

```

%_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_spiro.sas;
%put NOTE: Purpose              : table of spirometry;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADXP ADAM.ADSL;
%put NOTE: Output               : t_15_2_6_15(xp);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_aobyrne;
%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  JMH        1) Amended column widths and headers;
%put NOTE: 12Aug2014  JMH        2) Corrected code so data is shown for
overall column;
%put NOTE: 12Aug2014  JMH        3) Amended where statement;
%put NOTE: 23Sep2014  JMH        4) Amended clinical significance and
assigning of Baseline;
%put NOTE: 24Sep2014  JMH        5) Amended to match PK-02;
%put NOTE: 24Sep2014  JMH        6) Corrected stats;
%put NOTE: 24Sep2014  JMH        7) Amended data selection;
%put NOTE: 24Sep2014  JMH        8) Amended ordering;
%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_15(xp);

%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 missing(trtseqan) then delete;
    if index(trtseqa, 'Exposed') then delete;
    output;
    trtseqan=99;
    trtseqa='Overall Safety';
    output;
run;

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

data dumtrts; /*Use this to output any columns for which N=0*/
    attrib trtseqa length =$200.
           trtseqan length=8.;
    trtseqan=1;
    trtseqa='THS 2.2 Menthol - mCC';
    output;
    trtseqan=2;
    trtseqa='mCC - THS 2.2 Menthol';
    output;
    trtseqan=3;
    trtseqa='THS 2.2 Menthol - NRT gum';
    output;
    trtseqan=4;
    trtseqa='NRT gum - THS 2.2 Menthol';
    output;
    trtseqan=5;
    trtseqa='Enrolled not randomized';
    output;
run;

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

```

```

run;

/*Bring in appropriate data from ADXP*/
data adxp1;
    set adam.adxp(where=((paramcd in ('DFEVFVC' 'INTP' 'FEVMEAS'
'FVCMEAS' 'FEVPCT' 'FVCPCT'
'WFEVMEAS' 'WFVCMEAS' 'WFVCPCT' 'WFEVPCT' 'WFEVFVC' 'WINTP') /* 4)
JMH 23Sep2014 */ /* 7) JMH 24Sep2014 */
    or (paramcd='FEVFVC' and xpstat ne 'NOT DONE')) and
saffl = 'Y' and anl01fl='Y'));

    IF ANL01FL NE 'Y' THEN DELETE; /* 3) JMH 12Aug2014 */
    IF SAFFL NE 'Y' THEN DELETE; /* 3) JMH 12Aug2014 */

    if missing(trtseqan) then delete;
    if index(trtseqa,'Exposed') then delete;

/* 4) start JMH 23Sep2014 */
    IF ABLFL='Y' THEN DO;
        AVISIT='Baseline';
        AVISITN=100;
    END;
    IF AVISIT NE 'Baseline' AND AVISITN LE 100 THEN DELETE;
/* 4) end JMH 23Sep2014 */

    /* 2) START JMH 12Aug2014 */
    OUTPUT;
    TRTSEQAN=99;
    TRTSEQA='Overall Safety';
    OUTPUT;
/* 2) END JMH 12Aug2014 */

run;

/*INTP only*/
proc sort data=adxp1 out=adxp;
    by trtseqan trtseqa avisitn avisit usubjid avalc paramn param
XPCLSIG; /* 4) JMH 23Sep2014 */
run;

proc freq data=adxp(where=(paramcd in ('INTP' 'WINTP') and anl01fl='Y'))
noprint;
    table
    trtseqan*trtseqa*avisitn*avisit*aval*avalc*paramn*param*XPCLSIG / out
=intp1(drop=percent); /* 4) JMH 23Sep2014 */
run;

data intp2;
    merge intp1(in=a) dumtrts(in=b) tot2(rename=(count=total));
    by trtseqan trtseqa;
    if a or b;
    if b and not a then do;

```

```

        count = 0;
/*      avisitn=1;*/ /* 4) JMH 23Sep2014 */
/*      avisit='Screening';*/ /* 4) JMH 23Sep2014 */
/*      avalc='Normal';*/ /* 4) JMH 23Sep2014 */
        end;
        if total ne 0 then do;
            percent=count/total*100; /*This works out the percentages*/
        end;
run;

proc sort data=intp2 nodupkey out=trtvis(keep=trtseqan trtseqa avisitn
avisit avalc paramn param);
    by trtseqan trtseqa avisitn avisit paramn;
run;

data dumrows;
set trtvis;
    ATTRIB XPCLSIG LENGTH=$3.; /* 4) JMH 23Sep2014 */

    avalc='Normal';
    xpclsig = '';
    output;
    avalc='Abnormal';
    xpclsig = /*'N'*/'NCS'; /* 4) JMH 23Sep2014 */
    output;
    avalc='Abnormal';
    xpclsig = /*'Y'*/'CS'; /* 4) JMH 23Sep2014 */
    output;
run;

proc sort data=dumrows;
    by trtseqan trtseqa paramn param avisitn avisit avalc;
run;

proc sort data=intp2;
    by trtseqan trtseqa paramn param avisitn avisit avalc;
run;

data intp3;
    merge intp2(in=a) dumrows(in=b);
    by trtseqan trtseqa paramn param avisitn avisit avalc;
    if a or b;
    attrib statval length=$20.
        count1 length=$3.;
    if b and not a then do;
        count=0;
        percent=0;
    end;
    attrib paramc visit stat length = $100.;
    paramc=strip(param);

/* 4)start JMH 23Sep2014 */
/*if avisitn=1 then do; ord=1; visit=avisit; end;*/

```

```

/*else*/ if avisitn=/*99*/100 then do; ord=2; visit=avisit;
end;

else if avisitn=104 then do; ord=3; visit=avisit; end;
ELSE PUT "WA" "RNING: Unexpected value for avisitn, please
check " avisitn= ;
/* 4) end JMH 23Sep2014 */

if avalc='Normal' then do;
    stat='Normal - n (%)';
    statord=1;
end;
else if avalc='Abnormal' and xpclsig=/'N'/'NCS' then do; /*
4) JMH 23Sep2014 */
/*
    stat='Abnormal non-clinically relevant - n (%)';*/
    STAT='Abnormal non-clinically significant - n (%)'; /*
4) JMH 23Sep2014 */
    statord=2;
end;
else if avalc='Abnormal' and xpclsig=/'Y'/'CS' then do; /*
4) JMH 23Sep2014 */
/*
    stat='Abnormal clinically relevant - n (%)';*/
    STAT='Abnormal clinically significant - n (%)'; /* 4)
JMH 23Sep2014 */
    statord=3;
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 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 = count1 || ' ' || '(
' ||left(strip(put(round(percent,0.1),5.1))) || '%)';
    else if percent ge 10 then statval = count1 || ' ' || '(
' ||left(strip(put(round(percent,0.1),5.1))) || '%)';
end;

run;

proc sort data=intp3 nodupkey;
    by trtsega trtseqan avisitn avisit paramn paramc ord count total
percent visit statval statord stat xpclsig;
run;

proc sort data=intp3;

```

```

        by paramn paramc ord visit statord stat XPCLSIG;
run;

proc transpose data=intp3 out=intp4(where=(stat ne 'DUMMY')) prefix=t;
    by paramn paramc ord visit statord stat xpclsig;
    var statval;
    id trtsega;
    idlabel trtsega;
run;

data intp5;
    set intp4;

    if paramn=19 and ord=1 and statord in (2 3) then do;
        if t1='' then t1='0';
        if t2='' then t2='0';
        if t3='' then t3='0';
        if t4='' then t4='0';
        if t5='' then t5='0';
        if t99='' then t99='0';
    end;
run;
    /*End of INTP, will set on with rest of data later*/

/*Everything except INTP*/
data adxp_orig;
    set adxp(where=(paramcd not in ('INTP' 'WINTP')));
    /* 4) start JMH 23Sep2014 */
    /* if avisitn=1 then ord=1; */
    /*else*/ if avisitn=99 then ord=2;
    else if avisitn=104 then ord=3;
    ELSE PUT "WA" "RNING: Unexpected value for avisitn, please check "
AVISITN= ;
    /* 4) end JMH 23Sep2014 */
    statval=aval;

run;

data adxp_chg;
    set adxp(where=(avisitn = 104 and paramcd not in ('INTP'
'WINTP')));
    if avisitn=104 then ord=4;
    statval=chg;
run;

data adxp_all;
    set adxp_orig adxp_chg;

/* if paramcd='DFEVFVC' then do;*/ /* 7) JMH 24Sep2014 */
/* paramcd='FEVFVC';*/
/* paramn=18;*/
/* end;*/

```

```

/*IF PARAMN=20 THEN PARAMN=18.5;*/ /* 7) JMH 24Sep2014 */ /*
8) JMH 24Sep2014 */
if paramcd=/'FEVFVC'/'DFEVFVC' then param='Calculated ratio between
FEV1/FVC^{super 1}'; /* 7) JMH 24Sep2014 */

```

```
run;
```

```
%macro enrol;
```

```
  %let enrol=0;
```

```
  data adxp_all2;
```

```
    set adxp_all;
```

```
    if index(trtseqan,5) then call symput('enrol',1);
```

```
  run;
```

```
  %if &enrol=0 %then %do;
```

```
    proc sort data=adxp_all2 out=dum(keep=trtseqan trtsega paramn
paramcd param ord) nodupkey;
```

```
      by paramn param paramcd ord;
```

```
    run;
```

```
    data dum2;
```

```
      set dum;
```

```
      trtseqan=5;
```

```
      trtsega='Enrolled not randomized';
```

```
    run;
```

```
    data adxp_all3;
```

```
      set adxp_all2 dum2;
```

```
    run;
```

```
  %end;
```

```
  %else %if &enrol=1 %then %do;
```

```
    data adxp_all3;
```

```
      set adxp_all2;
```

```
    run;
```

```
  %end;
```

```
%mend;
```

```
%enrol;
```

```
proc sort data=adxp_all3;
```

```
  by trtseqan trtsega;
```

```
run;
```

```
data all;
```

```
  merge adxp_all3(in=a) dumtrts(in=b);
```

```
  by trtseqan trtsega;
```

```
  if a or b;
```

```
  if b and not a then statval='';
```

```
run;
```

```
proc sort data=all;
```

```
  by trtseqan trtsega paramn ord param avalu avisit;
```

```

run;

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

proc sort data=results01 out=results01a(where=(not missing(avalu))
keep=paramn ord param avalu avisit) nodupkey;
    by paramn ord param avalu avisit;
run;

proc sort data=results01(drop=avalu avisit);
    by paramn param ord;
run;

proc sort data=results01a;
    by paramn param ord;
run;

data results01b;
    merge results01(in=a) results01a;
    by paramn param ord;
    if a;
run;

data results02;
    set results01b;
    attrib meansd minmax n median length=$20. paramc visit length
= $100.;

    if paramn not in (5 8 14 17) then do;
        n          = left(compress(put(n1,8.)));
        if not missing(med1) then median =
left(compress(put(ROUND(med1,0.001),8.3))); /* 4) 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))||')'; /* 4) 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(med1,0.01),8.2))); /* 4) 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)) || ')'; /* 4) 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;

```



```

        paramc=strip(param)||' ('||strip(avalu)||')';

        if ord=1 then visit=avisit;
        else if ord=2 then visit=avisit;
        else if ord=3 then visit=avisit;
        else if ord=4 then visit=/*'Change from Day -1 at Day 4'*/
                                /*'Change from Baseline at
Day 4'*/ 'Change from Baseline'; /* 4) JMH 23Sep2014 */ /* 5) JMH
24Sep2014 */
run;

proc sort data=results02;
    by paramn paramc ord visit;
run;

proc transpose data=results02 out=results03 prefix=t name=varname;
    by paramn paramc ord visit;
    var n meansd median minmax;
    id trtsega;
    idlabel trtsega;
run;

data results04;
    set results03;
    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;

    drop varname;
run;

/*Now combine the stats with the classification results*/
data allresults;
    set results04(in=b) intp5(in=a);
run;

data labels;
    set allresults;
    /* 1) start JMH 12Aug2014 */
    /*    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)"; */

    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)";

/* 1) end JMH 12Aug2014 */
    if index(visit, '/') then visit=tranwrd(visit, '/', ' ');
/* 4) START JMH 23Sep2014 */
/*    if visit='Day -1' then visit='Baseline'; */
/*    if visit='Change from Day -1 at Day 4' then visit='Change from
baseline'; */
/**/
/*    if visit='Screening' then delete; */
/* 4) END JMH 23Sep2014 */

    IF PARAMN=10 THEN PARAMN=21; /* 8) JMH 24Sep2014 */
    ELSE IF PARAMN=19 THEN PARAMN=22; /* 8) JMH 24Sep2014 */

run;

/*options replace; */
proc sql noprint;
    create table table.T_15_02_06_15 as
    select paramc, visit, stat, t1, t2, t3, t4, t5, t99
    from labels
    order by paramn, ord, statord;
quit;
/*options noreplace; */

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

data paging;
    set labels;
        by paramn ord statord;
/*    if (first.ord and ln gt 5) or (paramn=19 and ord=2 and statord=1)
then ln=1; */
    IF (FIRST.ORD AND LN GT 5) OR (PARAMN IN (/*10 19*/21 22) AND
ORD=2 AND STATORD=1) /*OR (PARAMN=13 AND ORD=2 AND STATORD=1)*/ THEN
LN=1; /* 7) JMH 24SEP2014 */ /* 8) JMH 24Sep2014 */
    else ln+1;
    if ln=1 then page+1;

    flag=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.t106326 (read) ;
ods results off;
ods rtf toc_data
file="/cvn/projects/prj/data/000000106326/TFL/&TFL_Part./&tflno..rtf"
style=t106326 startpage=yes headery=1440 footery=1440 ;
ods noproctitle;
%do i=1 %to &page;

title ;
footnote;
%let wd=0;
%let supfl=0;
ods proclabel = ' ';

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

    /* Amend title as needed */
    _firtitl="Table 15.2.6.15 Summary of Spirometry Measurements
- Safety Population";
    _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;
    if index(paramc,"super") then call symput('supfl',"1");
    call symput('paramn',left(trim(paramn)));
    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 headline headskip missing nowd split = '$' %if
&i=1 %then %do; contents=' ' %end; %else %do; contents='' %end;;;
    column flag page paramn paramc ord visit statord stat ("Sequence
&linebot" t1 t2 t3 t4 t5) t99; ;

    define flag          / order order= internal noprint;
    define page          / order order = internal noprint;

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```

        define paramn      / order order = internal noprint;
        define ord         / order order = internal noprint;
        define statord     / order order = internal noprint;
        %if &paramn ne /*10*/21 and &paramn ne /*19*/22 %then %do; /* 8)
JMH 24Sep2014 */
        define paramc      / group style={just=left
cellwidth=1.8/*2.1*/cm} style(header)={just=center} 'Parameter$(units)';
/* 1) start JMH 12Aug2014 */
        define visit      / group style={just=left cellwidth=1.5cm}
style(header)={just=center} 'Study Day';
        define stat       / display style={just=left
cellwidth=1.4/*1.5*/cm}'Statistic';
        define t1         / display style={just=c cellwidth=/*1.6*/
1.7cm} style(header)={just=center};
        define t2         / display style={just=c cellwidth=/*1.6*/
1.7cm} style(header)={just=center};
        define t3         / display style={just=c cellwidth=/*1.6*/
1.7cm} style(header)={just=center};
        define t4         / display style={just=c cellwidth=/*1.6*/
1.7cm} style(header)={just=center};
        define t5         / display style={just=c cellwidth=/*1.6*/
1.7cm} style(header)={just=center};
        define t99        / display style={just=c cellwidth=/*1.6*/
1.7cm} style(header)={just=center}; /* 1) end JMH 12Aug2014 */
        %end;
        %else %do;
        define paramc      / group style={just=left cellwidth=1.8cm}
style(header)={just=center} 'Parameter$(units)';
        define visit      / group style={just=left cellwidth=1.3cm}
style(header)={just=center} 'Study Day';
        define stat       / display style={just=left
cellwidth=2cm}'Statistic';
        define t1         / display style={just=l cellwidth=1.6cm }
style(header)={just=center};
        define t2         / display style={just=l cellwidth=1.6cm }
style(header)={just=center};
        define t3         / display style={just=l cellwidth=1.6cm }
style(header)={just=center};
        define t4         / display style={just=l cellwidth=1.6cm }
style(header)={just=center};
        define t5         / display style={just=l cellwidth=1.6cm }
style(header)={just=center};
        define t99        / display style={just=l cellwidth=1.6cm }
style(header)={just=center};
        %end;

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

        break after page / page;

        compute after ord;
        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 all 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 defined as the last available time point
prior to the product test at 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).";
/* 4) JMH 23Sep2014 */
  %if &supfl=1 %then %do;
  line "Note: 1: Ratio is dervied in analysis datasets.";
  %end;
  line ' ';
  line 'Appendix 15.3.6.8';
  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_15.lst" new;
run;

proc contents data = table.T_15_02_06_15 varnum;
run;
ods listing close;

proc printto ; run;

```

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