

```
/*=====
=====*
```

```
| Covance Study Number   : 000000106343      |
| Program Name           : t_hpma_pp.sas      |
| Purpose                 : Program to create table 15.2.4.3.1      |
| Input Data              : ADAM.ADSL, ADAM.ADBX      |
|                          |                    |
| Output Data             : T_15_02_04_03_01      |
| Macros Called           : %m_printto, %param, %stats, %outrtf, %m_logchk      |
| Originally Performed by : Upender S          |
| Date                    : 28May2015          |
```

```
|
|
|=====
=====|
```

```
| Modification History      |
|-----|
| Modified by              :                    |
| Modification Date        :                    |
|
| Modification Description :                    |
```

```
+=====
=====*/
```

```
%m_printto(route=YES);
```

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

```
ods results on;
```

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

```
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;
```

```
data adbx;
```

```
set adam.adbx (where=((pprot1fl = "Y" or pprot2fl = "Y" or pprot3fl = "Y" or pprot4fl = "Y") and  
anl02fl='Y' ));
```

```
run;
```

```
data adbx1 (drop=trtpn rename=(trtpn_=trtpn));
```

```
set adbx;
```

```
if trtp='THSm2.2' then trtpn_=1;
```

```
if trtp='mCC' then trtpn_=2;
```

```
if trtp='SA' then trtpn_=trtpn;
```

```
if trtpn_=1 then cat='1';
```

```
if trtpn_=2 then cat='2';
```

```
if trtpn_=3 then cat='3';
```

```
run;
```

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

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

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

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

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

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

```
proc sql exec; select count(distinct usubjid) into: N3THS from adam.adsl(where=(trt01pn = 4 and  
pprot3fl = "Y"));quit;
```

```
proc sql exec; select count(distinct usubjid) into: N3MCC from adam.adsl(where=(trt01pn = 5 and  
pprot3fl = "Y"));quit;
```

```
proc sql exec; select count(distinct usubjid) into: N3SAA from adam.adsl(where=(trt01pn = 3 and  
pprot3fl = "Y"));quit;
```

```
proc sql exec; select count(distinct usubjid) into: N4THS from adam.adsl(where=(trt01pn = 4 and  
pprot4fl = "Y"));quit;
```

```
proc sql exec; select count(distinct usubjid) into: N4MCC from adam.adsl(where=(trt01pn = 5 and  
pprot4fl = "Y"));quit;
```

```
proc sql exec; select count(distinct usubjid) into: N4SAA from adam.adsl(where=(trt01pn = 3 and  
pprot4fl = "Y"));quit;
```

```
%macro param(paramcd=, x=);
```

```
data &paramcd._orig;
```

```
set adbx1;
```

```
where paramcd = "&paramcd.";
```

```
run;
```

```
%macro stats(colvar=);
```

```
data co_1;
```

```
set &paramcd._orig;;
```

```
where (pprot1fl = "Y" and 101<=avisitn <= 105) or (pprot2fl = "Y" and avisitn = 130) or (pprot3fl = "Y"  
and avisitn = 160) or (pprot4fl = "Y" and avisitn = 190);
```

```
where also paramcd = "&paramcd." and avalc ne "" ;
```

```
if avisit in ('DAY -1' 'DAY 0') then delete;
```

```
if not missing(&colvar.) and &colvar. > 0 then ageo=log(&colvar.);
```

```
if not missing(&colvar.) then dataflg=1;
```

```
keep usubjid paramn cat avisitn avisit &colvar. AQLFL ageo dataflg apuper apuperc;
```

```
run;
```

```
data baseline ;
```

```
set &paramcd._orig;;
```

```
where paramcd = "&paramcd." ;
```

```
if &colvar. ^=. and &colvar. > 0 then ageo=log(&colvar.);
```

```
if not missing(&colvar.) then dataflg=1;
```

```
    if ablfl='Y' and pprot1fl = "Y" then do; avisit='Baseline'; avisitn=10; apuper = 1; apuperc = "Period 1";  
output; end;
```

```
    if ablfl='Y' and pprot2fl = "Y" then do; avisit='Baseline'; avisitn=10; apuper = 2; apuperc = "Period  
2";output; end;
```

```
    if ablfl='Y' and pprot3fl = "Y" then do; avisit='Baseline'; avisitn=10; apuper = 3; apuperc = "Period 3";  
output; end;
```

```
    if ablfl='Y' and pprot4fl = "Y" then do; avisit='Baseline'; avisitn=10; apuper = 4; apuperc = "Period  
4";output; end;
```

```
    keep usubjid paramn cat avisitn avisit &colvar. AQLFL ageo apuper apuperc;  
run;
```

```
proc sort data=baseline NODUPKEY;  
by apuper apuperc usubjid cat avisit avisitn &colvar.;  
run;
```

```
data co_1b;  
set co_1 baseline;  
run;
```

```
proc sort data=co_1b; by apuper apuperc avisitn avisit cat; run;
```

```
** BLQ Counts **;
```

```
proc sort data=co_1b out=co_1bq nodupkey dupout=blqdups; by usubjid paramn cat avisitn ; run;
```

```

proc sql;

    create table co_2t as select apuper, apuperc, cat, count(distinct usubjid) as tot from co_1bq group by
    apuper, apuperc, cat order by apuper, apuperc,cat;

    create table co_2c as select apuper, apuperc,cat, avisitn, avisit, 'BLQ' as _stat_ length=8,
    sum(AQLFL='Y') as count from co_1bq

                                                                    group by apuper, apuperc,cat, avisitn,
    avisit order by apuper, apuperc, cat, avisitn;

    create table co_2s as select apuper, apuperc,cat, avisit, avisitn,count(distinct usubjid) as stot from
    co_1bq where dataflg=1

                                                                    group by apuper, apuperc, cat ,avisitn, avisit
    order by apuper, apuperc, cat, avisitn;

quit;


data co_2bX; /* 1) JH 23OCT2014 */

    merge co_2c(in=a) co_2t /*co_2s*/; /* 1) JH 23OCT2014 */

    by apuper apuperc cat;

    if a;

run;


/* 1) JH 23OCT2014 - START */

DATA CO_2B;

    MERGE CO_2BX(IN=A) CO_2S;

    BY apuper apuperc CAT AVISITN AVISIT;

    IF A;

RUN;

```

```
/* 1) JH 23OCT2014 - END */
```

```
proc sort data=co_1b ;  
by apuper apuperc avisitn avisit cat &colvar.;  
run;
```

```
** Normal Stats **;
```

```
proc means data=co_1b noprint;  
var &colvar.;  
by apuper apuperc avisitn avisit cat;  
output out=co_2s(drop=_freq_ _type_) n=n mean=mean std=std median=med min=min max=max  
p25=q25 p75=q75 lclm =cl95 uclm=cu95 ;  
run;
```

```
****combining BLQ stats with rest of the stats ****;
```

```
proc sort data=CO_2B ; by apuper apuperc avisitn avisit cat; run;
```

```
data co_2s_blq;  
merge co_2s (in=a) CO_2B (in=b drop=_stat_ tot stot rename=(count=blq));  
by apuper apuperc avisitn avisit cat;  
run;
```

```
data co_2s_1;
set co_2s_blq;

if apuper = 1 then do;
    period = "Period 1";
    if cat='1' then BigN= &N1THS;
    if cat='2' then BigN = &N1mcc;
    if cat='3' then BigN = &N1saa;
end;

else if apuper = 2 then do;
    period = "Period 2";
    if cat='1' then BigN= &n2ths;
    if cat='2' then BigN = &n2mcc;
    if cat='3' then BigN = &n2saa;
end;

else if apuper = 3 then do;
    period = "Period 3";
    if cat='1' then BigN= &N3THS;
    if cat='2' then BigN = &N3mcc;
    if cat='3' then BigN = &N3saa;
end;

else if apuper = 4 then do;
    period = "Period 4";
    if cat='1' then BigN= &N4THS;
    if cat='2' then BigN = &N4mcc;
```



```

if cat='3' then BigN = &N4saa;

end;

msng=BigN-n;

if .<msng^=0 then msng_prcnt=(msng/BigN)*100;

if .<blq^=0 then bloq_prcnt=(blq/N)*100;

run;


data co_2s_c;

length N mean_sd min_max median q25_q75 cl95_cu95 msg_pct blq_pct $50.;

set co_2s_1(rename=(n=n_orig));


if cl95 ne . then cl95 = 0.01*floor(100*cl95);

if cu95 ne . then cu95 = 0.01*ceil(100*cu95);


if n_orig ^=. then N = compress(put(n_orig,best.));

if .<msng^=0 then msg_pct=compress(put(msng, best.))||' ('||compress(put(msng_prcnt, 5.1))||')';

if .<blq^=0 then blq_pct=compress(put(blq, best.))||' ('||compress(put(bloq_prcnt, 5.1))||')';


if mean ^=. and std ^=. then mean_sd =strip(put(mean,12.2))||' ('||strip(put(std,12.3))||')';

if min ^=. and max ^=. then min_max = strip(put(min,12.1))||', '||strip(put(max,12.1));

if med ^=. then median = strip(put(med,12.2));

if q25 ^=. and Q75 ^=. then q25_q75= strip(put(q25,12.2))||', '||strip(put(q75,12.2));

if cl95 ^=. and cu95 ^=. then cl95_cu95= strip(put(cl95,12.2))||', '||strip(put(cu95,12.2));

run;

```

```

proc transpose data=co_2s_c out=co_2s_ct(rename=(_name=_stat_col1=&colvar.));

by apuper apuperc avisitn avisit cat;

var N msg_pct blq_pct mean_sd median min_max q25_q75 cl95_cu95;

run;

```

```

data co_2s_ct (rename=(stat=_stat_));

length stat $10.;

set co_2s_ct;

stat=_stat_;

drop _stat_;

run;

```

```

** Geometric Stas **;

proc means data=co_1b noprint mean std lclm uclm;

where &colvar ne .;

var ageo;

by apuper apuperc avisitn avisit cat;

output out=co_2gs mean=gmean std=gstd lclm=glclm uclm=guclm;

run;

```

```

data co_2gs_x (drop=gmean glclm guclm rename=(gmean_x=gmean glclm_x=glclm guclm_x=guclm ));

set co_2gs;

if gmean ne . then gmean_x=exp(gmean);

```

```
if glclm ne . then glclm_x=exp(glclm);  
if guclm ne . then guclm_x=exp(guclm);  
run;
```

```
data co_2gs_c;  
set co_2gs_x;
```

```
if glclm ne . then glclm = 0.01*floor(100*glclm);  
if guclm ne . then guclm = 0.01*ceil(100*guclm);
```

```
if gstd ^= . then CV=sqrt(exp(gstd*gstd)-1)*100;  
if gmean ^= . and CV ^= . then gmean_cv =strip(put(gmean,20.2))||" ("||strip(put(cv,20.3))||")";  
if glclm ^= . and guclm ^= . then glcm_guclm= strip(put(glclm,20.2))||", "||strip(put(guclm,20.2));  
if glclm= . and guclm= . then glcm_guclm= 'NA' ||", "||'NA';  
run;
```

```
proc transpose data=co_2gs_c out=co_2gs_ct( rename=(_name=_stat_ col1=&colvar.));  
by apuper apuperc avisitn avisit cat;  
var gmean_cv glcm_guclm;  
run;
```

```
data co_3;
```

```

    set co_2s_ct co_2gs_ct;

run;

proc sort data=co_3 out=co_4; by apuper apuperc avisitn avisit _stat_; run;

proc transpose data=co_4 out=transpose_&colvar. prefix=&colvar.;

    by apuper apuperc avisitn avisit _stat_;

    id cat;

    var &colvar.;

run;

%mend stats;

%stats(colvar=aval);

%stats(colvar=pchg);

data &paramcd;

merge transpose_aval (in=a drop=_name_)

           transpose_pchg(in=b drop=_name_);

by apuper apuperc avisitn avisit _stat_;

if a or b;

run;

data &paramcd._final;

length label $100.;

```

```

set &paramcd.;

if upcase(_stat_) = "N" then do; order = 1; label="n";end;

if upcase(_stat_)='MSG_PCT' then do; order=1.5; label='Missing, n (%)'; end;

if upcase(_stat_)='BLQ_PCT' then do; order=1.75; label='BLOQ, n (%)'; end;


if upcase(_stat_) = "GMEAN_CV" then do; order = 2; label="Geometric Mean (CV%)";end;

if upcase(_stat_) = "GLCM_GUCLM" then do; order = 3; label="95% CI of Geometric Mean";end;

if upcase(_stat_) = "MEDIAN" then do; order = 4; label="Median";end;

if upcase(_stat_) = "Q25_Q75" then do; order = 5; label="Q25, Q75";end;

if upcase(_stat_) = "MIN_MAX" then do; order = 6; label="Min, Max";end;

if upcase(_stat_) = "MEAN_SD" then do; order = 7; label="Mean (SD)";end;

if upcase(_stat_) = "CL95_CU95" then do; order = 8; label="95% CI of Mean";end;


ord = &x.;

run;


proc sort data=&paramcd._final;

by apuper apuperc avisitn avisit order;

run;


%mend param;


%param(paramcd=U3HPM24U, x=2);

%param(paramcd=U3HPMCRE, x=1);

```

```
proc sort data = adbx out=param (keep=paramcd param paramn avalu) nodupkey;
by paramcd;
run;
```

```
data final;
length paramcd $8.;
set U3HPMCRE_final(in=a)
      U3HPM24U_final(in=b);
      if a then paramcd = "U3HPMCRE";
      else if b then paramcd ="U3HPM24U";
run;
```

```
proc sort data=final;
by paramcd apuper apuperc avisitn avisit order;
run;
```

```
data final1;
merge final(in=a) param(in=b);
by paramcd;
if a;
run;
```

```
***set pchg to missing for paramcd = 20;
data final2;
```

```
set final1;

if paramn = 20 then do;

    array x pchg;;

    do over x;

        x = "";

    end;

end;

if upcase(avisit) = "BASELINE" then do;

    array y pchg;;

    do over y;

        y = "";

    end;

end;

if order in (2 3) then do;

    pchg1 = "";

    pchg2 = "";

    pchg3 = "";

end;

run;
```

```
data final3;

set final2;

rename label = txt

    aval1 = trt_4

    aval2 = trt_5
```

```

aval3 = trt_3

pchg1 = chg_4

pchg2 = chg_5

pchg3 = chg_3

order  = txtn;

run;

proc sort data= final3;

by paramn param apuper apuperc avisitn avisit txtn ;

run;

data final3a;

set final3;

if upcase(_stat_) = 'MSG_PCT' and cmiss(trt_3, trt_4, trt_5, chg_3, chg_4, chg_5)=6 then delete;

if upcase(_stat_) = 'BLQ_PCT' and cmiss(trt_3, trt_4, trt_5, chg_3, chg_4, chg_5)=6 then delete;

if upcase(_stat_) = 'BLQ_PCT' then call missing(chg_3, chg_4, chg_5);

if upcase(_stat_) = 'BLQ_PCT' then do;

array ms {3} trt_3 trt_4 trt_5;

do i = 1 to 3;

if ms{i} = " then ms{i} ='0';

end;

```



```
end;
```

```
if upcase(_stat_) = 'MSG_PCT' then do;
```

```
array mb {3} trt_3 trt_4 trt_5;
```

```
do i = 1 to 3;
```

```
if mb{i} = "" then mb{i} = '0';
```

```
end;
```

```
end;
```

```
run;
```

```
data tflds.t_15_02_04_03_01;
```

```
set final3a (drop=paramcd);
```

```
run;
```

```
data final_dp;
```

```
length period $200.;
```

```
set final3a;
```

```
by paramn param apuper apuperc avisitn avisit txtn ;
```

```
if apuper = 1 then do;
```

```
period = "Period 1";
```

```
THS = &N1THS;
```

```
mcc = &N1mcc;
```

```
sa = &N1saa;
```

```
end;

else if apuper = 2 then do;

period = "Period 2";

ths = &n2ths;

mcc = &n2mcc;

sa = &n2saa;

end;

else if apuper = 3 then do;

period = "Period 3";

ths = &n3ths;

mcc = &n3mcc;

sa = &n3saa;

end;

else if apuper = 4 then do;

period = "Period 4";

ths = &n4ths;

mcc = &n4mcc;

sa = &n4saa;

end;

if param="3-HPMA (µg)" then param="3-HPMA ("||'B5'X'||"g)";

run;

proc sql;
```

```
create table page as  
select distinct apuper, apuperc, paramn, avisitn  
from final_dp  
order by paramn, apuper, avisitn;  
quit;
```

```
data page1;  
set page;  
by paramn apuper avisitn;  
if _n_ = 0 then page = 0;  
page+ 1;  
run;
```

```
proc sql;  
create table final_page as  
select distinct a.*, b.page  
from final_dp as a  
left join page1 as b  
on a.paramn = b.paramn and a.avisitn = b.avisitn and a.apuper = b.apuper  
order by paramn, apuper, avisitn, txtn;  
quit;
```

```
data final_page;  
set final_page end=last;
```

```
by paramn apuper avisitn txtn;
```

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

```
run;
```

```
%let tfl = %str(T_15_02_04_03_01);
```

```
%let title1 = %str(Table 15.2.4.3.1 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - PP Set);
```

```
%let tflno=&tfl.;
```

```
/* Standard - leave this */
```

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

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

```
%let linetop = \brdrt\brdrs\brdrw30; * needs to be 1.5pt so calculated in twips (1/20 pt) ;
```

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

```
/* Standard - macro for paging */
```

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

```
%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;

    /* Amend title as needed */

    _firtitl="&title1.";

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

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

    call symput('pran', compress(put(paramn,best.)));

    if eof then do;

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

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

    call symput('period', strip(apuperc));

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

    call symput('N3', strip(put(sa, best.)));

```

```

        call symput('N4', strip(put(thb, best.)));

        call symput('N5', strip(put(mcc, best.)));

    end;

    drop _firtitl _upcas len;

run;

ods listing close;

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

        column page paramn apuper avisitn avisit txtn txt ("THSm2.2$(N=&N4)&linebot" trt_4 chg_4 )
("mCC$(N=&N5)&linebot" trt_5 chg_5)

                ("SA$(N=&N3)&linebot" trt_3 chg_3);

    define paramn          / order order = internal noprint;

    define page            / order order = internal noprint;

    define avisitn         / order order = internal noprint;

    define apuper          / order order = internal noprint;

    define txtn            / order order = internal noprint;

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

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

        define trt_3        /"Value" display style={JUST=c cellwidth=1.3cm}
style(header)={just=center} ;

        define trt_4        /"Value" display style={just=c cellwidth=1.3cm}
style(header)={just=center} ;

```

```

        define trt_5          /"Value" display style={just=c cellwidth=1.3cm}
style(header)={just=center};

%if &pran = 19 %then %do;

        define chg_3          /"% Change(*)" display style={JUST=c cellwidth=1cm}
style(header)={just=center};

        define chg_4          /"% Change(*)" display style={just=c cellwidth=1cm}
style(header)={just=center};

        define chg_5          /"% Change(*)" display style={just=c cellwidth=1cm}
style(header)={just=center};

%end;

%if &pran = 20 %then %do;

        define chg_3          /noprint;

        define chg_4          /noprint;

        define chg_5          /noprint ;

%end;


compute after avisitn;

        line " ";

endcomp;


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

line "\b\fs24\sa24&_FSRTITL." ; * \b = bold, \fs24 is font size 12pt, \sa24 is space after 12pt;

        line " ";

        line "Parameter (units): &param";

        LINE "Product Use Time Period: &period";

        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), while 'BLOQ' percentages are based on the number of subjects being summarized
(n).";

line ";

line 'Appendix 15.3.3.1';

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 ;

%outrtf(blankn=30, halfblank=N);

ods listing;

```


%m_logchk;