How SAS is Used at PRACS Institute

by
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and
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What is PRACS?

We are a CRO.

(Contract Research Organization)
What types of Studies?

Some of the types of studies:
- Bioequivalence
- Drug-Drug, Drug-food interaction
- Dermatology Bioequivalence (in vitro, in vivo)
- Cardiac Safety
How is SAS Used?

- Generate Randomizations
- Statistically Analyze Data
- Generate Graphs for Statistical Report
- Generate Tables and Listings for the Final Report
- Generate SAS datasets
Randomizations

%INCLUDE 'S:\SAS Server\Programs\Mac\x2way.mac';
/*
For a 2x2 crossover you will need to enter the following information:
(Directory path of Randomization folder,
Study Number,
"Test Product, Strength, Form and Conditions" - Do not use commas,
Total Number of Subjects,
Number of Subjects per Block,
Number of Alternates,
Random Number Seed for Subjects - Increase the number in this position to the next odd number,
Random Number Seed for Alternates - Increase the number in this position to the next odd number,
"Reason" - Enter the reason the randomization is being run in all lower case letters)
*/
%x2way(F:\PRACS##\STUDY###xxxx.yyy\Scientific Affairs\Statistics\Randomization,
  R0#-####,
  "Test Product Strength Form Conditions",
  "A: TEST PRODUCT",
  "B: REFERENCE PRODUCT",
  32,
  8,
  0,
  357941,
  355961,
  "reason");
RUN;
BE Randomization

%MACRO x2way(PATH, STUDNO, DRUG, TRT1, TRT2, NUMSUBJ, BLOCK_SZ, ALTS, R_SEED1, R_SEED2, REASON);

OPTIONS LINESIZE=100 PAGESIZE=60 NONUMBER;
TITLE1 *PRACS STUDY NO. &STUDNO*;
TITLE3 &DRUG;
TITLE5 &TRT1;
TITLE7 &TRT2;

***This section generates the balanced randomization code for the subjects;
DATA ONE;
   DO BLOCK=1 TO &NUMSUBJ/&BLOCK_SZ;
       DO DUMMY=1 TO &BLOCK_SZ;
          RAN_NO1=RANUNI(&R_SEED1);
          OUTPUT;
       END;
   END;
DATA ONE;
   SET ONE;
   RETAIN SUBJECT 0;
   SUBJECT=SUBJECT+1;
PROC RANK DATA=ONE OUT=TWO;
BY BLOCK;
VAR RAN_NO1;
RANKS RANK;
DATA SEQ1;
  SET TWO;
  IF RANK LE &BLOCK_SZ/2 THEN DO;
    SEQUENCE=1;
    PERIOD_1="A";
    PERIOD_2="B";
    END;
  ELSE DO;
    SEQUENCE=2;
    PERIOD_1="B";
    PERIOD_2="A";
    END;
PROC SORT DATA=SEQ1;
  BY SUBJECT;
  DATA SEQ;
  SET SEQ1 SEQ2;
%END;
%ELSE %IF &ALTS=0 %THEN %DO;
  DATA SEQ;
  SET SEQ1;
%END;
*PROC PRINT DATA=SEQ (KEEP=SUBJECT SEQUENCE PERIOD_1 PERIOD_2);
*RUN;
***This section creates a time and date stamp for use in the log;
DATA _NULL_;
  CALL SYMPUT('EXE_DATE',TRIM(LEFT(PUT(DATE(),MMDDYYs10.))));
  CALL SYMPUT('EXE_TIME',PUT(TIME(),TIME.));
RUN;
***This section creates a comma delimited file for use with data analysis and places it in the study folder;***
DATA _NULL_; 
    FILE "&PATH.\&STUDNO..csv" DSD DLM=','; 
    PUT "&STUDNO'' &DRUG;
DATA _NULL_; 
    FILE "&PATH.\&STUDNO..csv" MOD DSD DLM=','; 
    PUT "SUBJECT'' 'SEQUENCE'' 'PERIOD_1'' 'PERIOD_2'';
DATA _NULL_; 
    SET SEQ; 
    FILE "&PATH.\&STUDNO..csv" MOD DSD DLM=','; 
    PUT SUBJECT SEQUENCE PERIOD_1 PERIOD_2;
***This section prints the randomization code;***
PROC PRINT NOOBS; id SUBJECT; 
    VAR SEQUENCE PERIOD_1 PERIOD_2;
***This section adds the new randomization information to the randomization log;***
DATA _NULL_; 
    FILE "S:\SAS Server\programs\randomizations\log\randlog.csv" MOD DSD DLM=','; 
    PUT "&STUDNO'' ',' &BLOCK_SZ'' ',' &ALTS'' ',' &R_SEED1'' ',' &R_SEED2'' ',' &SYSUSERID'' ',' &EXE_DATE'' ',' &EXE_TIME'' ',' &REASON'' ; 
    RUN; 
***This section generates a text file for import into Study Monitor;***
DATA _NULL_; 
    SET SEQ; 
    FILE "F:\Random\&STUDNO..txt" DSD DLM=','; 
    PUT "&STUDNO'' ',' SUBJECT Z3. ',' PERIOD_1 PERIOD_2 ',' ',' '' @''; 
RUN; 
RUN; 
%MEND x2way;
<table>
<thead>
<tr>
<th>SUBJECT SEQUENCE</th>
<th>PERIOD_1</th>
<th>PERIOD_2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>2</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>3</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>4</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>5</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>6</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>7</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>8</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>9</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>10</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>11</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>12</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>13</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>14</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>15</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>16</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>17</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>18</td>
<td>1 A</td>
<td>B</td>
</tr>
<tr>
<td>19</td>
<td>2 B</td>
<td>A</td>
</tr>
<tr>
<td>20</td>
<td>1 A</td>
<td>B</td>
</tr>
</tbody>
</table>
Study txt file

R0#-####,01,A,B,,,,,@
R0#-####,02,B,A,,,,,@
R0#-####,03,B,A,,,,,@
R0#-####,04,A,B,,,,,@
R0#-####,05,B,A,,,,,@
R0#-####,06,B,A,,,,,@
R0#-####,07,A,B,,,,,@
R0#-####,08,B,A,,,,,@
R0#-####,09,B,A,,,,,@
R0#-####,10,B,A,,,,,@
R0#-####,11,B,A,,,,,@
R0#-####,12,B,A,,,,,@
Analyzing Data

%LET path= F:\PRACS\STUDY\XXXX.YYY\Statistics; /* path to study folder */
%LET sponsor= SPONSOR; /* COMPLETE SPONSOR NAME */
%LET test= TEST PRODU /* TEST DRUG NAME AMOUNT & FORM */
%LET studno= R0#-####; /* STUDY NUMBER */
%LET type= CONDITIONS; /* FASTING OR NON-FASTING */
%LET matrix= MATRIX; /* PLASMA, SERUM, OR WHOLE BLOOD ENTERED IN ALL CAPS */
*%LET draws= C1-C##; /* NUMBER OF DRAW TIMES (CONCENTRATIONS) */
*%LET concfile= CONCENTRATIONS_; /* INPUT: NAME OF CONCENTRATION FILE */
%LET pkfile= PK_; /* INPUT: NAME OF PK FILE */
%LET sumfile= SUMMARY_; /* OUTPUT: NAME OF SUMMARY OUTPUT FILE */
*%LET analyte= ; /* NAME OF ANALYTE IF MORE THAN ONE */
FILENAME CSVPK ";*Input pk parameters;
DATA PARAMS;
  INFILE CSVPK MISSOVER DSD;
  INPUT SUBJECT : SEQUENCE : PERIOD : PRODUCT :$ AUCT :
  AUCINF : CMAX : TMAX : KEL : THALF ;;
  LAUCT=LOG(AUCT);
  LAUCINF=LOG(AUCINF);
  LCMAX=LOG(CMAX);
RUN;
PROC SORT DATA=PARAMS;
  BY PRODUCT SUBJECT;
RUN;
PROC GLM DATA=PARAMS OUTSTAT=TANOVA;
/*Perform ANOVA using full model, TANOVA is the output from the ANOVA tables;

CLASS SEQUENCE SUBJECT PERIOD PRODUCT;
MODEL AUCT-LCMAX = SEQUENCE
SUBJECT(SEQUENCE) PRODUCT PERIOD/SS3;
ESTIMATE 'TEST-REFERENCE' PRODUCT 1 -1;
TEST H=SEQUENCE
E=SUBJECT(SEQUENCE)/HTYPE=3 ETYPE=3;
LSMEANS PRODUCT PERIOD/STDERR PDIFF
OUT=LSMEAN1; *LSMEAN1 includes the lsmeans of product and period means;
RUN;
DATA _NULL_; *Create an output file for the Summary Table in Excel;
    FILE "&path.SAS&sumfile..CSV" DSD DLM=';';
    PUT '_NAME_' ',' 'TEST' ',' 'REF' ',' 'GM_TEST' ',
        'GM_REF' ',' 'RATIO' ',' 'MSE' ',' 'LL90' ',' 'UL90' ',
        'PVALUE' ',' 'POWER' ',' 'CV';
RUN;

DATA _NULL_; SET SUMMARY_ALL;
    FILE "&path.SAS&sumfile..CSV" MOD DSD DLM=';';
    PUT '_NAME_' TEST REF GM_TEST GM_REF
        RATIO MSE LL90 UL90 PVALUE POWER CV;
RUN;
<table>
<thead>
<tr>
<th><em>NAME</em></th>
<th>TEST</th>
<th>REF</th>
<th>GM_TEST</th>
<th>GM_REF</th>
<th>RATIO</th>
<th>MSE</th>
<th>LL90</th>
<th>UL90</th>
<th>PVALUE</th>
<th>POWER</th>
<th>CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>LCMAX</td>
<td>7.370517</td>
<td>7.732923</td>
<td>1588.455</td>
<td>2282.264</td>
<td>0.005213</td>
<td>66.89832</td>
<td>72.41074</td>
<td>4.98E-12</td>
<td>1</td>
<td>7.229208</td>
<td></td>
</tr>
<tr>
<td>LAUCT</td>
<td>11.75226</td>
<td>12.07536</td>
<td>127040.6</td>
<td>175493.6</td>
<td>0.011708</td>
<td>68.2201</td>
<td>76.81566</td>
<td>2.14E-08</td>
<td>0.999986</td>
<td>10.85215</td>
<td></td>
</tr>
<tr>
<td>LAUCINF</td>
<td>11.86537</td>
<td>12.15666</td>
<td>142253.5</td>
<td>190356.7</td>
<td>0.009852</td>
<td>70.77127</td>
<td>78.9101</td>
<td>2.78E-08</td>
<td>0.999999</td>
<td>9.950112</td>
<td></td>
</tr>
<tr>
<td>LAUC12</td>
<td>9.166504</td>
<td>9.613874</td>
<td>9571.101</td>
<td>14971.05</td>
<td>0.010327</td>
<td>60.46564</td>
<td>67.59435</td>
<td>4.46E-11</td>
<td>0.999998</td>
<td>10.18835</td>
<td></td>
</tr>
<tr>
<td>CMAX</td>
<td>1608.35</td>
<td>2315.6</td>
<td>69.45716</td>
<td>25561.68</td>
<td>65.67102</td>
<td>73.2433</td>
<td>4.12E-11</td>
<td>1</td>
<td>0.121186</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUCTR</td>
<td>131149.5</td>
<td>181651.5</td>
<td>72.19842</td>
<td>3.72E+08</td>
<td>66.37545</td>
<td>78.02139</td>
<td>1.50E-07</td>
<td>0.999872</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUCINF</td>
<td>148830.9</td>
<td>198349.7</td>
<td>75.03457</td>
<td>3.71E+08</td>
<td>69.71069</td>
<td>80.35845</td>
<td>1.94E-07</td>
<td>0.999985</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUC12</td>
<td>9785.745</td>
<td>15230.06</td>
<td>64.25283</td>
<td>1498724</td>
<td>59.84501</td>
<td>68.66066</td>
<td>3.77E-11</td>
<td>1</td>
<td>0.121186</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TMAX</td>
<td>29.9</td>
<td>27.75</td>
<td>107.7477</td>
<td>38.66944</td>
<td>95.45961</td>
<td>120.0359</td>
<td>0.288662</td>
<td>0.760925</td>
<td>2.49E+10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>KEL</td>
<td>0.016475</td>
<td>0.018065</td>
<td>91.19845</td>
<td>1.47E-06</td>
<td>87.51987</td>
<td>94.87703</td>
<td>0.000603</td>
<td>1</td>
<td>0.121186</td>
<td></td>
<td></td>
</tr>
<tr>
<td>THALF</td>
<td>44.1945</td>
<td>39.6385</td>
<td>111.4939</td>
<td>14.90275</td>
<td>106.1534</td>
<td>116.8344</td>
<td>0.001526</td>
<td>0.999984</td>
<td>172222.9</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Ln-Transformed Data

<table>
<thead>
<tr>
<th>PK Variable</th>
<th>Least Squares Mean</th>
<th>Geometric Mean</th>
<th>90% Confidence Interval</th>
<th>P-values for Product Effects</th>
<th>Power of ANOVA</th>
<th>ANOVA % CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Reference</td>
<td>Test</td>
<td>Reference</td>
<td>% Ratio</td>
<td>(Lower Limit, Upper Limit)</td>
<td></td>
</tr>
<tr>
<td>Cmax</td>
<td>7.371</td>
<td>7.733</td>
<td>1588.46</td>
<td>2282.26</td>
<td>69.60</td>
<td>(66.9, 72.41)</td>
</tr>
<tr>
<td>AUC0-t</td>
<td>11.752</td>
<td>12.075</td>
<td>127040.57</td>
<td>175493.63</td>
<td>72.39</td>
<td>(68.22, 76.82)</td>
</tr>
<tr>
<td>AUC0-inf</td>
<td>11.865</td>
<td>12.157</td>
<td>142253.52</td>
<td>190356.73</td>
<td>74.73</td>
<td>(70.77, 78.91)</td>
</tr>
<tr>
<td>AUC0-12</td>
<td>9.167</td>
<td>9.614</td>
<td>9571.10</td>
<td>14971.05</td>
<td>63.93</td>
<td>(60.47, 67.59)</td>
</tr>
</tbody>
</table>

## Non-Transformed Data

<table>
<thead>
<tr>
<th>PK Variable</th>
<th>Least Squares Mean</th>
<th>90% Confidence Interval</th>
<th>P-values for Product Effects</th>
<th>Power of ANOVA</th>
<th>ANOVA % CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>Reference</td>
<td>Test</td>
<td>% Ratio</td>
<td>(Lower Limit, Upper Limit)</td>
<td></td>
</tr>
<tr>
<td>Cmax</td>
<td>1608.35</td>
<td>2315.60</td>
<td>69.46</td>
<td>(65.67, 73.24)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AUC0-t</td>
<td>131149.54</td>
<td>181651.54</td>
<td>72.20</td>
<td>(66.38, 78.02)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AUC0-inf</td>
<td>148830.88</td>
<td>198349.74</td>
<td>75.03</td>
<td>(69.71, 80.36)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>AUC0-12</td>
<td>9785.75</td>
<td>15230.06</td>
<td>64.25</td>
<td>(59.85, 68.66)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Tmax</td>
<td>29.90</td>
<td>27.75</td>
<td>107.75</td>
<td>(95.46, 120.04)</td>
<td>0.2887</td>
</tr>
<tr>
<td>Kel</td>
<td>0.0165</td>
<td>0.0181</td>
<td>91.20</td>
<td>(87.52, 94.88)</td>
<td>0.0006</td>
</tr>
<tr>
<td>T1/2</td>
<td>44.19</td>
<td>39.64</td>
<td>111.49</td>
<td>(106.15, 116.83)</td>
<td>0.0015</td>
</tr>
</tbody>
</table>

Geometric means are based on least squares means of ln-transformed values.
Using SAS to produce Graphs

```
%LET path= F:\PRACS##\STUDY\###XXXX.YYY\Statistics; /* path to study folder */
*%LET path= F:*%LET path= F:\PRACS06\STUDY\###XXXX.YYY\SCIENTIFIC AFFAIRS\Statistics; /* path to study folder */
%LET sponsor= Sponsor; /* Complete Sponsor Name */
%LET test= Drug; /* Complete Drug Name (same as in results template) */
%LET studyno= R0#-####; /* PRACS study number */
%LET type= Condition; /* Fasting or Non-Fasting */
%LET matrix= Matrix; /* Plasma, Serum, OR Whole Blood */
%LET draws= C1-C##; /* number of draw times (concentrations) */
%LET concfile= CONC_; /* name of concentration file */
%LET units= ng/mL; /* concentration units: ng/mL, pg/ml, or µg/mL */
%LET draw= ##; /* Last draw time */
%LET pageno= 0; /* The number BEFORE the page number graphs start on for final report (i.e. if the first page of the final report should be 53, you should put the number 52 in here */
%LET BY= 0; /* The x-axis will go from 0 to &draw by &by */
```
DATA ORIG1;
  INFILE CSVORIG MISSOVER DSD FIRSTOBS=2; /* Use if Lab data is Watson */
  INPUT Subject : Sequence : Period : Product : &draws ; /* Use if Lab data is Watson */
  LABEL
    C1='0.00 hr'
    C2='0.50 hr'
    C3='1.00 hr'
    C4='1.50 hr'
    C5='2.00 hr'
    C6='2.50 hr'
PROC SORT DATA=ORIG1;
  BY Subject;
RUN;

DATA ORIG;
  SET ORIG1 (KEEP= Subject Product &draws);
PROC TRANSPOSE DATA=ORIG OUT=T_ORIG;
  BY Subject;
  ID PRODUCT;
  VAR &draws;
RUN;

DATA A;
  SET T_ORIG;
  PRODUCT='A:TEST';
  CONC=A;
  TIME_T=_LABEL_; 
  KEEP PRODUCT Subject TIME_T CONC;

DATA B;
  SET T_ORIG;
  PRODUCT='B:REFERENCE';
  CONC=B;
  TIME_T=_LABEL_; 
  KEEP PRODUCT Subject TIME_T CONC;

DATA ALL;
  SET B A;
  TIME=INPUT(TIME_T, 4.2);
PROC SORT DATA=ALL;
  BY Subject PRODUCT TIME;
RUN;
PROC PRINT DATA=ALL; RUN;
data All1;
retain figure 0;
set all;
by Subject;
if first.Subject then figure=figure+1;
run;

data ALL2;
retain page &pageno.;
set ALL1;
by Subject;
if first.Subject then page=page+1;
run;

PROC SORT DATA=ALL2;
BY Subject page figure PRODUCT TIME;
run;
proc print data=ALL2;
run;
axis1 label=(font=complex 'Time (hours)') order=0 to &draw. BY &BY.;
axis2 label=(a=90 r=0 font=complex "Concentration (&units.)");
*axis2 label=(a=90 r=0 font=complex "Concentration (" font=greek 'm' font=complex 'g/mL')");
axis3 label=(font=complex 'Time (hours)') order=0 to &draw. BY &BY.;
axis4 logbase=10 logstyle=expand label=(a=90 r=0 font=complex "Concentration (&units.)");
*axis4 logbase=10 logstyle=expand label=(a=90 r=0 font=complex "Concentration (" font=greek 'm' font=complex 'g/mL')");
legend1 frame label=none shape=symbol(4,.6);

SYMBOL1 font=marker value=P I=JOIN C=BLUE l=1 w=1 h=.5;
SYMBOL2 V=Square I=JOIN C=magenta l=8 w=1 h=.6;
PROC GPLOT DATA=ALL2 uniform;
BY Subject page figure;
goptions hby=0 noborder vpos=42 hpos=98;
*fby=complex and hby=1 is for the font and height of by statement variables;
TITLE1 font=complex color=black height=1 justify=left "&sponsor." justify=right "&test.";
'Statistics - #byval2.' justify=right "&test.";
TITLE2 font=complex color=black height=1 justify=left "PRACS Study No. &studyno." justify=right "&type.";
TITLE3 font=complex color=red height=2 'PRELIMINARY';
TITLE4 font=complex color=black height=1.5 'Subject #byval1.';
TITLE5 font=complex color=black height=1 " ";
TITLE6 font=complex color=black height=1 'Figure 3.#byval3.a';
TITLE7 font=complex color=black height=1 "&matrix. Concentrations (0 - &draw. hours)"
TITLE8 font=complex color=black height=1 " ";
PLOT CONC*TIME=PRODUCT / skipmiss vaxis=axis2 haxis=axis1 legend=legend1;
RUN;
goptions hby=0 vpos=42 hpos=98;
TITLE1 font=complex color=black height=3 " ";
TITLE2 font=complex color=black height=1 'Figure 3.byval3.b';
TITLE3 font=complex color=black height=1 "&matrix. Concentrations (0 - &draw. hours)"
TITLE4 font=complex color=black height=1 " "
TITLE5 font=complex color=black height=1 'Semi-Logarithmic Scale'
TITLE6 font=complex color=black height=1 " "
footnote1 font=complex color=black height=1 'Statistics - #byval2.' justify=right
'PRACS Institute, Ltd. - Cetero Research'
footnote2 font=complex color=black height=1 " "
PLOT CONC*TIME=PRODUCT / skipmiss vaxis=axis4 haxis=axis3 legend=legend1;
RUN;

data numgraf;
rc=gset('catalog','work','gseg');
rc=ginit();
call gask('numgraph',grsegcnt,rc);
call symput('loop',int(grsegcnt/2));
rc=gterm();
run;

ods pdf file = "&path.\&studyno. Individual Graphs.pdf";
/* Use macro %DO loop to repeat TREPLAY statement */

%macro greplay;
proc greplay nofs igout=work.gseg gout=work.cat
tc=sashelp.templt;
tdef v2
  1/ color=white
  2/ color=white;
template v2;
%do i=1 %to &loop;
treplay 1:&i 2:%eval(&i+&loop);
run;
%end;
quit;
%mend greplay;
/* turn dispay on */
goptions display;
/* invoke GREPLAY macro */
%greplay
quit;

ods pdf close;
run;
quit;
Graphing the Concentration Data

Subject 7
Plasma Concentration (0 - 36 hours)
Semi-log scale

Mean Plasma Concentration (0 - 36 hours)
Semi-Logarithmic Scale
N=18

Concentration (ng/mL)

Time (hours)

A: TEST
B: REFERENCE
SAS for Data Management
Using the Escape Character

What is the Escape Character?
- The escape character is a character designated with the ODS ESCAPECHAR = option

What is it for?
- Through the use of control words SAS can use the escape character to take advantage of formatting in RTF, PDF, and HTML files

Common uses at PRACS for the escape character?
1. Superscripting / Subscripting
2. Pagination
3. Assigning style attributes
An example at PRACS

AE Report

1. Code
2. Output
Other uses

1. Other RTF control words
2. Changing Style attributes
   1. Code
   2. Output
3. Adding images
Millhouse: "Bart, I don't want you to see me cry."

Bart: "Oh come on, I've seen you cry a million times. You cry when you scrape your knee, you cry when they're out of chocolate milk, you cry when you're doing long division and you have a remainder left over."
Thank you
Adding RTF Control Words

Beginning with Release 8.1, you can use RTF control words within the TITLE and FOOTNOTE statements. You must set the attribute PROTECTSPECIALCHARS=OFF so that ODS does not try to protect these characters. Set the attribute within the style element SystemTitle for the titles and SystemFooter for the footnotes. Below is a list of some commonly used control words.


<table>
<thead>
<tr>
<th>Style</th>
<th>RTF Control Word</th>
<th>Example Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italicize</td>
<td>\i</td>
<td>\i italicized title;</td>
</tr>
<tr>
<td>Underline</td>
<td>\ul</td>
<td>\ul underline title;</td>
</tr>
<tr>
<td>Double underline</td>
<td>\dul</td>
<td>\dul title;</td>
</tr>
<tr>
<td>New line</td>
<td>\line</td>
<td>this is the first \line this is the second ;</td>
</tr>
<tr>
<td>Bullet</td>
<td>\bullet</td>
<td>\bullet bullet preceding title;</td>
</tr>
<tr>
<td>Emboss</td>
<td>\embo</td>
<td>\embo embossed title;</td>
</tr>
<tr>
<td>Engrave</td>
<td>\impr</td>
<td>\impr engraved title;</td>
</tr>
<tr>
<td>Subscript</td>
<td>\sub</td>
<td>This is a subscript T\sub 1;</td>
</tr>
<tr>
<td>Superscript</td>
<td>\super</td>
<td>This is a subscript T\super 2;</td>
</tr>
<tr>
<td>Outline</td>
<td>\outl</td>
<td>This is outlined;</td>
</tr>
<tr>
<td>Shadow</td>
<td>\shad</td>
<td>This is shadowed;</td>
</tr>
<tr>
<td>Strike</td>
<td>\strike</td>
<td>This is striked;</td>
</tr>
<tr>
<td>double strike</td>
<td>\strikedl</td>
<td></td>
</tr>
<tr>
<td>dotted underline</td>
<td>\uld</td>
<td>uld dotted underline;</td>
</tr>
<tr>
<td>Wave underline</td>
<td>\ulw</td>
<td>ulw wave underline;</td>
</tr>
<tr>
<td>Thick underline</td>
<td>\ulth</td>
<td>ulth thick underline;</td>
</tr>
<tr>
<td>foreground color</td>
<td>\cf2</td>
<td>cf2 foreground color;</td>
</tr>
<tr>
<td>Font size in half points</td>
<td>\fs24</td>
<td>\fs24 fonts increased;</td>
</tr>
<tr>
<td>Highlight</td>
<td>\highlightN</td>
<td>highlight2;</td>
</tr>
<tr>
<td>Alignment</td>
<td>\code{format}</td>
<td>Result</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Bold</td>
<td>\texttt{\b}</td>
<td>title \texttt{\b bold title};</td>
</tr>
<tr>
<td>Left aligned</td>
<td>\texttt{\ql}</td>
<td>title \texttt{\ql left aligned}.</td>
</tr>
<tr>
<td>Right aligned</td>
<td>\texttt{\qr}</td>
<td>title \texttt{\qr right aligned}.</td>
</tr>
<tr>
<td>Centered</td>
<td>\texttt{\qc}</td>
<td>title \texttt{\qc left aligned}.</td>
</tr>
</tbody>
</table>

Source:
http://support.sas.com/rnd/base/ods/templateFAQ/Template_rtf.html#escapechar
/* An example of In-Line formatting using ~S={style_attribute=attribute_value} */
data styles;
  input  #1 @1 style $80. ;
cards;
  ~S={font_face=Arial}Arial
  ~S={font_face=Times}Times
  ~S={font_style=Italic}Italic
  ~S={font_style=Roman}Roman
  ~S={font_style=Slant}Slant
  ~S={font_weight=bold}Bold
  ~S={font_weight=light}Light
  ~S={font_face=Arial font_style=Italic font_weight=bold} Bold Italic Arial
;run;
ods rtf;
ods escapechar = '~';
title '~S={font_weight=Extra_bold}A~S={font_weight=light}n ~S={font_style=Slant font_face=Arial
  font_weight=light}example of In-Line formatting';
proc print;run;
ods rtf close;
An example of In-Line formatting

<table>
<thead>
<tr>
<th>Obs</th>
<th>style</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Arial</td>
</tr>
<tr>
<td>2</td>
<td>Times</td>
</tr>
<tr>
<td>3</td>
<td><em>Italic</em></td>
</tr>
<tr>
<td>4</td>
<td>Roman</td>
</tr>
<tr>
<td>5</td>
<td>Slant</td>
</tr>
<tr>
<td>6</td>
<td>Bold</td>
</tr>
<tr>
<td>7</td>
<td>Light</td>
</tr>
<tr>
<td>8</td>
<td><strong>Bold Italic Arial</strong></td>
</tr>
</tbody>
</table>
PROC REPORT DATA= AE_FREQ SPLIT='#' HEADLINE HEADSKIP nowindows ;
by TRT;
COLUMN TRT SOC PT ('Subjects Who Experienced Indicated AE at Least Once by Intensity and Relationship' 'Mild' Mild_Y Mild_N) ('Moderate' Moderate_Y Moderate_N) ('Severe' Severe_Y Severe_N) TOTAL,('Total' Total_Y Total_N Total_N)Total_Over
OverFooter;
DEFINE TRT / ORDER NOPRINT;
DEFINE SOC / ORDER order=data WIDTH = 20 left FLOW 'System Organ Class' style={cellwidth=2in};
DEFINE PT   / display 'Preferred Term' WIDTH = 20 left FLOW style={cellwidth=1.1in};
DEFINE MILD_Y / DISPLAY 'Related' WIDTH = 10 center FLOW style={cellwidth=.75in};
DEFINE MILD_N / DISPLAY 'NR'  WIDTH = 10 center FLOW style={cellwidth=.75in};
DEFINE MODERATE_Y / DISPLAY 'Related' WIDTH = 10 center FLOW style={cellwidth=.75in};
DEFINE MODERATE_N / DISPLAY 'NR'  WIDTH = 10 center FLOW style={cellwidth=.75in};
DEFINE SEVERE_Y / DISPLAY 'Related' WIDTH = 10 center FLOW style={cellwidth=.75in};
DEFINE SEVERE_N / DISPLAY 'NR'  WIDTH = 10 center FLOW style={cellwidth=.75in};
DEFINE TOTAL  / ACROSS ' ' WIDTH = 10 center FLOW;
DEFINE TOTAL_Y / DISPLAY 'Related' WIDTH = 10 center FLOW style={cellwidth=.60in};
DEFINE TOTAL_N / DISPLAY 'NR'  WIDTH = 10 center FLOW style={cellwidth=.50in};
DEFINE TOTAL_OVER / DISPLAY 'Overall' WIDTH = 10 center FLOW style={cellwidth=.55in};
define OverFooter   / noprint missing;
break after SOC /SKIP;
break after TRT /page;
compute before _page_;
    trtvar = symget(TRT);
    line '';
    line "Treatment " TRT $1. ": Adverse Events";
    line "N = " trtvar $2. '^(super a)' ;
endcomp;
compute after _page_;
    line 5 "(super a) = Number of subjects dosed with Treatment " ;
    line 5 "(super b) = Total number of subjects reporting at least one incidence of respective adverse event";
    line 5 "(super c) = Total number of reported adverse events";
   line 5 OverFooter $100. ;
endcomp;
RUN;
ods rtf close;
### Treatment A: Adverse Events

N = 36

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac disorders</td>
<td>Tachycardia</td>
<td>Related</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Dry mouth</td>
<td>Related</td>
<td>2 (5.56%)</td>
<td>1 (2.78%)</td>
<td>0</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Nasopharyngitis</td>
<td>Related</td>
<td>0</td>
<td>1 (2.78%)</td>
<td>0</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Pain in extremity</td>
<td>Related</td>
<td>0</td>
<td>0</td>
<td>1 (2.78%)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
<td>Related</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Contusion</td>
<td>Related</td>
<td>1 (2.78%)</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Total Number of AEs reported**

| Total Number of AEs reported | 4 | 3 | 1 | 2 | 0 | 0 | 5 | 5 | 10 |

**Total Number of Subjects Reporting at Least One AE by Intensity and Relationship**

| Total Number of Subjects Reporting at Least One AE by Intensity and Relationship | 4 | 3 | 1 | 2 | 0 | 0 | 0 | 0 | 0 |
### Treatment A: Adverse Events

N = 36<sup>a</sup>

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Total No. of AEs&lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number of Subjects Reporting At Least One AE Over the Course of the Study</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5</td>
</tr>
</tbody>
</table>

<sup>a</sup> = Number of subjects dosed with Treatment  
<sup>b</sup> = Total number of subjects reporting at least one incidence of respective adverse event  
<sup>c</sup> = Total number of reported adverse events  
<sup>d</sup> = There was 1 subject who experienced both related and unrelated AEs
## Treatment B: Adverse Events

**N = 36**

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
<th>Related</th>
<th>NR</th>
<th>Related</th>
<th>NR</th>
<th>Related</th>
<th>NR</th>
<th>Related</th>
<th>NR</th>
<th>Total</th>
<th>NR</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Dry mouth</td>
<td>2 (5.56%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Dry throat</td>
<td>1 (2.78%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Feeling of body temperature change</td>
<td>0 (2.78%)</td>
<td>0</td>
<td>1 (2.78%)</td>
<td>45</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (2.78%)</td>
<td>45</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
<td>3 (8.33%)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Pharyngolaryngeal pain</td>
<td>0 (2.78%)</td>
<td>0</td>
<td>1 (2.78%)</td>
<td>22</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Pallor</td>
<td>0 (2.78%)</td>
<td>0</td>
<td>1 (2.78%)</td>
<td>45</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total Number of AEs reported</td>
<td></td>
<td>6</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>6</td>
<td>12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Number of Subjects Reporting at Least One AE by Intensity and Relationship</td>
<td></td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Treatment B: Adverse Events

N = 36\(^a\)

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Preferred Term</th>
<th>Total No. of AEs(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td>Total Number of Subjects Reporting At Least One AE Over the Course of the Study</td>
<td></td>
<td>Related</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) = Number of subjects dosed with Treatment  
\(^b\) = Total number of subjects reporting at least one incidence of respective adverse event  
\(^c\) = Total number of reported adverse events