FAST TRACKING FOR THE CLINICAL SCIENTIST USING SAS* SOFTWARE

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ABSTRACT

Clinical trial record keeping is one of the most important aspects for the success of the study, as well as being very time-consuming. The clinical scientist must monitor the progress of the study at periodic intervals. This situation requires that information concerning the investigating physicians, study coordinators, regional clinical associates, and the study patients be assembled in an efficient manner for quick and precise information retrieval. A certain amount of information can be monitored during a double-blind clinical trial. Keeping track of patient status and study finances can be done by the clinical scientist using a combination of basic SAS* software procedures. Most of the information can be immediately scanned after sorting and outputting it by study attributes. Legible output that does not require decoding by the clinical scientist is a must.

INTRODUCTION

In clinical studies of investigational drugs, clinical scientists or their counterparts require immediate and easy access to large numbers of study and financial records. Some basic SAS* procedures offer the means to implement this requirement. PROC SORT, PROC PRINT, PROC FORMAT, and PROC GCHART are used to produce appropriate output.

DISCUSSION

By the proper identification of the observations of all data sets which contain the demographic and procedural information, mainframe users may create hardcopy that can be used to convey desired facts quickly. This syntax is intended as the prelude to a menu-driven program using SAS/AF* software, thus creating a "user-friendly" environment for even the "computerphobic". Simple annotation of program syntax makes the generation of output easy for users with a brief acquaintance with SAS software. This syntax may also be used with SAS software for the PC.

Currently there are four printed output panels and one graphic display. PROC PRINT, the PUT statement for "pretty printing", and the HVAR feature of PROC GCHART were used to create these panels.

The first of these panels lists the investigating physician's identification including the protocol number, his/her name, professional address, telephone number, the study coordinator(s), and subinvestigator(s).

The second of the panels lists the patient's demographic by protocol and investigator. Patient number, patient's initials, date of birth, and sex are given in this program. These current examples use previous patients who were transferred from one protocol to another; therefore the panel contains the patient's previous investigational history.

A schedule of patient visits can be predetermined for a long-term study. Such a schedule is displayed in the third panel. It includes the patient's identification along with enrollment date, proposed visit dates, actual visit dates, and the difference (in days) between the two visit dates.

Current patient enrollment is often requested by study monitors. Hardcopy, both in printed and graphic form, easily supplies the desired information. In both cases, the enrolled, active, and discontinued study patient totals are presented in easily read fashion.

The development of the financial records panel is in progress.

CONCLUSION

This program is preliminary to a final menu-driven presentation using SAS/AF* software. Such a format will allow easy access to both novice and experienced SAS* software users.

REFERENCES


*SAS is the registered trademark of SAS Institute, Inc., Cary, NC, U.S.A.

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NOTE: THE EXECUTION T I M E OF THE PROCEDURE FORMAT USEO 0.16 SECONDS.
DATA ENTRY;
INFILE CARDS MISSOVER;
INPUT TYPE 1-2 $;
IF TYPE=4 THEN LINK TYPE1,3;
IF TYPE=4 THEN LINK TYPE4;
IF TYPE=5 THEN LINK TYPE5;
PROTOCOL=INT(INVNO/100);
INVNAME=INVNO;
FORMAT INVNAME NAME.;
OUTPUT: RETURN; •• 100

DATA ENTRY2; INPUT INTYPE 3-4 INVNO 6-10 INFO 11-72;
RETURN;

DATA ENTRY3: INPUT INTYPE 3-4 INVNO 6-10 PATNO 12-14 RNOCODE 16-19 INITS 21-23 PREPRTNO 25-27 PREPRTNO 31-33 PREINVO 35-39 PRVDRG $ 41-43 PRVDRGSE 45-49 GDP $57 BIRTHDAY = BDATE;
IF D='Y' THEN DISCNTN='YES';
ELSE DISCNTN='NO';
FORMAT BIRTHDAY DATE7. REASON RSN. PRVORG $PDG.
RETURN;

DATA ENTRY4: INPUT INTYPE 3-4 INVNO 6-10 PATNO 12-14 RNOCODE 16-19 INITS 21-23 VISITNO 25-26 28 PVC MMDDYY 35 AMMMDYY 35 AVO MMDDYY.
IF VISITNO=O THEN ENROLDATE=AVO;
IF ABS(AVO)<Q AND ABS(PAVO)<O THEN
DAYSDIFF=AVO-PAVO;
AVSTDATE = AVO;
RETURN;

NOTE: DATA SET WORK.ENTRY HAS 113 OBSERVATIONS AND 27 VARIABLES. 198 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.05 SECONDS.

PROC SORT DATA=ENTRY;
BY PROTOCOL INVNO TYPE INTYPE;
NOTE: 4 CYLINDERS DYNAMICALLY ALLOCATED ON SYSDA FOR EACH OF 3 SORT WORK DATA SETS.
NOTE: DATA SET WORK.ENTRY HAS 113 OBSERVATIONS AND 27 VARIABLES. 198 OBS/TRK.
NOTE: THE PROCEDURE SORT USED 0.19 SECONDS.

DATA ENTRV1 3: SET ENTRY;
BY PROTOCOL INVNO TYPE INTYPE-;
IF TYPE<4;
KEEP PROTOCOL INVNO INVNAME TVPE INTVPE INFO;
TITLE1 'DATA ENTRY1.3 SET ENTRY';
LABEL INFO='I'
INVNAME='INVESTIGATOR NAME'
SY PROTOCOL INVNO.
10 PROTOCOL INVNO:
VAR INFO;
RUN;
NOTE: DATA SET WORK.ENTRY1 3 HAS 17 OBSERVATIONS AND 6 VARIABLES. 442 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.05 SECONDS.

DATA MAKENICE; SET ENTRY1 3: FILE PRINT HEAVER+;
BY PROTOCOL INVNO TYPE INTYPE;
TITLE4 'PROFILE OF INVESTIGATING PHYSICIAN(S)';
TITLE5 ' ';
IF NOT FIRST.INVNO THEN GO TO NEXT;
PUT #12 PROTOCOL 3. 97 INVNO 5. 9;
NEXT;
PUT #40 INFO SCARG2.;
IF LAST.TYPE THEN PUT /;
RETURN;
NOTE: 19 LINES WERE WRITTEN TO FILE PRINT.
NOTE: DATA SET WORK.MAKENICE HAS 17 OBSERVATIONS AND 6 VARIABLES. 442 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.05 SECONDS AND PRINTED PAGE 1.

DATA ENTRY4: SET ENTRY;
BY PROTOCOL INVNO TYPE INTYPE;
IF TYPE=4;
IF SEX='F' THEN SEX='FEMALE'; ELSE SEX='MALE';
KEEP PROTOCOL INVNO TYPE PATNO RNOCODE INITS PREPRTNO PREPATNO
INVNAME PREVORS
PREINVO RNOCODE BDATE REASON SEX BIRTHDAY DISCNTN;
RETURN;

PROC PRINT DATA=ENTRY4 NOBS;
NOTE: DATA SET WORK.ENTRY4 HAS 13 OBSERVATIONS AND 18 VARIABLES. 386 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.05 SECONDS.

278 PROC SORT DATA=ENTRY4;
279 BY PROTOCOL INVNO TYPE PATNO;

NOTE: DATA SET WORK.ENTRY4 HAS 13 OBSERVATIONS AND 18 VARIABLES. 386 OBS/TRK.
NOTE: THE PROCEDURE SORT USED 0.14 SECONDS.

280 DATA PRETTY4; SET ENTRY4;
281 FILE PRINT HEADER=H LINESLEFT=LNLEFT NAPAGESIZE;
282 TITLE4 "DEMOGRAPHIC HISTORY OF STUDY PATIENTS";
283 TITLE4 " ";
284 DIALOG=LEFT(PUT(PRODGOSE,4.));
285 IF NOT FIRST.INVNO THEN GO TO NEXT;
286 PUT .13 PROTOCOL 3. +5 INVNAME NAME. +1 INVNO 5. ;
287 NEXT:
288 PUT .40 'PATIENT NUMBER: ' PATNO $CHAR3. +1 'PATIENT'S INITALS: ' INITS $CHARS. +1 'DATE OF BIRTH: ' BIRTHDAY DATE7. +1 'SEX: ' SEX $CHARS. ;
290 IF LAST.PATNO THEN PUT /;
291 IF LNLEFT>9 THEN RETURN;
292 PUT PAGE;
293 PUT 013 PROTOCOL 3. +5 INVNAME NAME. +1 INVNO 5. ;
294 RETURN;
295 PUT .10 'PROTOCOL NAME & NUMBER' ;
296 RETURN;
297 RUN;

NOTE: 115 LINES WERE WRITTEN TO FILE PRINT.
NOTE: DATA SET WORK.PRETTY4 HAS 13 OBSERVATIONS AND 19 VARIABLES. 146 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.08 SECONDS AND PRINTED PAGES 2 TO 5.

311 OPTIONS MISSING'' ;
312 DATA ENTRIES; SET ENTRY;
313 BY PROTOCOL INVNO TYPE PATNO;
314 IF TYPE=5;
315 KEEP PROTOCOL INVNO TYPE PATNO RNDCODE INITS VISITNO PVSTDATE AVSTSTATE;
316 ENCRODTE DAYSDIFF PVSTDATE AVSTSTATE;
317
NOTE: DATA SET WORK.ENTRIES HAS 83 OBSERVATIONS AND 15 VARIABLES. 410 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.06 SECONDS.

318 PROC SORT;
319 BY PROTOCOL INVNO TYPE PATNO VISITNO;
320 /*
321 PROC PRINT;
322 */

NOTE: DATA SET WORK.ENTRIES HAS 83 OBSERVATIONS AND 15 VARIABLES. 410 OBS/TRK.
NOTE: THE PROCEDURE SORT USED 0.14 SECONDS.

323 DATA TALLYS; SET ENTRIES;
324 BY PROTOCOL INVNO TYPE PATNO VISITNO;
325 IF FIRST.PATNO THEN TALLY=0; TALLY + 1;
326 IF LAST.PATNO;
327 VISITNO=-1;
328 OUTPUT; RETURN;

NOTE: DATA SET WORK.TALLYS HAS 13 OBSERVATIONS AND 16 VARIABLES. 364 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.04 SECONDS.

329 DATA ENTRIES; SET TALLYS ENTRIES;
330 BY PROTOCOL INVNO TYPE PATNO VISITNO;
331 RETAIN COUNT;
332 DROP TALLY;
333 IF VISITNO=0 THEN GO TO NEXT;
334 COUNT=TALLY; DELETE;
335 NEXT: OUTPUT; RETURN;

NOTE: DATA SET WORK.ENTRIES HAS 83 OBSERVATIONS AND 10 VARIABLES. 384 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.06 SECONDS.
DATA PRETTY5: SET ENTRYS;
TITLE4 'RECORD OF PATIENT VISITS';
TITLES ' ';
NOTE: DATA SET PRETTY5 HAS 83 OBSERVATIONS AND 16 VARIABLES. 384 DBS/TRK.
NOTE: THE DATA STATEMENT USED 0.04 SECONDS.

DATA PRETTY5: SET ENTRYS;
NOTE: DATA SET PRETTY5 HAS 83 OBSERVATIONS AND 16 VARIABLES. 384 DBS/TRK.
NOTE: THE DATA STATEMENT USED 0.07 SECONDS AND PRINTED PAGES 6 TO 9.

DISPLAV

RUN:
NOTE: 104 LINES WERE WRITTEN TO FILE PRINT.
NOTE: THE DATA STATEMENT USED 0.05 SECONDS.

DATA KOUNT: SET ENTRY4;
TITLE4 'STATUS OF PATIENT ENROLLMENT';
TITLES ' ':

BY PROTOCOL INVNO TYPE PATIllO;
IF FIRST.INVNO THEN DO;
TALLY=0; DOUNT=0;
END.
IF FIRST.PATNO THEN TALLY + 1;
IF DISCONT='YES' THEN DOUNT + 1;
IF LAST.INVNO;
ACTIVE=TALLY-DOUNT;
OUTPUT; RETURN;
NOTE: DATA SET WORK.KOUNT HAS 2 OBSERVATIONS AND 21 VARIABLES. 322 DBS/TRK.
NOTE: THE DATA STATEMENT USED 0.05 SECONDS.

DATA KOUNT: SET ENTRY4;
NOTE: 8 LINES WERE WRITTEN TO FILE PRINT.
NOTE: DATA SET WORK.KOUNT HAS 2 OBSERVATIONS AND 21 VARIABLES. 322 OBS/TRK.
NOTE: THE DATA STATEMENT USED 0.06 SECONDS AND PRINTED PAGE 9.

GOPTIONS DEVICE:ZETA8S7 NODI SPLAY
GOPTIONS Device: ZETA8S7 NODI SPLAY
GSFASP=ZETA8S7
GOPTIONS NOSYMBOL NOOASH NOTEXT82
GOPTIONS Device: ZETA8S7 NODI SPLAY
CBY~RED F8Y~COMPlEX:
GOPTIONS Device: ZETA8S7 NODI SPLAY
CBY~RED F8Y~COMPlEX:

DATA GRAPH; SET KOUNT;
VARIABLE=' ENROLLED'; PATIENT=TALLY;
OUTPUT;

VARIABLE='DISCONTINUED'; PATIENT=OKOUNT;
OUTPUT;

VARIABLE='ACTIVE'; PATIENT=NACTIVE;
OUTPUT;

NOTE: DATA SET WORK.GRAPH HAS 6 OBSERVATIONS AND 23 VARIABLES. 284 DBS/TRK.
NOTE: THE PROCEDURE SORT USED 0.14 SECONDS.

PROC SORT DATA=GRAPH; BY PROTOCOL INVNAME VARIABLE;
RUN;
NOTE: DATA SET WORK.GRAPH HAS 6 OBSERVATIONS AND 23 VARIABLES. 284 DBS/TRK.
NOTE: THE PROCEDURE SORT USED 0.14 SECONDS.

PROC GCHART DATA=GRAPH;
BY PROTOCOL;
AXIS1 ORDER=Q TO 10
MINOR-NONE
LABEL=(C=RED F=COMPLEX 'NUMBER OF PATIENTS');
PATTERN1 V=X1 C=RED;
PATTERN2 V=X1 C=BLUE;
PATTERN3 V=X1 C=GREEN;
NEAR VARIABLE / DISCRETE
MOHEADING
GROUP=INVNAME
PATTERN=MIPOINT
CTEXT=BLUE
CAXIS=BLUE
BAXIS=AXIS1
SUMVAR=PATIENT

NOTE: THE PROCEDURE GCHART USED 0.44 SECONDS.
PROTOCOL 489

INVESTIGATOR NUMBER 48922

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DEMOGRAPHIC HISTORY OF STUDY PATIENTS

PROTOCOL 489

INVESTIGATOR

NAME & NUMBER

489 PILLPUSHER 48922 PATIENT NUMBER: 001 PATIENT'S INITIALS: XXV DATE OF BIRTH: OCT 9379 SEX: FEMALE

RANDOMIZATION CODE: 1243
PREVIOUS PROTOCOL NUMBER: 399
PREVIOUS PATIENT NUMBER: 032
PREVIOUS INVESTIGATOR NUMBER: 399
PREVIOUS DRUG AND DOSE: THERAPY A 500
PREMATURE DISCONTINUATION: NO

REASON FOR PREMATURE DISCONTINUATION:

PATIENT NUMBER: 002 PATIENT'S INITIALS: MMQ DATE OF BIRTH: DEC 9379 SEX: MALE

RANDOMIZATION CODE: 1231
PREVIOUS PROTOCOL NUMBER: 399
PREVIOUS PATIENT NUMBER: 044
PREVIOUS INVESTIGATOR NUMBER: 399
PREVIOUS DRUG AND DOSE: THERAPY A 250
PREMATURE DISCONTINUATION: NO

REASON FOR PREMATURE DISCONTINUATION:

RECORD OF PATIENT VISITS

PROTOCOL 489

INVESTIGATOR

NAME & NUMBER

489 PILLPUSHER 48922 O PATIENT NUMBER: 001 PATIENT'S INITIALS: XXV DATE OF ENROLLMENT: 02 JAN 89

PROPOSED VISIT DATE ACTUAL VISIT DATE DIFFERENCE (IN DAYS)

1 C2FEB99 C2FEB99 0
2 C3APR99 C3APR99 0

0 PATIENT NUMBER: 002 PATIENT'S INITIALS: MMQ DATE OF ENROLLMENT: 16 JUN 89

PROPOSED VISIT DATE ACTUAL VISIT DATE DIFFERENCE (IN DAYS)

1 16JAN98 16JAN98 0
3 16AUG98 16AUG98 -3
5 16OCT98 16OCT98 -5
7 16DEC98 16DEC98 0

STATUS OF PATIENT ENROLLMENT

PROTOCOL 489 INVESTIGATOR: PILLPUSHER INV. NUMBER: 48922

NUMBER OF PATIENTS ENROLLED 2
NUMBER OF ACTIVE PATIENTS 2
NUMBER OF DISCONTINUED PATIENTS 0