

```

/*=====
*Covance Study ID   : 000000106343
*Program Name      : t_ae6010.sas
*Purpose           : Summary of Adverse Events by System Organ Class,Preferred Term
                    and Severity -Safety Population

*Input Data        : adam.adsl, ADAM.adae
*Output Data       :
*Macros Called      : m_printto m_logchk
*Programmed by     : Siva Karnati
*Creation Date      : 21 May 2015
*== Modification History =====
*Date      Initials  No. Reason;
*=====*/;

proc datasets library=work kill nolist; run;

%m_printto;

*=====;

* START OF PROGRAM CODE                               ;

*=====;

*=====;

```

```

* 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_10;

/* 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 safbfl="Y";

```

```

output;

    trt01a=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: _PT */

/*      from adsl where trt01a='Product Test';*/

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 anyaeft='Y' and anl01fl='Y' and asper=1 /*and aere="RELATED"*/;
```

```
    output;
```

```
    trtan=99;
```

```
    trta='Overall Safety';
```

```
output;
```

```
run;
```

```
data ae;
```

```
set ae;
```

```
aesev=propcase(aesev);
```

```
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,AESEV,AESEV as col length=200,

```

```
1.1 as ord from ae group by trtan,col,ord,AESEV order by col, ord;
```

```
create table ae_ipev as select count(usubjid) as ae_ev,trtan,AESEV,AESEV as col length=200,
```

```
1.1 as ord from ae group by trtan,col,ord,AESEV 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_sevovall,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 );
```

```
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;  
*drop aebodsys aedecod;  
run;
```

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

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

```
quit;
```

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

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

```
proc sort data=ae_sev; by aebodsys aedecod ; run;
```

```
proc sort data=a;by aebodsys aedecod ; run;
```

```
data a1;
```

```
set a ae_sev;
```

```
by aebodsys aedecod ;
```

```
if upcase(style) in ("MILD","MODERATE","SEVERE") then style="  "||strip(style);
```

```
drop aebodsys aedecod aesev;
```

```
run;
```

```
data a2;
```

```
set ae_any ae_sevovall(rename=(col=style)) a1;
```

```
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

" Haemoglobin decreased"=6.5

" Lymphocyte count increased"=6.6

" Carbon monoxide diffusing capacity decreased"=6.4

" 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 a2;

if upcase(strip(style)) not in ("MILD","MODERATE","SEVERE") then do;

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

end;

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

if upcase(strip(style)) in ("MILD") then ord3=ord2 + 0.01;

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

else if upcase(strip(style)) in ("SEVERE") then ord3=ord2+0.03;

else ord3=ord2;

if upcase(style) in ("MILD","MODERATE","SEVERE") then style=" "||strip(style);

run;

proc sort data=ae1;by ord; run;

%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.));

%mend;

```

```

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 ,6.6,6.8, 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="  || "Mild"; output;  
style="  || "Moderate";output;  
style="  || "Severe";output;  
end;  
drop i;  
run;
```

```
data dummy2(drop=ord rename=(ord2=ord));  
set dummy1;  
if style="  || "Mild" then ord2=ord + 0.01;  
if style="  || "Moderate" then ord2=ord+0.02;  
if style="  || "Severe" then ord2=ord+0.03;  
  
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;

retain cat1;

if cat ne . then cat1= cat;

if cat= . then cat=cat1;

drop cat1;

run;
```

```
proc sort data=dummy1a;by ord ;run;
```

```
proc sort data=ae1;by ord;run;

data ae1a;

merge ae1(in=a rename=(style=style1)) dummy1a(in=b );

by ord;

run;
```

```
data ae1a;

set ae1a;

if style="" then style=style1;

run;

data ae3_PRE;

set ae1a;

%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);  
cat=int(ord);  
keep ev_: style ord cat ths mcc sa pt tot;  
  
run;
```

```
/*POST RANDDOMIZATION SF AMB CONFIN PERIOD*/
```

```
%macro prand(asper= , outds=);
```

```
data ae;
```

```
set adam.adae;
```

```
    where safaf1='Y' and anl01fl='Y' and asper in (&asper.) /*and aere1="RELATED"*/;
```

```
    output;
```

```
    trtan=99;
```

```
    trta='Overall Safety';
```

```
output;
```

```
run;
```

```
data ae;
```

```
set ae;
```

```
aesev=propcase(aesev);
```

```
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,AESEV,AESEV as col length=200,
1.1 as ord from ae group by trtan,col,ord,AESEV order by col, ord;

create table ae_ipev as select count(usubjid) as ae_ev,trtan,AESEV,AESEV as col length=200,
1.1 as ord from ae group by trtan,col,ord,AESEV 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_sevovall,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_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;

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_socn,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 );
```

```
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;
```

```
*drop aebodsys aedecod;
```

```
run;
```

```
proc sql;
```

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

```
aesev,aesev as style length=200,
```

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

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

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



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

```
order by style, ord,AEBODSYS,aedecod,aesev,rtan;
```

```
quit;
```

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

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

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

```
proc sort data=ae_sev; by aebodsys aedecod ; run;
```

```
proc sort data=a;by aebodsys aedecod ; run;
```

```
data a1;
```

```
set a ae_sev;
```

```
by aebodsys aedecod ;
```

```
if upcase(style) in ("MILD","MODERATE","SEVERE") then style=" "||strip(style);
```

```
drop aebodsys aedecod aesev;
```

```
run;
```

```
data a2;
```

```
set ae_any ae_sevovall(rename=(col=style)) a1;
```

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

```
set a2;
```

```
if upcase(strip(style)) not in ("MILD","MODERATE","SEVERE") then do;
```

```

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

end;

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

if ord2 not
in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.96,9.60,9.61,16.90,16.91,16.92,16.93) then
do;

if upcase(strip(style)) in ("MILD") then ord3=ord2 + 0.01;

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

else if upcase(strip(style)) in ("SEVERE") then ord3=ord2+0.03;

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 upcase(strip(style)) in ("MILD") then ord3=ord2 + 0.001;

else if upcase(strip(style)) in("MODERATE") then ord3=ord2+0.002;

else if upcase(strip(style)) in ("SEVERE") then ord3=ord2+0.003;

else ord3=ord2;

end;

if upcase(style) in ("MILD","MODERATE","SEVERE") then style=" "||strip(propcase(style));

run;

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

%MEND;

```

```
%prand(asper=2 3 4,outds=prand);
```

```
/*CREATING DUMMY DATA SET*/
```

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

```
by aebodsys aedecod;
```

```
where asper in (2 3 4) and ANL01FL="Y";
```

```
run;
```

```
proc sort data=fdummy nodupkey out=a(keep=aebodsys);
```

```
by aebodsys;
```

```
run;
```

```
data y;
```

```
set fdummy;
```

```
length z $200.;
```

```
z=" "|aedecod;output;
```

```
z=" Mild";output;
```

```
z=" Moderate";output;
```

```
z=" Severe";output;
```

```
run;
```



```

proc sort data=y; by aebodsys;

run;

data x(rename=( z=style ord3=ord)drop=aebodsys aedecod ord1 ord2);

length z $200;

set a y;

by aebodsys;

if z=" " then z=aebodsys;


if upcase(strip(z)) not in ("MILD","MODERATE","SEVERE") then do;
ord1=input(put(z,$orda.),best.);
end;

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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.01;

else if upcase(strip(z)) in("MODERATE") then ord3=ord2+0.02;

else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.03;

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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.001;

else if upcase(strip(z)) in("MODERATE") then ord3=ord2+0.002;

```

```
else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.003;
else ord3=ord2;
end;
run;
```

```
proc sort data=x;by ord; run;
proc sort data=prand;by ord; run;
```

```
data prand1;
merge x(in=a) prand(in=b drop=style);
by ord;
run;
```

```
data prand3b;
set prand1;
select (ord);
```

```
when(0) style="Adverse event";
when(0.01) style=" Mild";
when(0.02) style=" Moderate";
when(0.03) style=" Severe";
otherwise ;
end;
run;
```

```

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;

run;

```

```

%prand(asper=2 ,outds=confi1);

```

```

/*CREATING DUMMY DATA SET FOR CONFIN PERIOD*/

```

```

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

by aebodsys aedecod;

where asper in (2) and ANL01FL="Y";

run;

```

```
proc sort data=fdummyc nodupkey out=ac(keep=aebodsys);  
by aebodsys;  
run;
```

```
data yc;  
set fdummyc;  
length z $200.;  
z=" "|aedecod;output;  
z=" Mild";output;  
z=" Moderate";output;  
z=" Severe";output;
```

```
run;
```

```
proc sort data=yc; by aebodsys;  
run;  
data xc(rename=( z=style ord3=ord)drop=aebodsys aedecod ord1 ord2);  
length z $200;  
set ac yc;  
by aebodsys;  
if z=" " then z=aebodsys;  
  
if upcase(strip(z)) not in ("MILD","MODERATE","SEVERE") then do;  
ord1=input(put(z,$orda.),best.);
```

```

end;

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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.01;

else if upcase(strip(z)) in("MODERATE") then ord3=ord2+0.02;

else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.03;

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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.001;

else if upcase(strip(z)) in("MODERATE") then ord3=ord2+0.002;

else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.003;

else ord3=ord2;

end;

run;

```

```

proc sort data=xc;by ord; run;

proc sort data=confi1;by ord; run;

```

```

data confi2;

merge xc(in=a) confi1(in=b drop=style);

```

```
by ord;
```

```
run;
```

```
data confi3b;
```

```
set confi2;
```

```
select (ord);
```

```
when(0) style="Adverse event";
```

```
when(0.01) style=" Mild";
```

```
when(0.02) style=" Moderate";
```

```
when(0.03) style=" Severe";
```

```
otherwise ;
```

```
end;
```

```
run;
```

```
data a;
```

```
length style $200.;
```

```
style=" Severe"; ord=0.03; cat=0; output;
```

```
run;
```

```
data confi;
```

```
set confi3b a;
```

```
by ord;
```

```
%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;  
  
run;
```

```
%prand(asper=3 ,outds=amb1);
```

```
/*CREATING DUMMY DATA SET FOR CONFIN PERIOD*/
```

```
proc sort data=adam.adae nodupkey out=fdummya(keep=aebodsys aedecod /*aerel aeexpec*/);  
by aebodsys aedecod;  
where asper in (3) and ANL01FL="Y" ;  
run;
```

```
proc sort data=fdummya nodupkey out=aa(keep=aebodsys);  
by aebodsys;  
run;
```

```
data ya;  
set fdummya;
```

```
length z $200.;
```

```
z=" "|aedecod;output;
```

```
z=" Mild";output;
```

```
z=" Moderate";output;
```

```
z=" Severe";output;
```

```
run;
```

```
proc sort data=ya; by aebodsys;
```

```
run;
```

```
data xa(rename=( z=style ord3=ord)drop=aebodsys aedecod ord1 ord2);
```

```
length z $200;
```

```
set aa ya;
```

```
by aebodsys;
```

```
if z=" " then z=aebodsys;
```

```
if upcase(strip(z)) not in ("MILD","MODERATE","SEVERE") then do;
```

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

```
end;
```

```
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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.01;
```



```

else if upcase(strip(z)) in ("MODERATE") then ord3=ord2+0.02;
else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.03;
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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.001;

else if upcase(strip(z)) in ("MODERATE") then ord3=ord2+0.002;
else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.003;
else ord3=ord2;
end;
run;

```

```

proc sort data=xa;by ord; run;
proc sort data=amb1;by ord; run;

```

```

data amb2;
merge xa(in=a) amb1(in=b drop=style);
by ord;
/*if a;*/
run;

```

```

data amb3b;
set amb2;
select (ord);

```

```
when(0) style="Adverse event";
```

```
when(0.01) style=" Mild";
```

```
when(0.02) style=" Moderate";
```

```
when(0.03) style=" Severe";
```

```
otherwise ;
```

```
end;
```

```
run;
```

```
data amb;
```

```
set amb3b ;
```

```
by ord;
```

```
%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=n96,pt=&_pt.,nam=pt,ev=ev96,ev1=ev_pt);*/
```

```
%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 tot="0" then call missing(ths,ev_ths,mcc,ev_mcc,sa,ev_sa,tot,ev_tot);
```

```
run;
```

```
%prand(asper=4 ,outds=sf1);
```

```
/*CREATING DUMMY DATA SET FOR CONFIN PERIOD*/
```

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

```
by aebodsys aedecod;
```

```
where asper in (4) and ANL01FL="Y";
```

```
run;
```

```
proc sort data=fdummys nodupkey out=as(keep=aebodsys);
```

```
by aebodsys;
```

```
run;
```

```
data ys;
```

```
set fdummys;
```

```
length z $200.;
```

```
/*if not(eof) then do;*/
```

```
z=" " | aedecod;output;
```

```
z=" Mild";output;
```

```
z=" Moderate";output;
```

```
z=" Severe";output;
```

```
/*end;*/
```

```
run;
```

```
proc sort data=ys; by aebodsys;
```

```
run;
```

```
data xs(rename=( z=style ord3=ord)drop=aebodsys aedecod ord1 ord2);
```

```
length z $200;
```

```
set as ys;
```

```
by aebodsys;
```

```
if z=" " then z=aebodsys;
```

```
if upcase(strip(z)) not in ("MILD","MODERATE","SEVERE") then do;
```

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

```
end;
```

```
retain ord2;
```

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

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

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

```
if upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.01;
```

```
else if upcase(strip(z)) in("MODERATE") then ord3=ord2+0.02;
```

```
else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.03;
```

```
else ord3=ord2;
```

```
end;
```

```
else if ord2 in(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 upcase(strip(z)) in ("MILD") then ord3=ord2 + 0.001;
```

```
else if upcase(strip(z)) in("MODERATE") then ord3=ord2+0.002;
```

```
else if upcase(strip(z)) in ("SEVERE") then ord3=ord2+0.003;
```

```
else ord3=ord2;
```

```
end;
```

```
run;
```

```
proc sort data=xs;by ord; run;
```

```
proc sort data=sf1;by ord; run;
```

```
data sf2;
```

```
merge xs(in=a) sf1(in=b drop=style);
```

```
by ord;
```

```
run;
```

```
data sf3b;
```

```
set sf2;
```

```
select (ord);
```

```
when(0) style="Adverse event";
```

```
when(0.01) style=" Mild";
```

```
when(0.02) style=" Moderate";
```

```
when(0.03) style=" Severe";
```

```
otherwise ;
```

```
end;
```

```
run;
```

```
data a;
```

```
length style $200.;
```

```
style=" Moderate"; ord=0.02; cat=0; output;
```

```
style=" Severe"; ord=0.03; cat=0; output;
```

```
run;
```

```
data sf;
```

```
set sf3b a;
```

```
by ord;
```

```
%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;
```

```
run;
```

```

data ae_fin;

set

ae3_pre(in=e)

prand(in=a)

        confi(in=b)

        amb(in=c)

sf(in=d);

length column $200;


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

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

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

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

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


run;

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

proc sql noprint;

        create table tflds.&tflno as

        select *

        from ae_fin

;

quit;

```

```

data ae_test;

set ae_fin;

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

j=length(orda);

if length(orda)>1 then orda1=substr(orda,1,j-1);

if orda1 ne " " then orda1a=input(orda1,best.);

drop j orda orda1;

run;

data as(rename=(ord=ord_as));

set ae_fin;

if ord in (1.1 1.2 2.1 2.2 2.3 2.4 2.5 2.6 3.1 3.2 3.3 4.1 4.2 4.3 5.1 5.2 5.3

5.4 5.5 5.6 5.7 5.8 5.9 5.91 5.92 5.93 5.94 6.1 6.2 6.3 6.4 6.5 6.6 6.8 7.1 7.2 7.3 7.4

8.1 8.2 8.3 8.4 8.5 8.6 8.7 8.8 8.9 9.1 9.2 9.3 9.4 9.5 9.6 9.61 9.7 9.8 9.9 9.91 9.92

9.93 9.95 10.1 10.2 10.3 10.4 11.1 11.2 11.3 12.1 12.2 12.3 12.4 13.1 13.2 13.3

13.4 13.5 13.6 13.7 14.1 14.2 14.3 15.1 16.1 16.2 16.3 16.4 16.5 16.6 16.7

16.8 16.9 16.91 16.92 16.93 17.1 17.2 17.3 17.4 17.5 17.6 );

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 ae5 as select a.*,b.flag_ths,b.flag_mcc,b.flag_sa,b.flag_pt from ae_test a left join as b on  
a.orda1a=b.ord_as and a.asper=b.asper order by asper, cat, ord ;
```

```
run;
```

```
data ae5a;
```

```
set ae5;
```

```
if ord not in (1.1 1.2 2.1 2.2 2.3 2.4 2.5 2.6 3.1 3.2 3.3 4.1 4.2 4.3 5.1 5.2 5.3  
5.4 5.5 5.6 5.7 5.8 5.9 5.91 5.92 5.93 5.94 6.1 6.2 6.3 6.4 6.5 6.6 6.8 7.1 7.2 7.3 7.4  
8.1 8.2 8.3 8.4 8.5 8.6 8.7 8.8 8.9 9.1 9.2 9.3 9.4 9.5 9.6 9.61 9.7 9.8 9.9 9.91 9.92  
9.93 9.95 10.1 10.2 10.3 10.4 11.1 11.2 11.3 12.1 12.2 12.3 12.4 13.1 13.2 13.3  
13.4 13.5 13.6 13.7 14.1 14.2 14.3 15.1 16.1 16.2 16.3 16.4 16.5 16.6 16.7  
16.8 16.9 16.91 16.92 16.93 17.1 17.2 17.3 17.4 17.5 17.6 ) 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;
```

```
drop flag_ths flag_mcc flag_sa flag_pt;
```

```
run;
```

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

```
set ae5a;
```

```
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 ae5a 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=44; *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;

  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;

drop ord1 style i nwraps fin j;

*keep ev_ : wrap ord cat ths mcc sa pt tot;

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 = \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, 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 nob=&noobs;
```

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

```
        _firtitl="Table 15.2.6.10 Summary of Adverse Events by System Organ Class and  
Preferred Term and Severity- Safety Population";
```

```
/*        _firtit2="Safety Time Period: Pre-Randomization";*/
```

```
_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('_FSRTITL1', trim(left(_firtit2)));*/
```

```
            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=6.3cm 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 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 "&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;
```

