

/*=====

*Covance Study ID : 000000106343

*Program Name : t_ae_soc_ip1.sas

*Purpose : Summary of Adverse Events,

System Organ Class,Preferred Term and Relationship to

Study Product Exposure and Expectedness -Safety

Population

*Input Data : adam.adsl, ADAM.adae

*Output Data :

*Macros Called : m_printto m_logchk

*Programmed by : Siva Karnati

*Creation Date : 17 May 2015

*== Modification History =====

*Date Initials No. Reason;

=====/;

%m_printto;

proc datasets library=work kill nolist;run;

*=====;

* 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_05;
```

```
/* Standard - leave this */
```

```
%let TFL_Part=%scan(&_amp;_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 safbfl="Y";
```

```
output;
```

```
trt01an=99;
```

```
trt01a='Overall Safety';
```

```

output;

run;

proc sql noprint;

    select count (distinct usubjid) into: _THS      from adsl where trt01a='THSm2.2';

    select count (distinct usubjid) into: _MCC      from adsl where trt01a='mCC';

    select count (distinct usubjid) into: _SA  from adsl where trt01a='SA';

    select count (distinct usubjid) into: _PT  from adsl where trt01a='Product Test';

    select count (distinct usubjid) into: _tot  from adsl where trt01a= 'Overall Safety';

quit;


%put THS=&_ths MCC=&_mcc SA=&_sa TOT=&_tot;


data N;

    length label $100.;

    label='Total';

    THS=strip(put(&_ths,best.));

    MCC=strip(put(&_mcc,best.));

    SA=strip(put(&_sa,best.));

    PT=strip(put(&_pt,best.));

    OVERALL_SF=strip(put(&_tot,best.));

    call symput('N3',strip(sa));

    call symput('N4',strip(ths));

    call symput('N5',strip(mcc));

    call symput('N96', strip(pt));

    call symput('N99',strip(OVERALL_SF));

```

```
run;
```

```
data adslp;
```

```
set adam.adsl;
```

```
where safaf1="Y";
```

```
output;
```

```
    trt01an=99;
```

```
    trt01a='Overall Safety';
```

```
output;
```

```
run;
```

```
proc sql noprint;
```

```
    select count (distinct usubjid) into: _THSp from adslp where trt01a='THSm2.2';
```

```
    select count (distinct usubjid) into: _MCCp from adslp where trt01a='mCC';
```

```
    select count (distinct usubjid) into: _SAp      from adslp where trt01a='SA';
```

```
    select count (distinct usubjid) into: _totp      from adslp where trt01a= 'Overall Safety';
```

```
quit;
```

```
%put THS=&_thsp MCC=&_mccp SA=&_sap TOT=&_totp;
```

```
data N;
```

```
    length label $100.;
```

```
    label='Total';
```

```
    THSp=strip(put(&_thsp,best.));
```

```

MCCp=strip(put(&_mccp,best.));
SAp=strip(put(&_sap,best.));
OVERALL_SFp=strip(put(&_totp,best.));
call symput('N3p',strip(sap));
call symput('N4p',strip(thsp));
call symput('N5p',strip(mccp));
call symput('N99p',strip(OVERALL_SFp));

run;

%put THS=&n3p MCC=&n4p SA=&n5p TOT=&n99p;

/*PRE RANDOMIZATION*/

data ae;

set adam.adae;

    where safbfl='Y' and anyae fl='Y' and anl01fl='Y' and asper=1 /*and aere l="RELATED"*/;

    output;

    trtan=99;

    trta='Overall Safety';

output;

run;

```

```

data aere1;

set ae;

where aere1="RELATED";

if aeexpec=" " then aeexpec="Missing";

run;


proc sql;

create table ae_n1 as select count(distinct usubjid) as ae_n,trtan,"Any adverse events" as style
length=200,

1 as ord from ae group by trtan,style,ord order by style, ord;


create table ae_ev1 as select count(usubjid) as ae_ev,trtan,"Any adverse events" as style length=200,

1 as ord from ae group by trtan,style,ord order by style, ord;


quit;

%macro trans(inds= ,byvar=,var=, outds=, prefix=);

proc transpose data=&inds. out=&outds.(drop=_name_) prefix=&prefix.;

by &byvar.;

var &var.;

id trtan;

run;

%mend;

%macro mrg(inds1= ,inds2=, byvar=,outds= );

proc sort data=&inds1.; by &byvar. ; run;

proc sort data=&inds2.;by &byvar.; run;

data &outds.;

```

```

merge &inds1. &inds2.;

by &byvar;

run;

%mend;

%trans(inds=ae_n1,byvar=style ord , outds=ae_N,var=ae_n,prefix=n);

%trans(inds=ae_ev1,byvar=style ord , outds=ae_ev,var=ae_ev,prefix=ev);

%mrg(inds1=ae_n,inds2=ae_ev,outds=ae_any,byvar=style ord );


proc sql;

create table ae_ipn as select count(distinct usubjid) as ae_n,trtan," Related to IP" as col length=200,
0.1 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;


create table ae_ipev as select count(usubjid) as ae_ev,trtan," Related to IP" as col length=200,
0.1 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;

quit;


%trans(inds=ae_ipn,byvar=col ord , outds=ae_ipn1,var=ae_n,prefix=n);

%trans(inds=ae_ipev,byvar=col ord , outds=ae_ipev1,var=ae_ev,prefix=ev);

%mrg(inds1=ae_ipn1,inds2=ae_ipev1,outds=ae_iprel,byvar=col ord );

```

```

proc sql;

create table ae_soc_n1 as select count(distinct usubjid) as ae_socn,AEBODSYS,trtan,
"soc" as style length=200,2 as ord from ae group by trtan,AEBODSYS,style,ord
order by style, ord ,AEBODSYS, trtan;

create table ae_soc_ev1 as select count(usubjid) as ae_socev,AEBODSYS,trtan,"soc" as style length=200,
2 as ord from ae group by trtan,AEBODSYS,style,ord order by style, ord,AEBODSYS, trtan;

quit;

%trans(inds=ae_soc_n1,byvar=style ord aebodsys, outds=ae_soc_N,var=ae_socn,prefix=n);
%trans(inds=ae_soc_ev1, outds=ae_soc_ev,byvar=style ord aebodsys,var=ae_socev,prefix=ev);
%mrg(inds1=ae_soc_n,inds2=ae_soc_ev,outds=ae_soc,byvar=style ord aebodsys );

```

```

proc sql;

create table ae_pt_n1 as select count(distinct usubjid) as ae_ptn,aedecod,AEBODSYS,trtan,
"soc" as style length=200,
3 as ord from ae group by trtan,AEBODSYS,aedecod,style,ord
order by style, ord ,AEBODSYS,aedecod ;

create table ae_pt_ev1 as select count(usubjid) as ae_ptev,AEBODSYS,aedecod,trtan,"soc" as style
length=200,
3 as ord from ae group by trtan,AEBODSYS,aedecod,style,ord

```



```
order by style, ord,AEBODSYS,aedecod,trtan;
```

```
quit;
```

```
%trans(inds=ae_pt_n1,byvar=style ord aebodsys aedecod, outds=ae_ptN,var=ae_ptn,prefix=n);
```

```
%trans(inds=ae_pt_ev1, outds=ae_ptev,byvar=style ord aebodsys AEDECOD,var=ae_ptev,prefix=ev);
```

```
%mrg(inds1=ae_ptn,inds2=ae_ptev,outds=ae_pt,byvar=style ord aebodsys aedecod );
```

```
proc sql;
```

```
create table ae_rel_n1 as select count(distinct usubjid) as ae_reln,aedecod,AEBODSYS,trtan,
```

```
aerel,"aerel" as style length=200,
```

```
4 as ord from aerel group by trtan,AEBODSYS,aedecod,aerel,style,ord
```

```
order by style, ord ,AEBODSYS,aedecod,aerel,trtan ;
```

```
create table ae_rel_ev1 as select count(usubjid) as ae_relev,AEBODSYS,aedecod,aerel,trtan,"aerel" as  
style length=200,
```

```
4 as ord from aerel group by trtan,AEBODSYS,aedecod,aerel,style,ord
```

```
order by style, ord,AEBODSYS,aedecod,aerel,trtan;
```

```
quit;
```

```
%trans(inds=ae_rel_n1,byvar=style ord aebodsys aedecod aerel , outds=ae_relN,var=ae_reln,prefix=n);
```

```
%trans(inds=ae_rel_ev1, outds=ae_relev,byvar=style ord aebodsys AEDECOD aereI
,var=ae_relev,prefix=ev);
```

```
%mrg(inds1=ae_reln,inds2=ae_relev,outds=ae_rel,byvar=style ord aebodsys aedecod aereI );
```

```
proc sql;
```

```
create table ae_rel_n1 as select count(distinct usubjid) as ae_reln,aedecod,AEBODSYS,trtan,AEEXPEC,
aereI,"aeexp" as style length=200,
```

```
5 as ord from aereI group by trtan,AEBODSYS,aedecod,aereI,AEEXPEC,style,ord
order by style, ord ,AEBODSYS,aedecod,AEEXPEC,trtan ;
```

```
create table ae_rel_ev1 as select count(usubjid) as
ae_relev,AEBODSYS,aedecod,aereI,AEEXPEC,trtan,"aeexp" as style length=200,
5 as ord from aereI group by trtan,AEBODSYS,aedecod,aereI,AEEXPEC,style,ord
order by style, ord,AEBODSYS,aedecod,aereI,AEEXPEC,trtan;
```

```
quit;
```

```
%trans(inds=ae_rel_n1,byvar=style ord aebodsys aedecod aereI AEEXPEC,
outds=ae_reln,var=ae_reln,prefix=n);
```

```
%trans(inds=ae_rel_ev1, outds=ae_relev,byvar=style ord aebodsys AEDECOD aereI
AEEXPEC,var=ae_relev,prefix=ev);
```

```
%mrg(inds1=ae_reln,inds2=ae_relev,outds=ae_exp,byvar=style ord aebodsys aedecod aereI AEEXPEC );
```

```

data a;

set ae_soc ae_pt ;

by aebodsys ;

if ord=3 then do;style=" " | strip(aedecod); end;

if ord=2 then do; style=strip(aebodsys); end;

run;


/*RELATED TO IP AND EXPECTEDNESS for overall*/


proc sql;

create table ae_ipexn as select count(distinct usubjid) as ae_n,trtan,aeexpec as col length=200,
1.11 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;


create table ae_ipexev as select count(usubjid) as ae_ev,trtan,aeexpec as col length=200,
1.11 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;

quit;


%trans(inds=ae_ipexn,byvar=col ord , outds=ae_ipexn1,var=ae_n,prefix=n);

%trans(inds=ae_ipexev,byvar=col ord , outds=ae_ipexev1,var=ae_ev,prefix=ev);

%mrg(inds1=ae_ipexn1,inds2=ae_ipexev1,outds=ae_ipexov,byvar=col ord );

data ae_ipexov;

set ae_ipexov;

select (col);

```

```
when ("N") col=" Not expected";
```

```
when("Y") col=" Expected";
```

```
otherwise;
```

```
end;
```

```
run;
```

```
/*RELATED TO IP*/
```

```
proc sql;
```

```
create table ae_ipn as select count(distinct usubjid) as ae_n,trtan," Related to IP" as col length=200,  
1.1 as ord from ae where aere="RELATED" group by trtan,col,ord order by col, ord;
```

```
create table ae_ipev as select count(usubjid) as ae_ev,trtan," Related to IP" as col length=200,  
1.1 as ord from ae where aere="RELATED" group by trtan,col,ord order by col, ord;
```

```
quit;
```

```
%trans(inds=ae_ipn,byvar=col ord , outds=ae_ipn1,var=ae_n,prefix=n);
```

```
%trans(inds=ae_ipev,byvar=col ord , outds=ae_ipev1,var=ae_ev,prefix=ev);
```

```
%mrg(inds1=ae_ipn1,inds2=ae_ipev1,outds=ae_iprel,byvar=col ord );
```

```
data a1;
```

```
set a ae_rel ae_exp;
```

```
by aebodsys aedecod ;
```

```
if ord=4 then do; style=" || "Related to IP"; end;
```

```
if ord= 5 then do;
  if aeexpec="N" then style="    ||"Not expected";
  if aeexpec="Y" then style="    ||"Expected";
  if aeexpec="Missing" then style="    ||"<Missing>";
end;

drop aebodsys aedecod aeexpec aere1;

run;
```

```
proc format;
value $preord
  "Any adverse events"=0
  "Eye disorders"=1
  " Conjunctival hyperaemia"=1.1
  "Gastrointestinal disorders"=2
  " Abdominal pain"=2.1
  " Constipation"=2.2
  " Dyspepsia"=2.3
  " Flatulence"=2.4
  " Nausea"=2.5
  " Vomiting"=2.6
  "General disorders and administration site conditions"=3
  " Induration"=3.1
  " Vessel puncture site bruise"=3.2
```

" Vessel puncture site haemorrhage"=3.3

"Infections and infestations"=4

" Sinusitis"=4.1

"Injury, poisoning and procedural complications"=5

" Administration related reaction"=5.1

" Excoriation"=5.2

" Procedural complication"=5.3

" Procedural hypotension"=5.4

"Investigations"=6

" Blood creatinine increased"=6.1

" Blood pressure increased"=6.2

" Blood triglycerides increased"=6.3

" Carbon monoxide diffusing capacity decreased"=6.4

" Haemoglobin decreased"=6.5

" Lymphocyte count increased"=6.6

" Neutrophil count decreased"=6.8

"Metabolism and nutrition disorders"=7

" Diabetic ketoacidosis"=7.1

" Hypercholesterolaemia"=7.2

" Hypertriglyceridaemia"=7.3

"Musculoskeletal and connective tissue disorders"=8

" Arthralgia"=8.1

" Back pain"=8.2

" Pain in extremity"=8.3

"Nervous system disorders"=9

```

" Dizziness"=9.1
" Headache"=9.2
" Presyncope"=9.3
" Syncope"=9.4
"Psychiatric disorders"=10
" Anxiety"=10.1
"Respiratory, thoracic and mediastinal disorders"=11
" Cough"=11.1
" Epistaxis"=11.2
" Throat irritation"=11.3
"Skin and subcutaneous tissue disorders"=12
" Pruritus"=12.1
" Skin irritation"=12.2
" Urticaria"=12.3;

```

```
run;
```

```

data ae1(drop=ord ord1 ord2 rename=(ord3=ord));

set ae_any ae_ipexov(rename=(col=style)) ae_iprel (rename=(col=style)) a1;

if propcase(strip(style)) not in ("Missing","Related To Ip","Related","Not Expected","Expected") then do;

ord1=input(put(style,$preord.),best.);

end;

retain ord2;

```

```

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

if strip(style)="Related to IP" then ord3=ord2 + 0.01;

else if strip(style)="Not Expected" then ord3=ord2+0.03;

else if strip(style)="Expected" then ord3=ord2+0.02;

else if strip(style)="Missing" then ord3=ord2+0.04;

else ord3=ord2;

run;

data dummy1;

length style $200.;

array a [39] _temporary_ (1.1,2.1,2.2,2.3,2.4,2.5, 2.6 ,3.1, 3.2, 3.3 ,

4.1, 5.1, 5.2, 5.3, 5.4, 6.1, 6.2, 6.3, 6.4 ,6.5 ,6.7,6.8, 7.1 7.2,7.3,8.1, 8.2, 8.3,

9.1 ,9.2, 9.3, 9.4, 10.1, 11.1, 11.2, 11.3, 12.1, 12.2, 12.3);

do i = 1 to dim(a);

ord= a(i);

style=" " || "Related to IP"; output;

style=" " || "Not expected";output;

style=" " || "Expected";output;

end;

drop i;

run;

data dummy2(drop=ord rename=(ord2=ord));

```



```
set dummy1;  
  
if style="  ||"Related to IP" then ord2=ord + 0.01;  
  
if style="  ||"Not expected" then ord2=ord+0.03;  
  
if style="  ||"Expected" then ord2=ord+0.02;  
  
run;
```

```
data dummy;  
  
length style $200.;  
  
style="Any adverse events";ord=0;cat=0;output;  
  
style="Eye disorders";ord=1;cat=1;output;  
  
style=" Conjunctival hyperaemia";ord=1.1;cat=1;output;  
  
style="Gastrointestinal disorders";ord=2;cat=2;output;  
  
style=" Abdominal pain";ord=2.1;cat=2;output;  
  
style=" Constipation";ord=2.2;cat=2;output;  
  
style=" Dyspepsia";ord=2.3;cat=2;output;  
  
style=" Flatulence";ord=2.4;cat=2;output;  
  
style=" Nausea";ord=2.5;cat=2;output;  
  
style=" Vomiting";ord=2.6;cat=2;output;  
  
style="General disorders and administration site conditions";ord=3;cat=3;output;  
  
style=" Induration";ord=3.1;cat=3;output;  
  
style=" Vessel puncture site bruise";ord=3.2;cat=3;output;  
  
style=" Vessel puncture site haemorrhage";ord=3.3;cat=3;output;  
  
style="Infections and infestations";ord=4;cat=4;output;  
  
style=" Sinusitis";ord=4.1;cat=4;output;  
  
style="Injury, poisoning and procedural complications";ord=5;cat=5;output;
```

style=" Administration related reaction";ord=5.1;cat=5;output;

style=" Excoriation";ord=5.2;cat=5;output;

style=" Procedural complication";ord=5.3;cat=5;output;

style=" Procedural hypotension";ord=5.4;cat=5;output;

style="Investigations";ord=6;cat=6;output;

style=" Blood creatinine increased";ord=6.1;cat=6;output;

style=" Blood pressure increased";ord=6.2;cat=6;output;

style=" Blood triglycerides increased";ord=6.3;cat=6;output;

style=" Carbon monoxide diffusing capacity decreased";ord=6.4;cat=6;output;

style=" Haemoglobin decreased";ord=6.5;cat=6;output;

style=" Lymphocyte count increased";ord=6.6;cat=6;output;

style=" Neutrophil count decreased";ord=6.8;cat=6;output;

style="Metabolism and nutrition disorders";ord=7;cat=7;output;

style=" Diabetic ketoacidosis";ord=7.1;cat=7;output;

style=" Hypercholesterolaemia";ord=7.2;cat=7;output;

style=" Hypertriglyceridaemia";ord=7.3;cat=7;output;

style="Musculoskeletal and connective tissue disorders";ord=8;cat=8;output;

style=" Arthralgia";ord=8.1;cat=8;output;

style=" Back pain";ord=8.2;cat=8;output;

style=" Pain in extremity";ord=8.3;cat=8;output;

style="Nervous system disorders";ord=9;cat=9;output;

style=" Dizziness";ord=9.1;cat=9;output;

style=" Headache";ord=9.2;cat=9;output;

style=" Presyncope";ord=9.3;cat=9;output;

style=" Syncope";ord=9.4;cat=9;output;

```

style="Psychiatric disorders";ord=10;cat=10;output;

style=" Anxiety";ord=10.1;cat=10;output;

style="Respiratory, thoracic and mediastinal disorders";ord=11;cat=11;output;

style=" Cough";ord=11.1;cat=11;output;

style=" Epistaxis";ord=11.2;cat=11;output;

style=" Throat irritation";ord=11.3;cat=11;output;

style="Skin and subcutaneous tissue disorders";ord=12;cat=12;output;

style=" Pruritus";ord=12.1;cat=12;output;

style=" Skin irritation";ord=12.2;cat=12;output;

style=" Urticaria";ord=12.3;cat=12;output;

run;

proc sort data=dummy;by ord;run;

proc sort data=dummy2;by ord;run;

data dummy1a;

set dummy dummy2;

by ord;

run;

proc sort data=dummy1a;by ord ;run;

proc sort data=ae1;by ord;run;

data ae2;

merge ae1(in=a drop=style ) dummy1a(in=b );

by ord;

run;

```

```

data ae2a;

length style $200.;

style="  Not expected"; ord=0.03; output;

run;

data ae2;

set ae2 ae2a ;

by ord;

cat=int(ord);

if ord=0.01 then style="  ||"Related to IP" ;

if ord=0.02 then style="  Expected";

if ord=0.03 then  style="  ||"Not expected";

run;


%macro arm(var_n= ,pt=, nam= ,ev=,ev1=);

if &var_n ^= . then do;

    pct= '('||strip(put(round((&var_n/&pt*100),0.01),5.1))||)';

    &nam= strip(put(&var_n,best.))||" "||strip(pct);

end;

    if &nam=" " then &nam="0";

    if &ev. ne . then &ev1.=strip(put(&ev.,best.));

    if &ev1.=" " then &ev1="0";

%mend;


data ae3_PRE;

```

```

set ae2;

%arm(var_n=n4,pt=&_ths.,nam=ths,ev=ev4,ev1=ev_ths);

%arm(var_n=n5,pt=&_mcc.,nam=mcc,ev=ev5,ev1=ev_mcc);

%arm(var_n=n3,pt=&_sa.,nam=sa,ev=ev3,ev1=ev_sa);

%arm(var_n=n96,pt=&_pt.,nam=pt,ev=ev96,ev1=ev_pt);

%arm(var_n=n99,pt=&_tot.,nam=tot,ev=ev99,ev1=ev_tot);

keep ev_: style ord cat ths mcc sa pt tot;

run;

```

```

%MACRO RAND(asper= ,final=);

```

```

data ae;

set adam.adae;

    where safbfl='Y' and anyae1='Y' and anl01fl='Y' and asper in (&asper.) /*and aere1="RELATED"*/;

    output;

    trtan=99;

    trta='Overall Safety';

output;

run;

data aere1;

set ae;

```

```
where aere1="RELATED";
```

```
if aeexpec=" " then aeexpec="Missing";
```

```
run;
```

```
proc sql;
```

```
create table ae_n1 as select count(distinct usubjid) as ae_n,trtan,"Any adverse events" as style  
length=200,
```

```
1 as ord from ae group by trtan,style,ord order by style, ord;
```

```
create table ae_ev1 as select count(usubjid) as ae_ev,trtan,"Any adverse events" as style length=200,
```

```
1 as ord from ae group by trtan,style,ord order by style, ord;
```

```
quit;
```

```
%macro trans(inds= ,byvar=,var=, outds=, prefix=);
```

```
proc transpose data=&inds. out=&outds.(drop=_name_) prefix=&prefix.;
```

```
by &byvar.;
```

```
var &var.;
```

```
id trtan;
```

```
run;
```

```
%mend;
```

```
%macro mrg(inds1= ,inds2=, byvar=,outds= );
```

```
proc sort data=&inds1.; by &byvar. ; run;
```

```
proc sort data=&inds2.;by &byvar.; run;
```

```
data &outds.;
```

```
merge &inds1. &inds2.;
```

```
by &byvar;
```

```
run;  
  
%mend;  
  
%trans(inds=ae_n1,byvar=style ord , outds=ae_N,var=ae_n,prefix=n);  
  
%trans(inds=ae_ev1,byvar=style ord , outds=ae_ev,var=ae_ev,prefix=ev);  
  
%mrg(inds1=ae_n,inds2=ae_ev,outds=ae_any,byvar=style ord );
```

```
proc sql;  
  
create table ae_ipn as select count(distinct usubjid) as ae_n,trtan," Related to IP" as col length=200,  
0.1 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;
```

```
create table ae_ipev as select count(usubjid) as ae_ev,trtan," Related to IP" as col length=200,  
0.1 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;  
  
quit;
```

```
%trans(inds=ae_ipn,byvar=col ord , outds=ae_ipn1,var=ae_n,prefix=n);  
  
%trans(inds=ae_ipev,byvar=col ord , outds=ae_ipev1,var=ae_ev,prefix=ev);  
  
%mrg(inds1=ae_ipn1,inds2=ae_ipev1,outds=ae_iprel,byvar=col ord );
```

```
proc sql;
```

```
create table ae_soc_n1 as select count(distinct usubjid) as ae_socn,AEBODSYS,trtan,  
"soc" as style length=200,2 as ord from ae group by trtan,AEBODSYS,style,ord  
order by style, ord ,AEBODSYS, trtan;
```

```
create table ae_soc_ev1 as select count(usubjid) as ae_socev,AEBODSYS,trtan,"soc" as style length=200,  
2 as ord from ae group by trtan,AEBODSYS,style,ord order by style, ord,AEBODSYS, trtan;
```

```
quit;
```

```
%trans(inds=ae_soc_n1,byvar=style ord aebodsys, outds=ae_soc_N,var=ae_socn,prefix=n);  
%trans(inds=ae_soc_ev1, outds=ae_soc_ev,byvar=style ord aebodsys,var=ae_socev,prefix=ev);  
%mrg(inds1=ae_soc_n,inds2=ae_soc_ev,outds=ae_soc,byvar=style ord aebodsys );
```

```
proc sql;
```

```
create table ae_pt_n1 as select count(distinct usubjid) as ae_ptn,aedecod,AEBODSYS,trtan,  
"soc" as style length=200,  
3 as ord from ae group by trtan,AEBODSYS,aedecod,style,ord  
order by style, ord ,AEBODSYS,aedecod ;
```

```
create table ae_pt_ev1 as select count(usubjid) as ae_ptev,AEBODSYS,aedecod,trtan,"soc" as style  
length=200,  
3 as ord from ae group by trtan,AEBODSYS,aedecod,style,ord  
order by style, ord,AEBODSYS,aedecod,trtan;
```



```
quit;
```

```
%trans(inds=ae_pt_n1,byvar=style ord aebodsys aedecod, outds=ae_ptN,var=ae_ptn,prefix=n);  
%trans(inds=ae_pt_ev1, outds=ae_ptev,byvar=style ord aebodsys AEDECOD,var=ae_ptev,prefix=ev);  
%mrg(inds1=ae_ptn,inds2=ae_ptev,outds=ae_pt,byvar=style ord aebodsys aedecod );
```

```
proc sql;
```

```
create table ae_rel_n1 as select count(distinct usubjid) as ae_reln,aedecod,AEBODSYS,trtan,  
aerel,"aerel" as style length=200,  
4 as ord from aerel group by trtan,AEBODSYS,aedecod,aerel,style,ord  
order by style, ord ,AEBODSYS,aedecod,aerel,trtan ;
```

```
create table ae_rel_ev1 as select count(usubjid) as ae_relev,AEBODSYS,aedecod,aerel,trtan,"aerel" as  
style length=200,  
4 as ord from aerel group by trtan,AEBODSYS,aedecod,aerel,style,ord  
order by style, ord,AEBODSYS,aedecod,aerel,trtan;
```

```
quit;
```

```
%trans(inds=ae_rel_n1,byvar=style ord aebodsys aedecod aerel , outds=ae_relN,var=ae_reln,prefix=n);  
%trans(inds=ae_rel_ev1, outds=ae_relev,byvar=style ord aebodsys AEDECOD aerel  
,var=ae_relev,prefix=ev);
```

```
%mrg(inds1=ae_reln,inds2=ae_relev,outds=ae_rel,byvar=style ord aebodsys aedecod aereI );
```

```
proc sql;
```

```
create table ae_rel_n1 as select count(distinct usubjid) as ae_reln,aedecod,AEBODSYS,trtan,AEEXPEC,  
aereI,"aeexp" as style length=200,
```

```
5 as ord from aereI group by trtan,AEBODSYS,aedecod,aereI,AEEXPEC,style,ord
```

```
order by style, ord ,AEBODSYS,aedecod,AEEXPEC,trtan ;
```

```
create table ae_rel_ev1 as select count(usubjid) as
```

```
ae_relev,AEBODSYS,aedecod,aereI,AEEXPEC,trtan,"aeexp" as style length=200,
```

```
5 as ord from aereI group by trtan,AEBODSYS,aedecod,aereI,AEEXPEC,style,ord
```

```
order by style, ord,AEBODSYS,aedecod,aereI,AEEXPEC,trtan;
```

```
quit;
```

```
%trans(inds=ae_rel_n1,byvar=style ord aebodsys aedecod aereI AEEXPEC,  
outds=ae_reln,var=ae_reln,prefix=n);
```

```
%trans(inds=ae_rel_ev1, outds=ae_relev,byvar=style ord aebodsys AEDECOD aereI  
AEEXPEC,var=ae_relev,prefix=ev);
```

```
%mrg(inds1=ae_reln,inds2=ae_relev,outds=ae_exp,byvar=style ord aebodsys aedecod aereI AEEXPEC );
```

```
data a;
```

```

set ae_soc ae_pt ;

by aebodsys ;

if ord=3 then do;style=" " | strip(aedecod); end;

if ord=2 then do; style=strip(aebodsys); end;

run;

```

```

/*RELATED TO IP AND EXPECTEDNESS for overall*/

```

```

proc sql;

create table ae_ipexn as select count(distinct usubjid) as ae_n,trtan,aeexpec as col length=200,

1.11 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;

create table ae_ipexev as select count(usubjid) as ae_ev,trtan,aeexpec as col length=200,

1.11 as ord from ae where aere1="RELATED" group by trtan,col,ord order by col, ord;

quit;

```

```

%trans(inds=ae_ipexn,byvar=col ord , outds=ae_ipexn1,var=ae_n,prefix=n);

%trans(inds=ae_ipexev,byvar=col ord , outds=ae_ipexev1,var=ae_ev,prefix=ev);

%mrg(inds1=ae_ipexn1,inds2=ae_ipexev1,outds=ae_ipexov,byvar=col ord );

data ae_ipexov;

set ae_ipexov;

select (col);

when ("N") col=" Not expected";

when("Y") col=" Expected";

```

```

otherwise;

end;

run;

/*RELATED TO IP*/

proc sql;

create table ae_ipn as select count(distinct usubjid) as ae_n,trtan," Related to IP" as col length=200,
1.1 as ord from ae where aere="RELATED" group by trtan,col,ord order by col, ord;

create table ae_ipev as select count(usubjid) as ae_ev,trtan," Related to IP" as col length=200,
1.1 as ord from ae where aere="RELATED" group by trtan,col,ord order by col, ord;

quit;

%trans(inds=ae_ipn,byvar=col ord , outds=ae_ipn1,var=ae_n,prefix=n);

%trans(inds=ae_ipev,byvar=col ord , outds=ae_ipev1,var=ae_ev,prefix=ev);

%mrg(inds1=ae_ipn1,inds2=ae_ipev1,outds=ae_iprel,byvar=col ord );

data a1;

set a ae_rel ae_exp;

by aebodsys aedecod ;

if ord=4 then do; style=" ||"Related to IP"; end;

if ord= 5 then do;

if aeexpec="N" then style=" ||"Not expected";

```

```
if aeexpec="Y" then style="    ||"Expected";  
if aeexpec="Missing" then style="    ||"<Missing>";  
end;  
run;
```

```
proc format;  
value $orda  
"Any adverse events"=0  
"Blood and lymphatic system disorders"=1  
" Anaemia"=1.1  
" Leukocytosis"=1.2  
"Cardiac disorders"=2  
" Palpitations"=2.1  
"Ear and labyrinth disorders"=3  
" Ear pain"=3.1  
"Eye disorders"=4  
" Conjunctivitis"=4.1  
" Eye pruritus"=4.2  
" Scleral haemorrhage"=4.3  
"Gastrointestinal disorders"=5  
" Abdominal pain"=5.1  
" Constipation"=5.2  
" Diarrhoea"=5.3
```

- " Dry mouth"=5.4
- " Flatulence"=5.5
- " Gingival bleeding"=5.6
- " Gingival pain"=5.7
- " Lip dry"=5.8
- " Nausea"=5.9
- " Paraesthesia oral"=5.91
- " Salivary hypersecretion"=5.92
- " Toothache"=5.93
- " Vomiting"=5.94
- "General disorders and administration site conditions"=6
- " Chest discomfort"=6.1
- " Feeling hot"=6.2
- " Non-cardiac chest pain"=6.3
- " Pyrexia"=6.4
- "Infections and infestations"=7
- " Oral herpes"=7.1
- " Pharyngitis"=7.2
- " Upper respiratory tract infection"=7.3
- " Urinary tract infection"=7.4
- "Injury, poisoning and procedural complications"=8
- " Administration related reaction"=8.1
- " Arthropod bite"=8.2
- " Contusion"=8.3
- " Excoriation"=8.4

- " Laceration"=8.5
- " Ligament sprain"=8.6
- " Muscle strain"=8.7
- " Thermal burn"=8.8
- " Wound"=8.9
- "Investigations"=9
 - " Alanine aminotransferase increased"=9.1
 - " Aspartate aminotransferase increased"=9.2
 - " Blood bilirubin increased"=9.3
 - " Blood cholesterol increased"=9.4
 - " Blood potassium increased"=9.5
 - " Blood triglycerides increased"=9.6
 - " Carbon monoxide diffusing capacity decreased"=9.61
 - " Forced expiratory volume decreased"=9.7
 - " Gamma-glutamyltransferase increased"=9.8
 - " Haemoglobin decreased"=9.9
 - " Lymphocyte count increased"=9.91
 - " Neutrophil count decreased"=9.92
 - " Protein urine"=9.93
 - " Total lung capacity decreased"=9.94
 - " Vital capacity decreased"=9.95
- "Metabolism and nutrition disorders"=10
 - " Hypercholesterolaemia"=10.1
 - " Hyperglycaemia"=10.2
 - " Hypertriglyceridaemia"=10.3

" Increased appetite "=10.4

"Musculoskeletal and connective tissue disorders "=11

" Back pain "=11.1

" Muscle spasms "=11.2

" Pain in extremity "=11.3

"Nervous system disorders "=12

" Dizziness "=12.1

" Headache "=12.2

" Paraesthesia "=12.3

" Presyncope "=12.4

"Psychiatric disorders "=13

" Abnormal dreams "=13.1

" Anxiety "=13.2

" Depressed mood "=13.3

" Insomnia "=13.4

" Nightmare "=13.5

" Restlessness "=13.6

" Tension "=13.7

"Renal and urinary disorders "=14

" Dysuria "=14.1

" Proteinuria "=14.2

" Glycosuria "=14.3

"Reproductive system and breast disorders "=15

" Erectile dysfunction "=15.1

"Respiratory, thoracic and mediastinal disorders "=16

" Cough"=16.1

" Dyspnoea"=16.2

" Nasal congestion"=16.3

" Nasal discomfort"=16.4

" Oropharyngeal pain"=16.5

" Pulmonary congestion"=16.6

" Respiratory disorder"=16.7

" Rhinitis allergic"=16.8

" Rhinorrhoea"=16.9

" Sinus congestion"=16.91

" Sneezing"=16.92

" Upper-airway cough syndrome"=16.93

"Skin and subcutaneous tissue disorders"=17

" Acne"=17.1

" Blister"=17.11

" Cold sweat"=17.2

" Dry skin"=17.3

" Erythema"=17.4

" Pruritus"=17.5

" Rash"=17.6

"Vascular disorders"=18

" Peripheral coldness"=18.1

;

```
run;
```

```
data &final.(drop=ord ord1 ord2 rename=(ord3=ord));;
```

```
set ae_any ae_ipexov(rename=(col=style)) ae_iprel (rename=(col=style)) a1;
```

```
if propcase(strip(style)) not in ("Missing", "Related To Ip", "Related", "Not Expected", "Expected") then do;
```

```
ord1=input(put(style,$orda.),best.);
```

```
end;
```

```
if style="RELATED" then style=" Related to IP";
```

```
if style="Not expected" then style=" Not expected";
```

```
if style="Expected" then style=" Expected";
```

```
retain ord2;
```

```
if ord1 ne . then ord2=ord1;
```

```
if ord1 = . then ord1=ord2 ;
```

```
if ord2 not in(5.91,5.92,5.93,5.94,9.91,9.92,9.93,9.94,9.95,9.61,16.90,16.91,16.92,16.93) then do;
```

```
if style in (" Related to IP", " Related to IP") then ord3=ord2 + 0.01;
```

```
else if strip(style) in("Not expected") then ord3=ord2+0.03;
```

```
else if strip(style) in("Expected") then ord3=ord2+0.02;
```

```
else if style in (" <Missing>", " <Missing>") then ord2=ord2+0.04;
```

```
else ord3=ord2;
```

```
end;
```

```
else if ord2 in (5.91,5.92,5.93,5.94,9.91,9.92,9.93,9.94,9.95,9.61,16.90,16.91,16.92,16.93) then do;
```

```
if style in (" Related to IP", " Related to IP") then ord3=ord2 + 0.001;
```

```
else if style in(" Not expected", " Not expected") then ord3=ord2+0.003;
```

```
else if style in(" Expected", " Expected") then ord3=ord2+0.002;
```

```
else if style in (" <Missing>", " <Missing>") then ord2=ord3+0.004;
```

```
else ord3=ord2;

end;

run;

proc sort data=&final.;by ord; run;

%MEND;
```

```
%rand(asper=2 3 4,final=prand1);
```

```
proc sort data=adam.adae nodupkey out=fdummy(keep=aebodsys aedecod aerel aeexpec);

by aebodsys aedecod;

where asper in (2 3 4);

run;

data decod_dummy;

set fdummy;

do i = 1 to 3;

output;

end;

run;

data decod_dummy;

length aerel $11 aeexpec $14;

set decod_dummy;

if i=1 then aerel='RELATED';

If i =2 then aeexpec='Expected';
```

```

if i=3 then AEEXPEC='Not expected';

if aere1="" then aere1='RELATED';

run;

proc sort data=decod_dummy ;

by aebodsys aeDecod aere1 aeexpec ;

run;

proc sort data=prand1;

by aebodsys aeDecod aere1 aeexpec;

run;

data prand2;

    merge prand1 decod_dummy ;

    by aebodsys aeDecod aere1 aeexpec ;

if aere1="RELATED" and aeexpec=" " and style=" " then style="RELATED";

if aeexpec="Expected" and style=" " then style="Expected";

if aeexpec="Not expected" and style=" " then style="Not expected";

    run;


data prand3(drop=ord ord1 ord2 rename=(ord3=ord));;

set prand2 ;

if propcase(strip(style)) not in ("Missing","Related To Ip","Related","Not Expected","Expected") then do;

ord1=input(put(style,$ord.),best.);

end;

if style="RELATED" then style="    Related to IP";

if style="Not expected" then style="    Not expected";

```

```

if style="Expected" then style="    Expected";

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

if ord2 not in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)
then do;

if style in ("    Related to IP","    Related to IP") then ord3=ord2 + 0.01;

else if strip(style) in("Not expected") then ord3=ord2+0.03;

else if strip(style) in("Expected") then ord3=ord2+0.02;

else if style in ("    <Missing>","    <Missing>") then ord2=ord2+0.04;

else ord3=ord2;

end;

else if ord2 in
(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93) then do;

if style in ("    Related to IP","    Related to IP") then ord3=ord2 + 0.001;

else if style in("    Not expected","    Not expected") then ord3=ord2+0.003;

else if style in("    Expected","    Expected") then ord3=ord2+0.002;

else if style in ("    <Missing>","    <Missing>") then ord2=ord3+0.004;

else ord3=ord2;

end;

run;

proc sort data=prand3;by ord n99;run;

data prand3a;

set prand3;

by ord n99;

if last.ord;

```

```

drop AEBODSYS AEDECOD aere1 AEEXPEC;

run;

DATA PRAND3B;

SET ae2a prand3a;

by ord;

run;

DATA

%macro arm(var_n= ,pt=, nam= ,ev=,ev1=);

if(_n_=1) then do;

    if(lengthn(vnamex("&var_n."))< 1 ) then do;

        &var_n =.;

    end;

    if(lengthn(vnamex("&ev."))< 1 ) then do;

        &ev =.;

    end;

end;

if &var_n ^= . then do;

    pct= '(' || strip(put(round((&var_n/&pt*100),0.01),5.1)) || ')';

    &nam= strip(put(&var_n,best.)) || " " || strip(pct);

end;

    if &nam=" " then &nam="0";

    if &ev. ne . then &ev1.=strip(put(&ev.,best.));

    if &ev1.=" " then &ev1="0";

%mend;

```

```

data prand;

set prand3b;

%arm(var_n=n4,pt=&_thsp.,nam=ths,ev=ev4,ev1=ev_ths);

%arm(var_n=n5,pt=&_mccp.,nam=mcc,ev=ev5,ev1=ev_mcc);

%arm(var_n=n3,pt=&_sap.,nam=sa,ev=ev3,ev1=ev_sa);

%arm(var_n=n99,pt=&_totp.,nam=tot,ev=ev99,ev1=ev_tot);

cat=int(ord);

keep ev_: style ord cat ths mcc sa tot;

if cat=0 and ord=0.03 and tot eq "0" then delete;

run;

%rand(asper=2,final=confi1 );

proc sort data=adam.adae nodupkey out=fdummyc(keep=aebodsys aedecod aerel aeexpec);

by aebodsys aedecod;

where asper in (2 );

run;

data decod_dummyc;

set fdummyc;

do i = 1 to 3;

output;

end;

run;

data decod_dummyc;

```

```

length aere1 $11 aeexpec $14;

set decod_dummyc;


if i=1 then aere1='RELATED';

If i =2 then aeexpec='Expected';

if i=3 then AEEXPEC='Not expected';

if aere1="" then aere1='RELATED';

run;

proc sort data=decod_dummyc ;

by aebodsys aeecod aere1 aeexpec ;

run;

proc sort data=confi1;

by aebodsys aeecod aere1 aeexpec;

run;

data confi2;

    merge confi1 decod_dummyc ;

    by aebodsys aeecod aere1 aeexpec ;

if aere1="RELATED" and aeexpec=" " and style=" " then style="RELATED";

if aeexpec="Expected" and style=" " then style="Expected";

if aeexpec="Not expected" and style=" " then style="Not expected";


run;


data confi3(drop=ord ord1 ord2 rename=(ord3=ord));;

```



```

set confi2;

if propcase(strip(style)) not in ("Missing","Related To Ip","Related","Not Expected","Expected") then do;

ord1=input(put(style,$orda.),best.);

end;

if style="RELATED" then style="  Related to IP";

if style="Not expected" then style="    Not expected";

if style="Expected" then style="      Expected";

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

if ord2 not in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)
then do;

if style in ("  Related to IP"," Related to IP") then ord3=ord2 + 0.01;

else if strip(style) in("Not expected") then ord3=ord2+0.03;

else if strip(style) in("Expected") then ord3=ord2+0.02;

else if style in ("    <Missing>"," <Missing>") then ord2=ord2+0.04;

else ord3=ord2;

end;

else if ord2 in
(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93) then do;

if style in ("  Related to IP"," Related to IP") then ord3=ord2 + 0.001;

else if style in("    Not expected"," Not expected") then ord3=ord2+0.003;

else if style in("      Expected"," Expected") then ord3=ord2+0.002;

else if style in ("    <Missing>"," <Missing>") then ord2=ord3+0.004;

else ord3=ord2;

end;

```

```

run;

proc sort data=confi3;by ord n99;run;

data confi3a;

set confi3;

by ord n99;

if last.ord;

drop AEBODSYS AEDECOD aere1 AEEXPEC;

run;

DATA confi3b;

SET ae2a confi3a;

by ord;

run;

data confi;

set confi3b;

%arm(var_n=n4,pt=&_thsp.,nam=ths,ev=ev4,ev1=ev_ths);

%arm(var_n=n5,pt=&_mccp.,nam=mcc,ev=ev5,ev1=ev_mcc);

%arm(var_n=n3,pt=&_sap.,nam=sa,ev=ev3,ev1=ev_sa);

%arm(var_n=n99,pt=&_totp.,nam=tot,ev=ev99,ev1=ev_tot);

cat=int(ord);

keep ev_: style ord cat ths mcc sa tot;

if cat=0 and ord=0.03 and tot eq "0" then delete;

run;

```

```
%rand(asper=3,final=amb1);
```

```
proc sort data=adam.adae nodupkey out=fdummya(keep=aebodsys aedecod aerel aeexpec);
```

```
by aebodsys aedecod;
```

```
where asper in ( 3);
```

```
run;
```

```
data decod_dummya;
```

```
set fdummya;
```

```
do i = 1 to 3;
```

```
output;
```

```
end;
```

```
run;
```

```
data decod_dummya;
```

```
length aerel $11 aeexpec $14;
```

```
set decod_dummya;
```

```
if i=1 then aerel='RELATED';
```

```
if i =2 then aeexpec='Expected';
```

```
if i=3 then AEEXPEC='Not expected';
```

```
if aerel="" then aerel='RELATED';
```

```
run;
```

```
proc sort data=decod_dummya ;
```

```
by aebodsys aedecod aerel aeexpec ;
```

```
run;
```

```
proc sort data=amb1;
```

```
by aebodsys aedecod aere1 aeexpec;
```

```
run;
```

```
data amb2;
```

```
merge amb1 decod_dummya ;
```

```
by aebodsys aedecod aere1 aeexpec ;
```

```
if aere1="RELATED" and aeexpec=" " and style=" " then style="RELATED";
```

```
if aeexpec="Expected" and style=" " then style="Expected";
```

```
if aeexpec="Not expected" and style=" " then style="Not expected";
```

```
run;
```

```
data amb3(drop=ord ord1 ord2 rename=(ord3=ord));;
```

```
set amb2;
```

```
if propcase(strip(style)) not in ("Missing","Related To Ip","Related","Not Expected","Expected") then do;
```

```
ord1=input(put(style,$orda.),best.);
```

```
end;
```

```
if style="RELATED" then style=" Related to IP";
```

```
if style="Not expected" then style=" Not expected";
```

```
if style="Expected" then style=" Expected";
```

```
retain ord2;
```

```
if ord1 ne . then ord2=ord1;
```

```
if ord1 = . then ord1=ord2 ;
```

```
if ord2 not in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)  
then do;
```

```
if style in (" Related to IP"," Related to IP") then ord3=ord2 + 0.01;
```

```

else if strip(style) in("Not expected") then ord3=ord2+0.03;

else if strip(style) in("Expected") then ord3=ord2+0.02;

else if style in ("    <Missing>", "    <Missing>") then ord2=ord2+0.04;

else ord3=ord2;

end;

else if ord2 in
(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93) then do;

if style in ("    Related to IP", "    Related to IP") then ord3=ord2 + 0.001;

else if style in("    Not expected", "    Not expected") then ord3=ord2+0.003;

else if style in("    Expected", "    Expected") then ord3=ord2+0.002;

else if style in ("    <Missing>", "    <Missing>") then ord2=ord3+0.004;

else ord3=ord2;

end;

run;

proc sort data=amb3;by ord n99;run;

data amb3a;

set amb3;

by ord n99;

if last.ord;

drop AEBODSYS AEDECOD aere1 AEEXPEC;

run;

data ae4;

length style $200.;

style="    Expected"; ord=0.02; cat=0; output;

run;

DATA amb3b;

```

```
SET ae2a amb3a ae4;

by ord;

run;

data amb;

set amb3b;

%arm(var_n=n4,pt=&_thsp.,nam=ths,ev=ev4,ev1=ev_ths);

%arm(var_n=n5,pt=&_mccp.,nam=mcc,ev=ev5,ev1=ev_mcc);

%arm(var_n=n3,pt=&_sap.,nam=sa,ev=ev3,ev1=ev_sa);

%arm(var_n=n99,pt=&_totp.,nam=tot,ev=ev99,ev1=ev_tot);

cat=int(ord);

keep ev_: style ord cat ths mcc sa tot;

if cat=0 and ord=0.03 and tot eq "0" then delete;


run;
```

```
data sf1;

length column $200;

column="Safety Follow-Up";asper=4; cat=50;ord=50;output;

run;
```

```
data ae_fin;

set

ae3_pre(in=e)
```

```

prand(in=a)

    confi(in=b)

    amb(in=c)

sf1(in=d);

length column $200;


    if e then do ;column="Pre-Randomization";asper=1; end;

    if a then do ;column="Post-Randomization";asper=1.1; end;

    if b then do;column="Confinement";asper=2; end;

        if c then do;column="Ambulatory";asper=3; end;

        if d then do;column="Safety Follow-Up";asper=4; cat=50;ord=50; end;

if tot="0" and strip(style)^="Related to IP" then call
missing(th, ev_th, mcc, ev_mcc, sa, ev_sa, pt, ev_pt, tot, ev_tot);

if tot="0" and strip(style)="Related to IP" then call missing(ev_th, ev_mcc, ev_sa, ev_pt, ev_tot);

if th="0" then ev_th=" ";

if mcc="0" then ev_mcc=" ";

if sa="0" then ev_sa=" ";

if pt="0" then ev_pt=" ";

if tot="0" then ev_tot=" ";

run;


proc sort data=ae_fin;by asper ord cat;run;

proc sql noprint;

    create table tflds.&tflno as

    select *

    from ae_fin

```

```
where asper ne 4;
```

```
quit;
```

```
data ae_fin1;
```

```
set ae_fin;
```

```
if strip(style) in ("Expected" "Not expected") and ord not in(0.02,0.03) and tot=" " then delete;
```

```
if ord eq 0.03 and tot=" " then do;
```

```
ths="0" ;mcc="0";sa="0";pt="0";tot="0";
```

```
end;
```

```
run;
```

```
data ae_s(rename=(ord=cat));
```

```
set ae_fin1;
```

```
where ord in(1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18);
```

```
if ths="0" then flag_ths=1;
```

```
if mcc="0" then flag_mcc=1;
```

```
if sa="0" then flag_sa=1;
```

```
if pt="0" then flag_pt=1;
```

```
keep flag_: ord asper;
```

```
run;
```

```
proc sql;
```

```
create table ae6 as select a.*,b.flag_ths ,b.flag_mcc,b.flag_sa,b.flag_pt from ae_fin1 a left join ae_s b on  
a.cat=b.cat and a.asper=b.asper order by asper,cat,ord;
```

```
quit;
```

```
data ae6a;
```



```
set ae6;

if ord not in (1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18) then do;

if flag_ths=1 then ths=" ";

if flag_mcc=1 then mcc=" ";

if flag_sa=1 then sa=" ";

if flag_pt=1 then pt=" ";

end;

run;
```

```
data ae4(rename=(wrap=style));

set ae6a;

attrib wrap length = $200;

ord1=strip(put(ord,best.));

wrap = style;
```

```
i=45; *This is the max length allowed on a single line - change as needed;

if index(ord1,".")>0 then do;

if length(wrap)>i then do;

nwrops = int(length(wrap)/i); *Calculate how many lines the text will wrap over;

do while(nwrops > 0);

fin=0;

j = i*nwrops; *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;
```

```

        if asper ne 1 then do;
wrap=substR(wrap,1,j-1) || "^n ^S={foreground=white}.^S={} " || substr(wrap,j+1);
        end;
        else if asper eq 1 then do;
                wrap=substR(wrap,1,j-1) || "^n ^S={foreground=white}.^S={} " || substr(wrap,j+1);

        end;

        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;

drop _style_ _ord1_ i nwraps fin j;
run;

proc sort data=ae4;by asper _ord_ cat;run;

data paging;

    set ae4;

        by asper cat _ord_;

if first.asper or _ln_ gt 9 then _ln_=1; /*Check for page overflows, this may need changing*/
else _ln_+1;

```

```

    if ln=1 or first.asper then page+1;

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

        flag=1;

run;


/* Standard - leave this */

%let escape char='^';

options number nodate orientation=landscape /*papersize=&P_PGSize*/ missing=' ';

ods escapechar='^';

%let linetop = \brdt\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, halfblk=N);

%if &halfblk=N %then %let halfblk=;

%else %if &halfblk=Y %then %let halfblk=~;

/* 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", ""));

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

```

```
run;
```

```
ods path stdlib.t106343 (read) ;
```

```
ods results off;
```

```
ods rtf toc_data/* contents*/
```

```
file="/cvn/projects/prj/data/000000106343/TFL/&TFL_Part./Tables/&tflno..rtf" style=t106343
```

```
startpage=yes headery=1440 footery=1440 ;
```

```
ods noproctitle;
```

```
%do i=1 %to &page;
```

```
title ;
```

```
footnote;
```

```
%let wd=0;
```

```
%LET NOOBS=0;
```

```
ods proclabel = ' ';
```

```
data comp;
```

```
    set paging end=eof;
```

```
        where page=&i;
```

```
        if asper=4 then call symput("noobs","1");
```

```
%put  nobs=&noobs;
```

```
    /* Amend title as needed */
```

```
        _firtitl="Table 15.2.6.5 Summary of Adverse Events by System Organ Class and  
Preferred Term and Relationship to Study Product Exposure and Expectedness - 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('perid', strip(column));
```

```
call symput('asper1', compress(put(asper,best.)));
```

```
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 page cat ord asper

```
("System Organ Class" ("Preferred Term" style))

("THSm2.2 $(N=&n4) &linebot" (" n(%) Events" ths ev_ths))

("mCC$(N=&n5) &linebot" (" n(%) Events" mcc ev_mcc)

("SA $(N=&n3) &linebot" (" n(%) Events" sa ev_sa ))

("Product Test$(N=&n96) &linebot" (" n(%) Events" pt ev_pt))

%if &asper1.=1 %then %do; ("Overall$Safety$(N=&n99) &linebot" ("n(%) Events" tot
ev_tot)) %end;

%else %do;("Overall$Safety$(N=&n99p) &linebot" ("n(%) Events" tot ev_tot)) %end;

;
```

```
define page / order order = internal noprint;

define cat / order order = internal noprint;

define ord / order order = internal noprint;

define asper/order order=internal noprint;

define style / display style={just=left cellwidth=6.2cm asis = on}' ';

define ths / display style={just=c cellwidth=2.0cm} style(header)={just=left} "";

define ev_ths / display style={JUST=c cellwidth=1.1cm} style(header)={just=left} "";

define mcc / display style={just=c cellwidth=2.0cm} style(header)={just=right} "";

define ev_mcc / display style={JUST=c cellwidth=1.1cm} style(header)={just=l} "";

define sa / display style={just=c cellwidth=2.0cm} style(header)={just=right} "";

define ev_sa / display style={JUST=c cellwidth=1.10cm} style(header)={just=l} "";

%if &asper1.=1 %then %do;

define pt / display style={just=c cellwidth=2.0cm} style(header)={just=right} "";

define ev_pt /display style={JUST=c cellwidth=1.10cm} style(header)={just=l} "";
```

```

%end;

%else %do;

define pt      / noprint "";

define ev_pt    /noprint "";

                %end;

define tot      / display style={just=c cellwidth=2.0cm} style(header)={just=right} "";

define ev_tot    / display style={JUST=c cellwidth=1.10cm} style(header)={just=l} "";

```

break after page / page;

```

compute after cat;

line " ";

endcomp;

```

COMPUTE AFTER PAGE/STYLE={JUST=CENTER CELLWIDTH=5CM PROTECTSPECIALCHARS=OFF};

%IF &NOOBS. = 1 %THEN %DO;

LINE "No adverse events related to study product exposure and expectedness were reported in
Safety Follow-Up period ";

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 " ";

line "Safety Time Period: &perid";

/*line "\b\fs24\sa24&_FSRTITL1." ;*/

line "&linebot";

endcomp;

compute after _page_ / style={just=left protectspecialchars=off pretext="&linetop."};

%if &asper1.=1 %then %do;

LINE 'Note: "Product Test" refers to all subjects who tested the THS Product but were not
randomized. The Overall Safety refers to all subjects exposed to THSm2.2.';

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

line 'Note: IP = Investigational product(THSm2.2 or mCC)';

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

line ' ';

line 'Appendix 15.3.6.1';

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

%end;

%else %do;

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

line 'Note: IP = Investigational product(THSm2.2 or mCC)';

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

line ' ';

line 'Appendix 15.3.6.1';

```



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

```
%end;
```

```
endcomp;
```

```
run;
```

```
%end;
```

```
ods rtf close;
```

```
ods results on;
```

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

```
%mend ;
```

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

```
%m_logchk;
```

