

/*=====*

| Covance Study Number : COV- 106343 |
| Client Protocol ID : ZRHM-REXA-08-US |
| Program Name : t_anal_lung_pp.sas |
| Purpose : Table Analysis of additional biomarkers Mixed model |
| Input Data : ADXP ADSL |
| Output Data : T_15_02_04_71 |
|
| Macros Called : |
|
| Originally Performed by : Sree Bikki |
| Date/Time billed : 16Mar2016 |
|

+=====+

| Modification History |
| Programmer : |
| Date : |
| Reason for Change : |

+=====*/

options noquotelenmax;

proc datasets lib=work kill memtype=data nolist;

run;

```
%m_printto;
```

```
proc sql;
```

```
select count(distinct usubjid) into: N1THS from adam.adsl(where=(trt01pn = 4 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N1MCC from adam.adsl(where=(trt01pn = 5 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N1SAA from adam.adsl(where=(trt01pn = 3 and pprot1fl = "Y"));
```

```
select count(distinct usubjid) into: N4THS from adam.adsl(where=(trt01pn = 4 and pprot4fl = "Y"));
```

```
select count(distinct usubjid) into: N4MCC from adam.adsl(where=(trt01pn = 5 and pprot4fl = "Y"));
```

```
select count(distinct usubjid) into: N4SAA from adam.adsl(where=(trt01pn = 3 and pprot4fl = "Y"));
```

```
quit;
```

```
%let tflno=T_15_02_04_71;
```

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

```
%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;

```

```

data adam_adxp ;

    set adam.adxp ;

    if apuper = 1 then do;

        ppfl=PPROT1FL;

    end;

    else if apuper = 4 then do;

        ppfl=PPROT4FL;

    end;

run ;

data adam_adxp_1(rename= (paramn= paramn1)) ;

    set adam_adxp;

    if paramn in (51 54 61 64 65 63 20 11 9 8 5 4 6 ) and ppfl='Y' and anl01fl='Y' and dtype ne "LOCF" ;

run ;

```

```

data adam_adxp_1;

set adam_adxp_1;

param = strip(param)||" ("||strip(avalu)||")";

if paramn1 = 51 then paramn = 1;

```

```
if paramn1 = 54 then paramn = 2;  
if paramn1 = 6 then paramn = 3;  
if paramn1 = 4 then paramn = 4;  
if paramn1 = 65 then paramn = 5;  
if paramn1 = 64 then paramn = 6;  
if paramn1 = 63 then paramn = 7;  
if paramn1 = 61 then paramn = 8;  
if paramn1 = 11 then paramn = 9;  
if paramn1 = 20 then paramn = 10;  
if paramn1 = 9 then paramn = 11;  
if paramn1 = 8 then paramn = 12;  
if paramn1 = 5 then paramn = 13;  
drop paramn1;  
run;
```

```
data adxp;  
set adam_adxp_1 ;  
run;
```

```
proc sort data=adxp;  
by trtpn trtp paramn param paramcd apuper apuperc avisitn avisit;  
run;
```

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

```
data temp;
```

```
    set adxp;
```

```
    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;
```

```
quit;
```

```
***Create param temp;
```

```
proc freq data=adxp;
```

```
table paramn*paramcd*param*apuper*apuperc / list out=temp_p(drop=count percent);
```

```
run;
```

```
***Calculate STAT;
```

```
data anal;
```

```
    set adxp;
```

```
run;
```

```

proc sort data=anal;

by paramn paramcd param apuper apuperc avisitn avisit;

run;


%let l_name = %str(L_15_04_04_71);

%let t_title_l = %nrbrquote(Listing 15.4.4.71 Analysis of Full Lung Function Results â€™ PP Set);


ods rtf

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

title "&t_title_l";

options orientation=landscape;


***Calculate STAT using MIXED model;

Proc mixed data=anal;

    by paramn paramcd param apuper apuperc avisitn avisit;

    Class trtp sex UCPDGR1;

    Model aval = base sex UCPDGR1 trtp;

    Lsmeans trtp / pdiff =control('mCC') alpha=0.05 cl;

    Lsmeans trtp / pdiff =control('SA') alpha=0.05 cl;


    ods output diffs = diffs;

    ods output covparms = fit;

    ods output lsmeans = lsmeans;

Run;

```

```

***prepare mean and ci for each group;

data lsmeans(where=(colord ne .));

    length out stat $100;

    merge lsmeans(in=a) dectemp;

    by paramn;

    if a;

***ordering columns of treatments*;

    if trtp='THSm2.2' then colord=1;

    else if trtp='mCC' then colord=2;

    else if trtp='SA' then colord=3;


    estimatee=estimate;

    lowere=Lower;

    uppere=Upper;

        ***Gmean (CV%) row*;

    ord=2;

    stat='LS Mean';

        if estimatee ne . then out=compress(put(round(estimatee,0.01),best.));

    output;


    ord=3;

    stat='95% CI';

        if nmiss(lowere,uppere)=0 then out=compress(put(floor(100*lowere)/100,12.2))||',
'|compress(put(ceil(100*uppere)/100,12.2));

    output;

```

```
run;
```

```
***prepare mean and ci for difference;
```

```
data diff;
```

```
merge diffs(in=a where=(trtp='THSm2.2')) fit(in=b rename=(estimate=rootmse));
```

```
by paramn paramcd param apuper apuperc avisitn avisit;
```

```
if a;
```

```
run;
```

```
data diff;
```

```
length out stat $100;
```

```
merge diff(in=a) dectemp(in=c);
```

```
by paramn;
```

```
if a;
```

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

```
if _trtp='mCC' then colord=4;
```

```
if _trtp='SA' then colord=5;
```

```
estimatee=estimate;
```

```
lowere=Lower;
```

```
uppere=Upper;
```

```
ord=3;
```

```
stat='95% CI';
```

```
if lowere ne . and uppere ne . then do;
```

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

```
end;
```



```
output;
```

```
ord=2;
```

```
stat='LS Mean';
```

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

```
output;
```

```
run;
```

```
***Calculate N;
```

```
proc univariate data=anal noprint;
```

```
where BASE ne .;
```

```
by paramn paramcd param apuper apuperc avisitn avisit;
```

```
class trtp;
```

```
var aval;
```

```
output out=num1 n=n1;
```

```
run;
```

```
ods rtf close;
```

```
data num1;
```

```
length trtp $7;
```

```
set num1(rename=(trtp=trtp1));
```

```
trtp = trtp1;
```

```
drop trtp1;
```

```

run;

data num1;

    merge num1(in=a) dectemp;

    by paramn;

    if a;

    ***ordering columns of treatments*;

    if trtp='THSm2.2' then colord=1;

    else if trtp='mCC' then colord=2;

    else if trtp='SA' then colord=3;


ord=1;

stat='n';

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

    if colord ne .;

run;


/**p-value;*/

data pval1;

    length out stat $100;

    set diffs(keep=paramn paramcd param avisitn avisit apuper apuperc trtp_trtp probt);

    by paramn avisitn avisit;

    where trtp="THSm2.2" and paramcd in ("DLCO" "KCO");


    ***ordering columns of treatments*;

    if first.avisitn then colord=4;

```

```

if last.avisitn then colord=5;

    ord=4;

    stat='p-value';

if probt = <.0001 then out="<0.001";

else do;

    pval_=probt/2;

    if pval_ < 0.001 then out="<0.001";

    else if pval_ > 0.999 then out=">0.999";

    else if 0.001 < pval_ < 0.999 then out=put(pval_,5.3);

end;

if _trtp='SA' then call missing(out);

run;

```

```

data tabout;

    set lsmeans diff num1 pval1;

    by paramn paramcd param apuper apuperc avisitn avisit ;

run;

```

```

proc sort data=tabout nodupkey;

by paramn paramcd param apuper apuperc avisitn avisit ord stat out colord;

run;

```

```

proc transpose data=tabout out=fin(drop=_NAME_) prefix=col;

```

```
by paramn paramcd param apuper apuperc avisitn avisit ord stat;  
  
id colord;  
  
var out;  
  
run;
```

```
data final;  
  
    set fin;  
  
run;
```

```
proc sort data=final;  
  
by paramn apuper apuperc avisitn ord;  
  
run;
```

```
data final;  
  
    set final;  
  
    by paramn apuper apuperc avisitn ord;  
  
    page = paramn;  
  
    if last.paramn then call symput('tpage',put(page,best.));  
  
    if paramn = . then delete;  
  
run;
```

```
%put &tpage;  
  
%let tpage=&tpage;
```

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

```
    set final;
```

```
run;
```

```
%let title =%str(Table 15.2.4.71 Analysis of Full Lung Function Results - PP Set);
```

```
%put &tpage;
```

```
options number nodate orientation=landscape /* papersize=&p_pgsz */ 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);
```

```
%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/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;
```

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

```
    _firtitl="&title.";
```

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

```
    len=&blankn.-length("(page &i of &tpage)");
```

```
    if eof then do;
```

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

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

```
/*      call symput('period', strip(apuperc));*/
```

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

```
    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;

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

```
column page paramn apuper 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 apuper    / order order = internal noprint;
```

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

```
define avisit    / order style={just=left cellwidth=4cm} style(header)={just=left} "Variable" id;
```

```
define stat      / display style={just=left cellwidth=2cm} 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=2cm} style(header)={just=center} "mCC";
```

```
define col3      / display style={just=c cellwidth=2cm} style(header)={just=center} "SA";
```

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

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

```

compute after avisitn;

    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 " ";

        line "Parameter (units):&param";

/*        line "Product Use Time Period: &period";*/

        line "&linebot";


endcomp;


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

    line 'Note: Adjusted least squares (LS) means and confidence intervals (CIs) from an
Mixed 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 'Note: p-value for one-sided test for comparison between THSm2.2 and mCC are
only presented for Diffusion Capacity for Lung CO and Rate Constant of CO.';

    line ' ';

    line 'Appendix 15.3.6.11';

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

```



```
endcomp;
```

```
run;
```

```
%end;
```

```
ods rtf close;
```

```
ods results on;
```

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

```
%mend;
```

```
%outrtf(blankn=36, halfblk=N);
```

```
ods listing;
```

```
%m_logchk2;
```

```
proc printto ;
```

```
run;
```