

```
*****;
* Project          : ZRHM-REXA-07-JP
*
* Program name     : t150204040101_ZRHM-REXA-07_V1.sas
*
* Author          : M. SUN
*
* Date created     : 06/08/2015
*
* Purpose         : Table 15.2.4.4.1.1 Descriptive Statistics of S-PMA
                  : Urinary Concentration Adjusted for Creatinine (units)
                  : in 24-hour Urine Collection by Sex  PP Set
*
* Revision History :
*
* Date      Author      Ref      Revision (Date in YYYYMMDD format)
*
*****;
```

```
%let prgname=T150204040101_ZRHM_REXA_07_JP_V1;
```

```
options mprint;
ods escapechar='^';
```

```
options sasautos=("W:\pmp07\macros" sasautos) notes;
%init(delivery=9);
%titlecsv(prgname=&prgname.,version=3);
%put &endpoint;
```

```
options missing="";
```

```
*libname adam 'W:\pmp07\Data\ADAM' access=readonly;
```

```
%macro t_desc_ms_2(par=,pop=,period=,chg=,sec=,dec=1);
```

```
%let dec1=%eval(&dec+1);
%let dec2=%eval(&dec+2);
```

```
proc sort data=adam.adbx(keep=usubjid paramcd param APUPER avisitn avisit ATPTN ATPT aval &chg ablf1 BLOQFL AULQFL anl02
fl) out=_adbx;
where paramcd in ("&par") and anl02fl='Y';
by usubjid;
run;
```

```
%do i=1 %to 4; /* for 4 period*/
```

```
data _pop1 _pop2 _pop3 _pop4 _pop5 _pop6 _pop7 _pop8;
set adam.adsl;
if %if &pop=fas %then &pop.fl; %else &pop.&i.fl; ='Y';
if trt01p='THSm2.2' and sex='M' then output _pop1;
else if trt01p='THSm2.2' and sex='F' then output _pop2;
else if trt01p='mCC' and sex='M' then output _pop3;
else if trt01p='mCC' and sex='F' then output _pop4;
else if trt01p='SA' and sex='M' then output _pop5;
else if trt01p='SA' and sex='F' then output _pop6;
if sex='M' then output _pop7;
else if sex='F' then output _pop8;
keep usubjid;
run;
```

```
data _adbx&i;
set _adbx;
if _n_=1 then call symputx("para",param);
if aval ne 0 then logaval=log(AVAL);
if APUPER=&i then output;
if ablf1='Y' then do;
APUPER=0;
output;
end;
run;
```

```
proc sort data=_adbx&i;
by usubjid APUPER avisitn atptn;
run;
```

```
%do j=1 %to 8; /* for 8 groups, including total*/
```

```
%global totn&i&j;
data _null_;
set _pop&j end=eof;
if eof then call symputx("totn&i&j",_n_);
run;
```

```
%let cannotlog=0;
%put &cannotlog;
```

```

data _data&j;
  merge _pop&j(in=x) _adb&i(in=y);
  by usubjid;
  if x;
  length atime $80;
  if apuper=0 then atime='Baseline';
  else if avisitn ne 105 then atime=propcase(avisit);
  else atime=propcase(atpt);

  if aval=0 then call symputx('canotlog',1);
run;
%put &canotlog;
proc sort data=_data&j;
  by apuper avisitn atptn atime;
run;

proc means data = _data&j noprint;
  where aval>.;
  by apuper avisitn atptn atime;
  var aval;
  output out=temp&j n=n mean=mean std=std median=median min=min max=max q1=q1 q3=q3 lclm=lclm uclm=uclm;
run;

proc means data = _data&j noprint;
  where logaval>.;
  by apuper avisitn atptn atime;
  var logaval;
  output out=templog&j mean=logmean std=logstd lclm=loglclm uclm=loguclm;
run;

proc freq data=_data&j noprint;
  tables apuper*avisitn*atptn*atime/out=tempBLO&j(rename=(count=blcount));
  where BLOQFL='Y';
run;

proc freq data=_data&j noprint;
  tables apuper*avisitn*atptn*atime/out=tempaul&j(rename=(count=auccount));
  where AULQFL='Y';
run;

data _res&j.1;
merge temp&j templog&j tempBLO&j(where=(blcount>0)) tempaul&j(where=(auccount>0));
  by apuper avisitn atptn atime;
  length col&j.1 $20 stat $40;
  dord=1;
  ord=1; stat='n'; col&j.1 = put(n, 8.); output;
  if 0<n<&&totn&i&j then do;
    ord=2; stat='Missing, n (%)'; col&j.1 = put(&&totn&i&j-n, 8.)||' ('||strip(put((&&totn&i&j-n)/&&totn&i&j*100, 5.1))|'|')'; output;
  end;
  ord=3; stat='BLOQ, n (%)';
  if blcount>0 then col&j.1 = put(blcount, 8.)||' ('||strip(put(blcount/&&totn&i&j*100, 5.1))||')';
  else col&j.1=''; output;
  if auccount>0 then do;
    ord=4; stat='ALOQ, n (%)'; col&j.1 = put(auccount, 8.)||' ('||strip(put(auccount/&&totn&i&j*100, 5.1))||')'; output;
  end;

  geomean = exp(logmean); /* Ratio of geometric mean */
  geoLCL = exp(loglclm); /* 95% CI lower bound */
  geoUCL = exp(loguclm); /* 95% CI upper bound */
  CVperc=100*sqrt(exp(logstd**2)-1);

  ord=5; stat='Geometric Mean (CV%)'; col&j.1=strip(put(round(geomean,1E-&dec1), 8.&dec1))||' ('||strip(put(round(ceil(CVperc*100)/100,0.01), 8.2)) ||')'; output;
  ord=6; stat='95% CI of Geometric Mean'; col&j.1=strip(put(round(floor(geoLCL*1E&dec1)/1E&dec1,1E-&dec1), 8.&dec1))||', '||strip(put(round(ceil(geoUCL*1E&dec1)/1E&dec1,1E-&dec1), 8.&dec1)); output;

  ord=7; stat='Median'; col&j.1 =put(round(median,1E-&dec1), 8.&dec1); output;
  ord=8; stat='Q25, Q75'; col&j.1 =strip(put(round(q1,1E-&dec1),8.&dec1))||', '||strip(put(round(q3,1E-&dec1), 8.&dec1)); output;
  ord=9; stat='Min, Max'; col&j.1 = strip(put(round(min,1E-&dec1), 8.&dec1))||', '||strip(put(round(max,1E-&dec1), 8.&dec1)); output;
  ord=10; stat='Mean (SD)';
  if std > . then col&j.1 = strip(put(round(mean,1E-&dec1), 8.&dec1))||' ('||strip(put(round(ceil(std*1E&dec2)/1E&dec2, 8.&dec2))||')';
  else col&j.1 = strip(put(round(mean,1E-&dec1), 8.&dec1))||' (NA)'; output;
  ord=11; stat='95% CI of Mean';
  col&j.1 =strip(put(round(floor(lclm*1E&dec1)/1E&dec1,1E-&dec1), 8.&dec1))||', '||strip(put(round(ceil(uclm*1E&dec1)/1E&dec1,1E-&dec1), 8.&dec1)); output;
run;

/***** change*****/

proc means data = _data&j noprint;
  where &chg>. and apuper>0;
  by apuper avisitn atptn atime;

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var &chg;
output out=tempc&j n=n mean=mean std=std median=median min=min max=max q1=q1 q3=q3 lclm=lclm uclm=uclm;
run;

data _res&j.2;
set tempc&j;
by apuper avisitn atptn atime;
length col&j.1 $20 stat $40;
dord=2;
ord=1; stat='n'; col&j.1 = put(n, 8.); output;
/*
if 0<n<&&totn&i&j then do;
ord=2; stat='Missing, n (%)'; col&j.1 = put(&&totn&i&j-n, 8.)||' ('||strip(put((&&totn&i&j-n)/&&totn&i&j*100, 5.1))|
'|)'; output;
end;
*/
ord=7; stat='Median'; col&j.1 =put(round(median,1E-&dec1), 8.&dec1); output;
ord=8; stat='Q25, Q75'; col&j.1 =strip(put(round(q1,1E-&dec1),8.&dec1))||', '||strip(put(round(q3,1E-&dec1), 8.&dec
1)); output;
ord=9; stat='Min, Max'; col&j.1 = strip(put(round(min,1E-&dec), 8.&dec))||', '||strip(put(round(max,1E-&dec), 8.&dec))
; output;
ord=10; stat='Mean (SD)';
if std > . then col&j.1 = strip(put(round(mean,1E-&dec1), 8.&dec1))||' ('||strip(put(round(ceil(std*1E&dec2)/1E&dec2,
1E-&dec2), 8.&dec2))||')';
else col&j.1 = strip(put(round(mean,1E-&dec1), 8.&dec1))||' (NA)'; output;
ord=11; stat='95% CI of Mean';
col&j.1 =strip(put(round(floor(lclm*1E&dec1)/1E&dec1,1E-&dec1), 8.&dec1))||', '||strip(put(round(ceil(uclm*1E&dec1)/1E
&dec1,1E-&dec1), 8.&dec1)); output;
keep apuper stat avisitn atptn atime ord dord col&j.1;
run;

%end;

data _res&i;
merge _res11 _res21 _res31 _res41 _res51 _res61
_res12 _res22 _res32 _res42 _res52 _res62;
by apuper avisitn atptn atime dord ord;
period=&i;
run;

%end;

data &par;
set _res1-_res4;
by period apuper avisitn atptn dord atime ord;
run;

data &par;
set &par;
by period apuper avisitn atptn dord atime ord;
length para $100;
para="&para";
sec=&sec;

lagcol11=lag(col11);
lagcol21=lag(col21);
lagcol31=lag(col31);
lagcol41=lag(col41);
lagcol51=lag(col51);
lagcol61=lag(col61);

array cols[6] col11 col21 col31 col41 col51 col61;
array lagcols[6] lagcol11 lagcol21 lagcol31 lagcol41 lagcol51 lagcol61;

if ord=2 then do i=1 to 6;
if cols[i]='' and lagcols[i]>' ' then cols[i]='0';
end;
keep sec period apuper avisitn atptn atime dord ord stat para col;
run;

data &par;
set &par;
by period apuper avisitn atptn dord atime ord;
length para $100;
para="&para";
sec=&sec;

lagcol11=lag(col11);
lagcol21=lag(col21);
lagcol31=lag(col31);
lagcol41=lag(col41);
lagcol51=lag(col51);
lagcol61=lag(col61);

array cols[6] col11 col21 col31 col41 col51 col61;
array lagcols[6] lagcol11 lagcol21 lagcol31 lagcol41 lagcol51 lagcol61;

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    if ord=3 and dord=1 then do i=1 to 6;
        if cols[i]='' and lagcols[i]>' ' then cols[i]='0';
    end;
    keep sec period apuper avisitn atptn atime dord ord stat para col;
run;

proc datasets library=work memtype=data nolist;
delete _: temp;;
run;quit;

%mend;

%t_desc_ms_2(par=USPMACRE,pop=pprot,period=%str(1,2,3,4),chg=PCHG,sec=1);

data USPMACRE;
set USPMACRE;
by sec period apuper avisitn atptn dord ;
output;
if first.dord then do;
ord=-99;
array cols stat col;
do over cols;
cols='';
end;
output;
end;
run;

proc sort data=USPMACRE;
by sec period apuper avisitn atptn dord ord;
run;

%macro doreport;
data final;
set USPMACRE;
by sec period apuper avisitn atptn dord ;
/*
if first.atptn then ctpg+1;
if _n_=1 then pagen=1;
if ctpg>2 or (first.period and _n_ ne 1) then do;
pagen+1;
ctpg=1;
end;
*/
if first.dord then pagen+1;
if atime ne 'Baseline' and dord=2 then atime='% Change from baseline to '||strip(atime);
run;

data final;
set final end=eof;
by pagen;
if eof then call symputx("totalpage",pagen);
run;

data odata.&prgname.;
retain pagen para apuper avisitn atptn atime dord ord stat col11 col21 col31 col41 col51 col61;
set final;
run;

%trtrtfg(pgmname=&outname., pgmid=1, new=0, style=, bookmark=%lowcase(&outname.));

%do i=1 %to &totalpage;

data final&i;
set final;
where pagen=&i;
call symputx("period",period);
run;

title; footnote;
/*
title1 bold j=1 "&title1 &title2";
title2 " ";

title3 j=1 h=9pt "Product Use Time Period: Period &period";

footnote1 bold h=12pt "_____";
footnote2 j=1 h=9pt "Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating Sys
tem 2.2 Menthol.";
footnote3 j=1 h=9pt "Note: * % change from baseline, where baseline is defined as the last assessment prior to first ran
domized product use ";
"in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.";
footnote4 j=1 h=9pt " ";
footnote5 h=9pt j=1 "&APPENDIX.";
footnote6 h=9pt j=1 "Study ID:ZRHM-REXA-07-JP Program: &prgname..sas Status: &repversion./&fdate.
Page: &i. of &totalpage";

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*/

proc report data=final&i headskip headline nowd split='-' style=[outputwidth=100%] style(header column)=[protectspecial
chars=off];

    column pagen apuper avisitn atptn dord atime ord stat ("^R/RTF'\brdrb\brdrs ' THSm2.2" col11 col21)
    ("^R/RTF'\brdrb\brdrs ' mCC" col31 col41) ("^R/RTF'\brdrb\brdrs ' SA" col51 col61);
    define pagen /order order=internal noprint;
    define apuper /order order=internal noprint;
    define avisitn /order order=internal noprint;
    define atptn /order order=internal noprint;
    define dord /order order=internal noprint;
    define atime /order "Timepoint" style(column)=[cellwidth=11% just=l] style(header)=[just=l];
    define ord /order order=internal noprint;
    define stat /display "Statistic" style(column)=[cellwidth=17% just=l] style(header)=[just=l];
    define col11 /display "Males-(N=&&totn&period.1)" style(column)=[cellwidth=9% just=c];
    define col21 /display "Females-(N=&&totn&period.2)" style(column)=[cellwidth=9% just=c];
    define col31 /display "Males-(N=&&totn&period.3)" style(column)=[cellwidth=9% just=c];
    define col41 /display "Females-(N=&&totn&period.4)" style(column)=[cellwidth=9% just=c];
    define col51 /display "Males-(N=&&totn&period.5)" style(column)=[cellwidth=9% just=c];
    define col61 /display "Females-(N=&&totn&period.6)" style(column)=[cellwidth=9% just=c];

COMPUTE before pagen;
LINE @1 " ";
ENDCOMP;

COMPUTE after dord;
LINE @1 " ";
ENDCOMP;

compute before _page_ /style=[fontweight=bold fontsize=3.75];
line @1 "&title1 &title2";
line @1 " ";
line @1 "Product Use Time Period: Period &period";
line @1 "^R/RTF'\brdrb\brdrs\brdrw30\brsp20\b ' ";
endcomp;

compute after _page_ /style=[fontsize=1.75];
line @1 "Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 = Tobacco Heating System 2.2 Ment
hol.";
line @1 "Note: * % change from baseline, where baseline is defined as the last assessment prior to first randomized prod
uct use "
"in mCC / THS 2.2 Menthol arms or the last assessment prior to 10 AM on Day 1 in the SA arm.";
line @1 " ";
line @1 "&APPENDIX.";
line @1 "Study ID:ZRHM-REXA-07-JP Program: &fprgname..sas Status: &repversion./&fdate. Page: &i.
of &totalpage";

endcomp;

run;

%end;

ods listing;
ods rtf close;
%mend;

%doreport;

```