

# How SAS is Used at PRACS Institute

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# **PRACS Institute, Ltd. –Cetero Research**

**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\####xxx.yy\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;
```

R##-### DRUG XYZ 400 MG TABLETS FASTING

SUBJECT SEQUENC PERIOD\_1 PERIOD\_2

1	1 A	B
2	1 A	B
3	2 B	A
4	2 B	A
5	1 A	B
6	2 B	A
7	1 A	B
8	2 B	A
9	1 A	B
10	1 A	B
11	2 B	A
12	2 B	A
13	1 A	B
14	2 B	A
15	1 A	B
16	2 B	A
17	2 B	A
18	1 A	B
19	2 B	A
20	1 A	B

# 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\###XXX.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 */
```

# Reading in parameters

```
FILENAME CSVPK "&path.\SAS\&pkfile..CSV"; *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;
```

```
TITLE7 'STATISTICAL ANALYSIS OF PHARMACOKINETIC  
PARAMETERS';
```

```
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;
```

# Summary.csv

_NAME_	TEST	REF	GM_TEST	GM_REF	RATIO	MSE	LL90	UL90	PVALUE	POWER	CV
LCMAX	7.370517	7.732923	1588.455	2282.264	69.59998	0.005213	66.89832	72.41074	4.98E-12	1	7.229208
LAUCT	11.75226	12.07536	127040.6	175493.6	72.39041	0.011708	68.2201	76.81566	2.14E-08	0.999986	10.85215
LAUCINF	11.86537	12.15666	142253.5	190356.7	74.72997	0.009852	70.77127	78.9101	2.78E-08	0.999999	9.950112
LAUC12	9.166504	9.613874	9571.101	14971.05	63.93071	0.010327	60.46564	67.59435	4.46E-11	0.999998	10.18835
CMAX	1608.35	2315.6			69.45716	25561.68	65.67102	73.2433	4.12E-11	1	
AUCT	131149.5	181651.5			72.19842	3.72E+08	66.37545	78.02139	1.50E-07	0.999872	
AUCINF	148830.9	198349.7			75.03457	3.71E+08	69.71069	80.35845	1.94E-07	0.999985	
AUC12	9785.745	15230.06			64.25283	1498724	59.84501	68.66066	3.77E-11	1	
TMAX	29.9	27.75			107.7477	38.66944	95.45961	120.0359	0.288662	0.760925	2.49E+10
KEL	0.016475	0.018065			91.19845	1.47E-06	87.51987	94.87703	0.000603	1	0.121186
THALF	44.1945	39.6385			111.4939	14.90275	106.1534	116.8344	0.001526	0.999984	172222.9

**PRELIMINARY**

Table 4  
Summary of Statistical Analysis  
N=20

Ln-Transformed Data									
PK Variable	Least Squares Mean		Geometric Mean		% Ratio	90% Confidence Interval	P-values for Product Effects	Power of ANOVA	ANOVA % CV
	Test	Reference	Test	Reference		(Lower Limit, Upper Limit)			
C <sub>max</sub>	7.371	7.733	1588.46	2282.26	69.60	(66.9, 72.41)	<0.0001	1.0000	7.23
AUC <sub>0-t</sub>	11.752	12.075	127040.57	175493.63	72.39	(68.22, 76.82)	<0.0001	1.0000	10.85
AUC <sub>0-inf</sub>	11.865	12.157	142253.52	190356.73	74.73	(70.77, 78.91)	<0.0001	1.0000	9.95
AUC <sub>0-12</sub>	9.167	9.614	9571.10	14971.05	63.93	(60.47, 67.59)	<0.0001	1.0000	10.19

Non-Transformed Data							
PK Variable	Least Squares Mean			% Ratio	90% Confidence Interval	P-values for Product Effects	Power of ANOVA
	Test	Reference			(Lower Limit, Upper Limit)		
C <sub>max</sub>	1608.35	2315.60	69.46	(65.67, 73.24)	<0.0001	1.0000	
AUC <sub>0-t</sub>	131149.54	181651.54	72.20	(66.38, 78.02)	<0.0001	0.9999	
AUC <sub>0-inf</sub>	148830.88	198349.74	75.03	(69.71, 80.36)	<0.0001	1.0000	
AUC <sub>0-12</sub>	9785.75	15230.06	64.25	(59.85, 68.66)	<0.0001	1.0000	
T <sub>max</sub>	29.90	27.75	107.75	(95.46, 120.04)	0.2887	0.7609	
Kel	0.0165	0.0181	91.20	(87.52, 94.88)	0.0006	1.0000	
T <sub>1/2</sub>	44.19	39.64	111.49	(106.15, 116.83)	0.0015	1.0000	

Geometric means are based on least squares means of ln-transformed values.

Copy summary information from SAS output and paste in cells below:

_NAME_	TEST	REF	GM_TEST	GM_REF	RATIO	MSE	LL90	UL90	PVALUE	POWER	CV
LCMAX	7.370517426	7.732923342	1588.455478	2282.264297	69.5999793	0.005212536	66.89832308	72.41074058	4.98189E-12	1	7.22920794
LAUCT	11.75226176	12.07535805	127040.5695	175493.6337	72.39041489	0.011708115	68.2200992	76.81566326	2.14301E-08	0.999985808	10.8521535
LAUCINF	11.86536613	12.15665513	142253.5245	190356.7333	74.72996725	0.009851784	70.771273	78.91009684	2.78277E-08	0.999998913	9.95011166
LAUC12	9.166503576	9.613873911	9571.101494	14971.05442	63.93071072	0.010326746	60.46564043	67.59435184	4.46213E-11	0.999997693	10.1883515
C <sub>MAX</sub>	1608.35	2315.6	69.45716013	25561.68056	65.67102436	73.24329591	4.12003E-11	1			
AUCT	131149.542	181651.5355	72.19842191	372080793.6	66.37545158	78.02139223	1.49834E-07	0.999871965			
AUCINF	148830.8755	198349.7405	75.03457031	370843321.2	69.7106859	80.35845473	1.94109E-07	0.999985385			
AUC12	9785.745	15230.06	64.25283288	1498723.695	59.84500938	68.66065639	3.77337E-11	0.999999974			
T <sub>MAX</sub>	29.9	27.75	107.7477478	38.66944444	95.45961194	120.0358836	0.288662143	0.760924668	2.4944E+10		
KEL	0.016475	0.018065	91.19845004	1.46861E-06	87.51986786	94.87703222	0.000602809	1	0.12118631		
THALF	44.1945	39.6385	111.4938759	14.90275	106.153387	116.8343648	0.001525665	0.999984116	172222.929		

# Using SAS to produce Graphs

```
%LET path= F:\PRACS##\STUDY\###XXXX.YYY\Statistics;          /* path to study folder */
*%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 */
```

```
OPTIONS LS=101 PS=60 PAGENO=1 ORIENTATION=PORTRAIT TOPMARGIN="0.75 IN" BOTTOMMARGIN="0.75 IN" RIGHTMARGIN="0.75 IN" LEFTMARGIN="1 IN";
```

```
FILENAME CSVORIG "&path.\SAS\&concfle..CSV";
```

```
DATA ORIG1;
```

```
INFILE CSVORIG MISSEVER 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 l=JOIN C=BLUE l=1 w=1 h=.5;
SYMBOL2 V=Square l=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;
```

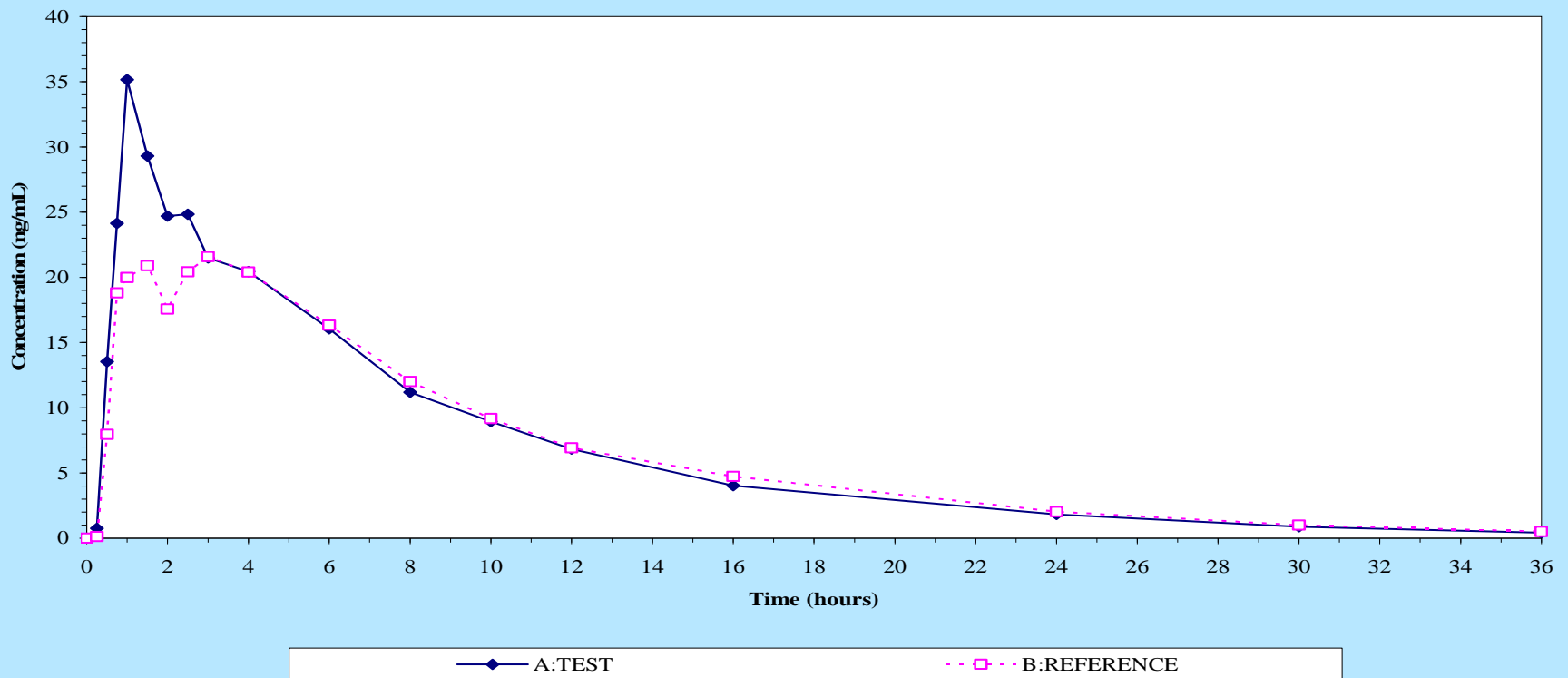
```
ods pdf file = "&path.\&studyno. Individual Graphs.pdf";
```

```
/* 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 display on */
goptions display;
/* invoke GREPLAY macro */
%greplay
quit;

ods pdf close;
run;
quit;
```

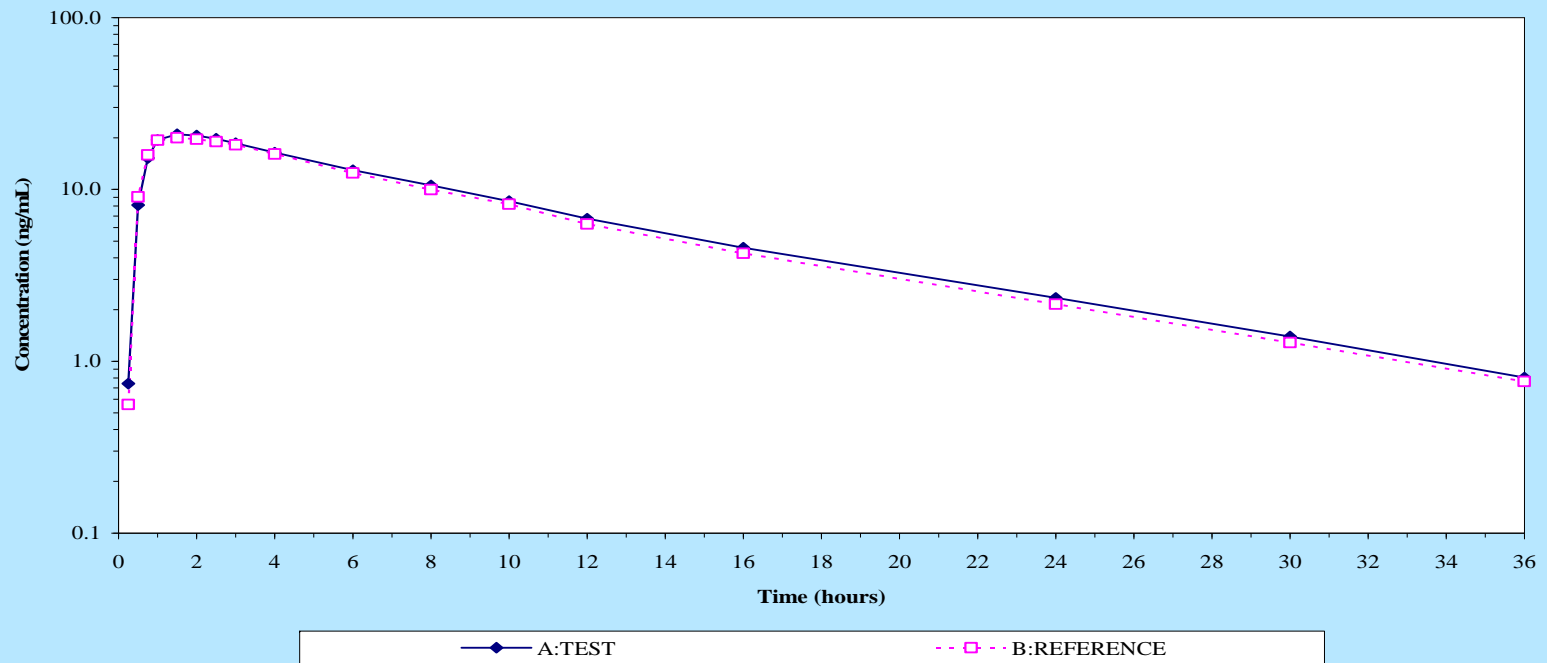
# Graphing the Concentration Data

**Subject 7**  
**Plasma Concentration (0 - 36 hours)**



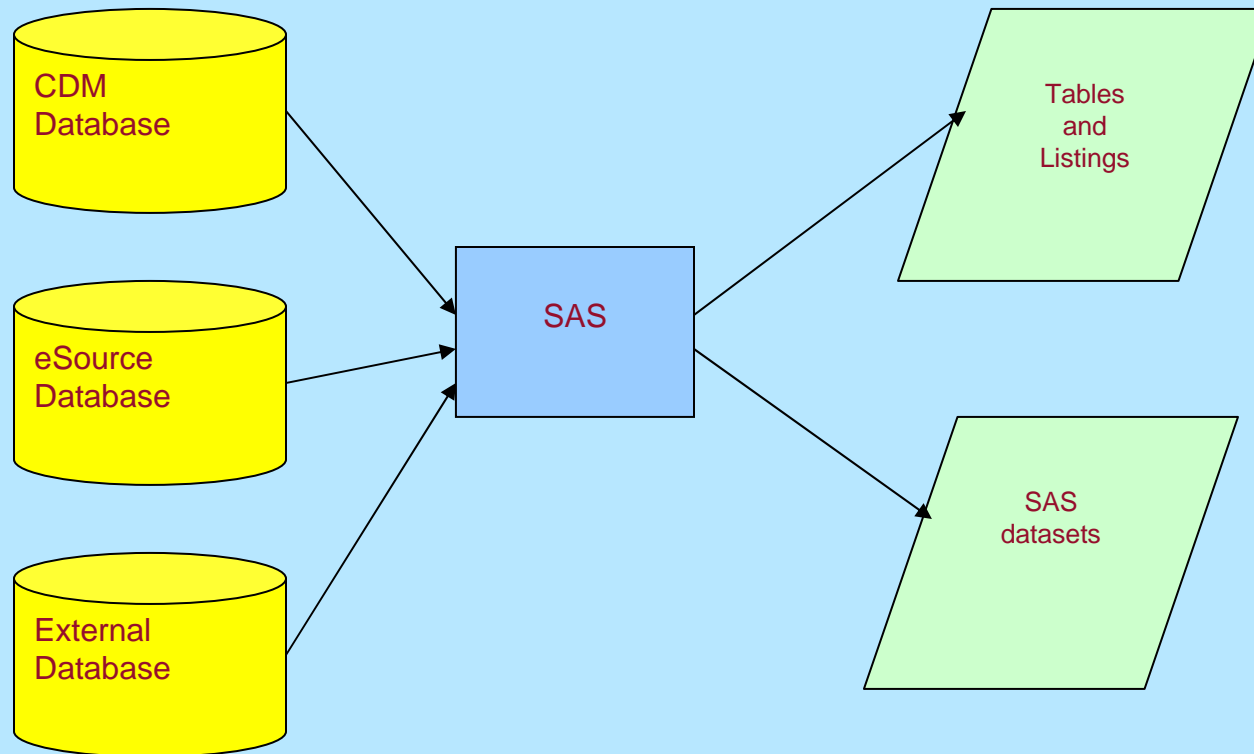
# Semi-log scale

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



# **SAS for Data Management**

# DM process



# 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

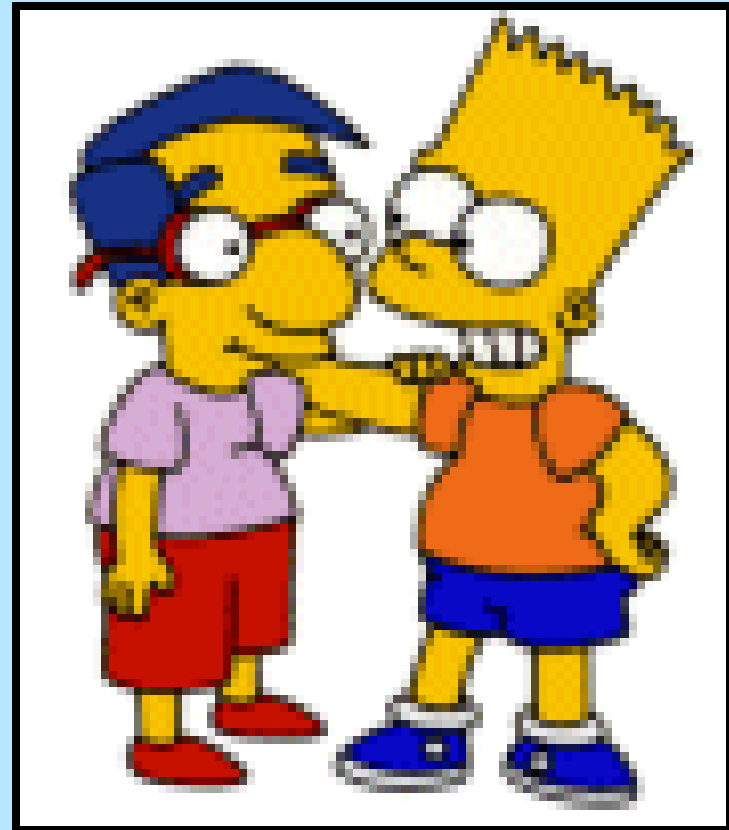
# Other uses

1. Other RTF control words
2. Changing Style attributes
  1. Code
  2. Output
3. Adding images

# Simpson's Quote

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.

See <http://msdn.microsoft.com/library/?url=/library/en-us/dnrftspec/html/rftspec.asp?frame=true> for a complete list.

Style	RTF Control Word	Example Code
Italicize	\i	title '\i italicized title';
Underline	\ul	title '\ul underline title';
Double underline	\dul	title '\dul title';
New line	\line	title 'this is the first \line this is the second';
Bullet	\bullet	title '\bullet bullet preceding title';
Emboss	\embo	title '\embo embossed title';
Engrave	\impr	title '\impr engraved title';
Subscript	\sub	title 'This is a subscript T\sub 1';
Superscript	\super	title 'This is a subscript T\super 2';
Outline	\outl	title '\outl This is outlined';
Shadow	\shad	title '\shad This is shadowed';
Strike	\strike	title '\strike This is striked';
double strike	\strikedl	
dotted underline	\uld	title '\uld dotted underline';
Wave underline	\ulw	title '\ulw wave underline';
Thick underline	\ulth	title '\ulth thick underline';
foreground color	\cfn	title '\cf2 foreground color';
Font size in half points	\fs24	title '\fs40 fonts increased';
Highlight	\highlightN	title '\highlight2';

Bold	\b	title '\b bold title';
Left aligned	\ql	title '\ql left aligned.
Right aligned	\qr	title '\qr right aligned.
centered	\qc	title '\qc left aligned.

Source:

[http://support.sas.com/rnd/base/ods/templateFAQ/Template\\_rtf.html#escapechar](http://support.sas.com/rnd/base/ods/templateFAQ/Template_rtf.html#escapechar)

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/* 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;

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*An example of In-Line formatting*

<b>Obs</b>	<b>style</b>
<b>1</b>	Arial
<b>2</b>	Times
<b>3</b>	<i>Italic</i>
<b>4</b>	Roman
<b>5</b>	<i>Slant</i>
<b>6</b>	<b>Bold</b>
<b>7</b>	Light
<b>8</b>	<b><i>Bold Italic Arial</i></b>

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ods rtf file ="&path.\SAS\Aes\AEfreq_%SYSFUNC(date(), DATE9.).rtf" style=Custom;
ods escapechar = '~';

TITLE1 j=1 &SponsorName. j=r 'Page ~{thispage} of ~{lastpage}';
TITLE2 j=1 &StudyName.;

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~{super b}'
    ('Mild' Mild_Y Mild_N) ('Moderate' Moderate_Y Moderate_N) ('Severe' Severe_Y Severe_N)) TOTAL, (('Total' Total_Y 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 '~\li (%) percentage of subjects reporting at least one incidence of respective adverse event';
    line @5 '~\li Subject numbers of subjects reporting at least one incidence of respective adverse event';
    line @5 '~\li Note: Superscript above the subject number indicates the number of multiple occurrences of the indicated AE
experienced by that subject';
    line @5 '~{super c} = Total number of reported adverse events';
    line @5 OverFooter $100.;
  endcomp;

RUN;

ods rtf close;

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Treatment A: Adverse Events N = 36 <sup>a</sup>										
		Subjects Who Experienced Indicated AE at Least Once by Intensity and Relationship <sup>b</sup>						Total No. of AEs <sup>c</sup>		
		Mild		Moderate		Severe		Total		
System Organ Class	Preferred Term	Related	NR	Related	NR	Related	NR	Related	NR	Overall
Cardiac disorders	Tachycardia	1 (2.78%) 01	0	0	0	0	0	1	0	1
Gastrointestinal disorders	Dry mouth	2 (5.56%) 16, 20	1 (2.78%) 01	0	0	0	0	2	1	3
Infections and infestations	Nasopharyngitis	0	1 (2.78%) 09	0	0	0	0	0	1	1
Musculoskeletal and connective tissue disorders	Pain in extremity	0	0	1 (2.78%) 46	0	0	0	1	0	1
Nervous system disorders	Dizziness	0	0	0	1 (2.78%) 45	0	0	0	1	1
	Headache	1 (2.78%) 48	0	0	1 (2.78%) 47	0	0	1	1	2
Vascular disorders	Contusion	0	1 (2.78%) 47	0	0	0	0	0	1	1
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		4	3	1	2	0	0			

Treatment A: Adverse Events N = 36 <sup>a</sup>										
		Subjects Who Experienced Indicated AE at Least Once by Intensity and Relationship <sup>b</sup>						Total No. of AEs <sup>c</sup>		
		Mild		Moderate		Severe		Total		
System Organ Class	Preferred Term	Related	NR	Related	NR	Related	NR	Related	NR	Overall
Total Number of Subjects Reporting At Least One AE Over the Course of the Study								5	4	8 <sup>d</sup>
<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 (%) percentage of subjects reporting at least one incidence of respective adverse event Subject numbers of subjects reporting at least one incidence of respective adverse event Note: Superscript above the subject number indicates the number of multiple occurrences of the indicated AE experienced by that subject <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 <sup>a</sup>										
		Subjects Who Experienced Indicated AE at Least Once by Intensity and Relationship <sup>b</sup>						Total No. of AEs <sup>c</sup>		
		Mild		Moderate		Severe		Total		
System Organ Class	Preferred Term	Related	NR	Related	NR	Related	NR	Related	NR	Overall
Gastrointestinal disorders	Dry mouth	2 (5.56%) 16, 39	0	0	0	0	0	2	0	2
	Dry throat	1 (2.78%) 12	0	0	0	0	0	1	0	1
General disorders and administration site conditions	Feeling of body temperature change	0	1 (2.78%) 45 <sup>2</sup>	0	0	0	0	0	2	2
Nervous system disorders	Dizziness	0	0	0	1 (2.78%) 45 <sup>2</sup>	0	0	0	2	2
	Headache	3 (8.33%) 18, 20, 24	0	0	0	0	0	3	0	3
Respiratory, thoracic and mediastinal disorders	Pharyngolaryngeal pain	0	1 (2.78%) 22	0	0	0	0	0	1	1
Skin and subcutaneous tissue disorders	Pallor	0	1 (2.78%) 45	0	0	0	0	0	1	1
Total Number of AEs reported		6	4	0	2	0	0	6	6	12
Total Number of Subjects Reporting at Least One AE by Intensity and Relationship		6	2	0	1	0	0			

Treatment B: Adverse Events N = 36 <sup>a</sup>										
		Subjects Who Experienced Indicated AE at Least Once by Intensity and Relationship <sup>b</sup>						Total No. of AEs <sup>c</sup>		
		Mild		Moderate		Severe		Total		
System Organ Class	Preferred Term	Related	NR	Related	NR	Related	NR	Related	NR	Overall
Total Number of Subjects Reporting At Least One AE Over the Course of the Study								6	2	8
<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 (%) percentage of subjects reporting at least one incidence of respective adverse event Subject numbers of subjects reporting at least one incidence of respective adverse event Note: Superscript above the subject number indicates the number of multiple occurrences of the indicated AE experienced by that subject <sup>c</sup> = Total number of reported adverse events										