

/*-----

Covance Study ID : COV-000000106343

Program Name : t_bx_bm_pp.sas

Purpose : Table 15.2.4.32.1(Descriptive Statistics of Descriptive Statistics of PGF and DTX-B2 - PP Set;

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 mprint symbolgen;

```
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_01;
```

```
%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*/
```

```

%macro trt(period= );

%global N&period.THS;

%global N&period.MCC;

%global N&period.SAA;

proc sql;

select count(distinct usubjid) into: N&period.THS from adam.adsl(where=(trt01an = 4 and
pprot&period.fl = "Y"));

select count(distinct usubjid) into: N&period.MCC from adam.adsl(where=(trt01an = 5 and
pprot&period.fl = "Y"));

select count(distinct usubjid) into: N&period.SAA from adam.adsl(where=(trt01an = 3 and
pprot&period.fl = "Y"));

quit;

%mend;


%trt(period=1);

%trt(period=2);

%trt(period=3);

%trt(period=4);


/*Bring in param raw value data from ADBX*/;


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

data adbx_bm&period.;

```

```
set adam.adbx(where=(anl02fl='Y' and pprot&period.fl='Y' and paramcd in ("&parmcd") and  
&avisit));
```

```
run;
```

```
data adbx_bm&period. ;
```

```
set adbx_bm&period. ;
```

```
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=adbx_bm&period. ;
```

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

```
run;
```

```
proc means data=adbx_bm&period. noprint;
```

```
var aval;
```

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

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

```
run;
```

```
data bpstat&period.;
```

```
set bpstat&period.;
```

```

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

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

*for <missing, n(%)>;

if trtan=3 then do;

if &&N&period.SAA.=n1

then missc="";

else

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

end;

else if trtan=4 then do;

if &&N&period.THS.=n1

then missc="";

else

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

end;

else if trtan=5 then do;

if

&&N&period.MCC.=n1 then missc="";

else

missc=strip(put((&&N&period.MCC.-n1), 8.)) || ' (' || strip(put(((&&N&period.MCC.-
n1)*100)/&&N&period.MCC., 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=bpstat&period.;

    by trtan trta avisitn avisit;

run;

```

```

proc transpose data=bpstat&period. out=t_bpstat&period.;

    by trtan trta avisitn avisit;

    var n missc meansd minmax median quart aci;

run;

```

```

data sa&period. ths&period. mcc&period.;

    length stat rawval $50;

    set t_bpstat&period. (drop=trtan rename=( _name_ =stat col1=rawval)) ;

        if trta='SA' then output sa&period.;

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

        else if trta='mCC' then output mcc&period.;

run;

```

```

proc sort data=sa&period. (rename=(rawval=saval)) ;

```

```

    by avisitn avisit stat;

run;

proc sort data=ths&period. (rename=(rawval=thsva));

    by avisitn avisit stat;

run;

proc sort data=mcc&period. (rename=(rawval=mccval));

    by avisitn avisit stat;

run;

data stat_&parm._&period.;

    merge sa&period. (drop=trta ) ths&period. (drop=trta) mcc&period.;

        by avisitn avisit stat;

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

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

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

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

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

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

        else if upcase(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;

        period=&period;

```

```
run;
```

```
%mend rawval;
```

```
%rawval (period=1, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4'  
'Day 5' 'Day 6/Discharge Confinement'))), parmcd=UPGF2CRE,parm=pgf, num=1);
```

```
%rawval (period=2, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 30'))),  
parmcd=UPGF2CRE,parm=pgf, num=1);
```

```
%rawval (period=3, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 60'))),  
parmcd=UPGF2CRE,parm=pgf, num=1);
```

```
%rawval (period=4, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 90' 'Day 91/Discharge  
Ambulatory'))), parmcd=UPGF2CRE, parm=pgf, num=1);
```

```
%rawval (period=1, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4'  
'Day 5' 'Day 6/Discharge Confinement'))), parmcd=UTXB2CRE,parm=dtx, num=2);
```

```
%rawval (period=2, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 30'))),  
parmcd=UTXB2CRE,parm=dtx, num=2);
```

```
%rawval (period=3, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 60'))),  
parmcd=UTXB2CRE,parm=dtx, num=2);
```

```
%rawval (period=4, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 90' 'Day 91/Discharge  
Ambulatory'))), parmcd=UTXB2CRE,parm=dtx, num=2);
```

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

```
%macro rawval_l (period=, avisit=, parmcd=,parm=, num=);
```

```
data l_adbx_bc&period. ;
```

```
set adam.adbx(where=(anl02fl='Y' and pprot&period.fl='Y' and paramcd in ("&parmcd") and  
&avisit));
```

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

```
run;
```



```

data l_adbx_bc&period. ;

set l_adbx_bc&period. ;

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

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

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

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

run;


proc sort data=l_adbx_bc&period. ;

    by trtan trta avisitn avisit;

run;


proc means data=l_adbx_bc&period. noprint;

    var aval;

    by trtan trta avisitn avisit;

    output out=l_bpstat&period. mean=mean1 std=sd1 lclm =lci1 uclm=uci1 nmiss=miss;

run;


data _bpstat&period._&parmcd;

length paramcd $ 20;

set l_bpstat&period. ;

        paramcd="&parmcd";

mean=exp(mean1);

lclm=exp(lci1);

```

```

uclm=exp(uci1);

keep paramcd trta trtan avisit avisitn mean lclm uclm;

run;

```

```

data l_bpstat&period.;

set l_bpstat&period.;

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 l_bpstat&period.;

set l_bpstat&period.;

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=l_bpstat&period. ;
```

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

```
run;
```

```
proc transpose data=l_bpstat&period. out=l_t_bpstat&period. ;
```

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

```
var meansd aci;
```

```
run;
```

```
data l_sa&period. l_ths&period. l_mcc&period.;
```

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

```
set l_t_bpstat&period. (drop=trtan rename=(_name_=stat col1=rawval)) ;
```

```
if trta='SA' then output l_sa&period.;
```

```
else if trta='THSm2.2' then output l_ths&period.;
```

```
else if trta='mCC' then output l_mcc&period.;
```

```
run;
```

```
proc sort data=l_sa&period. (rename=(rawval=saval)) ;
```

```
by avisitn avisit stat;
```

```
run;
```

```
proc sort data=l_ths&period. (rename=(rawval=thsval));
```

```
by avisitn avisit stat;
```

```
run;
```

```

proc sort data=l_mcc&period. (rename=(rawval=mccval));

    by avisitn avisit stat;

run;

data stat_&parm._&period.;

    merge l_sa&period. (drop=trta ) l_ths&period. (drop=trta) l_mcc&period.;

        by avisitn avisit stat;

    if upcase(stat)='MEANSD' then do; stat='Geometric Mean (CV%)'; sort=2.2; end;

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

        order=&num;

        period=&period;

run;

%mend rawval_l;

%rawval_l (period=1, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day
4' 'Day 5' 'Day 6' 'Day 6/Discharge Confinement'))), parmcd=UPGF2CRE,parm=pgf_l, num=1);

%rawval_l (period=2, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 30'))),
parmcd=UPGF2CRE,parm=pgf_l, num=1);

%rawval_l (period=3, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 60'))),
parmcd=UPGF2CRE,parm=pgf_l, num=1);

%rawval_l (period=4, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 90' 'Day 91/Discharge
Ambulatory' ))), parmcd=UPGF2CRE, parm=pgf_l, num=1);

%rawval_l (period=1, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day
4' 'Day 5' 'Day 6/Discharge Confinement'))),parmcd=UTXB2CRE,parm=dtx_l, num=2);

%rawval_l (period=2, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 30'))),
parmcd=UTXB2CRE,parm=dtx_l, num=2);

```

```
%rawval_l (period=3, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 60')),
parmcd=UTXB2CRE,parm=dtx_l, num=2);

%rawval_l (period=4, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 90' 'Day 91/Discharge
Ambulatory' )), parmcd=UTXB2CRE,parm=dtx_l, num=2);
```

```
data stat_bx ;;

set stat_pgf_1 stat_pgf_2 stat_pgf_3 stat_pgf_4 stat_pgf_l_1 stat_pgf_l_2 stat_pgf_l_3 stat_pgf_l_4
stat_dtx_1 stat_dtx_2 stat_dtx_3 stat_dtx_4 stat_dtx_l_1 stat_dtx_l_2 stat_dtx_l_3 stat_dtx_l_4;

run;
```

```
proc sort data=stat_bx;

by period order avisitn avisit sort;

run;
```

```
data stat_bx_bm_pp ;

length param $50;

set _bpstat1_upgf2cre (where=(avisitn in (98 105)))

                                _bpstat2_upgf2cre (where=(avisitn in (130)))

    _bpstat3_upgf2cre (where=(avisitn in (160)))

                                _bpstat4_upgf2cre (where=(avisitn in (190)))

    _bpstat1_utxb2cre (where=(avisitn in (98 105)))

                                _bpstat2_utxb2cre (where=(avisitn in (130)))

    _bpstat3_utxb2cre (where=(avisitn in (160)))

                                _bpstat4_utxb2cre (where=(avisitn in (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_pp,varlist=param paramcd, lenlist= $60 $8);
```

```
proc sort data=stat_bx_bm_pp out=tflds.T_15_02_04_32_01_f;
```

```
  by paramn avisitn ;
```

```
run;
```

```
/*Bring in sbp and dbp percent change data from ADBX*/
```

```
%macro pchgval (period=, avisit=, parmcd=,parm=, num=);
```

```
%trt(period=&period.);
```

```
data adbx_bm&period.;
```

```
  set adam.adbx(where=(anl02fl='Y' and pprot&period.fl='Y' and paramcd in ("&parmcd") and  
&avisit));
```

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

```
run;
```

```
data adbx_bm&period. ;
```

```

set adbx_bm&period. ;

    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=adbx_bm&period. ;

    by trtan trta avisitn avisit;

run;


proc means data=adbx_bm&period. noprint;

/* where ablfl ='Y' or avisitn in (106 130 160 191);*/

    var pchg;

    by trtan trta avisitn avisit;

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

run;


data pbpstat&period.;

    set pbpstat&period.;

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

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

    *for <missing, n(%>;

```

```

                                if trtan=3 then do;

                                if &&N&period.SAA.=n1

then missc="";

                                else

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

                                end;

                                else if trtan=4 then do;

                                if &&N&period.THS.=n1

then missc="";

                                else

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

                                end;

                                else if trtan=5 then do;

                                if

&&N&period.MCC.=n1 then missc="";

                                else

missc=strip(put((&&N&period.MCC.-n1), 8.)) || ' (' || strip(put(((&&N&period.MCC.-
n1)*100)/&&N&period.MCC., 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=pbpstat&period.;
```

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

```
run;
```

```
proc transpose data=pbpstat&period. out=t_pbpstat&period.;
```

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

```
var n missc meansd minmax median quart aci;
```

```
run;
```

```
data psa&period. pths&period. pmcc&period.;
```

```
length stat pchg $50;
```

```
set t_pbpstat&period. (drop=trtan rename=(_name_=stat col1=pchg)) ;
```

```
if trta='SA' then output psa&period.;
```

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

```
else if trta='mCC' then output pmcc&period.;
```

```
run;
```

```
proc sort data=psa&period. (rename=(pchg=sapchg));
```

```
by avisitn avisit stat;
```

```
run;
```

```
proc sort data=pths&period. (rename=(pchg=thspchg));
```

```

    by avisitn avisit stat;

run;

proc sort data=pmcc&period. (rename=(pchg=mccpchg));

    by avisitn avisit stat;

run;

data stat_&parm._&period.;

    merge psa&period. (drop=trta) pths&period. (drop=trta) pmcc&period.;

        by avisitn avisit stat;

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

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

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

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

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

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

    else if upcase(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;

        period=&period;

run;

%mend;

```

```
%pchgval (period=1, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4'
'Day 5' 'Day 6/Discharge Confinement'))), parmcd=UPGF2CRE,parm=chgpgef, num=1);
```

```
%pchgval (period=2, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 30')),
parmcd=UPGF2CRE,parm=chgpgef, num=1);
```

```
%pchgval (period=3, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 60')),
parmcd=UPGF2CRE,parm=chgpgef, num=1);
```

```
%pchgval (period=4, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 90' 'Day 91/Discharge
Ambulatory'))), parmcd=UPGF2CRE, parm=chgpgef, num=1);
```

```
%pchgval (period=1, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4'
'Day 5' 'Day 6/Discharge Confinement'))), parmcd=UTXB2CRE,parm=chgdtg, num=2);
```

```
%pchgval (period=2, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 30')),
parmcd=UTXB2CRE,parm=chgdtg, num=2);
```

```
%pchgval (period=3, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 60')),
parmcd=UTXB2CRE,parm=chgdtg, num=2);
```

```
%pchgval (period=4, avisit=%str(avisit in ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day 90' 'Day 91/Discharge
Ambulatory'))), parmcd=UTXB2CRE,parm=chgdtg, num=2);
```

```
data stat_bxpchg;
```

```
    set stat_chgpgef_1 stat_chgpgef_2 stat_chgpgef_3 stat_chgpgef_4
```

```
        stat_chgdtg_1 stat_chgdtg_2 stat_chgdtg_3 stat_chgdtg_4;
```

```
run;
```

```
proc sort data=stat_bxpchg;
```

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

```
run;
```

```
data stat;
```

```
merge stat_bx stat_bxpchg (drop=stat trta);
```

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

```
length param $100 ths mcc sa $8;
```

```
if period =1 then do; ths="&&N1THS"; mcc="&&N1MCC"; sa="&&N1SAA"; end;
```

```
if period =2 then do; ths="&&N2THS"; mcc="&&N2MCC"; sa="&&N2SAA"; end;
```

```
if period =3 then do; ths="&&N3THS"; mcc="&&N3MCC"; sa="&&N3SAA"; end;
```

```
if period =4 then do; ths="&&N4THS"; mcc="&&N4MCC"; sa="&&N4SAA"; end;
```

```
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;
```

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

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

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

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

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

        from stat

        order by order, period, param, avisitn, sort;

quit;

proc sort data=stat;

    by order period avisitn avisit sort;

run;

data paging;

    set stat;

    by order period avisitn avisit sort ;

    if first.period or ln > 6 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 /*papersize=&p_pgsize*/ 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 15.2.4.32.1 Descriptive Statistics of 8-epi-PGF2alpha (pg/mg creat) and 11 DTX-B2
(pg/mg creat) - PP Set";

  _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.)));

        call symput('perid', strip(put(period, best8.)));

        call symput('N3', strip(sa));

        call symput('N4', strip(th));

        call symput('N5', strip(mcc));

  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 period order page avisitn param avisit stat
```

```
("THSm2.2#(N=&N4)&linebot" thsval thspchg) ("mCC#(N=&N5)&linebot" mccval  
mccpchg) ("SA#(N=&N3)&linebot" saval sapchg);
```

```
define period / order order = internal noprint;
```

```
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 mcccchg / 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 " ";
```

```
line "Product Use Time Period: Period &perid.";
```

```
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 'Note: 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, halfblnk=N);
```

```
ods listing close;
```

```
proc printto ; run;
```

```
%m_logchk;
```

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

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

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

