

/\*-----

Covance Study ID : COV-000000106343

Program Name : t\_vs\_bwvc\_fas.sas

Purpose : Table 15.2.4.33.2(Descriptive Statistics of ody weight (kg) and waist circumference (cm)-FAS);

Author : cvn\_pshe

Date of Creation : 14MAY015

Input Data : ADAM.ADSL, ADAM.ADVS,

Output Data :

Macros Called :

-----

Modification History

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Modified by :

Modification Date :

Modification Description:

-----\*/

proc datasets lib=work kill memtype=data nolist;

run;

%m\_printto;

options notes nosource;

options replace;

```
options notes source source2 nofullstimer validvarname=upcase missing=' ';
```

```
ods _all_ close;
```

```
ods listing;
```

```
*=====;
```

```
* START OF PROGRAM CODE                               ;
```

```
*=====;
```

```
%let tflno=T_15_02_04_33_02;
```

```
%let TFL_Part=%scan(&_amp;_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", ""));
```

```
            call
```

```
symput('TFLprg',reverse(scan(strip(reverse(compress("&_SASPROGRAMFILE", ""))),1,"/")));
```

```
run;
```

```
*****;
```

```
* read in data ;
```

```
*****;
```

```
/*Use ADSL to get N values for column headers*/
```

```
data adsl;
```

```

        set adam.adsl(where=(fasfl='Y'));

run;

proc sort data=adsl nodupkey out=adsl1;

    by usubjid trt01an trt01a;

run;

proc freq data=adsl1(where=(not missing(trt01an))) noprint;

    table trt01an*trt01a/ out =tot(drop=percent rename=(count=total));

run;

data tot2;

    set tot;

    call symput('trt' || strip(put(trt01an,best.)),strip(put(total,best.)));

run;

%put trt3=&trt3; %put trt5=&trt5; %put trt4=&trt4;

/*Bring in sbp and dbp raw value data from ADVS*/

%macro rawval (parmcd=,parm=, num=);

data advs_bp;

    set adam.advs(where=(anl01fl='Y' and fasfl='Y' and paramcd in ("&parmcd")));

run;

data advs_bp ;

```

```
set advs_bp ;
```

```
    if ablfl ='Y' then do; avisit='Baseline'; avisitn=98; end;
```

```
    if avisit='Screening' and ablfl =' ' then delete;
```

```
    else if avisit='Day -2' and ablfl =' ' then delete;
```

```
    else if avisit='Day -1' and ablfl =' ' then delete;
```

```
    else if avisit='Day 0' and ablfl =' ' then delete;
```

```
run;
```

```
proc sort data=advs_bp ;
```

```
    by trtan trta avisitn avisit;
```

```
run;
```

```
proc means data=advs_bp noprint;
```

```
    var aval;
```

```
    by trtan trta avisitn avisit;
```

```
    output out=bpstat n=n1 mean=mean1 std=sd1 median=median1 min=min1 max=max1 q1=q1 q3=q3  
    lclm =lci1 uclm=uci1;
```

```
run;
```

```
data bpstat_&parmcd ;
```

```
    set bpstat (rename=(mean1=mean lci1=lclm uci1=uclm)) ;
```

```
        parmcd="&parmcd";
```

```
    keep  parmcd trta trtan avisit avisitn mean lclm uclm;
```

```
run;
```

```
data bpstat1;
```

```

set bpstat;

attrib meansd minmax n median missc quart length=$20.;

    if &num=2 then do;

n = left(compress(put(n1,8.)));

                                *for <missing, n(%)>;

                                if trtan=3 then do;

                                    if &trt3.=n1 then

missc="";

                                    else

missc=strip(put((&trt3.- n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 8.1)) || ")";

                                    end;

                                else if trtan=4 then do;

                                    if &trt4.=n1 then

missc="";

                                    else

missc=strip(put((&trt4.- n1), 8.)) || ' (' || strip(put(((&trt4.-n1)*100)/&trt4., 8.1)) || ")";

                                    end;

                                else if trtan=5 then do;

                                    if &trt5.=n1

then missc="";

                                    else

missc=strip(put((&trt5.-n1), 8.)) || ' (' || strip(put(((&trt5.-n1)*100)/&trt5., 8.1)) || ")";

                                    end;

```

```

    IF NOT MISSING(MEDIAN1) THEN MEDIAN =
LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.1),10.1)));

```

```

    IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.1),10.1))) || " (" || STRIP(PUT(0.01*CEIL(SD1/0.01),10.2)) || ")";

```

```

IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.)) || ",
" || strip(put(max1, 10.));

IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.1),10.1))) || ', ' || LEFT(COMPRESS(PUT(ROUND(Q3,0.1),10.1))));

IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI = STRIP(PUT(0.1*FLOOR(LCI1/0.1),10.1)) || ',
' || STRIP(PUT(0.1*CEIL(UCI1/0.1),10.1));

end;

else if &num=1 then do;

n = left(compress(put(n1,8.)));

*for <missing, n(%)>;

if trtan=3 then do;

if &trt3.=n1 then

missc="";

else

missc=strip(put((&trt3.- n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 8.1)) || ")";

end;

else if trtan=4 then do;

if &trt4.=n1 then

missc="";

else

missc=strip(put((&trt4.- n1), 8.)) || ' (' || strip(put(((&trt4.-n1)*100)/&trt4., 8.1)) || ")";

end;

else if trtan=5 then do;

if &trt5.=n1

then missc="";

else

missc=strip(put((&trt5.-n1), 8.)) || ' (' || strip(put(((&trt5.-n1)*100)/&trt5., 8.1)) || ")";

end;

```

```

        IF NOT MISSING(MEDIAN1) THEN MEDIAN =
LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.01),10.2)));

    IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.01),10.2))) || "
(" || STRIP(PUT(0.001*CEIL(SD1/0.001),10.3)) || ")";

    IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.1)) || ",
" || strip(put(max1, 10.1));

    IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.01),10.2))) || ', ' || LEFT(COMPRESS(PUT(ROUND(Q3,0.01),10.2))));

    IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI = STRIP(PUT(0.01*FLOOR(LCI1/0.01),10.2))
|| ', ' || STRIP(PUT(0.01*CEIL(UCI1/0.01),10.2));

    end;

    drop n1 mean1 sd1 median1 min1 max1 q1 q3 lci1 uci1 _type_ _freq_;

run;

proc sort data=bpstat1;

    by trtan trta avisitn avisit;

run;

proc transpose data=bpstat1 out=t_bpstat1;

    by trtan trta avisitn avisit;

        var n missc meansd minmax median quart aci;

run;

data sa ths mcc;

    length stat rawval $50;

    set t_bpstat1 (drop=trtan rename=( _name_ =stat col1=rawval)) ;

        if trta='SA' then output sa;

```

```

        else if trta='THSm2.2' then output ths;

        else if trta='mCC' then output mcc;

run;

proc sort data=sa (rename=(rawval=saval)) ;

    by avisitn avisit stat;

run;

proc sort data=ths (rename=(rawval=thsvall));

    by avisitn avisit stat;

run;

proc sort data=mcc (rename=(rawval=mccval));

    by avisitn avisit stat;

run;

data stat_&parm;

    merge sa (drop=trta ) ths (drop=trta) mcc;

        by avisitn avisit stat;

        if stat='N' then do; stat='n'; sort=1; end;

        else if stat='MISSC'      then do; stat='Missing, n(%)'; sort=2; end;

    else if stat='MEANSd' then do; stat='Mean (SD)'; sort=2.2; end;

        else if stat='ACI' then do; stat='95% CI'; sort=3; end;

        else if stat='MEDIAN' then do; stat='Median'; sort=4; end;

        else if stat='QUART' then do; stat='Q25, Q75'; sort=5; end;

    else if stat='MINMAX' then do; stat='Min, Max'; sort=6; end;

    order=&num;

```



```
run;
```

```
%mend rawval;
```

```
%rawval (parmcd=WEIGHT,parm=bw, num=1);
```

```
%rawval (parmcd=WSTCIR,parm=wc, num=2);
```

```
data stat_bwwc;
```

```
    set stat_bw stat_wc;
```

```
run;
```

```
proc sort data=stat_bwwc nodupkey;
```

```
    by order avisitn avisit sort;
```

```
run;
```

```
data stat_bwwc_fas ;
```

```
    length param $50;
```

```
    set bpstat_weight (where=(avisitn in (98 191)))
```

```
        bpstat_wstcir (where=(avisitn in (98 191)));
```

```
        if paramcd='WEIGHT' then do; paramn = 1015; param='Weight (kg)'; end;
```

```
        else if paramcd='WSTCIR' then do; paramn = 1026; param='Waist Circumference  
(cm)'; end;
```

```
        logf=0;
```

```
run;
```

```
%m_chglength(inds=stat_bwwc_fas,varlist=param paramcd, lenlist= $60 $8);
```

```
proc sort data=stat_bwwc_fas out=tflds.T_15_02_04_33_02_f;
```

```
by paramn avisitn ;
```

```
run;
```

```
/*Bring in sbp and dbp percent change data from ADVS*/
```

```
%macro pchgval (paramcd=,parm=, num=);
```

```
data advs_bp;
```

```
set adam.advs(where=(anl01fl='Y' and fasfl='Y' and paramcd in ("&paramcd")));
```

```
run;
```

```
data advs_bp ;
```

```
set advs_bp ;
```

```
if ablfl ='Y' then do; avisit='Baseline'; avisitn=98; end;
```

```
if avisit='Screening' and ablfl =" then delete;
```

```
else if avisit='Day -2' and ablfl =" then delete;
```

```
else if avisit='Day -1' and ablfl =" then delete;
```

```
else if avisit='Day 0' and ablfl =" then delete;
```

```
run;
```

```
proc sort data=advs_bp ;
```

```
by trtan trta avisitn avisit;
```

```
run;
```

```

proc means data=advs_bp noprint;

/* where avisitn in (98 106 130 160 191);*/

var pchg;

by trtan trta avisitn avisit;

output out=pbpstat n=n1 mean=mean1 std=sd1 median=median1 min=min1 max=max1 q1=q1 q3=q3
lclm =lci1 uclm=uci1;

run;


data pbpstat1;

set pbpstat;

attrib meansd minmax n median missc quart length=$20.;

            if &num=2 then do;

n = left(compress(put(n1,8.)));

                                *for <missing, n(%)>;

                                if trtan=3 then do;

                                                                if &trt3.=n1 then

missc="";

                                                                else

missc=strip(put((&trt3.- n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 8.1)) || ")";

                                                                end;

                                else if trtan=4 then do;

                                                                if &trt4.=n1 then

missc="";

                                                                else

missc=strip(put((&trt4.- n1), 8.)) || ' (' || strip(put(((&trt4.-n1)*100)/&trt4., 8.1)) || ")";

```

```

end;

else if trtan=5 then do;

if &trt5.=n1

then missc="";

else

missc=strip(put((&trt5.-n1), 8.)) || ' (' || strip(put(((&trt5.-n1)*100)/&trt5., 8.1)) || ")";

end;

IF NOT MISSING(MEDIAN1) THEN MEDIAN =
LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.1),10.1)));

IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.1),10.1))) || " (" || STRIP(PUT(0.01*CEIL(SD1/0.01),10.2)) || ")";

IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.)) || ",
" || strip(put(max1, 10.));

IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.1),10.1))) || ', ' || LEFT(COMPRESS(PUT(ROUND(Q3,0.1),10.1))));

IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI = STRIP(PUT(0.1*FLOOR(LCI1/0.1),10.1)) || ',
' || STRIP(PUT(0.1*CEIL(UCI1/0.1),10.1));

end;

else if &num=1 then do;

n = left(compress(put(n1,8.)));

*for <missing, n(%)>;

if trtan=3 then do;

if &trt3.=n1 then

missc="";

else

missc=strip(put((&trt3.- n1), 8.)) || ' (' || strip(put(((&trt3.-n1)*100)/&trt3., 8.1)) || ")";

end;

```

```

else if trtan=4 then do;

if &trt4.=n1 then

missc="";

else

missc=strip(put((&trt4.-n1), 8.)) || ' (' || strip(put(((&trt4.-n1)*100)/&trt4., 8.1)) || ")";

end;

else if trtan=5 then do;

if &trt5.=n1

then missc="";

else

missc=strip(put((&trt5.-n1), 8.)) || ' (' || strip(put(((&trt5.-n1)*100)/&trt5., 8.1)) || ")";

end;

IF NOT MISSING(MEDIAN1) THEN MEDIAN =
LEFT(COMPRESS(PUT(ROUND(MEDIAN1,0.01),10.2)));

IF NOT MISSING(MEAN1) AND NOT MISSING(SD1) THEN meansd =
LEFT(COMPRESS(PUT(ROUND(MEAN1,0.01),10.2))) || "
(" || STRIP(PUT(0.001*CEIL(SD1/0.001),10.3)) || ")";

IF NOT MISSING(MIN1) AND NOT MISSING(MAX1) THEN minmax = strip(put(min1, 10.1)) || ",
" || strip(put(max1, 10.1));

IF NOT MISSING(Q1) AND NOT MISSING(Q3) THEN QUART =
LEFT(COMPRESS(PUT(ROUND(Q1,0.01),10.2))) || ', ' || LEFT(COMPRESS(PUT(ROUND(Q3,0.01),10.2))));

IF NOT MISSING(LCI1) AND NOT MISSING(UCI1) THEN ACI = STRIP(PUT(0.01*FLOOR(LCI1/0.01),10.2))
|| ', ' || STRIP(PUT(0.01*CEIL(UCI1/0.01),10.2));

end;

drop n1 mean1 sd1 median1 min1 max1 q1 q3 lci1 uci1 _type__freq_;

run;

proc sort data=pbpstat1;

by trtan trta avisitn avisit;

```

```
run;
```

```
proc transpose data=pbpstat1 out=t_pbpstat1;
```

```
by trtan trta avisitn avisit;
```

```
var n missc meansd minmax median quart aci;
```

```
run;
```

```
data psa pths pmcc;
```

```
length stat pchg $50;
```

```
set t_pbpstat1 (drop=trtan rename=( _name_ =stat col1=pchg)) ;
```

```
if trta='SA' then output psa;
```

```
else if trta='THSm2.2' then output pths;
```

```
else if trta='mCC' then output pmcc;
```

```
run;
```

```
proc sort data=psa (rename=(pchg=sapchg));
```

```
by avisitn avisit stat;
```

```
run;
```

```
proc sort data=pths (rename=(pchg=thspchg));
```

```
by avisitn avisit stat;
```

```
run;
```

```
proc sort data=pmcc (rename=(pchg=mccpchg));
```

```
by avisitn avisit stat;
```

```
run;
```

```

data stat_&parm;

merge psa (drop=trta) pths (drop=trta) pmcc;

        by avisitn avisit stat;

        if stat='N' then do; stat='n'; sort=1; end;

        else if stat='MISSC'      then do; stat='Missing, n(%)'; sort=2; end;

else if stat='MEANSD' then do; stat='Mean (SD)'; sort=2.2; end;

        else if stat='ACI' then do; stat='95% CI'; sort=3; end;

        else if stat='MEDIAN' then do; stat='Median'; sort=4; end;

        else if stat='QUART' then do; stat='Q25, Q75'; sort=5; end;

        else if stat='MINMAX' then do; stat='Min, Max'; sort=6; end;

        order=&num;

run;

%mend;

%pchgval (parmcd=WEIGHT,parm=bwpchg, num=1);

%pchgval (parmcd=WSTCIR,parm=wcpchg, num=2);

data stat_bwwcpchg ;

    set stat_bwpchg stat_wcpchg;

run;

proc sort data=stat_bwwcpchg nodupkey;

    by order avisitn avisit sort;

run;

```

```

data stat;

    merge stat_bwwc (drop=stat trta) stat_bwwcpchg;

        by order avisitn avisit sort;

run;


proc sort data=stat;

    by order avisitn sort;

run;


data stat;

    set stat;

        length param $100;

        if sapchg='0' then sapchg="";

        if thspchg='0' then thspchg="";

        if mccpchg='0' then mccpchg="";

        if order=1 then param='Body weight (kg)';

        else if order=2 then param='Waist circumference (cm)';

        if sort=. then delete;

        if avisitn =130 and order =2 then delete;

        if stat='Missing, n(%)' and avisit='Baseline' then do;

            if saval="" then saval='0';

```



```

        if mccval="" then mccval='0';

        if thsval="" then thsval='0';

        sapchg="";

        mccpchg="";

        thspchg="";

    end;

    else if stat='Missing, n(%)' and avisit ^= 'Baseline' then do;

        if saval="" then saval='0';

        if mccval="" then mccval='0';

        if thsval="" then thsval='0';

        if sapchg="" then sapchg='0';

        if mccpchg="" then mccpchg='0';

        if thspchg="" then thspchg='0';

    end;

    if avisit='Baseline' and saval='0' and mccval='0' and thsval='0' then delete;

    if avisit ^= 'Baseline' and saval='0' and mccval='0' and thsval='0' and sapchg='0'
and mccpchg='0' and thspchg='0' then delete;

run;

* output dataset*;

proc sql noprint;

    create table tflds.&tflno as

    select param as parameter, avisit as timepoint, stat, thsval, thspchg, mccval, mccpchg, saval,
sapchg

    from stat

```

```
        order by param, order, avisitn, sort;;
```

```
quit;
```

```
data paging;
```

```
    set stat;
```

```
    by order avisitn sort;
```

```
    if first.avisitn then ln=1; /*Amend to look presentable, and avoid page overflows*/
```

```
    else ln+1;
```

```
    if ln=1 then page+1;
```

```
    call symput("page",compress(put(page,best.)));
```

```
run;
```

```
data paging;
```

```
    set paging;
```

```
        by page;
```

```
            if first.page then param=param;
```

```
            else param="";
```

```
run;
```

```
options number nodate orientation=landscape papersize=Letter /*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.t106343 (read) ;

ods results off;

ods rtf toc_data file="/cvn/projects/prj/data/000000106343/TFL/&TFL_Part./Tables/&tflno..rtf"
style=t106343 startpage=yes headery=1440 footery=1440 ;

ods noproctitle;

%do i=1 %to &page;


title ;

footnote;

ods proclabel = ' ';


data comp;

    set paging end=eof;

        where page=&i;


/* Amend title as needed */

    _firtitl="Table 15.2.4.33.2 Descriptive Statistics of Body weight (kg) and waist circumference (cm) -
FAS";

    _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;

drop _firtitl _upcas len;

run;

ods proclabel = ' ';

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;

proc report data = comp headline headskip nowd split = '#' /*ps = 60 ls = 120*/%if &i=1 %then %do;
contents=' ' %end; %else %do; contents="" %end;;

        column order page avisitn param avisit stat

                ("THSm2.2#(N=&trt4)&linebot" thsval thspchg) ("mCC#(N=&trt5)&linebot" mccval
mccpchg) ("SA#(N=&trt3)&linebot" saval sapchg);

        define order      / order order = internal noprint;

define page      / order order = internal noprint;

define avisitn    / order order=internal noprint;

define param      / "Parameter (units)" style={just=left cellwidth=2.5cm} style(header)={just=left} ;

                define avisit    / group "Timepoint" style={just=left cellwidth=2.5cm}
style(header)={just=left} ;

```

```

define stat      / display "Statistic" style={just=left cellwidth=2cm} style(header)={just=left} ;
define thsval    / display "Raw value" style={just=c cellwidth=2cm} ;
define thspchg   / display "% Change(*)" style={just=c cellwidth=2cm} ;
define mccval    / display "Raw value" style={just=c cellwidth=2cm} ;
define mccpchg   / display "% Change(*)" style={just=c cellwidth=2cm} ;
define saval     / display "Raw value" style={just=c cellwidth=2cm} ;
define sapchg    / display "% Change(*)" style={just=c cellwidth=2cm} ;

```

```

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: mCC = Menthol conventional cigarettes; SA = Smoking abstinence; THSm2.2 =  
Tobacco Heating System 2.2 Menthol.';
```

```
line "Note: Percentages are based on the number of subjects indicated in the column header (N).";
```

```
line 'Note: * % change from baseline, where baseline is defined as the last assessment  
prior to first randomized product use in mCC / THS 2.2 Menthol arms or the';
```

```
line 'last assessment prior to 10 AM on Day 1 in the SA arm.';
```

```
line ' ';
```

```
line "Appendix 15.3.6.12";
```

```
line "Study ID:ZRHM-REXA-08-US Program:&TFLprg Status: &status" &_blankn.*"\~\"  
"&sysdate" &_blankn.*"\~\" "(Page &i of &page)";
```

```
endcomp;
```

```
run;
```

```
%end;
```

```
ods rtf close;
```

```
ods results on;
```

```
ods path sashelp.tmplmst (read);
```

```
%mend ;
```

```
%outrtf(blankn=36, halfblank=N);
```

```
ods listing close;
```

```
proc printto ; run;
```

```
%m_logchk;
```

```
*=====;
```

\* END OF PROGRAM CODE ;

\*=====;