REPORT QUALITY TABLES WITH SAS

E.Placa , P. Smith (CIBA-GEIGY, BASEL) , G.Stein (ESSEX CHEMIE, LUZERN)

TABULAR OUTPUT OF SAS DATA.

Procedure TABLES.

This procedure provides tabulations of SAS data sets in a form suitable for inclusion as documentation in a Statistical or Clinical Trial Report. Tables can be up to 130 characters in width, and on the laser printer, up to 84 lines per page. The procedure offers the option of printing the table(s) directly or saving them on a "print file", the contents of which can be edited (e.g. addition of footnotes) before printing .

In addition to simple tabulations (patient listings), a special option is available whereby summary statistics (means, standard deviations, frequency counts, percentages etc.) can be tabulated with minimum specification by the user. Also available when using this option is the facility to perform simple one-way "tests of homogeneity" of groups of patients. Details are given later.

To produce tables using this procedure, the user is required to set up two members - one describing the layout of the table and the variables to be printed, and the other containing SAS statements generating a SAS data set of the observations and variables to be tabulated.

Table description member

The table description is set out in a hierarchical structure, within which the table is defined column by column. For example, if a table such as

TABLE OF ADVERSE EFFECTS REPORTED AT VISIT 2
PLAN NR/LT3 TRIAL 10105

TREATMENT	PERSONAL DATA PATNO AGE SEX	ADVERSE EFFECTS REPORTED AT VISIT 2 DAY SYMPTOM/SIGN

is required, then the sequence in which the table would be defined is as follows :-

Title	TABLE OF ADVERSE EFFECTS REPORTED AT VISIT 2 PLAN NR/LT3 TRIAL 10105
Title Variable	TREATMENT Variable giving the treatment value
Title	PERSONAL DATA
Title Variable	PATNO Variable giving the patient number
Title Variable	AGE Variable giving the patient's age
Title Variable	SEX Variable giving the patient's sex
Title	ADVERSE EFFECT REPORTED AT VISIT 2
Title Variable	DAY Variable giving the day of report (for each 'repeat')
Title Variable	SYMPTOM/SIGN Variable giving the adverse effect (for each 'repeat')

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

Table description member (cont.)

From this, it is clear that only two types of statement are required to define the table fully - TITLE and VARIABLE - and both have the same general form :-

< statement identifier > < space > < statement >

The TITLE type statement has the specific form :-

< level > < space > < free text >

The level identifier can be either A, B, C or D. Up to 5 lines of text may follow a single level identifier, with all continuations beginning in column 3. For example :-

```
Col
1234...
A TABLE OF ADVERSE EFFECTS REPORTED
  PLAN NR/LT3  TRIAL 10105
  PREPARATION CGP12,345
```

A level "A" statement is always the first statement for a given table. The "free text" given in the statement is left-justified at the top of the table as a table heading.

Level "B", "C" and "D" statements are used to define column headings within the table. Level "D" statements are subordinate to level "C" statements and similarly level "C" statements are subordinate to level "B". The physical position of a level "B" heading is calculated by the procedure, with consideration of the level "C" and "D" headings subordinate to it, such that the actual text is centred.

The VARIABLE type statement has the following format :-

V <space> I<SAS variable expression>IR/LIBYP/BYL/BYI<SAS format>

The last three fields (R/L, BYP/BYL/BY, <SAS format>) are optional, but if any options are omitted only TRAILING field delimiters can be suppressed. VARIABLE type statements can occur after a level "B", "C" or "D" TITLE statement, and if necessary more than one can be associated with the same TITLE statement.

FIELD DELIMITERS

The delimiter "I" can be changed if this symbol is used elsewhere in the statement (for example, the SAS variable expression may be used to concatenate two or more variables, in which case the symbol "I" is used — e.g. PUT(SYSBP,3.)||'/'||PUT(DIABP,3.)).
The delimiter being used appears in column 3 of the "V" statement, and the same character must be used throughout the same statement. However, different delimiters can be used in different "V" statements within the same table description member.

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

Table description member (cont.)

SAS VARIABLE EXPRESSION

Any valid SAS expression is permissible here, for example :-

AGE PUT(SEX,SEXF.) SUM(HOURS,MINS/60) etc.

R/L

This field allows the variable value to be printed right (R) or left (L) justified under its appropriate heading. This may be omitted, with the default that the value will be centred under the heading.

BYP/BYL/BY

BYP: A new page is started each time the value of the SAS variable expression changes.

BYL: A separating line is printed each time the value of the SAS variable expression changes.

BY: The value of the SAS variable expression is printed only when a change occurs.

The default is that the variable value is printed for each observation on the SAS data set being tabulated.

SAS FORMAT

Any valid SAS format is permissible here, e.g. SEXF. 4.1 $6. etc.

Example

The example given on page 1 will be used to illustrate the structure of the table description member.

```
A TABLE OF ADVERSE EFFECTS REPORTED AT VISIT 2
  PLAN NR/LTS  TRIAL 10105

B TREATMENT                                  Each treatment starts on a new page.
V |TRMTNO|L|BYP|$TRMTNOF.|                   Variable decoded by format $TRMTNOF.
                                             Treatment name left-justified.
B PERSONAL DATA

D PATNO                                      PATNO, AGE and SEX are at
V |PATNO|R||4.|                              level "D" within the level "B"
                                             title of PERSONAL DATA.
D AGE                                        All variables are right-justified
V |AGE|R||3.|                                in printing.

D SEX                                        Variable SEX decoded by format SEXF.
V |SEX|R||SEXF.|

B ADVERSE EFFECTS                            Continuation of "B" TITLE statement
  REPORTED AT VISIT 2

D DAY                                        DAY and SYMPTOM/SIGN "D" titles
V |DAYADRA2|R||3.|                           within the "B" title ADVERSE EFFECTS
V |DAYADRB2|R||3.|                           DAYADR(A/B/C)2 are generated in the
V |DAYADRC2|R||3.|                           SAS statements member.  ADR(A/B/C)2
                                             are decoded using format $SYMP.
D SYMPTOM/SIGN                               Three repeats of adverse effects at
V |ADRA2|L||$SYMP.|                          Visit 2 are tabulated.
V |ADRB2|L||$SYMP.|
V |ADRC2|L||$SYMP.|
```

All four TITLE statement levels are not required in every table. In such cases, the levels selected need not be strictly alphabetical, as can be seen from the above example. Note that the level "A" title must always be given, as this denotes the start of the table.

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

SAS statements member

Two types of SAS statements member are possible, depending on whether or not the option of tabulating standard summary statistics is to be used. The use of this option is indicated by a membername with "@" as the first character. Obviously, the standard summary statistics can be obtained by writing a specific SAS program, but in many cases, this can be tedious and repetitive. However, if this option of the procedure is used, only the variables for which summary statistics are required are specified — the procedure writes the SAS program to obtain the summary statistics itself. The more usual type of SAS statements member is considered first.

A. SAS statements member for patient listings etc.
This contains a set of SAS instructions to derive the set of variables and the observations (cases) which are to be tabulated. Usually, it will consist of :-

- a DATA step in which patients to be excluded from the table are dropped and/or new variables are created,
- a FORMAT procedure to decode "multiple choice" responses,
- a SORT procedure to sort the data in the required order.

The major functions of the SAS statements member are :-

1. To obtain only a subset of the patients for a particular tabulation — for example, all patients reporting adverse effects during the trial (IF ADRA2='' THEN DELETE;).
2. To calculate new variables for tabulation — for example, the interval between start of treatment and reporting of adverse effects.
   DAYADR = MDY(MMADR,DDADR,YYADR)- MDY(MMT,DDT,YYT);
3. To obtain a patient-by-patient data set rather than a data set organised visit-by-visit (or vice-versa).
4. To specify non-standard formats for decoding 'multiple choice' responses.

The resulting SAS working data set of the observations and variables to be tabulated should always be named DAT.

Example

The SAS statements member required to produce the data for the example on Page 8 would be as follows :-

```
DATA DAT; SET SAS.nrlt3;    * nrlt3 is the name of the SAS data set;
                            * SAS is the DDNAME of the SAS data base;
  IF ADRA2='' AND ADRB2='' AND ADRC2=''  THEN DELETE;
  DAYADRA2=MDY(MMADRA2,DDADRA2,YYADRA2) - MDY(MMT,DDT,YYT);
  DAYADRB2=MDY(MMADRB2,DDADRB2,YYADRB2) - MDY(MMT,DDT,YYT);
  DAYADRC2=MDY(MMADRC2,DDADRC2,YYADRC2) - MDY(MMT,DDT,YYT);
PROC SORT; BY TRMTNO;
```

REPORT QUALITY TABLES WITH SAS

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

SAS statements member (cont.)

B. Tabulation of standard summary statistics.
The option of the TABLES procedure which permits summary statistics for variables to be tabulated requires that these summary statistics must be tabulated by a "classification" or "sort" variable (see Run Instructions). For example, summary statistics such as
median age, mean height, frequency count of the number of females
might be tabulated for subgroups of the patient population (e.g. treatment groups) and for the patient population as a whole (i.e. all treatment groups combined). A maximum of two classification variables are permitted. These are given when submitting the procedure to run.

The SAS statements member must be created according to a number of conventions. The membername must have "@" as the first character, to indicate to the procedure that this option is being used. Then, within the member itself, the conventions adopted are best illustrated by an example.

Example

```
Col
1234567....
AGE  D100*(YOB>=YEAR)+(YEAR-YOB)
HEI  MHEIGHT
SEX  FSEX-SEX+(SEX=2);
@     IF CENTRE=1 THEN DELETE;
BPS  MBPS1
BPD  MBPD1
SEV  FSEVER1-SEVER1+(SEVER1=2 OR SEVER1=3);
@     ARRAY SCALE(I) SCALE1-SCALE20;
@     TOT=0;
@     DO OVER SCALE;  TOT = SUM(TOT,SCALE);  END;
TOT  DTOT
      PROC FORMAT;
        VALUE TT 1='CGP12,345' 2=PLACEBO
                 99999='ALL TRTS'  999999='TEST HOM.';
```

Interpretation of the SAS statements member

1. A SAS statement of the form
   DATA DAT; SET SAS.xxxxx;
   where xxxxx is the SAS data set name given when submitting the job (see Run Instructions), is inserted automatically by the procedure at the start of the SAS statements member.

REPORT QUALITY TABLES WITH SAS

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

SAS statements member (cont.)

B. Tabulation of standard summary statistics (cont.)

2. Then there are three basic statement types in the SAS statements member, and these are identified according to the contents of columns 1-5 of the line.

a) A permissible SAS variable name in columns 1-5.
In this case, the format of the line is as follows :-

Cols 1-5	:	Permissible SAS variable name. All summary statistics (see later) will be obtained for this variable.
Col 6	:	"M" if test of homogeneity of MEANS, "D" if - - - - - - - - MEDIANS, "F" if - - - - - - - - FREQUENCIES, blank if no test of homogeneity is required for that variable.
Cols 7-72	:	Any permissible SAS expression used to define the variable named in columns 1-5.

In the example given on the previous page, the first line would be interpreted as follows :-
Summary statistics will be calculated for variable
AGE = 100*(YOB>=YEAR) + (YEAR-YOB);
and a test of homogeneity of the median AGE of subgroups of the patient population (identified by "classification" variables) will be done.

b) The character "@" in column 1.
In this case, the format of the line is :-

Col 1	:	@
Cols 2-6	:	blank
Cols 7-72	:	any SAS statement permissible within the DATA step

This type of statement has three basic functions :-
(1) as a continuation of the previous line, or
(2) to insert some SAS statements to delete certain patients from the analysis (e.g. 4th line of the example) or to create new variables (e.g. lines 8-10 of the example).
(3) to insert any general SAS statements which are permitted within the data step (e.g. ARRAY, IF...THEN..., DO...)

c) Columns 1-5 blank.
Statements of this type can only appear after all type "a" and type "b" statements. The format of the line in this case is :-

Cols 1-6	:	blank
Cols 7-72	:	SAS procedures or a new DATA step.

In the example, a PROC FORMAT is used to define decoding texts for treatment codes.

REPORT QUALITY TABLES WITH SAS

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

SAS statements member (cont.)

B. Tabulation of standard summary statistics (cont.)

Summary statistics

For each SAS variable name given in columns 1-5 of the SAS statements member, the SAS procedure UNIVARIATE is run to obtain the summary statistics as an output data set. For example, the summary statistics for variable AGE can be tabulated by using the following variable names in the Tables Description member :-

NAGE	number of observations on which the calculations are based
MAGE	mean AGE
FAGE	the sum of AGE (used mainly with binary ("0/1") types of variables)
SAGE	the standard deviation of AGE
AAGE	the maximum AGE
IAGE	the minimum AGE
RAGE	the range of AGE
DAGE	the median AGE

In addition to those variable names defined in columns 1-5 of the SAS statements member, the variable PAT is also included in the list of variables for which summary statistics are calculated. The variable PAT always has a value for each patient, so that the derived variable NPAT can be used to give the number of observations on the data set.

The UNIVARIATE procedure is run using the "classification" variables when submitting the job (see Run Instructions) as "BY" variables. The "classification" variables must be numeric. Using two such variables, CENTRE and TREAT, PROC UNIVARIATE is run four times :-

```
PROC UNIVARIATE;  BY CENTRE TREAT;
PROC UNIVARIATE;  BY CENTRE;
PROC UNIVARIATE;  BY TREAT;
PROC UNIVARIATE;
```

and the output data sets from each are combined together. In combining these data sets, a value of TREAT=. refers to "all treatments". In such a case, the value of TREAT is set to 99999 and hence the need for the value 99999='ALL TRTS' in the PROC FORMAT of the example.

Tests of homogeneity.

This is an optional feature available only when the summary statistics are being tabulated. Three possibilities exist :-

1. Homogeneity of means - by an F-test obtained from the parametric one-way analysis of variance given by SAS procedure NPAR1WAY.
2. Homogeneity of medians - by the K-way Kruskal-Wallis test given by the SAS procedure NPAR1WAY.
3. Homogeneity of frequencies - by the Chi-square test (with correction for continuity, where appropriate) given by the SAS procedure FREQ.

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TABULAR OUTPUT OF SAS DATA (CONT.)

Procedure TABLES.

SAS statements member (cont.)

B. Tabulation of standard summary statistics (cont.)

Note that if two "classification" variables are specified, then homogeneity tests are restricted to testing between the levels of the second class variable for each level of the first class variable. For example, with CENTRE as first "class" variable and TREAT as second "class" variable, tests of homogeneity of treatment groups are made separately for each centre.

The result of the test of homogeneity can be included in the tabulation by referring to variables

P1xxxxx and P2xxxxx (xxxxx is the variable name given in columns 1-5 of the SAS stmnts member)

in the Tables Description member. The possible values of P1xxxxx and P2xxxxx are :-

P1xxxxx	NOT	SIG	SIG	N/A
P2xxxxx	SIG	5%	1%	blank

"N/A" appears when the warning concerning the appropriateness of the Chi-square statistic due to small expected cell frequencies is given by the SAS procedure FREQ.

Other features of the TABLES procedure

1. More than one table description can be saved on the same member. Care should be taken that the corresponding SAS statements member is suitable for all tables in the tables description member.

2. The tables description and SAS statements members are assumed to be saved in the same library.

3. The tables can be written to a print file if necessary.

   The file should be allocated before use, and should have the the following characteristics :-

RECFM	LRECL	BLKSIZE	DSORG	
FB	140	6160	PS	Not numbered

   TABLES will add new tables to the tables already on the print file.

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1. *Examples of listings.*

TABLE 1.5
CONCOMITANT MEDICATIONS AND MEDICAL CONDITIONS (PATIENT LISTING)
TRIAL AB/123

COUNTRY CENTRE	PERSONAL DATA				TRIAL	VISIT	(MED) CONCOMITANT MEDICATIONS (CON) CONCOMITANT MEDICAL CONDITIONS			
	PAT NO.	AGE	SEX	DOSE	START VIS:1		MEDICATION / CONDITION	DOSAGE	START	END
FRANCE 1	101	53	M	20MG	23SEP82	(1) 23SEP82	MED: TRASICOR R 160 MG	1 CP/J	19NOV81	
						(1) 23SEP82	MED: PERSANTIINR 75	3 CP/J	MAY81	
						(1) 23SEP82	CON: RHEUMATISM NOS		29	
						(1) 23SEP82	CON: APPENDECTOMY		34	
						(1) 23SEP82	CON: HERNIA DIAPHRAGMATIC		76	
	102	64	F	0MG	10NOV82	(1) 10NOV82	MED: OXPRENOLOL HYDROCHLORIDE	1C/J	10CT82	
						(1) 10NOV82	MED: GINKGO TREE LEAVES EXTRACT	3C/J	OCT81	
						(1) 10NOV82	CON: HYSTERECTOMY		50	
	103	58	F	15MG	18NOV82	(1) 18NOV82	MED: ANAFRANIL 25	2 CP/J	75	
						(1) 18NOV82	MED: OXPRENOLOL HYDROCHLORIDE	1C/J	10CT82	
						(1) 18NOV82	CON: OBESITY		50	
						(1) 18NOV82	CON: POLYP OF CORPUS UTERI		76	
						(1) 18NOV82	CON: DEPRESSIVE DISORDER NOS		75	
	104	60	F	10MG	02DEC82	(1) 2DEC82	MED: INDAPAMIDE	1 CP	OCT78	
						(1) 2DEC82	MED: COMPRALGYL	20 CP/MOIS	80	
						(1) 2DEC82	MED: TRASICOR R	1 CP/J	21OCT82	
						(1) 2DEC82	MED: GINKGO TREE LEAVES EXTRACT	150 GOUTTE	80	
						(2) 9DEC82	MED: INDAPAMIDE	1 CP/J	OCT82	23OCT82
						(2) 9DEC82	MED: COMPRALGYL	20 CP/MOIS	80	23OCT82
						(2) 9DEC82	MED: GINKGO TREE LEAVES EXTRACT	150 GOUTTE	80	23OCT82
						(1) 2DEC82	CON: HERNIA DIAPHRAGMATIC		OCT64	
	105	63	F	20MG	06JAN83	(1) 6JAN83	MED: OXPRENOLOL HYDROCHLORIDE	1C/J	10NOV82	
	106	64	F	0MG	11JAN83	(1) 11JAN83	MED: OXPRENOLOL HYDROCHLORIDE	1C/J	10CT82	
						(1) 11JAN83	CON: HERNIA DIAPHRAGMATIC		75	
	107	58	F	10MG	19MAY83	(1) 19MAY83	MED: OXPRENOLOL HYDROCHLORIDE	160MG/J	10MAR83	
						(1) 19MAY83	CON: HYSTERECTOMY		78	
						(1) 19MAY83	CON: OOPHORECTOMY		78	
	108	64	M	15MG	13JAN83	(1) 13JAN83	MED: OXPRENOLOL HYDROCHLORIDE	1C/J	10CT82	
						(1) 13JAN83	MED: TORENTAL 400	3C/J	80	

TABLE 3.5
PULSE RATE, BLOOD PRESSURE, BODY WEIGHT, VISITS 1-4 (PATIENT LISTING)
GLOBAL EVALUATION OF THERAPEUTIC EFFECT, VISIT 4
TRIAL AB/123

COUNTRY CENTRE	PERSONAL DATA				VISIT			PULSE RATE (BEATS/MIN)				BLOOD PRESSURE (MM HG)				WEIGHT	GLOBAL EVALUATION	
								SUPINE		STANDING		SUPINE		STANDING			EFFICACY	TOLER.
	PAT NO.	AGE	SEX	DOSE	N	DATE	TIME	1ST	2ND	1ST	2ND	1ST	2ND	1ST	2ND	(KG)		
GERMANY 1	1	57	F	20MG	1	11APR83	10:00	72	70	76	76	164/101	162/ 99	152/ 98	152/ 99	64		
					2	18APR83	10:00	66	66	70	70	165/104	162/100	168/105	166/105	63		
					3	25APR83	10:30	74	76	76	76	165/103	160/101	166/107	166/108	64		
					4	PREM DISCONT						/	/	/	/			
	2	40	M	10MG	1	11APR83	10:00	58	58	60	60	159/ 98	157/ 98	154/ 96	152/ 98	65		
					2	18APR83	10:00	54	54	58	58	150/ 98	145/100	145/105	144/105	102		
					3	25APR83	10:00	54	54	60	60	138/ 78	134/ 80	133/ 82	132/ 82	86		
					4	02MAY83	10:00	54	54	66	66	164/ 90	159/ 90	163/ 90	161/ 90	86	EFFECTIVE	VERY GOOD
	3	40	M	0MG	1	18APR83	10:15	70	70	72	74	160/ 97	162/ 95	160/105	161/103	72		
					2	25APR83	10:15	76	76	80	80	152/ 95	150/ 97	140/ 97	142/ 97	74		
					3	02MAY83	10:15	68	70	70	74	144/ 88	147/ 90	144/ 91	140/ 90	73		
					4	09MAY83	10:15	68	70	70	72	144/ 84	146/ 88	144/ 91	140/ 93	77	EFFECTIVE	VERY GOOD
	4	58	F	20MG	1	18MAY83	9:45	66	66	72	72	158/102	154/105	157/104	155/104	67		
					2	25MAY83	9:45	66	66	72	72	144/102	146/105	157/105	158/106	67		
					3	01JUN83	9:45	64	64	74	74	147/ 88	149/ 88	140/ 95	141/ 95	66		
					4	PREM DISCONT						/	/	/	/			

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2. Example of laboratory data lisiting.

TABLE 5.1
LABORATORY DATA + INDICATES VALUE ABOVE NORMAL RANGE
. - INDICATES VALUE BELOW NORMAL RANGE

TRIAL AB/123

COUNTRY CENTRE	PERSONAL DATA					BLOOD ANALYSIS				DIFFERENTIAL WBC					
	PATNO	AGE	SEX	DOSE		RBC 10E12/L	H-GLOB G/DL	H-CRIT %	WBC 10E3/MM3	NEU %	LYM %	EOS %	MON %	BAS %	PLATELET 10E3/MM3
ITALY 2	401	42	M	20MG	BEFORE	5.04	15.0	48.0	6.8	56	40	1	3	.	.
					AFTER	5.00	14.9	48.0	7.4	58	37	1	4	.	.
	402	52	F	10MG	BEFORE	3.95-	12.3	40.0	5.8	58	35	2	4	1	160
					AFTER	3.88-	12.4	40.0	6.7	70	28	.	2	.	230
	403	60	F	15MG	BEFORE	4.12	14.0	43.0	8.3	64	30	2	3	1	.
					AFTER	4.31	14.2	43.0	7.3	60	35	1	4	.	.
	404	48	M	0MG	BEFORE	4.20	14.1	43.0	7.4	70	28	.	2	.	230
					AFTER	4.43	14.3	44.0	8.1	66	32	1	2	1	260
	405	34	M	20MG	BEFORE	5.70	16.8	50.7	9.8	67	30	.	3	.	297
					AFTER	5.55	16.0	50.0	8.6	68	28	1	3	.	215
	406	50	F	15MG	BEFORE	4.90	15.1	47.0	7.6	55	40	2	3	.	.
					AFTER	5.00	14.9	46.0	6.8	58	37	1	4	.	.
	407	41	F	10MG	BEFORE	4.48	13.2	39.0	6.3	66	30	1	2	1	.
					AFTER	4.53	13.4	40.0	6.0	66	32	.	2	.	.
	408	62	M	0MG	BEFORE	4.50	13.6	45.0	6.9	67	30	.	3	.	.
					AFTER	4.61	13.5	45.0	7.9	69	25	1	5	.	.
	409	56	M	20MG	BEFORE	5.20	16.9	52.0	8.0	64	29	.	6	1	190
					AFTER	5.00	16.3	50.0	8.2	65	30	1	4	.	210
	410	51	M	0MG	BEFORE	5.52	16.7	51.0	7.6	55	39	2	4	.	260
					AFTER	5.50	16.5	51.0	8.3	56	38	1	5	.	290
	411	43	M	10MG	BEFORE	4.60	15.0	43.0	5.8	56	40	2	2	.	310
					AFTER	4.50	15.0	42.0	6.3	66	32	.	2	.	290
	412	60	M	15MG	BEFORE	5.40	16.6	54.0	8.6	68	30	.	2	.	240
					AFTER	5.30	16.8	55.0+	8.0	66	32	.	2	.	200

REPORT QUALITY TABLES WITH SAS

E.Placa , P. Smith (CIBA–GEIGY, BASEL) , G.Stein (ESSEX CHEMIE, LUZERN)

3. *Example of summary statistics.*

TABLE 1.1
DEMOGRAPHIC SUMMARY
AB/123

TREATMENT SEQUENCE	AGE				SEX FEMALES			HEIGHT			WEIGHT			NO. OF IN PATS.			BLOOD PRESSURE						PULSE		
																	SYSTOLIC			DIASTOLIC					
	MED	MIN	MAX	N	F	%	N	MEAN	SD	N	MEAN	SD	N	F	%	N	MEAN	SD	N	MEAN	SD	N	MEAN	SD	N
ACT - PLAC	29	16	48	17	9	53	17	166.9	8.07	17	66.6	12.8	17	0	0.0	17	125	13.5	17	77.2	8.08	17	75.1	9.29	17
PLAC - ACT	30	15	58	15	3	20	15	172.7	8.71	15	68.7	12.6	15	2	13	15	133	19.9	15	80.4	9.81	15	71.2	8.44	15
BOTH SEQ.	30	15	58	32	12	38	32	169.7	8.75	32	67.6	12.6	32	2	6.3	32	129	17	32	78.7	8.93	32	73.3	8.98	32
TEST HOM.	NOT SIG				NOT SIG			NOT SIG			NOT SIG			N/A			NOT SIG			NOT SIG			NOT SIG		

TABLE 1.2
EEG TRIAL START SUMMARY
AB/123

TREATMENT SEQUENCE	OVERALL RATING										GENERAL DISTURBANCE									
	NORMAL		EQUIVOCAL		MOD. ABNORMAL		SEVERELY ABNORMAL		MOD/SEV ABNORM.		NORMAL		EQUIVOCAL		MOD. DISTURBED		SEVERELY DISTURBED		MOD/SEV DISTURBED	
	F	%	F	%	F	%	F	%	F	%	F	%	F	%	F	%	F	%	F	%
ACT - PLAC N= 17	3	18	4	24	8	47	2	12	10	59	3	18	6	35	7	41	1	5.9	8	47
PLAC - ACT N= 15	3	20	7	47	4	27	1	6.7	5	33	4	27	7	47	4	27	0	0.0	4	27
BOTH SEQS. N= 32	6	19	11	34	12	38	3	9.4	15	47	7	22	13	41	11	34	1	3.1	12	38
TEST HOM									NOT SIG										NOT SIG	

TABLE 3.1A
EFFICACY - PULSE RATE, BLOOD PRESSURE, GLOBAL EVALUATION (BY COUNTRY)
(EXCLUDING PROTOCOL VIOLATORS)
TRIAL AB/123

COUNTRY & DOSE	VISIT	PULSE RATE (BEATS/MIN)						BLOOD PRESSURE (MM HG)												THERAPEUTIC EFFICACY		
		SUPINE			STANDING			SYSTOLIC SUPINE			DIASTOLIC SUPINE			SYSTOLIC STANDING			DIASTOLIC STANDING			EFFECTIVE		
		N	MEAN	STD	N	MEAN	STD	N	MEAN	STD	N	MEAN	STD	N	MEAN	STD	N	MEAN	STD	N	F	%
D, F, I 0MG N= 40	VIS:2	40	69.8	9.2	40	73.8	8.6	40	172.3	18.3	40	104.2	7.6	40	169.9	17.0	40	105.4	6.8	35	9	25.7
	VIS:3	40	69.5	8.4	40	73.4	8.5	40	166.6	18.6	40	101.4	9.2	40	164.4	16.9	40	103.7	11.3			
	VIS:4	38	69.2	7.2	37	74.3	9.1	33	164.6	18.0	38	100.0	8.2	38	161.1	16.3	38	100.9	9.3			
	V2-V4	38	0.9	5.6	37	-0.3	6.0	33	6.5	10.5	38	3.4	7.4	38	8.2	11.2	38	4.5	7.6			
10MG N= 39	VIS:2	39	69.1	9.7	38	72.8	8.7	39	169.2	12.8	39	103.9	7.4	39	165.0	14.4	39	105.5	9.6	34	28	82.4
	VIS:3	39	71.3	9.1	39	76.2	9.7	39	154.4	13.2	39	94.2	10.8	39	150.0	13.7	39	94.7	12.0			
	VIS:4	37	71.6	9.8	37	75.6	9.9	37	151.1	10.8	37	92.1	7.8	37	148.6	11.2	37	93.2	9.0			
	V2-V4	37	-2.5	9.2	37	-2.7	10.0	37	17.8	13.8	37	11.8	7.2	37	15.8	14.3	37	12.5	8.7			
15MG N= 40	VIS:2	40	72.8	9.2	39	76.3	10.0	40	168.1	13.3	40	103.1	6.6	39	167.7	12.5	39	103.5	7.0	37	31	83.8
	VIS:3	39	74.6	11.2	39	78.6	12.7	39	154.2	14.6	39	92.1	9.8	39	152.7	14.9	39	93.3	11.0			
	VIS:4	38	72.2	10.1	38	75.9	10.2	38	150.8	12.3	38	89.9	9.6	38	148.8	13.2	38	91.4	10.7			
	V2-V4	38	0.9	7.7	37	0.8	7.1	38	16.5	13.0	38	13.2	9.0	37	18.2	13.3	37	12.4	8.9			
20MG N= 38	VIS:2	38	68.6	8.4	37	72.0	8.3	38	172.2	15.8	38	104.6	6.6	38	167.6	16.5	38	105.1	9.6	32	27	84.4
	VIS:3	38	70.9	9.0	38	74.7	7.4	38	152.3	17.6	38	89.6	11.3	38	149.3	17.5	38	89.3	11.9			
	VIS:4	33	69.3	7.2	33	73.6	8.0	33	150.9	16.1	33	88.8	9.7	33	146.6	18.0	33	87.7	9.9			
	V2-V4	33	-1.1	6.6	32	-1.9	6.6	33	20.7	10.2	33	16.5	7.6	33	19.8	13.1	33	18.2	8.6			
ALL N=157	VIS:2	157	70.1	9.2	154	73.8	9.0	157	170.4	15.2	157	103.9	7.0	156	167.6	15.2	156	104.9	8.3	138	95	68.8
	VIS:3	156	71.6	9.4	156	75.7	9.9	156	157.0	16.8	156	94.4	11.1	156	154.2	16.9	156	95.4	12.6			
	VIS:4	146	70.6	8.7	145	74.9	9.4	146	154.5	15.6	146	92.8	9.8	146	151.5	15.8	146	93.5	10.8			
	V2-V4	146	-0.4	7.5	143	-1.0	7.7	146	15.2	13.0	146	11.1	9.1	145	15.3	13.6	145	11.7	9.7			