

```

/*=====

*Covance Study ID   : 000000106343

*Program Name       : t_ae6011.sas

*Purpose            : Summary of Adverse Events by Product Use Category System Organ
                        Class,Preferred Term and Severity -Safety Population

*Input Data         : adam.adsl, ADAM.adae

*Output Data        :

*Macros Called       : m_printto m_logchk

*Programmed by      : Siva Karnati

*Creation Date       : 21 May 2015

*== Modification History =====

*Date      Initials  No. Reason;

*=====*/;

%m_printto;

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_11;

/* 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 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 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 _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(&_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 &Nthscc &Nthsths &NTHSdual &Nmccc &Nsaabs &Nsanoabs &Nsapreoabs;
```

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

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

```
data ae;
```

```
set adam.adae;
```

```
    where safafi='Y' and anl01fi='Y' and asper=3 and trtan=&trtan.;
```

```
    output;
```

```
run;
```

```
data ae;
```

```
set ae;
```

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

```
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_ipn as select count(distinct usubjid) as ae_n, gpucat1n, AESEV, AESEV as col length=200,
1.1 as ord from ae group by gpucat1n, col, ord, AESEV order by col, ord;

create table ae_ipev as select count(usubjid) as ae_ev, gpucat1n, AESEV, AESEV as col length=200,
1.1 as ord from ae group by gpucat1n, col, ord, AESEV order by col, ord;

quit;

```

```

%trans(inds=ae_ipn, byvar=col ord , outds=ae_ipn1, var=ae_n, prefix=n);
%trans(inds=ae_ipev, byvar=col ord , outds=ae_ipev1, var=ae_ev, prefix=ev);
%mrg(inds1=ae_ipn1, inds2=ae_ipev1, outds=ae_sevovall, byvar=col ord );

```

```

proc sql;

create table ae_soc_n1 as select count(distinct usubjid) as ae_socn, AEBODSYS, 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_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;

```



```
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,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,gpucat1n;  
  
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;  
  
run;
```

```
proc sql;  
  
create table ae_rel_n1 as select count(distinct usubjid) as ae_reln,aedecod,AEBODSYS,gpucat1n,  
aesev,aesev as style length=200,  
  
4 as ord from ae group by gpucat1n,AEBODSYS,aedecod,aesev,style,ord  
  
order by style, ord ,AEBODSYS,aedecod,aesev,gpucat1n ;
```

```
create table ae_rel_ev1 as select count(usubjid) as ae_relev,AEBODSYS,aedecod,aesev,gpucat1n,aesev  
as style length=200,  
  
4 as ord from ae group by gpucat1n,AEBODSYS,aedecod,aesev,style,ord  
  
order by style, ord,AEBODSYS,aedecod,aesev,gpucat1n;
```

```
quit;
```

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

```

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

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

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

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

data a1;

set a ae_sev;

by aebodsys aedecod ;

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

drop aebodsys aedecod aesev;

run;


data a2;

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

run;


proc format;

value $orda

"Any adverse events"=0

"Blood and lymphatic system disorders"=1

" Anaemia"=1.1

" Leukocytosis"=1.2

"Cardiac disorders"=2

" Palpitations"=2.1

```

"Ear and labyrinth disorders"=3

" Ear pain"=3.1

"Eye disorders"=4

" Conjunctivitis"=4.1

" Eye pruritus"=4.2

" Scleral haemorrhage"=4.3

"Gastrointestinal disorders"=5

" Abdominal pain"=5.1

" Constipation"=5.2

" Diarrhoea"=5.3

" Dry mouth"=5.4

" Flatulence"=5.5

" Gingival bleeding"=5.6

" Gingival pain"=5.7

" Lip dry"=5.8

" Nausea"=5.9

" Paraesthesia oral"=5.91

" Salivary hypersecretion"=5.92

" Toothache"=5.93

" Vomiting"=5.94

"General disorders and administration site conditions"=6

" Chest discomfort"=6.1

" Feeling hot"=6.2

" Non-cardiac chest pain"=6.3

" Pyrexia"=6.4

"Infections and infestations"=7

" Oral herpes"=7.1

" Pharyngitis"=7.2

" Upper respiratory tract infection"=7.3

" Urinary tract infection"=7.4

"Injury, poisoning and procedural complications"=8

" Administration related reaction"=8.1

" Arthropod bite"=8.2

" Contusion"=8.3

" Excoriation"=8.4

" Laceration"=8.5

" Ligament sprain"=8.6

" Muscle strain"=8.7

" Thermal burn"=8.8

" Wound"=8.9

"Investigations"=9

" Alanine aminotransferase increased"=9.1

" Aspartate aminotransferase increased"=9.2

" Blood bilirubin increased"=9.3

" Blood cholesterol increased"=9.4

" Blood potassium increased"=9.5

" Blood triglycerides increased"=9.6

" Carbon monoxide diffusing capacity decreased"=9.61

" Forced expiratory volume decreased"=9.7

" Gamma-glutamyltransferase increased"=9.8

" Haemoglobin decreased"=9.9

" Lymphocyte count increased"=9.91

" Neutrophil count decreased"=9.92

" Protein urine"=9.93

" Total lung capacity decreased"=9.94

" Vital capacity decreased"=9.95

"Metabolism and nutrition disorders"=10

" Hypercholesterolaemia"=10.1

" Hyperglycaemia"=10.2

" Hypertriglyceridaemia"=10.3

" Increased appetite"=10.4

"Musculoskeletal and connective tissue disorders"=11

" Back pain"=11.1

" Muscle spasms"=11.2

" Pain in extremity"=11.3

"Nervous system disorders"=12

" Dizziness"=12.1

" Headache"=12.2

" Paraesthesia"=12.3

" Presyncope"=12.4

"Psychiatric disorders"=13

" Abnormal dreams"=13.1

" Anxiety"=13.2

" Depressed mood"=13.3

" Insomnia"=13.4

" Nightmare"=13.5

" Restlessness"=13.6

" Tension"=13.7

"Renal and urinary disorders"=14

" Dysuria"=14.1

" Proteinuria"=14.2

" Glycosuria"=14.3

"Reproductive system and breast disorders"=15

" Erectile dysfunction"=15.1

"Respiratory, thoracic and mediastinal disorders"=16

" Cough"=16.1

" Dyspnoea"=16.2

" Nasal congestion"=16.3

" Nasal discomfort"=16.4

" Oropharyngeal pain"=16.5

" Pulmonary congestion"=16.6

" Respiratory disorder"=16.7

" Rhinitis allergic"=16.8

" Rhinorrhoea"=16.9

" Sinus congestion"=16.91

" Sneezing"=16.92

" Upper-airway cough syndrome"=16.93

"Skin and subcutaneous tissue disorders"=17

" Acne"=17.1

" Blister"=17.11

" Cold sweat"=17.2

" Dry skin"=17.3

" Erythema"=17.4

" Pruritus"=17.5

" Rash"=17.6

"Vascular disorders"=18

" Peripheral coldness"=18.1

;

run;

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

set a2;

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

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

end;

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

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

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

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



```

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

else ord3=ord2;

end;

else if ord2 in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)
then do;

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

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

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

else ord3=ord2;

end;


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


run;


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

%MEND;


/*THS*/

%prand(trtan=4,outds=ths1);


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

by aebodsys aedecod;

where asper in (3) and trtan=4 ;

```

```
run;
```

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

```
by aebodsys;
```

```
run;
```

```
data ya;
```

```
set fdummya;
```

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

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

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

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

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

```
run;
```

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

```
run;
```

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

```
length z $200;
```

```
set aa ya;
```

```
by aebodsys;
```

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

```

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

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

end;

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

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

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

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

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

else ord3=ord2;

end;

else if ord2 in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)
then do;

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

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

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

else ord3=ord2;

end;

run;


proc sort data=xa;by ord; run;

proc sort data=ths1;by ord; run;

```

```
data ths2;  
  
merge xa(in=a) ths1(in=b drop=style);  
  
by ord;  
  
run;
```

```
data ths3b;  
  
set ths2;  
  
select (ord);
```

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

```
%macro arm(var_n= ,pt=, nam= ,ev=,ev1=);  
  
if(_n_=1) then do;  
  
    if(lengthn(vnamex("&var_n."))< 1 ) then do;  
  
        &var_n =.;  
  
    end;  
  
    if(lengthn(vnamex("&ev."))< 1 ) then do;  
  
        &ev =.;  
  
    end;
```

```

end;

if &var_n ^= . then do;

    pct= '(' || strip(put(round((&var_n/&pt*100),0.01),5.1)) || ');'

    &nam= strip(put(&var_n,best.)) || " " || strip(pct);

end;

    if &nam=" " then &nam="0";

    if &ev. ne . then &ev1.=strip(put(&ev.,best.));

%mend;

data ths;

set ths3b;

%arm(var_n=n1,pt=&nthsc.,nam=thsc.,ev=ev1,ev1=ev_thsc.);

%arm(var_n=n2,pt=&nthsths.,nam=thsths,ev=ev2,ev1=ev_thsths);

%arm(var_n=n3,pt=&nthsdual.,nam=thsdual,ev=ev3,ev1=ev_thsdual);

cat=int(ord);

keep ev_: style ord cat thsths thsc thsdual ;

if thsc="0" and ev_thsc="0" and thsths="0" and ev_thsths="0" and thsdual="0" and ev_thsdual="0"

then call missing(thsc, ev_thsc,thsths, ev_thsths, thsdual, ev_thsdual);

run;

```

```
/*MCC*/
```

```
%prand(trtan=5,outds=mcc1);
```

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

```
by aebodsys aedecod;
```

```
where asper in (3) and trtan=5 ;
```

```
run;
```

```
proc sort data=fdummym nodupkey out=am(keep=aebodsys);
```

```
by aebodsys;
```

```
run;
```

```
data ym;
```

```
set fdummym;
```

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

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

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

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

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

```
run;
```

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

```

run;

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

length z $200;

set am ym;

by aebodsys;

if z=" " then z=aebodsys;


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

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

end;

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

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

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

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

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

else ord3=ord2;

end;

else if ord2 in(5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)
then do;

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

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

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

else ord3=ord2;

```

```
end;
```

```
run;
```

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

```
proc sort data=mcc1;by ord; run;
```

```
data mcc2;
```

```
merge xm(in=a) mcc1(in=b drop=style);
```

```
by ord;
```

```
/*if a,*/
```

```
run;
```

```
data mcc3b;
```

```
set mcc2;
```

```
select (ord);
```

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

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

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

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

```
otherwise ;
```

```
end;
```

```
run;
```



```
data mccc;  
set mccc3b;  
%arm(var_n=n1,pt=&nmccc.,nam=mccc,ev=ev1,ev1=ev_mccc);  
if style= " " then call missing(mccc,ev_mccc);  
cat=int(ord);  
keep ev_: style ord cat mccc;  
if mccc="0" and ev_mccc="0" then call missing(mccc,ev_mccc);  
run;
```

```
/*SA*/
```

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

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

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

```

data ys;

set fdummys;

length z $200.;

z=" " | aedecod;output;

z=" Mild";output;

z=" Moderate";output;

z=" Severe";output;

run;


proc sort data=ys; by aebodsys;

run;

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

length z $200;

set as ys;

by aebodsys;

if z=" " then z=aebodsys;


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

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

end;

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

```

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

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

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

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

```
else ord3=ord2;
```

```
end;
```

```
else if ord2 in(5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.60,9.61,16.90,16.91,16.92,16.93)  
then do;
```

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

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

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

```
else ord3=ord2;
```

```
end;
```

```
run;
```

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

```
proc sort data=sa1;by ord; run;
```

```
data sa2;
```

```
merge xs(in=a) sa1(in=b drop=style);
```

```
by ord;
```

```
run;
```

```
data sa3b;
```

```

set sa2;

select (ord);

when(0) style="Adverse event";

when(0.01) style=" Mild";

when(0.02) style=" Moderate";

when(0.03) style=" Severe";

otherwise ;

end;

run;

```

```

data sa;

set sa3b;

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

%arm(var_n=n5,pt=&Nsapreoabs.,nam=sapreoabs,ev=ev5,ev1=ev_sapreoabs);

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

cat=int(ord);

if sanoabs="0" and sapreoabs="0" and saabs="0" and ev_sanoabs="0" and ev_sapreoabs="0" and
ev_saabs="0" then

call missing(sanoabs, sapreoabs ,saabs, ev_sanoabs ,ev_sapreoabs, ev_saabs);

keep ev_ : style ord cat sanoabs sapreoabs saabs ev_sanoabs ev_sapreoabs ev_saabs ;

run;

```

```
data ae_fin;
```

```
set
```

```
ths(in=a)
```

```
    mcc(in=b)
```

```
    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;
```

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

```
proc sql noprint;
```

```
    create table tflds.&tflno as
```

```
    select *
```

```
    from ae_fin ;
```

```
quit;
```

```

data ae_test;

set ae_fin;

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

j=length(orda);

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

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

drop j orda orda1;

run;

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

set ae_fin;

if ord in (1.1 1.2 2.1 2.2 2.3 2.4 2.5 2.6 3.1 3.2 3.3 4.1 4.2 4.3 5.1 5.2 5.3
5.4 5.5 5.6 5.7 5.8 5.9 5.91 5.92 5.93 5.94 6.1 6.2 6.3 6.4 6.5 6.6 6.8 7.1 7.2 7.3 7.4
8.1 8.2 8.3 8.4 8.5 8.6 8.7 8.8 8.9 9.1 9.2 9.3 9.4 9.5 9.6 9.61 9.7 9.8 9.9 9.91 9.92
9.93 9.95 10.1 10.2 10.3 10.4 11.1 11.2 11.3 12.1 12.2 12.3 12.4 13.1 13.2 13.3
13.4 13.5 13.6 13.7 14.1 14.2 14.3 15.1 16.1 16.2 16.3 16.4 16.5 16.6 16.7
16.8 16.9 16.91 16.92 16.93 17.1 17.2 17.3 17.4 17.5 17.6 );

if thscc="0" then flag_ths=1;

if thsths="0" then flag_thsths=1;

if thsdual="0" then flag_thsdual=1;

if sanoabs="0" then flag_sanoabs=1;

if sapreoabs="0" then flag_sapreoabs=1;

if saabs="0" then flag_saabs=1;

keep flag_ : ord asper;

run;

```

```
proc sql;
```

```
create table ae5 as select a.*,b.flag_ths  
,b.flag_thsths,b.flag_thsdual,b.flag_sanoabs,b.flag_sapreoabs,b.flag_saabs  
from ae_test a left join as b on a.orda1a=b.ord_as and a.asper=b.asper order by asper, cat, ord ;  
run;
```

```
data ae5a;
```

```
set ae5;
```

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

```
if flag_ths=1 then thscc=" ";
```

```
if flag_thsths=1 then thsths=" ";
```

```
if flag_thsdual=1 then thsdual=" ";
```

```
if flag_sanoabs=1 then sanoabs=" ";
```

```
if flag_sapreoabs=1 then sapreoabs=" ";
```

```
if flag_saabs=1 then saabs=" ";
```

```
end;
```

```
drop flag_ths flag_thsths flag_thsdual flag_sanoabs flag_sapreoabs flag_saabs;
```

```
run;
```

```

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

set ae5a;

where ord in(1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18);


if thscc="0" then flag_ths=1;

if thsths="0" then flag_thsths=1;

if thsdual="0" then flag_thsdual=1;

if sanoabs="0" then flag_sanoabs=1;

if sapreoabs="0" then flag_sapreoabs=1;

if saabs="0" then flag_saabs=1;

keep flag_: ord asper;

run;

proc sql;

create table ae6 as select a.*,b.flag_ths
,b.flag_thsths,b.flag_thsdual,b.flag_sanoabs,b.flag_sapreoabs,b.flag_saabs from ae5a a left join ae_s b
on a.cat=b.cat and a.asper=b.asper order by asper,cat,ord;

quit;

data ae6a;

set ae6;

if ord not in (1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18) then do;

if flag_ths=1 then thscc=" ";

if flag_thsths=1 then thsths=" ";

if flag_thsdual=1 then thsdual=" ";

if flag_sanoabs=1 then sanoabs=" ";

```



```
if flag_sapreoabs=1 then sapreoabs=" ";
```

```
if flag_saabs=1 then saabs=" ";
```

```
end;
```

```
run;
```

```
data paging;
```

```
set ae6a;
```

```
by asper cat ord;
```

```
if first.asper or ln gt 10 then ln=1; /*Check for page overflows, this may need changing*/
```

```
else ln+1;
```

```
if ln=1 or first.asper then page+1;
```

```
call symput("page",compress(put(page,best.)));
```

```
flag=1;
```

```
run;
```

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

```
%let escape char='|';
```

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

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

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

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

```

/* Standard - macro for paging */

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

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

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

/* Standard - leave this */

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

/* Standard - leave this */

data _null_;

    tmp("&TFL_Part";

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

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

        call symput('TFLprg',reverse(scan(strip(reverse(compress("&_SASPROGRAMFILE", ""))),1,"/")));

run;


ods path stdlib.t106343 (read) ;

ods results off;

ods rtf toc_data/* contents*/
file="/cvn/projects/prj/data/000000106343/TFL/&TFL_Part./Tables/&tflno..rtf" style=t106343
startpage=yes headery=1440 footery=1440 ;

ods noproctitle;

%do i=1 %to &page;

```

```

title ;

footnote;

%let wd=0;

%LET NOOBS=0;

ods proclabel = ' ';


data comp;

    set paging end=eof;

        where page=&i;

/*      if asper in (2,3) then call symput("noobs","1");*/

%put  nob=&noobs;

/* Amend title as needed */

        _firtitl="Table 15.2.6.11 Summary of Adverse Events by Product Use Category, System
Organ Class, Preferred Term and Severity - 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 style page cat ord asper
```

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

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

```
("THS 2.2 $(N=&nthsths) &linebot" (" n(%) Events" thsths ev_thsths))
```

```
("Dual$(N=&nths dual) &linebot" (" n(%) Events" thsdual ev_thsdual) )
```

```
("CC $(N=&nthsc) &linebot" (" n(%) Events" thsc ev_thsc )))
```

```
%end;
```

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

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

```
("CC $(N=&n mccc) &linebot" (" n(%) Events" mccc ev_mccc)) )
```

```
%end;
```

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

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

```
  ("Abstinent $(N=&Nsaabs) &linebot" (" n(%)  Events" saabs ev_saabs))
```

```
  ("Predominantly $ Abstinent $(N=&Nsapreoabs) &linebot" (" n(%)  Events" sapreoabs  
ev_sapreoabs))
```

```
  ("Not Abstinent $(N=&Nsanoabs) &linebot" (" n(%)  Events" sanoabs ev_sanoabs) ))
```

```
%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 thsths    / display style={just=c cellwidth=1.0cm} style(header)={just=left} "";
```

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

```
  define thscc    / display style={just=c cellwidth=1.0cm} style(header)={just=center}  
  "";
```

```
  define ev_thscc    / display style={JUST=c cellwidth=1.1cm}  
style(header)={just=center} "";
```

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

```

define ev_thsdual / 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 mccc / display style={just=center cellwidth=1.0cm} style(header)={just=l} "";

define ev_mccc / display style={JUST=center cellwidth=1.1cm}
style(header)={just=right} "";

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

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

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

define ev_sanoabs / 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: IP = Investigational product (THSm2.2 or mCC).';
```

```
line 'Note: Percentages are based on the number of subjects indicated in the column  
header (N).';
```

```
line ' ';
```

```
line 'Appendix 15.3.6.1';
```

```
line "Study ID: ZRHM-REXA-08-US Program: &TFLprg Status: &status"  
&_blankn.*"\~\~" "&sysdate" &_blankn.*"\~\~" "(Page &i of &page)";
```

```
endcomp;
```

```
run;
```

```
%end;
```

```
ods rtf close;
```

```
ods results on;
```

```
ods path sashelp.tmplmst (read);
```

```
%mend ;
```

```
%outtrtf(blankn=36, halfblnk=N);
```

```
%m_logchk;
```

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

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

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