

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

```
| Covance Study Number   : 000000106343      |
| Program Name           : t_hpma_fas.sas      |
| Purpose                : Program to create table 15.2.4.3.2      |
| Input Data             : ADAM.ADSL, ADAM.ADBX      |
|                         |                      |
| Output Data            : T_15_02_04_03_02      |
| 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=((fasfl = "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;
```

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

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

```
select count(distinct usubjid) into: NSAA from adam.adsl(where=(trt01pn = 3 and FASFL = "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 ( 101<=avisitn <= 105 or avisitn = 130 or avisitn = 160 or 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 fasfl = "Y" then do; avisit='Baseline'; avisitn=10; apuper = 1; apuperc = "Period 1";  
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 ;
```

```
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 cat= '1' then BigN= &NTHS;
```

```
if cat= '2' then BigN = &NMCC;
```

```
if cat= '3' then BigN = &NSAA;
```

```
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,12.2))||" ("||strip(put(cv,12.3))||")";

if glclm^=. and guclm^=. then glcm_guclm= strip(put(glclm,12.2))||", "||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 paramn = 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_) = '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;
```

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

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

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

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

```
end;
```

```
end;
```

```
if paramn=45 then do;
```

```
if upcase(_stat_) = 'MSG_PCT' then do;  
  if cmiss(chg_3, chg_4, chg_5) ne 3 then do;  
    array mc {3} chg_3 chg_4 chg_5;  
    do i = 1 to 3;  
      if mc{i} = " then mc{i} = '0';  
    end;  
  end;  
end;
```

```
end;
```

```
end;
```

```
end;
```

```
run;
```

```
data tflds.t_15_02_04_03_02;  
set final3a (drop=paramcd);  
run;
```

```
data final_dp;  
length period $200.;  
set final3a;  
by paramn param apuper apuperc avisitn avisitn txtn ;  
if apuper = 1 then do;  
  period = "Period 1";
```



```
end;

else if apuper = 2 then do;

period = "Period 2";

end;

else if apuper = 3 then do;

period = "Period 3";

end;

else if apuper = 4 then do;

period = "Period 4";

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_02);
```

```
%let title1 = %str(Table 15.2.4.3.2 Descriptive Statistics of 3-HPMA in 24-hour Urine Collection - FAS );
```

```
%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(&NSAA., best.)));

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

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

    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 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 "&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, halfblnk=N);

ods listing;


%m_logchk;
```