

```

%_mprintto;
options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
/* 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",""));
run;
%put NOTE:
=====;
%put NOTE: Covance Study Number : 000000106324;
%put NOTE: Client Protocol ID   : ZRHR-REXC-03-EU;
%put NOTE: Program Name        : tl_anlpkconc.sas;
%put NOTE: Purpose              : Analysis of Change from Day 0 Plasma
Nicotine and Cotinine Concentrations at 08:00 PM on Day 5 - FAS;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADPC;
%put NOTE: Output               : L_15_04_04_51(PKCONC)
T_15_02_04_51(PKCONC) ;
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_vmurray;
%put NOTE: Creation Date        : 2014-06-12;
%put NOTE: SAS Version          : 9.3;
%put NOTE: ;
%put NOTE: == Latest Run
=====;
%put NOTE: Run by                : &sysuserid;
%put NOTE: Date/Time             :
%sysfunc(putn(%sysfunc(date()),e8601da.))T%sysfunc(putn(%sysfunc(time()),
e86011z.));
%put NOTE: ;
%put NOTE: == Modification History
=====;
%put NOTE: Date      Initials   No. Reason;
%put NOTE: 01Aug2014  AMH        1) Center output ;
%put NOTE: 01Aug2014  AMH        2) Ammend footnotes;
%put NOTE: 01Aug2014  AMH        3) Add additional reference;
%put NOTE: 01Aug2014  AMH        4) Add where clause used on dataset ;
%put NOTE: 12SEP2014  APH        5) AMEND BASELINE FOOTNOTE TO SAY DAY
0;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing=' '
NOQUOTELNMAX/*turn off warnings about quoted strings too long*/;
ods _all_ close;
ods listing;

/*formats macro and appendix output macros*/

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%include
"/cvn/projects/prj/development/000000106324/dev/adhoc/TMPLTMIX.sas";

*=====;
* START OF PROGRAM CODE ;
*=====;

*****;
* read in data ;
*****;
/* Calculate totals for products */

%macro table(paramcd,title,pop,popfl,tab,tabout,var);

DATA ADSL;
    SET ADAM.ADSL(WHERE=(&popfl='Y'));
    IF INDEX(TRT01A,'THS 2.2') THEN COLORD=1;
    OUTPUT;
    IF INDEX(TRT01A,'CC') THEN COLORD=2;
    OUTPUT;
    IF INDEX(TRT01A,'SA') THEN COLORD=3;
    OUTPUT;
RUN;

PROC SORT DATA=ADSL NODUPKEY OUT=ADSL1;
    BY COLORD SUBJID;
RUN;

PROC FREQ DATA=ADSL1(WHERE=(NOT MISSING(COLORD))) NOPRINT;
    TABLE COLORD/ OUT =TOTALS2(DROP=PERCENT RENAME=(COUNT=TOTAL));
RUN;

DATA _NULL_;
    SET TOTALS2;
    CALL SYMPUT('TOT'||STRIP(PUT(COLORD,BEST.)),STRIP(PUT(TOTAL,BEST.)));
RUN;

proc sort data=adam.adpc(where=(FASFL='Y' AND ANL01FL='Y' AND avisitn in
(105))) /* 4) AMH 01Aug2014 */
    out=adpcin;
    by SUBJID;
run;

data adpc1;
    set adpcin;
    time=('20:00't-atm)/60; /*time from 8PM in minutes*/
    if time lt 0 then time=time*-1;
run;

proc sort data=adpc1;by subjid param time;run;

data adpc2;
set adpc1;

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by subjid param time;
if first.param then output;
run;

%fmt(datain=adpc2, start=trtan, label=trta, name=trt);

data adpc;
    set adpc2;
    format trtan trt.;
    if trta not in ('THS 2.2' 'CC') then delete;
run;

proc sort data=adpc;by paramn paramn avisit;run;

title1 j=1 "PAGESPLIT"; /*do not change*/
title2 j=1 'Proc Mixed Procedure';
TITLE3 J=L "The where clause used on the dataset adam.adpc: fasfl='Y' and
anl01fl='Y'"; /* 4) AMH 01Aug2014 */
%let tflno=L_15_04&tabout(PKCONC);

%mixout1(fileout=/cvn/projects/prj/data/000000106324/TFL/&TFL_Part./&tflno);
options ps=20 byline;

proc mixed data=adpc method=reml maxiter=200 order=internal;
    by paramn param avisit;
    class trtan sexc ucpdgr1;
    model chg = base trtan sexc ucpdgr1 / outp=pred;
    lsmeans trtan / pdiff=control('CC') alpha=0.05 cl;
    ods output lsmeans=lsmeans;
    ods output diffs=diffs;
    ods output covparms=covparms(rename=(estimate=residual));

run;

data diffs2;
merge diffs covparms;
by paramn param avisit;
run;

/*Residual Plots*/
title3 j=1 'Residual Plots';
options ps=27; /*change this for proc plot*/

proc rank data=pred out=resid normal=vw ;
    by paramn param avisit;
    ranks nscore;
    var resid;
run;

proc plot data=resid hpercent=50;
    by paramn param avisit;
    plot resid*pred / vref=0;

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plot resid*nscore;
run;
quit;

%mixout2(blankn=60, halfblnk=N,title=Listing 15.4.&tab &title - &pop);

/*data counts*/
/*timepoints*/
proc univariate data=adpc noprint;
  by paramn param avisit;
  class trtan;
  var chg;
  output out=num1 n=n1;
run;

/*Manipulate datasets for output all relevent stats on each row*/
/*_____*/
data tabout;
  length out $100 stat $100;
  set lsmeans(in=a) diffs2(in=b) num1(in=c);
  /*ordering columns of treatments*/
  if b then colord=3;
  else if trtan=1 then colord=1;
  else if trtan in (2) then colord=2;

  /* N row*/
  if c then do;
    ord=1;
    stat='n';
    out=compress(put(n1,best.));
    output;
  end;

  if a then do;
    estimatee=estimate;
    lowere=lower;
    uppere=upper;

/*Gmean (CV%) row*/
    ord=2;
    stat='LS Mean';
    out=compress(put(round(estimatee,0.01),8.2));
    output;
/*95% CI row*/
    ord=3;
    stat='95% CI';
    out=compress(put(floor(100*lowere)/100,8.2)||',
'||compress(put(ceil(100*uppere)/100,8.2))||',
    output;
  end;
  if b then do;

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/*Back transformation*/
estimatee=estimate;
lowere=lower;
uppere=upper;
    ord=2;
    stat='LS Mean';
    out=compress(put(round(estimatee,0.01),8.2));
    output;
/*95% CI row*/
    ord=3;
    stat='95% CI';
    out=compress(put(floor(100*lowere)/100,8.2))||',
'||compress(put(ceil(100*uppere)/100,8.2));
    output;

    end;
run;

/*Add labels for all number variables*/
/*_____*/
data tabout1;
    set tabout;

/*Variable label*/
var=param;
run;

/*transpose for output*/
proc sort data=tabout1;
    by var paramn avisit ord stat;
run;

proc transpose data=tabout1 out=ttabout(drop=_NAME_) prefix=col;
    by var paramn avisit ord stat;
    id colorid;
    var out;
run;

/* Standard - macro for paging */
%macro outrtf(blankn=68, halfblnk=N, ref=);

%if &halfblnk=N %then %let halfblnk=;
%else %if &halfblnk=Y %then %let halfblnk=\~;

    %let tflno=T_15_02&tabout(PKCONC);

/* Standard - leave this */
%let TFL_Part=%scan(&_SASPROGRAMFILE,-3,%str(/));

/* Standard - leave this */
data _null_;
    tmp="&TFL_Part";

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        if tmp not in ("dev" "qc") then call symput("TFL_Part", "prod");
        call symput('TFLpath', compress("&_SASPROGRAMFILE", ""));
run;

proc sort data=ttabout;by paramn;run;

/*page numbers*/
data paging;
set ttabout;

page=1;

call symput('tpage',put(page,2.));

run;

/* Standard - leave this */
options number nodate orientation=landscape papersize=&p_pgsz missing='
' NOQUOTELNMAX/*turn off warnings about quoted strings too long*/;
ods escapechar='^';
%let linetop = \brdrt\brdrs\brdrw30; * needs to be 1.5pt so calculated
in twips (1/20 pt) ;
%let linebot = \brdrb\brdrs\brdrw30;
%let linebot2 = \brdrb\brdrs\brdrw15;

ods path stdlib.tl06324 (read) ;
ods results off;
ods rtf toc_data/* contents*/
file="/cvn/projects/prj/data/000000106324/TFL/&TFL_Part./&tflno..rtf"
style=tl06324 startpage=yes headery=1440 footery=1440 ;
ods noproctitle;

%do i=1 %to &tpage;

ODS PROCLABEL = ' ';
title ;
footnote;
%let wd=0;

proc sort data=paging;by ord;run;

data comp;
set paging end=eof;
by ord;
where page=&i;
flag=1;
_firtitl="Table 15.2.&tab &title - &pop";
_upcas=(length(_firtitl)-
length(compress(_firtitl,'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;
len=&blankn.-length("(Page &i of &tpage)");
if eof then do;

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        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 missing nowd spanrows split =
'#'
%IF &I=1 %THEN %DO; CONTENTS=' ' %END; %ELSE %DO; CONTENTS='' %END;;
    column flag page var ord stat coll col2 col3;

    define flag / order noprint;
        define page          / order order = internal noprint;
        define var           / group style={just=left cellwidth=2.5cm} "Variable
(units)";

        define ord          / order order=internal noprint;
        define stat         / display style={just=left cellwidth=3cm}
"Statistic";

        define coll         / display style={just=c/*d*/ cellwidth=3cm}
style(header)={just=center} "THS 2.2#(N=&tot1)"; /* 1) AMH 01Aug2014 */
        define col2        / display style={just=c/*d*/ cellwidth=3cm}
style(header)={just=center} "CC#(N=&tot2)"; /* 1) AMH 01Aug2014 */
        define col3        / display style={just=c/*d*/ cellwidth=3cm}
style(header)={just=center} "THS - CC"; /* 1) AMH 01Aug2014 */

        break before flag / page %IF &I=1 %THEN %DO;
            CONTENTS="&_FSRTITL" %END; %ELSE %DO; CONTENTS='' %END;;

        compute before page / style={protectspecialchars=off};
            line "&linetop";
        endcomp;

        compute after var / style={protectspecialchars=off};
            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;

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        compute after _page_ / style={just=left protectspecialchars=off
pretext="&linetop."};
        LINE "Note: CC = Conventional cigarettes; THS = Tobacco Heating
System."; /* 2) AMH 01Aug2014 */
        line "Note: Adjusted least squares (LS) means and confidence
intervals (CIs) from an ANCOVA model conducted on the change from Day 0
in Day 5 (result closest to 08:00 PM) values with log-transformed Day 0
value, study arm, sex and CC consumption reported at screening as fixed
effect factors."/* 5) APH 12SEP2014 */
/*        line "Note: CC = Conventional cigarettes; THS = Tobacco Heating
System."*/
        line "";
        line "Appendix &ref.";
        line "Path: &TFLpath." &_blankn.*"\~\~" "(Page &i of
&tpage)";
        line "Program Run: &sysdate   &sysuserid   Program Status:
&status";
        endcomp;

run;
%end;
ods rtf close;
ods results on;
ods path reset;

%mend outrtf;

%outrtf(blankn=60, halfblnk=N, ref=15.4.&tab and 15.3.3.4); /* 3) AMH
01Aug2014 */

%mend table;

%table(paramcd=,title=%str(Analysis of Change from Day 0 Plasma Nicotine
and Cotinine Concentrations at 08:00 PM on          Day 5),
pop=FAS,popfl=fasfl,tab=4.41,tabout=_04_41,var=);

*=====;
* END OF PROGRAM CODE                               ;
*=====;

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