

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

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

```
*Program Name : t_ae_soc_sum.sas
```

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

```
and Preferred Term Safety Population
```

```
Table 15.2.6.3
```

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

```
*Output Data :
```

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

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

```
*Creation Date : 5 May 2015
```

```
*== Modification History =====
```

```
*Date Initials No. Reason;
```

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

```
proc datasets library=work kill nolist;run;
```

```
%m_printto;
```

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

```
* START OF PROGRAM CODE ;
```

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

```
/* Standard - just change the number to match the listing you're working on. Also change the letters in the*/
```

```
/* bracket, eg ccb = current cigarette brands. Make sure to do this at the top of the code too. */
```

```
/**/
```

```

%let tflno=T_15_02_06_03;

/* 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;

    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 anyae fl='Y' and anl01fl='Y' and asper=1;

    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

" Carbon monoxide diffusing capacity decreased"=6.7

" 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 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=" Carbon monoxide diffusing capacity decreased";ord=6.7;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=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 &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 anyae1='Y' and anl01fl='Y' and asper in(&asper.);

    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_socnv,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_socnv,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

" Carbon monoxide diffusing capacity decreased"=9.96

"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 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=" Carbon monoxide diffusing capacity decreased";ord=9.96;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=" Glycosuria";ord=14.3;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;

    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_&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 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;

IF MISSING(style) THEN do;

    ord=14;

    cat=14;

    call missing(ths, ev_ths, mcc,    ev_mcc,        sa,    ev_sa ,tot
,ev_tot);

    end;

run;

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

set ae_fin;

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;

    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;

    wrap=substrR(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;

run;

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

set ae4;

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 ae4 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;
```

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

```
proc sql noprint;

    create table tflds.&tfino as

    select *

    from ae_fin;

quit;
```

```
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 /*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 escapechar='^';
```

```
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 15.2.6.3 Summary of 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=6.0cm 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: 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, halfblnk=N);
```

```
%m_logchk;
```

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

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

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