

A User-Friendly and Flexible System for Generating Data Listings With Easy Documentation and Validation

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Abstract

As the size and volume of SAS-generated reports submitted to the Food and drug Administration (FDA) and other governmental and private organizations has grown, program validity and the resultant reliability of such reports have become concerns. To address these issues, we developed an extremely flexible SAS-based system to generate data listings which are defined by a self-documenting parameter file.

The parameters that control the specific layout of each requested listing reside in a common file. This file and all of the custom code required for specific listings are maintained in a single SAS catalog for easy maintenance and documentation. The user interface is through a SAS EIS/AF application that provides context-sensitive help and popup menu selection of variables and report attributes. A selection menu provides the interface to individual report requests and automatically tracks the datetimes of the source data sets and output listings to warn the user if a listing is no longer current with the data.

Introduction

Programs to generate tables have been a regular occurrence in SUGI proceedings for more than a decade. One of the best was presented by John Henry King at SUGI in 1984 and that macro system and especially his template approach, has been adopted in our program. The impetus for this particular program was to address the need for program validation which was impractical with a proliferation of program variations that tried to address the very specific needs of individual data listings. The EIS/AF front-end was added to make the system easier to use than calling macros with dozens of parameters. These parameters are stored in a flat file that provides an easy summary for documenting the specifics of each listing request. The same SAS catalog also houses the SAS code that is specific to each individual listing which allows almost unlimited flexibility in the presentation of information.

System Description

The template approach taken by John Henry King allows the use of a visual metaphor for the data listing. In particular, variables to be printed are listed by name from left to right on one record, with the corresponding ordered formats in another record and the starting columns for each variable marked by asterisks in a third record. These records, as well as those containing column headings, are all aligned in the input screen to present a template of how the data will actually appear in the output. This approach makes it easy to insert or delete fields, change locations or formats, and align headings with their corresponding data fields.

One of the requirements we have is that all related data be presented in a single data listing if at all possible, for ease of review. Since we have a limited number of printing positions across the page, more data can be squeezed into a single listing by using both preceding and trailing prints around each "regular" data record. For example, each observation or block of observations (a block being user-defined) is often preceded by a bold header record which contains all of the standard identifiers (subject #, treatment, strata, etc.). This prevents all of this redundant information from eating up valuable printing space in the data listing. Similarly, there are often data fields which are sparse (rarely contain data) yet large; these we handle with trailing prints after the main data, so that multiple lines are only output when these fields are used. The trailing prints are also great for comments, both solicited and not. The listing-specific SAS code that is integrated into the program allows complete control of the formatting of this "occasional" data.

An attempt was made to incorporate a macro developed by Beverly and Screen (1993) to handle the numbering of pages in the form "Page X of Y". However, reading and writing in the same data step did not appear to work in the CMS environment, so the macro was modified to read from one flat file and write to another.

Besides the nicety of verifying that output files post-dated the data sets from which they were derived, the GUI using EIS and AF allowed the installation of context-sensitive help and pick lists for completing the information needed for the parameter file.

Example

Data from a recent study carried out by Ross Products Division Abbott Laboratories is used to illustrate the degree to which data listings can be customized using this system. Figure 1 shows a parameter file that will generate two data listings, each involving treatment administration. Figure 2 shows the outputs produced from this parameter file.

The various lines in the parameter file contain the following information:

L - a short label for screen presentation.

DS - first word is the data set used as program input, any additional words are data sets from which the first is generated and hence on which it's validity with respect to updates depends.

CS - reference to any listing-specific SAS code such as macros to preceding or trailing comments. The program assumes that 3 macros have been defined by the user in this reference:

PRECOMM

- defines PUTs for any special data to be output prior to the regular data observation

POSTCOMM

- defines PUTs for information to trail the regular data observation

POSTGRP

- defines PUTs for information to follow the group of regular data (including POSTCOMM output)

COMx - Detailed description of the listing being generated

HL - a page header line that is left-justified

H - a non-justified header line

V - list of variables from the first data set listed in the preceding DS observation in the order in which they are to be printed across the page

C - asterisks in the columns corresponding to the pointer positions desired for printing each variable in the V record above.

F - correspondingly-ordered formats for the variables in the V record above.

SL - a list of variables by which the data will be sorted for printing.

PB - the variable from the SL list above upon which you wish to start a new page for FIRST.VAR=1 .

GB - the variable from the SL list for which FIRST.VAR and LAST.VAR define groups of observations that are NOT to be split across pages.

GHV - list of variables that are to appear in a bold header as identifiers preceding the regular data.

GHF - formats for the variables in the GHV record above

GHL - labels to proceed each of the variables in the GHV record above. For example "INV" is used for investigator, as in "INV: Van Meurs".

END - signals the end of records for a particular listing request.

Each time a listing is modified, the modified parameter file records are appended to this file so as to provide an audit trail for every listing generated, not just the final version.

Although not shown in the example, the final version of the system will write the last execution time of the listing back to the parameter file to allow the comparison with retrieved dates and times of last modification for the data sets listed in the DS record. This will allow the program to inform the user that a prior listing is now out-of-date as the data sets upon which it is based have been updated since the last output run.

References

Beverly, Bryan K. and Screen, Phillip J. (1993), "PAGE_COUNT.SAS: The Solution to Customized Pagination of Your PROC REPORT Output, Proceedings of the Eighteenth Annual SAS Users Group International Conference, Cary,NC:SAS Institute Inc.,119-124.

King, John Henry (1988), "A SAS Macro System for Customized Report Writing", Proceedings of the Thirteenth Annual SAS Users Group International Conference, Cary,NC:SAS Institute Inc.,853-858.

Readers interested in the programming details of this system may contact Bill Adams at:

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Figure 1. Parameter File for the Example

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L      FORM 08 - Dosing Problems
DS     TEMP.RX
CS     PRESENT1
COM1   Lists all data from Form 8 except for suctioning information
COM2   Lists explanation for why dose wasnt administered if so
COM3   Lists comments on any dosing problems
HL     '2    "||dt||" <PROGRAM1 T75BRM1A>'
HL     '2    Drug X in Population Y' HL '2    Final Study Report'
H
HL     '1                                Appendix A.08'
H
HL     '1                                Treatment Administration - Part I'
H
HL     uline
H
H                                Type
H                                of Position
H     Dose for Dose On Ventil- of
H     No. Dose? Given? ECMO? ation Infant Sedated? Paralyzed?
HL     uline
C      *      *      *      *      *      *      *      *
V      dose eligible admin ecmo vent pos sed para
F      1. $yn. $yn. $yn. $vnt. pos. $yn. $yn.
SL     inv rx subject diag oi dose
PB     inv
GB     subject
GHV    inv rx subject diag oi
GHF    $invname. rx. 7. $diag. roi.
GHL    INV RX SUBJECT DIAGNOSIS OI
END

L      FORM 09 - Dosing Timing
DS     TEMP.RX
CS     PRESENT2
COM1   Lists all data from Form 9 plus suctioning information
HL     '2    "||dt||" <PROGRAM1 T75BRM1A>'
HL     '2    Drug X in Population Y'
HL     '2    Final Study Report'
H
HL     '1                                Appendix A.09'
H
HL     '1                                Treatment Administration - Part II'
H
HL     uline
H
H      Suctioned <2 Hrs Treatment Treatment
H      of Rx Completion Started Completed Administered
H      Dose -----
H      No. Y/N Date Time Date Tme Date Time Rx Volume Lot Numbers
H      uline
C      *      *      *      *      *      *      *      *      *      *      *
V      dose suct suctda sucttm startda starttm trtda trttm trt voladm lot1 lot2 lot3
F      1. $yn. $8. 4. $8. 4. $8. 4. $trt. 4.1 $10. $10. $10.
SL     inv rx subject diag oi dose
PB     inv
GB     subject
GHV    inv rx subject diag oi
GHL    INV RX SUBJECT DIAGNOSIS OI
GHF    $invname. rx. 7. $diag. roi.
END

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Appendix A.08
Treatment Administration - Part I

Dose No.	Eligible for Dose?	Dose Given?	On ECHO?	Type of Ventilation	Position of Infant	Sedated?	Paralyzed?	TREATMENT ADMINISTRATION PROBLEMS							
								Bloody Suction	Brady-cardia	Hypoxia	Respir. Acid.	Pallor	ETT Occlusion	Reflux	Other
INV: Van Meurs RX: C SUBJECT: 32115 DIAGNOSIS: Disease A OI: 23-30															
1	Yes	Yes	No	Convent	Supine	Yes	Yes	No	No	Yes	Yes	No	No	Yes	Yes
Other Problem Specified: Required handbagging during and after dosing for de- saturations and elevated															
Other Problem Specified: TCC02.															
2	Yes	Yes	No	Convent	Supine	Yes	No	No	No	No	No	No	No	No	No
3	Yes	Yes	No	Convent	Supine	Yes	No	No	No	Yes	Yes	No	No	No	Yes
Other Problem Specified: Multiple desaturations and increases in TCC02 into the 50's. Handbagged. took															
Other Problem Specified: 1/2 hour to dose because of desats.															
4	Yes	Yes	No	Convent	Supine	No	No	No	No	Yes	Yes	No	No	No	Yes
Other Problem Specified: 02 sat down to 84 and TCC02 up to 54. Handbagged.															
INV: Van Meurs RX: C SUBJECT: 32118 DIAGNOSIS: Disease A OI: 23-30															
1	Yes	Yes	No	Oscil.	Supine	Yes	Yes	No	No	Yes	No	No	No	No	No
2	Yes	Yes	No	Oscil.	Supine	Yes	Yes	Yes	No	No	No	No	No	No	No
3	Yes	Yes	No	Oscil.	Supine	Yes	No	No	No	Yes	No	No	No	No	No
4	Yes	Yes	No	Oscil.	Supine	Yes	No	No	No	Yes	No	No	No	Yes	No
INV: Van Meurs RX: C SUBJECT: 32119 DIAGNOSIS: Disease A OI: 23-30															
1	Yes	Yes	No	Jet	Supine	Yes	No	Yes	No	Yes	No	No	No	Yes	No
2	Yes	Yes	Yes	Convent	Supine	Yes	No	Yes	No	No	No	No	No	No	No
3	Yes	Yes	Yes	Convent	Supine	Yes	No	No	No	No	No	No	No	No	No
4	Yes	Yes	Yes	Convent	Supine	Yes	No	No	No	No	No	No	No	No	No
5	Yes	Yes	Yes	Convent	Supine	Yes	No	No	No	No	No	No	No	No	No
INV: Van Meurs RX: C SUBJECT: 32214 DIAGNOSIS: Disease C OI: 23-30															
1	Yes	Yes	No	Oscil.	Supine	Yes	No	No	No	Yes	No	No	No	No	Yes
Other Problem Specified: Map drop to 35 inned post dosing, then back up to 95-100. MAP dropped to															
Other Problem Specified: 35 inned. post dose, then rose slowly back to 50's. No apparant reason.															
2	Yes	Yes	No	Oscil.	Supine	Yes	No	No	No	Yes	No	No	No	No	No
3	Yes	Yes	No	Oscil.	Supine	Yes	No	No	No	Yes	No	No	No	No	No
4	Yes	Yes	No	Oscil.	Supine	Yes	No	No	No	Yes	No	No	No	No	Yes
Other Problem Specified: MAP drop from 63-40 with 02 drop during procdure.															

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Figure 2. Sample Output based on Example 1

Appendix A.09

Treatment Administration - Part II

Dose No.	Suctioned <2 Hrs of Rx Completion		Treatment Started		Treatment Completed		Administered		Lot Numbers
	Y/N	Date	Time	Date	Time	Date	Time	Rx Volume	
INV: Van Meurs RX: C SUBJECT: 32115 DIAGNOSIS: Disease A OI: 23-30									
1	No			01/27/93	215	Rx B	15.0	66710z7	66710z7
2	No			01/27/93	900	Rx B	15.0	66710z7	66710z7
3	No			01/27/93	1600	Rx B	15.6	66710z7	66710z7
4	No			01/27/93	2120	Rx B	15.4	66710z7	66710z7
INV: Van Meurs RX: C SUBJECT: 32118 DIAGNOSIS: Disease A OI: 23-30									
1	Yes	06/03/93	1640	06/03/93	856	Rx B	15.2	66710z7	66710z7
Reason Suctioned < 2 hrs: O2 desaturations.									
2	Yes	06/03/93	1640	06/03/93	1500	Rx B	15.2	66710z7	66710z7
Reason Suctioned < 2 hrs: Arterial saturation and P02 drop.									
3	No			06/03/93	2327	Rx B	15.2	66710z7	66710z7
4	No			06/04/93	540	Rx B	15.2	66710z7	66710z7
INV: Van Meurs RX: C SUBJECT: 32119 DIAGNOSIS: Disease A OI: 23-30									
1	No			08/31/93	50	Rx B	11.0	74780z7	74780z7
2	No			08/31/93	655	Rx B	11.0	74780z7	74780z7
3	No			08/31/93	1330	Rx B	11.0	74780z7	74780z7
4	No			08/31/93	1845	Rx B	11.0	74780z7	74780z7
5	No			09/01/93	1230	Rx B	11.0	74780z7	74780z7
INV: Van Meurs RX: C SUBJECT: 32214 DIAGNOSIS: Disease C OI: 23-30									
1	No			08/18/93	1708	Rx B	14.4	74 780z7	74 780z7
2	Yes	08/19/93	34	08/18/93	2305	Rx B	14.4	74 780z7	74 780z7
Reason Suctioned < 2 hrs: Per bedside RN: Infant doing poorly post dose with low									
Reason Suctioned < 2 Hrs: saturations. Tried suctioning to get sats up.									
3	No			08/19/93	520	Rx B	14.4	74 780z7	74 780z7
4	No			08/19/93	1104	Rx B	14.8	74780z7	74780z7

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Figure 2(continued).