

```

/*=====
*Covance Study ID   : 000000106343
*Program Name       : t_ae608.sas
*Purpose            : Summary of Adverse Events Leading to Study Product Discontinuation
                        interruption,or Reduction by Product Use Category
                        System Organ Class,Preferred Term -Safety Population

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

%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_08;
```

```
/* 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 safaf1="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: _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.));

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

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

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

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

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

run;
```

```
data adslp;
```

```
set adam.adsl;  
where safafi="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 _mcc=&_mcc _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(&_mcc,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 &Nthscc &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 and
anl03fl='Y' ;

      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_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,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

"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 &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(_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_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=saabs,ev=ev6,ev1=ev_saabs);

keep ev_ : style ord cat noabs preabs saabs ;

run;

data ae3_mcc;

set mcc1;

%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_mcc(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;
```

```
if asper =3 and style eq " " then do;
```

```
call missing(noabs,ev_noabs,preabs,ev_preabs,saabs,ev_saabs);
```

```
cat=14;
```

```
ord=14;
```

```
end;
```

```
if asper=1 and style eq " " then do;
```

```
call missing(ths,ev_ths,dual,ev_dual,cc,ev_cc);
```

```
cat=14;
```

```
ord=14;
```

```
end;
```

```
if asper=2 and style eq " " then do;
```

```
call missing(cc,ev_cc);
```

```
cat=14;
```

```
ord=14;
```

```
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 paging;
```

```
    set ae_fin;
```

```
        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 escscape char='|';
```

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

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

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

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

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

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

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

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

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

```
%let TFL_Part=%scan(&_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", ""));
```

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

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

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

```
_firtitl="Table 15.2.6.8 Summary of Adverse Events Leading to Study Product  
Discontinuation, Interruption or Reduction 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=&nths dual) &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" saabs ev_saabs))

        ("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 saabs     / display style={just=c cellwidth=1.0cm} style(header)={just=l} "";  
    define ev_saabs   / 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 AFTER PAGE/STYLE={JUST=CENTER CELLWIDTH=5CM PROTECTSPECIALCHARS=OFF};

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

LINE "No adverse events leading to Study Product Discontinuation, Interruption or Reduction  
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 " ";

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=36, halfblk=N);
```

```
%m_logchk;
```

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

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

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