

```

/*=====
| Covance Study Number      : 000000106343      |
| Program Name              : t_mhbma_fas.sas    |
| Purpose                   : Program to create table 15.2.4.2.2 |
| Input Data                : ADAM.ADSL, ADAM.ADBX      |
| Output Data               : T_15_02_04_02_02      |
| Macros Called             : %m_printto, %param, %stats, %outrtf, %m_logchk |
| Originally Performed by   : Upender S          |
| Date                     : 28APR2015            |
|=====
| Modification History
|-----
| Modified by              :
| Modification Date        :
| Modification Description :
+=====*/

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

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

```
ods results on;
ods path sashelp.tmp1mst (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 an102f1='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 ablf1='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 /*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;
/*where &colvar ne .;*/
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_b1q;
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_b1q;

```

```

if cat= '1' then BigN= &NTHS;
if cat= '2' then BigN = &NMCC;
if cat= '3' then BigN = &NSAA;

msgng=BigN-n;
if .<msgng^=0 then msgng_prcnt=(msgng/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 c195_cu95 msg_pct blq_pct $50.;
set co_2s_1(rename=(n=n_orig));

if c195 ne . then c195 = 0.01*floor(100*c195);
if cu95 ne . then cu95 = 0.01*ceil(100*cu95);

if n_orig ^=. then N = compress(put(n_orig,best.));
if .<msgng^=0 then msg_pct=compress(put(msgng, best.))||' ('||compress(put(msgng_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 c195^=. and cu95^=. then c195_cu95= strip(put(c195,12.2))||', '||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 c195_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,12.2));
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;

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```

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=UMHBM24U, x=2);
%param(paramcd=UMHBMCRE, x=1);

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

data final;
  length paramcd $8.;
  set UMHBMCRE_final(in=a)
      UMHBM24U_final(in=b);
  if a then paramcd = "UMHBMCRE";
  else if b then paramcd = "UMHBM24U";
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 = 48;
data final2;
  set final1;
  if paramn = 46 then do;
    array x pchg;;
    do over x;
      x = "";
    end;
  end;
  if upcase(avisit) = "BASELINE" then do;
    array y pchg;;

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```

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;
run;

data tflds.t_15_02_04_02_02;
  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";
  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;
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_02_02);
%let title1 = %str(Table 15.2.4.2.2 Descriptive Statistics of MHBMA 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=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;

/* Amend title as needed */
_firtitl="&title1.";

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```

_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;

* most set up in template others below;
* title arial 12pt bold with 12pt paragraph space below;
* all headers to be arial 11pt bold;
* data arial 10pt;
* headers to be central, text values left aligned and numeric centered around decimal point;
/* Update with your variables as needed */
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 = 45 %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 = 46 %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 mC
C / 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' percentage
s 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."~\~" "(Pa
ge &i of &page)";
endcomp;
run;
%end;
ods rtf close;

```

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

```
%mend ;
```

```
%outtrtf(blankn=30, halfblnk=N);  
ods listing;
```

```
%m_logchk;
```