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Covance Study ID : COV-000000106343

Program Name : t\_bx\_bm\_pp.sas

Purpose : Table 15.2.4.32.1.1(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 :

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Modification History

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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_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;

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

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

%trt(period=&period.);

data adbx_bm&period.;

        set adam.adbx(where=(anl02fl='Y' and pprot&period.fl='Y' and anl03fl='Y' and parmcd 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=sdt1 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(sdt1) THEN MEANSD =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.1),10.1))) || ' (' ||
LEFT(COMPRESS(PUT(0.01*CEIL(sdt1/0.01),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 sdt1 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=thsval));  
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'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 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=UTXB2CRE,parm=dtx, num=1);

```

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

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

%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=1);
```

```
/*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 anl03fl='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 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=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 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/Discharge Confinement'))),parmcd=UTXB2CRE,parm=dtx_l, num=1);

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

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

```

```

data stat_bx ;;

  set 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;


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

%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 anl03fl='Y' and parmcd 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.;
```

```
    *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;

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

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=UTXB2CRE,parm=chgdtx, num=1);

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

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

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

```



```
data stat_bxpchg;

    set stat_chgdtx_1 stat_chgdtx_2 stat_chgdtx_3 stat_chgdtx_4;

run;
```

```
proc sort data=stat_bxpchg;

    by period order avisitn avisit sort;

run;
```

```
data stat;

    merge stat_bx (drop=stat trta) stat_bxpchg;

        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='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,
sav, 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_pgsz*/ 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 15.2.4.32.1.1 Descriptive Statistics of 11-DTX-B2 (pg/mg creat) Excluding Assessments
within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-DTX-B2 - 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(thhs));

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 order page avisitn param avisit stat

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

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 '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 ;
```

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