

```

%_mprintto;
options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
%put NOTE:
=====;
%put NOTE: Covance Study Number : 000000106324;
%put NOTE: Client Protocol ID   : ZRHR-REXC-03-EU;
%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_13(chem);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jriley;
%put NOTE: Creation Date        : 2014-07-31;
%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  JR        1) Amended zero presentation;
%put NOTE: 01Aug2014  JMH        2) Amended paging;
%put NOTE: 01Aug2014  JMH        3) Amended so low value - n (%) is
output;
%put NOTE: 04Aug2014  JMH        4) Amended presentation;
%put NOTE: 15Sep2014  KB         5) Amended LBCLSIG to ACLSIG;
%put NOTE: 15Sep2014  KB         6) Set Baseline timepoint;
%put NOTE: 15Sep2014  KB         7) Amended relevant to significant;
%put NOTE: 15Sep2014  KB         8) Amended stats for n less than 4;
%put NOTE: 17Sep2014  JMH        9) Amended order of dual programming
dataset;
%put NOTE: 17Sep2014  JMH        10) Amended in line with ADaM updates
regarding derived parameters;
%put NOTE: 17Sep2014  JMH        11) Amended proc freq to deal with
clinical significance;
%put NOTE: 18Sep2014  JR         12) Amended baseline footnote;
%put NOTE: 19Sep2014  KB         13) Amended stats to use round function
;
%put NOTE: ;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

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

%let tflno=T_15_02_06_13(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(trt01a,'Exposed') then delete;
    output;
    trt01an=99;
    trt01a='Overall Safety';
    output;
run;

proc freq data=adsl noprint;
    table trt01an*trt01a/ out =tot(drop=percent rename=(trt01an=trtan
trt01a=trta));
run;

data dumtrts; /*Use this to output any columns for which N=0*/
    attrib trta length =$40.
                                trtan length=8.;
    trtan=1;
    trta='THS 2.2';
    output;
    trtan=2;
    trta='CC';
    output;
    trtan=3;
    trta='SA';
    output;
    trtan=97;
    trta='Enrolled not randomized';
    output;
run;

data tot2;
    merge tot(in=a) dumtrts(in=b);

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        by trtan trta;
        if a or b;
        if b and not a then count=0;
        call symput('trt' || compress(put(trtan,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(trta) then delete;
    if index(trta,'Exposed') then delete;
/* 6) START KB 15Sep2014 */
/*    if avisit='Day 0' then avisit='Baseline';*/
    IF ABLFL='Y' THEN DO;
        AVISIT='Baseline';
        AVISITN=100;
    END;
    IF AVISIT NE 'Baseline' AND AVISITN LE 99 THEN DELETE;
/* 6) END KB 15Sep2014 */
    avisit=tranwrd(avisit,'/',' ');
    if not index(param,'(') then
param=upcase(substr(param,1,1))||lowercase(substr(param,2));
    else if index(param,'(') then
param=upcase(substr(param,1,1))||lowercase(scan(substr(param,2),1,'('))||'('
' ||scan(param,2,'(');
    output;
    trtan=99;
    trta='Overall Safety';
    output;
run;

data adlb_orig adlb_chg;
    set adlb;
    statval=aval;
    output adlb_orig;
    if avisitn ne 106 then delete;
    avisit='Change from baseline';
    avisitn=999;
    statval=chg;
    output adlb_chg;
run;

data adlb_all;
    set adlb_orig adlb_chg;
run;

proc sort data=adlb_all;
    by trtan trta;
run;

data all;
    merge adlb_all(in=a) dumtrts(in=b);

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```

        by trtan trta;
        if a or b;
        if b and not a then statval='';
run;

proc sort data=all;
    by trtan trta paramn param paramcd avisitn avisit anrlo anrhi;
run;

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

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

    if paramcd in ('BILDIR' 'PROT' /*'DK'*/'K' 'BILI') then do;    /* 10)
JMH 17Sep2014 */
        n = left(compress(put(n1,8.)));
        if not missing(med1) then median =
left(compress(put(ROUND(med1,0.01),8.2))); /* 13) KB 19Sep2014 */
        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)) || ')'; /* 13) KB 19Sep2014 */
        if not missing(min1) and not missing(max1) then minmax =
left(compress(put(ROUND(min1,0.1),8.1))) || ', ' ||
left(compress(put(ROUND(max1,0.1),8.1))); /* 13) KB 19Sep2014 */
        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))); /* 13) KB 19Sep2014 */
        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)) || ')'; /* 13) KB 19Sep2014
*/
        if not missing(min1) and not missing(max1) then minmax =
left(compress(put(ROUND(min1,0.01),8.2))) || ', ' ||
left(compress(put(ROUND(max1,0.01),8.2))); /* 13) KB 19Sep2014 */
        end;
    else do;
        n = left(compress(put(n1,8.)));
        if not missing(med1) then median =
left(compress(put(ROUND(med1,0.1),8.1))); /* 13) KB 19Sep2014 */
        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)) || ')'; /* 13) KB 19Sep2014 */
        if not missing(min1) and not missing(max1) then minmax =
left(compress(put(ROUND(min1,1.),8.))) || ', ' ||
left(compress(put(ROUND(max1,1.),8.))); /* 13) KB 19Sep2014 */

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end;

/* 8) START KB 15Sep2014 */
IF N1 LT 4 THEN DO;
    MEDIAN = "NC";
    MEANSD = "NC";
    MINMAX = "NC";
END;
/* 8) END KB 15Sep2014 */

drop n1 mean1 std1 med1 min1 max1;
run;

data results03;
    set results02;
    attrib paramc 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' then do;
        if anrhi=30 then do;
            paramn=7;
            paramc=strip(paramc)||' ' ||('Females');
        end;
        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;

    drop anrlo anrhi;
run;

proc sort data=results03;
    by paramn paramc avisitn avisit;
run;

proc transpose data=results03 out=results04 prefix=t name=varname;
    by paramn paramc avisitn avisit;
    var n meansd median minmax;
    id trtan;
    idlabel trta;
run;

data results05;

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        set results04;
        by paramn paramc avisitn avisit;
        attrib stat length = $100.;
        if first.avisitn then statord=1;
        else statord+1;
        if varname='N' then stat='n';
        else if varname='MEANS' then stat='Mean (SD)';
        else if varname='MEDIAN' then stat='Median';
        else if varname='MINMAX' then stat='Min, Max';

        if paramn='' then delete;

        drop varname;
run;

/*Obtaining categorical stats*/
data adlb_orig2;
    set adlb;
    statval=anrind;
run;

data adlb_all2;
    set adlb_orig2;
run;

proc sort data=adlb_all2;
    by trtan trta;
run;

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

proc sort data=all2;
    by trtan trta paramn param paramcd avisitn avisit anrlo anrhi
/*lbclsig*/ACLSIG; /* 5) KB 15Sep2014 */
run;

proc freq data=all2 noprint ;
    by trtan trta paramn param paramcd avisitn avisit anrlo anrhi;
    tables statval / out=stats(drop=percent);
run;

/* 11) start JMH 17Sep2014 */
DATA ALL2_TEST;
    SET ALL2;
    WHERE ACLSIG='CS';
    STATVALDUM='Y';
RUN;
/* 11) end JMH 17Sep2014 */

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proc freq data=/*all2*/ALL2_TEST noprint; /* 11) JMH 17Sep2014 */
    by trtan trta paramn param paramcd avisitn avisit anrlo anrhi
/*lbclsig*/ACLSIG; /* 5) KB 15Sep2014 */
    tables /*statval*/STATVALDUM /
out=statsab(where=(/*lbclsig='Y'*/ACLSIG='CS') drop=percent); /* 5) KB
15Sep2014 */ /* 11) JMH 17Sep2014 */
run;

data statsab2;
    set statsab;
        ATTRIB STATVAL LENGTH=$50.; /* 11) JMH 17Sep2014 */
    statval='ABNORMAL';
    drop /*lbclsig*/ACLSIG; /* 5) KB 15Sep2014 */
run;

data stats2a;
    set stats statsab2;
run;

proc sort data=stats2a;
    by trtan trta;
run;

data stats2;
    merge stats2a tot2;
    by trtan trta;
run;

data stats3;
    set stats2(rename=(statval=statistic));
    format statval $20. paramc 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 (%)'; /* 7) KB
15Sep2014 */
        statord=8;
    end;

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

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

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        else count1=strip(put(count,best.));

        count1=trim(count1);

    if total ne 0 then do;
        percent=count/total*100;
    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' then do;
        if anrhi=30 then do;
            paramn=7;
            paramc=strip(paramc)||' ' || ('(Females)');
        end;
        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;

    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 avisitn avisit stat statord;
run;

proc transpose data=stats3a out=stats4(drop=_) prefix=t;
    by paramn paramc avisitn avisit stat statord;
    var statval;
    id trtan;

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        idlabel trta;
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 stat avisit $40.;
    by paramn paramc;

    do i=/*1*/2 to 3; /* 6) KB 15Sep2014 */
        do j=5 to 8;
/*          if i=1 then do; avisit='Screening'; avisitn=1; end;*/ /* 6)
KB 15Sep2014 */
            /*else*/ if i=2 then do; avisit='Baseline'; avisitn=100; end;
/* 6) KB 15Sep2014 */
            else if i=3 then do; avisit='Day 6/ Discharge'; avisitn=106;
end;
                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
(%)';*/
                ELSE IF J=8 THEN STAT='Abnormal clinically significant - n
(%)'; /* 7) KB 15Sep2014 */
                statord=j;
                output;
            end;
        end;
run;

proc sort data=stats4;
    by paramn paramc avisitn avisit statord stat;
run;

proc sort data=extra;
    by paramn paramc avisitn avisit statord stat;
run;

data stats5;
    merge stats4 extra;
    by paramn paramc avisitn avisit statord stat;
run;
/* Start 1) JR 01Aug2014 */
PROC SORT DATA=RESULTS05(WHERE=(STAT='n')) OUT=MISSFLAGS;
    BY PARAMN PARAMC AVISITN; /* 3) JMH 01Aug2014 */
RUN;

DATA MISSFLAGS2;
    SET MISSFLAGS;

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        IF STRIP(T1)='' THEN MFLAG1=1;
        IF STRIP(T2)='' THEN MFLAG2=1;
        IF STRIP(T3)='' THEN MFLAG3=1;
        IF STRIP(T97)='' THEN MFLAG97=1;
        IF STRIP(T99)='' THEN MFLAG99=1;

        DROP T: STAT:; /* 3) JMH 01Aug2014 */

RUN;

PROC SORT DATA=RESULTS05; BY PARAMN PARAMC AVISITN AVISIT; RUN;
PROC SORT DATA=MISSFLAGS2; BY PARAMN PARAMC AVISITN AVISIT; RUN;
PROC SORT DATA=STATS5; BY PARAMN PARAMC AVISITN AVISIT STATORD; RUN; /*
3) JMH 01Aug2014 */

DATA RESULTS05_A;
    MERGE RESULTS05 MISSFLAGS2;
    BY PARAMN PARAMC AVISITN AVISIT;
RUN;

DATA STATS5A;
    MERGE STATS5 MISSFLAGS2(WHERE=(AVISITN NE 999)); /* 4) JMH
04Aug2014 */
    BY PARAMN PARAMC AVISITN AVISIT;
    IF STAT='n' THEN DELETE;
RUN;

data results06;
    set results05_A stats5A;

    array a[5] t1 t2 t3 t97 t99;
    array B[5] MFLAG1 MFLAG2 MFLAG3 MFLAG97 MFLAG99;
    do i=1 to 5;
        if statord>4 AND B[i] NE 1 then if missing(a[i]) then
a[i]='0';
    end;
        if stat='n' and statord=1 then do;
            if missing(t1) then t1='0';
            if missing(t2) then t2='0';
            if missing(t3) then t3='0';
            if missing(t97) then t97='0';
            if missing(t99) then t99='0';
        end;
run;
/* End 1) JR 01Aug2014 */
proc sort data=results06;
    by paramn paramc avisitn avisit statord;
run;

proc sql noprint;
    create table table.T_15_02_06_13 as
    select paramc, avisit, stat, t1, t2, t3, t97, t99
    from results06

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```

/*      order by paramn, avisitn, statord;*/
      ORDER BY PARAMN, PARAMC, AVISITN, AVISIT, STATORD; /* 9) JMH
17Sep2014 */
quit;

data paging;
  set results06;
  by paramn paramc avisitn avisit statord;

  flag=1;

/*      if avisitn<999 and ln gt 8 then ln=1;*/
/*      else if avisitn=999 and ln>12 then ln=1;*/
      IF FIRST.AVISITN THEN LN=1; /* 2) JMH 01Aug2014 */
  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.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 &page;
ods proclabel = ' ';

title ;
footnote;
%let wd=0;

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

  /* Amend title as needed */
  _firtitl="Table 15.2.6.13 Summary of Clinical Chemistry Parameters
- Safety Population";

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        _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.)));
        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) avisitn ("Study Day" avisit) statord ("Statistic" stat)
        (("THS 2.2#(N=&trt1)" T1) ("CC#(N=&trt2)" T2) ("SA#(N=&trt3)" T3)
        ("Enrolled Not #Randomized#(N=&trt97)"
T97)) ("Overall#Safety#(N=&trt99)" T99) ;
    define flag          / order order=internal noprint;
    define page          / order order = internal noprint;
    define paramn        / order order=internal noprint;
    define avisitn       / order order = internal noprint;
    define statord       / order order=internal noprint;
    define paramc        / group style={just=left cellwidth=3.2cm}
style(header)={just=center} "";
    define avisit        / 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=2cm}
style(header)={just=center} "";
    define t2            / display style={just=c cellwidth=2cm}
style(header)={just=center} "";
    define t3            / display style={just=c cellwidth=2cm}
style(header)={just=center} "";
    define t97           / display style={just=c cellwidth=2cm}
style(header)={just=center} "";
    define t99           / display style={just=c cellwidth=2cm}
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 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: CC = Conventional cigarettes; SA = Smoking
abstinence; 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.";
            line "Note: Percentages are based on the number of subjects
indicated in the column header (N).";
            line "Note: Baseline is the last assessment prior to first
product use in CC/THS 2.2 arms on Day 1 or last assessment prior to 06:29
AM in SA arm on Day 1."; /* 12) JR 18Sep2014 */
/*            line "Note: Baseline is defined as the last assessment prior
to 06:29 AM on Day 1.";*/
            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_13.lst" new;
run;

proc contents data = table.T_15_02_06_13 varnum;
run;
ods listing close;

proc printto ; run;

```

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