

```
/*=====
```

```
*Covance Study ID   : 000000106343
```

```
*Program Name       : t_cohb_pp_cc.sas
```

```
*Purpose            : Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set
```

Table 15.2.4.1.1.2

```
*Input Data         : adam.adsl, ADAM.adbx
```

```
*Output Data        : tflds.T_15_02_04_01_01_02
```

```
*Macros Called       : %m_printto, %m_logchk, %fmmeans, %mmeans, %trt, %mfinp, %outrtf
```

```
*Programmed by      : L.Ma
```

```
*Creation Date       : 2015-05-14
```

```
*=====
```

```
*Modification History
```

```
*Date    Initials  No. Reason;
```

```
*=====*/
```

```
options notes nosource;
```

```
proc datasets lib=work nolist memtype=data kill; quit;
```

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

```
ods _all_ close;
```

```
ods listing;
```

```
%m_printto;
```

```
/*Macro to get N values from adam.adsl for column headers for each period per mock*/
```

```
%macro trt(pfl=);
```

```
%global trt1 trt2 trt3 trt4 trt5 trt6;
```

```
data adsl;
```

```
    set adam.adsl(where=&pfl.);
```

```
    if          trt01pn=4 and ucpdgr1='10-19 cig/day' then trt=1;
```

```
    else if trt01pn=4 and ucpdgr1='>19 cig/day'      then trt=2;
```

```
    else if trt01pn=5 and ucpdgr1='10-19 cig/day' then trt=3;
```

```
    else if trt01pn=5 and ucpdgr1='>19 cig/day'      then trt=4;
```

```
    else if trt01pn=3 and ucpdgr1='10-19 cig/day' then trt=5;
```

```
    else if trt01pn=3 and ucpdgr1='>19 cig/day'      then trt=6;
```

```
run;
```

```
proc freq data=adsl noprint;
```

```
    table trt/ out =tot(drop=percent rename=(count=total));
```

```
run;
```

```
data tot2;
```

```
    set tot;
```

```
    call symput('trt' || compress(put(trt,best.)), compress(put(total,best.)));
```

```
run;
```

```
%mend trt;
```

```
/*Bring in data from ADBX for Blood COHb*/
```

```
data adbx1;
```

```

set adam.adbx;

where anl02fl='Y' AND PARCAT1 = 'BIOMARKERS' AND PARAM = 'COHb (%)' AND LBSPEC =
'BLOOD' AND AVISIT ne 'DAY -1';

if          trtpn=4 and ucpdgr1='10-19 cig/day'    then trt=1;
else if trtpn=4 and ucpdgr1='>19 cig/day'          then trt=2;
else if trtpn=5 and ucpdgr1='10-19 cig/day'        then trt=3;
else if trtpn=5 and ucpdgr1='>19 cig/day'          then trt=4;
else if trtpn=3 and ucpdgr1='10-19 cig/day'        then trt=5;
else if trtpn=3 and ucpdgr1='>19 cig/day'          then trt=6;

if ablfl='Y' then avisit='Baseline';

run;

/*macro for general mean stats(n mean std median min max Q25 Q75 lclm uclm)for each period per
mock;*/

%macro mmeans(pfl=, prd=, class=, var=, out=);

/*get N values for column headers for each period*/

%trt(pfl=&pfl.);

/*Bring in data from ADBX for Blood COHb - PP Set by Cigarette Consumption for each period per
Mock*/

data adbx;

set adbx1;

where &prd.;

/*Keep data in one obs. per 5/15/2015 JH email*/

if avisit='Baseline' then do; avisitn=100; atpt="DAY 0 - 20:00 - 21:30"; atptn=100; end;

run;

```

```

/*get general mean stats;*/

proc means data=adbx noprint nway;

    var &var.;

    class &class. trt;

    output out=results02 n=n1 mean=mean1 std=std1 median=median1 min=min1 max=max1 q1=q1
    q3=q3 lclm=lci1 uclm=uci1;

run;


data results03;

    set results02;

    attrib meansd length=$20.

        minmax length=$20.

        n    length=$20.

        miss length=$20.

        median length=$20.

        quart aci length=$20.;

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

    *for <missing, n(%)>;

        if trt=1 then do;

            *format missing cell to 0 per John email on 8-5-2015;

            if &trt1.=n1 then miss="0";

            else miss=strip(put((&trt1.-n1), 8.)) || ' (' || strip(put(((&trt1.-
n1)*100)/&trt1., 8.1)) || "));

```

```

end;

else if trt=2 then do;

    if &trt2.=n1 then miss="0";

    else miss=strip(put((&trt2.-n1), 8.)) || ' (' || strip(put(((&trt2.-
n1)*100)/&trt2., 8.1)) || ")";

end;

else if trt=3 then do;

    if &trt3.=n1 then miss="0";

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

end;

else if trt=4 then do;

    if &trt4.=n1 then miss="0";

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

end;

else if trt=5 then do;

    if &trt5.=n1 then miss="0";

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

end;

else if trt=6 then do;

    if &trt6.=n1 then miss="0";

    else miss=strip(put((&trt6.-n1), 8.)) || ' (' || strip(put(((&trt6.-
n1)*100)/&trt6., 8.1)) || ")";

end;

```

```

    if not missing(median1) then median = left(compress(put(round(median1,0.01),8.2)));

    if not missing(mean1) and not missing(std1) then meansd =
left(compress(put(round(mean1,0.01),8.2))) || ' (' || left(compress(put(0.001*ceil(std1/0.001),8.3))) ||
');

    if not missing(min1) and not missing(max1) then minmax = left(compress(put(min1,8.1))) || ', ' ||
left(compress(put(max1,8.1)));

    if not missing(lci1) and not missing(uci1) then aci = strip(put(0.01*floor(lci1/0.01),8.2)) || ', ' ||
strip(put(0.01*ceil(uci1/0.01),8.2));

    if not missing(q1) and not missing(q3) then quart = strip(strip(put(round(q1, 0.01),8.2)) || ', ' ||
strip(put(round(q3, 0.01),8.2)));

    drop n1 mean1 std1 median1 min1 max1 q1 q3 uci1 lci1 ;

```

```
run;
```

```
proc transpose data=results03 out=&out prefix=r name=varname;
```

```
by &class.;
```

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

```
id trt;
```

```
run;
```

```
data &out.;
```

```
set &out.;
```

```
length stat $200;
```

```
if upcase(varname)='N' then do; statord=1; stat='n'; end;
```

```
if upcase(varname)='MISS' then do; statord=2; stat='Missing, n (%)'; end;
```

```
if upcase(varname)='MEDIAN' then do; statord=7; stat='Median'; end;
```

```
if upcase(varname)='QUART' then do; statord=8; stat='Q25, Q75'; end;
```

```
if upcase(varname)='MINMAX' then do; statord=9; stat='Min, Max'; end;
```

```

        if upcase(varname)='MEANS' then do; statord=10; stat='Mean (SD)'; end;

        if upcase(varname)='ACI'          then do; statord=11; stat='95% CI of Mean'; end;

run;

%mend mmeans;

%mmmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Baseline' 'Day 1' 'Day 2' 'Day 3' 'Day 4'
'Day 5')), class=avisitn avisit atptn atpt, var=aval, out=out_p1);

%mmmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Baseline' 'Day 90')), class=avisitn avisit
atptn atpt, var=aval, out=out_p4);

%mmmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 1' 'Day 2' 'Day 3' 'Day 4' 'Day 5')),
class=avisitn avisit atptn atpt, var=pchg, out=out_c1);

%mmmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 90' )), class=avisitn avisit atptn atpt,
var=pchg, out=out_c4);

/*macro for Geometric Mean per mock;*/

%macro mmeans(prd=, class=, var=, out=);

/*Bring in data from ADBX for Blood COHb - PP Set by Cigarette Consumption for each period per
Mock*/

data adbx;

    set adbx1;

    where &prd.;

    /*Keep data in one obs. per 5/15/2015 JH email*/

    if avisit='Baseline' then do; avisitn=100; atpt="DAY 0 - 20:00 - 21:30"; atptn=100; end;

    if aval ne 0 and aval ne . then logaval=log(aval);

run;

```

```

proc means data=adbx noprint nway;

  var &var.;

  class &class. trt;

    output out=results02 mean=mean std=std1 lclm=lci1 uclm=uci1;

run;

data results03;

  set results02;

  gmean1=exp(mean);

  gmean=left(compress(put(round(gmean1,0.01), 8.2)));

  gcv=compress(put(0.001*ceil((sqrt(exp(std1*std1)-1)*100)/0.001),8.3));

  glci=exp(lci1);

  guci=exp(uci1);

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

  else gmeancv=left(trim(gmean));

  if not missing(glci) and not missing(guci) then ci = strip(strip(put(0.01*floor(glci/0.01),8.2)) || ', '
|| strip(put(0.01*ceil(guci/0.01),8.2)));

run;

proc transpose data=results03 out=&out. prefix=r name=varname;

  by &class;

  var gmeancv ci;

  id trt;

run;

```



```

data &out.;

    set &out.;

    length stat $200;

    if upcase(varname)='GMEANCV' then do; statord=5; stat='Geometric Mean (CV%)'; end;

    if upcase(varname)='CI' then do; statord=6; stat='95% CI of Geometric Mean'; end;

run;

```

```

%mend mmeans;

```

```

%mmeans(prd=(PPROT1FL='Y' and avisit in ('Baseline' 'Day 1' 'Day 2' 'Day 3' 'Day 4' 'Day 5')),
class=avisitn avisit atptn atpt, var=logaval, out=out_g1);

```

```

%mmeans(prd=(PPROT4FL='Y' and avisit in ('Baseline' 'Day 90')), class=avisitn avisit atptn atpt,
var=logaval, out=out_g4);

```

```

*check data for BLOQ/ALOQ ;

```

```

proc freq data=adbx1(where=(AQLFL='Y' ));

```

```

    table AVALC;

```

```

run;

```

```

*** Checked data of BLOQ/ALOQ for this table. ***;

```

```

*per Jh email on Wed 7/1/2015 9:34 AM ---- we only need to present BLOQ as a line item if there are
BLOQ values for a given parameter/timepoint;

```

```

proc freq data=adam.adbx(where=(anl02fl='Y' AND PARCAT1 = 'BIOMARKERS' AND PARAM = 'COHb (%)'
AND LBSPEC = 'BLOOD' AND AQLFL='Y' ));

```

```

    table AVALC;

```

```

run;

```

```

*no data for BLOQ values so no need to present BLOQ n(%) row.;

```

```

/*macro to set together for each period ;*/

%macro mfinp(dsn=, dsng=, dsnc=, out=);

data out1;

    retain avisitn avisit atptn tp stat r1 r2 r3 r4 r5 r6 statord statord1 ;

    length tp $200;

    set &dsn.(in=p) &dsng.(in=g) &dsnc.(in=c) ;


    if p or g then statord1=1;

    if c then do; statord1=2; avisit=%nrstr("%Change from baseline to ")|| avisit; end;


    *format avisit/tp per mock;

    tp=avisit;

    if avisit="Day 5" then do; /*per JH email on Tue 4/28/2015 10:50 AM*/

        tp=atpt;

        if index(tp,'WITHIN 15 MIN PRIOR TO SMOKING') then tp=tranwrd(tp,'WITHIN 15 MIN
PRIOR TO SMOKING','Within 15 Min Prior To Smoking'); /*per client comments on Tue 6/30/2015*/

        if index(tp,'DAY 5 -') then tp=tranwrd(tp,'DAY 5 -','Day 5, ');

    end;


    ***delete <missing, n(%)> if no missing n data for the row;

    if stat="Missing, n (%)" and r1="0" and r2="0" and r3="0" and r4="0" and r5="0" and r6="0" then
delete;

    else if stat="Missing, n (%)" and avisit="Day 5" and index(tp, "Within 15 Min Prior To
Smoking")>0 and r1="0" and r2="0" and r3="0" and r4="0" and r5="" and r6="" then delete;

    else if stat="Missing, n (%)" and avisit="Day 5" and index(tp, "08:00 - 09:30")>0 and r1="" and
r2="" and r3="" and r4="" and r5="0" and r6="0" then delete;

```

```
        keep avisitn avisit atptn statord tp stat r1 r2 r3 r4 r5 r6 statord1;
run;
```

```
proc sort data = out1 out=&out.;
        by avisitn atptn statord1 statord;
run;
%mend mfinp;
```

```
%mfinp(dsn=out_p1, dsng=out_g1, dsnc=out_c1, out=finalp1);
%mfinp(dsn=out_p4, dsng=out_g4, dsnc=out_c4, out=finalp4);
```

```
/*create final dataset per mock;*/
```

```
data final;
        set finalp1(in=p1) finalp4(in=p4) ;
        if p1 then period="1";
        if p4 then period="4";
run;
```

```
*****,
```

```
*create new page for each timepoint for report ;
```

```
*****,
```

```
proc sql;
        create table page as
        select distinct period, avisitn, atptn, statord1, tp
```

```

        from final

        order by period, avisitn, atptn, statord1, tp;

quit;


data page1;

    set page;

    by period avisitn atptn statord1 tp;

    if _n_ = 0 then page = 0;

    page + 1;

run;


proc sql;

    create table final_page as

    select distinct a.*, b.page

    from final as a

    left join page1 as b

    on a.avisitn=b.avisitn and a.tp = b.tp and a.period=b.period and a.statord1=b.statord1 and
a.atptn=b.atptn

    order by period, page, avisitn, avisit, atptn, statord1, statord;

quit;


data final_page(rename=(r1=THSm_m r2=THSm_f r3=mCC_m r4=mCC_f r5=SA_m r6=SA_f));

    set final_page end=last;

    by period page avisitn atptn statord1 statord;

    if last then call symputx("page", page);

run;

```

```

/*output report data; */

%let tflno=T_15_02_04_01_01_02;

data tflds.&tflno(keep=avisitn avisit tp stat THSm_m mCC_m SA_m THSm_f mCC_f SA_f statord period
page);

    set final_page;

run;

*****.
,

*create output report ;

*****.
,

/*get N for each period for column header*/

proc sql;

select count(distinct usubjid) into: N1THS1 from adam.adsl(where=(trt01pn = 4 and pprot1fl = "Y" and
ucpdgr1='10-19 cig/day'));

select count(distinct usubjid) into: N1THS2 from adam.adsl(where=(trt01pn = 4 and pprot1fl = "Y" and
ucpdgr1='>19 cig/day'));

select count(distinct usubjid) into: N1MCC1 from adam.adsl(where=(trt01pn = 5 and pprot1fl = "Y" and
ucpdgr1='10-19 cig/day'));

select count(distinct usubjid) into: N1MCC2 from adam.adsl(where=(trt01pn = 5 and pprot1fl = "Y" and
ucpdgr1='>19 cig/day'));

select count(distinct usubjid) into: N1SAA1 from adam.adsl(where=(trt01pn = 3 and pprot1fl = "Y" and
ucpdgr1='10-19 cig/day'));

```

```
select count(distinct usubjid) into: N1SAA2 from adam.adsl(where=(trt01pn = 3 and pprot1fl = "Y" and ucpdgr1='>19 cig/day'));
```

```
select count(distinct usubjid) into: N4THS1 from adam.adsl(where=(trt01pn = 4 and pprot4fl = "Y" and ucpdgr1='10-19 cig/day'));
```

```
select count(distinct usubjid) into: N4THS2 from adam.adsl(where=(trt01pn = 4 and pprot4fl = "Y" and ucpdgr1='>19 cig/day'));
```

```
select count(distinct usubjid) into: N4MCC1 from adam.adsl(where=(trt01pn = 5 and pprot4fl = "Y" and ucpdgr1='10-19 cig/day'));
```

```
select count(distinct usubjid) into: N4MCC2 from adam.adsl(where=(trt01pn = 5 and pprot4fl = "Y" and ucpdgr1='>19 cig/day'));
```

```
select count(distinct usubjid) into: N4SAA1 from adam.adsl(where=(trt01pn = 3 and pprot4fl = "Y" and ucpdgr1='10-19 cig/day'));
```

```
select count(distinct usubjid) into: N4SAA2 from adam.adsl(where=(trt01pn = 3 and pprot4fl = "Y" and ucpdgr1='>19 cig/day'));
```

```
quit;
```

```
options number nodate orientation=landscape 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=130, halfbink=N);
```

```
%let title1 = %nrbrquote (Table 15.2.4.1.1.2 Descriptive Statistics of Blood COHb (%) by Cigarette Consumption - PP Set);
```

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

```
%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;
```

```
    %let wd=0;
```

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

```
    data comp;
```

```
        set final_page end=eof;
```

```
where page=&i;
```

```
if _n_ =1 then
```

```
do;
```

```
call symput('title2', "Product Use Time Period: Period " || Period );
```

```
*create trt1/trt2/trt3 N for each period for column header;
```

```
if period="1" then do;
```

```
call
```

```
symput('trt1', strip(put(&N1THS1., best.)));
```

```
call
```

```
symput('trt2', strip(put(&N1THS2., best.)));
```

```
call
```

```
symput('trt3', strip(put(&N1MCC1., best.)));
```

```
call
```

```
symput('trt4', strip(put(&N1MCC2., best.)));
```

```
call
```

```
symput('trt5', strip(put(&N1SAA1., best.)));
```

```
call
```

```
symput('trt6', strip(put(&N1SAA2., best.)));
```

```
end;
```

```
else if period="4" then do;
```

```
call
```

```
symput('trt1', strip(put(&N4THS1., best.)));
```

```
call
```

```
symput('trt2', strip(put(&N4THS2., best.)));
```

```
call
```

```
symput('trt3', strip(put(&N4MCC1., best.)));
```



```

call
symput('trt4', strip(put(&N4MCC2., best.)));

call
symput('trt5', strip(put(&N4SAA1., best.)));

call
symput('trt6', strip(put(&N4SAA2., best.)));

end;

end;

/* Amend title as needed */
    _firtitl="&title1.";
    _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 listing close;

proc report data = comp headline headskip nowd split = '$' %if &i=1 %then %do; contents=' '
%end; %else %do; contents='' %end;;;

    column tp stat ("THSm2.2&linebot" THSm_m THSm_f )

```

```
("mCC&linebot" mCC_m mCC_f)
```

```
("SA&linebot" SA_m SA_f);
```

```
define tp /"Timepoint" order order=internal style={just=left cellwidth=1.0cm}  
style(header)={just=left} ;
```

```
define stat /"Statistic" display style={just=left cellwidth=1.9cm}  
style(header)={just=left} ;
```

```
define THSm_m /"10-19 cig/day$(N=&trt1)" display style={just=c  
cellwidth=1.2cm} style(header)={just=center} ;
```

```
define mCC_m /"10-19 cig/day$(N=&trt3)" display style={just=c  
cellwidth=1.2cm} style(header)={just=center} ;
```

```
define SA_m /"10-19 cig/day$(N=&trt5)" display style={just=c  
cellwidth=1.2cm} style(header)={just=center};
```

```
define THSm_f /">19 cig/day$(N=&trt2)" display style={JUST=c cellwidth=1.1cm}  
style(header)={just=center};
```

```
define mCC_f /">19 cig/day$(N=&trt4)" display style={just=c cellwidth=1.1cm}  
style(header)={just=center};
```

```
define SA_f /">19 cig/day$(N=&trt6)" display style={just=c cellwidth=1.1cm}  
style(header)={just=center};
```

```
compute after tp;
```

```
line " ";
```

```
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 "\b\fs24\sa24&title2." ;
```

```

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

        line ' ';

        line 'Appendix 15.3.3.2';

        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;

%outrtf(blankn=36, halfblank=N);

ods listing;

%m_logchk;

/***** END OF FILE t_cohb_pp_cc.sas *****/

```

