

/*-----

Covance Study ID : COV-000000106343

Program Name : t_vs_bp_fas.sas

Purpose : Table 15.2.4.44.2(Descriptive Statistics of CYP2A6 ACTIVITY (%) - FAS;

Author : cvn_pshe

Date of Creation : 11MAY015

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_62_02;*/
```

```
%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;
```

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

```
* read in data ;
```

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

```
%macro cypactfas (blankn=, halfblnk=, tflno=, act=, title=);
```

```
/*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 trt01an trt01a subjid;
```

```
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' || compress(put(trt01an,best.)), compress(put(total, best.)));
```

```
run;
```

```
/*Bring in appropriate data from ADBX*/
```

```
data adbx1;
```

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

```
run;
```

```
data adbx;
```

```
        set adbx1;

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

run;
```

```
data adbx_orig;

        set adbx;

        statval=aval;

type='abs';

output;

statval=pchg;

type='pchg';

output;

run;
```

```
proc sort data=adbx_orig;

        by type trtan trta avisitn avisit atptn atpt;

run;
```

```
proc means data=adbx_orig noprint;

        var statval;

        by type trtan trta avisitn avisit atptn atpt;

        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;
```



```

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(MEDIAN1,0.001),10.3)));

```

```

%IF NOT MISSING(MEAN1) AND NOT MISSING(STD1) %THEN MEANSD =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.001),10.3))) || ' (' ||
LEFT(COMPRESS(PUT(0.0001*CEIL(STD1/0.0001),10.4))) || ')';

```

```

%IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) %THEN MINMAX =
LEFT(COMPRESS(PUT(ROUND(MIN1,0.01),10.2))) || ', ' ||
LEFT(COMPRESS(PUT(ROUND(MAX1,0.01),10.2)));

```

```

%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));

```

```

%IF NOT MISSING(Q1) AND NOT MISSING(Q3) %THEN QUART =
STRIP(PUT(0.001*FLOOR(Q1/0.001),10.3)) || ', ' || STRIP(PUT(0.001*CEIL(Q3/0.001),10.3));

```

```

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

```

```

/*Obtain subjects with values BLOQ*/

```

```

data adbx_bloq;
    set adbx;
    where bloqfl='Y';
    statval=aval;
    type='abs';
    output;

```

```

statsval=pchg;

type='pch';

output;

run;

proc freq data=adbx_blq noprint;

    table type*trtan*trta*avisitn*avisit*atptn*atpt/ out =blq(drop=percent);

run;

%if &halfblnk=N %then %let halfblnk=;

%else %if &halfblnk=Y %then %let halfblnk=~;

%let dsid=%sysfunc(open(blq));

%let nsum=%sysfunc(attrn(&dsid.,nobs));

%let rc=%sysfunc(close(&dsid.));

%put "Check " &nsum.;

%if &nsum. lt 1 %then %do;

    proc sort data=adbx_orig nodupkey out=tpts(keep=type avisitn avisit atptn atpt trtan
trta);

        by trtan trta type avisitn avisit atptn atpt;

run;

```

```

        data blq1;

            set tpts;

            attrib blq length=$50.;

            IF TYPE='abs' THEN blq='0';

        run;

%end;


%else %do;

/* 6) start JMH 09Oct2014 */

/*      proc sort data=blq(rename=(trtan=trt01an trta=trt01a));*/
/*          by trt01an trt01a;*/
/*      run;*/

/**/

/*      data blq1;*/
/*          attrib blq length=$50.;*/
/*          merge blq(in=a) tot;*/
/*          by trt01an trt01a;*/
/*          if not a then do;*/
/*              count=0;*/
/*          end;*/
/*          percent=count/total*100;*/
/*          */
/*          if count=0 then blq='0';*/
/*          else if percent=100 then blq= put(count,3.) || ' (100%)';*/
/*          else blq=put(count,3.) || ' (' || put(percent,4.1) || '%)';*/

```



```
/*              rename trt01an=trtan trt01a=trta;          */
```

```
/*              run;*/
```

```
/**/
```

```
/*              proc sort data=blq1;*/
```

```
/*              by paramn param trtan trta type avisitn avisit atptn atpt;*/
```

```
/*              run;*/
```

```
PROC SORT DATA=ADBX_ORIG NODUPKEY OUT=TPTS(KEEP=TYPE PARAMN PARAM AVISITN AVISIT  
ATPTN ATPT TRTAN TRTA);
```

```
BY TRTAN TRTA TYPE PARAMN PARAM AVISITN AVISIT ATPTN ATPT;
```

```
RUN;
```

```
DATA BLQTOTS;
```

```
SET RESULTS03(RENAME=(N1=TOTAL));
```

```
KEEP TYPE PARAM: TR: AVISIT: ATPT: TOTAL;
```

```
RUN;
```

```
PROC SORT DATA=BLQTOTS; by TYPE trtan trta PARAMN PARAM AVISITN AVISIT; RUN;
```

```
PROC SORT DATA=TPTS; by TYPE trtan trta PARAMN PARAM AVISITN AVISIT; RUN;
```

```
DATA TOT_BLQ;
```

```
MERGE TPTS BLQTOTS;
```

```
BY TYPE TRTAN TRTA PARAMN PARAM AVISITN AVISIT;
```

```
RUN;
```

```
PROC SORT DATA=TOT_BLQ;
```

```
BY TYPE PARAMN PARAM TRTAN TRTA AVISITN AVISIT ATPTN ATPT;
```

```
RUN;
```

```
DATA BLQ1;
```

```
ATTRIB BLQ LENGTH=$50.;
```

```
MERGE BLQ(IN=A) TOT_BLQ;
```

```
BY TYPE PARAMN PARAM TRTAN TRTA AVISITN AVISIT ATPTN ATPT;
```

```
IF NOT A THEN DO;
```

```
    COUNT=0;
```

```
END;
```

```
IF TOTAL NE 0 THEN PERCENT=COUNT/TOTAL*100;
```

```
ELSE PERCENT=0;
```

```
IF COUNT=0 THEN BLQ='0';
```

```
ELSE IF PERCENT=100 THEN BLQ= PUT(COUNT,3.) || ' (100%)';
```

```
ELSE BLQ=PUT(COUNT,3.) || '  
( ' || LEFT(STRIP(PUT(ROUND(PERCENT,0.1),5.1))) || '%)';
```

```
IF TYPE='pch' THEN BLQ='';
```

```
RUN;
```

```
%end;
```

```
/*Obtain the geometric mean*/
```

```
data gmean;
```

```
set adbx_orig(where=(type='abs'));
```

```
statval1=statval;
```

```

        if aval > 0 then ln_statval1=log(statval1);
run;

proc means data=gmean noprint;

    output out=gmean1 mean=mean std=std1 lclm=lci1 uclm=uci1 nmiss=miss;

    var ln_statval1;

    by trtan trta type avisitn avisit atptn atpt;

run;


data gmean2;

    set gmean1;

    gmean1=exp(mean);

    if miss=0 then do;

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

        if not missing(std1) then gcv=compress(put(0.01*ceil((sqrt(exp(std1*std1)-1)*100)/0.01),8.2));

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

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

    end;

    keep type trtan trta avisitn avisit atptn atpt gmean gcv glci guci std1 miss;

run;


/*Combine the Gmean and BLQ with other stats*/

proc sort data=results03;

    by trtan trta type avisitn avisit atptn atpt;

```

```
run;
```

```
data results04;
```

```
merge results03 gmean2 blq1;
```

```
attrib gmeancv length=$20.;
```

```
by trtan trta type avisitn avisit atptn atpt;
```

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

```
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))));
```

```
END;
```

```
run;
```

```
proc sort data=results04;
```

```
by trtan trta type avisitn avisit atptn atpt;
```

```
run;
```

```
proc sort data=blq1;
```

```
by trtan trta type avisitn avisit atptn atpt;
```

```
run;
```

```
data results05;
```

```
merge results04 (drop=blq) blq1;
```

```
by trtan trta type avisitn avisit atptn atpt;
```

```
run;
```

```
proc sort data=results05;
```

```
  by type avisitn avisit atptn atpt;
```

```
run;
```

```
proc transpose data=results05(where=(type='abs')) out=results06 prefix=r name=varname;
```

```
  by avisitn avisit atptn atpt;
```

```
  var n meansd median minmax aci quart blq gmeancv missc ci;
```

```
  id trtan;
```

```
  idlabel trta;
```

```
run;
```

```
proc transpose data=results05(where=(type='pch' and avisitn>100)) out=results06c prefix=c  
name=varname;
```

```
  by avisitn avisit atptn atpt;
```

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

```
  id trtan;
```

```
  idlabel trta;
```

```
run;
```

```
proc sort data=results06;
```

```
  by avisitn avisit atptn atpt varname;
```

```
run;
```

```
proc sort data=results06c;
```

```

    by avisitn avisit atptn atpt varname;

run;

data results07;

    merge results06 results06c;

    by avisitn avisit atptn atpt varname;

    attrib stat variable length = $100.;

    varname=upcase(varname);

variable=proprcase(avisit);

if varname='N' then do; statord=1; stat='n'; end;

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

        else if varname='BLQ' then do;

statord=2;

stat='BLOQ - n (%)';

                                delete;

        end;

        else if varname='GMEANCV' then do;

statord=3;

stat='Geometric Mean (CV%)';

        end;

else if varname='CI' then do;

statord=4;

stat='95% CI of Geometric Mean';

```

```
end;

else if varname='MEDIAN' then do;

    statord=5;

    stat='Median';

end;

else if varname='QUART' then do;

    statord=6;

    stat='Q25, Q75';

end;

else if varname='MINMAX' then do;

    statord=7;

    stat='Min, Max';

end;

else if varname='MEANS' then do;

    statord=8;

    stat='Mean (SD)';

end;

else if varname='ACI' then do;

    statord=9;

    stat='95% CI of Mean';

end;

drop varname;

run;

data results08;
```

```

set results07;

if stat='Missing, n (%)' and atptn ne . then delete;

run;

data labels;

set results08;

attrib r3 label = "Value"

r4 label = "Value"

r5 label = "Value"

c3 label = '%Change(*)'

c4 label = '%Change(*)'

c5 label = '%Change(*)';

/*          if index(variable,'T0') then variable=tranwrd(variable,'T0','T${sub 0}');*/

if stat="Missing, n(%)" and r3="" and r4="" and r5="" and c3="" and c4="" and c5="" then delete;

flag=1;

run;

proc sql noprint;

create table tflds.&tflno as

select avisitn, atpt, variable, statord, stat, r3 as thsm2_2, c3 as thsm2_2_chg, r4 as mCC, c4 as

mCC_chg, r5 as SA, c5 as SA_chg

from labels

order by avisitn, atptn, statord;

quit;

```



```

proc sort data=labels;

    by avisitn atptn statord;

run;

data paging;

    set labels;

    by avisitn atptn statord;

    if /*(first.avisitn or first.atptn) or*/ ln > 8/*16*/ then ln=1; /*Amend to look presentable, and avoid
page overflows*/ /* 3) JR 15Jul2014 */

    else ln+1;

    if ln=1 then page+1;

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

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;

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/*2*/;
```

```
%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="&title";
```

```
_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;

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 missing headline headskip missing nowd split = '$' %if &i=1 and &j=1 %then
%do; contents=' ' %end; %else %do; contents="" %end;;;

        column flag page avisitn atptn variable statord stat

                %if &j=1 %then %do; ("THSm2.2 $(N=&trt3)&linebot" r3 c3) ("mCC$(N=&trt4)&linebot"
r4 c4) /*%end;*/

                /*%else %if &j=2 %then %do;*/ ("SA$(N=&trt5)&linebot" r5 c5) %end;;

define flag      / order order = internal noprint;

define page      / order order = internal noprint;

define avisitn   / order order=internal noprint;

define atptn     / order order=internal noprint;

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

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

define r4        / display style={just=c cellwidth=2cm} style(header)={just=center};

define c4        / display style={just=c cellwidth=2cm} style(header)={just=center};

define r5        / display style={just=c cellwidth=2cm} style(header)={just=center};

define c5        / display style={just=c cellwidth=2cm} style(header)={just=center};

                %end;

break before flag / page %if &i=1 and &j=1 %then %do;

contents="&_fsrtitl" %end; %else %do; contents=" %end;;

break after page / page;

compute after variable;

                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 15.3.1.2, 15.3.1.5, 15.3.1.7, 15.3.1.11, 15.3.6.10, and 15.3.6.11";

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 ;*/

/*%outrtf(blankn=36, halfblnk=N);*/

```

```
%mend cypactfas;
```

```
%cypactfas (blankn=36, halfblk=N, tflno=T_15_02_04_62_02, act=CYP2A6, title=%str(Table 15.2.4.62.2  
Descriptive Statistics of CYP2A6 Activity (%) - FAS));
```

```
proc printto ; run;
```

```
%m_logchk;
```

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

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

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