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%_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_adv1.sas;
%put NOTE: Purpose              : table of serious adverse events;
%put NOTE: ;
%put NOTE: Input Data           : ADAM.ADAE;
%put NOTE: Output               : t_15_2_6_8(ae);
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jhardman;
%put NOTE: Creation Date        : 2014-07-25;
%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: ;
%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_08(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");

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        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;
    headorder1=99;
    headtext1='Overall Safety';
    output;
run;

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

data tot2;

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        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 aeser='Y';
    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;

data adverse02;
    merge ae(in=a) dumtrts(in=b);
    by headorder1 headtext1;
    if a or b;
    aerel=upcase(aerel);
    aerelsp=upcase(aerelsp);
    aesev=upcase(aesev);
    aeacnpl=upcase(aeacnpl);
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;

    if first.headtext1 then do;
        subjid = .;

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        aeterm='';
    output;
end;
run;

* Create values for table rows;
data adverse04;
    set adverse03;
    length rowtext $200;
    * All adverse events;
    roworder1 = 2;
    roworder2 = 1;
    rowtext = 'Serious adverse events (SAE)';
    output;
    * Serious adverse events - header;
    roworder1 = 3;
    roworder2 = 1;
    rowtext = 'AE serious';
    output;
* Serious adverse events - fatal;
    roworder1 = 3;
    roworder2 = 2;
    rowtext = '$S={foreground=white} . $S={} Fatal';
    if subjid = . or aesdth = 'Y' then output;
    * Serious adverse events - life threatening;
    roworder1 = 3;
    roworder2 = 3;
    rowtext = '$S={foreground=white} . $S={} Life-threatening';
    if subjid = . or aeslife = 'Y' then output;
    * Serious adverse events - hospitalization;
    roworder1 = 3;
    roworder2 = 4;
    rowtext = '$S={foreground=white} . $S={} Requires hospitalization';
    if subjid = . or aeshosp = 'Y' then output;
    * Serious adverse events - disability;
    roworder1 = 3;
    roworder2 = 5;
    rowtext = '$S={foreground=white} . $S={} Results in $n
$S={foreground=white} . $S={} disability/incapacity';
    if subjid = . or aesdisab = 'Y' then output;
    * Serious adverse events - anomaly/birth defect;
    roworder1 = 3;
    roworder2 = 6;
    rowtext = '$S={foreground=white} . $S={} Congenital $n
$S={foreground=white} . $S={} anomaly/birth defect';
    if subjid = . or aescong = 'Y' then output;
    *Related to THS 2.2/CC - header;
    roworder1 = 4;
    roworder2 = 1;
    rowtext = 'AE related to THS 2.2/CC';
    output;
    *Related to THS 2.2/CC - missing;
    roworder1 = 4;
    roworder2 = 2;

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        rowtext = '$S={foreground=white} . $S={} Missing';
if subjid = . or aere1 = '' then output;
    *Related to THS 2.2/CC - not related;
roworder1 = 4;
roworder2 = 3;
rowtext = '$S={foreground=white} . $S={} Not related';
if subjid = . or aere1 in('N' 'NO' 'NOT RELATED' 'No') then output;
    *Related to THS 2.2/CC - related;
roworder1 = 4;
roworder2 = 4;
rowtext = '$S={foreground=white} . $S={} Related';
if subjid = . or aere1 in('Y' 'YES' 'RELATED' 'Yes') then output;
    *Related to THS 2.2/CC - related - missing;
roworder1 = 4;
roworder2 = 5;
    rowtext = '$S={foreground=white} . $S={} Missing';
if subjid = . or (aere1 in('Y' 'YES' 'RELATED' 'Yes') and aeexpec =
') then output;
    *Related to THS 2.2/CC - related - expected;
roworder1 = 4;
roworder2 = 6;
rowtext = '$S={foreground=white} . $S={} Expected';
if subjid = . or (aere1 in('Y' 'YES' 'RELATED' 'Yes') and aeexpec
in('Y' 'YES' 'Yes')) then output;
    *Related to IP - related - not expected;
roworder1 = 4;
roworder2 = 7;
rowtext = '$S={foreground=white} . $S={} Not expected';
if subjid = . or (aere1 in('Y' 'YES' 'RELATED' 'Yes') and aeexpec
in('N' 'NO' 'No')) then output;

    *Related to study procedure;
roworder1 = 6;
roworder2 = 1;
rowtext = 'AE related to study procedure';
output;
    *Related to study procedure - missing;
roworder1 = 6;
roworder2 = 2;
rowtext = '$S={foreground=white} . $S={} Missing';
if subjid = . or aere1sp = '' then output;
    *Related to study procedure - not related;
roworder1 = 6;
roworder2 = 3;
rowtext = '$S={foreground=white} . $S={} Not related';
if subjid = . or aere1sp in('N' 'NO' 'NOT RELATED' 'No') then output;
    *Related to study procedure - related;
roworder1 = 6;
roworder2 = 4;
rowtext = '$S={foreground=white} . $S={} Related';
if subjid = . or aere1sp in('Y' 'YES' 'RELATED' 'Yes') then output;
* AE severity;
roworder1 = 7;
roworder2 = 1;

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rowtext = 'AE severity';
output;
* Severity for all adverse events - mild;
roworder1 = 7;
roworder2 = 3;
rowtext = '$S={foreground=white} . $S={} Mild';
if subjid = . or aesev = 'MILD' then output;
* Severity for all adverse events - moderate;
roworder1 = 7;
roworder2 = 4;
rowtext = '$S={foreground=white} . $S={} Moderate';
if subjid = . or aesev = 'MODERATE' then output;
* Severity for all adverse events - severe;
roworder1 = 7;
roworder2 = 5;
rowtext = '$S={foreground=white} . $S={} Severe';
if subjid = . or aesev = 'SEVERE' or missing(aesev) then output;
    *Action taken due to AE;
    roworder1= 8;
    roworder2=1;
    rowtext='Action taken due to AE';
    output;
    *Action taken - discontinuation from study;
roworder1 = 8;
roworder2 = 2;
rowtext = '$S={foreground=white} . $S={} Product use interrupted';
    if subjid = . or aeacnpl='PRODUCT USE INTERRUPTED' then output;
    *Action taken - product use stopped;
roworder1 = 8;
roworder2 = 3;
rowtext = '$S={foreground=white} . $S={} Product use stopped';
if subjid = . or aeacnpl='PRODUCT USE STOPPED' then output;
    *Action taken - product use reduced;
roworder1 = 8;
roworder2 = 4;
rowtext = '$S={foreground=white} . $S={} Product use reduced';
if subjid = . or aeacnpl='PRODUCT USE REDUCED' then output;
    *Action taken - not applicable;
roworder1 = 8;
roworder2 = 5;
rowtext = '$S={foreground=white} . $S={} Not applicable';
if subjid = . or aeacnpl='NOT APPLICABLE' then output;
    *Action taken - none;
roworder1 = 8;
roworder2 = 6;
rowtext = '$S={foreground=white} . $S={} None';
if subjid = . or aeacnpl='NONE' then output;
    *Action taken -treatment given;
roworder1 = 8;
roworder2 = 7;
rowtext = '$S={foreground=white} . $S={} Treatment given';
if subjid= . then output;
    *Action taken -treatment given - yes;
roworder1 = 8;

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roworder2 = 9;
rowtext = '$S={foreground=white} . $S={} Yes';
if subjid = . or aecontrt = 'Y' then output;
    *Action taken -treatment given - no;
roworder1 = 8;
roworder2 = 10;
rowtext = '$S={foreground=white} . $S={} No';
if subjid = . or aecontrt = 'N' then output;
    *Action taken - Other action taken;
roworder1 = 8;
roworder2 = 11;
rowtext = '$S={foreground=white} . $S={} Other action taken';
if subjid = . or anl05fl = 'Y' then output;
run;

data adael;
    set adsl;
    headorder1=trt01an;
    headtext1=trt01a;
    drop trt01an trt01a;
run;

proc sql;
    create table results01 as
    select headorder1, headtext1, count(distinct usubjid) as treated
    from adael
    group by headorder1, headtext1;
quit;

proc sort data=adverse04 out=adverse04_a nodupkey; by headorder1
headtext1 roworder1 roworder2 rowtext usubjid aeterm; run;

proc sql;
    create table results02 as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(aeterm) as events
    from adverse04_a
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

proc sql;
    create table results02_allaes as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(aeterm) as events,
        count(distinct subjid) as subjects
    from adverse04_a(where=(roworder1 in(2 8)))
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

/*SERIOUS*/
proc sort data=adverse04_a(where=(not missing(subjid) and roworder1=3 and
roworder2 not in(1 )) keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aesern aeser aeseq) out=ser;

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        by headorder1 headtext1 usubjid roworder2;
run;

proc sort data=ser(keep=headorder1 headtext1 roworder1 roworder2 rowtext
usubjid subjid aebodsys aeterm aesern aaser aeseq) nodupkey out=ser1;
    by headorder1 headtext1 usubjid roworder2;
run;

data ser2;
    set ser1;
    by headorder1 headtext1 usubjid;
    if first.usubjid;
    serflag=1;
run;

/*RELATED TO THS 2.2/CC*/
proc sort data=adverse04_a(where=(not missing(subjid) and roworder1=4 and
roworder2 not in(1 5 6 7)) keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aereln aerel aeseq) out=relip;
    by headorder1 headtext1 usubjid descending roworder2;
run;

proc sort data=relip(keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aereln aerel aeseq) nodupkey
out=relip1;
    by headorder1 headtext1 usubjid descending roworder2;
run;

data relip2;
    set relip1;
    by headorder1 headtext1 usubjid;
    if first.usubjid;
    relipflag=1;
run;

/*RELATED TO IP - EXPECTED*/
proc sort data=adverse04_a(where=(not missing(subjid) and roworder1=4 and
roworder2 in(5 6 7)) keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aeexpec aeseq) out=expecip;
    by headorder1 headtext1 usubjid roworder2;
run;

proc sort data=expecip(keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aeexpec aeseq) nodupkey
out=expecip1;
    by headorder1 headtext1 usubjid roworder2;
run;

data expecip2;
    set expecip1;
    by headorder1 headtext1 usubjid;
    if first.usubjid;
    expecipflag=1;
run;

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/*related to sp*/
proc sort data=adverse04_a(where=(not missing(subjid) and roworder1=6 and
roworder2 not in(1 6 7)) keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aerelspn aerelsp aeseq) out=relsp;
    by headorder1 headtext1 usubjid descending roworder2;
run;

proc sort data=relsp(keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aerelspn aerelsp aeseq) nodupkey
out=relsp1;
    by headorder1 headtext1 usubjid descending roworder2;
run;

data relsp2;
    set relsp1;
    by headorder1 headtext1 usubjid;
    if first.usubjid;
    relspflag=1;
run;

/*SEVERITIES*/
proc sort data=adverse04_a(where=(not missing(subjid) and roworder1=7 and
roworder2 not in(1)) keep=headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aebodsys aeterm aesev aesev aeseq) out=sev;
    by headorder1 headtext1 usubjid descending roworder2;
run;

proc sort data=sev(keep=headorder1 headtext1 roworder1 roworder2 rowtext
usubjid subjid aebodsys aeterm aesev aesev aeseq) nodupkey out=sev1;
    by headorder1 headtext1 usubjid descending roworder2;
run;

data sev2;
    set sev1;
    by headorder1 headtext1 usubjid;
    if first.usubjid;
    sevflag=1;
run;

/*MERGE BACK ONTO ORIGINAL DATA TO INCLUDE FLAGS*/

proc sort data=adverse04_a; by headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aeseq; run;
proc sort data=ser2; by headorder1 headtext1 roworder1 roworder2 rowtext
usubjid subjid aeseq; run;
proc sort data=relip2; by headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aeseq; run;
proc sort data=expecip2; by headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aeseq; run;
proc sort data=relsp2; by headorder1 headtext1 roworder1 roworder2
rowtext usubjid subjid aeseq; run;

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proc sort data=sev2; by headorder1 headtext1 roworder1 roworder2 rowtext
usubjid subjid aeseq; run;

data alldata;
    merge adverse04_a(in=a) ser2(in=b) relip2(in=c) relsp2(in=e)
sev2(in=f) expecip(in=g);
    by headorder1 headtext1 roworder1 roworder2 rowtext usubjid subjid
aeseq;
    if b and not a then serflag=1;
    if c and not a then relipflag=1;
    if e and not a then relspflag=1;
    if f and not a then sevflag=1;
    if g then expecipflag=1;
run;

proc sql;
    create table results02_ser as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(distinct subjid) as subjects
    from alldata(where=(serflag=1))
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

proc sql;
    create table results02_relip as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(distinct subjid) as subjects
    from alldata(where=(relipflag=1))
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

proc sql;
    create table results02_expecip as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(distinct subjid) as subjects
    from alldata(where=(expecipflag=1))
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

proc sql;
    create table results02_relsp as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(distinct subjid) as subjects
    from alldata(where=(relspflag=1))
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

proc sql;
    create table results02_sev as
    select headorder1, headtext1, roworder1, roworder2, rowtext, subjid,
count(distinct subjid) as subjects
    from alldata(where=(sevflag=1))
    group by headorder1, headtext1, roworder1, roworder2, rowtext;
quit;

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```

proc sort data=results02_ser; by headorder1 headtext1 roworder1 roworder2
rowtext subjid; run;
proc sort data=results02_relip; by headorder1 headtext1 roworder1
roworder2 rowtext subjid; run;
proc sort data=results02_relsp; by headorder1 headtext1 roworder1
roworder2 rowtext subjid; run;
proc sort data=results02_sev; by headorder1 headtext1 roworder1 roworder2
rowtext subjid; run;
proc sort data=results02_expecip; by headorder1 headtext1 roworder1
roworder2 rowtext subjid; run;

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data allcounts;
    set results02_ser results02_relip results02_relsp results02_sev
results02_expecip;
    by headorder1 headtext1 roworder1 roworder2 rowtext subjid;
    subjects1=subjects;
run;

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proc sort data=results02; by headorder1 headtext1 roworder1 roworder2
rowtext subjid; run;
proc sort data=results02_allaes; by headorder1 headtext1 roworder1
roworder2 rowtext subjid; run;

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data results02_comb;
    merge allcounts(in=a) results02(where=(roworder1 not in(2 8)) in=b)
results02_allaes(rename=(events=events1 subjects=subjects1)in=c);
    by headorder1 headtext1 roworder1 roworder2 rowtext subjid;
    if b and a then test=1;
run;

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data results03;
    merge results02_comb(in=a) results01(keep=headorder1 headtext1
treated);
    by headorder1 headtext1;
    if a;

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    subjects=subjects1;
    if missing(events) then events=events1;

    if events ne 0 and missing(subjid) then delete;

    drop subjects1 events1;
run;

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data results04;
    set results01 results03;

    if index(rowtext,'Missing') and events=0 and (subjects=0 or
missing(subjects)) then delete;
run;

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proc sort data=results04;
    by headorder1 headtext1 roworder1 roworder2 rowtext;

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run;

* Create data set with all combinations of row values and column values;
* This creates a data set with an observation for each table cell;
proc sql;
  create table results05 as
  select *
  from (select distinct headorder1, headtext1, roworder1, roworder2,
rowtext from results04);
quit;

* Sort the all combinations data set by section heading order, row order
and column order;
proc sort data=results05;
  by headorder1 headtext1 roworder1 roworder2 rowtext ;
run;

* Merge the results data set with the all combinations data set;
* This effectively adds observations with missing results for table cells
with no results;
* This allows text to be created for these table cells if necessary;
data results06;
  merge results04 results05;
  by headorder1 headtext1 roworder1 roworder2 rowtext ;
run;

* Convert results to text values for the summary table;
data results07;
  set results06;
  length text text2 text3 $200. ;
  if (events = . and subjects = .) or missing(events) and
missing(subjects) then do;
    events = 0;
    subjects = 0;
  end;

  if treated ne 0 then percent = 100 * subjects / treated;

  if missing(roworder1) or roworder1 = 1 then delete;

  if roworder1 ne 2 and roworder2 = 1 then do;
    text='';
    text2='';
    text3='';
  end;
  else if roworder1 eq 8 and roworder2 = 7 then do; /*Blank row for
treatments given header*/
    text='';
    text2='';
    text3='';
  end;
  else do;
    /*n value*/
    if missing(subjects) then text='0';

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        else text=put(subjects,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(events) or events=0 then text2='';
        else text2=compress(put(events,3.));
        end;

        if missing(subjects) and not missing(subjid) and roworder2 ne 1
then delete; /*This deletes subjects where it isn't worst case scenario*/
        keep headorder1 headtext1 roworder1 roworder2 rowtext text text2 text3;
run;

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proc sort data=results07 nodupkey; by headorder1 headtext1 roworder1
roworder2 rowtext text text2 text3; run;

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data dumtrts; /*Use this to output any columns for which N=0*/
    attrib headtext1 length=$200.
            rowtext length=$70.
            headorder1 length=8.;

    roworder1=2;
    roworder2=1;
    rowtext='Serious adverse events (SAE)';

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

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run;
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data results07a;
    merge results07(in=a) dumtrts(in=b);
    by headorder1 headtext1 roworder1 roworder2 rowtext;
    if a or b;
    if b and not a then do;
        text='0';
    end;

```

```

        text2='';
        text3='';
    end;

    if roworder1=4 and roworder2=6 and left(strip(text))='0' and
left(strip(text2))='' then delflag=1;
    if roworder1=4 and roworder2=7 and left(strip(text))='0' and
left(strip(text2))='' then delflag=1;
    if roworder1=5 and roworder2=6 and left(strip(text))='0' and
left(strip(text2))='' then delflag=1;
    if roworder1=5 and roworder2=7 and left(strip(text))='0' and
left(strip(text2))='' then delflag=1;

run;

proc sort data=results07a; by roworder1 roworder2 rowtext delflag ; run;

* Transpose the results;
proc transpose data=results07a out=results08_n prefix=n;
    by roworder1 roworder2 rowtext;
    id headorder1;
    idlabel headtext1;
    var text ;
run;

proc transpose data=results07a out=results08_e prefix=e;
    by roworder1 roworder2 rowtext;
    id headorder1;
    idlabel headtext1;
    var text2 ;
run;

proc transpose data=results07a out=results08_p prefix=p;
    by roworder1 roworder2 rowtext;
    id headorder1;
    idlabel headtext1;
    var text3 ;
run;

data results08;
    merge results08_n results08_e results08_p;
    by roworder1 roworder2;
run;

proc sort data=results07a out=delflags (keep=roworder1 roworder2 delflag)
nodupkey;
    by roworder1 roworder2;
run;

data results08a;
    merge results08 delflags;
    by roworder1 roworder2;

```

```

run;

proc transpose data=results08a(where=(roworder1 in (4) and roworder2 in(6
7))) out=tdelflags prefix=d;
    by roworder1;
    id roworder2;
    idlabel rowtext;
    var delflag;
run;

data tdelflags2;
    set tdelflags;
    if d6=1 and d7=1 then remove=1;
run;

proc transpose data=tdelflags2(where=(not missing(remove)))
out=removedata;
    by roworder1;
    id remove;
    var d6 d7;
run;

data removedata1;
    set removedata;
    rename _label_=rowtext;
    rename _1=remove;
    roworder2=input(left(strip(tranwrd(_name_,'D','')),8.));
    drop _name_;
run;

data results08b;
    merge results08 removedata1;
    by roworder1 roworder2 rowtext;
    if remove=1 then delete;
run;

data missflags;
    set results08b;
    where index(rowtext,'Related');
    if n1='0' or missing(n1) then mflag1=1;
    if n2='0' or missing(n2) then mflag2=1;
    if n3='0' or missing(n3) then mflag3=1;
    if n98='0' or missing(n98) then mflag98=1;
    keep roworder1 mflag;;
run;

proc sort data=results08b; by roworder1; run;
proc sort data=missflags; by roworder1 ; run;

data results08c;
    merge results08b missflags;
    by roworder1;
run;

```

```

data labels;
    set results08c;
    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 roworder2 not in (6 7) and roworder1 ne 3 then do;
    mflag1=.;
    mflag2=.;
    mflag3=.;
    mflag4=.;
    mflag6=.;
end;

    flag=1;

run;

data empty_test;
    set labels;
    where roworder1=2 and roworder2=1;
    if left(strip(n99))='0' then noobs=1;
    else noobs=0;

    flag=1; /*use this to merge back onto data*/
    keep noobs flag;
run;

data final4;
    merge labels empty_test;
    by flag;

    if noobs=1 and roworder1 ne 2 then delete;
run;

data final5;
    set final4;
    attrib rowtext_x length=$200. label='Unformatted text'
           rowtext label='Formatted text';

```



```

if noobs ne 1 and roworder2 ne 1 and rowtext ne '$S={foreground=white} .
$S={} Treatment given' then do;
  array a [3] n1 n2 n3;
  array b [3] e1 e2 e3;
  array c [3] mflag1 mflag2 mflag3;
  do i=1 to 3;
    if c[i] ne 1 then do;
      if missing(a[i]) then a[i] ='0';
      end;
      else if c[i] eq 1 then do;
        if a[i]='0' then a[i]='';
        if b[i]='0' then b[i]='';
        end;
      end;
    end;

    if missing(n99) then n99='0';
  end;
  else if noobs=1 then do; /*Set all to missing*/
    array d [5] n1 n2 n3 n98 n99;
    do i=1 to 5;
      d[i]='';
    end;

    rowtext='';

  end;

  /*Create unformatted variable for qc*/

  rowtext_x=tranwrd(rowtext,'$S={foreground=white} .
$S={} ', '');
  rowtext_x=tranwrd(rowtext_x,'$S={foreground=white} .
$S={} ', '');

  rowtext_x=tranwrd(rowtext_x,' $n ', '');
  rowtext_x=tranwrd(rowtext_x,' ', '');
  rowtext_x=left(trim(rowtext_x));

  run;

proc sql noprint;
  create table table.T_15_02_06_08 as
  select rowtext, rowtext_x, n1, p1, e1, n2, p2, e2, n3, p3, e3, n98,
p98, e98, n99, p99, e99
  from final5
  order by roworder1, roworder2;
quit;

data paging;
  set final5;
  by roworder1 roworder2;

```

```

        if (first.roworder1 and ln ge 13) 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;

/* Standard - leave this */
options number nodate orientation=landscape papersize=&P_PGSize 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=130, 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;
ods proclabel = ' ';

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

    call symput('noobs',noobs);

    /* Amend title as needed */
    _firtitl="Table 15.2.6.8 Summary of Serious Adverse Events -
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;
    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 nowd split = '$' %if &i=1 %then
%do; contents=' ' %end; %else %do; contents='' %end;;
    column flag page roworder1 roworder2 rowtext  ("THS 2.2 $(N=&trt1)
&linebot" ("n (%) Events" n1 p1 e1)) ("CC$(N=&trt2) &linebot" ("n (%)
Events" n2 p2 e2))

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

        ("Overall$Safety$(N=&trt99) &linebot" ("n (%) Events" n99
p99 e99)); ;

    define flag                / order order = internal noprint;
    define page                / order order = internal noprint;
    define roworder1          / order order = internal noprint;
    define roworder2          / order order = internal noprint;
    define rowtext             / display style={just=left
cellwidth=4cm}' ';
    define n1                  / display style={just=d cellwidth=0.3cm}
style(header)={just=right} "";
    define p1                  / display style={just=d cellwidth=1.3cm}
style(header)={just=center} "";
    define e1                  / display
style={JUST=left cellwidth=1.2cm} style(header)={just=l} "";
    define n2                  / display style={just=d cellwidth=0.3cm}
style(header)={just=right} "";
    define p2                  / display style={just=d cellwidth=1.3cm}
style(header)={just=center} "";
    define e2                  / display style={JUST=left
cellwidth=1.2cm } style(header)={just=l} "";
    define n3                  / display style={just=d cellwidth=0.3cm}
style(header)={just=right} "";
    define p3                  / display style={just=d cellwidth=1.3cm}
style(header)={just=center} "";
    define e3                  / display
style={JUST=left cellwidth=1.2cm} style(header)={just=l} "";
    define n98                 / display style={just=d cellwidth=0.3cm}
style(header)={just=right} "";
    define p98                 / display style={just=d cellwidth=0.8cm}
style(header)={just=center} "";
    define e98                 / display style={JUST=left
cellwidth=0.8cm} style(header)={just=l} "";
```

```

        define n99          / display style={just=d cellwidth=0.5cm}
style(header)={just=right} "";
        define p99          / display style={just=d cellwidth=1.3cm}
style(header)={just=center} "";
        define e99          / display style={JUST=left
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;

%if &noobs. ne 1 %then %do;
compute after roworder1;
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 serious adverse events 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 "&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 15.3.6.1.2';
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_01.lst" new;
run;

proc contents data = table.T_15_02_06_01 varnum;
run;
ods listing close;
proc printto ; run;
*=====;
* END OF PROGRAM CODE ;
*=====;
```