

```
options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
```

```
/*=====
*Covance Study ID      : 000000106331
*Program Name          : t_oxyst_pp.sas
*Purpose               : Table 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters  PP set
*Input Data            : adam.adsl, ADAM.adbx
*Output Data           : tflds.T_15_02_04_66_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(ROUTE=YES);
```

```
%macro trt(pfl= );
proc sql;
%global trt1 trt2 trt3;
select count(distinct usubjid) into: trt1 from adam.adsl(when=(trt01pn = 4 and &pfl.));
select count(distinct usubjid) into: trt2 from adam.adsl(when=(trt01pn = 5 and &pfl.));
select count(distinct usubjid) into: trt3 from adam.adsl(when=(trt01pn = 3 and &pfl.));
quit;
%mend trt;
```

```
*check trt no randomized for each period;
```

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

```
%trt(pfl=&pfl.);
```

```
data adbx1;
set adam.adbx;
```

```
if an102f1='Y' and PARAMCD in ('P6HYDCH' 'P7AHYDCH' 'P56AEPCH' 'P7KETCH' 'P7BHYDCH' 'P56BEPCH' 'P24HYDCH'
'P25HYDCH' 'P22HYDCH' 'P4BHYDCH' 'P27HYDCH' 'PCHOL') 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 ablf1='Y' then avisit='Baseline';
if avisit ne 'Day 0';
run;
```

```
proc means data=adbx noprint nway;
var &var.;
class &class. trt;
where AQLFL='Y';
output out=resultsbn(drop=_type_ _freq_) n=bn;
run;
```

```
proc means data=adbx noprint nway;
var &var.;
class &class. trt;
output out=resultsbn_(drop=_type_ _freq_) n=n_1;
run;
```

```
proc sort data=resultsbn;
by &class. trt;
run;
```

```
proc sort data=resultsbn_;
by &class. trt;
run;
```

```
data resultsbn1;
attrib bl length=$20.;
merge resultsbn(in=a) resultsbn_(in=b);
by &class. trt;
if bn ne . and n_1 ne . then p1=strip(put((bn*100)/n_1,11.1));
if bn ne . then bl=strip(put(bn, best.)) || ' (' || strip(p1)|| ")";
```

```

run;

proc means data=adbx noprint nway;
  var &var.;
  class &class. trt;
  output out=results02(drop=_type_ _freq_) 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.)));

  if trt=1 then do;
    if &trt1.=n1 then miss="";
    else miss=strip(put((&trt1.-n1), 8.)) || ' (' || strip(put(((&trt1.-n1)*100)/&trt1., 11.1)) || ")";
  end;
  else if trt=2 then do;
    if &trt2.=n1 then miss="";
    else miss=strip(put((&trt2.-n1), 8.)) || ' (' || strip(put(((&trt2.-n1)*100)/&trt2., 11.1)) || ")";
  end;
  else if trt=3 then do;
    if &trt3.=n1 then miss="";
    else miss=strip(put((&trt3.-n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 11.1)) || ")";
  end;

  if not missing(median1) then median = left(compress(put(round(median1,0.01),11.2)));
  if not missing(mean1) and not missing(std1) then meansd = left(compress(put(round(mean1,0.01),11.2)) || ' (' || left(compress(put(0.001*ceil(std1/0.001),11.3)) || ')');
  if not missing(min1) and not missing(max1) then minmax = left(compress(put(min1,11.1)) || ', ' || left(compress(put(max1,11.1)) || ')');
  if not missing(lci1) and not missing(uci1) then aci = strip(put(0.01*floor(lci1/0.01),11.2)) || ', ' || strip(put(0.01*ceil(uci1/0.01),11.2));
  if not missing(q1) and not missing(q3) then quart = strip(strip(put(round(q1, 0.01),11.2)) || ', ' || strip(put(round(q3, 0.01),11.2)));
  drop n1 std1 median1 min1 max1 q1 q3 ;
run;

data &out._f(keep=param paramn paramcd mean1 lci1 uci1 avisitn trt avisit) ;
  set results03;

run;

proc sort data=results03;
  by &class.;
run;

proc sort data=resultsbn1;
  by &class.;
run;

data results04;
merge results03(in=a) resultsbn1(in=b );
  by &class. trt;
run;

proc sort data=results04;
  by &class. trt;
run;

proc transpose data=results04(drop=mean1 uci1 lci1 bn) out=&out prefix=r_ name=varname;
  by &class.;
  var n miss bl meansd median minmax aci quart;
  id trt;
run;

data &out.;
  set &out.;
  length stat $200 r1-r3 $ 30;
  if lowercase(varname)='n' then do; statord=1; stat='n'; end;
  if lowercase(varname)='miss' then do; statord=2; stat='Missing, n (%)'; end;

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if lowercase(varname)='bl' then do; statord=3; stat='BLOQ, n (%)'; end;
if lowercase(varname)='median' then do; statord=7; stat='Median'; end;
if lowercase(varname)='quart' then do; statord=8; stat='Q25, Q75'; end;
if lowercase(varname)='minmax' then do; statord=9; stat='Min, Max'; end;
if lowercase(varname)='meansd' then do; statord=10; stat='Mean (SD)'; end;
if lowercase(varname)='aci' then do; statord=11; stat='95% CI of 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;
if statord=3 then do;
    if r1='' then r1='0';
    if r2='' then r2='0';
    if r3='' then r3='0';
end;

if statord=2 then do;
    if r1='' then r1='0';
    if r2='' then r2='0';
    if r3='' then r3='0';
end;

drop r_1 r_2 r_3;
run;
%mend mmeans;

%mmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 6/Discharge Confinement')), class=paramn PARAMCD PARAM avi
sitn avisit atptn atpt, var=aval, out=out_p1);
%mmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 0' 'Day 90')), class=paramn PARAMCD PARAM avisitn avisit atptn atp
t, var=aval, out=out_p4);

%mmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 6/Discharge Confinement')), class=paramn PARAMCD PARAM avi
sitn avisit atptn atpt, var=pchg, out=out_c1);
%mmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 0' 'Day 90')), class=paramn PARAMCD PARAM avisitn avisit atptn atp
t, var=pchg, out=out_c4);

data tflds.t_15_02_04_66_01_f;
    set out_p1_f out_p4_f out_c1_f out_c4_f;
run;

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

data adbx1;
    set adam.adbx;

    if anl02f1='Y' AND PARAMCD in ('P6HYDCH' 'P7AHYDCH' 'P56AEPCH' 'P7KETCH' 'P7BHYDCH' 'P56BEPCH' 'P24HYDCH'
    'P25HYDCH' 'P22HYDCH' 'P4BHYDCH' 'P27HYDCH' 'PCHOL')
    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 do; avisit='Baseline'; end;

if avisit ne 'Day 0';
    if aval not in (. 0) then logaval=log(aval);
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;

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```

data results03;
  set results02;
  gmean1=exp(mean);
  gmean=left(compress(put(round(gmean1,0.01), 11.2))), 11.2));
  gcv=compress(put(0.001*ceil((sqrt(exp(std1*std1)-1)*100)/0.001),11.3));
  if lci1 ne . then glci=exp(lci1);
  if uci1 ne . then 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),11.2)) || ', ' || strip(put(0.01*ceil(gu
ci/0.01),11.2))));
  else if glci eq . and guci eq . then ci='NC, NC';
run;

data &out._f1(keep=param paramn paramcd gmean gcv gmean1 glci guci gmeancv ci avisitn trt avisit ) ;
  set results03;
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;
  if lowercase(varname)='gmeancv' then do; statord=5; stat='Geometric Mean (CV%)'; end;
  if lowercase(varname)='ci' then do; statord=6; stat='95% CI of Geometric Mean'; end;
run;

%mend mmeans;

%mmeans(prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 6/Discharge Confinement')), class=paramn PARAMCD PARAM avisitn avisit atptn at
pt , var=logaval, out=out_g1);
%mmeans(prd=(PPROT4FL='Y' and avisit in ('Day 0' 'Day 90')), class=paramn PARAMCD PARAM avisitn avisit atptn atpt, var=logaval, out
=out_g4);

data tflds.t_15_02_04_66_01_f;
  set out_g1_f1(in=a) out_g4_f1(in=b);
  if a then periodn=1;
  if b then periodn=4;

  if trt=1 then trtpn=4;
  else if trt=2 then trtpn=5;
  else if trt=3 then trtpn=3;

run;

*check data for BLOQ/ALLOQ ;
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 paramn 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 paramn paramcd param avisitn avisit atptn atpt statord stat varname;
run;

data &out.;
  retain paramn 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 paramn paramcd param avisitn avisit atptn atpt statord stat varname;
  if a;

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if avisit="Baseline" then tp=avisit;
else tp=propcase(atpt);

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

keep paramn 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 paramn ne .;
if stat='95% CI of Geometric Mean' then do;
  if r1='' then r1='NC, NC';
  if r2='' then r2='NC, NC';
  if r3='' then r3='NC, NC';
end;

if stat='95% CI of Mean' then do;
  if r1='' then r1='NC, NC';
  if r2='' then r2='NC, NC';
  if r3='' then r3='NC, NC';
  if tp='Baseline' then do;
    if c1='' then c1='NC, NC';
    if c2='' then c2='NC, NC';
    if c3='' then c3='NC, NC';
  end;
end;
run;

*****;
*create new page for each timepoint for report ;
*****;
proc sql;
create table page as
select distinct paramn, paramcd, period, avisitn, tp
from final
order by paramn , paramcd , period, avisitn, tp;
quit;

data page1;
set page;
by paramn 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.paramn=b.paramn and a.paramcd=b.paramcd and a.avisitn=b.avisitn and a.tp = b.tp and a.period=b.period
order by paramn, 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 paramn paramcd period page avisitn atptn statord;
if last then call symputx("page", page);
if statord=3 then do;
  c1='';
  c2='';
  c3='';
end;
if r1='' and r2='' and r3='' and c1='' and c2='' and c3='' then delete;
if stat='BL0Q, n (%)' and r1='0' and r2='0' and r3='0' then delete;
run;

%let tfino=T_15_02_04_66_01;

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```

data tflds.&tflno(keep=paramn paramcd param avisitn avisit tp stat THSm mCC SA THSm_chg mCC_chg SA_chg statord period page);
  set final_page;
run;

*****;
*create output report ;
*****;

proc sql;

select count(distinct usubjid) into: N1THS from adam.adsl(where=(trt01pn = 4 and pprot1f1 = "Y"));
select count(distinct usubjid) into: N1MCC from adam.adsl(where=(trt01pn = 5 and pprot1f1 = "Y"));
select count(distinct usubjid) into: N1SAA from adam.adsl(where=(trt01pn = 3 and pprot1f1 = "Y"));

select count(distinct usubjid) into: N2THS from adam.adsl(where=(trt01pn = 4 and pprot2f1 = "Y"));
select count(distinct usubjid) into: N2MCC from adam.adsl(where=(trt01pn = 5 and pprot2f1 = "Y"));
select count(distinct usubjid) into: N2SAA from adam.adsl(where=(trt01pn = 3 and pprot2f1 = "Y"));

select count(distinct usubjid) into: N3THS from adam.adsl(where=(trt01pn = 4 and pprot3f1 = "Y"));
select count(distinct usubjid) into: N3MCC from adam.adsl(where=(trt01pn = 5 and pprot3f1 = "Y"));
select count(distinct usubjid) into: N3SAA from adam.adsl(where=(trt01pn = 3 and pprot3f1 = "Y"));

select count(distinct usubjid) into: N4THS from adam.adsl(where=(trt01pn = 4 and pprot4f1 = "Y"));
select count(distinct usubjid) into: N4MCC from adam.adsl(where=(trt01pn = 5 and pprot4f1 = "Y"));
select count(distinct usubjid) into: N4SAA from adam.adsl(where=(trt01pn = 3 and pprot4f1 = "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 15.2.4.66.1 Descriptive Statistics of Oxysterol Parameters - PP Set);

%let TFL_Part=%scan(&_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=14
40 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;

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        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 after tp;
    line " ";
endcomp;

compute before _page_ / style={just=left protectspecialchars=off};
    line "\b\fs24\sa24&_FSRTITL." ;
    line " ";
    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 / THSm2.2 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), while 'BLOQ' percentag
es are based on the number of subjects being summarized (n).";
    line " ";
    line 'Appendix 15.3.6.22';
    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 outrtf;

%outrtf(blankn=36, halfblnk=N);
ods listing;

%m_logchk2;

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