

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

```
| Covance Study Number   : 000000106343          |
```

```
| Program Name           : t_anl_hst.sas          |
```

```
| Purpose                 : Analysis of HST
|
```

```
| Input Data              : ADXT                   |
```

```
| Output Data              : T_15_02_04_61         |
```

```
| Macros Called            : m_printto, m_logchk    |
```

```
| Originally Performed by : kpothuri               |
```

```
| Date                     : 14MAY2015             |
```

```
|                          |
```

```
|=====
=====|
```

```
| 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;

HST;

data HST;

    set adam.ADXT;

    where DTYPE ne "LOCF" and

        propcase(avisit) in ("Day 1", "Day 4", "Day 5", "Day 30", "Day 60", "Day 90")

        and paramcd in
("ANPC","ATVOL","AAVGVI","AAVGDI","ATDI","AAVGQMI","AAVGQCI","ATII","AAVGII","ATDFI","ATWI",
"AAVGWI"

        "AAVGPMI","AAVGPCI","ASMINT","APTI","APFEQ");

```

```

run;

*HST counts;

%macro count (wh=, pop=);

proc sort data=HST out=HST_mx&pop (where=(BASE ne . and UCPDGR1 ne " and &wh)); by trtp param
avisit usbjid; run; *for proc mixed datasets;

proc freq data=HST_mx&pop noprint;

    table trtp*param*paramn*avisit*avisitn/out=f_HST (drop=percent);

run;

proc sort data=f_HST; by param avisit; run;

proc transpose data=f_HST out=t_HST&pop (drop=_:);

    id trtp;

    var count;

    by param paramn avisit avisitn;

run;

%mend count;

*PP set;

%count (wh=%str(PPROT1FL="Y" and avisit in ("Day 1", "Day 2", "Day 3", "Day 4", "Day 5")), pop=1);

%count (wh=%str(PPROT2FL="Y" and avisit = "Day 30"), pop=2);

%count (wh=%str(PPROT3FL="Y" and avisit = "Day 60"), pop=3);

%count (wh=%str(PPROT4FL="Y" and avisit = "Day 90"), pop=4);


*PP set;

data count_pp (drop=THSM2_2 MCC rename=(THS_=THSM2_2 MCC_=MCC));

length THS_ MCC_ $18 _name_ $10;

    set t_HST1 t_HST2 t_HST3 t_HST4;

```

```

THS_=put(THSM2_2, best.);

MCC_=put(MCC, best.);

num=0.5;

_name_="n";

run;

data mix; *all pp set days;

    set HST_mx1 HST_mx2 HST_mx3 HST_mx4;

run;

%let l_name = %str(L_15_04_04_61);

%let t_title_l = %nrquote(Listing 15.4.4.61 Analysis of HST Parameters per Cigarette - PP Set);

*HST stats - PP set;

%macro p (mx=, pop=);

proc sort data=&mx; by param paramn avisit avisitn; run;

proc mixed data=&mx;

    by param paramn avisit avisitn;

    Class trtp sex UCPDGR1;

    Model aval = base sex UCPDGR1 trtp;

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

    ods output lsmeans=lsmeans (where=(trtp ne "SA") keep=param paramn avisit avisitn trtp lower
upper estimate); *each arm;

    ods output diffs=diffs (where=(trtp="THSm2.2") keep=param paramn avisit avisitn trtp _trtp lower
upper estimate); *differences;

```

```

run;

*lsmean and C.I. for differences;

data diffs_;

length labnum $10;

    set diffs;

    format lower upper estimate;

    if trtp="THSm2.2" then labnum="MCC";

run;

data LSM_CL;

    set diffs_;

    if lower^=. and upper ^=. then

        Cl=compress(put(floor(100*lower)/100,12.2))||',
' || compress(put(ceil(100*upper)/100,12.2));

    lsmean_=put(round(estimate,0.01),12.2);

run;

proc transpose data=LSM_CL out=t_LSM_CL (rename=(mcc=ths_mcc_diff));

    id labnum;

    var lsmean_ Cl;

    by param paramn avisit avisitn;

run;

*lsmean, C.I.;

proc sort data=lsmeans out=lsmeans_ nodupkey; by _all_; run;

data lsmeans_;

```

```

        set lsmeans_;

        format lower upper estimate;

run;

data stat;

        set lsmeans_;

        lsmean_=put(round(estimate,0.01),12.2);

        if lower^=. and upper ^=. then

                CI=compress(put(floor(100*Lower)/100,8.2))||',
'| |compress(put(ceil(100*Upper)/100,8.2));

run;

proc transpose data=stat out=t_stat;

        id trtp;

        var lsmean_ CI;

        by param paramn avisit avisitn;

run;

*put stats together;

proc sort data=t_LSM_CL; by param paramn avisit avisitn _name_; run;

proc sort data=t_stat; by param paramn avisit avisitn _name_; run;

data p;

        merge t_LSM_CL t_stat;

        by param paramn avisit avisitn _name_;

        if _name_="LSMEAN_" then do; _name_="LS Mean"; num=1; end;

        if _name_="CI" then do; _name_="95% CI"; num=2; end;

```

```

        if _name_="95% CI" and THS_MCC_DIFF="" and THSM2_2="" and MCC="" then do;

            THS_MCC_DIFF="NA"; THSM2_2="NA"; MCC="NA";

        end;

run;

proc sort data=p; by paramn avisitn num; run;

data form;

    set count&pop p;

run;

proc sort data=form; by paramn avisitn num; run;

data form_1;

length label $100;

    set form;

    by paramn avisitn num;

    if not first.avisitn then avisit="";

    label=avisit;

run;

%mend p;

%p (mx=mix, pop=_pp);

ods rtf

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

title "&t_title_1";

options orientation=landscape;

%p (mx=mix, pop=_pp);

```

ods rtf close;

data dummy;

length label \$100;

num=0.2; paramn=50; label="Total number of puffs (average over visit)"; AVISITN=101; output;

num=0.2; paramn=51; label="Total puff volume (mL) (average over visit)"; AVISITN=101; output;

num=0.2; paramn=52; label="Average puff volume (mL) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=53; label="Average puff duration (s) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=54; label="Total puff duration (s) (average over visit)"; AVISITN=101; output;

num=0.2; paramn=55; label="Average flow (mL/s) (average over visit)"; AVISITN=101; output;

num=0.2; paramn=56; label="Average Peak flow (mL/s) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=57; label="Total inter puff interval (s) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=58; label="Average inter puff interval (s) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=59; label="Total smoking duration (s) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=60; label="Total work (mJ) (average over visit)"; AVISITN=101; output;

num=0.2; paramn=61; label="Average Work (mJ) (average over visit)"; AVISITN=101; output;

num=0.2; paramn=62; label="Average pressure drop (mmWg) (average over visit)";
AVISITN=101; output;

num=0.2; paramn=63; label="Average Peak pressure drop (mmWg) (average over visit)";
AVISITN=101; output;

num=0.2; paramn=64; label="Smoking Intensity (mL/s) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=65; label="Puffing Time Index (%) (average over visit)"; AVISITN=101; output;

num=0.2; paramn=66; label="Puff Frequency (puffs/min) (average over visit)"; AVISITN=101;
output;

num=0.2; paramn=50; label="Total number of puffs (average over visit) (cont...)"; AVISITN=130;
output;

num=0.2; paramn=51; label="Total puff volume (mL) (average over visit) (cont...)"; AVISITN=130;
output;

num=0.2; paramn=52; label="Average puff volume (mL) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=53; label="Average puff duration (s) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=54; label="Total puff duration (s) (average over visit) (cont...)"; AVISITN=130;
output;

num=0.2; paramn=55; label="Average flow (mL/s) (average over visit) (cont...)"; AVISITN=130;
output;

num=0.2; paramn=56; label="Average Peak flow (mL/s) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=57; label="Total inter puff interval (s) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=58; label="Average inter puff interval (s) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=59; label="Total smoking duration (s) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=60; label="Total work (mJ) (average over visit) (cont...)"; AVISITN=130;
output;

num=0.2; paramn=61; label="Average Work (mJ) (average over visit) (cont...)"; AVISITN=130;
output;

num=0.2; paramn=62; label="Average pressure drop (mmWg) (average over visit) (cont...)";
AVISITN=130; output;

num=0.2; paramn=63; label="Average Peak pressure drop (mmWg) (average over visit)
(cont...)"; AVISITN=130; output;

```

        num=0.2; paramn=64; label="Smoking Intensity (mL/s) (average over visit) (cont...)";
AVISITN=130; output;

        num=0.2; paramn=65; label="Puffing Time Index (%) (average over visit) (cont...)"; AVISITN=130;
output;

        num=0.2; paramn=66; label="Puff Frequency (puffs/min) (average over visit) (cont...)";
AVISITN=130; output;

run;


data comb;

        set dummy form_1;

run;

proc sort data=comb; by paramn avisitn num; run;


data final;

        set comb;

        if avisitn in (101,102,103,104) then pg=1; *marks the divide for each param into 2 pages;

        else pg=2;

run;


proc sort data=final; by paramn pg; run;

data final_1;

        set final;

        by paramn pg;

        if first.pg then page+1;


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

run;

```

```
%put &page;
```

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

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

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

```
    set final_1;
```

```
run;
```

```
/* 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, halfblk=N);
```

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

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

```

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 page=&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 page avisitn label _name_ THSM2_2 MCC THS_MCC_DIFF;

        define page / order order = internal noprint;

        define avisitn / order order = internal noprint;

        define label /"Variable" display style={asis=on just=left cellwidth=3.5cm}
style(header)={just=left};

        define _name_ /"Statistic" display style={just=left cellwidth=1.2cm} style(header)={just=left};

        define THSM2_2 /"THSm2.2" display style={just=c cellwidth=1.2cm}
style(header)={just=center} ;

        define MCC /"mCC" display style={just=c cellwidth=1.2cm}
style(header)={just=center};

```

```
define THS_MCC_DIFF /"THSm2.2 - mCC$ Difference" display style={just=c  
cellwidth=1.4cm} style(header)={just=center};
```

```
break after page / page;
```

```
compute after avisitn;
```

```
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: 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; THSm2.2 = Tobacco Heating System  
2.2 Menthol.';
```

```
line " ";
```

```
line 'Appendix 15.3.7.1';
```

```

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 ;

%outtrtf(blankn=36, halfblnk=N);

ods listing;

%mend anlout;

%anlout (din=final_1, tfl=%str(T_15_02_04_61), tabname=%str(Table 15.2.4.61   Analysis of HST
Parameters per Cigarette - PP Set));

*=====;

* END OF PROGRAM CODE                               ;

*=====;

%m_logchk;

```

