

/*-----

Covance Study ID : COV-000000106343

Program Name : t_bx_bm_fas.sas

Purpose : Table 15.2.4.32.2(Descriptive Statistics of 8-epi-PGF2± (units) and 11 DTX-B2 (units)
â€“ FAS);

Author : cvn_pshe

Date of Creation : 14MAY2015

Input Data : ADAM.ADSL, ADAM.ADBX,

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_32_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 parm raw value data from ADBX*/

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

data adbx;

    set adam.adbx(where=(anl02fl='Y' and fasfl='Y' and parmcd in ("&parmcd")));

run;

data adbx ;

    set adbx ;

        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=adbx ;

    by trtan trta avisitn avisit;

run;


proc means data=adbx 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 ;

    length paramcd $ 20;

    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=\$25.;

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=thsval));

    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'D 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;

        if stat='Mean (SD)' then delete;

    else if stat='95% CI' then delete;

        order=&num;

run;

```

```
%mend rawval;
```

```
%rawval (parmcd=UPGF2CRE,param=pgf, num=1);
```

```
%rawval (parmcd=UTXB2CRE,param=dtx, num=2);
```

```
/*Bring in parm raw value data to log scale from ADBX*/
```

```
%macro rawval_l (parmcd=,param=, num=);
```

```
data adbx_l;
```

```
    set adam.adbx(where=(anl02fl='Y' and fasfl='Y' and paramcd in ("&parmcd")));
```

```
    if nmiss(aval)=0 then aval=log(aval);
```

```
run;
```

```
data adbx_l ;
```

```
    set adbx_l ;
```

```
        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;
```

```
run;
```

```
proc sort data=adbx_l ;
```

```
    by trtan trta avisitn avisit;
```

```
run;
```

```
proc means data=adbx_l noprint;
```



```

var aval;

by trtan trta avisitn avisit;

output out=bpstat_l mean=mean1 std=sd1 lclm =lci1 uclm=uci1 nmiss=miss;

run;

```

```

data bpstat_1_&parmcd ;

length paramcd $ 20;

set bpstat_l;

           paramcd="&parmcd";

mean=exp(mean1);

lclm=exp(lci1);

uclm=exp(uci1);

keep  paramcd trta trtan avisit avisitn mean lclm uclm;

run;

```

```

data bpstat_l;

set bpstat_l;

           length gmean gcv $30 glci guci 8;

gmean1=exp(mean1);

if miss=0 then do;

           gmean=left(compress(put(gmean1,10.1)));

           if not missing(sd1) then gcv=strip(put(0.01*ceil((sqrt(exp(sd1*sd1)-1)*100)/0.01),10.2));

           if not missing(lci1) then glci=exp(lci1);

           if not missing(uci1) then guci=exp(uci1);

end;

```

```
run;
```

```
data bpstat1_l;
```

```
set bpstat_l;
```

```
attrib meansd aci length=$20.;
```

```
IF MISS=0 THEN DO;
```

```
    if not missing(gcv) then meansd=left(trim(gmean)) || ' (' || left(trim(gcv)) || ')';
```

```
    else gmeancv=left(trim(gmean));
```

```
    if not missing(glci) and not missing(guci) then aci = strip(strip(put(0.1*floor(glci/0.1),10.1)) || ',  
' || strip(put(0.1*ceil(guci/0.1),10.1))));
```

```
END;
```

```
drop mean1 sd1 lci1 uci1 _type_ _freq_;
```

```
run;
```

```
proc sort data=bpstat1_l;
```

```
by trtan trta avisitn avisit;
```

```
run;
```

```
proc transpose data=bpstat1_l out=t_bpstat1_l;
```

```
by trtan trta avisitn avisit;
```

```
var meansd aci;
```

```
run;
```

```
data sa ths mcc;
```

```
length stat rawval $50;
```

```
set t_bpstat1_l (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=thsvall));

    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='MEANS'D then do; stat='Geometric Mean (CV%)'; sort=2.2; end;

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

        order=&num;

run;

%mend rawval_;

```

```
%rawval_l (parmcd=UPGF2CRE,parm=pgf_l, num=1);
```

```
%rawval_l (parmcd=UTXB2CRE,parm=dtx_l, num=2);
```

```
data stat_bx ;;
```

```
set stat_pgf stat_pgf_l stat_dtx stat_dtx_l;
```

```
run;
```

```
proc sort data=stat_bx;
```

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

```
run;
```

```
data stat_bx_bm_fas ;
```

```
length param $50;
```

```
set bpstat_1_upgf2cre (where=(avisitn in (98 105 130 160 190)))
```

```
bpstat_1_utxb2cre (where=(avisitn in (98 105 130 160  
190)));
```

```
if paramcd='UPGF2CRE' then do; paramn = 3073; param='Prostaglandin F2  
Alpha (pg/mg creat)'; logf=1;end;
```

```
else if paramcd='UTXB2CRE' then do; paramn = 3076; param='11-Dehydro-  
Thromboxane B2 (pg/mg creat)'; logf=1;end;
```

```
run;
```

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

```

proc sort data=stat_bx_bm_fas out=tflds.T_15_02_04_32_02_f;

    by paramn avisitn ;

run;

/*Bring in parm percent change data from ADBX*/

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

data adbx;

    set adam.adbx(where=(anl02fl='Y' and fasfl='Y' and parmcld in ("&parmcld")));

run;

data adbx ;

    set adbx ;

        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;

run;

proc sort  data=adbx ;

    by trtan trta avisitn avisit;

run;

proc means data=adbx 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=$25.;

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;

if stat='Mean (SD)' then do; stat='Geometric Mean (CV%)'; sapchg=""; thspchg="";
mccpchg=""; end;

else if stat='95% CI' then do; stat='95% CI of Geometric Mean'; sapchg=""; thspchg=""; mccpchg=""; end;

order=&num;

run;

%mend;

%pchgval (parmcd=UPGF2CRE,parm=chgpgef, num=1);
%pchgval (parmcd=UTXB2CRE,parm=chgdtx, num=2);

data stat_bxpchg ;
    set stat_chgpgef stat_chgdtx;
run;

proc sort data=stat_bxpchg ;
    by order avisitn avisit sort;
run;

data stat;
    merge stat_bx (drop=stat trta) stat_bxpchg;
        by order avisitn avisit sort;
run;

```

```

proc sort data=stat;

    by order avisitn sort;

run;

data stat;

    set stat;

        length param $100;

        if avisit= 'Baseline' and stat ne 'n' then do; sapchg=""; thspchg=""; mccpchg=""; end;

        if order=1 then param='Prostaglandin F2 Alpha (pg/mg creat)';
        else if order=2 then param='11-Dehydro-Thromboxane B2 (pg/mg creat)';

        if avisit='Day 0' then delete;

        if sort=. then delete;

        if avisit='Baseline' then do; sapchg=""; mccpchg=""; thspchg=""; end;

run;

* output dataset*;

proc sql noprint;

    create table tflds.&tflno as

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

    from stat

    order by param, order, avisitn, sort;;

```

```
quit;
```

```
data paging;
```

```
set stat;
```

```
by order avisitn sort;
```

```
if first.avisitn then ln=1; /*Amend to look presentable, and avoid page overflows*/
```

```
else ln+1;
```

```
if ln=1 then page+1;
```

```
call symput("page",compress(put(page,best.)));
```

```
run;
```

```
data paging;
```

```
set paging;
```

```
by page;
```

```
if first.page 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 page=&i;


/* Amend title as needed */

    _firtitl="Table 15.2.4.32.2 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2
(pg/mg creat) - 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 = '#' %if &i=1 %then %do; contents=' ' %end;
%else %do; contents="" %end;;

    column order page 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 page      / order order = internal noprint;

define avisitn   / order order=internal noprint;

define param     / "Parameter (units)" style={just=left cellwidth=2.5cm} style(header)={just=left} ;

           define avisit     / group "Timepoint" style={just=left cellwidth=2cm}
style(header)={just=left} ;

define stat      / display "Statistic" style={just=left cellwidth=4.3cm} 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 page / page;

```

```

compute after avisitn;

```

```

    line " ";

```

```

endcomp;

```

```

compute before page / 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 15.3.3.1";

        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=36, halfblk=N);


ods listing close;


proc printto ; run;

%m_logchk;

*=====;

* END OF PROGRAM CODE                                ;

```

*=====;