

```

options notes nosource;

proc datasets lib=work nolist memtype=data kill; quit;

/*=====
=====

*Covance Study ID   : 000000106331

*Program Name       : t_ames_pp.sas

*Purpose            : Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units) – PP Set

                                Table 15.2.4.64.1

*Input Data         : adam.adsl, ADAM.adbx

*Output Data        : tflds.T_15_02_04_64_01

*Macros Called      : %m_printto, %mmeans, %mfinp, %outrtf, %m_logchk2

*Programmed by      : Ranju Gautam

*Creation Date      : 2015-05-26

*== Modification History
=====

*Date      Initials  No. Reason;

*=====
=====*/

%m_printto;


%macro trt(pfl= );

proc sql;

    %global trt1 trt2 trt3;

    select count(distinct usubjid) into: trt1 from adam.adsl(where=(trt01pn = 4 and &pfl.));

    select count(distinct usubjid) into: trt2 from adam.adsl(where=(trt01pn = 5 and &pfl.));

```

```

        select count(distinct usubjid) into: trt3 from adam.adsl(where=(trt01pn = 3 and &pfl.));

quit;

%mend trt;


%macro mmeans(pfl=, prd=, class=, var=, out=);


%trt(pfl=&pfl.);


data adbx1;

    set adam.adbx;

    where anl02fl='Y' and PARAMCD in ('UAMES24U' 'UAMES')

    AND &prd.;

    if          trtpn=4 then trt=1;

    else if trtpn=5 then trt=2;

    else if trtpn=3 then trt=3;

run;


data adbx;

    set adbx1;

    if ablfl='Y' then avisit='Baseline';

    if avisit ne 'Day 0';

run;


proc means data=adbx noprint nway;

    var &var.;

```

```

class &class. trt;

output out=results02 n=n1 mean=mean1 std=std1 median=median1 min=min1 max=max1 q1=q1
q3=q3 lclm=lci1 uclm=uci1;

run;

data results03;

set results02;

attrib meansd length=$30.

minmax length=$20.

n length=$20.

miss length=$20.

median length=$20.

quart aci length=$20.;

n = left(compress(put(n1,8.)));

*for <missing, n(%)>;

if trt=1 then do;

if &trt1.=n1 then miss="";

else miss=strip(put((&trt1.-n1), 9.)) || '(' || strip(put(((&trt1.-
n1)*100)/&trt1., 9.1)) || "%");

end;

else if trt=2 then do;

if &trt2.=n1 then miss="";

else miss=strip(put((&trt2.-n1), 9.)) || '(' || strip(put(((&trt2.-
n1)*100)/&trt2., 9.1)) || "%");

end;

else if trt=3 then do;

```

```

                                if &trt3.=n1 then miss="";

                                else miss=strip(put((&trt3.-n1), 9.)) || ' ' || strip(put((((&trt3.-
n1)*100)/&trt3., 9.1)) || " ");

                                end;

if not missing(median1) then median = left(compress(put(round(median1,0.01),9.2)));

if not missing(mean1) and not missing(std1) then meansd =
left(compress(put(round(mean1,0.01),9.2))) || ' (' || left(compress(put(0.001*ceil(std1/0.001),10.3))) ||
');

if not missing(min1) and not missing(max1) then minmax = left(compress(put(min1,9.1))) || ', ' ||
left(compress(put(max1,9.1)));

if not missing(lci1) and not missing(uci1) then aci = strip(put(0.01*floor(lci1/0.01),9.2)) || ', ' ||
strip(put(0.01*ceil(uci1/0.01),9.2));

if not missing(q1) and not missing(q3) then quart = strip(strip(put(round(q1, 0.01),9.2)) || ', ' ||
strip(put(round(q3, 0.01),9.2)));

drop n1 mean1 std1 median1 min1 max1 q1 q3 uci1 lci1 ;

run;

proc transpose data=results03 out=&out prefix=r_ name=varname;

by &class.;

var n miss meansd median minmax aci quart;

id trt;

run;

data &out.;

set &out.;

length stat $200 r1-r3 $ 30;

```

```

        if r_1 ne "" then r1=r_1;

    if r_2 ne "" then r2=r_2;

    if r_3 ne "" then r3=r_3;


    if upcase(varname)='N'           then do; statord=1; stat='n'; end;

    if upcase(varname)='MISS'        then do; statord=2; stat='Missing, n (%)'; end;

    if upcase(varname)='MEDIAN' then do; statord=7; stat='Median'; end;

    if upcase(varname)='QUART'       then do; statord=8; stat='Q25, Q75'; end;

    if upcase(varname)='MINMAX' then do; statord=9; stat='Min, Max'; end;

    if upcase(varname)='MEANSD' then do; statord=10; stat='Mean (SD)'; end;

    if upcase(varname)='ACI'         then do; statord=11; stat='95% CI of Mean'; end;


    drop r_1 r_2 r_3;


run;

%mend mmeans;


%mmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 5')), class=PARAMCD
PARAM avisitn avisit atptn atpt , var=aval, out=out_p1);

%mmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 90' 'Day 0')), class=PARAMCD
PARAM avisitn avisit atptn atpt , var=aval, out=out_p4);


%mmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 5')), class=PARAMCD
PARAM avisitn avisit atptn atpt , var=pchg, out=out_c1);

%mmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 0' 'Day 90' )), class=PARAMCD
PARAM avisitn avisit atptn atpt , var=pchg, out=out_c4);

```

```
%macro mmeans(prd=, class=, var=, out=);
```

```
data adbx1;
```

```
    set adam.adbx;
```

```
    where anl02fl='Y' AND PARAMCD in ('UAMES24U' 'UAMES')
```

```
    AND &prd.;
```

```
    if          trtpn=4 then trt=1;
```

```
    else if trtpn=5 then trt=2;
```

```
    else if trtpn=3 then trt=3;
```

```
run;
```

```
data adbx;
```

```
    set adbx1;
```

```
    if ablfl='Y' then
```

```
    avisit='Baseline';
```

```
    if avisit ne 'Day 0';
```

```
        if aval not in (. 0) then logaval=log(aval);
```

```
run;
```

```
*if aval=0 then present as NC for that treatment arm;
```

\*to find out the aval=0 for each ;

```
data aval0(keep=paramcd param trt avisitn avisit atptn atpt aval);
```

```
set adbx;
```

```
if aval=0 then output;
```

```
run;
```

```
proc sql noprint;
```

```
select count (distinct usubjid) into :aval1 from adbx1 where aval=0 and trt=1;
```

```
select count (distinct usubjid) into :aval2 from adbx1 where aval=0 and trt=2;
```

```
select count (distinct usubjid) into :aval3 from adbx1 where aval=0 and trt=3;
```

```
quit;
```

```
%put &aval1 &aval2 &aval3;
```

\*all treatment have aval=0;

```
proc means data=adbx noprint nway;
```

```
var &var.;
```

```
class &class. trt;
```

```
output out=results02 mean=mean std=std1 lclm=lci1 uclm=uci1;
```

```
run;
```

```
data results03_;
```

```
set results02;
```

```
gmean1=exp(mean);
```

```
gmean=left(compress(put(round(gmean1,0.01), 9.2))), 9.2));
```

```

gcv=compress(put(0.001*ceil((sqrt(exp(std1*std1)-1)*100)/0.001),9.3));

glci=exp(lci1);

guci=exp(uci1);

if not missing(gcv) then gmeancv=left(trim(gmean)) || ' (' || left(trim(gcv)) || ')';

else gmeancv=left(trim(gmean));

if not missing(glci) and not missing(guci) then ci = strip(strip(put(0.01*floor(glci/0.01),9.2)) || ', '
|| strip(put(0.01*ceil(guci/0.01),9.2)));

run;

```

```

*to get the NC for aval=0;

proc sort data=results03_;

by paramcd param trt avisitn avisit atptn atpt;

run;

```

```

proc sort data=aval0 nodupkey;

by paramcd param trt avisitn avisit atptn atpt;

run;

```

```

data results03;

merge results03_(in=a) aval0(in=b);

by paramcd param trt avisitn avisit atptn atpt;

if aval=0 then do;

ci='NC';

gmeancv='NC';

end;

```



```
run;
```

```
proc sort data=results03;
```

```
by &class;
```

```
run;
```

```
proc transpose data=results03 out=&out. prefix=r_ name=varname;
```

```
by &class;
```

```
var gmeancv ci;
```

```
id trt;
```

```
run;
```

```
data &out.;
```

```
set &out.;
```

```
length stat $200 r1-r3 $ 30 ;
```

```
if upcase(varname)='GMEANCV' then do; statord=5; stat='Geometric Mean (CV%)'; end;
```

```
if upcase(varname)='CI' then do; statord=6; stat='95% CI of Geometric Mean'; end;
```

```
if r_1 ne " then r1=r_1;
```

```
if r_2 ne " then r2=r_2;
```

```
if r_3 ne " then r3=r_3;
```

```
drop r_1 r_2 r_3;
```

```
run;
```

```
%mend mmeans;
```

```
%mmeans(prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 5')), class=PARAMCD PARAM avisitn avisit atptn  
atpt , var=logaval, out=out_g1);
```

```
%mmeans(prd=(PPROT4FL='Y' and avisit in ('Day 0' 'Day 90')), class=PARAMCD PARAM avisitn avisit  
atptn atpt, var=logaval, out=out_g4);
```

```
*check data for BLOQ/ALOQ ;
```

```
proc freq data=adbx;
```

```
    table AVALC;
```

```
run;
```

```
%macro mfinp(dsn=, dsng=, dsnc=, out=);
```

```
data dsn1;
```

```
    set &dsn.(in=p) &dsng.(in=g) ;
```

```
run;
```

```
proc sort data=dsn1 out=ds1;
```

```
    by paramcd param avisitn avisit atptn atpt statord stat varname;
```

```
run;
```

```

data dsnc;

    set &dsnc.;

    if avisit="Baseline" then delete;

run;


proc sort data=dsnc out=ds2;

    by paramcd param avisitn avisit atptn atpt statord stat varname;

run;


data &out.;

    retain paramcd param avisitn avisit atptn tp stat r1 c1 r2 c2 r3 c3 statord;

    merge ds1(in=a) ds2(in=c rename=(r1=c1 r2=c2 r3=c3));

    by paramcd param avisitn avisit atptn atpt statord stat varname;

    if a;

    if avisit="Baseline" then tp=avisit;

    else tp=propcase(atpt);

```

\*\*\*should delete <missing, n(%)> if no missing n;

\*\*\*4/22/2015 email from Jonh:

sometimes tables will have a value in brackets < > e.g., <Missing> or <BLOQ> as shown above.

This means to only report that value (after removing the brackets) in the table if there are such values to report.

For example, if there are 40 people in a treatment group and 30 are males and 9 are females then <Missing> would have 1.

However, if there are no missing values for sex then <Missing> should not be reported at all.

\*\*\*,

```

        if stat="Missing, n(%)" and r1="" and r2="" and r3="" and c1="" and c2="" and c3="" then delete;

        keep paramcd param avisitn avisit atptn statord tp stat r1 c1 r2 c2 r3 c3;

run;

%mend mfinp;

%mfinp(dsn=out_p1, dsng=out_g1, dsnc=out_c1, out=finalp1);

%mfinp(dsn=out_p4, dsng=out_g4, dsnc=out_c4, out=finalp4);

data final;

    set finalp1(in=p1) finalp4(in=p4) ;

    if p1 then period="1";

    if p4 then period="4";

    if statord in (1 2 5 6 7) then brk=1;

    if statord in (8 9 10 11) then brk=2;

run;

*****
*create new page for each timepoint for report ;
*****

proc sql;

    create table page as

```

```
select distinct paramcd, period, avisitn, tp
from final

order by paramcd , period, avisitn, tp;

quit;
```

```
data page1;

set page;

by paramcd period avisitn tp ;

if _n_ = 0 then page = 0;

page + 1;

run;
```

```
proc sql;

create table final_page as

select distinct a.*, b.page

from final as a

left join page1 as b

on a.paramcd=b.paramcd and a.avisitn=b.avisitn and a.tp = b.tp and a.period=b.period

order by paramcd , period, page, avisitn, avisit, atptn, statord;

quit;
```

```
data final_page(rename=(r1=THSm c1=THSm_chg r2=mCC c2=mCC_chg r3=SA c3=SA_chg));

set final_page end=last;

by paramcd period page avisitn atptn statord;

if last then call symputx("page", page);
```

```
run;
```

```
%let tflno=T_15_02_04_64_01;
```

```
data tflds.&tflno(keep=paramcd param avisitn avisit tp stat THSm mCC SA THSm_chg mCC_chg SA_chg  
stator period page);
```

```
set final_page;
```

```
run;
```

```
%put &page;
```

```
*****,
```

```
*create output report ;
```

```
*****,
```

```
proc sql;
```

```
select count(distinct usubjid) into: N1THS from adam.adsl(where=(trt01pn = 4 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N1MCC from adam.adsl(where=(trt01pn = 5 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N1SAA from adam.adsl(where=(trt01pn = 3 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N2THS from adam.adsl(where=(trt01pn = 4 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N2MCC from adam.adsl(where=(trt01pn = 5 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N2SAA from adam.adsl(where=(trt01pn = 3 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N3THS from adam.adsl(where=(trt01pn = 4 and pprot3fl = "Y"));
select count(distinct usubjid) into: N3MCC from adam.adsl(where=(trt01pn = 5 and pprot3fl = "Y"));
select count(distinct usubjid) into: N3SAA from adam.adsl(where=(trt01pn = 3 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N4THS from adam.adsl(where=(trt01pn = 4 and pprot4fl = "Y"));
select count(distinct usubjid) into: N4MCC from adam.adsl(where=(trt01pn = 5 and pprot4fl = "Y"));
select count(distinct usubjid) into: N4SAA from adam.adsl(where=(trt01pn = 3 and pprot4fl = "Y"));
```

```
quit;
```

```
options number nodate orientation=landscape missing=' ';
```

```
ods escapechar='$';
```

```
%let linetop = \brdrt\brdrs\brdrw30;
```

```
%let linebot = \brdrb\brdrs\brdrw30;
```

```
%macro outrtf(blankn=130, halfblnk=N, dsn=);
```

```
%let title1 = %str(Table 15.2.4.64.1 Descriptive Statistics of Ames Mutagenicity Test (YG1024+S9) (units)
- PP Set);
```

```
%let TFL_Part=%scan(&_amp;_SASPROGRAMFILE,-3,%str(/));
```

```
data _null_;
```

```
tmp="&TFL_Part";
```

```
if tmp not in ("dev" "qc") then call symput("TFL_Part", "prod");
```

```

call symput('TFLpath', compress("&_SASPROGRAMFILE", ""));

call symput('TFLprg', reverse(scan(strip(reverse(compress("&_SASPROGRAMFILE", ""))), 1, "/")));

run;


%if &halfblnk=N %then %let halfblnk=;

%else %if &halfblnk=Y %then %let halfblnk=~;


ods path stdlib.t106343 (read) ;

ods results off;

ods rtf toc_data file="/cvn/projects/prj/data/000000106343/TFL/&TFL_Part./Tables/&tflno..rtf"
style=t106343 startpage=yes headery=1440 footery=1440 ;

ods noproctitle;

%do i=1 %to &page;

    title ;

    footnote;

    %let wd=0;

    ods proclabel = ' ';

    data comp;

        set final_page end=eof;

        where page=&i;

        if _n_ =1 then

            do;

                call symput('title3', "Product Use Time Period: Period " || Period );

```



```

                                if period="1" then do;

                                                                 call
symput('trt1', strip(put(&N1THS., best.)));

                                                                 call
symput('trt2', strip(put(&N1MCC., best.)));

                                                                 call
symput('trt3', strip(put(&N1SAA., best.)));

                                                                 end;

                                else if period="4" then do;

                                                                 call
symput('trt1', strip(put(&N4THS., best.)));

                                                                 call
symput('trt2', strip(put(&N4MCC., best.)));

                                                                 call
symput('trt3', strip(put(&N4SAA., best.)));

                                                                 end;

                                end;


                                _firtitl="&title1.";

                                _upcas=(length("Path: &TFLpath.")-
length(compress("Path:&TFLpath.",'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;

                                len=&blankn.-length("(page &i of &page)");


                                if eof then do;

                                        call symput('_FSRTITL', trim(left(_firtitl)));

                                        call symput('_blankn', compress(put(len,best.)));

                                        call symput('param', strip(param));

                                end;

```

```

drop _firtitl _upcas len;

run;

ods listing close;

proc report data = comp headline headskip nowd split = '$' %if &i=1 %then %do;
contents=' ' %end; %else %do; contents="" %end;;;

column tp stat ("THSm2.2$(N=&trt1)$&linebot" THSm THSm_chg )

("mCC$(N=&trt2)$&linebot" mCC mCC_chg)

("SA$(N=&trt3)$&linebot" SA SA_chg);

define tp /"Timepoint" order order=internal style={just=left
cellwidth=0.9cm} style(header)={just=left} ;

define stat /"Statistic" display style={just=left cellwidth=1.9cm}
style(header)={just=left} ;

define THSm /"Value" display style={just=c
cellwidth=1.2cm} style(header)={just=center} ;

define mCC /"Value" display style={just=c cellwidth=1.2cm}
style(header)={just=center} ;

define SA /"Value" display style={just=c cellwidth=1.2cm}
style(header)={just=center};

define THSm_chg /"% Change(*)" display style={JUST=c
cellwidth=1cm} style(header)={just=center};

define mCC_chg /"% Change(*)" display style={just=c cellwidth=1cm}
style(header)={just=center};

define SA_chg /"% Change(*)" display style={just=c cellwidth=1cm}
style(header)={just=center};

```

```

compute before _page_ / style={just=left protectspecialchars=off};

line "\b\fs24\sa24&_FSRTITL." ;

line "Parameter (units): &param";

line "\b\fs24\sa24&title3." ;

line " ";

line "&linebot";

endcomp;


compute after _page_ / style={just=left protectspecialchars=off
pretext="&linetop."};

line 'Note: mCC = Menthol Conventional cigarettes; SA = Smoking
abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.';

LINE 'Note: * % Change from baseline, where baseline is defined as the
last assessment prior to first randomized product use in mCC / THS 2.2 Menthol arms or the last
assessment prior to 10AM on Day 1 in the SA arm.';

line "Note: 'Missing' percentages are based on the number of subjects
indicated in the column header (N).";

line ' ';

line 'Appendix 15.3.5.1';

line "Study ID: ZRHM-REXA-08-US   Program: &TFLprg   Status:
&status" &_blankn.*"\~\~" "&sysdate" &_blankn.*"\~\~" "(Page &i of &page)";

endcomp;

run;

%end;

ods rtf close;

```

```
ods results on;
```

```
ods path sashelp.tmplmst (read);
```

```
%mend ;
```

```
%outtrtf(blankn=36, halfblnk=N);
```

```
ods listing;
```

```
%m_logchk2;
```