

```

%_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_labchem.sas;
%put NOTE: Purpose              : Summary of Clinical Chemistry
Parameters - Safety Population;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADSL ADAM.ADLB;
%put NOTE: Output               : t_15_02_06_10(chem);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jriley;
%put NOTE: Creation Date        : 2014-08-06;
%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: 12Aug2014   JR        1)  Amended y to Y for clin sig;
%put NOTE: 23Sep2014   JMH        2)  Amended in line with client
comments;
%put NOTE: 24Sep2014   JMH        3)  Added in a blank line;
%put NOTE: 24Sep2014   JMH        4)  Amended sorting;
%put NOTE: ;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

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

%let tflno=T_15_02_06_10(chem);

%let TFL_Part=%scan(&_SASPROGRAMFILE,-3,%str(/));

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 ;
*****;

/*Use ADSL to get N numbers for column headers*/
data adsl;
    set adam.adsl;
        where saffl = 'Y';
        if index(trtseqa,'Exposed') then delete;
    output;
    trtseqa=99;
    trtseqa='Overall Safety';
    output;
run;

proc freq data=adsl noprint;
    table trtseqa*trtseqa/ out =tot(drop=percent);
run;

data dumtrts; /*Use this to output any columns for which N=0*/
    attrib trtseqa length =$200.
            trtseqa length=8.;

    trtseqa=1;
    trtseqa='THS 2.2 Menthol - mCC';
    output;
    trtseqa=2;
    trtseqa='mCC - THS 2.2 Menthol';
    output;
    trtseqa=3;
    trtseqa='THS 2.2 Menthol - NRT gum';
    output;
    trtseqa=4;
    trtseqa='NRT gum - THS 2.2 Menthol';
    output;
    trtseqa=5;
    trtseqa='Enrolled not randomized';
    output;
run;

data tot2;
    merge tot(in=a) dumtrts(in=b);
    by trtseqa trtseqa;
    if a or b;
    if b and not a then count=0;
    call symput('trt' || compress(put(trtseqa,best.))),
compress(count));
    rename count=total;
run;

/* Chemistry data */
data adlb;

```

```

        set adam.adlb(where=(saffl = 'Y' and parcat1='Clinical Chemistry'
and anl01fl='Y'));
        if missing(trtsega) then delete;
        if index(trtsega,'Exposed') then delete;
/* 2) start JMH 23Sep2014 */
        IF ABLFL='Y' THEN DO;
            AVISIT='Baseline';
            AVISITN=100;

        END;
        IF AVISIT NE 'Baseline' AND AVISITN LE 99 THEN DELETE;
/* 2) end JMH 23Sep2014 */
        if not index(param,'(') then
param=upcase(substr(param,1,1))||lowcase(substr(param,2));
        else if index(param,'(') then
param=upcase(substr(param,1,1))||lowcase(scan(substr(param,2),1,'('))||'('
' ||scan(param,2,'(');
        output;
        trtsega=99;
        trtsega='Overall Safety';
        output;
run;

data adlb_orig;
    set adlb;
    if avisitn=1 then ord=1; /*Screening*/
    else if avisitn=/*99*/100 then ord=2;/*Admission (Day-1)*/ /* 2)
JMH 23Sep2014 */
    else if avisitn=104 then ord=3;/*Discharge*/
    statval=aval;
run;

data adlb_chg;
    set adlb(where=(avisitn in(104))); /*Only keep day after baseline*/
    if avisitn=104 then ord=4;/*Change from Baeline to Discharge*/
    statval=chg;
run;

data adlb_all;
    set adlb_orig adlb_chg;
run;

proc sort data=adlb_all;
    by trtsega trtsega;
run;

data all;
    merge adlb_all(in=a) dumtrts(in=b);
    by trtsega trtsega;
    if a or b;
    if b and not a then statval='';
run;

proc sort data=all;
    by trtsega trtsega paramn param paramcd ord anrlo anrhi;

```

```

run;

proc univariate data=all noprint;
    var statval;
    by trtsega trtsega paramn param paramcd ord anrlo anrhi;
    output out=results01 N=N1 mean=mean1 std=std1 median=med1 min=min1
max=max1;
run;

data results02;
    set results01;
    attrib meansd length=$20.
            minmax length=$20.
            n      length=$20.
            median length=$20.;

    if paramcd in ('BILDIR' 'PROT' /*'DK'*/'K' 'BILI') then do; /* 2)
JMH 23Sep2014 */
        n = left(compress(put(n1,8.)));
        if not missing(med1) then median =
left(compress(put(ROUND(med1,0.01),8.2))); /* 2) JMH 23Sep2014 */
        if not missing(mean1) and not missing(std1) then meansd =
left(compress(put(ROUND(mean1,0.01),8.2))) || ' (' ||
compress(put(0.001*ceil(std1/0.001),8.3)) || ')'; /* 2) JMH 23Sep2014 */
        if not missing(min1) and not missing(max1) then minmax =
left(compress(put(min1,8.1))) || ', ' || left(compress(put(max1,8.1)));
        end;
    ELSE if paramcd in ('CREAT') then do;
        n = left(compress(put(n1,8.)));
        if not missing(med1) then median =
left(compress(put(ROUND(med1,0.001),8.3))); /* 2) JMH 23Sep2014 */
        if not missing(mean1) and not missing(std1) then meansd =
left(compress(put(ROUND(mean1,0.001),8.3))) || ' (' ||
compress(put(0.0001*ceil(std1/0.0001),8.4)) || ')'; /* 2) JMH 23Sep2014
*/
        if not missing(min1) and not missing(max1) then minmax =
left(compress(put(min1,8.2))) || ', ' || left(compress(put(max1,8.2)));
        end;
    else do;
        n = left(compress(put(n1,8.)));
        if not missing(med1) then median =
left(compress(put(ROUND(med1,0.1),8.1))); /* 2) JMH 23Sep2014 */
        if not missing(mean1) and not missing(std1) then meansd =
left(compress(put(ROUND(mean1,0.1),8.1))) || ' (' ||
compress(put(0.01*ceil(std1/0.01),8.2)) || ')'; /* 2) JMH 23Sep2014 */
        if not missing(min1) and not missing(max1) then minmax =
left(compress(put(min1,8.))) || ', ' || left(compress(put(max1,8.)));
        end;

    drop n1 mean1 std1 med1 min1 max1;
run;

data results03; /*Create text as required in output*/
    set results02;

```

```

        attrib paramc length = $100.
            visit length = $100.;

    if not missing(anrlo) and not missing(anrhi) then do;
        paramc=strip(param)||' $n'||strip(anrlo)||'-'||strip(anrhi);
    end;
    else if missing(anrlo) and missing(anrhi) then do;
        paramc=strip(param);
    end;
    else if missing(anrlo) then do;
        paramc=strip(param)||' $n'||'<'||strip(anrhi);
    end;

    if paramcd='GGT' and anrhi=30 then paramn=7;

    if paramcd='GGT' then do;
        if anrhi=30 then paramc=strip(paramc)||' '||('Females');
        else if anrhi=80 then paramc=strip(paramc)||' '||('Males');
    end;
    if paramcd='CREAT' then do;
        if anrhi=0.79 then paramc=strip(paramc)||' '||('Females');
        else if anrhi=1.04 then paramc=strip(paramc)||' '||('Males');
    end;

/* 2) start JMH 23Sep2014 */
/* if ord=1 then visit='Screening';*/
/*else*/ if ord=2 then visit=/'Day -1/Admission'/'Baseline';
else if ord=3 then visit='Day 4/Discharge';
else if ord=4 then visit=/'Change from Admission'/'Change from
Baseline';
ELSE PUT "WA" "RNING: Unexpected value of ord, please check data "
ORD= TRTSEQA= ;
/* 2) End JMH 23Sep2014 */

    drop anrlo anrhi;
run;

proc sort data=results03;
    by paramn paramc ord visit;
run;

proc transpose data=results03 out=results04 prefix=t name=varname;
    by paramn paramc ord visit;
    var n meansd median minmax;
    id trtseqan;
    idlabel trtseqa;
run;

data results05;
    set results04;
    attrib stat length = $100.;
    if varname='N' then do; statord=1; stat='n'; end;
    else if varname='MEANSD' then do; statord=2; stat='Mean (SD)'; end;
    else if varname='MEDIAN' then do; statord=3; stat='Median'; end;

```

```

        else if varname='MINMAX' then do; statord=4; stat='Min, Max'; end;

    if paramn='' then delete;

        drop varname;
run;

/*Obtaining categorical stats*/
data adlb_orig2;
    set adlb;
    if avisitn=1 then ord=1; /*Screening*/
    else if avisitn=/*99*/100 then ord=2; /*Admission (Day-1)*/ /* 2)
JMH 23Sep2014 */
    else if avisitn=104 then ord=3; /*Discharge*/
    statval=anrind;
run;

data adlb_all2;
    set adlb_orig2;
run;

proc sort data=adlb_all2;
    by trtseqan trtseqa;
run;

data all2;
    merge adlb_all2(in=a) dumtrts(in=b);
    by trtseqan trtseqa;
    if a or b;
    if b and not a then statval='';
run;

proc sort data=all2;
    by trtseqan trtseqa paramn param paramcd ord anrlo anrhi
/*lbclsig*/ACLSIG; /* 2) JMH 23Sep2014 */
run;

proc freq data=all2 noprint ;
    by trtseqan trtseqa paramn param paramcd ord anrlo anrhi;
    tables statval / out=stats(drop=percent);
run;

/* 2) start JMH 23Sep2014 */
DATA ALL2_TEST;
    SET ALL2;
    WHERE ACLSIG='CS';
    STATVALDUM='Y';
RUN;
/* 2) end JMH 23Sep2014 */

proc freq data=/*all2*/ALL2_TEST noprint; /* 2) JMH 23Sep2014 */
    by trtseqan trtseqa paramn param paramcd ord anrlo anrhi
/*lbclsig*/ACLSIG; /* 2) JMH 23Sep2014 */

```

```

        tables /*statval*/STATVALDUM /
out=statsab(/*where=(lbclsig=**/'Y'*/**'Y')*/ drop=percent); /* 1) JR
12Aug2014 */ /* 2) JMH 23Sep2014 */
run;

data statsab2;
    set statsab;

    statval='ABNORMAL';

    drop /*lbclsig*/ACLSIG; /* 2) JMH 23Sep2014 */
run;

data stats2a;
    set stats statsab2;
run;

proc sort data=stats2a;
    by trtseqan trtseqa;
run;

data stats2;
    merge stats2a tot2;
    by trtseqan trtseqa;

run;

data stats3;
    set stats2(rename=(statval=statistic));
    format statval $20. paramc visit stat $100.;

    if statistic='LOW' then do;
        stat='Low value - n (%)';
        statord=5;
    end;
    else if statistic='NORMAL' then do;
        stat='Normal value - n (%)';
        statord=6;
    end;
    else if statistic='HIGH' then do;
        stat='High value - n (%)';
        statord=7;
    end;
    else if statistic='ABNORMAL' then do;
/*
        stat='Abnormal clinically relevant - n (%)';*/
        STAT='Abnormal clinically significant - n (%)'; /* 2) JMH
23Sep2014 */
        statord=8;
    end;

    if count=0 then statval = strip(put(count,best.)) ;

    if count lt 10 then count1=' ' || compress(put(count,best.));
    else count1=strip(put(count,best.));

```

```

        count1=trim(count1);

if total ne 0 then do;
    percent=count/total*100; /*This works out the percentages*/
end;

    if count=0 then do;
        statval = ' 0          ' ;
    end;
    else do;
        if percent=100 then statval = strip(put(count,best.)) || '
(100  %)' ;
        else if percent lt 10 then statval = strip(count1) || ' ( '
|| strip(put(round(percent,0.1),5.1)) || '%)';
        else if percent ge 10 then statval = strip(count1) || ' ( '
|| strip(put(round(percent,0.1),5.1)) || '%)';
    end;

    if not missing(anrlo) and not missing(anrhi) then do;
        paramc=strip(param)||' $n' ||strip(anrlo)||'-' ||strip(anrhi);
    end;
    else if missing(anrlo) and missing(anrhi) then do;
        paramc=strip(param);
    end;
    else if missing(anrlo) then do;
        paramc=strip(param)||' $n' ||'<' ||strip(anrhi);
    end;

    if paramcd='GGT' and anrhi=30 then paramn=7;

    if paramcd='GGT' then do;
        if anrhi=30 then paramc=strip(paramc)||' ' ||('Females');
        else if anrhi=80 then paramc=strip(paramc)||' ' ||('Males');
    end;
    if paramcd='CREAT' then do;
        if anrhi=0.79 then paramc=strip(paramc)||' ' ||('Females');
        else if anrhi=1.04 then paramc=strip(paramc)||' ' ||('Males');
    end;

/* 2) start JMH 23Sep2014 */
/*    if ord=1 then visit='Screening';*/
/*else*/ if ord=2 then visit=/'Day -1/Admission'/'Baseline';
    else if ord=3 then visit='Day 4/Discharge';
    else if ord=4 then visit=/'Change from Admission'/'Change from
Baseline';
        ELSE PUT "WA" "RNING: Unexpected value of ord, please check data "
ORD= TRTSEQA= ;
/* 2) End JMH 23Sep2014 */

    drop count count1 total percent anrlo anrhi;
run;

```



```

proc sort data=stats3 out=stats3a(where=(not missing(statistic) and not
missing(paramc)));
    by paramn paramc ord visit stat statord;
run;

proc transpose data=stats3a out=stats4(drop=_) prefix=t;
    by paramn paramc ord visit stat statord;
    var statval;
    id trtsega;
    idlabel trtsega;
run;

proc sort data=stats3(where=(not missing(paramc)))
out=stats3b(keep=paramc paramn) nodupkey;
    by paramn paramc;
run;

data extra(drop=i j);
    set stats3b;
    format visit stat $100.;
    by paramn paramc;

    do i=1 to 3;
        do j=5 to 8;
            if i=1 then visit='Screening';
            else if i=2 then visit=/'Day -1/Admission'/'Baseline'; /*
2) JMH 23Sep2014 */
            else if i=3 then visit='Day 4/Discharge';
            ord=i;
            if j=5 then stat='Low value - n (%)';
            else if j=6 then stat='Normal value - n (%)';
            else if j=7 then stat='High value - n (%)';
            else if j=8 then stat=/'Abnormal clinically relevant - n
(%)'/'Abnormal clinically significant - n (%)'; /* 2) JMH 23Sep2014 */
            statord=j;
            output;
        end;
    end;

run;

proc sort data=stats4;
    by paramn paramc ord visit statord stat;
run;

proc sort data=extra;
    by paramn paramc ord visit statord stat;
run;

data stats5;
    merge stats4 extra(WHERE=(VISIT NE 'Screening')); /* 2) JMH 23Sep2014
*/
    by paramn paramc ord visit statord stat;
run;

```

```

/* Setting them together */
data results06;
    set results05 stats5;
    if stat in ('n' 'Low value - n (%)' 'Normal value - n (%)' 'High
value - n (%)'
                                /*'Abnormal clinically relevant -
n (%)'*/ 'Abnormal clinically significant - n (%)') then do; /* 2) JMH
23Sep2014 */
        if missing(t1) then t1='0';
        if missing(t2) then t2='0';
        if missing(t3) then t3='0';
        if missing(t4) then t4='0';
        if missing(t5) then t5='0';
        if missing(t99) then t99='0';
    end;
    if ord=2 then visit='Baseline';
    else if ord=3 then visit=tranwrd(visit,'/', '/' );
    else if ord=4 then visit='Change from Baseline';
run;

proc sort data=results06;
    by paramn paramc ord visit statord;
run;

data labels;
    set results06;
    attrib t1 label = "THS 2.2 Menthol -$mCC $(N=&trt1)"
        t2 label = "mCC -$THS 2.2 Menthol$(N=&trt2)"
        t3 label = "THS 2.2 Menthol -$NRT gum $(N=&trt3)"
        t4 label = "NRT gum -$THS 2.2 Menthol$(N=&trt4)"
        t5 label = "Enrolled not$randomized$(N=&trt5)"
        t99 label = "Overall$Safety$(N=&trt99)";

run;

proc sort data=labels;
    by paramn paramc ord visit statord;
run;

proc sql noprint;
    create table table.T_15_02_06_10 as
    select paramc, visit, stat, t1, t2, t3, t4, t5, t99
    from labels
    order by paramn, PARAMC, ord, visit, statord; /* 4) JMH 24Sep2014
*/
quit;

data paging;
    set labels;
    by paramn paramc ord visit statord;

    flag=1;

```

```

        if first.ord then ln=1;
        else ln+1;
        if ln=1 then page+1;
        call symput("page",compress(put(page,best.)));
run;

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=, 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;
ods proclabel = ' ';

title ;
footnote;
%LET PARAM=0;

data comp;
    set paging end=eof;
    by paramn paramc ord visit statord;
    where page=&i;

    /* Amend title as needed */
    _firtitl="Table 15.2.6.10    Summary of Clinical Chemistry
Parameters - Safety Population";
    _upcas=(length(_firtitl)-
length(compress(_firtitl,'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.)));
        if index(paramc,'Gamma') or index(paramc,'Creat') then call
symput('param',1);
    end;
    drop _firtitl _upcas len;
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;
/* Update with your variables as needed */
proc report data = comp missing headline headskip nowd split = '#' %if
&i=1 %then %do; contents=' ' %end; %else %do; contents='' %end;;;
    column flag page paramn ("Parameter (units)#Reference range"
paramc) ord ("Study Day" visit) statord ("Statistic" stat)
("Sequence &linebot." ("THS 2.2 Menthol -#mCC#(N=&trt1)" T1)
("mCC -#THS 2.2 Menthol#(N=&trt2)" T2)
("THS 2.2 Menthol -#NRT gum#(N=&trt3)" T3)
("NRT gum#- THS 2.2 Menthol#(N=&trt4)" T4)
("Enrolled Not #Randomized#(N=&trt5)" T5))
("Overall#Safety#(N=&trt99)" T99) ;
    define flag          / order order=internal noprint;
    define page          / order order = internal noprint;
    define paramn        / order order=internal noprint;
    define ord           / order order = internal noprint;
    define statord       / order order=internal noprint;
    define paramc        / group style={just=left cellwidth=3.2cm}
style(header)={just=center} "";
    define visit         / group style={just=left cellwidth=1.8cm}
style(header)={just=center} "";
    define stat          / display style={just=left cellwidth=2.9cm}
style(header)={just=center} "";
    define t1            / display style={just=C cellwidth=1.7cm}
style(header)={just=center} "";
    define t2            / display style={just=C cellwidth=1.7cm}
style(header)={just=center} "";
    define t3            / display style={just=C cellwidth=1.7cm}
style(header)={just=center} "";
    define t4            / display style={just=C cellwidth=1.7cm}
style(header)={just=center} "";
    define t5            / display style={just=center
cellwidth=2cm} style(header)={just=center} "";
    define t99           / display style={just=C cellwidth=1.7cm}
style(header)={just=center} "";

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

    break after page / page;

    COMPUTE AFTER ORD; /* 3) JMH 24Sep2014 */
        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: mCC = menthol conventional cigarettes; NRT gum =
Nicotine Replacement Therapy gum; THS = Tobacco Heating System.';
  line "Note: Enrolled Not Randomized refers to all subjects
enrolled but not randomized. Overall Safety refers to enrolled subjects
exposed to THS 2.2 Menthol or NRT gum.";
  line "Note: Percentages are based on the number of subjects
indicated in the column header (N).";
/*  line 'Note: Baseline is Day -1.';*/
  LINE "Note: Baseline is the last available time point prior
to the product test (THS 2.2 Menthol or NRT gum) at Admission (Day -1).";
/* 2) JMH 23Sep2014 */
  %if &param=1 %then %do;
    line "Note: Gamma Glutamyl Transferase and Creatinine are
summarized seperately by sex.";
  %end;
  line "";
  line "Appendix 15.3.6.4";
  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=70, halfblnk=N);
ods listing;
proc printto print = "&table./T_15_02_06_10.lst" new;
run;

proc contents data = table.T_15_02_06_10 varnum;
run;
ods listing close;

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

```