

/\*=====

\*Covance Study ID : 000000106343

\*Program Name : t\_cyp1a2\_excl\_pp.sas

\*Purpose : Table 15.2.4.23.1.1 Descriptive Statistics of CYP1A2 Activity (%) - PP;

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

\*Output Data :

\*Macros Called :

\*Programmed by : cvn\_pshe

\*Creation Date : 2015-05-13

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

ods \_all\_ close;

ods listing;

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

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

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

```
%let tflno=T_15_02_04_23_01_01;
```

```
%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;
```

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

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

```
proc sql;
```

```
    %global trt1 trt2 trt3;
```

```
    select count(distinct usubjid) into: trt1 from adam.adsl(where=(trt01an = 4 and &pfl.));
```

```
    select count(distinct usubjid) into: trt2 from adam.adsl(where=(trt01an = 5 and &pfl.));
```

```
    select count(distinct usubjid) into: trt3 from adam.adsl(where=(trt01an = 3 and &pfl.));
```

```
quit;
```

```
%mend;
```

```
/*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 plasma cyp2a6 activity - PP Set for each period per Mock*/
```

```
data adbx1;
```

```
    set adam.adbx;
```

```
    where anl02fl='Y' and anl03fl='Y' and paramcd in ('CYP1A2') and &prd.;
```

```
    if          trtan=4 then trt=1;
```

```
    else if trtan=5 then trt=2;
```

```
    else if trtan=3 then trt=3;
```

```
run;
```

```
data adbx;
```

```
    set adbx1;
```

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

```
run;
```

```
proc means data=adbx noprint nway;
```

```
    var &var.;
```

```
    class &class. trt;
```

```
output out=results02 n=n1 mean=mean1 std=sd1 median=median1 min=min1 max=max1 q1=q1  
q3=q3 lclm=lci1 uclm=uci1;
```

```
run;
```

```
/*get N for baseline(for calculate change volume of <missing, n(%>)*/*
```

```
data bs;
```

```
set results02;
```

```
if avisit="Baseline";
```

```
run;
```

```
data tot;
```

```
set bs;
```

```
call symput('trtb' || compress(put(trt,best.)), compress(put(n1,best.)));
```

```
run;
```

```
%put trtb1=&trtb1 trtb2=&trtb2 trtb3=&trtb3;
```

```
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;

                                if &trt1.=n1 then

miss="";

                                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="";

                                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="";

                                else

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

                                end;

```

```

IF NOT MISSING(MEDIAN1) THEN MEDIAN = LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.001),10.3)));

```

```

IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.001),10.3))) || "
(" || STRIP(PUT(0.0001*CEIL(SD1/0.0001),10.4)) || "%";

```

```

IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.2)) || ",
" || strip(put(max1, 10.2));

```

```

IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.001),10.3))) || ', ' ||
LEFT(COMPRESS(PUT(ROUND(Q3,0.001),10.3)));;

```

```
IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI =  
STRIP(PUT(0.001*FLOOR(LCI1/0.001),10.3)) || ', ' || STRIP(PUT(0.001*CEIL(UCI1/0.001),10.3));
```

```
drop n1 mean1 sd1 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 varname='N' then do; statord=1; stat='n'; end;
```

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

```
if varname='MEDIAN' then do; statord=5; stat='Median'; end;
```

```
if varname='QUART' then do; statord=6; stat='Q25, Q75'; end;
```

```
if varname='MINMAX' then do; statord=7; stat='Min, Max'; end;
```

```
if varname='MEANSD' then do; statord=8; stat='Mean (SD)'; end;
```

```
if varname='ACI' then do; statord=9; stat='95% CI of Mean'; end;
```

```
run;
```

```
%mend;
```

```
%mmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4' 'Day  
5' 'Day 6/Discharge Confinement')), class=avisitn avisit atptn atpt, var=aval, out=out_p1);
```

```
%mmeans(pfl=(PPROT2FL='Y'), prd=(PPROT2FL='Y' and avisit in ('Day 30' 'Day 0')), class=avisitn avisit  
atptn atpt, var=aval, out=out_p2);
```

```
%mmeans(pfl=(PPROT3FL='Y'), prd=(PPROT3FL='Y' and avisit in ('Day 60' 'Day 0')), class=avisitn avisit  
atptn atpt, var=aval, out=out_p3);
```

```
%mmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 90' 'Day 0')), class=avisitn avisit  
atptn atpt, var=aval, out=out_p4);
```

```
%mmeans(pfl=(PPROT1FL='Y'), prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4' 'Day  
5' 'Day 6/Discharge Confinement')), class=avisitn avisit atptn atpt, var=pchg, out=out_c1);
```

```
%mmeans(pfl=(PPROT2FL='Y'), prd=(PPROT2FL='Y' and avisit in ('Day 0' 'Day 30' )), class=avisitn avisit  
atptn atpt, var=pchg, out=out_c2);
```

```
%mmeans(pfl=(PPROT3FL='Y'), prd=(PPROT3FL='Y' and avisit in ('Day 0' 'Day 60' )), class=avisitn avisit  
atptn atpt, var=pchg, out=out_c3);
```

```
%mmeans(pfl=(PPROT4FL='Y'), prd=(PPROT4FL='Y' and avisit in ('Day 0' '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 for each period per Mock*/
```

```
data adbx1;
```

```
    set adam.adbx;
```

```
    where anl02fl='Y'and anl03fl='Y' and paramcd in ('CYP1A2') and &prd.;
```

```
    if          trtan=4 then trt=1;
```

```
    else if trtan=5 then trt=2;
```

```
    else if trtan=3 then trt=3;
```

```
run;
```

```
data adbx;
```

```

set adbx1;

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

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(gmean1,0.001), 8.3)));

if not missing(std1) then gcv=compress(put(0.0001*ceil((sqrt(exp(std1*std1)-
1)*100)/0.0001),8.4));

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(0.001*floor(glci/0.001),8.3)) ||
', ' || strip(put(0.001*ceil(guci/0.001),8.3)));

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 varname='GMEANCV' then do; statord=3; stat='Geometric Mean (CV%)'; end;

    if varname='CI' then do; statord=4; stat='95% CI of Geometric Mean'; end;

run;

%mend;

%mmeans(prd=(PPROT1FL='Y' and avisit in ('Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4' 'Day 5' 'Day 6/Discharge
Confinement')), class=avisitn avisit atptn atpt, var=logaval, out=out_g1);

%mmeans(prd=(PPROT2FL='Y' and avisit in ('Day 30' 'Day 0')), class=avisitn avisit atptn atpt, var=logaval,
out=out_g2);

%mmeans(prd=(PPROT3FL='Y' and avisit in ('Day 60' 'Day 0')), class=avisitn avisit atptn atpt, var=logaval,
out=out_g3);

%mmeans(prd=(PPROT4FL='Y' and avisit in ('Day 90' 'Day 0')), class=avisitn avisit atptn atpt, var=logaval,
out=out_g4);

*check data for BLOQ/ALOQ ;

proc freq data=adbx;

    table bloqfl*aulqfl;

run;

```

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

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

```
data ds1;
```

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

```
run;
```

```
proc sort data=ds1 out=ds1;
```

```
    by avisitn avisit atptn statord;
```

```
run;
```

```
*delete baseline part for Change column;
```

```
data dsnc;
```

```
    set &dsnc.;
```

```
    if avisit="Baseline" then delete;
```

```
run;
```

```
proc sort data=dsnc out=ds2;
```

```
    by avisitn avisit atptn statord;
```

```
run;
```

```
data &out.;
```

```
    retain avisitn avisit atptn tp stat r1 c1 r2 c2 r3 c3 statord;
```

```
    merge ds1(in=a) ds2(in=c rename=(r1=c1 r2=c2 r3=c3) drop=ATPT VARNAME STAT);
```

```
    by avisitn avisit atptn statord;
```

```

if a;

if avisit="DAY 5" then tp=atpt;

else tp=propcase(avisit);

***should delete <missing, n(%)> if no missing n;

if stat="Missing, n(%)" and r1="" and r2="" and r3="" and c1="" and c2="" and c3="" then delete;

keep avisitn avisit atptn statord tp stat r1 c1 r2 c2 r3 c3;

run;

%mend;

%mfinp(dsn=out_p1, dsng=out_g1, dsnc=out_c1, out=finalp1);

%mfinp(dsn=out_p2, dsng=out_g2, dsnc=out_c2, out=finalp2);

%mfinp(dsn=out_p3, dsng=out_g3, dsnc=out_c3, out=finalp3);

%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";

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

```

```

        if r1="" then r1='0';

            if r2="" then r2='0';

                if r3="" then r3='0';

            end;

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

            if r1="" then r1='0';

                if r2="" then r2='0';

                    if r3="" then r3='0';

                if c1="" then c1='0';

                    if c2="" then c2='0';

                        if c3="" then c3='0';

                    end;

                if stat='BLOQ, n (%)' then do;

                    if r3="" then r3='0';

                        if r2="" then r2='0';

                            if r1="" then r1='0';

                        end;

                end;

run;

/*output report data; */

proc sql noprint;

    create table tflds.&tflno as

        select period, avisitn, atptn, tp, statord, stat, r1 as thsm2_2, c1 as thsm2_2_chg, r2 as mCC, c2 as
mCC_chg, r3 as SA, c3 as SA_chg

        from final

```

```

        order by period, avisitn, atptn, statord;

quit;

proc sort data=final;

        by period avisitn atptn statord;

run;

data paging;

    set final;

    by period avisitn atptn statord;

    if first.period or ln > 8/*16*/ 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;

*****
,

*create output report ;

*****
,

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

proc sql;

select count(distinct usubjid) into: N1THS from adam.adsl(where=(trt01an = 4 and pprot1fl = "Y"));

select count(distinct usubjid) into: N1MCC from adam.adsl(where=(trt01an = 5 and pprot1fl = "Y"));

```

```
select count(distinct usubjid) into: N1SAA from adam.adsl(where=(trt01an = 3 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N2THS from adam.adsl(where=(trt01an = 4 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N2MCC from adam.adsl(where=(trt01an = 5 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N2SAA from adam.adsl(where=(trt01an = 3 and pprot2fl = "Y"));
```

```
select count(distinct usubjid) into: N3THS from adam.adsl(where=(trt01an = 4 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N3MCC from adam.adsl(where=(trt01an = 5 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N3SAA from adam.adsl(where=(trt01an = 3 and pprot3fl = "Y"));
```

```
select count(distinct usubjid) into: N4THS from adam.adsl(where=(trt01an = 4 and pprot4fl = "Y"));
```

```
select count(distinct usubjid) into: N4MCC from adam.adsl(where=(trt01an = 5 and pprot4fl = "Y"));
```

```
select count(distinct usubjid) into: N4SAA from adam.adsl(where=(trt01an = 3 and pprot4fl = "Y"));
```

```
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, halfblnk=N, dsn=);
```

```
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;
```

```
%let subpage=1;
```

```
%do j=1 %to &subpage;
```

```
%let maxpage=%eval(&page*&subpage);
```

```
%let npage=%eval(&subpage*&i+&j-&subpage);
```

```
data comp;
```

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

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

```
/* Amend title as needed */
```

```
    _firtitl="Table 15.2.4.23.1.1 Descriptive Statistics of CYP1A2 Activity (%) Excluding Assessments within  
5 Half-Lives of a Concomitant Medication Affecting CYP1A2 Activity - PP Set";
```

```
    _upcas=(length("Path: &TFLpath.")-  
length(compress("Path:&TFLpath.",'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;
```

```
    len=&blankn.-length("(page &npage of &maxpage)");
```

```
    if eof then do;
```

```

call symput('_FSRTITL', trim(left(_firtitl)));

call symput('_blankn', compress(put(len,best.)));

end;

```

```

drop _firtitl _upcas len;

```

```

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(&N1THS., best.)));

```

```

                                call

```

```

symput('trt2', strip(put(&N1MCC., best.)));

```

```

                                call

```

```

symput('trt3', strip(put(&N1SAA., best.)));

```

```

                                end;

```

```

        else if period="2" then do;

```

```

                                call

```

```

symput('trt1', strip(put(&N2THS., best.)));

```

```

                                call

```

```

symput('trt2', strip(put(&N2MCC., best.)));

```

```

                                call

```

```

symput('trt3', strip(put(&N2SAA., best.)));

```

```

                                end;

```

```

        else if period="3" then do;

```



```

call
symput('trt1', strip(put(&N3THS., best.)));

call
symput('trt2', strip(put(&N3MCC., best.)));

call
symput('trt3', strip(put(&N3SAA., best.)));

end;

else if period="4" then do;

call
symput('trt1', strip(put(&N4THS., best.)));

call
symput('trt2', strip(put(&N4MCC., best.)));

call
symput('trt3', strip(put(&N4SAA., best.)));

end;

end;

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;

/* Update with your variables as needed */

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

```

```

column page avisitn atptn tp statord stat

%if &j=1 %then %do; ("THSm2.2 $(N=&trt1)&linebot" r1 c1) ("mCC$(N=&trt2)&linebot"
r2 c2)

("SA$(N=&trt3)&linebot" r3 c3) %end;;

define page      / order order = internal noprint;

define avisitn   / order order=internal noprint;

define atptn     / order order=internal noprint;

define tp        / group style={just=left cellwidth=3.2cm} style(header)={just=center} "Timepoint";

define statord   / order order = internal noprint;

define stat      / display style={just=left cellwidth=3.2cm} style(header)={just=center} "Statistic";

%if &j=1 %then %do;

    define r1          /"Value" display style={just=c cellwidth=2cm}
style(header)={just=center} ;

    define r2          /"Value" display style={just=c cellwidth=2cm}
style(header)={just=center} ;

    define r3          /"Value" display style={just=c cellwidth=2cm}
style(header)={just=center};

    define c1          /"% Change(*)" display style={JUST=c cellwidth=2cm}
style(header)={just=center};

    define c2          /"% Change(*)" display style={just=c cellwidth=2cm}
style(header)={just=center};

    define c3          /"% Change(*)" display style={just=c cellwidth=2cm}
style(header)={just=center};

%end;

break after page / page;

```

```

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 "&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: 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 15.3.4.1";

    line "Study ID:ZRHM-REXA-08-US Program:&TFLprg Status: &status" &_blankn.*"\~\~"
"&sysdate" &_blankn.*"\~\~" "(Page &i of &page)";

endcomp;

run;

%end;

```

```
%end;
```

```
ods rtf close;
```

```
ods results on;
```

```
ods path sashelp.tmplmst (read);
```

```
%mend ;
```

```
%outtrtf(blankn=36, halfblnk=N);
```

```
ods listing close;
```

```
proc printto ; run;
```

```
%m_logchk;
```

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

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

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