

```

%_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_adv6.sas;
%put NOTE: Purpose              : table of adverse eventsrelated to study
procedure by organ class and preferred term;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADAE;
%put NOTE: Output               : t_15_2_6_6(ae);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jhardman;
%put NOTE: Creation Date        : 2014-07-04;
%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:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

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

/* Standard - just change the number to match the listing you're working
on. Also change the letters in the*/
/* bracket, eg ccb = current cigarette brands. Make sure to do this at
the top of the code too. */

      %let tflno=T_15_02_06_06(ae);

/* Standard - leave this */
%let TFL_Part=%scan(&_SASPROGRAMFILE,-3,%str(/));

/* Standard - leave this */
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 ;
*****;

data adsl;
    set adam.adsl;
    where saffl = 'Y';
    attrib headtext1 length =$200.
                headorder1 length=8.;

    if missing(trt01a) or trt01a='Screen failure' then delete;
    if index(trt01a,'Enroll') then do;
        trt01an=98;
        trt01a='Exposed not randomized';
    end;
    headorder1=trt01an;
    headtext1=trt01a;
    output;
    trt01an=99;
    headorder1=99;
    trt01a='Overall Safety';
    headtext1='Overall Safety';
    output;
run;

data dumtrts; /*Use this to output any columns for which N=0*/
    attrib headtext1 length =$200.
                headorder1 length=8.;

    headorder1=1;
    headtext1='THS 2.2';
    output;
    headorder1=2;
    headtext1='CC';
    output;
    headorder1=3;
    headtext1='SA';
    output;
    headorder1=98;
    headtext1='Exposed not randomized';
    output;
run;

proc freq data=adsl noprint;
    table headorder1*headtext1/ out =tot(drop=percent);
run;

data tot2;
    merge tot(in=a) dumtrts(in=b);
    by headorder1 headtext1;

```

```

        if b and not a then count=0;
        call symput('trt' || compress(put(headorder1,best.)),
compress(count));
run;

/*Now bring in AE data*/
data ae(drop=aebodsys1 aeecod1);
    set adam.adae(rename =(aebodsys=aebodsys1 aeecod=aeecod1));
    where saffl='Y' and anyae1='Y' and anl01fl='Y' and aerelsp
in('RELATED' 'Related');
    attrib headtext1 length =$200.
                                headorder1 length=8.
                                aebodsys length=$200.
                                aeecod length=$200.;

    aebodsys=aebodsys1;
    aeecod=aeecod1;
    if missing(trta) or trta='Screen failure' then delete;
    if missing(aebodsys) then aebodsys='Missing';
    if index(trta,'Enroll') then do;
        trtan=98;
        trta='Exposed not randomized';
    end;
    headorder1=trtan;
    headtext1=trta;
    output;
    headorder1=99;
    headtext1='Overall Safety';
    output;
run;

proc sort data=ae; by headorder1 headtext1; run;

data adverse02;
    set ae;
run;

* Create an additional observation with missing VOL value for each table
section;
* This is used to ensure that all table rows are output, even for rows
with no adverse events;

data adverse03;
    set adverse02;
    output;
    aebodsys='Any Adverse events';
    output;
run;

/** Number of Ae's overall **/
proc freq data=adverse03 noprint;
    tables headorder1*headtext1*aebodsys / out=ovall(rename=(count=tot)
drop=percent);
run;

```

```

    /*** getting number of subjects studied ***/
proc sort data=adverse03 out=nae3 nodupkey;
    by headorder1 headtext1 aebodsys subjidn;
run;

proc freq data=nae3 noprint;
    tables headorder1*headtext1*aebodsys/ out=novall(rename=(count=ntot)
drop=percent);
run;

data otot;
    merge oval1 novall;
    by headorder1 headtext1 aebodsys;
run;

/*** number of subjects and aes in overall **/
data overall;
    set otot;
        if aebodsys='Any Adverse events' then sort2=1;
        else sort2=2;
    sort3=0;
run;

data body2;
    set overall;
        if aebodsys='Any Adverse events' then do; sort2=1; sort3=0;
end;
        else do; sort2=2; sort3=0; end;
run;

/** bodysystem by prefterm **/
proc freq data=adverse03 noprint;
    tables headorder1*headtext1*aebodsys*aedecod /
out=preft(rename=(count=tot) drop=percent);
run;

/*** getting number of subjects studied ***/
proc sort data=adverse03 out=npae2 nodupkey;
    by headorder1 headtext1 aebodsys aedecod subjidn;
run;

proc freq data=npae2 noprint;
    tables headorder1*headtext1*aebodsys*aedecod /
out=npreftr(rename=(count=ntot) drop=percent);
run;

data prefterm;
    merge preft npreftr;
    by headorder1 headtext1 aebodsys aedecod;
run;

data aedecod;
    set prefterm;

```

```

        if aebodsys='Any Adverse events' then do; sort2=1; sort3=0;
end;
    else do; sort2=2; sort3=1; end;
run;

/*Set together the body systems on their own, and the body systems with
preferred terms*/
data all;
    set overall aedecod;
run;

proc sort data=all out=all2;
    by headorder1 headtext1 sort2 aebodsys aedecod;
run;

data format;
    merge all2(in=a) dumtrts tot;
    by headorder1 headtext1;
        if not a then do;
            sort2=1;
            sort3=0;
            aebodsys='Any Adverse events';
        end;
run;

data format2;
    set format;
    attrib text text2 text3 format=$200.;
    /* Percentage of subjects*/
    if not missing(count) then percent=put((ntot/count)*100,8.1);
    else percent='0';

    /* display variables*/

        /*          else text=put(ntot,3.)||'
('||compress(put(percent,8.1))||')';*/

        /*n value*/
        if missing(ntot) then text='0';
        else text=put(ntot,3.);

        /*% value*/
        if missing(percent) then text3='';
        else if percent=100 then text3='(100 %)';
        else if percent ge 10 then text3='(
'||compress(put(percent,8.1))||'%)';
        else if percent lt 10 then text3='(
'||compress(put(percent,8.1))||'%)';

        /*events value*/
        if missing(tot) then text2='';
        else text2=compress(put(tot,3.));

```

```

        if aebodsys='Any Adverse events' and not missing(aedecod)
then delete;
        drop percent;
run;

proc sort data=format2 nodupkey; by headorder1 headtext1 aebodsys
tot ntot sort2 sort3 aedecod count text text3 text2; run;

proc sort data=format2; by headorder1 headtext1 sort2 aebodsys sort3
aedecod; run;

proc sort data=format2 out=format3; by sort2 aebodsys sort3 aedecod;
run;

/*Transpose n values*/
proc transpose data=format3 out=nformat prefix=n;
  by sort2 aebodsys sort3 aedecod;
  var text;
  id headorder1;
  idlabel headtext1;
run;

/*Transpose % values*/
proc transpose data=format3 out=performat prefix=p;
  by sort2 aebodsys sort3 aedecod;
  var text3;
  id headorder1;
  idlabel headtext1;
run;

/*Transpose event values*/
proc transpose data=format3 out=eformat prefix=e;
  by sort2 aebodsys sort3 aedecod;
  var text2;
  id headorder1;
  idlabel headtext1;
run;

data tformat;
  merge nformat eformat performat;
  by sort2 aebodsys sort3 aedecod;
run;

data tsort2;
  set tformat;
  n99n=input(n99,8.);
  e99n=input(e99,8.);
run;

proc sort data=tsort2 out=allsorts;
  by sort2 sort3 descending n99n descending e99n aebodsys;
run;

```

```

/* Create a variable to sort body systems by most frequent - ODD*/
data sorting;
  set allsorts(where=(sort2=2 and sort3=0) keep=sort2 aebodsys sort3
n99n e99n);
  by sort2 sort3 descending n99n descending e99n aebodsys;
  if first.aebodsys then odd+1;
  keep sort2 aebodsys odd;
run;

/*Merge this back onto data so that ODD (the ordering variable for body
systems) is merged onto all preferred terms*/
proc sort data=allsorts; by sort2 aebodsys; run;
proc sort data=sorting; by sort2 aebodsys; run;

data sorting2;
  merge sorting allsorts;
  by sort2 aebodsys;
run;

proc sort data=sorting2;
by sort2 odd sort3 descending n99n descending e99n aeDecod;
run;

/*Now create a variable to sort preferred terms within each body system
by most frequent - ODD2*/
data sorting3;
  set sorting2(where=(sort2=2 and sort3=1) keep=sort2 aebodsys odd
sort3 aeDecod n99n e99n);
  by sort2 odd sort3 descending n99n descending e99n aeDecod;
  if first.aeDecod then odd2+1;
  keep sort2 aebodsys odd sort3 aeDecod odd2;
run;

/*Merge this back onto data so that ODD2 can be used to order the
preferred terms within body systems*/
proc sort data=sorting2; by sort2 odd aebodsys sort3 aeDecod; run;
proc sort data=sorting3; by sort2 odd aebodsys sort3 aeDecod; run;

data sorting4;
  merge sorting2 sorting3;
  by sort2 odd aebodsys sort3 aeDecod;
run;

proc sort data=sorting4 out=final;
  by sort2 odd sort3 odd2;
run;

%macro empty();
%let dsid=%sysfunc(open(ae));
%let nsum1=%sysfunc(attrn(&dsid.,nobs));
%let rc=%sysfunc(close(&dsid.));

```

```

%if &nsum1. lt 1 %then %do;
data final3;
    flag=1; page=1; aeDecod=''; aeBodsys=.; sort2=.; sort3=.; odd=.;
odd2=.; column=.; column2=''; n1=.; n2=.; n3=.; n98=.; n99=.;
    p1=.; p2=.; p3=.; p98=.; p99=.; e1=.; e2=.; e3=.; e98=.;
e99=.; ln=1; noobs=1;
    output;
run;
%end;
%else %do;
data final2;
    set final;
    attrib column format=$200. label='Formatted text'
        column2 format=$200. label='Unformatted text';

/*Create indents as required in output*/
attrib wrap length = $200;
wrap = aeDecod;

i=21; *This is the max length allowed on a single line - change as
needed;
if length(wrap)>i then do;
    nwraps = int(length(wrap)/i); *Calculate how many lines the text will
wrap over;
    do while(nwraps > 0);
        fin=0;
        j = i*nwraps; *Calculate starting point - loop will cycle backwards
from this point looking for a space;
        do while(fin=0 and j gt 1);
            if substr(wrap,j,1)=' ' then do;
                wrap=substR(wrap,1,j-1) || " |S={foreground=white} . |S={} " ||
substr(wrap,j+1);
                fin=1;
            end;
            else j=j-1; *No space found - move back one character;
        end;
        nwraps=nwraps-1; *Once this wrap is handled, move up a line until all
are handled (when nwraps = 0);
    end;
end;

if sort3=1 then column2 = aeDecod;
if sort2=2 and sort3=0 then column2=trim(aeBodsys);
if sort2=1 then do; column2='Any adverse events related to study
procedure'; odd2=0; end;

if sort3=1 then column = "|S={foreground=white} . |S={} " || wrap ;
if sort2=2 and sort3=0 then column=trim(aeBodsys);
if sort2=1 then do; column='Any adverse events related to study
procedure'; odd2=0; end;

run;

```



```

/*Create code to set flags so we know which values should be set to blank
in the output*/
proc sort data=final2(where=(sort3=0)) out=blanks;
    by sort2 sort3;
run;

data blanks1;
    set blanks;
        if (n1=0 or missing(n1)) and (e1=0 or missing(e1)) then
del1=1;
        if (n2=0 or missing(n2)) and (e2=0 or missing(e2)) then
del2=1;
        if (n3=0 or missing(n3)) and (e3=0 or missing(e3)) then
del3=1;
        if (n98=0 or missing(n98)) and (e98=0 or missing(e98)) then
del98=1;
    keep sort2 sort3 aebodsys del;;
run;

proc sort data=final2; by sort2 aebodsys; run;
proc sort data=blanks1; by sort2 aebodsys; run;

data final3;
    merge final2 blanks1;
    by sort2 aebodsys;

    noobs=0;
run;

proc sort data=final3;
    by sort2 odd aebodsys sort3 odd2 ;
run;
%end;
%mend;
%empty();

data labels;
    set final3;
    attrib n1 label = " n"
           n2 label = " n"
           n3 label = " n"
           n98 label = " n"
           n99 label = " n"
           p1 label = '(%)'
           p2 label = '(%)'
           p3 label = '(%)'
           p98 label = '(%)'
           p99 label = '(%)'
           e1 label = "Events"
           e2 label = "Events"
           e3 label = "Events"
           e98 label = "Events"
           e99 label = "Events";

```

```

        if sort3=0 then do; /*Zero still wants to be displayed for body
system as this is hte top level*/
            del1=.;
            del2=.;
            del3=.;
            del98=.;

```

```

        end;
run;

```

```

data final4;
    set labels;

```

```

        array a [5] n1 n2 n3 n98 n99;
            array b [5] del1 del2 del3 del98 del99;
        array c [5] e1 e2 e3 e98 e99;
        do i=1 to 5;
            if b[i] ne 1 and noobs ne 1 then do;
                if missing(a[i]) then a[i] ='0';
                end;
                if length(left(strip(c[i])))=2 then c[i]=
'|S={foreground=white}.|S={} ' || left(strip(c[i]));
                if length(left(strip(c[i])))=1 then c[i]=
'|S={foreground=white} .|S={} ' || left(strip(c[i]));
            end;

```

```

                flag=1;

```

```

        run;

```

```

proc sql noprint;
    create table table.T_15_02_06_06 as
        select column, column2, n1, p1, e1, n2, p2, e2, n3, p3, e3, n98,
p98, e98, n99, p99, e99
        from final4
        order by sort2, odd, aebodsys, sort3, odd2;
quit;

```

```

data paging;
    set final4;
    by sort2 odd aebodsys sort3 odd2;
    if (ln gt 6 and first.odd) or ln gt 10 then ln=1;
    else ln+1;

```

```

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

```

```

        retain sort4;
        if first.aebodsys then sort4+1;
run;

```

```

/* Standard - leave this */
options nonumber 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;
/* Standard - macro for paging */
%macro outrtf(blankn=70, halfblnk=N);

%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;

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

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

    call symput('noobs',compress(noobs));

    /* Amend title as needed */
    _firtitl="Table 15.2.6.6 Summary of Adverse Events Related
to Study Procedure by System Organ Class";
    _upcas=(length("Path: &TFLpath.")-
length(compress("Path:&TFLpath.",'ABCDEFGHIJKLMNOPQRSTUVWXYZ')))/2;
    len=&blankn.-lengthH("(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 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;
/* 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 sort2 odd sort4 sort3 odd2 ("System Organ Class" column)
("THS 2.2 $(N=&trt1) &linebot" n1 p1 e1) ("CC$(N=&trt2) &linebot" n2 p2
e2)

("SA $(N=&trt3) &linebot" n3 p3 e3) ("Exposed
Not$Randomized$(N=&trt98) &linebot" n98 p98 e98)

("Overall$Safety$(N=&trt99) &linebot" n99 p99 e99); ;
define flag / order order = internal noprint;
define page / order order = internal noprint;
define sort2 / order order=internal noprint;
define odd / order order=internal noprint;
define sort4 / order order=internal noprint;
define sort3 / order order=internal noprint;
define odd2 / order order=internal noprint;

define column / group style={just=left cellwidth=3.4cm}
style(header)={just=center} "Preferred Term";
define n1 / display style={just=d cellwidth=0.5cm}
style(header)={just=right} ;
define p1 / display style={just=d cellwidth=1.2cm}
style(header)={just=center} ;
define e1 / display
style={JUST=left cellwidth=1.2cm} style(header)={just=l} ;
define n2 / display style={just=d cellwidth=0.5cm}
style(header)={just=right} ;
define p2 / display style={just=d cellwidth=1.2cm}
style(header)={just=center} ;
define e2 / display style={just=left
cellwidth=1.2cm } style(header)={just=l} ;
define n3 / display style={just=d cellwidth=0.5cm}
style(header)={just=right} ;
define p3 / display style={just=d cellwidth=1.2cm}
style(header)={just=center} ;
define e3 / display
style={just=left cellwidth=1.2cm} style(header)={just=l} ;
define n98 / display style={just=d cellwidth=0.5cm}
style(header)={just=right} ;
define p98 / display style={just=c cellwidth=1.2cm}
style(header)={just=center} ;
define e98 / display style={just=left
cellwidth=1.2cm} style(header)={just=l} ;
define n99 / display style={just=d cellwidth=0.5cm}
style(header)={just=right} ;
define p99 / display style={just=d cellwidth=1.2cm}
style(header)={just=center} ;
define e99 / display style={JUST=left
cellwidth=1.2cm} style(header)={just=l} ;

```

```

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

break after page / page;

%if &noobs. ne 1 %then %do;
    compute after sort4;
    line " ";
endcomp;
%end;

compute before page / style={protectspecialchars=off};
line "&linetop";
endcomp;

    compute after page/style={just=center cellwidth=5cm
protectspecialchars=off};
%if &noobs. = 1 %then %do;
    line "No adverse events related to study procedure were reported";
    line " ";
%end;
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 "\b\fs24\sa24and Preferred Term - Safety Population";
    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: Exposed Not Randomized refers to all subjects
exposed to THS 2.2 but not randomized. Overall Safety refers to all
subjects exposed to THS 2.2.';
    line 'Note: Percentages are based on the number of subjects
indicated in the column header (N).';
    line ' ';
    line 'Appendix 15.3.6.1.1';
    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_06.lst" new;
run;

proc contents data = table.T_15_02_06_06 varnum;
run;
ods listing close;

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