

/*-----

Covance Study ID : COV-000000106343

Program Name : t_vs_bp_fas.sas

Purpose : Table 15.2.4.26.2(Descriptive Statistics of Blood Pressure (mmHg) PP);

Author : cvn_pshe

Date of Creation : 14MAY015

Input Data : ADAM.ADSL, ADAM.ADVS

Output Data :

Macros Called :

Modification History

Modified by :

Modification Date :

Modification Description:

-----*/

proc datasets lib=work kill memtype=data nolist;

run;

%m_printto;

options notes nosource;

options replace;

```
options notes source source2 nofullstimer validvarname=upcase missing=' ';
```

```
ods _all_ close;
```

```
ods listing;
```

```
*=====;
```

```
* START OF PROGRAM CODE                               ;
```

```
*=====;
```

```
%let tflno=T_15_02_04_26_02;
```

```
%let TFL_Part=%scan(&_amp;_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;
```

```
*****;
```

```
* read in data ;
```

```
*****;
```

```
/*Use ADSL to get N values for column headers*/
```

```
data adsl;
```

```

        set adam.adsl(where=(fasfl='Y'));

run;

proc sort data=adsl nodupkey out=adsl1;

    by usubjid trt01an trt01a;

run;

proc freq data=adsl1(where=(not missing(trt01an))) noprint;

    table trt01an*trt01a/ out =tot(drop=percent rename=(count=total));

run;

data tot2;

    set tot;

    call symput('trt' || strip(put(trt01an,best.)),strip(put(total,best.)));

run;

/*Bring in sbp and dbp raw value data from ADVS*/

%macro rawval (parmcd=,parm=, num=);

data advs_bp;

    set adam.advs(where=(anl01fl='Y' and fasfl='Y' and trtan ne 98 and paramcd in ("&parmcd")));

run;

data advs_bp ;

    set advs_bp ;

        if abfl = 'Y' then do; avisit='Baseline'; avisitn=98; end;

```

```

        if avisit='Screening' and ablfl =" then delete;

        else if avisit='Day -2' and ablfl =" then delete;

        else if avisit='Day -1' and ablfl =" then delete;

        else if avisit='Day 0' and ablfl =" then delete;

run;


proc sort data=advs_bp ;

    by trtan trta avisitn avisit;

run;


proc means data=advs_bp noprint;

    var aval;

    by trtan trta avisitn avisit;

    output out=bpstat n=n1 mean=mean1 std=sd1 median=median1 min=min1 max=max1 q1=q1 q3=q3
    lclm =lci1 uclm=uci1;

run;


data bpstat_&parmcd ;

    set bpstat (rename=(mean1=mean lci1=lclm uci1=uclm)) ;

        paramcd="&parmcd";

    keep  paramcd trta trtan avisit avisitn mean lclm uclm;

run;


data bpstat1;

    set bpstat;

    attrib meansd minmax n median missc quart length=$20.;

```

```

n = left(compress(put(n1,8.)));

*for <missing, n(%)>;

    if trtan=3 then do;

        if &trt3.=n1 then

            missc="";

        else

            missc=strip(put((&trt3.- n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 8.1)) || ")";

        end;

    else if trtan=4 then do;

        if &trt4.=n1 then

            missc="";

        else

            missc=strip(put((&trt4.- n1), 8.)) || ' (' || strip(put(((&trt4.-n1)*100)/&trt4., 8.1)) || ")";

        end;

    else if trtan=5 then do;

        if &trt5.=n1

            then missc="";

        else

            missc=strip(put((&trt5.-n1), 8.)) || ' (' || strip(put(((&trt5.-n1)*100)/&trt5., 8.1)) || ")";

        end;

    IF NOT MISSING(MEDIAN1) THEN MEDIAN =
LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.1),10.1)));

    IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.1),10.1))) || " (" || STRIP(PUT(0.01*CEIL(SD1/0.01),10.2)) || ")";

    IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.)) || ",
" || strip(put(max1, 10.));

```

```

    IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.1),10.1))) || ', ' || LEFT(COMPRESS(PUT(ROUND(Q3,0.1),10.1)));;

    IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI = STRIP(PUT(0.1*FLOOR(LCI1/0.1),10.1)) || ',
' || STRIP(PUT(0.1*CEIL(UCI1/0.1),10.1));

    drop n1 mean1 sd1 median1 min1 max1 q1 q3 lci1 uci1 _type_ _freq_;

run;

proc sort data=bpstat1;

    by trtan trta avisitn avisit;

run;

proc transpose data=bpstat1 out=t_bpstat1;

    by trtan trta avisitn avisit;

        var n missc meansd minmax median quart aci;

run;

data sa ths mcc;

    length stat rawval $50;

    set t_bpstat1 (drop=trtan rename=( _name_ =stat col1=rawval)) ;

        if trta='SA' then output sa;

        else if trta='THSm2.2' then output ths;

        else if trta='mCC' then output mcc;

run;

proc sort data=sa (rename=(rawval=saval)) ;

    by avisitn avisit stat;

```

```

run;

proc sort data=ths (rename=(rawval=thsva));

    by avisitn avisit stat;

run;

proc sort data=mcc (rename=(rawval=mccval));

    by avisitn avisit stat;

run;

data stat_&parm;

    merge sa (drop=trta ) ths (drop=trta) mcc;

        by avisitn avisit stat;

        if stat='N' then do; stat='n'; sort=1; end;

        else if stat='MISSC'      then do; stat='Missing, n(%)'; sort=2; end;

    else if stat='MEANS' then do; stat='Mean (SD)'; sort=2.2; end;

        else if stat='ACI' then do; stat='95% CI'; sort=3; end;

        else if stat='MEDIAN' then do; stat='Median'; sort=4; end;

        else if stat='QUART' then do; stat='Q25, Q75'; sort=5; end;

    else if stat='MINMAX' then do; stat='Min, Max'; sort=6; end;

        order=&num;

run;

%mend rawval;

%rawval (parmcd=SYSBP,parm=sbp, num=1);

%rawval (parmcd=DIABP,parm=dbp, num=2);

```

```
data stat_bp ;;
```

```
    set stat_sbp stat_dbp;
```

```
run;
```

```
proc sort data=stat_bp;
```

```
    by order avisitn avisit sort;
```

```
run;
```

```
data stat_bp_fas ;
```

```
    length param $50;
```

```
    set bpstat_sysbp (where=(avisitn in (98 106 130 160 191)))
```

```
        bpstat_diabp (where=(avisitn in (98 106 130 160 191)));
```

```
                                if paramcd='SYSBP' then do; paramn = 1001; param='Systolic Blood Pressure  
(mmHg)'; end;
```

```
                                else if paramcd='DIABP' then do; paramn = 1002; param='Diastolic Blood  
Pressure (mmHg)'; end;
```

```
                                logf=0;
```

```
run;
```

```
%m_chglength(inds=stat_bp_fas,varlist=param paramcd, lenlist= $60 $8);
```

```
proc sort data=stat_bp_fas out=tflds.T_15_02_04_26_02_f;
```



```

    by paramn avisitn ;

run;

/*Bring in sbp and dbp percent change data from ADVS*/

%macro pchgval (parmcd=,parm=, num=);

data advs_bp;

    set adam.advs(where=(anl01fl='Y' and fasfl='Y' and trtan ne 98 and parmcd in ("&parmcd")));

run;

data advs_bp ;

    set advs_bp ;

        if ablfl ='Y' then do; avisit='Baseline'; avisitn=98; end;

        if avisit='Screening' and ablfl =" then delete;

        else if avisit='Day -2' and ablfl =" then delete;

        else if avisit='Day -1' and ablfl =" then delete;

        else if avisit='Day 0' and ablfl =" then delete;

run;

proc sort data=advs_bp ;

    by trtan trta avisitn avisit;

run;

proc means data=advs_bp noprint;

    var pchg;

```

```

by trtan trta avisitn avisit;

output out=pbpstat n=n1 mean=mean1 std=sd1 median=median1 min=min1 max=max1 q1=q1 q3=q3
lclm =lci1 uclm=uci1;

run;

data pbpstat1;

set pbpstat;

attrib meansd minmax n median missc quart length=$20.;

n = left(compress(put(n1,8.)));

n = left(compress(put(n1,8.)));

*for <missing, n(%>;

if trtan=3 then do;

if &trt3.=n1 then

missc="";

else

missc=strip(put((&trt3.- n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 8.1)) || ")";

end;

else if trtan=4 then do;

if &trt4.=n1 then

missc="";

else

missc=strip(put((&trt4.- n1), 8.)) || ' (' || strip(put(((&trt4.-n1)*100)/&trt4., 8.1)) || ")";

end;

else if trtan=5 then do;

if &trt5.=n1

then missc="";

```

```

else
missc=strip(put((&trt5.-n1), 8.)) || ' (' || strip(put(((&trt5.-n1)*100)/&trt5., 8.1)) || ")";

end;

IF NOT MISSING(MEDIAN1) THEN MEDIAN =
LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.1),10.1)));

IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.1),10.1))) || " (" || STRIP(PUT(0.01*CEIL(SD1/0.01),10.2)) || ")";

IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.)) || ",
" || strip(put(max1, 10.));

IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.1),10.1))) || ', ' || LEFT(COMPRESS(PUT(ROUND(Q3,0.1),10.1)));

IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI = STRIP(PUT(0.1*FLOOR(LCI1/0.1),10.1)) || ',
' || STRIP(PUT(0.1*CEIL(UCI1/0.1),10.1));

drop n1 mean1 sd1 median1 min1 max1 q1 q3 lci1 uci1 _type_ _freq_;

run;

proc sort data=pbpstat1;

by trtan trta avisitn avisit;

run;

proc transpose data=pbpstat1 out=t_pbpstat1;

by trtan trta avisitn avisit;

var n missc meansd minmax median quart aci;

run;

data psa pths pmcc;

length stat pchg $50;

```

```

set t_pbpstat1 (drop=trtan rename=(_name_=stat col1=pchg)) ;

        if trta='SA' then output psa;

        else if trta='THSm2.2' then output pths;

        else if trta='mCC' then output pmcc;

run;


proc sort data=psa (rename=(pchg=sapchg));

    by avisitn avisit stat;

run;

proc sort data=pths (rename=(pchg=thspchg));

    by avisitn avisit stat;

run;

proc sort data=pmcc (rename=(pchg=mccpchg));

    by avisitn avisit stat;

run;


data stat_&parm;

    merge psa (drop=trta) pths (drop=trta) pmcc;

        by avisitn avisit stat;

        if stat='N' then do; stat='n'; sort=1; end;

        else if stat='MISSC'      then do; stat='Missing, n(%)'; sort=2; end;

    else if stat='MEANSd' then do; stat='Mean (SD)'; sort=2.2; end;

        else if stat='ACI' then do; stat='95% CI'; sort=3; end;

        else if stat='MEDIAN' then do; stat='Median'; sort=4; end;

        else if stat='QUART' then do; stat='Q25, Q75'; sort=5; end;

```

```

        else if stat='MINMAX' then do; stat='Min, Max'; sort=6; end;

                order=&num;

run;

%mend;

%pchgval (parmcd=SYSBP,parm=sbppchg, num=1);
%pchgval (parmcd=DIABP,parm=dbppchg, num=2);

data stat_bppchg ;
    set stat_sbppchg stat_dbppchg;
run;

proc sort data=stat_bppchg nodupkey;
    by order avisitn avisit sort;
run;

data stat;
    merge stat_bp (drop=stat trta) stat_bppchg;
                by order avisitn avisit sort;
run;

proc sort data=stat;
    by order avisitn sort;
run;

```

```
data stat;
```

```
set stat;
```

```
length param $100;
```

```
if sapchg='0' then sapchg="";
```

```
if thspchg='0' then thspchg="";
```

```
if mccpchg='0' then mccpchg="";
```

```
if avisitn in (121) then delete;
```

```
if order=1 then param='Systolic blood Pressure (mmHg)';
```

```
else if order=2 then param='Diastolic blood Pressure (mmHg)';
```

```
if sort=. then delete;
```

```
if stat='Missing, n(%)' and avisit='Baseline' then do;
```

```
if saval="" then saval='0';
```

```
if mccval="" then mccval='0';
```

```
if thsval="" then thsval='0';
```

```
sapchg="";
```

```
mccpchg="";
```

```
thspchg="";
```

```
end;
```

```
else if stat='Missing, n(%)' and avisit ^= 'Baseline' then do;
```

```
if saval="" then saval='0';
```

```

        if mccval="" then mccval='0';

        if thsval="" then thsval='0';

        if sapchg="" then sapchg='0';

        if mccpch="" then mccpch='0';

        if thspchg="" then thspchg='0';

    end;

run;

* output dataset*;

proc sql noprint;

    create table tflds.&tflno as

        select param as parameter, avisit as timepoint, stat, thsval, thspchg, mccval, mccpch, saval,
        sapchg

        from stat

        order by param, order, avisitn, sort;;

quit;

/*Report*/

Data stat_1;

    set stat end=last;

    where order=1 and avisit not in ('Day 60' 'Day 91/Discharge Ambulatory');

    pagen=ceil(_n_/14);

    if last then call symputx('lpagea', pagen);

run;

Data stat_2;

```

```
set stat end=last;

where order=1 and avisit in ('Day 60' 'Day 91/Discharge Ambulatory');

pagen=ceil(_n_/7) + &lpagea.;

if last then call symputx('lpageb', pagen);

run;
```

```
Data stat_3;

set stat end=last;

where order=2 and avisit not in ('Day 60' 'Day 91/Discharge Ambulatory');

pagen=ceil(_n_/14) + &lpageb.;

if last then call symputx('lpagec', pagen);

run;
```

```
Data stat_4;

set stat end=last;

where order=2 and avisit in ('Day 60' 'Day 91/Discharge Ambulatory');

pagen=ceil(_n_/7) + &lpagec.;

if last then call symputx('page', pagen);

run;
```

```
data paging;

set stat_1 stat_2 stat_3 stat_4;

by pagen;

if first.pagen then param=param;

else param=";
```



```
run;
```

```
options number nodate orientation=landscape papersize=Letter 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;
```

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

```
%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;
```

```
ods proclabel = ' ';
```

```
data comp;
```

```
set paging end=eof;
```

```
where pagen=&i;
```

```

/* Amend title as needed */

_firtitl="Table 15.2.4.26.2 Descriptive Statistics of Blood Pressure (mmHg) - FAS";

_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.)));

end;


drop _firtitl _upcas len;

run;


ods proclabel = ' ';

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;

proc report data = comp headline headskip nowd split = '#' /*ps = 60 ls = 120*/%if &i=1 %then %do;
contents=' ' %end; %else %do; contents=" %end;;

        column order pagen avisitn param avisit stat

                ("THSm2.2#(N=&trt4)&linebot" thsval thspchg) ("mCC#(N=&trt5)&linebot" mccval
mccpchg) ("SA#(N=&trt3)&linebot" saval sapchg);

```

```

define order    / order order = internal noprint;

define pagen    / order order = internal noprint;

define avisitn  / order order=internal noprint;


define param    / "Parameter (units)" style={just=left cellwidth=3cm} style(header)={just=left} ;

define avisit   / group "Timepoint" style={just=left cellwidth=2.8cm}
style(header)={just=left} ;

define stat     / display "Statistic" style={just=left cellwidth=2.2cm} style(header)={just=left} ;

define thsval   / display "Raw value" style={just=c cellwidth=2.2cm} ;

define thspchg  / display "% Change(*)" style={just=c cellwidth=2.2cm} ;

define mccval   / display "Raw value" style={just=c cellwidth=2.2cm} ;

define mccpchg  / display "% Change(*)" style={just=c cellwidth=2.2cm} ;

define saval    / display "Raw value" style={just=c cellwidth=2.2cm} ;

define sapchg   / display "% Change(*)" style={just=c cellwidth=2.2cm} ;


break after pagen / page;


compute after avisitn;

line " ";

endcomp;


compute before pagen / style={protectspecialchars=off};

line "&linetop";

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 "&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: Percentages are based on the number of subjects indicated in the column header (N).";

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 ';

line 'last assessment prior to 10 AM on Day 1 in the SA arm.';

line ' ';

line "Appendix 15.3.6.9";

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=36, halfblank=N);
```

```
ods listing close;
```

```
proc printto ; run;
```

```
%m_logchk;
```

```
*=====;
```

```
* END OF PROGRAM CODE ;
```

```
*=====;
```