

```

%_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_vit.sas;
%put NOTE: Purpose              : table of vital signs;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADVS ADAM.ADSL;
%put NOTE: Output               : t_15_2_6_16(vs);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jriley;
%put NOTE: Creation Date        : 2014-07-24;
%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: 04Aug2014   JR        1) Stats not summarised if n < 4;
%put NOTE: 04Aug2014   JMH       2) Amended update 1);
%put NOTE: 18Sep2014   JR        3) Amended baseline footnote;
%put NOTE: 19Sep2014   KB        4) Amended page overflow;
%put NOTE: 19Sep2014   KB        5) Amended footnote;
%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_16(vs);

%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;

```

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*****;
* 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);
run;

data dumtrts; /*Use this to output any columns for which N=0*/
    attrib trt01a length =$40.
                trt01an length=8.;
    trt01an=1;
    trt01a='THS 2.2';
    output;
    trt01an=2;
    trt01a='CC';
    output;
    trt01an=3;
    trt01a='SA';
    output;
    trt01an=97;
    trt01a='Enrolled not randomized';
    output;
run;

data tot2;
    merge tot(in=a) dumtrts(in=b);
    by trt01an trt01a;
    if a or b;
    if b and not a then count=0;
    call symput('trt' || compress(put(trt01an,best.))),
compress(count));
run;

/*Bring in appropriate data from ADVS*/
data advs;
    set adam.advs;
    where saffl = 'Y' and anl01fl='Y';
    if missing(trta) then delete;
    if index(paramcd,'SU')=0 then delete;
    if index(trta,'Exposed') then delete;

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        output;
        trtan=99;
        trta='Overall Safety';
        output;
run;

data advs_orig;
    set advs;
    if ablfl='Y' then do; avisitn=100; avisit='Baseline'; end;
    if avisit ne 'Baseline' and avisitn lt 101 then delete; /*Only want
baseline and days of the study*/
    else if avisitn=100 then ord=0; /*Baseline*/
    else if avisitn=101 then ord=1; /*Day 1*/
    else if avisitn=102 then ord=2; /*Day 2*/
    else if avisitn=103 then ord=3; /*Day 3*/
    else if avisitn=104 then ord=4; /*Day 4*/
    else if avisitn=105 then ord=5; /*Day 5*/
    else if avisitn=106 then ord=6; /*Discharge*/
    else put "WA" "RNING: Unexpected avisitn " usubjid= avisitn=;
    statval=aval;
run;

data advs_chg;
    set advs(where=(avisitn in(101 102 103 104 105 106))); /*Only keep
days after baseline*/
    if avisitn=101 then ord=1; /*Change from Baseline to Day 1*/
    else if avisitn=102 then ord=2; /*Change from Baseline to Day 2*/
    else if avisitn=103 then ord=3; /*Change from Baseline to Day 3*/
    else if avisitn=104 then ord=4; /*Change from Baseline to Day 4*/
    else if avisitn=105 then ord=5; /*Change from Baseline to Day 5*/
    else if avisitn=106 then ord=6; /*Change from Baseline to
Discharge*/
    else put "WA" "RNING: Unexpected avisitn " usubjid= avisitn=;
    statval=chg;
run;

/*Transpose for raw values*/
proc sort data=advs_orig;
    by trtan trta paramn ord param avalu avisit;
run;

proc univariate data=advs_orig noprint;
    var statval;
    by trtan trta paramn ord param avalu avisit;
    output out=results01_orig n=nlo mean=meanlo std=stdlo median=medlo
min=minlo max=maxlo;
run;

/*Transpose for change from baseline values*/
proc sort data=advs_chg;
    by trtan trta paramn ord param avalu avisit;
run;

proc univariate data=advs_chg noprint;

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var statval;
by trtan trta paramn ord param avalu avisit;
output out=results01_chg n=n1c mean=mean1c std=std1c median=med1c
min=min1c max=max1c;
run;

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data results01;
merge results01_orig results01_chg;
by trtan trta paramn ord param avalu avisit;
run;

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data results02;
set results01;
/* Start 1) JR 04Aug2014 */
IF N1O GE 4 THEN DO;
attrib meansdo length=$100.
minmaxo length=$100.
no length=$100.
mediano length=$100.;

no = left(compress(put(n1o,8.)));
if not missing(medlo) then mediano =
left(compress(put(medlo,8.1)));
if not missing(meanlo) and not missing(stdlo) then
meansdo = left(compress(put(meanlo,8.1))) || ' (' ||
compress(put(0.01*ceil(stdlo/0.01),8.2)) || ')';
if not missing(minlo) and not missing(maxlo) then
minmaxo = left(compress(put(minlo,8.))) || ', ' ||
left(compress(put(maxlo,8.)));
END;
/* 2) start JMH 04Aug2014 */
/* ELSE DO; */
/* NO='0'; */
/* MEDIANO=''; */
/* MEANSDO=''; */
/* MINMAXO=''; */
ELSE IF N1O NE 0 THEN DO;
NO = LEFT(COMPRESS(PUT(N1O,8.)));
MEDIANO='NC';
MEANSDO='NC';
MINMAXO='NC';
END;
ELSE IF N1O=0 THEN DO;
NO = LEFT(COMPRESS(PUT(N1O,8.)));
MEDIANO='';
MEANSDO='';
MINMAXO='';
END;
/* 2) END JMH 04Aug2014 */

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IF N1C GE 4 THEN DO;
attrib meansdc length=$100.
minmaxc length=$100.
nc length=$100.

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                                medianc length=$100.;

                                nc          = left(compress(put(nlc,8.)));
                                if not missing(medlc) then medianc =
left(compress(put(medlc,8.1)));
                                if not missing(meanlc) and not missing(stdlc) then
meansdc = left(compress(put(meanlc,8.1))) || ' (' ||
compress(put(0.01*ceil(stdlc/0.01),8.2)) || ')';
                                if not missing(minlc) and not missing(maxlc) then
minmaxc = left(compress(put(minlc,8.))) || ', ' ||
left(compress(put(maxlc,8.)));
                                END;
/* 2) START JMH 04Aug2014 */
/*          ELSE DO; */
/*          NC='0'; */
/*          MEDIANC=''; */
/*          MEANSDC=''; */
/*          MINMAXC=''; */
ELSE IF N1C NE 0 THEN DO;
    NC = LEFT(COMPRESS(PUT(N1C,8.)));
    MEDIANC='NC';
    MEANSDC='NC';
    MINMAXC='NC';
END;
ELSE IF N1C = 0 OR MISSING(N1C) THEN DO;
    NC = LEFT(COMPRESS(PUT(N1c,8.)));
    MEDIANC='';
    MEANSDC='';
    MINMAXC='';
END;

IF AVISIT='Baseline' THEN DO;
    NC = '';
    MEDIANC='';
    MEANSDC='';
    MINMAXC='';
END;
/* 2) END JMH 04Aug2014 */
/* end 1) JR 04Aug2014 */
    drop nlo meanlo stdlo medlo minlo maxlo nlc meanlc stdlc medlc
minlc maxlc;

    if index(meansdo,'-0.0') then meansdo=tranwrd(meansdo,'-0.0','0.0');
    if index(meansdc,'-0.0') then meansdc=tranwrd(meansdc,'-
0.0','0.0');
run;

data results03; /*Create text as required in output*/
    set results02;
    attrib paramc length = $100.
                                visit length = $100.;

    if avalu='BREATHS/MIN' then avalu=tranwrd(avalu,'/','/$n');

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        if paramn=1 then paramc=strip(param)||' ('||strip(avalu)|| ')';
        else if paramn=2 then paramc=strip(param)||' ('||strip(avalu)||')';
        else if paramn=3 then paramc=strip(param)||'
('||strip(LOWCASE(avalu))||')';
        else if paramn=4 then paramc=strip(param)||'
('||strip(LOWCASE(avalu))|| ')';

        visit=avisit;
run;

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

proc transpose data=results03 out=results04_orig1 prefix=o name=varname;
    by paramn paramc ord visit;
    var no meansdo mediano minmaxo;
    id trtan;
    idlabel trta;
run;

data results04_orig;
    set results04_orig1;
    varname=tranwrd(varname,'O','C');
run;

proc transpose data=results03 out=results04_chg prefix=c name=varname;
    by paramn paramc ord visit;
    var nc meansdc medianc minmaxc;
    id trtan;
    idlabel trta;
run;

proc sort data=results04_orig;
    by paramn paramc ord visit varname;
run;

proc sort data=results04_chg;
    by paramn paramc ord visit varname;
run;

data results04;
    merge results04_orig results04_chg;
    by paramn paramc ord visit varname;
run;

data results05;
    set results04;
    attrib stat length = $100.;
    if varname='NC' then do; statord=1; stat='n'; end;
    else if varname='MEANSDC' then do; statord=2; stat='Mean (SD)';
end;

    else if varname='MEDIANC' then do; statord=3; stat='Median'; end;
    else if varname='MINMAXC' then do; statord=4; stat='Min, Max'; end;

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        drop varname;
run;

data results06;
    set results05;
    if stat='n' then do;
        if missing(o1) then o1='0';
        if missing(o2) then o2='0';
        if missing(o3) then o3='0';
        if missing(o97) then o97='0';
        if missing(o99) then o99='0';
    if ord ne 0 then do;
        if missing(c1) then c1='0';
        if missing(c2) then c2='0';
        if missing(c3) then c3='0';
        if missing(c97) then c97='0';
        if missing(c99) then c99='0';
    end;
end;

run;

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

data allresults;
    set results06;
    by paramn paramc ord statord;

    flag=1;
run;

data labels;
    set allresults;
    attrib
        o1 label = "Raw value"
        o2 label = "Raw value"
        o3 label = "Raw value"
        o97 label = "Raw value"
        o99 label = "Raw value"
        c1 label = "Change"
        c2 label = "Change"
        c3 label = "Change"
        c97 label = "Change"
        c99 label = "Change";

    /* 2) START JMH 04Aug2014 */
    /* 1) JR 04Aug2014 */
    /*IF STATORD = 1 AND ORD=0 THEN DO; */
    /*    IF O1 NE '0' THEN C1='';*/
    /*    IF O2 NE '0' THEN C2='';*/
    /*    IF O3 NE '0' THEN C3='';*/
    /*    IF O97 NE '0' THEN C97='';*/

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/*      IF O99 NE '0' THEN C99=''; */
/*END; */
/* 2) END JMH 04Aug2014 */
run;

proc sql noprint;

create table table.t_15_02_06_16 as
select paramc, visit, stat, o1, c1, o2, c2, o3, c3, o97, c97, o99, c99
from labels
order by paramn, ord, statord;

quit;

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

data paging;
    set labels;
    by paramn ord statord;

    flag=1;

    if first.ord and ln ge 10 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;

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.t106324 (read) ;
ods results off;
ods rtf toc_data/* contents*/
file="/cvn/projects/prj/data/000000106324/TFL/&TFL_Part./&tflno..rtf"
style=t106324 startpage=yes headery=1440 footery=1440 ;
ods noproctitle;
%do i=1 %to &page;

title ;

```



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footnote;
%let wd=0;
%let subpage=2;
%LET NC=0; /* 2) JMH 04Aug2014 */

%do j=1 %to &subpage;

%let maxpage=%eval(&page*&subpage);

%let npage=%eval(&subpage*&i+&j-&subpage);

ods proclabel = ' ';

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

    /* 2) START JMH 04Aug2014 */
    %IF &J=1 %THEN %DO;
        IF INDEX(O1,'NC') OR INDEX(O2,'NC') OR INDEX(O3,'NC')
        OR INDEX(C1,'NC') OR INDEX(C2,'NC') OR INDEX(C3,'NC') THEN
CALL SYMPUT('NC',1);
    %END;
    %ELSE %IF &J=2 %THEN %DO;
        IF INDEX(O97,'NC') OR INDEX(O99,'NC') OR INDEX(C97,'NC') OR
INDEX(C99,'NC') THEN CALL SYMPUT('NC',1);
    %END;
    /* 2) END JMH 04Aug2014 */

        _firtitl="Table 15.2.6.16 Summary of Supine Vital Signs -
Safety Population";
        _upcas=(length("Path: &TFLpath.")-
length(compress("Path:&TFLpath.",'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;
        len=&blankn.-length("(Page &npage of &maxpage)");
        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;
ods listing close;
proc report data = comp missing headline headskip nowd split = '$'
SPANROWS %if &i=1 and &j=2 %then %do; contents=' ' %end; %else %do;
contents=' ' %end;; /* 4) KB 19Sep2014 */

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```

column flag page paramn paramc ord visit statord stat %if &j=1
%then %do; ("THS 2.2 $(N=&trt1) &linebot" o1 c1) ("CC $(N=&trt2)
&linebot" o2 c2) ("SA $(N=&trt3) &linebot" o3 c3) %end;

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%else %if &j=2 %then %do; ("Enrolled Not$Randomized$(N=&trt97)
&linebot" o97 c97) ( "Overall$Safety$(N=&trt99) &linebot" o99 c99) %end;;

```

```

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=2.2cm}
style(header)={just=center} 'Parameter$(units)';
define visit         / group style={just=left cellwidth=1.7cm}
style(header)={just=center} 'Study Day';
define stat          / display style={just=left
cellwidth=1.8cm} style(header)={just=center} 'Statistic';
%if &j=1 %then %do;
define o1            / display style={just=center
cellwidth=1.4cm} style(header)={just=center};
define c1            / display style={just=center
cellwidth=1.4cm} style(header)={just=center};
define o2            / display style={just=center
cellwidth=1.4cm} style(header)={just=center};
define c2            / display style={just=center
cellwidth=1.4cm} style(header)={just=center};
define o3            / display style={just=center
cellwidth=1.4cm} style(header)={just=center};
define c3            / display style={just=center
cellwidth=1.4cm} style(header)={just=center};
%end;
%else %if &j=2 %then %do;
define o97           / display style={just=center
cellwidth=2.2cm} style(header)={just=center};
define c97           / display style={just=center
cellwidth=2.2cm} style(header)={just=center};
define o99           / display style={just=center
cellwidth=1.5cm} style(header)={just=center};
define c99           / display style={just=center
cellwidth=1.5cm} 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;

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```

compute after ord;
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: CC = Conventional cigarettes; SA = Smoking
abstinence; THS = Tobacco Heating System.';
  line 'Note: Enrolled Not Randomized refers to all subjects
who were enrolled but not randomized. Overall Safety refers to enrolled
subjects exposed to THS 2.2.';
  line 'Note: Change is change from baseline, where 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.'; /* 3) JR
18Sep2014 */
/*      line 'Note: Change is change from baseline, where baseline is
defined as the last assessment prior to 06:29 AM on Day 1.';*/
  %IF &NC=1 %THEN %DO; /* 2) JMH 04Aug2014 */
/*      LINE 'NC = Not calculated';*/
  LINE 'Note: NC = Not calculated'; /* 5) KB 19Sep2014 */
  %END;
  line ' ';
  line 'Appendix 15.3.6.7';
  line "Path: &TFLpath." &_blankn.*"\~\~" "(Page &npage of
&maxpage)"; ;
  line "Program Run: &sysdate   &sysuserid   Program Status:
&status";
endcomp;
run;
%end;
%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_16.lst" new;
run;

proc contents data = table.t_15_02_06_16 varnum;
run;
ods listing close;

proc printto ; run;

```

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