

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

```
| Covance Study Number   : 000000106343          |
|
| Program Name           : t_anl_exp.sas          |
|
| Purpose                 : Analysis of Biomarkers of Exposure in 4hr Fraction on Day 90 - PP    |
|                         |                       |
| Input Data              : ADBX                  |
|
| Output Data             : tflds.T_15_02_04_34, tflds.T_15_02_04_34_F, RTF                    |
|                         |                       |
| Macros Called           : m_printto, m_logchk    |
|
| Originally Performed by : kpothuri              |
|
| Date                   : 15JUNE2015             |
|                         |                       |
|                         |                       |
```

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|=====
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```

```
| Modification History    |
|-----|
```

```
| Modified by            :                       |
|
| Modification Date      :                       |
|
| Modification Description :                     |
```

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

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

```
ods _all_ close;
```

```
ods listing;
```

```
%m_printto(route=YES);
```

```

*=====;

* START OF PROGRAM CODE                                ;

*=====;

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

%let TFL_Part=%scan(&_SASPROGRAMFILE,-3,%str(/));

/* Standard - leave this */

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;

proc sort data=adam.adbx out=adbxin1; by trtp paramn;

    where anl02fl="Y" and pprot4fl="Y" and avisitn=190 and

    paramn in (145,119,162,147,166,152,113,155,122,110,116,158,125,138,185,141);

run;

data adbxin1;

    set adbxin1;

    if paramn=145 then paramn=1;

```

```

    if paramn=119 then paramn=2;
    if paramn=166 then paramn=3;
    if paramn=152 then paramn=4;
    if paramn=113 then paramn=5;
    if paramn=155 then paramn=6;
    if paramn=122 then paramn=7;
    if paramn=110 then paramn=8;
    if paramn=116 then paramn=9;
    if paramn=158 then paramn=10;
    if paramn=125 then paramn=11;
    if paramn=138 then paramn=12;
    if paramn=185 then paramn=13;
    if paramn=141 then paramn=14;
    if paramn=162 then paramn=15;
    if paramn=147 then paramn=16;

run;

*Counts;

proc freq data=adbxin1 (where=(BASE ne . and UCPDGR1 ne '')) noprint;
    table paramn*param*trtp/out=f_param (drop=percent);
run;

proc transpose data=f_param out=t_count;
    id trtp;
    var count;

```

```

        by paramn param;

run;

data t_count_1 (drop=_label_ THSM2_2 SA MCC rename=(THSM2_2_2=THSM2_2 SA_=SA MCC_=MCC));

length THSM2_2_2 SA_ MCC_ $18.;

    set t_count;

    THSM2_2_2=put(THSM2_2,best.);

    SA_=put(SA,best.);

    MCC_=put(MCC,best.);

    if _name_="COUNT" then _name_="A_COUNT";

run;

```

```

data adbx1 missing;

    set adbxin1;

    if aval not in (.,0) and base not in (.,0) then do; *need to add BASE for missing value calculation;

        logaval=log(aval);

            logbase=log(base);

        output adbx1;

    end;

    else output missing;

run;

```

```

proc sort data=adbx1; by paramn; run;

```

```
%let l_name = %str(L_15_04_04_34);
```

```
%let t_title_l = %nrbrquote(Listing 15.4.4.34 Analysis of Biomarkers of Exposure in 4-hour Fraction versus  
mCC and SA on Day 90 Visit â€™ PP Set);
```

```
ods rtf
```

```
file="/cvn/projects/prj/data/000000106343/TFL/dev/Tables/&l_name..rtf";
```

```
title "&t_title_l";
```

```
options orientation=landscape;
```

```
proc glm data=adbx1;
```

```
    class trtp sex UCPDGR1;
```

```
    by paramn param avisitn avisit;
```

```
    model logaval = logbase sex UCPDGR1 trtp;
```

```
    lsmeans trtp / pdiff alpha=0.05 cl;
```

```
    ods output LSMeanCL=LSMeanCL (keep=paramn param trtp lowercl uppercl lsmean); *lsmean,  
C.I.;
```

```
    ods output LSMeanDiffCL=LSMeanDiffCL (keep=paramn param avisitn avisit trtp _trtp lowercl  
uppercl difference); *lsmean and C.I. for ratios;
```

```
    ods output FitStatistics=ROOTMSE (keep=paramn param rootmse); *RootMSE;
```

```
run;
```

```
ods rtf close;
```

```
*lsmean and C.I. for ratios;
```

```
data LSMeanDiffCL_1;
```

```
    merge LSMeanDiffCL ROOTMSE;
```

```
    by paramn param;
```

```

format lowercl uppercl difference rootmse;

if trtp="SA" and _trtp="mCC" then delete;

run;

data LSM_CL;

set LSMeanDiffCL_1;

if trtp="SA" and _trtp="THSm2.2" then do;

    diff_neg=difference*(-1);

    UC=LowerCL*(-1);

    LC=UpperCL*(-1);

end;

else do;

    diff_neg=difference;

    LC=LowerCL;

    UC=UpperCL;

end;

diff_=exp(diff_neg);

L_CI_=exp(LC);

U_CI_=exp(UC);

CI=compress(put(floor(100*L_CI_*100)/100,12.2))||',
'|compress(put(ceil(100*U_CI_*100)/100,12.2));

MSE=(rootmse)**2;

```

```

CV_=10000*sqrt(exp(MSE)-1);

CV=put((ceil(CV_)/10000)*100,12.2);

B_Ismean=compress(put(round(100*diff_,0.01),12.2))||'('||compress(CV)||')';

if _trtp="THSm2.2" then _trtp="SA";

run;

proc transpose data=LSM_CL out=t_LSM_CL (rename=(SA=ths_sa_ratio mcc=ths_mcc_ratio));

    id _trtp;

    var B_Ismean CI;

    by paramn param;

run;

*Ismean, C.I.;

data LSMeanCL;

    set LSMeanCL;

    format lowercl uppercl lsmean;

run;

data stat;

    set LSMeanCL;

    B_Ismean=put(exp(Ismean),8.2);

    LowerCL_=exp(LowerCL);

    UpperCL_=exp(UpperCL);

```

```
        CI=compress(put(floor(100*LowerCL_)/100,8.2))||',  
'||compress(put(ceil(100*UpperCL_)/100,8.2));
```

```
run;
```

```
proc transpose data=stat out=t_stat;
```

```
    id trtp;
```

```
    var B_lsmean CI;
```

```
    by paramn param;
```

```
run;
```

```
data set90;
```

```
    set t_count_1 t_stat;
```

```
run;
```

```
proc sort data=set90; by paramn param _name_; run;
```

```
proc sort data=t_lsm_cl; by paramn param _name_; run;
```

```
data set90_a;
```

```
length _name_ $30;
```

```
    merge set90 t_lsm_cl;
```

```
    by paramn param _name_;
```

```
    if _name_="A_COUNT" then do;
```

```
        _name_="n";
```

```
    end;
```

```
    else if _name_="B_LSMEAN" then do;
```

```
        _name_="Geometric LS Mean (CV%)";
```

```
    end;
```



```
        else if _name_="CI" then do;
            _name_="95% CI";
        end;
run;
```

```
proc sort data=set90_a out=set90_a1 (keep=param paramn) nodupkey; by paramn paramn; run;
```

```
data set90_a1;
    set set90_a1;
    do i=1 to 4;
        paramn1=i;
        output;
    end;
run;
```

```
data set90_a2;
    set set90_a1;
length _name_ $30;
    if paramn1=1 then _name_="";
    if paramn1=2 then _name_="n";
    if paramn1=3 then _name_="Geometric LS Mean (CV%)";
    if paramn1=4 then _name_="95% CI";
run;
```

```
proc sort data=set90_a2; by paramn param _name_; run;
```

```
proc sort data=set90_a; by paramn param _name_; run;
```

```
data set90_b;
```

```
    merge set90_a2 set90_a;
```

```
    by paramn param _name_;
```

```
run;
```

```
proc sort data=set90_b; by paramn param paramn1; run;
```

```
data page;
```

```
    set set90_b;
```

```
    if ln gt 7 then ln=1;
```

```
    else ln+1;
```

```
    if ln=1 then pageord+1;
```

```
run;
```

```
%macro anlout (din=, tfl=, tabname=);
```

```
%let tflno=&tfl.;
```

```
data tflds.&tflno;
```

```
    set &din end=last;
```

```
    by pageord;
```

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

```
run;
```

```
%put &page;
```

```
/* Standard - leave this */
```

```
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;
```

```
/* Standard - macro for paging */
```

```
%macro outrtf(blankn=130, halfblnk=N);
```

```
%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 tflds.&tflno end=eof;

        where pageord=&i;

/* Amend title as needed */

        _firtitl="&tabname";

        _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;

\* 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 pageord paramn param _name_ THSM2_2 mcc sa THS_MCC_RATIO THS_SA_RATIO;

    define pageord /order order = internal noprint;

    define paramn /order order = internal noprint;

    define param /"Biomarker" group style(column)={just=left cellwidth=1.7cm asis=on}
style(header)={just=left};

    define _name_ /"Statistic" display style={just=left cellwidth=2.1cm} style(header)={just=left};

    define THSM2_2 /"THSm2.2" display style={just=c cellwidth=1.4cm}
style(header)={just=center};

    define mcc /"mCC" display style={just=c cellwidth=1.4cm}
style(header)={just=center};

    define sa /"SA" display style={just=c cellwidth=1.4cm}
style(header)={just=center};

    define THS_MCC_RATIO /"THSm2.2 : mCC| Ratio (%)" display style={just=c
cellwidth=1.4cm} style(header)={just=center};

    define THS_SA_RATIO /"THSm2.2 : SA| Ratio (%)" display style={just=c
cellwidth=1.2cm} style(header)={just=center};

    break after pageord / page;

    compute after param;

    line " ";

endcomp;

```

```

compute before pageord / 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 "- PP Set";

        line "&linebot";

endcomp;


compute after _page_ / style={just=left protectspecialchars=off pretext="&linetop."};

    line 'Note: Adjusted geometric least squares (LS) means and confidence intervals (CIs)
from an ANCOVA model conducted with log-transformed baseline values, sex, average daily mCC
consumption, and randomized arm as fixed effect factors. Geometrical CV% of the ratio is estimated
from the residual mean squares.';

    line 'Note: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 =
Tobacco Heating System 2.2 Menthol.';

    line ";

    line 'Appendix 15.3.3.5';

    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, halfblnk=N);
```

ods listing;

```
%mend anlout;
```

```
%anlout (din=page, tfl=%str(T_15_02_04_34), tabname=%str(Table 15.2.4.34 Analysis of Biomarkers
of Exposure in 4-hour Fraction versus mCC and SA on Day 90 Visit));
```

\*=====;

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

\* \_\_\_\_\_,

```
%m_logchk;
```

