''")
```

```
// convert data file to a merge file and copy to clipboard
```

```
ImportDoImport ()
PosDocTop ()
SelectDocBottom ()
EditCopy ()
Close (No!)
```

```
//do the merge
MergeSelect (All!)
```

```
// form file name, data file source, location of merged
// document
```

```
MergeRun (FormFile!; vForm;DataFileType: Clipboard!;
OutputFileType: ToNewDoc!)
```

```
// name of the document containing the merged table
```

```
FileSave(vTable;WordPerfect_60!)
Close
```

REPORT MACRO

Carrying this a giant step forward, another WordPerfect macro, a Report macro, has been written to produce the final report. First the Report macro runs each individual table macro (the command is NEST) and creates a WordPerfect file for each table. Next the Report macro inserts each table in the correct order into a single large document. Also, the macro can issue additional WordPerfect commands, such as headers, footers, and page numbers, to bring the final document into its desired form.

Report Macro

Application (A1; "WordPerfect"; Default; "US")

PERSISTALL DEFAULTUNITS(Inches!)
VARERRCHK(OFF!)

DISPLAY(Off!)

//play macro to create table RANDOM1
FileNew()
NEST("D:\P995\MACROS\RANDOM1")

//play macro to create table RANDOM2
FileNew()
NEST("D:\P995\MACROS\RANDOM2")

//play macro to create table RANDOM3
FileNew()
NEST("D:\P995\MACROS\RANDOM3")

//play macro to create table RANDOM4
FileNew()
NEST("D:\P995\MACROS\RANDOM4")

//Assemble report
FileNew()

//insert cover sheet
FileInsert("D:\P995\RPT\FORM\DSMB.WPD";No!;Insert!)
PosDocBottom ()
HardPageBreak ()

//insert Table of Contents
FileInsert("D:\P995\RPT\DSMBCONT.WPD")
PosDocBottom ()
HardPageBreak ()

//discontinue the header that is used in the Table of Contents
HeaderA(Off!)

//put page numbers on bottom of pages, starting with page 1
PageNumberPosition (Position: BottomCenter!
Default: DontUseDefaultValues!)
PageNumberMethod(Numbers!) PageNumber(1)

//insert the table RANDOM1 -file created by macro RANDOM1
FileInsert("D:\P995\RPT\TABLES\RANDOM1.WPD" ;

No!;Insert!)
PosDocBottom ()

//insert the table RANDOM2 - file created by macro RANDOM2
FileInsert("D:\P995\RPT\TABLES\RANDOM2.WPD";
No!;Insert!)
PosDocBottom ()
HardPageBreak ()

//insert the table RANDOM3 - file created by macro RANDOM3
FileInsert("D:\P995\RPT\TABLES\RANDOM3.WPD";
No!;Insert!)
PosDocBottom ()
HardPageBreak ()

//insert the table RANDOM4 - file created by macro RANDOM4
FileInsert("D:\P995\RPT\TABLES\RANDOM4.WPD";
No!;Insert!)

CONCLUSION

We prepare the study report by running SAS programs to prepare the data files and by playing one WordPerfect macro. Thus we have eliminated time-consuming and error-prone repetitive transcribing and checking.

ACKNOWLEDGMENTS

The WordPerfect macros were written for WordPerfect version 7. Some changes to the macros may be required for other versions.

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¹The Digitalis Investigation Group (1996)
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