

```

%_mprintto;
options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
%put NOTE:
=====;
%put NOTE: Covance Study Number : 000000106326;
%put NOTE: Client Protocol ID   : ZRHM-PK-05-JP;
%put NOTE: Program Name        : t_demog2s.sas;
%put NOTE: Purpose              :table of demographics group 1 PK split
by sex;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADBX ADAM.ADSL ADAM.ADQSDND;
%put NOTE: Output               : t_15_2_1_4_2_1(dm);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jhardman;
%put NOTE: Creation Date        : 2014-08-07;
%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: 11Aug2014   JR        1)  Changed mCC to mCC;
%put NOTE: 23Sep2014   JR        2)  FTND footnote added;
%put NOTE: 24Sep2014   JMH       3)  Amended paging to match PK-02;
%put NOTE: ;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

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

/* Standard - just change the number to match the listing you're working
on. Also change the letters in the*/
/* bracket, eg ccb = current cigarette brands. Make sure to do this at
the top of the code too. */
%let tflno=T_15_02_01_04_02_01(dm);

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

/* Standard - leave this */

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

*****;
* read in data ;
*****;

data allpk;
    set adam.adsl(where=(pprotfl='Y'));

    trta='Overall PK';
    trtan=9;
    output;
run;

/*Find the number of people in each treatment sequence for table
headers*/
data adsl;
    set adam.adsl(where=(analgr1n=1 and pprotfl='Y'));

    trtan=trt01an;
    trta=trt01a;
    output;
    trtan=trt02an;
    trta=trt02a;
    output;
    trtan=8;
    trta='Group-1 PK';
    output;
run;

data adsl1;
    set adsl allpk;
run;

proc sort data=adsl1;
    by trtan trta sexn sexc;
run;

proc freq data=adsl1 noprint;
    tables trta*trtan*sexn*sexc / out=adsltotst(where=(not missing(trtan))
drop=percent);
run;

data tot2a;
    set adsltotst;

    rename count=total;
    trtans=input(strip(put(trtan,best.))||strip(put(sexn,best.)),best.);

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```

        call
symput('trt'||strip(put(trtan,best.))||strip(put(sexn,best.)),strip(put(c
ount,best.)));

run;

proc sort data=tot2a;
    by trtans trta;
run;

/*CYP and FTNS*/
/* Creating period 1 treatments */
data adsl2;
    set adam.adsl(where=(pprotfl='Y' and analgrln=1));

    trtan=trt01an;
    trta=trt01a;

    keep usubjid trtan trta trt02a trt02an;
run;

/* Obtaining data for CYP and FTND */
data cyp;
    set adam.adbx(where=(paramcd='CYP2A6' and pprotfl='Y' and
analgrln=1));
    rename aval=cypn avalc=cypc;
    keep usubjid aval avalc;
run;

proc sort data=adam.adqsnd(where=(paramcd='FTNDSC' and pprotfl='Y' and
analgrln=1)) out=adqsnd(keep=usubjid avalcat1 aval rename=(avalcat1=ftcat
aval=ftsc));
    by usubjid;
run;

data cypqs(where=(not missing(trta)));
    merge adsl2 adqsnd cyp;
    by usubjid;
    if ftcat='Mild' then ftcatn=1;
    if ftcat='Moderate' then ftcatn=2;
    if ftcat='Severe' then ftcatn=3;
    output;
    trta=trt02a;
    trtan=trt02an;
    output;
    trtan=8;
    trta='Group-1 PK';
    output;

    dummy=1;
run;

data cypqs2;
    set cypqs;

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run;

/* Overall PK data */
data cyppk;
    set adam.adbx(where=(paramcd='CYP2A6' and pprotfl='Y'));

    trta='Overall PK';
    TRTAN=9;
    output;
    rename aval=cypn avalc=cypc;
    keep usubjid aval avalc;
run;

data adqsndpk;
    set adam.adqsnd(where=(paramcd='FTNDSC' and pprotfl='Y'));
    trta='Overall PK';
    trtan=9;
    output;
    rename avalcat1=ftcat aval=ftsc;
    keep usubjid avalcat1 aval ;
run;

data cypqspk;
    merge allpk(keep=usubjid trtan trta) adqsndpk cyppk;
    by usubjid;
    if ftcat='Mild' then ftcatn=1;
    if ftcat='Moderate' then ftcatn=2;
    if ftcat='Severe' then ftcatn=3;
run;

data cypqsall;
    set cypqs2 cypqspk;
    dummy=1;
run;

proc sort data=cypqsall;
    by usubjid trtan trta;
run;

proc sort data=adsl1;
    by usubjid trtan trta;
run;

data adslall;
    merge adsl1 cypqsall;
    by usubjid trtan trta;

    trtans=input(strip(put(trtan,best.))||strip(put(sexn,best.)),best.);

run;

proc sort data=adslall(where=(not missing(trtan)));
    by trtans trta;
run;

```

```

/*Macro for all the class variables*/

%macro _class(var1=, var2=, dout1=, dout2=, var=, num=);

proc freq data=adslall noprint;
    table trtans*trta*&var1*&var2 / out =&dout1(drop=percent);
run;

data &dout2._1;
    merge &dout1(in=a) tot2a;
    by trtans trta;
    if a;
    percent=count/total*100; /*This works out the percentages*/
run;

data &dout2;
    set &dout2._1;
    format var $200. stat $20. svar $20.;
    order=&num;
    var=trim(&var2);
    stat='n (%)';
    if percent=100 then svar = strip(put(count,best.)) || ' (100 %)' ;
    else if percent lt 10 then svar = strip(put(count,best.)) || ' ' ||
' ( ' ||left(strip(put(round(percent,0.1),5.1))) || '%)';
    else if percent ge 10 then svar = strip(put(count,best.)) || ' ' ||
' ( ' ||left(strip(put(round(percent,0.1),5.1))) || '%)';
    run;

proc sort data=&dout2 ; by order &var1 var stat; run;

proc transpose data=&dout2 out=&dout2._2 prefix=t;
    by order &var1 var stat;
    var svar;
    id trtans;
    idlabel trta;
run;

/*Dummy will add a blank line, only the variable name for TFLs will be
presented*/
data dummy;
    format var $200. stat $20.;
    var="&var";
    stat=' ' ;
    order=&num;
    %if &num=8 %then %do;
        output;
        var='JAPANESE';
        stat='n (%)';
        output;
        var='NOT JAPANESE';
        stat='n (%)';
        output;
    %end;

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```

        %if &num=5 %then %do;
            output;
            var='Underweight';
            stat='n (%)';
            output;
            var='Normal weight';
            stat='n (%)';
            output;
            var='Overweight';
            stat='n (%)';
            output;
            var='Obese';
            stat='n (%)';
            output;
        %end;
        %if &num=12 %then %do;
            output;
            var='1-5 mg';
            stat='n (%)';
            output;
            var='6-8 mg';
            stat='n (%)';
            output;
            var='9-10 mg';
            stat='n (%)';
            output;
            var='>10 mg';
            stat='n (%)';
            output;
        %end;
run;

%if &num=5 or &num=8 or &num=16 or &num=17 OR &NUM=12 %then %do;
    proc sort data=&dout2._2;
        by var;
    run;

    proc sort data=dummy;
        by var;
    run;
%end;

data all&num.;
    format var $200. stat $20.;
    %if &num=8 or &num=5 or &num=12 %then %do; merge dummy
&dout2._2; %end; %else %do; set dummy &dout2._2; %end; /* 1) KB
18Jul2014 */
    %if &num=8 or &num=5 or &num=12 %then %do;
        by var;
    %end;

    %if &num=5 %then %do;
        if var='Underweight' then sort=1;
        else if var='Normal weight' then sort=2;

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        else if var='Overweight' then sort=3;
        else if var='Obese' then sort=4;
    %end;
    %if &num=8 %then %do;
        if var='JAPANESE' then sort=1;
        else if var='NOT JAPANESE' then sort=2;
    %end;
    %if &num=2 %then %do;
        if var='<= 0.6 mg' THEN SORT=1;
        ELSE IF VAR='> 0.6 - 1.0 mg' THEN SORT=2;
    %END;
    %if &num=9 %then %do;
        if var='10-19 cig/day' then sort=1;
        else if var='>19 cig/day' then sort=2;
    %end;
    %if &num=12 %then %do;
        if var='1-5 mg' then sort=1;
        else if var='6-8 mg' then sort=2;
        else if var='9-10 mg' then sort=3;
        else if var='>10 mg' then sort=4;
    %end;
    %if &num=14 %then %do;
        if var='Mild' then sort=1;
        else if var='Moderate' then sort=2;
        else if var='Severe' then sort=3;
    %end;
    drop &var1;
run;

proc sort data=all&num.;
    by sort;
run;

%mend _class;
%_class(var1=nicogrln, var2=nicogr1, dout1=nicolev, dout2=nicolev2,
var=ISO nicotine level, num=2);
%_class(var1=bmigrln, var2=bmigr1, dout1=bmiclass, dout2=bmiclass2,
var=BMI classifications,num=5);
%_class(var1=ethnrcn, var2=ethnic, dout1=ethnicity, dout2=ethnicity2,
var=Ethnicity, num=8);
%_class(var1=ucpdgrln, var2=ucpdgr1, dout1=ccconsum, dout2=ccconsum2,
var=Daily mCC consumption at Admission,num=9); /* 1) JR 11Aug2014 */
%_class(var1=targrln, var2=targr1, dout1=taryield, dout2=taryield2,
var=mCC ISO tar yield at Admission ,num=12); /* 1) JR 11Aug2014 */
%_class(var1=ftcatn, var2=ftcat, dout1=ftsc1, dout2=ftsc2, var=FTND total
score classifications ,num=14);

/*End of macro for all the class variables*/

/*Start of code for all the continuous variables*/
data adslall1;
    set adslall;

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        height2=height/100;
run;

proc means data=adslall1 noprint;
    by trtans trta;
    var age weightb1 height2 bmi nicobl tarb1 ftsc cypn; /*Make sure all
variables in the split macro are here too*/
    output out=stats;
    output out=median median=;
run;

data stats1;
    set stats median(in=in2);
    if in2 then _STAT_ = 'MEDIAN';
    rename _stat_=_name_;
run;

data stats2;
    set stats1;
    format stat $20.;
    if _name_='N'      then order2=1001;
    if _name_='MEAN'   then order2=1002;
    if _name_='STD'    then order2=1003;
    if _name_='MEDIAN' then order2=1004;
    if _name_='MIN'    then order2=1005;
    if _name_='MAX'    then order2=1006;

    if _name_ eq 'STD' then stat='SD';
        ELSE IF _NAME_='N' THEN STAT='n';
    else stat=propcase(_name_);

run;

%macro split(set=,num=,var=,stat=,units=,dp=);

    data &set;
        format stat $20. svar $20.;
        set stats2(keep=trtans trta order2 stat &var);

        order=&num;

        %if &num=3 or &num=15 | &num=11 %then %do;
            if order2=1003 then
svar=compress(put(0.01*ceil(&var/0.01),8.2));
            %end;
        %if &num=4 or &num=7 or &num=10 %then %do;
            if order2=1003 then
svar=compress(put(0.001*ceil(&var/0.001),8.3));
            %end;
        %if &num=6 or &num=13 %then %do;

```



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        if order2=1003 then
svar=compress(put(0.0001*ceil(&var/0.0001),8.4));
        %end;
        else if order2=1001 then svar=compress(put(&var,8.));
        else if order2=1002 or order2=1004 then
svar=compress(put(&var,8.%eval(&dp+1)));
        else svar=compress(put(&var,8.&dp));
run;

/*Combine meand and SD*/
data meansd&num;
    set &set(keep=trtans trta stat order2 svar &var);
    where stat in('Mean' 'SD'); /*Only keep mean and SD as this
is all we want here*/
run;

proc sort data=meansd&num; by trtans trta; run;

proc transpose data=meansd&num out=meansd&num.a prefix=m;
    by trtans trta;
    id order2;
    idlabel stat;
    var svar;
run;

data meansd&num.b;
    format stat $20. svar $20.;
    set meansd&num.a;
    svar=left(compress(m1002)) ||' (' || left(compress(m1003)) ||
')';

    stat='Mean (SD)';
    order2=1002;
    order=&num;
    drop m1002 m1003;
run;
/*End of combining mean and SD*/

```

```

/*Combine Min and Max*/
data minmax&num;
    set &set(keep=trtans trta stat order2 svar &var);
    where stat in('Min' 'Max'); /*Only keep min and max as this
is all we want here*/
run;

proc sort data=minmax&num; by trtans trta; run;

proc transpose data=minmax&num out=minmax&num.a prefix=m;
    by trtans trta;
    id order2;
    idlabel stat;
    var svar;
run;

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data minmax&num.b;
    format stat $20. svar $20.;
    set minmax&num.a;
    svar=left(compress(m1005)) ||', ' || left(compress(m1006));
    stat='Min, Max';
    order2=1005;
    order=&num;
    drop m1005 m1006;
run;
/*End of combining min and max*/

/*Combine the new datasets which have Min, Max and Mean (SD)*/
data minmaxmeansd;
    set minmax&num.b meansd&num.b;
run;

/*Add these new datasets to the original dataset, deleting individual
min, max, mean and SD*/
data comb&set;
    set &set(where=(order2 not in(1002 1003 1005 1006)))
minmaxmeansd;
run;

proc sort data= comb&set; by order order2 stat; run;

/*Transpose the data by treatment sequence*/
proc transpose data=comb&set out=trans&set prefix=t;
    by order order2 stat;
    var svar;
    id trtans;
    idlabel trta;
run;

/*This dummy will add in line with only the variable name to present in
the TFLs*/
data dummy;
    format var $200. stat $20.;
    var="&stat (&units)";
    stat=' ';
    order=&num;
run;

/*Add the dummy to the transposed dataset*/
data all&num.;
    format var $200. stat $20.;
    merge dummy trans&set;
    by order;
run;

proc sort data=all&num.; by order2; run;

```

```

%mend split;

%split(set=age,      num=3, var=age,      stat=Age,      units=years,
dp=0);
%split(set=bmi,      num=4, var=bmi,      stat=BMI,
units=kg/m2, dp=1);
%split(set=height,   num=6, var=height2,  stat=Height,   units=m,
dp=2);
%split(set=weight,   num=7, var=weightbl, stat=Weight,   units=kg,
dp=1);
%split(set=niconum,  num=10, var=nicobl,  stat=mCC nicotine yield at
Admission, units=mg, dp=1); /* 1) JR 11Aug2014 */
%split(set=tarnum,   num=11, var=tarbl,   stat=mCC ISO tar yield at
Admission, units=mg, dp=0); /* 1) JR 11Aug2014 */
%split(set=ftsc,     num=15, var=ftsc,     stat=FTND total score,
dp=0);
%split(set=cyp,      num=13, var=cypn,     stat=CYP2A6 activity,
units=%, dp=2);

/*End of macro for continuous variables*/

/*Combine all the dataets which have been made from the macros and
make any formatting changes*/
data combined;
    set all2 all13 all14 all15 all16 all17 all18 all19 all110 all111 all112
all113 all114 all115 ;

    if var='JAPANESE' then var='Japanese';
    else if var='NOT JAPANESE' then var='Not Japanese';

    if order in (2 5 8 9 12 14) and not missing(stat) then
var='$S={foreground=white} . $S={}' || var;

    attrib wrap length = $200;
    wrap = var;

    if order=5 then do;
        i=37; *this is the max length allowed on a single line - change
as needed;
        if length(wrap)>i then do;
            nwraps = int(length(wrap)/i); *calculate how many lines the
text will wrap over;
            do while(nwraps > 0);
                fin=0;
                j = i*nwraps; *calculate starting point - loop will cycle
backwards from this point looking for a space;
                do while(fin=0 and j gt 1);
                    if substr(wrap,j,1)=' ' then do;
                        wrap=substr(wrap,1,j-1) || "$n $s={foreground=white} .
$s={}" || substr(wrap,j+1);
                        fin=1;
                    end;
                end;
            end;
        end;
    end;

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        else j=j-1; *no space found - move back one character;
    end;
    nwraps=nwraps-1; *once this wrap is handled, move up a line
until all are handled (when nwraps = 0);
    end;
end;
end;

if order=15 then var=tranwrd(var,'(',')','');

if order in ( 2 5 8 9 12 14) then do;
    array prod [8] t41 t42 t51 t52 t81 t82 t91 t92;
    do i=1 to 8;
        if not missing(stat) and missing(prod[i]) then prod[i]='0';
    end;
end;
run;

/*This just sets the labels for the table header, taken from teh shell*/
data labels;
    set combined;
    by order;
    if order in(3 4 6 7 10 11 13 15) then do;
        if not first.order then var=' ';
    end;
    attrib t41 label = "Males$(N=&trt41)"
    t42 label = "Females$(N=&trt42)"
           t51 label = "Males$(N=&trt51)"
    t52 label = "Females$(N=&trt52)"
           t81 label = "Males$(N=&trt81)"
    t82 label = "Females$(N=&trt82)"
           t91 label = "Males$(N=&trt91)"
    t92 label = "Females$(N=&trt92)";
/* 3) start JMH 24Sep2014 */
/*      if order in (2 3 4) then pageord=1;*/
/*      else if order in (5 6 7) then pageord=2;*/
/*      else if order in (8 9 10) then pageord=3; */
/*      else if order in (11 12 13) then pageord=4; */
/*      else if order in (14 15) then pageord=5;*/
    IF ORDER IN (2 3 4) THEN PAGEORD=1;
    ELSE IF ORDER IN (5 6) THEN PAGEORD=2;
    ELSE IF ORDER IN (7 8 9) THEN PAGEORD=3;
    ELSE IF ORDER IN (10 11 12) THEN PAGEORD=4;
    ELSE IF ORDER IN (13 14 15) THEN PAGEORD=5;
/* 3) end JMH 24Sep2014 */

run;

proc sql noprint;
    create table table.t_15_02_01_04_02_01 as
    select var, stat, t41, t42, t51, t52, t81, t82
    from labels
    order by PAGEORD, order, order2, sort; /* 3) JMH 24Sep2014 */
quit;

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data paging;
  set labels;
    by pageord order ORDER2 SORT; /* 3) JMH 24Sep2014 */

    if first.pageord or ln gt 12 then ln=1; /*Check for page overflows,
this may need changing*/
    else ln+1;
    if ln=1 then page+1;
    call symput("page",compress(put(page,best.)));
    flag=1;
run;

/* Standard - leave this */
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;

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

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

ods path stdlib.tl06326 (read) ;
ods results off;
ods rtf toc_data/* contents*/
file="/cvn/projects/prj/data/000000106326/TFL/&TFL_Part./&tflno..rtf"
style=tl06326 startpage=yes headery=1440 footery=1440 ;
ods noproctitle;
%do i=1 %to &page;

title ;
footnote;
%let wd=0;
%LET FLAG=0;
ods proclabel = ' ';

data comp;
  set paging end=eof;
  where page=&i;

  /* Amend title as needed */
  _firtitl="Table 15.2.1.4.2.1 Summary of Demographics and Other
Baseline Characteristics by Sex - Group-1 PK Population";
  _upcas=(length("Path: &TFLpath.")-
length(compress("Path:&TFLpath.",'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;
  len=&blankn.-length("(page &i of &page)");

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        if eof then do;
            call symput('_FSRTITL', trim(left(_firtitl)));
            call symput('_blankn', compress(put(len,best.)));
        end;
        if order in(11 12) then call symput('flag',1);
        drop _firtitl _upcas len;
run;

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* 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 */
ods listing close;
proc report data = comp headline headsip nowd split = '$' /*ps = 60 ls =
120*/%if &i=1 %then %do; contents=' ' %end; %else %do; contents='' %end;;
        column flag page order var stat ("THS 2.2 Menthol" t41 t42) ("mCC"
t51 t52) ("Group-1 PK" t81 t82) ;

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        define flag          / order order = internal noprint;
        define page          / order order = internal noprint;
        define order         / order order = internal noprint;
        define var           / display style={just=left cellwidth=3cm}
"Variable" style(header)={just=center};
        define stat          / display style={just=left cellwidth=1.5cm}
"Statistic" style(header)={just=center};
        define t41           / display style={just=center cellwidth=2cm }
style(header)={just=center};
        define t42           / display style={just=center cellwidth=2cm }
style(header)={just=center};
        define t51           / display style={just=center cellwidth=2cm }
style(header)={just=center};
        define t52           / display style={just=center cellwidth=2cm }
style(header)={just=center};
        define t81           / display style={just=center cellwidth=2cm }
style(header)={just=center};
        define t82           / display style={just=center cellwidth=2cm }
style(header)={just=center};

```

```

break before flag / page
        %if &i=1 %then %do; contents("&_fsrtitl" %end;
        %else %do; contents='' %end;;

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break after page / page;

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compute after order;
        line " ";
endcomp;

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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: mCC = menthol conventional cigarettes; THS = Tobacco
Heating System.';
  line 'Note: BMI = Body Mass Index.';
  LINE 'Note: FTND = Fagerstrom Test for Nicotine Dependence.';
/* 2) JR 23Sep2014 */
  line 'Note: Percentages are based on the number of subjects
indicated in the column header (N).';
  line ' ';
  line "Appendix 15.3.1.2, 15.3.1.6, 15.3.1.9, 15.3.1.10";
  line "Path: &TFLpath." &_blankn.*"\~\~" "(Page &i of &page)"; ;
  line "Program Run: &sysdate &sysuserid Program Status:
&status";
endcomp;
run;
%end;
ods rtf close;
ods results on;
ods path sashelp.tmplmst (read);

%mend ;

%outrtf(blankn=67, halfblnk=N);
ods listing;
proc printto print = "&table./t_15_02_01_04_02_01.lst" new;
run;

proc contents data = table.t_15_02_01_04_02_01 varnum;
run;
ods listing close;

proc printto ; run;
*=====;
* END OF PROGRAM CODE ;
*=====;

```