

Programmatic Generation of Table Specifications Using the SAS Macro Facility

Weimin "William" Sun, Ph.D. Biostatistician
 Caroline Stewart, B.S. Clinical Programmer

Pharmaceutical Research Associates, 2400 Old Ivy Road, Charlottesville, VA 22903

ABSTRACT

When preparing a data analysis plan for a clinical trial, we often need to create table specifications prior to the availability of database. Many times, these table specifications are produced using word processing software, which may not be efficient. To increase efficiency, the following two steps have been defined as part of a systematic process to programmatically produce table specifications:

- Generate dummy SAS® data sets based upon the efficacy and safety variables defined in a protocol;
- Use a generic SAS macro and the REPORT procedure to produce desired tables based upon the dummy data sets created.

By the end of this process, not only are the desired table specifications produced, but also the table-production programs and a format library (which contains titles, footnotes, and variable formats) as side products. When producing real tables, we need only to generate those analysis datasets that are in the same structure as the dummy datasets, and run the table-production programs on the real datasets. This method has been shown to be very efficient. There are two generic SAS macros, MDATSET and SUMCLIN, which may help users to produce dummy datasets and summary tables, respectively. This paper illustrates functionality of the macros and demonstrates their application to a hypothetical study.

1. GENERATION OF MOCK DATASETS

A mock SAS dataset consists of a set of dummy continuous and categorical variables. We assume that any dummy continuous variable is normally distributed with a known mean and standard deviation and any dummy categorical variable is uniformly distributed over a known number of categories.

To create a dummy continuous variable, say, AGE, we use the following data step statement:

```
AGE= INPUT (PUT (&MEAN+&STD*RANNOR (1998),BEST8.),&CONFMT);
```

where the seed of the RANNOR function is arbitrary and the macro variables *MEAN*, *STD*, and *CONFMT* allow us to control the range and the value format of the continuous variable. For example, if *&CONFMT=3.*, *&MEAN=35*, and *&STD=4*, then values of the variable AGE are all integral numbers with the mean and standard deviation as specified.

A natural method to create a dummy categorical variable is to let it repeatedly adopt, as its value, a random sequence of its categories. We apply the PLAN procedure to fulfill this task. The code segment is as follows:

```
DATA _NULL_;
  CALL SYMPUT("REP",COMPRESS(PUT(&OBS/&LEVELS+1,8)));
RUN;

PROC PLAN;
  FACTORS REPT=&REP ORDERED &CAT=&LEVELS RANDOM/NOPRINT;
  OUTPUT OUT=_MDATA0_;
RUN;
```

where the data null step records the repetition of the random sequence, and the macro variables *OBS*, *CAT*, and *LEVELS* contain values for the number of observations, the name of the categorical variable, and the number of levels, respectively.

There are two types of mock datasets that we often create; datasets having one observation per patient and datasets having multiple observations per patient. The former may record all unique information of patients such as demographic and baseline information, study termination status, randomization code, etc., and the latter may record data from repeated measures such as adverse events, concomitant medications, laboratory evaluations, vital signs, etc. For each study, we first generate a mock population dataset that has such variables as patient identifications, randomization code, and demographic and baseline information. A mock dataset having multiple observations per patient is then created by concatenating N copies of the population dataset with concomitant definitions of dummy variables, where N is a hypothetical

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multiplication factor of observations. The multiplication factor may be any integer other than 1.

To efficiently create mock datasets for a clinical trial, we have written a SAS macro called MDATASET. This macro can help us create one mock dataset per invocation. A mock population dataset is always created first for each study. The macro invocation below creates a mock population dataset POP:

Code 1.1

```
MDATASET(OUTSET=POP,
PTS =|12|11|10|,
VARS =@CAT-INV @LEVELS=4
      @CAT-SEX @LEVELS=2
      @CAT-RACE @LEVELS=3
      @CON-AGE @MEAN=45 @STD=2 @CONFMT=2.
      @CON-DIAS @MEAN=80 @STD=2 @CONFMT=3.
      @CON-SYST @MEAN=120 @STD=3 @CONFMT=3.
      @CON-RESP @MEAN=20 @STD=1 @CONFMT=2.
      @CON-PULS @MEAN=70 @STD=2 @CONFMT=3.);
```

- The parameter OUTSET specifies the output dataset.
- The parameter PTS specifies the number of patients of each treatment group delimited by the symbol '|', and instructs the macro to create patient-number and treatment-code variables.
- The parameter VARS specifies a sequence of variables that are intended to be included in the output dataset, where the keyword @CON specifies a continuous variable and the keyword @CAT specifies a categorical variable. Dummy variables for investigator number (INV), sex, race, age, diastolic blood pressure (DIAS), systolic blood pressure (SYST), respiration rate (RESP), and pulse rate (PULS) are requested through this parameter.

The resulting dummy dataset POP is displayed as follows:

Output 1.1

PT	TMT	AGE	DIAS	SYST	RESP	PULS	INV	SEX	RACE
1	1	43	82	123	19	68	4	2	1
2	1	45	78	120	18	70	2	1	2
3	1	43	78	117	17	68	3	2	3
4	1	43	82	120	18	70	1	1	1
5	1	41	82	120	18	68	4	2	3
6	1	45	86	123	19	70	1	1	2
7	1	43	78	120	18	72	3	2	1
8	1	43	76	120	20	72	2	1	2
9	1	49	78	123	20	72	3	2	3
10	1	49	84	117	19	72	1	1	3
11	1	45	78	120	19	72	2	2	1
12	1	43	82	120	18	70	4	1	2
13	2	45	80	120	19	68	1	2	3
14	2	45	80	120	19	70	3	1	1
15	2	41	82	123	20	72	2	1	2
16	2	45	80	123	20	68	4	2	3
17	2	45	82	120	19	72	4	1	1

18	2	47	80	117	20	66	3	2	2
19	2	49	78	123	22	68	1	2	2
20	2	43	80	123	19	70	2	1	1
21	2	43	82	123	20	72	2	1	3
22	2	45	84	117	21	70	4	2	2
23	2	43	80	123	20	70	3	2	1
24	3	47	76	117	21	70	1	1	3
25	3	47	78	120	19	68	2	2	2
26	3	45	80	120	20	70	3	1	1
27	3	43	80	120	19	72	4	1	3
28	3	43	78	117	21	72	1	2	3
29	3	45	84	126	22	66	2	2	1
30	3	43	82	120	21	68	3	1	2
31	3	45	80	111	19	70	4	1	1
32	3	45	78	117	19	68	1	2	3
33	3	45	84	120	20	68	2	1	2

The macro creates each dummy variable independent to the others. So, the variables are all mutually uncorrelated. The levels of a categorical variable are either consecutive integers starting at 1 or character values (if a keyword @CATFMT is specified). Within the macro, the value of the parameter VARS is decomposed according to the delimiter '!'. Each factor of the decomposition represents a request for a dummy variable. The macro substitutes the string "; %LET" for the prefix "@" of each specified keyword, such as @CON, @CAT, @MEAN, @LEVELS, etc. Therefore, these keywords are internally converted to the %LET macro statements for macro variable definition.

Based upon the mock population dataset, a mock dataset with multiple observations per patient may be produced by using the macro with a specification of a parameter BYVARS. This parameter specifies a sequence of categorical variables with their levels for the macro to create multiple observations per patient identified by the combination level of the categorical variables. For instance, the macro invocation below generates a mock dataset AE for adverse events:

Code 1.2

```
MDATASET(POPSET=POP,
OUTSET=AE,
BYVARS=@CAT-BODYSYS @LEVELS=13 @CATFMT=BODYSYS.
      @CAT-PREFTERM @LEVELS=8 @CATFMT=PREFTERM.
VARS =@CAT-GRADE @LEVELS=5
      @CAT-RELATED @LEVELS=2
      @CAT-PERIOD @LEVELS=2);
```

The parameter BYVARS specifies two categorical variables; body system (BODYSYS) and preferred term (PREFTERM). The option @CATFMT specifies a format for the levels of the corresponding categorical variable and triggers the macro to make it a character variable. This macro execution creates a mock dataset AE with each patient reporting 8 different adverse events (preferred term) of each body system (13 levels). In addition, the variables GRADE, RELATED, and PERIOD are created to identify the severity, relation to treatment, and time period

of each adverse event, respectively. Similarly, the macro invocation below generates a mock dataset MED for prior and concomitant medications:

Code 1.3

```
%DATASET (POPSET=POP,
          OUTSET=MED,
          BYVARS=@CAT-PREFMED @LEVELS=8 @CATFMT=PREFMED. ,
          VARS =@CAT-PHARMCAT @LEVELS=12 @CATFMT=PHARMCAT. |
          @CAT-MPERIOD @LEVELS=2 ) ;
```

This execution creates eight observations per patient identified by the levels of the categorical variable PREFTERM (preferred term of medication), and associates a pharmaceutical category (a total of twelve levels) of medication with each dummy observation. The categorical variable MPERIOD alternatively identifies each observation as prior or concomitant medication.

2. GENERATION OF TABLE SPECIFICATIONS

Based upon a few mock datasets, we use another comprehensive macro SUMCLIN to generate a report-ready dataset upon which one or more summary tables can be easily produced by using the REPORT procedure. This macro is built over a few functional macros that were developed at PRA by the author and were presented at NESUG'96. To produce a summary of demographic and baseline variables AGE, SEX, RACE, and DIAS (diastolic BP) of the mock data set POP created in the previous section, for example, you can use the following macro invocation:

Code 2.1

```
%SUMCLIN (INSET=POP,
          OUTSET=RESULT,
          TMT =TMT,
          INV =INV,
          PT =PT,
          DEMOG =@CON=AGE @STATSET={1|2|3|8|11} @GRPTIT=AGE |
          @CAT=SEX @CATFMT=SEXFMT. @GRPTIT=SEX |
          @CAT=RACE @CATFMT=RACEFMT. @GRPTIT=RACE |
          @CON=DIAS @STATSET={1|2|3|8|11} @GRPTIT=DIAS. BP );
```

- The parameters INSET and OUTSET specify the input and output datasets, respectively;
- The parameter TMT specifies the treatment-code variable;
- The parameters INV and PT specify patient-identification variables (investigator and patient number);

- The parameter DEMOG specifies a list of continuous and categorical variables delimited by the symbol '|' and the associated keywords are explained as follows:
 - @CON specifies a continuous variable;
 - @CAT specifies a categorical variable;
 - @STATSET specifies a set of descriptive summary statistics, such as the mean, standard deviation, minimum, median, maximum, etc., in their code delimited by the symbol '|' for the corresponding continuous variable;
 - @CATFMT specifies a format for the levels of the corresponding categorical variable;
 - @GRPTIT specifies a string of descriptive text for the corresponding variable.

The output dataset from each invocation of the macro is prepared in such a way that a simple application of the REPORT procedure to the dataset can produce a desired summary table. The output dataset from this macro call is displayed as follows:

Output 2.1

SKIP	VARIABLE	C1	C2	C3	C4
1	AGE				
1	N	12	11	10	33
1	MEAN	44.3	44.6	44.8	44.6
1	STD	2.5	2.2	1.5	2.0
1	MEDIAN	43.0	45.0	45.0	45.0
1	MAX	49.0	49.0	47.0	49.0
2	GENDER				
2	FEMALE	6 (50.0)	6 (54.5)	4 (40.0)	16 (48.5)
2	MALE	6 (50.0)	5 (45.5)	6 (60.0)	17 (51.5)
3	RACE				
3	WHITE	4 (33.3)	4 (36.4)	3 (30.0)	11 (33.3)
3	BLACK	4 (33.3)	4 (36.4)	3 (30.0)	11 (33.3)
3	ASIAN	4 (33.3)	3 (27.3)	4 (40.0)	11 (33.3)
4	DIASTOLIC BP				
4	N	12	11	10	33
4	MEAN	80.3	80.7	80.0	80.4
4	STD	3.1	1.6	2.7	2.5
4	MEDIAN	80.0	80.0	80.0	80.0
4	MAX	86.0	84.0	84.0	86.0

where the output variable SKIP is created to identify each summary block, which can be used as an order-skip variable when calling the REPORT procedure. The variable VARIABLE describes each summary row. The output variables C1, C2, and C3 have summary values for the three treatment groups, respectively, and C4 has summary value across treatment groups.

Upon this output dataset, a summary table may be produced by using the following REPORT code:

Code 2.2

```
PROC REPORT DATA=RESULT PS=50 LS=68 SPLIT="|" SPACING=2 HEADLINE;
  COLUMN ('---' SKIP VARIABLE C1-C4);
  DEFINE SKIP/ID ORDER NOPRINT;
  DEFINE VARIABLE/ID DISPLAY "Variable" WIDTH=14 LEFT FLOW;
  DEFINE C1/DISPLAY "TMT 1" -- (N=ANPT1) WIDTH=11 CENTER;
  DEFINE C2/DISPLAY "TMT 2" -- (N=ANPT2) WIDTH=11 CENTER;
  DEFINE C3/DISPLAY "TMT 3" -- (N=ANPT3) WIDTH=11 CENTER;
  DEFINE C4/DISPLAY "TOTAL" -- (N=ANPT4) WIDTH=11 CENTER;
  BREAK AFTER SKIP/SKIP;
RUN;
```

The resulting table is presented below:

Output 2.2

Variable	TMT 1 (N=12)	TMT 2 (N=11)	TMT 3 (N=10)	TOTAL (N=33)
AGE				
N	12	11	10	33
MEAN	44.3	44.6	44.8	44.6
STD	2.5	2.2	1.5	2.0
MEDIAN	43.0	45.0	45.0	45.0
MAX	49.0	49.0	47.0	49.0
GENDER				
FEMALE	6 (50.0)	6 (54.5)	5 (50.0)	17 (51.5)
MALE	6 (50.0)	5 (45.5)	5 (50.0)	16 (48.5)
RACE				
WHITE	4 (33.3)	3 (27.3)	4 (40.0)	11 (33.3)
BLACK	4 (33.3)	4 (36.4)	3 (30.0)	11 (33.3)
ASIAN	4 (33.3)	4 (36.4)	3 (30.0)	11 (33.3)
DIASTOLIC BP				
N	12	11	10	33
MEAN	80.3	80.7	80.0	80.4
STD	3.1	1.6	2.7	2.5
MEDIAN	80.0	80.0	80.0	80.0
MAX	86.0	84.0	84.0	86.0

Since this table is produced based upon a mock dataset, the numbers included in the table is meaningless. We define a macro parameter DUMMYFMT that takes a logical value 1 (yes) or 0 (no) to indicate if the numbers need to be masked by a string 'xxx' for frequencies and 'xxx.x' for others. The macro saves all numeric results to character output variables such as C1, C2, etc. through using the PUT data step function with numerical formats. There are a few keywords defined with the macro for users to control the numerical formats. When the parameter DUMMYFMT is flagged (has a value of 1), the macro internally associates a numeric format FAKEFMT. to each resulting numeric variable regardless the input from users. The numeric format is defined by using the following FORMAT code:

```
PROC FORMAT;
  VALUE FAKEFMT 1-99999='XXX' OTHER='XXX.X';
RUN;
```

If the macro specification of the previous example (Code 2.1) were replaced by:

Code 2.3

```
%SUMCLIN(INSERT=POP,
  OUTSET=RESULT,
  TMT =TMT,
  INV =INV,
  PT =PT,
  DEMOG =@CON=AGE @STATSET=|1|2|3|8|11| @GRPTIT=AGE |
  @CAT=SEX @CATFMT=SEXFMT. @GRPTIT=GENDER |
  @CAT=RACE @CATFMT=RACEFMT. @GRPTIT=RACE |
  @CON=DIAS @STATSET=|1|2|3|8|11| @GRPTIT=DIAS. BP |
  DUMMYFMT=1);
```

then the output (Output 2.2) would have become:

Output 2.3

Variable	TMT 1 (N=12)	TMT 2 (N=11)	TMT 3 (N=10)	TOTAL (N=33)
AGE				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
MEDIAN	XXX.X	XXX.X	XXX.X	XXX.X
MAX	XXX.X	XXX.X	XXX.X	XXX.X
GENDER				
FEMALE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MALE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
RACE				
WHITE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
BLACK	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
ASIAN	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
DIASTOLIC BP				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
MEDIAN	XXX.X	XXX.X	XXX.X	XXX.X
MAX	XXX.X	XXX.X	XXX.X	XXX.X

This is an example of a table specification that usually needs to be done as part of an analysis plan for each study. Advantages of producing table specifications programmatically are as follows:

- Derived datasets and analysis variables may be more vividly described through a set of mock datasets at the time which an analysis plan is prepared;
- All proposed tables are achievable programmatically because their specifications are produced through real SAS code;
- Upon completion of generation of table specifications, the set of table-production programs and their associated formats of variables, titles, footnotes, labels, etc., are all well prepared prior to the availability of the real database. This procedure takes

a little more time at the stage of preparing the analysis plan, but it will save a tremendous amount of time at the stage of producing real tables.

- When the true database of the study is ready, real tables can be easily produced by reassigning a value of 0 to the parameter DUMMYFMT for each macro invocation.

This approach has been applied to many studies. In average, programming time of producing a summary table can be cut by 40-60%. This type of efficiency is very important for a contract research organization like Pharmaceutical Research Associates (PRA). Programmers and statisticians at PRA have to work on table production year round, and they have benefited from the existence of these two macros.

For another example, the macro invocation plus the PROC REPORT code below makes a specification of summary of adverse events by body system and preferred term based upon the mock dataset AE resulted from Code 1.2:

Code 2.4

```
%SUMCLIN(INSET =AE,
  POPSET=POP,
  OUTSET=RESULT,
  TMT      =TMT,
  INV      =INV,
  FT       =FT,
  AEFREQ   = @AETERM  @PREFTERM
            @BODYSYS  @BODYSYS
            @ANYAE=ANY BODY SYSTEM,
  DUMMYFMT=1);

PROC REPORT DATA=RESULT PS=50 LS=132 SPLIT="|" SPACING=2 HEADLINE;
  COLUMN ('---' PAGE SKIP VARIABLE C1-C4);
  DEFINE PAGE/ID ORDER NOPRINT;
  DEFINE SKIP/ID ORDER NOPRINT;
  DEFINE VARIABLE/ID DISPLAY "Variable" WIDTH=19 LEFT FLOW;
  DEFINE C1/DISPLAY "TMT 1|--" (N=ANPT1)" WIDTH=11 CENTER;
  DEFINE C2/DISPLAY "TMT 2|--" (N=ANPT2)" WIDTH=11 CENTER;
  DEFINE C3/DISPLAY "TMT 3|--" (N=ANPT3)" WIDTH=11 CENTER;
  DEFINE C4/DISPLAY "TOTAL|--" (N=ANPT4)" WIDTH=11 CENTER;
  BREAK AFTER PAGE/PAGE;
  BREAK AFTER SKIP/SKIP;
RUN;
```

- The parameter AEFREQ specifies the task of summarizing adverse events, where the keyword @AETERM and @BODYSYS specify the preferred-term and body-system variables, respectively.
- The keyword @ANYAE specifies a string of descriptive text for a summary row of adverse events across all preferred terms and body systems.
- The output variable PAGE and SKIP are created for the REPORT procedure to use as page-break and skip-break variables, respectively.

The output from the REPORT procedure is as follows:

Output 2.4

Variable	TMT 1 (N=12)	TMT 2 (N=12)	TMT 3 (N=10)
ANY BODY SYSTEM	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
BODY AS A WHOLE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 7	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 8	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
CARDIOVASCULAR	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 7	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 8	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
DIGESTIVE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 7	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 8	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

3. APPLICATIONS TO A HYPOTHETICAL STUDY

A hypothetical study is created here to clearly illustrate a sample application of these two macros to analyses of clinical data. This hypothetical study is assumed to be 4 weeks, multi-center (4 levels), randomized, parallel, multi-dose (2 levels: low and high), double-blind, and placebo-controlled. A total of 150 patients will be randomly assigned to one of three treatment groups: low dose, high dose, and placebo. There will be 50 patients in each group. Baseline evaluations will include age, sex, race, height, weight, respiration (RESP) and heart-pulse rates (PULSE), systolic (SYST) and diastolic (DIAS) blood pressures, hemoglobin (HGB), hematocrit (HCT), and serum iron (IRON). Efficacy assessments include HGB, HCT, and IRON made at Weeks 1, 2, 3, and 4 or at the termination of the study. Concomitant medications and adverse events will be recorded during the study period. In addition, the vital signs WEIGHT, RESP, PULSE, SYST, and DIAS will be evaluated once more at the end of study.

The primary efficacy variable of the study is hemoglobin evaluated at the end of study, which will be analyzed by using analysis of variance with effects of center, treatment, and their interaction. Except for an overall treatment comparison, other comparisons of interest are high-dose vs. placebo, low-dose vs. placebo, and high-dose vs. low-

dose in the mean change of hemoglobin from baseline. The other efficacy variables will be analyzed in the same manner.

A Mock Population Dataset

The macro application below creates a mock population dataset **MOCKPOP** with the variables described above as well as variables for treatment group (*TMT*) and patient number (*PT*). The variables *TMT* and *PT* are created due to the specification of the parameter *PTS* which informs the macro the number of treatment groups and the number of patients per treatment group, respectively. In addition, a flag variable for completeness (*COMP*) and a categorical variable of six levels for reason of discontinuation (*REASON*) are also defined with the dataset. The subsequent data step ensures that the categorical variable *REASON* is defined only when a patient does not complete the study (*COMPLETE*=2). There are a total of 22 variables and 150 observations in this mock dataset.

```

%MDATASET(OUTSET=MOCKPOP,
  PTS =|50|50|50|,
  VARS
    @CAT=CENTER @LEVELS=4
    @CAT=SEX @LEVELS=2
    @CAT=RACE @LEVELS=4
    @CON=AGE @MEAN=45 @STD=5 @CONFMT=2.
    @CON=DIAS1 @MEAN=80 @STD=2 @CONFMT=3.
    @CON=SYST1 @MEAN=120 @STD=3 @CONFMT=3.
    @CON=RESP1 @MEAN=20 @STD=1 @CONFMT=2.
    @CON=PULSE1 @MEAN=70 @STD=2 @CONFMT=3.
    @CON=WEIGHT1 @MEAN=140 @STD=20 @CONFMT=3.
    @CON=DIAS2 @MEAN=80 @STD=2 @CONFMT=3.
    @CON=SYST2 @MEAN=120 @STD=3 @CONFMT=3.
    @CON=RESP2 @MEAN=20 @STD=1 @CONFMT=2.
    @CON=PULSE2 @MEAN=70 @STD=2 @CONFMT=3.
    @CON=WEIGHT2 @MEAN=140 @STD=20 @CONFMT=3.
    @CON=HEIGHT @MEAN=5.9 @STD=1 @CONFMT=3.1
    @CON=HGB @MEAN=9.5 @STD=1 @CONFMT=4.1
    @CON=HCT @MEAN=29 @STD=3 @CONFMT=4.1
    @CON=IRON @MEAN=11 @STD=1 @CONFMT=4.1
    @CAT=COMP @LEVELS=2
    @CAT=REASON @LEVELS=6
  );

```

```

DATA MOCKPOP;
  SET MOCK POP;
  IF COMPLETE=1 THEN REASON=.;
RUN;

```

The variable *DIAS1* and *DIAS2* are baseline and post-baseline evaluations of diastolic blood pressure. The other vital signs variables are similarly defined.

A Mock Efficacy Dataset

This mock dataset **MOCKEFF** is created based upon the mock dataset **MOCKPOP**. The three efficacy variables *HGB*, *HCT*, and *IRON* are generated for each patient at each week. The keyword *@CATFMT* specifies a format *weekfmt* for the corresponding variable *WEEK* and instructs the macro to define it as a character variable.

```

PROC FORMAT;
  VALUE WEEKFMT 1="Week 1" 2="Week 2" 3="Week 3" 4="Week 4";
RUN;

```

```

%MDATASET(POPSET=MOCKPOP(KEEP=CENTER PT SEX),
  OUTSET=MOCKEFF,
  BYVARS=@CAT=WEEK @LEVELS=4 @CATFMT=WEEKFMT.
  VARS
    @CON=HGB @MEAN=9.5 @STD=1 @CONFMT=4.
    @CON=HCT @MEAN=29 @STD=3 @CONFMT=4.1
    @CON=IRON @MEAN=11 @STD=1 @CONFMT=4.1
  );

```

A Mock Medication Dataset

The macro invocation below creates a mock medication dataset **MOCKMED**. Each patient is assumed to take one medication (either pre-baseline or post-baseline) from each medication category. The **FORMAT** procedure defines formats *medcat* and *medpref* that are used for the macro to create the medication category and medication preferred term as character variables. The variable *PERIOD* is created to identify if the medication is taken before or during the treatment.

```

PROC FORMAT;
  VALUE MEDPREF 1="MEDICATION 1" 2="MEDICATION 2" 3="MEDICATION 3"
    4="MEDICATION 4" 5="MEDICATION 5" 6="MEDICATION 6";
  VALUE MEDCAT 1="CATEGORY 1" 2="CATEGORY 2" 3="CATEGORY 3"
    4="CATEGORY 4" 5="CATEGORY 5" 6="CATEGORY 6";
%MDATASET(POPSET=MOCKPOP(KEEP=CENTER PT SEX),
  OUTSET=MOCKMED,
  BYVARS=@CAT=MEDCAT @LEVELS=6 @CATFMT=MEDCAT.
  VARS
    @CAT=PREFTERM @LEVELS=6 @CATFMT=MEDPREF.
    @CAT=PERIOD @LEVELS=2 @CATFMT=PERIOD.
  );

```

A Mock Adverse Events Dataset

The mock adverse-events dataset **MOCKAE** is created by the following macro invocation:

```

PROC FORMAT;
  VALUE BODYFMT
    1 = "BODY AS A WHOLE"
    2 = "CARDIOVASCULAR"
    3 = "DIGESTIVE"
    4 = "ENDOCRINE"
    5 = "HEMATIC"
    6 = "METABOLIC/MEDIMUNE"
    7 = "MUSCULOSKELETAL"
    8 = "NERVOUS/PSYCHIATRIC"
    9 = "RESPIRATORY"
    10 = "SKIN"
    11 = "SPECIAL SENSES"
    12 = "UROGENITAL"
  ;
  VALUE PREFMT
    1 = "PREFERRED TERM 1"
    2 = "PREFERRED TERM 2"
    3 = "PREFERRED TERM 3"
    4 = "PREFERRED TERM 4"
    5 = "PREFERRED TERM 5"
    6 = "PREFERRED TERM 6"
    7 = "PREFERRED TERM 7"
    8 = "PREFERRED TERM 8"
  ;
%MDATASET(POPSET=MOCKPOP(KEEP=CENTER PT SEX),
  OUTSET=MOCKAE,
  BYVARS=@CAT=BODYSYS @LEVELS=12 @CATFMT=BODYFMT.
    @CAT=PREFTERM @LEVELS=8 @CATFMT=PREFMT.
  VARS
    @CAT=RELATED @LEVELS=2
    @CAT=INTENS @LEVELS=3
  );

```

The parameter BYVARS specify two categorical variables *BODYSYS* and *PREFTERM* that represent the body system and preferred term of an adverse event, respectively. This specification implies that each patient will report eight different adverse events of each body system. The variable *RELATED* is created to record if an event is related to treatment or not (1=yes, 2=no), and *INTENS* is created to record the intensity of an adverse event with three levels; 1='mild', 2='moderate', and 3='severe'.

Utilizing the mock datasets created above, table specifications for the following summaries can be easily produced:

- Patient Disposition
- Patient Disposition by Center
- Demographic and Baseline Characteristics
- Demographic and Baseline Characteristics by Center
- Prior and Concomitant Medications
- Efficacy Assessments
- Adverse Events by Body System
- Adverse Events by Body System and Intensity
- Vital Signs

Each table specification is generated with an execution of SUMCLIN followed by an application of the REPORT procedure. Since the REPORT code is very straightforward (see Code 2.2) and is very similar from one application to another, the following applications present only macro specification part.

Patient Disposition

The keyword @CATFMT specifies a format for each of the categorical variable, and @INDENT specifies spaces to indent the text of the output variable *VARIABLE* for the summary of the corresponding variable (the default is 2).

```

%SUMCLIN (INSET =MOCKPOP,
          OUTSET=RESULT,
          TMT   =TMT,
          PT    =PT,
          DEMOG =@CAT=COMP @CATFMT=COMP. @INDENT=0
          @CAT=REASON @CATFMT=REASON. @INDENT=2
          @GRP=TT=Reason of Discontinuation,
          DUMMYFMT=1);

```

Variable	Low (N=50)	High (N=50)	Placebo (N=50)
Completed	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Discontinued	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Reason of Discontinuation			
Lack of Compliance	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Abnormal Lab. Values	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Adverse Event	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Death	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Lost of Follow-up	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Other	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

Patient Disposition by Center

The macro SUMCLIN features a parameter STRATA to enable users to specify a categorical variable for a summary stratified by the categorical variable. Hence, this task can be easily achieved by adding a parameter specification "STRATA=center" to the previous example. The code and its results are as follows:

```

%SUMCLIN (INSET =MOCKPOP,
          OUTSET=RESULT,
          TMT   =TMT,
          PT    =PT,
          DEMOG =@CAT=COMP @CATFMT=COMP. @INDENT=0
          @CAT=REASON @CATFMT=REASON. @INDENT=2
          @GRP=TT=Reason of Discontinuation,
          STRATA=CENTER,
          DUMMYFMT=1);

```

CENTER=1

Variable	Low (N=13)	High (N=12)	Placebo (N=13)
Completed	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Discontinued	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Reason of Discontinuation			
Lack of Compliance	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Abnormal Lab. Values	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Adverse Event	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Lost of Follow-up	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Other	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

CENTER=2

Variable	Low (N=12)	High (N=13)	Placebo (N=13)
Completed	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Discontinued	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Reason of Discontinuation			
Lack of Compliance	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Abnormal Lab. Values	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Adverse Event	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Lost of Follow-up	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Other	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

Demographic and Baseline Characteristics

The keyword @STATSET selects a set of descriptive statistics for a continuous variable and @CATVAL specifies all possible categories of a categorical variable in case that there are a few categories defined in a case report form but not observed.

```

%SUMCLIN (INSET =MOCKPOP,
          OUTSET=RESULT,
          TMT   =TMT,
          PT    =PT,

```

```

DEMOG -@CAT-SEX @CATPAT-SEXPAT. @GRPTIT-Gender
@CON-AGE @STATSET-|1|2|3 @GRPTIT-Age
@CAT-Race @CATPAT-RACEPAT. @GRPTIT-Race
@CON-DIAS1 @STATSET-|1|2|3 @GRPTIT-Diastolic BP
@CON-SYST1 @STATSET-|1|2|3 @GRPTIT-Systolic BP
@CON-PULSE1 @STATSET-|1|2|3 @GRPTIT-Pulse Rate
@CON-RESP1 @STATSET-|1|2|3 @GRPTIT-Respiration
@CON-WEIGHT1 @STATSET-|1|2|3 @GRPTIT-Weight
@CON-HEIGHT @STATSET-|1|2|3 @GRPTIT-Height
DUMMYFMT=1;

```

Variable	Low (N=50)	High (N=50)	Placebo (N=50)	TOTAL (N=150)
Gender				
FEMALE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MALE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Age				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
Race				
WHITE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
BLACK	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
ASIAN	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
OTHER	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
Diastolic BP				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
Systolic BP				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
Pulse Rate				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
Respiration				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X
Height				
N	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X

Demographic and Baseline Characteristics by Center

This task can be achieved in the same manner as in the example above for patient disposition by center. Specifically, this can be done by adding the parameter specification "STRATA=center" to the macro invocation of the previous example.

Prior and Concomitant Medications

The parameter POPSET specifies a population dataset that is used for the macro to count the number of treatment groups and the number of patients per treatment group. The parameter AEFREQ is specified to summarize medications in the same manner as to summarize adverse

events (count the number of events by patient). The keywords @AETERM and @BODYSYS specify the preferred-medication-term and medication-category variables, respectively. The parameter RSTRATA is defined within the macro to specify a set of categorical variables for a stratified summary. Here, the variable PERIOD is specified to the parameter, which instructs the macro to summarize medications by time period; prior and concomitant medications. This stratification variable is included in the output dataset and can be included in the BY statement of the REPORT code for a stratified print of the results.

```

%SUMCLIN(INSET -MOCKED,
POPSET -MOCKPOP,
OUTSET -RESULT,
TMT -TMT,
PT -PT,
AEFREQ -AETERM -MEDTERM
@BODYSYS -MEDCAT
@AETERM=ANY MEDICATIONS,
RSTRATA =PERIOD,
DUMMYFMT=1);

```

PERIOD=Prior Medication				
Variable	Low (N=50)	High (N=50)	Placebo (N=50)	TOTAL (N=150)
ANY MEDICATIONS	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
CATEGORY 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
CATEGORY 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

PERIOD=Concomitant Medication				
Variable	Low (N=50)	High (N=50)	Placebo (N=50)	TOTAL (N=150)
ANY MEDICATIONS	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
CATEGORY 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
CATEGORY 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
MEDICATION 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

Efficacy Assessments

The parameter DEMOG is specified in the macro invocation below to summarize more than one variable, and the parameter STRATA is specified to analyze the efficacy variables stratified by visit week. The keyword @PFLAG is flagged to instruct the macro to perform p-value calculations. The keywords @CLASSES and @EFFECTS specify the class variables and model effects of a linear fixed model, respectively, upon which the p-values of treatment effects are calculated. The keyword @PAIRWISE is flagged to instruct the macro to perform a pair-wise comparison of treatment groups and report the associated p-value.

```
%SUMCLIN(INSET =MOCKEFT,
          POPSET=MOCKPOP,
          OUTSET=RESULT,
          TMT =TMT,
          PT =PT,
          DEMOG =@CON=CHG_HGB @STATSET =1|2|3
          @GRPTIT =Hemoglobin @PFLAG=1
          @PAIRWISE=1 @CLASSES=CENTER TMT
          @EFFECTS =CENTER TMT CENTER*TMT
          @CON=CHG_HCT @GRPTIT =Hematocrit @PFLAG=1
          @CON=CHG_IRON @GRPTIT = Serum Iron @PFLAG=1
          RSTRATA =WEEK,
          DUMMYFMT=1);
```

WEEK=Week 1

Variable	Low (N=50)	High (N=50)	Placebo (N=50)	P	P1_2	P1_3	P2_3
Hemoglobin							
N	XXX	XXX	XXX	X.XXX	X.XXX	X.XXX	X.XXX
MEAN	XXX.X	XXX.X	XXX.X				
STD	XXX.X	XXX.X	XXX.X				
Hematocrit							
N	XXX	XXX	XXX	X.XXX	X.XXX	X.XXX	X.XXX
MEAN	XXX.X	XXX.X	XXX.X				
STD	XXX.X	XXX.X	XXX.X				
Serum Iron							
N	XXX	XXX	XXX	X.XXX	X.XXX	X.XXX	X.XXX
MEAN	XXX.X	XXX.X	XXX.X				
STD	XXX.X	XXX.X	XXX.X				

WEEK=Week 2

Variable	Low (N=50)	High (N=50)	Placebo (N=50)	P	P1_2	P1_3	P2_3
Hemoglobin							
N	XXX	XXX	XXX	X.XXX	X.XXX	X.XXX	X.XXX
MEAN	XXX.X	XXX.X	XXX.X				
STD	XXX.X	XXX.X	XXX.X				
Hematocrit							
N	XXX	XXX	XXX	X.XXX	X.XXX	X.XXX	X.XXX
MEAN	XXX.X	XXX.X	XXX.X				
STD	XXX.X	XXX.X	XXX.X				
Serum Iron							
N	XXX	XXX	XXX	X.XXX	X.XXX	X.XXX	X.XXX
MEAN	XXX.X	XXX.X	XXX.X				
STD	XXX.X	XXX.X	XXX.X				

Adverse Events and Vital Signs

The code below generates specifications for three summary tables; summary adverse events by body system, summary of adverse events by body system and intensity, and summary of vital signs. The data step is used to derive variables of change from baseline in vital signs. In this step, an index ID is defined to identify the time point of the vital signs. The parameter TXSTRATA is flagged to instruct the macro to transpose the results along the levels of the stratification variable so that summaries at different levels stay column by column. Similarly, the keyword TXINT is flagged to transpose the results along the intensity levels.

Summary of Adverse Events by Body System

```
%SUMCLIN( INSET =MOCKAE, POPSET=MOCKPOP,
          OUTSET=RESULT, TMT =TMT, PT=PT,
          AREFREQ= EASTERN =PREFTERM
          @BODYSYS =BODYSYS
          @ANYAE=ANY BODY SYSTEM,
          DUMMYFMT=1);
```

Variable	Low (N=50)	High (N=50)	Placebo (N=50)
ANY BODY SYSTEM	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
BODY AS A WHOLE	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 3	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 4	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 5	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 6	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 7	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 8	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
CARDIOVASCULAR	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 1	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)
PREFERRED TERM 2	XXX (XXX.X)	XXX (XXX.X)	XXX (XXX.X)

Summary of Adverse Events by Body System and Intensity

```
%SUMCLIN( INSET =MOCKAE, POPSET=MOCKPOP,
          OUTSET=RESULT, TMT =TMT, PT=PT,
          AREFREQ= EASTERN=PREFTERM @BODYSYS=BODYSYS
          @INTENSITY=INTENS @TXINT=1
          @ANYAE=ANY BODY SYSTEM,
          DUMMYFMT=1);
```

Summary of Vital Signs

```
DATA VITAL(KEEP=CENTER PT ID DIAS SYST PULS RESP);
SET MOCKPOP;
ID=1; DIAS=DIAS1, SYST=SYST1, PULS=PULSE1, RESP=RESP1; OUTPUT;
ID=2; DIAS=DIAS2, SYST=SYST2, PULS=PULSE2, RESP=RESP2; OUTPUT;
ID=3; DIAS=DIAS2-DIAS1, SYST=SYST2-SYST1,
      PULS=PULSE2-PULSE1, RESP=RESP2-RESP1; OUTPUT;
RUN;

%SUMCLIN( INSET =VITAL, POPSET=MOCKPOP,
          OUTSET=RESULT, TMT =TMT, PT=PT,
          DEMOG=@CON=SYST @STATSET=1|2|3|8|11 @GRPTIT=Systemic BP
          @CON=DIAS @STATSET=1|2|3|8|11 @GRPTIT=Diastolic BP
          @CON=PULS @STATSET=1|2|3|8|11 @GRPTIT=Pulse Rate
          @CON=RESP @STATSET=1|2|3|8|11 @GRPTIT=Respiration
          STRATA =ID,
          TXSTRATA=1,
          DUMMYFMT=1);
```

Summary of Adverse Events by Body System and Intensity

Variable	Low (N=50)				High (N=50)				Placebo (N=50)			
	Mi	Mo	Se	Any	Mi	Mo	Se	Any	Mi	Mo	Se	Any
ANY BODY SYSTEM	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
BODY AS A WHOLE	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 1	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 2	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 3	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 4	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 5	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 6	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 7	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 8	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
CARDIOVASCULAR	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 1	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 2	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 3	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 4	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 5	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 6	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 7	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)
PREFERRED TERM 8	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)	XXX	XXX	XXX	XXX (XXX.X)

Summary of Vital Signs

Variable	Low (N=50)			High (N=50)			Placebo (N=50)			TOTAL (N=150)		
	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change	Pre	Post	Change
Systolic BP												
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MIN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MAX	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
Diastolic BP												
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MIN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MAX	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
Pulse Rate												
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MIN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MAX	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
Respiration												
N	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
MEAN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
STD	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MIN	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
MAX	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X

Specifications for a total of nine summary tables were generated above. By the end of this process, not only is a set of table specifications generated, but also the programs, specifications of analysis datasets, and a format library of titles, footnotes, and variable formats are concurrently created as a side product. This approach has been applied to a few studies and has been shown to be very efficient. Tremendous programming time needed to produce real tables may be saved when table specifications are prepared using this approach.

4. REFERENCES

William Sun & David Lago (1996), *Macros Developed for Statistical Summary and Tabulation of Clinical Data*, NESUG'96 Proceedings, 316-325.

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