

```

%_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_adv6.sas;
%put NOTE: Purpose              : table of adverse events by organ class
and preferred term and relationship to product;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADAE;
%put NOTE: Output               : t_15_2_6_3(ae);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jhardman;
%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) Presented related rows for Any
adverse events;
%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_03(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';
  if missing(trtseql) then delete;
  if index(trtseql,'Enroll') then do;
    trtseql=6;
    trtseql='Exposed not randomized';
  end;
  headorder1=trtseql;
  headtext1=trtseql;
  output;
  trtseql=99;
  headorder1=99;
  trtseql='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 Menthol - mCC';
  output;
  headorder1=2;
  headtext1='mCC - THS 2.2 Menthol';
  output;
  headorder1=3;
  headtext1='THS 2.2 Menthol - NRT gum';
  output;
  headorder1=4;
  headtext1='NRT gum - THS 2.2 Menthol';
  output;
  headorder1=6;
  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;
    attrib aebodsys length=$200.;
    set adam.adae;
    where saffl='Y' and anyae1='Y' and anl01fl='Y';
    if missing(trtseqan) then delete;
    if missing(aebodsys) then aebodsys='Missing';
    if index(trtseqa,'Enroll') then do;
        trtseqan=6;
        trtseqa='Exposed not randomized';
    end;
    headorder1=trtseqan;
    headtext1=trtseqa;
    output;
    headorder1=99;
    headtext1='Overall Safety';
    output;
run;

```

```

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

```

```

data adverse02;
    set ae;
run;

```

```

proc sort data=adverse02; by headorder1 headtext1; 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;
    by headorder1 headtext1;
    output;
    aebodsys='Any Adverse events';
    output;
    if first.headorder1 then do;
        subjid = .;
        aebodsys='not needed';
    output;
    end;
run;

```

```

/*Number of AE's within Relationships - EXCLUDING Any Adverse events*/
proc freq data=adverse03(where=(aerel1 ne 'NOT RELATED' and aebodsys ne
'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel1 /
out=totrelip(rename=(count=tot) drop=percent);
run;

proc freq data=adverse03(where=(aerel2 ne 'NOT RELATED' and aebodsys ne
'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel2 /
out=totrelnrt(rename=(count=tot) drop=percent);
run;

proc freq data=adverse03(where=(aeexpec='Y' and aerel1 ne 'NOT RELATED'
and aebodsys ne 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel1*aeexpec /
out=totexpecip(rename=(count=tot) drop=percent);
run;

proc freq data=adverse03(where=(aeexpec1='Y' and aerel2 ne 'NOT
RELATED' and aebodsys ne 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel2*aeexpec1 /
out=totexpecnrt(rename=(count=tot) drop=percent);
run;

    /*** getting number of subjects studied within relationships -
EXCLUDING Any Adverse events***/
proc sort data=adverse03(where=(not missing(subjidn) and aebodsys ne
'Any Adverse events')) out=nae3_rel nodupkey;
    by headorder1 headtext1 aebodsys aedecod subjidn aerel1 aerel2 ;
run;

proc freq data=nae3_rel(where=(aerel1 ne 'NOT RELATED' and aebodsys ne
'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel1 /
out=ntotrelip(rename=(count=ntot) drop=percent);
run;

proc freq data=nae3_rel(where=(aerel2 ne 'NOT RELATED' and aebodsys ne
'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel2 /
out=ntotrelnrt(rename=(count=ntot) drop=percent);
run;

proc freq data=nae3_rel(where=(aeexpec='Y' and aerel1 ne 'NOT RELATED'
and aebodsys ne 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aedecod*aerel1*aeexpec /
out=ntotexpecip(rename=(count=ntot) drop=percent);
run;

proc freq data=nae3_rel(where=(aeexpec1='Y' and aerel2 ne 'NOT RELATED'
and aebodsys ne 'Any Adverse events')) noprint;

```

```

    tables headorder1*headtext1*aebodsys*aedecod*aerel2*aeexpect1 /
out=ntotexpectnrt(rename=(count=ntot) drop=percent);
run;

data relcounts_ip(where=(aerel1 ne 'NOT RELATED'));
    merge totrelip ntotrelip;
    by headorder1 headtext1 aebodsys aedecod aerel1;
run;

data relcounts_nrt(where=(aerel2 ne 'NOT RELATED'));
    merge totrelnrt ntotrelnrt;
    by headorder1 headtext1 aebodsys aedecod aerel2;
run;

data relcountsna;
    set relcounts_ip(in=a) relcounts_nrt(in=b);
    if a then do; sort3=2; rel=aerel1; end;
    else if b then do; sort3=3; rel=aerel2; end;

    if aebodsys='Any Adverse events' then sort2=1;
    else sort2=2;
run;

data expectcounts_ip(where=(aerel1 ne 'NOT RELATED'));
    merge totexpectip ntotexpectip;
    by headorder1 headtext1 aebodsys aedecod aerel1 aeexpect;
run;

data expectcounts_nrt(where=(aerel2 ne 'NOT RELATED'));
    merge totexpectnrt ntotexpectnrt;
    by headorder1 headtext1 aebodsys aedecod aerel2 aeexpect1;
run;

data expectcountsna;
    set expectcounts_ip(in=a) expectcounts_nrt(in=b);
    if a then do; sort3=2.5; expect=aeexpect; end;
    else if b then do; sort3=3.5; expect=aeexpect1; end;

    if aebodsys='Any Adverse events' then sort2=1;
    else sort2=2;
run;

/*Number of AE's within Relationships - Any Adverse events ONLY*/

proc freq data=adverse03(where=(aerel1 ne 'NOT RELATED' and
aebodsys eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel1 /
out=alltotrelip(rename=(count=tot) drop=percent);
run;

proc freq data=adverse03(where=(aerel2 ne 'NOT RELATED' and aebodsys eq
'Any Adverse events')) noprint;

```

```

    tables headorder1*headtext1*aebodsys*aerel2 /
out=alltotrelnrt(rename=(count=tot) drop=percent);
run;

```

```

    proc freq data=adverse03(where=(aeexpec='Y' and aerel1 ne 'NOT
RELATED' and aebodsys eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel1*aeexpec /
out=alltotexpecip(rename=(count=tot) drop=percent);
run;

```

```

    proc freq data=adverse03(where=(aeexpec1='Y' and aerel2 ne 'NOT
RELATED' and aebodsys eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel2*aeexpec1 /
out=alltotexpecnrt(rename=(count=tot) drop=percent);
run;

```

```

/*** getting number of subjects studied within relationships - Any
Adverse events ONLY****/

```

```

    proc sort data=adverse03(where=(not missing(subjidn) and aebodsys eq
'Any Adverse events')) out=allnae3_rel nodupkey;
    by headorder1 headtext1 aebodsys aerel1 aerel2 subjidn;
run;

```

```

    proc freq data=allnae3_rel(where=(aerel1 ne 'NOT RELATED' and aebodsys
eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel1 /
out=allntotrelip(rename=(count=ntot) drop=percent);
run;

```

```

    proc freq data=allnae3_rel(where=(aerel2 ne 'NOT RELATED' and aebodsys
eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel2 /
out=allntotrelnrt(rename=(count=ntot) drop=percent);
run;

```

```

    proc freq data=allnae3_rel(where=(aeexpec='Y' and aerel1 ne 'NOT
RELATED' and aebodsys eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel1*aeexpec /
out=allntotexpecip(rename=(count=ntot) drop=percent);
run;

```

```

    proc freq data=allnae3_rel(where=(aeexpec1='Y' and aerel2 ne 'NOT
RELATED' and aebodsys eq 'Any Adverse events')) noprint;
    tables headorder1*headtext1*aebodsys*aerel2*aeexpec1 /
out=allntotexpecnrt(rename=(count=ntot) drop=percent);
run;

```

```

    data allrelcounts_ip(where=(aerel1 ne 'NOT RELATED'));
    merge alltotrelip allntotrelip;
    by headorder1 headtext1 aebodsys aerel1;
run;

```

```

data allrelcounts_nrt(where=(aerel2 ne 'NOT RELATED'));
  merge alltotrelnrt allntotrelnrt;
  by headorder1 headtext1 aebodsys aerel2;
run;

data allrelcounts;
  set allrelcounts_ip(in=a) allrelcounts_nrt(in=b);
  if a then do; sort3=2; rel=aerel1; end;
  else if b then do; sort3=3; rel=aerel2; end;

  if aebodsys='Any Adverse events' then sort2=1;
  else sort2=2;
run;

data allexpeccounts_ip(where=(aerel1 ne 'NOT RELATED'));
  merge alltotexpecip allntotexpecip;
  by headorder1 headtext1 aebodsys aerel1;
run;

data allexpeccounts_nrt(where=(aerel2 ne 'NOT RELATED'));
  merge alltotexpecnrt allntotexpecnrt;
  by headorder1 headtext1 aebodsys aerel2;
run;

data allexpeccounts;
  set allexpeccounts_ip(in=a) allexpeccounts_nrt(in=b);
  if a then do; sort3=2.5; expec=aeexpec; end;
  else if b then do; sort3=3.5; expec=aeexpec1; end;

  if aebodsys='Any Adverse events' then sort2=1;
  else sort2=2;
run;

/*Combine datasets to include all data*/
data relcounts;
  set relcountsna allrelcounts ;
run;

data expeccounts;
  set expeccountsna allexpeccounts ;
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 subjdn;

```

```

run;

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

data otot;
  merge ovall 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+1;
  sort3=0;
run;

/** bodsys ordered ***/
proc freq data=adverse03 noprint;
  tables headorder1*headtext1*aebodsys / out=taebod(rename=(count=tot)
drop=percent);
run;

/** getting number of subjects studied ***/
proc sort data=adverse03 out=nae2 nodupkey;
  by headorder1 headtext1 aebodsys subjidn;
run;

proc freq data=nae2 noprint;
  tables headorder1*headtext1*aebodsys / out=aebod(rename=(count=ntot)
drop=percent);
run;

data body;
  merge taebod aebod;
  by headorder1 headtext1 aebodsys;
run;

data body2;
  set body;
  if aebodsys='Any Adverse events' then do; sort2=1; sort3=0;
end;
  else do; sort2+1; 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=nprefit(rename=(count=ntot) drop=percent);
run;

data prefterm;
    merge preft nprefit;
    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=1; sort3=1; end;
run;

data all_a;
    set overall body2 aeDecod;
        if aebodsys='not needed' then delete;
        if aebodsys='Any Adverse events' then sort2=1;
        else sort2=2;
run;

proc sort data=all_a;
    by headorder1 headtext1 aebodsys aeDecod sort2 sort3;
run;

proc sort data=relcounts;
    by headorder1 headtext1 aebodsys aeDecod sort2 sort3;
run;

proc sort data=expeccounts;
    by headorder1 headtext1 aebodsys aeDecod sort2 sort3;
run;

data all;
    merge all_a relcounts expeccounts;
    by headorder1 headtext1 aebodsys aeDecod sort2 sort3;
    if aebodsys='not needed' then delete;
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;
      ntot=0;
      aebodsys='Any Adverse events';
      flag=1;
      flagc='dum';
    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';

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

  /*% value*/
  if missing(percent) or percent=0 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.));

  drop percent;
run;

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

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

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

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

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        idlabel headtext1;
run;

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

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

        data tformat;
            merge nformat eformat performat;
            by sort2 aebodsys sort3 aedecod rel expec;
            if rel='N' then delete;

            if aebodsys='Any Adverse events' and not missing(aedecod)
then delete;
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 aeDecod; run;
proc sort data=sorting3; by sort2 odd aebodsys aeDecod; run;

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

proc sort data=sorting4 out=final2;
    by aebodsys aeDecod;
run;

/*Get a list of aeDecods to merge on blank related to IP and NRT gum
columns*/

DATA FINAL2_EXTRA; /* 1) JMH 12Aug2014 */
    SET FINAL2;
    IF SORT2=2 AND SORT3=0 THEN DELETE;
RUN;

proc sort data=FINAL2_EXTRA/*final2(where=(sort3 ne 0 ))*/ nodupkey
out=terms(keep= rel aebodsys sort2 aeDecod odd odd2); /* 1) JMH
12Aug2014 */
    by aebodsys aeDecod ;
run;

data terms2;
    set terms;
    sort3=1;
    output;
    sort3=2;
    output;
    sort3=3;
    output;
run;

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```

proc sort data=final2;
    by sort2 sort3 aedecod;
run;

proc sort data=terms2 nodupkey out=terms2a;
    by sort2 sort3 aedecod aebodsys odd odd2 ;
run;

data final2a;
    merge final2(in=a) terms2A(in=b);
    by sort2 sort3 aedecod;
    if a or b;

    if aebodsys='Any Adverse events' and sort3=1 then delete;
/*This isn't needed as there is no AEDECOD*/
run;

proc sort data=final2a;
    by sort2 odd odd2 aedecod;
run;

data expecrows1;
    set final2a;
    where sort3=2 and not missing(n99);
    sort3=2.5;
    keep sort2 aebodsys aedecod sort3 odd odd2;
run;

data expecrows2;
    set final2a;
    where sort3=3 and not missing(n99);
    sort3=3.5;
    keep sort2 aebodsys aedecod sort3 odd odd2;
run;

proc sort data=final2a; by sort2 aebodsys aedecod sort3; run;
proc sort data=expecrows1; by sort2 aebodsys aedecod sort3; run;
proc sort data=expecrows2; by sort2 aebodsys aedecod sort3; run;

data final2b;
    merge final2a expecrows1 expecrows2;
    by sort2 aebodsys aedecod sort3;
run;

proc sort data=final2b;
    by sort2 odd odd2 aedecod;
run;

data final3;
    set final2b;
    attrib column format=$200. label='AE text formatted'
           column1 format=$200. label='AE text';

```

```

attrib wrap length = $200;
wrap = aeDecod;

if sort2=2 and sort3=1 then do;
i=18; *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) || "$n $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;
end;
end;

```

```

if sort2=1 then do;
    if sort3=0 then column1='Adverse events (AE)';
    else if sort3=2 then column1="Related to IP";
    else if sort3=2.5 then column1="Expected";
    else if sort3=3 then column1="Related to NRT gum";
    else if sort3=3.5 then column1="Expected";
end;
else if sort2=2 then do;
    if sort3=0 then column1=left(trim(aebodsys));
    else if sort3=1 then column1=trim(aeDecod);
    else if sort3=2 then column1="Related to IP";
    else if sort3=2.5 then column1="Expected";
    else if sort3=3 then column1="Related to NRT gum";
    else if sort3=3.5 then column1="Expected";
end;

```

```

if sort2=1 then do;
    if sort3=0 then column='Adverse events (AE)';
    else if sort3=2 then column="$S={foreground=white} .
$S={}Related to IP";
    else if sort3=2.5 then column="$S={foreground=white} .
$S={}Expected";
    else if sort3=3 then column="$S={foreground=white} .
$S={}Related to NRT gum";
    else if sort3=3.5 then column="$S={foreground=white} .
$S={}Expected";

```

```

        end;
        else if sort2=2 then do;
            if sort3=0 then column=left(trim(aebodsys));
            else if sort3=1 then column="$S={foreground=white} .
$S={} " || strip('(')||trim(wrap)||strip(')');
            else if sort3=2 then column="$S={foreground=white} .
$S={}Related to IP";
            else if sort3=2.5 then column="$S={foreground=white} .
$S={}Expected";
            else if sort3=3 then column="$S={foreground=white} .
$S={}Related to NRT gum";
            else if sort3=3.5 then COLUMN="$S={foreground=white} .
$S={}Expected";
        end;
    run;

proc sort data=final3(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 (n4=0 or missing(n4)) and (e4=0 or missing(e4)) then
del4=1;
        if (n6=0 or missing(n6)) and (e6=0 or missing(e6)) then
del6=1;
    keep sort2 sort3 aebodsys del: odd odd2;
run;

proc sort data=final3; by sort2 odd aebodsys; run;
proc sort data=blanks1; by sort2 odd aebodsys; run;

data final3a;
    merge final3 blanks1;
    by sort2 odd aebodsys;
run;

proc sort data=final3a(where=(sort3=1)) out=pblanks;
    by sort2 sort3;
run;

data pblanks1;
    set pblanks;
        if (n1=0 or missing(n1)) and (e1=0 or missing(e1)) then
pdell1=1;
        if (n2=0 or missing(n2)) and (e2=0 or missing(e2)) then
pdell2=1;

```

```

        if (n3=0 or missing(n3)) and (e3=0 or missing(e3)) then
pdel3=1;
        if (n4=0 or missing(n4)) and (e4=0 or missing(e4)) then
pdel4=1;
        if (n6=0 or missing(n6)) and (e6=0 or missing(e6)) then
pdel6=1;
        keep sort2 sort3 aebodsys aedecod pdel: odd odd2;
run;

proc sort data=final3a; by sort2 odd odd2 aebodsys aedecod; run;
proc sort data=pblanks1; by sort2 odd odd2 aebodsys aedecod; run;

data final3b;
    merge final3a pblanks1;
    by sort2 odd odd2 aebodsys aedecod;
run;

proc sort data=final3b;
    by sort2 odd aebodsys odd2 sort3 aedecod;
run;

data labels;
    set final3b;
    attrib n1 label = "n"
            n2 label = "n"
            n3 label = "n"
            n4 label = "n"
            n6 label = "n"
            n99 label = "n"
            p1 label = ' (%) '
            p2 label = ' (%) '
            p3 label = ' (%) '
            p4 label = ' (%) '
            p6 label = ' (%) '
            p99 label = ' (%) '
            e1 label = "Events"
            e2 label = "Events"
            e3 label = "Events"
            e4 label = "Events"
            e6 label = "Events"
            e99 label = "Events";

    if sort3=0 then do;
        del1=.;
        del2=.;
        del3=.;
        del4=.;
        del6=.;
    end;
    if sort3=1 then do;
        pdel1=.;
        pdel2=.;
        pdel3=.;
        pdel4=.;

```



```

        pdel6=.;
    end;

run;

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

%if &halfblnk=N %then %let halfblnk=;
%else %if &halfblnk=Y %then %let halfblnk=~;

data final4;
    set labels;

    array a [3] n1 n2 n4;
    array b [3] e1 e2 e4;
        array c [3] del1 del2 del4;
        array d [3] pdel1 pdel2 pdel4;
    do i=1 to 3;
        if c[i] ne 1 and d[i] ne 1 then do;
            if missing(a[i]) then a[i] ='0';
            end;
            if length(left(strip(b[i])))=1 then b[i]=
'$S={foreground=white}.$S={}' || left(strip(b[i]));
            end;

            if missing(n99) then n99='0';
            if length(left(strip(e99)))=1 then e99=
'$S={foreground=white}.$S={}' || left(strip(e99));

            flag=1;
        end;
    run;

proc sql noprint;
    create table table.T_15_02_06_03 as
    select column, column1, aebodsys, aedecod, n1, p1, e1, n2, p2, e2,
n3, p3, e3, n4, p4, e4, n6, p6, e6, n99, p99, e99
    from final4
    order by sort2, odd, aebodsys, odd2, sort3, aedecod;
quit;

data paging;
    set final4;
        by sort2 odd aebodsys odd2 sort3 aedecod;

    if (first.odd2 and ln gt 6) 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;

ods path stdlib.tl06326 (read) ;
ods results off;
ods rtf toc_data/* contents*/
file="/cvn/projects/prj/data/000000106326/TFL/&TFL_Part./&tflno..rtf"
style=tl06326 startpage=yes headery=1440 footery=1440 ;
ods noproctitle;
%do i=1 %to &page;

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

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

    /* Amend title as needed */
    _firtitl="Table 15.2.6.3 Summary of Adverse Events by System
Organ Class and Preferred Term and Relationship to";
    _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 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 = '$' %if
&i=1 %then %do; contents=' ' %end; %else %do; contents='' %end;;
column flag page sort2 odd sort4 odd2 sort3 column ("Sequence &linebot"
("THS 2.2 Menthol$- mCC $(N=&trt1) &linebot" n1 p1 e1)

("mCC -$THS 2.2 Menthol$(N=&trt2) &linebot" n2 p2 e2)

("THS 2.2 Menthol$- NRT gum $(N=&trt3) &linebot" n3 p3 e3)

("NRT gum -$THS 2.2 Menthol$(N=&trt4) &linebot" n4 p4 e4)

("Exposed Not$Randomized$(N=&trt6) &linebot" n6 p6 e6))

("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 odd2            / order order=internal noprint;
    define sort3         / order order=internal noprint;

    define column        / group style={just=left cellwidth=3.5cm} ""
style(header)={just=center};
    define n1            / display style={just=d cellwidth=0.2cm}
style(header)={just=right};
    define p1            / display style={just=d cellwidth=1.2cm}
style(header)={just=center};
    define n2            / display style={just=d cellwidth=0.2cm}
style(header)={just=right};
    define p2            / display style={just=d cellwidth=1.2cm}
style(header)={just=center};
    define n3            / display style={just=d cellwidth=0.2cm}
style(header)={just=right};
    define p3            / display style={just=d cellwidth=1.2cm}
style(header)={just=center};
    define n4            / display style={just=d cellwidth=0.2cm}
style(header)={just=right};
    define p4            / display style={just=d cellwidth=1.2cm}
style(header)={just=center};
    define n6            / display style={just=d cellwidth=0.2cm}
style(header)={just=right};
    define p6            / display style={just=d cellwidth=1cm}
style(header)={just=center};
    define n99           / display style={just=d cellwidth=0.2cm}
style(header)={just=right};

```

```

        define p99                / display style={just=d cellwidth=1.2cm}
style(header)={just=center};
        define e1                / display
style={cellwidth=1.2cm} style(header)={just=center};
        define e2                / display
style={cellwidth=1.2cm} style(header)={just=center};
        define e3                / display
style={cellwidth=1.2cm} style(header)={just=center};
        define e4                / display
style={cellwidth=1.2cm} style(header)={just=center};
        define e6                / display
style={cellwidth=1.2cm} style(header)={just=center};
        define e99               / display
style={cellwidth=1.2cm} 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 sort4;
    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 "\b\fs24\sa24Study Product Exposure for
Investigational Product (THS 2.2 Menthol or mCC) and Reference Point ";
    line "\b\fs24\sa24Product (NRT gum) - Safety
Population";
    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: Exposed Not Randomized refers to all subjects
exposed to THS 2.2 Menthol or NRT gum but not randomized. Overall Safety
refers to all subjects exposed to THS 2.2 Menthol or NRT gum.';
    line 'Note: IP = Investigational Product (THS 2.2 Menthol /
mCC).';
    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_03.lst" new;
run;

proc contents data = table.T_15_02_06_03 varnum;
run;
ods listing close;

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