Individual Summaries: Bigger Needles in Smaller Haystacks

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Abstract

At times an individual experimental unit may be very influential in an analysis. Finding a way to concisely display all relevant information in a visually appealing manner can be a challenge. This paper will present a method for placing SAS® software output into a standard word processor document.

Introduction

In the pharmaceutical industry decisions are based not only on the results of statistical analysis combining all patients into an anonymous group, but also by looking at those patients who experience rare or life-threatening reactions to a new drug. But, new drugs are tested in sick people and a bad reaction may not be related to the drug. Identifying which reactions are related to the drug can be like searching for a needle in a haystack. Looking through less data at a time (smaller haystacks) and making the important data stand out (bigger needles) is essential to that process.

A great deal of information is collected about each participant in a clinical trial and all of that information is interrelated. If a patient experiences a heart attack while on an experimental drug his entire medical profile can be of interest. Medical history, current non-study drug therapy, other adverse reactions, recent vital signs and other items are each important in determining the role of the experimental drug in the attack. To make that determination all of this information must be reported in a way convenient for review.

A Simple (Flawed) Approach

Certainly the simplest method would be to create lists using the PRINT procedure. It is common, indeed required by the Food and Drug Administration, to create a list of all adverse reactions, a list of all non-study drug therapies, etc. However, since these lists combined run to several hundred thousand pages, getting a picture of a single patient's overall health from these lists can be very time consuming and unsatisfactory.

A Less-Than-Satisfactory Approach

It is possible, using a DATA _NULL_, to write a selected patient's data into a file. This method allows you to subset and simplify databases before printing and substantially reduces both CPU time and reviewer time. The results are adequate to meet the need, but they aren't visually appealing and they don't take full advantage of available publishing technology. In short, they are ugly.

Going One Step Farther

Ideally, the output obtained from the DATA _NULL_ could be pulled into a word processor and made to be consistent with the level of publishing expected in the computer age. The result could be placed in a table and manipulated to be easy to read and pretty.

Many word processors commonly available have the ability to create form letters by reading text from a separate database. It is possible to take advantage of that function to create the summaries described above.

For the purposes of this paper an example case summary was prepared using Microsoft Word.

The merge commands and symbols selected are appropriate for that software. The procedure can be generalized to other products.

Creating the Template

Before the doing anything with the data itself, it is necessary to decide on the layout of your final product. Placing the output in a table is visually striking and makes the process of establishing the layout simpler.

Open a new Word document, select Table from the toolbar and Insert Table from the pull down menu. Select the number of rows and columns you want. Each cell in the table will represent one section of data, not a single number.

protocol		
Demographics		
Vital Signs Study Day 1	**Vital Signs** Study Day 2	**Vital Signs** Study Day 3
Medical History		
Adverse Events		

Be sure that the font you've selected is monospace. Otherwise all the work you did in the DATA _NULL_ to line up your columns will be lost. Courier (W1) is appropriate.

Preparing the Output

In carrying output to a word processor you will need a flat ASCII file. These can be obtained in SAS by selecting the NOPRINT option on the FILE statement and writing you data using the PUT command.

To use Word's mail merge the first row of your SAS output, what Word calls the header row, must contain the names of the fields you are pulling into your document. This can be done with a DATA _NULL_ writing to a non-print file.

```
data _null_;
  file ics noprint;

  put 'protnum # demo # vital1 # vital2 #
       vital3 # medhx # ae ~';
run;
```

The symbol '#' is used to mark the end of a field (cell) and the symbol '~' is used to mark the end of a record (patient). You may select the symbols you wish from a list provided by Word.

Then you create the contents of each cell of your table using DATA _NULL_'s. The end of each cell is marked with a '#' and each patient with a '~'.

A macro can be used allow you to select the patients you wish to summarize.

```
%macro ics(patient);

  data _null_;
    set protnum (where=(patient=&patient))
                end=eof;
    file ics noprint mod;
    put
      ...

    if eof then put '#';
  run;

...

  data ae;
     set ae (where=(patient=&patient))
                end=eof;
    file ics noprint mod;
    put
      ...

    if eof then put '~';

%mend ics;

%ics(patient=1066);
```

%ics(patient=1080);

etc.

It may be necessary to move your output file onto another platform before merging with you template. Since the output file is a simple ASCII file, it may be copied without any special preparation.

Entering the Merge Commands

Once the output file is available to Word it is possible to place the output in your template. In the template file created earlier select Tools from the tool bar and from the pull down menu select Mail Merge...

A new dialog box called the Mail Merge Helper will open. In this box select Create then Form Letters. You will want to use the Active document (your template). Choose Get Data from the Helper and Open Source File. Select the output file created in SAS.

You will be prompted to identify your field and record delimiters. Word provides a list of possibilities.

When you have selected your delimiters you will receive a warning that no merge fields have been selected. You will be given the chance to edit your document and add merge fields. Position your cursor and press Alt+Shft+F to obtain a list of field names to enter and add the appropriate one.

<<protnum_>>		
Demographics <<demo_>>		
Vital Signs Study Day 1 <<vital1_>>	**Vital Signs** Study Day 2 <<vital2_>>	**Vital Signs** Study Day 3 <<vital3>>
Medical History <<medhx_>>		
Adverse Events <<ae_>>		

Then select merge-to-file for a permanent electronic copy or merge-to-printer for a hard copy.

Broadening the Process

This same process can be used to create word-processed tables from any SAS output or to drop a p-value into a report.

This approach may also save hours of word-processing time. Frequently, tables produced in SAS are laboriously re-entered into a word processor. Since the same template may be used repeatedly for tables of similar structure and since a one page template may be used to produce much longer tables, the savings can be considerable.

Conclusion

There are an increasing number of technologies available in the modern world. To take full advantage of them we need to be able to carry data and processes from one product to the next. It is possible to take your output beyond the bounds of your program and the results can be outstanding.

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EXAMPLE 1: This is an individual case summary created by using DATA _NULLS_.

Protocol: Samp-1-SUGI
Individual Summary Patient: 1066

Treatment: Strange Brew

DEMOGRAPHICS

Investigator: 1 Patient: 1066
Age: 70 Race: Caucasian Sex: Male
Height (cm): 184 Weight (kg): 98.8
Max Dose: 1.5 Days on drug: 78 Did pt complete? Yes

VITAL SIGNS Study Day 1				VITAL SIGNS Study Day 2				VITAL SIGNS Study Day 3			
Time	DBP	SBP	HR	Time	DBP	SBP	HR	Time	DBP	SBP	HR
0 hr	109	187	62	0 hr	99	176	63	0 hr	85	149	55
15 min	102	167	63	15 min	96	170	60	15 min	84	134	53
1 hr	123	183	64	1 hr	83	146	70	1 hr	71	124	69
4 hr	102	167	66	4 hr	91	145	63	4 hr	78	124	59

MEDICAL HISTORY

Body System	Diagnosis	Recovery	Day*
This patient has no significant medical diagnoses.			

ADVERSE EVENTS

Dictionary Term	Severity	Onset Day*	Dose
HYPERLIPEMIA	2	-813	.
DIZZINESS	3	23	0.6
HEADACHE	3	23	0.6
INFECTION	1	40	0.9
PARESTHESIA	1	56	1.5

EXAMPLE 2: This is an individual case summary created by importing SAS output into WORD.

Protocol: Samp-01-SUGI23
Individual Summary Patient 1066
Treatment: Strange Brew

Demographics

Investigator: 1 Patient: 1066
Age: 70 Race: Caucasian Sex: Male
Height (cm): 184 Weight (kg): 98.8
Max Dose: 1.5 Days on drug: 78 Did pt complete? Yes

Vital Signs
Study Day 1

Time	DBP	SBP	HR
0 hr	109	187	62
15 min	102	167	63
1 hr	123	183	64
4 hr	102	167	66

Vital Signs
Study Day 2

Time	DBP	SBP	HR
0 hr	99	176	63
15 min	96	170	60
1 hr	83	146	70
4 hr	91	145	63

Vital Signs
Study Day 3

Time	DBP	SBP	HR
0 hr	85	149	55
15 min	84	134	53
1 hr	71	124	60
4 hr	78	124	59

Medical History

Body System	Diagnosis	Recovery	Day*
This patient has no significant medical diagnoses.			

* Day relative to start of Study Drug.

Adverse Events

Dictionary Term	Severity	Onset Day*	Dose
HYPERLIPEMIA	2	-813	.
DIZZINESS	3	23	0.6
HEADACHE	3	23	0.6
INFECTION	1	40	0.9
PARESTHESIA	1	56	1.5

* Day relative to start of Study Drug.