

/*=====*

| Covance Study Number : COV- 106331 |
| Client Protocol ID : ZRHM-REXA-08-US |
| Program Name : t_anl_cyp.sas |
| Purpose : Table Analysis of 11-DTX-B2 |
| Input Data : ADBX ADSL |
| Output Data : T_15_02_04_25_01_01, T_15_02_04_25_02_01 |
| |

| Macros Called : |
| |

| Originally Performed by : Seroan Zheng |
| Date/Time billed : 12May2015 |
| |

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| Modification History |
| |

| Programmer : Serona Zheng |
| Date : 01Jun2015 |

| Reason for Change : 1. Update GLM model to lsmeans trtpn / pdiff alpha=0.05 cl|
| 2. Remove P-value |
| |

| Programmer : Serona Zheng |
| Date : 08Sep2015 |

| Reason for Change : Change footnote |
| |

| Programmer : Serona Zheng |

| Date : 14Sep2015 |

| Reason for Change : Added base ne . and UCPDGR1 ne " condition to select analysis subjects based on client comments |

| Programmer : Nina Burghard |

| Date : 21Sep2015 |

| Reason for Change : Added options to remomve by line has been truncated.... |

+=====*/

options noquotelenmax;

***Create log file;

proc printto new

log="/cvn/projects/prj/development/000000106343/dev/tables/log/t_anl_dtx.log" ;

run;

%macro t_anl_dtx(t_name=,dsin=,conf1=,by_var1=,t_title=,t_title_l=,l_name=,appendix=);

%let pgrname=t_anl_dtx.sas;

%let table=&tflout.;

%let tflno=&t_name;

%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", ""));  
run;
```

```
***Get raw data;
```

```
data anl1;
```

```
    set adam.&dsin;
```

```
    &conf1
```

```
***Calculate LOG;
```

```
    if aval not in (.,0) then do;
```

```
        logaval=log(aval);
```

```
        if base not in (.,0) then logbase=log(base);
```

```
    end;
```

```
    if trtp = 'SA' then trtpn = 3;
```

```
    else if trtp = 'THSm2.2' then trtpn = 1;
```

```
    else if trtp = 'mCC' then trtpn = 2;
```

```
run;
```

```
proc sort data=anl1;by &by_var1;run;
```

```
***Get decimal length;
```

```
data temp;
```

```
    set anl1;
```

```

        declen=lengthn(scan(strip(put(aval, best.)),2,"."));
run;

proc sql;

    create table dectemp

    as select distinct paramn, max(declen) as declen

    from temp

    group by paramn;


        select max(declen) into: last

        from dectemp;

quit;


%if &t_name=T_15_02_04_25_01_01 or &t_name=T_15_02_04_25_02_01 %then %do;

    data dectemp;

        set dectemp;

        declen = 1;

    run;

proc sql;

    select max(declen) into: last

    from dectemp;

quit;

%end;


ods listing close;

```

```

***Calculate STAT;

%macro glm_nco(dsin=,conf=,var=,base=,dsout=,dsoutf=);

data anal;

    set &dsin;

/*    if &conf;*/

run;


proc sort data=anal;by paramn paramcd param avisitn ;run;


options ls=max;

proc glm data=anal;

    class trtpn sexc UCPDGR1;

    by paramn paramcd param avisitn avisit;

    model &var = &base sexc UCPDGR1 trtpn;

    lsmeans trtpn / pdiff alpha=0.05 cl;

    ods output LSMeanCL=LSMeanCL (keep=avisitn avisit paramn paramcd param trtpn lowercl
uppercl lsmean); *lsmean, C.I.;

    ods output LSMeanDiffCL=LSMeanDiffCL (keep=avisitn avisit paramn paramcd param trtpn
_trtpn lowercl uppercl difference where=(trtpn=1)); *lsmean and C.I. for ratios;

    ods output FitStatistics=ROOTMSE (keep=avisitn avisit paramn paramcd param rootmse);
*RootMSE;

run;


*lsmean and C.I. for ratios;

data lsm_cl;

    merge LSMeanDiffCL(in=a) rootmse;

```

```

        by paramn paramcd param avisitn avisit;

        if a;

run;

data LSM_CL; *(drop=difference LowerCL UpperCL L_CI U_CI);

        length out stat $200;

        merge lsm_cl(in=a) dectemp;

        by paramn;

        if a;

***ordering columns of treatments*;

        if _trtpn=2 then colord=4;

        else if _trtpn=3 then colord=5;


        %if &var=logaval %then %do;

                estimatee=exp(difference);

                lowere=exp(LowerCL);

                uppere=exp(UpperCL);

ord=3;

stat='95% CI';

                out=compress(put(floor(100*lowere*100)/100,12.2))||',
'| |compress(put(ceil(100*uppere*100)/100,12.2));

                output;


        %end;

        %else %do;

                estimatee=difference;

```

```

        lowere=LowerCL;

        uppere=UpperCL;

ord=3;

stat='95% CI';

out=compress(put(floor(100*lowere)/100,12.2))||', '||compress(put(ceil(100*uppere)/100,12.2));

        output;

%end;

%if &var=logaval %then %do;

        MSE=(rootmse)**2;

        CV_=100*sqrt(exp(MSE)-1);

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

ord=2;

stat='Geometric LS Mean (CV%)';

        out=compress(put(round(100*estimatee,0.01),12.2))||' ('||COMPRESS(cv)||')';

        output;

%end;

%else %do;

        ord=2;

stat='Geometric LS Mean (CV%)';

        out=compress(put(round(estimatee,0.01),12.2));

        output;

%end;

run;

```

*lsmean, C.I.;

```
proc sort data=lsmeanc1 out=lsmeanc11 nodupkey; by paramn avisitn trtpn lowercl uppercl lsmean; run;
```

```
data lsm_ci; *(drop=LowerCL UpperCL);
```

```
length out stat $200;
```

```
merge LSMeanCL1(in=a rename=(trtpn=trtpn1)) dectemp;
```

```
by paramn;
```

```
if a;
```

```
trtpn = input(trtpn1,best.);
```

```
***ordering columns of treatments*;
```

```
if trtpn=1 then colord=1;
```

```
else if trtpn=2 then colord=2;
```

```
else if trtpn=3 then colord=3;
```

```
%if &var=logaval %then %do;
```

```
estimatee=exp(lsmean);
```

```
lowere=exp(LowerCL);
```

```
uppere=exp(UpperCL);
```

```
%end;
```

```
%else %do;
```

```
estimatee=lsmean;
```

```
lowere=LowerCL;
```

```
uppere=UpperCL;
```

```
%end;
```



```

        ***Gmean (CV%) row*;

ord=2;

stat='Geometric LS Mean (CV%)'; /* 1) APH 03NOV2014 */

        out=compress(put(round(estimatee,0.01),12.2));

output;

ord=3;

stat='95% CI';

out=compress(put(floor(100*lowere)/100,12.2))||', '||compress(put(ceil(100*uppere)/100,12.2));

        output;

run;

***Calculate N;

proc univariate data=anal noprint;

        by paramn paramcd param avisitn avisit;

class trtpn;

var &var;

output out=num1 n=n1;

run;

data num1;

        set num1;

        by paramn avisitn;

***ordering columns of treatments*;

        if trtpn=1 then colord=1;

```

```
else if trtpn=2 then colord=2;
```

```
else if trtpn=3 then colord=3;
```

```
ord=1;
```

```
stat='n';
```

```
out=compress(put(n1,best.));
```

```
run;
```

```
data tabout;
```

```
set lsm_cl lsm_ci /*pval1*/ num1;
```

```
by paramn avisitn;
```

```
run;
```

```
proc sort data=tabout; by paramn paramcd param avisitn avisit ord stat;
```

```
proc transpose data=tabout out=&dsout.(drop=_NAME_) prefix=col;
```

```
by paramn paramcd param avisitn avisit ord stat;
```

```
id colord;
```

```
var out;
```

```
run;
```

```
options ls=132;
```

```
%mend;
```

```
***Create model result to lst file;
```

```
ods rtf
```

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

```
run;
```

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

```
%glm_nco(dsin=anl1,var=logaval,base=logbase,dsout=anl_f);
```

```
ods rtf close;
```

```
data final1;
```

```
    set anl_f;
```

```
    logf = 1;
```

```
run;
```

```
proc sort data=final1;by logf paramn avisitn ord;run;
```

```
data final2;
```

```
    set final1;
```

```
    by logf paramn avisitn ord;
```

```
    if first.paramn then do; sum = 0; group + 1; end;
```

```
    sum +1;
```

```
    if sum > 6 then do;
```

```
        group +1;
```

```
        sum = 1;
```

```
    end;
```

```

        page = group;

run;

proc sort data=final2 out=final;by page logf paramn avisitn ord;run;

data _null_;

    set final;

    by logf paramn;

    if last.paramn then call symput('tpage',strip(put(page,3.)));

    if first.logf then call symput('tpage' || strip(put(logf,best.)),strip(put(page,3.)));

run;

%put &tpage;

data tflds.&tflno.;

    set final;

run;

options number nodate mprint mlogic orientation=landscape /* papersize=&p_pgsz */ missing=' ';

%let linetop = \brdrt\brdrs\brdrw30; * needs to be 1.5pt so calculated in twips (1/20 pt) ;

%let linebot = \brdrb\brdrs\brdrw30;

ods escapechar='$';

ods path stdlib.t106343 (read) ;

ods results off;

ods rtf toc_data file="/cvn/projects/prj/data/000000106343/TFL/dev/Tables/&tflno..rtf" style=t106343
startpage=yes headery=1440 footery=1440 ;

ods noproctitle;

```

```
%do i=1 %to &tpage;
```

```
title ;
```

```
footnote;
```

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

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

```
data comp;
```

```
    set final end=eof;
```

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

```
    call symput('param',param);
```

```
    *** Amend title as needed;
```

```
    _firtitl="&t_title";
```

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

```
    drop _firtitl ;
```

```
run;
```

```
* 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 %then %do;  
contents=' ' %end; %else %do; contents="" %end;; ;
```

```
    column page paramn avisitn avisit  ord stat col1 col2 col3 col4 col5;
```

```

define page      / order order=internal noprint;

define paramn    / order order = internal noprint;

define avisitn   / order order = internal noprint;

define ord       / order order=internal noprint;

/*  define id     / order order=internal noprint;*/


define avisit    / order style={just=left cellwidth=2cm} style(header)={just=left} "Variable" ;

define stat      / display style={just=left cellwidth=3.5cm} style(header)={just=left} "Statistic";

define col1      / display style={just=c cellwidth=2cm} style(header)={just=center} "THSm2.2";

define col2      / display style={just=c cellwidth=2.5cm} style(header)={just=center} "mCC";

define col3      / display style={just=c cellwidth=2.5cm} style(header)={just=center} "SA";


        %if &i < &tpage1 %then %do;

                define col4      / display style={just=c cellwidth=2.5cm} style(header)={just=center} "THSm2.2 -
mCC Difference";

                define col5      / display style={just=c cellwidth=2.5cm} style(header)={just=center} "THSm2.2 -
SA Difference";

                %end;

        %else %do;

                define col4      / display style={just=c cellwidth=2.7cm} style(header)={just=center} "THSm2.2 : mCC
$Ratio (%)";

                define col5      / display style={just=c cellwidth=2.7cm} style(header)={just=center} "THSm2.2 : SA
$Ratio (%)";

                %end;

        break after page / page;

```

```
compute after avisitn;
```

```
    line " ";
```

```
endcomp;
```

```
compute before page / style={just=left protectspecialchars=off fontsize=10pt};
```

```
    line "&linetop";
```

```
        line "&param";
```

```
        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 "&linebot";
```

```
endcomp;
```

```
%if &i < &tpage1 %then %do;
```

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

```
        line 'Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an  
ANCOVA model conducted with baseline value, study arm, sex and mCC consumption reported at  
screening as fixed effect factors.';
```

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

```
        line ' ';
```

```
%end;
```

```
%else %do;
```

```
    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 on log-transformed values with log-transformed baseline value, study arm, sex and mCC consumption reported at screening 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 ' ';

%end;

line "Appendix: &appendix";

line "Study ID: ZRHM-REXA-08-US" " " "Program: &pgname" " " "Status: &status"
" "&sysdate" " " "(Page &i of &tpage)";

endcomp;

run;

ods path WORK.TEMPLAT(UPDATE)

SASUSER.TEMPLAT(READ)

SASHELP.TMPLMST(READ) ;

%end;

ods rtf close;

/* ods path show;*/

%mend;

***For table 15.2.4.25.1.1;

%t_anl_dtx(t_name=T_15_02_04_25_01_01,

l_name=L_15_04_04_25_01_01,

dsin=adbx,


```
conf1=%str(if anl03fl = 'Y' and upcase(parcat2) = 'RISK MARKERS' and paramcd =  
'UTXB2CRE' and base ne . and UCPDGR1 ne " and ((pprot1fl = 'Y' and avisitn = 105)
```

```
or (pprot2fl = 'Y' and avisitn = 130) or (pprot3fl = 'Y' and avisitn = 160) or  
(pprot4fl = 'Y' and avisitn in (190 191))));,
```

```
by_var1=paramn paramcd param avisitn avisit,
```

```
t_title=%nrbquote(Table 15.2.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat)  
Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-  
DTX-B2 - PP Set),
```

```
t_title_l=%nrbquote(Listing 15.4.4.25.1.1 Analysis of 11-DTX-B2 (pg/mg creat)  
Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-  
DTX-B2 - PP Set),
```

```
appendix=%str(15.3.3.1)
```

```
);
```

```
***For table 15.2.4.25.2.1;
```

```
%t_anl_dtx( t_name=T_15_02_04_25_02_01,
```

```
l_name=L_15_04_04_25_02_01,
```

```
dsin=adbx,
```

```
conf1=%str(if anl03fl = 'Y' and upcase(parcat2) = 'RISK MARKERS' and paramcd =  
'UTXB2CRE' and base ne . and UCPDGR1 ne " and ((fasfl = 'Y' and avisitn = 105)
```

```
or (fasfl = 'Y' and avisitn = 130) or (fasfl = 'Y' and avisitn = 160) or (fasfl = 'Y' and  
avisitn in (190 191))));,
```

```
by_var1=paramn paramcd param avisitn avisit,
```

```
t_title=%nrbquote(Table 15.2.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat)  
Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-  
DTX-B2 - FAS),
```

```
t_title_l=%nrbquote(Listing 15.4.4.25.2.1 Analysis of 11-DTX-B2 (pg/mg creat)  
Excluding Assessments within 5 Half-Lives of a Concomitant Medication Affecting the Production of 11-  
DTX-B2 - FAS),
```

```
appendix=%str(15.3.3.1)
```

```
);
```

```
proc printto ;
```

```
run;
```

```
ods path WORK.TEMPLAT(UPDATE)
```

```
SASUSER.TEMPLAT(READ)
```

```
SASHELP.TMPLMST(READ) ;
```

```
ods listing;
```

```
options quotelenmax;
```

```
proc datasets kill lib=work memtype=data;run;
```

```
***check the log, if there is any findings, please make sure to resolve;
```

```
%m_chklog(TFL_part=dev,pgm_type=tables,pgm_name=t_anl_dtx,serv=dev,covstudyid=000000106343)  
;
```