

```

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

*Input Data         : adam.adsl, ADAM.adae
*Output Data        :
*Macros Called       : m_printto m_logchk
*Programmed by      : Siva Karnati
*Creation Date       : 16 May 2015

*== Modification History =====
*Date      Initials  No. Reason;
*=====*/;

proc datasets library=work kill nolist;run;

%m_printto;

*=====;
* START OF PROGRAM CODE                ;
*=====;

proc datasets library=work kill nolist;run;

/* 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_04;
```

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

```
%let TFL_Part=%scan(&_amp;_SASPROGRAMFILE,-3,%str(/));
```

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

```
data _null_;
```

```
tmp="&TFL_Part";
```

```
if tmp not in ("dev" "qc") then call symput("TFL_Part", "prod");
```

```
call symput('TFLpath', compress("&_SASPROGRAMFILE", ""));
```

```
run;
```

```
*****,
```

```
* read in data ;
```

```
*****,
```

```
data adsl;
```

```
set adam.adsl;
```

```
where safbfl="Y";
```

```
output;
```

```
trt01an=99;
```

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

```
output;
```

```
run;

proc sql noprint;

    select count (distinct usubjid) into: _THS

        from adsl where trt01a='THSm2.2';

    select count (distinct usubjid) into: _MCC

        from adsl where trt01a='mCC';

    select count (distinct usubjid) into: _SA

        from adsl where trt01a='SA';

    select count (distinct usubjid) into: _PT

        from adsl where trt01a='Product Test';

    select count (distinct usubjid) into: _tot

        from adsl where trt01a= 'Overall Safety';

quit;
```

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

```
data N;

    length label $100.;

    label='Total';

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

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

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

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

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

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

```
call symput('N4',strip(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;  
run;
```

```
proc sql;  
  
create table gpu as select gpucat1,trt01a,trt01an ,gpucat1n,count(distinct usubjid) as cnt from adslp  
group by trt01an,gpucat1n,gpucat1,trt01a;  
  
quit;
```

```
proc sql noprint;  
  
select cnt into: _THScc from gpu where trt01a='THSm2.2' and gpucat1="CC";  
  
select cnt into: _THSths from gpu where trt01a='THSm2.2' and gpucat1="THS 2.2";  
  
select cnt into: _THSdual from gpu where trt01a='THSm2.2' and gpucat1="Dual";
```

```
select cnt into: _THSnoabs from gpu where trt01a='THSm2.2' and gpucat1="Not  
Abstinent";
```

```
select cnt into: _mccc from gpu where trt01a='mCC' and gpucat1="CC";
```

```
select cnt into: _sanoabs from gpu where trt01a = 'SA' and gpucat1="Not Abstinent";
```

```
select cnt into: _sapreoabs from gpu where trt01a='SA' and gpucat1="Predominantly  
Abstinent";
```

```
select cnt into: _saabs from gpu where trt01a='SA' and gpucat1="Abstinent";
```

```
quit;
```

```
%put thscc=&_THScc thsths=&_THSths _THSdual=&_THSdual _mccc=&_mccc _saabs=&_saabs  
_sanoabs=&_sanoabs sapreoabs=&_sapreoabs ;
```

```
data N;
```

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

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

```
thscc=strip(put(&_thscc,best.));
```

```
thsths=strip(put(&_thsths,best.));
```

```
THSdual=strip(put(&_THSdual,best.));
```

```
mccc=strip(put(&_mccc,best.));
```

```
saabs=strip(put(&_saabs,best.));
```

```
sanoabs=strip(put(&_sanoabs,best.));
```

```
sapreoabs= strip(put(&_sapreoabs,best.));
```

```
call symput('Nthscc',strip(thscc));
```

```
call symput('Nthsths',strip(thsths));
```

```
call symput('NTHSdual',strip(THSdual));
```

```
call symput('Nmccc',strip(mccc));
```

```

call symput('Nsaabs',strip(saabs));

call symput('Nsanoabs',strip(sanoabs));

call symput('Nsapreoabs',strip(sapreoabs));


run;

%put &Nthsc &Nthsths &NTHSdual &Nmccc &Nsaabs &Nsanoabs &Nsapreoabs;


%macro prod(trtan=,outds=);

data ae;

set adam.adae;

    where safaf='Y' and anyae='Y' and anl01fl='Y' and asper=3 and /*trtan=4*/trtan=&trtan ;

    output;

run;


proc sql;

create table ae_n1 as select count(distinct usubjid) as ae_n,gpucat1n,"Any adverse events" as style
length=200,

1 as ord from ae group by gpucat1n,style,ord order by style, ord;


create table ae_ev1 as select count(usubjid) as ae_ev,gpucat1n,"Any adverse events" as style
length=200,

1 as ord from ae group by gpucat1n,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 gpucat1n;
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,gpucat1n,
"soc" as style length=200,2 as ord from ae group by gpucat1n,AEBODSYS,style,ord
order by style, ord ,AEBODSYS, gpucat1n;

create table ae_soc_ev1 as select count(usubjid) as ae_socev,AEBODSYS,gpucat1n,"soc" as style
length=200,

```

```
2 as ord from ae group by gpucat1n,AEBODSYS,style,ord order by style, ord,AEBODSYS, gpucat1n;
```

```
quit;
```

```
%macro trans1(inds=,byvar=,var=, outds=, prefix=);
```

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

```
by &byvar.;
```

```
var &var.;
```

```
id gpucat1n;
```

```
run;
```

```
%mend;
```

```
%trans1(inds=ae_soc_n1,byvar=style ord aebodsys, outds=ae_soc_N,var=ae_socn,prefix=n);
```

```
%trans1(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,gpucat1n,
```

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

```
3 as ord from ae group by gpucat1n,AEBODSYS,aedecod,style,ord
```

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



```
create table ae_pt_ev1 as select count(usubjid) as ae_ptev,AEBODSYS,aedecod,gpucat1n,"soc" as style
length=200,
```

```
3 as ord from ae group by gpucat1n,AEBODSYS,aedecod,style,ord
```

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

```
quit;
```

```
%trans1(inds=ae_pt_n1,byvar=style ord aebodsys aedecod, outds=ae_ptN,var=ae_ptn,prefix=n);
```

```
%trans1(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 &outds.;
```

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

```
by ord;
```

```
if a;
```

```
run;
```

```
%mend;
```

```
%prod(trtan=4,outds=ths1);
```

```
%prod(trtan=3,outds=sa1);
```

```
%prod(trtan=5,outds=mcc1)
```

```
%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_ths;

set ths1;

%arm(var_n=n2,pt=&Nthsths.,nam=ths,ev=ev2,ev1=ev_ths);

%arm(var_n=n3,pt=&NTHSdual.,nam=dual,ev=ev3,ev1=ev_dual);

%arm(var_n=n1,pt=&Nthsc.,nam=cc,ev=ev1,ev1=ev_cc);

keep ev_: style ord cat ths cc dual ;

run;

data ae3_sa;

set sa1;

%arm(var_n=n4,pt=&Nsanoabs.,nam=noabs,ev=ev4,ev1=ev_noabs);

%arm(var_n=n5,pt=&Nsapreabs.,nam=preabs,ev=ev5,ev1=ev_preabs);

%arm(var_n=n6,pt=&Nsaabs.,nam=abs,ev=ev6,ev1=ev_abs);

keep ev_: style ord cat noabs preabs abs ;

run;

data ae3_mcc;

```

```

set mccc1;

%arm(var_n=n1,pt=&Nmccc.,nam=cc,ev=ev1,ev1=ev_cc);

keep ev_: style ord cat cc ;

run;

data ae_fin;

set

ae3_ths(in=a)
    ae3_mccc(in=b)
    ae3_sa(in=c);

length column $200;

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

    if a then do ;column="THS";asper=1; end;

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

run;

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 cc="0" then flag_cc=1;

```

```
if dual="0" then flag_dual=1;
```

```
if noabs="0" then flag_noabs=1;
```

```
if preabs="0" then flag_preabs=1;
```

```
if abs="0" then flag_abs=1;
```

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

```
run;
```

```
proc sql;
```

```
create table ae5 as select a.*,b.flag_ths ,b.flag_cc,b.flag_dual,b.flag_noabs,b.flag_preabs,flag_abs 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_cc=1 then cc=" ";
```

```
if flag_dual=1 then dual=" ";
```

```
if flag_noabs=1 then noabs=" ";
```

```
if flag_preabs=1 then preabs=" ";
```

```
if flag_abs=1 then abs=" ";
```

```
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 paging;

set ae5a;

by asper cat ord;

if first.asper or ln gt 8 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, 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/* contents*/
file="/cvn/projects/prj/data/000000106343/TFL/&TFL_Part./Tables/&tflno..rtf" style=t106343
startpage=yes headery=1440 footery=1440 ;

ods noproctitle;

%do i=1 %to &page;

title ;

footnote;

%let wd=0;

%LET NOOBS=0;

```



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

```
data comp;
```

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

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

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

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

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

```
        _firtitl="Table 15.2.6.4 Summary of Adverse Events by Product Use Category, 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
```

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

```
    ("Within THS 2.2 $(N=&n4) &linebot"
```

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

```
    ("THS 2.2 $(N=&nthsths) &linebot" (" n(%)  Events" ths ev_ths))
```

```
    ("Dual$(N=&nthsdual) &linebot" (" n(%)  Events" dual ev_dual) )
```

```
    ("CC $(N=&nthsc) &linebot" (" n(%)  Events" cc ev_cc )))
```

```
%end;
```

```
%if &asper1.=2 %then %do;
```

```
    ("Within mCC $(N=&n5) &linebot"
```

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

```
    ("CC $(N=&nmccc) &linebot" ("n(%)      Events" cc ev_cc)) )
```

```
%end;
```

```

%if &asper1.=3 %then %do;

    ("Within SA $(N=&n3) &linebot"

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

    ("Abstinent $(N=&Nsaabs) &linebot" (" n(%) Events" abs ev_abs))

    ("Predominantly $ Abstinent $(N=&Nsapreoabs) &linebot" (" n(%) Events" preabs ev_preabs))

    ("Not Abstinent $(N=&Nsanoabs) &linebot" ("n(%) Events" noabs ev_noabs) ))

%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;

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

    define style    / display style={just=left cellwidth=5.5cm asis = on}' ';

    define ths    / display style={just=c cellwidth=1.0cm} style(header)={just=left} "";

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

    define cc    / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";

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

    define dual    / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";

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

%end;

%if &asper1.=2 %then %do;

```

```

define style / display style={just=left cellwidth=5.5cm asis = on}' ';
define cc / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";
define ev_cc / display style={JUST=c cellwidth=1.1cm} style(header)={just=l} "";

%end;

%if &asper1.=3 %then %do;

define style / display style={just=left cellwidth=5.5cm asis = on}' ';
define abs / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";
define ev_abs / display style={JUST=c cellwidth=1.1cm} style(header)={just=l} "";
define preabs / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";
define ev_preabs / display style={JUST=c cellwidth=1.1cm} style(header)={just=l}
"";

define noabs / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";
define ev_noabs / display style={JUST=c cellwidth=1.1cm} style(header)={just=l} "";

%end;

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 "&linebot";

endcomp;

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

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)";

endcomp;

run;

%end;

ods rtf close;

ods results on;

ods path sashelp.tmplmst (read);

%mend ;

```

```
%outrtf(blankn=25, halfblnk=N);
```

```
%m_logchk;
```

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

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

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