In drug research it is often necessary to produce a randomization schedule which assigns the treatment each patient is to receive. The purpose of this paper is to demonstrate, via SAS, the production of these tables using Procedures PLAN, PRINTTO and MATRIX, for the Randomized Block Design (balanced). Then, a check for "unusual" randomizations is made by computing the number of runs for each treatment by block.

The concepts and methods presented herein can be applied to many statistical designs but our discussion and example will treat only the Randomized Block Design (balanced) with parameters $B$, $P$ and $T$ where:

- $B$ = number of Blocks,
- $P$ = number of Patients per Block,
- $T$ = number of Treatments.

In our example which follows $B=3$, $P=15$ and $T=3$. Hence, the total number of patients randomized is $B \cdot P = 45$ and the number of treatment repeats within a block is $R = P/T = 5$. The output of PROC PLAN, in this example, is read into a new data set via PROC PRINTTO. Then the desired randomization schedule is produced via PROC MATRIX.

The MATRIX procedure also provides a convenient method of computing the number of runs per treatment by block. The two different types of objects for counting the number of runs associated with treatment $A$, say, are: (1) treatment $A$ and (2) not treatment $A$. Since, within each block, we have $R$ objects of one kind (treatment $A$) and $P-R$ objects of the other kind (not treatment $A$) the mean number of runs is:

$$E(\text{Runs}) = 1 + \frac{2R \cdot (P-R)}{P}.$$

and the standard deviation is:

$$\text{S.D.} = \frac{2R \cdot (P-R) \cdot (2R \cdot (P-R) - R)}{P^2 \cdot (P-1)}.$$

The minimum number of runs is 2 and the maximum is $2R + 1$, (when $T = 2$ the maximum is $2R$). These two parameters together with the mean and standard deviation can be used to identify "unusual" randomizations.

Returning to our example, with $R=5$ and $P=15$ we have:

- $E(\text{Runs}) = 7.67$ and
- $\text{S.D.} = 1.64$

**EXAMPLE**

(Note: expressions that need to be changed for different values of B, P and T are preceded by comment statements and underlined).

```
// EXEC SAS
//T2VFP001 DD UNIT=SYSDA, SPACE=(TRK,(15,5))
OPTIONS NODATE NONUMBER;
PROC PRINTTO UNIT=20 NEW;
DATA INITIAL;
*PROVIDE VALUES OF B,P, AND T WHERE
*B=NUMBER OF BLOCKS
*T=NUMBER OF TREATMENTS;
*P=NUMBER OF PATIENTS PER BLOCK;
*REP/T MUST BE AN INTEGER;
B=3;
T=3;
P=15;
R=P/T;
PROC=BP;
DATA PLAN;
PROC PLAN;
*INPUT THE VALUES OF B AND P;
FACTORS B=3 P=15;
PROC PRINTTO;
DATA PTO;FILE PRINT NOPRINT;
IMPUTE FT2VFP001;
INPUT@2 BLOCK #INPUT = IMPUT;
*INPUT THE VALUE OF P AS YP;
IF BLOCK > 0 THEN INPUT Y1=YP;
IF BLOCK=0 THEN OUTPUT;
DROP BLOCK;
DATA B;
PROC MATRIX;
FETCH INIT DATA=INITIAL;
```

*Developmental work on this paper was completed prior to employment at ABBOTT LABS.*
DATA; SET RUN;  
TITLE: NUMBER OF RUNS BY TREATMENT AND BLOCK;  
PROC PRINT;  
ID ROW;  
DATA; SET TREAGUT;  
DROP ROW;  

TITLE: RANDOMIZATION SCHEDULE;  
* INPUT TITLE OF STUDY;  
TITLE2 DRUG A VS DRUG B IN THE TREATMENT OF KURTOSIS;  
TITLE3 DR, STATISTICS;  
TITLE4 PROTOCOL & UI;  
* DEFINE TREATMENTS BY NAME;  
IF TRT=1 THEN TREATMENT='PLACEBO';  
IF TRT=2 THEN TREATMENT='DRUG_A';  
IF TRT=3 THEN TREATMENT='DRUG_B';  
DROP TRT;  
PROC PRINT; ID PatNO;  

NUMBER OF RUNS BY TREATMENT AND BLOCK  
WHERE THE COLUMNS ARE TREATMENTS AND THE ROWS ARE BLOCKS  
<table>
<thead>
<tr>
<th>ROW</th>
<th>COL1</th>
<th>COL2</th>
<th>COL3</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROW1</td>
<td>4</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>ROW2</td>
<td>8</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>ROW3</td>
<td>8</td>
<td>11</td>
<td>8</td>
</tr>
</tbody>
</table>
# RANDOMIZATION SCHEDULE

**Drug A vs Drug B in the Treatment of Kurtosis**

Dr., Statistics

Protocol 001

<table>
<thead>
<tr>
<th>PATNO</th>
<th>TREATMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>PLACEBO</td>
</tr>
<tr>
<td>2</td>
<td>DRUG_B</td>
</tr>
<tr>
<td>3</td>
<td>DRUG_A</td>
</tr>
<tr>
<td>4</td>
<td>DRUG_B</td>
</tr>
<tr>
<td>5</td>
<td>DRUG_A</td>
</tr>
<tr>
<td>6</td>
<td>DRUG_A</td>
</tr>
</tbody>
</table>

... and so on...

| 49    | PLACEBO   |
| 50    | DRUG_A    |
| 51    | DRUG_B    |
| 52    | DRUG_A    |
| 53    | DRUG_B    |
| 54    | DRUG_B    |

**REFERENCE:**