

```
/*=====
```

```
*Covance Study ID : 000000106343
```

```
*Program Name : t_ae6012.sas
```

```
*Purpose : Summary of Serious Adverse Events by System Organ
```

```
Class,Preferred Term -Safety Population
```

```
*Input Data : adam.adsl, ADAM.adae
```

```
*Output Data : T_15_02_06_12
```

```
*Macros Called : m_printto m_logchk
```

```
*Programmed by : Siva Karnati
```

```
*Creation Date : 21 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_12;
```

```
/* 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("&_amp;_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(th));

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 anl01fl='Y' and asper= 1 and aeser="Y" ;

    output;

    trtan=99;

    trta='Overall Safety';

output;

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_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 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"=6.4

" Lymphocyte count increased"=6.5

" Total lung capacity decreased"=6.6

"Metabolism and nutrition disorders"=7

" Diabetic ketoacidosis"=7.1

"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 rename=(ord1=ord));
```

```
set ae_any a;
```

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

```
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=" Haemoglobin decreased";ord=6.4;cat=6;output;

style=" Lymphocyte count increased";ord=6.5;cat=6;output;

style=" Total lung capacity decreased";ord=6.6;cat=6;output;

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

style=" Diabetic ketoacidosis";ord=7.1;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=ae1;by ord;run;

data ae2;

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

by ord;

if a;

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;

    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 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 period(safl=,asper=,per=);
```

```
data ae;
```

```
set adam.adae;
```

```
    where &safl.='Y' and anl01fl='Y' and asper in(&asper.) and aeser='Y';
```

```
    output;
```

```
    trtan=99;
```

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

```
output;
```

```
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_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 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

" 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

"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 ae1(drop=ord rename=(ord1=ord));
```

```
set ae_any a;
```

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

```
run;
```

```
data dummy;
```

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

```
style="Any adverse events";ord=0;cat=0;output;
```

```
style="Blood and lymphatic system disorders";ord=1;cat=1;output;
```

```
style=" Anaemia";ord=1.1;cat=1;output;
```

```
style=" Leukocytosis";ord=1.2;cat=1;output;
```

```
style="Cardiac disorders";ord=2;cat=2;output;
```

```
style=" Palpitations";ord=2.1;cat=2;output;
```

```
style="Ear and labyrinth disorders";ord=3;cat=3;output;
```

```
style=" Ear pain";ord=3.1;cat=3;output;
```

```
style="Eye disorders";ord=4;cat=4;output;
```

```
style=" Conjunctivitis";ord=4.1;cat=4;output;
```

```
style=" Eye pruritus";ord=4.2;cat=4;output;
```

```
style=" Scleral haemorrhage";ord=4.3;cat=4;output;
```

```
style="Gastrointestinal disorders";ord=5;cat=5;output;
```

```
style=" Abdominal pain";ord=5.1;cat=5;output;
```

```
style=" Constipation";ord=5.2;cat=5;output;
```

```
style=" Diarrhoea";ord=5.3;cat=5;output;
```

style=" Dry mouth";ord=5.4;cat=5;output;

style=" Flatulence";ord=5.5;cat=5;output;

style=" Gingival bleeding";ord=5.6;cat=5;output;

style=" Gingival pain";ord=5.7;cat=5;output;

style=" Lip dry";ord=5.8;cat=5;output;

style=" Nausea";ord=5.9;cat=5;output;

style=" Paraesthesia oral";ord=5.91;cat=5;output;

style=" Salivary hypersecretion";ord=5.92;cat=5;output;

style=" Toothache";ord=5.93;cat=5;output;

style=" Vomiting";ord=5.94;cat=5;output;

style="General disorders and administration site conditions";ord=6;cat=6;output;

style=" Chest discomfort";ord=6.1;cat=6;output;

style=" Feeling hot";ord=6.2;cat=6;output;

style=" Non-cardiac chest pain";ord=6.3;cat=6;output;

style=" Pyrexia";ord=6.4;cat=6;output;

style="Infections and infestations";ord=7;cat=7;output;

style=" Oral herpes";ord=7.1;cat=7;output;

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

style=" Upper respiratory tract infection";ord=7.3;cat=7;output;

style=" Urinary tract infection";ord=7.4;cat=7;output;

style="Injury, poisoning and procedural complications";ord=8;cat=8;output;

style=" Administration related reaction";ord=8.1;cat=8;output;

style=" Arthropod bite";ord=8.2;cat=8;output;

style=" Contusion";ord=8.3;cat=8;output;

style=" Excoriation";ord=8.4;cat=8;output;

style=" Laceration";ord=8.5;cat=8;output;

style=" Ligament sprain";ord=8.6;cat=8;output;

style=" Muscle strain";ord=8.7;cat=8;output;

style=" Thermal burn";ord=8.8;cat=8;output;

style=" Wound";ord=8.9;cat=8;output;

style="Investigations";ord=9;cat=9;output;

style=" Alanine aminotransferase increased";ord=9.1;cat=9;output;

style=" Aspartate aminotransferase increased";ord=9.2;cat=9;output;

style=" Blood bilirubin increased";ord=9.3;cat=9;output;

style=" Blood cholesterol increased";ord=9.4;cat=9;output;

style=" Blood potassium increased";ord=9.5;cat=9;output;

style=" Blood triglycerides increased";ord=9.6;cat=9;output;

style=" Forced expiratory volume decreased";ord=9.7;cat=9;output;

style=" Gamma-glutamyltransferase increased";ord=9.8;cat=9;output;

style=" Haemoglobin decreased";ord=9.9;cat=9;output;

style=" Lymphocyte count increased";ord=9.91;cat=9;output;

style=" Neutrophil count decreased";ord=9.92;cat=9;output;

style=" Protein urine";ord=9.93;cat=9;output;

style=" Total lung capacity decreased";ord=9.94;cat=9;output;

style=" Vital capacity decreased";ord=9.95;cat=9;output;

style="Metabolism and nutrition disorders";ord=10;cat=10;output;

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

style=" Hyperglycaemia";ord=10.2;cat=10;output;

style=" Hypertriglyceridaemia";ord=10.3;cat=10;output;

style=" Increased appetite";ord=10.4;cat=10;output;

style="Musculoskeletal and connective tissue disorders";ord=11;cat=11;output;

style=" Back pain";ord=11.1;cat=11;output;

style=" Muscle spasms";ord=11.2;cat=11;output;

style=" Pain in extremity";ord=11.3;cat=11;output;

style="Nervous system disorders";ord=12;cat=12;output;

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

style=" Headache";ord=12.2;cat=12;output;

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

style=" Presyncope";ord=12.4;cat=12;output;

style="Psychiatric disorders";ord=13;cat=13;output;

style=" Abnormal dreams";ord=13.1;cat=13;output;

style=" Anxiety";ord=13.2;cat=13;output;

style=" Depressed mood";ord=13.3;cat=13;output;

style=" Insomnia";ord=13.4;cat=13;output;

style=" Nightmare";ord=13.5;cat=13;output;

style=" Restlessness";ord=13.6;cat=13;output;

style=" Tension";ord=13.7;cat=13;output;

style="Renal and urinary disorders";ord=14;cat=14;output;

style="Dysuria";ord=14.1;cat=14;output;

style=" Proteinuria";ord=14.2;cat=14;output;

style="Reproductive system and breast disorders";ord=15;cat=15;output;

style=" Erectile dysfunction";ord=15.1;cat=15;output;

style="Respiratory, thoracic and mediastinal disorders";ord=16;cat=16;output;

style=" Cough";ord=16.1;cat=16;output;

style=" Dyspnoea";ord=16.2;cat=16;output;

```
style=" Nasal congestion";ord=16.3;cat=16;output;  
style=" Nasal discomfort";ord=16.4;cat=16;output;  
style=" Oropharyngeal pain";ord=16.5;cat=16;output;  
style=" Pulmonary congestion";ord=16.6;cat=16;output;  
style=" Respiratory disorder";ord=16.7;cat=16;output;  
style=" Rhinitis allergic";ord=16.8;cat=16;output;  
style=" Rhinorrhoea";ord=16.9;cat=16;output;  
style=" Sinus congestion";ord=16.91;cat=16;output;  
style=" Sneezing";ord=16.92;cat=16;output;  
style=" Upper-airway cough syndrome";ord=16.93;cat=16;output;  
style="Skin and subcutaneous tissue disorders";ord=17;cat=17;output;  
style=" Acne";ord=17.1;cat=17;output;  
style=" Blister";ord=17.11;cat=17;output;  
style=" Cold sweat";ord=17.2;cat=17;output;  
style=" Dry skin";ord=17.3;cat=17;output;  
style=" Erythema";ord=17.4;cat=17;output;  
style=" Pruritus";ord=17.5;cat=17;output;  
style=" Rash";ord=17.6;cat=17;output;  
style="Vascular disorders";ord=18;cat=18;output;  
style=" Peripheral coldness";ord=18.1;cat=18;output;
```

```
run;
```

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

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

```
data ae2;
```

```
merge ae1(in=a) dummy(in=b drop=style);
```

```
by ord;
```

```
if a;
```

```
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.));
```

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

```
%mend;
```

```

data ae3_&per.;

set ae2;

%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);


keep ev_: style ord cat ths mcc sa tot;


run;

%mend period;

%period(safl=safafl,asper=2 3 4,per=prand);

%period(safl=safafl,asper=2,per=confi );

%period(safl=safafl,asper=3,per=amb);

%period(safl=safafl,asper=4,per=sf);

```

```

data ae_fin;

set

ae3_pre(in=e)

ae3_prand(in=a)

```

```

ae3_confi(in=b)
ae3_amb(in=c)
ae3_sf(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; end;
IF MISSING(style) THEN do;
    ord=14;
    cat=14;
    call missing(ths, ev_ths, mcc,pt,ev_pt, ev_mcc, sa, ev_sa ,tot
,ev_tot);
    end;

run;

```

```

proc sort data=ae_fin;by asper ord cat;run;
proc sql noprint;
    create table tflds.&tflno as
    select *

```

```

        from ae_fin where style ne " ";

quit;

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

set ae_fin;

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

run;

data ae5a;

set ae5;

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 paging;
```

```
set ae5a;
```

```
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 missing=' ';
```

```
ods escapechar='|';
```

```
%let linetop = \brdrt\brdrs\brdrw30; * needs to be 1.5pt so calculated in twips (1/20 pt) ;
```

```
%let linebot = \brdrb\brdrs\brdrw30;
```

```
/* Standard - macro for paging */
```

```
%macro outrtf(blankn=130, halfblnk=N);
```

```
%if &halfblnk=N %then %let halfblnk=;
```

```
%else %if &halfblnk=Y %then %let halfblnk=\~;
```

```
/* 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 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*/ tot eq " " then call symput("noobs","1");

%put nob=&noobs;

/* Amend title as needed */

_firtitl="Table 15.2.6.12 Summary of Serious Adverse Events by System Organ Class and
Preferred Term-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=5.5cm 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 Serious adverse events by System Organ Class and Preferred Term were reported during this 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 "&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: 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: 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;
```

```
*=====;
```

```
* END OF PROGRAM CODE ;
```

```
*=====;
```