

/*-----

Covance Study ID : COV-000000106343

Program Name : t_cyp1a2_fas.sas

Purpose : Table 15.2.4.23.2(Descriptive Statistics of CYP1A2 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_23_02;
```

```
%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*/

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 ("CYP1A2")));

run;


data adbx;

    set adbx1;

```

```
        if ablf='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=sd1 median=median1 min=min1 max=max1 q1=q1  
    q3=q3 lclm=lci1 uclm=uci1;  
run;
```

```
data results03;  
    set results02;
```

```

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

*for <missing, n(%)>;

                                if trtan=3 then do;

                                                if &trt3.=n1 then

missc="";

                                                else

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

                                                end;

                                else if trtan=4 then do;

                                                if &trt4.=n1 then

missc="";

                                                else

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

                                                end;

                                else if trtan=5 then do;

                                                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(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 mean1 sd1 median1 min1 max1 q1 q3 uci1 lci1 ;
```

```
run;
```

```
/*Obtain subjects with values BLOQ*/
```

```
data adbx_blq;
```

```
    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;
```

```
%macro outrtf(blankn=, halfblk=);
```

```
%if &halfblk=N %then %let halfblk=;
```

```
%else %if &halfblk=Y %then %let halfblk=~;
```

```
%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;
```

```
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(gmean1,8.3)));

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

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

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=propcase(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='MEANSD' 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 avisit='Baseline' then do;
```

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

```
        if r4="" then r4='0';
```

```
            if r5="" then r5='0';
```

```
end;
```

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

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

```
        if r4="" then r4='0';
```

```
            if r5="" then r5='0';
```

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

```
        if c4="" then c4='0';
```

```
            if c5="" then c5='0';
```

```
end;
```

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

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

```
        if r2="" then r2='0';  
        if r1="" then r1='0';  
    end;
```

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

```
flag=1;  
    if avisitn in (100 105) then period=1;  
        else if avisitn= 190 then period=4;  
run;
```

```
proc sql noprint;  
    create table tflds.&tflno as  
        select period, avisitn, atpt, variable as avisit, statord, stat, r4 as thsm2_2, c4 as thsm2_2_chg, r5  
as mCC, c5 as mCC_chg, r3 as SA, c3 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 ln > 8 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 = \brdr\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;
```

```
%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 15.2.4.23.2 Descriptive Statistics of CYP1A2 Activity (%) - FAS";
```

```
    _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 $(N=&trt4)&linebot" r4 c4) ("mCC$(N=&trt5)&linebot"  
r5 c5) ("SA$(N=&trt3)&linebot" r3 c3) %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=1.7cm} style(header)={just=l} "Timepoint";
```

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

```
define stat / display style={just=left cellwidth=2.9cm} style(header)={just=center} "Statistic";
```

```
%if &j=1 %then %do;
```

```
define r3 / display style={just=c cellwidth=2.6cm} style(header)={just=center};
```

```
define c3 / display style={just=c cellwidth=2.4cm} style(header)={just=center};
```

```
define r4 / display style={just=c cellwidth=2.6cm} style(header)={just=center};
```

```

define c4      / display style={just=c cellwidth=2.4cm} style(header)={just=center};
define r5      / display style={just=c cellwidth=2.6cm} style(header)={just=center};
define c5      / display style={just=c cellwidth=2.4cm} 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 15.3.4.1";
```

```
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, halfblk=N);
```

```
proc printto ; run;
```

```
%m_logchk;
```

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

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

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

