

```

/*=====
*Covance Study ID   : 000000106343
*Program Name       : t_ae606.sas
*Purpose            : Summary of Adverse Events by Product Use Category,
                                System Organ Class, Preferred Term and Relationship to
                                Study Product Exposure and Expectedness -Safety
Population

*Input Data         : adam.adsl, ADAM.adae
*Output Data        : T_15_02_06_06
*Macros Called       : m_printto m_logchk
*Programmed by      : Siva Karnati
*Creation Date       : 19 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_06;

```

```
/* 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 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(ths));
    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 _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('Nthsc',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 safbfl='Y' and anyaeft='Y' and anl01fl='Y' and asper =3 and trtan=&trtan;

    output;

run;


data aere1;

set ae;

where aere1="RELATED";

if aeexpec=" " then aeexpec="Missing";

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," Related to IP" as col length=200,

0.1 as ord from ae where aere1="RELATED" group by gpucat1n,col,ord order by col, ord;


create table ae_ipev as select count(usubjid) as ae_ev,gpucat1n," Related to IP" as col length=200,

0.1 as ord from ae where aere1="RELATED" group by gpucat1n,col,ord 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_iprel,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_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;
```

```
%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 );
```

```
proc sql;
```

```
create table ae_rel_n1 as select count(distinct usubjid) as ae_reln,aedecod,AEBODSYS,gpucat1n,
```

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

```
4 as ord from aerel group by gpucat1n,AEBODSYS,aedecod,aerel,style,ord
```

```
order by style, ord ,AEBODSYS,aedecod,aerel,gpucat1n ;
```

```
create table ae_rel_ev1 as select count(usubjid) as ae_relev,AEBODSYS,aedecod,aerel,gpucat1n,"aerel"  
as style length=200,
```

```
4 as ord from aerel group by gpucat1n,AEBODSYS,aedecod,aerel,style,ord
```

```
order by style, ord, AEBODSYS, aedecod, aere1, gpucat1n;
```

```
quit;
```

```
%trans(inds=ae_rel_n1, byvar=style ord aebodsys aedecod aere1 , outds=ae_reln, var=ae_reln, prefix=n);
```

```
%trans(inds=ae_rel_ev1, outds=ae_relev, byvar=style ord aebodsys AEDECOD aere1  
, var=ae_relev, prefix=ev);
```

```
%mrg(inds1=ae_reln, inds2=ae_relev, outds=ae_rel, byvar=style ord aebodsys aedecod aere1 );
```

```
proc sql;
```

```
create table ae_rel_n1 as select count(distinct usubjid) as  
ae_reln, aedecod, AEBODSYS, gpucat1n, AEEXPEC,
```

```
aere1, "aeexp" as style length=200,
```

```
5 as ord from aere1 group by gpucat1n, AEBODSYS, aedecod, aere1, AEEXPEC, style, ord
```

```
order by style, ord , AEBODSYS, aedecod, AEEXPEC, gpucat1n ;
```

```
create table ae_rel_ev1 as select count(usubjid) as
```

```
ae_relev, AEBODSYS, aedecod, aere1, AEEXPEC, gpucat1n, "aeexp" as style length=200,
```

```
5 as ord from aere1 group by gpucat1n, AEBODSYS, aedecod, aere1, AEEXPEC, style, ord
```

```
order by style, ord, AEBODSYS, aedecod, aere1, AEEXPEC, gpucat1n;
```

```
quit;
```

```
%trans(inds=ae_rel_n1,byvar=style ord aebodsys aedecod aere1 AEEXPEC,
outds=ae_relN,var=ae_relN,prefix=n);

%trans(inds=ae_rel_ev1, outds=ae_relev,byvar=style ord aebodsys AEDECOD aere1
AEEXPEC,var=ae_relev,prefix=ev);

%mrg(inds1=ae_relN,inds2=ae_relev,outds=ae_exp,byvar=style ord aebodsys aedecod aere1 AEEXPEC );
```

```
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;
```

```
/*RELATED TO IP AND EXPECTEDNESS for overall*/
```

```
proc sql;

create table ae_ipexn as select count(distinct usubjid) as ae_n,gpucat1n,aeexpec as col length=200,
1.11 as ord from ae where aere1="RELATED" group by gpucat1n,col,ord order by col, ord;

create table ae_ipexev as select count(usubjid) as ae_ev,gpucat1n,aeexpec as col length=200,
1.11 as ord from ae where aere1="RELATED" group by gpucat1n,col,ord order by col, ord;

quit;
```

```

%trans(inds=ae_ipexn,byvar=col ord , outds=ae_ipexn1,var=ae_n,prefix=n);

%trans(inds=ae_ipexev,byvar=col ord , outds=ae_ipexev1,var=ae_ev,prefix=ev);

%mrg(inds1=ae_ipexn1,inds2=ae_ipexev1,outds=ae_ipexov,byvar=col ord );

data ae_ipexov;

set ae_ipexov;

select (col);

when ("N") col="  Not expected";

when("Y") col="  Expeted";

otherwise;

end;

run;

/*RELATED TO IP*/

proc sql;

create table ae_ipn as select count(distinct usubjid) as ae_n,gpucat1n," Related to IP" as col length=200,

1.1 as ord from ae where aere="RELATED" group by gpucat1n,col,ord order by col, ord;

create table ae_ipev as select count(usubjid) as ae_ev,gpucat1n," Related to IP" as col length=200,

1.1 as ord from ae where aere="RELATED" group by gpucat1n,col,ord 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_iprel,byvar=col ord );
```

```
data a1;
```

```
set a ae_rel ae_exp;
```

```
by aebodsys aedecod ;
```

```
if ord=4 then do; style=" " || "Related to IP"; end;
```

```
if ord= 5 then do;
```

```
if aeexpec="N" then style=" " || "Not expected";
```

```
if aeexpec="Y" then style=" " || "Expected";
```

```
if aeexpec="Missing" then style=" " || "<Missing>";
```

```
end;
```

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

set ae_any ae_ipexov(rename=(col=style)) ae_iprel (rename=(col=style)) a1;

if propcase(strip(style)) not in ("Missing","Related To Ip","Related","Not Expected","Expected") then do;

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

end;

if style="RELATED" then style=" Related to IP";

if style="Not expected" then style=" Not expected";

if style="Expected" then style=" Expected";

retain ord2;

if ord1 ne . then ord2=ord1;

if ord1 = . then ord1=ord2 ;

if ord2 not in(5.91,5.92,5.93,5.94,9.91,9.92,9.93,9.94,9.95,9.96,16.90,16.91,16.92,16.93) then do;

if style in (" Related to IP"," Related to IP") then ord3=ord2 + 0.01;

else if strip(style) in("Not expected") then ord3=ord2+0.03;

```

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

else if style in ("    <Missing>","    <Missing>") then ord2=ord2+0.04;

else ord3=ord2;

end;

else if ord2 in (5.91,5.92,5.93,5.94,9.91,9.92,9.93,9.94,9.95,9.96,16.90,16.91,16.92,16.93) then do;

if style in ("    Related to IP","    Related to IP") then ord3=ord2 + 0.001;

else if style in("    Not expected","    Not expected") then ord3=ord2+0.003;

else if style in("    Expected","    Expected") then ord3=ord2+0.002;

else if style in ("    <Missing>","    <Missing>") then ord2=ord3+0.004;

else ord3=ord2;

end;

run;

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

%MEND;

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

data oveall_ths1;

set ths1;

where ord in(0.0.01,0.03);

run;

data ex;

style="    Expected";ord=0.02;output;

run;

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

```

```
by aebodsys aedecod;
```

```
where asper in ( 3 ) and trtan=4;
```

```
run;
```

```
proc sort data=fdummy nodupkey out=a(keep=aebodsys);
```

```
by aebodsys;
```

```
run;
```

```
data y;
```

```
set fdummy;
```

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

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

```
z=" Related to IP";output;
```

```
z=" Expected";output;
```

```
z=" Not expected";output;
```

```
run;
```

```
data a;
```

```
set a;
```

```
run;
```

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

```
run;
```

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

```
length z $200;
```

```
set a y;
```

```

by aebodsys;

if z=" " then z=aebodsys;

if z not in ("    <Missing>","    <Missing>","    Related to IP","    Related to IP","    Not expected","    Not
expected","    Expected","    Expected") 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(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.96,16.90,16.91,16.92,16.93) then
do;

if z in ("    Related to IP","    Related to IP") then ord3=ord2 + 0.01;

else if strip(z) in("Not expected") then ord3=ord2+0.03;

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

else if z in ("    <Missing>","    <Missing>") then ord2=ord3+0.04;

else ord3=ord2;

end;

if ord2 in(5.90,5.91,5.92,5.93,5.94,9.90,9.91,9.92,9.93,9.94,9.95,9.96,16.90,16.91,16.92,16.93) then do;

if z in ("    Related to IP","    Related to IP") then ord3=ord2 + 0.001;

else if strip(z) in("Not expected") then ord3=ord2+0.003;

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

else if z in ("    <Missing>","    <Missing>") then ord2=ord3+0.004;

else ord3=ord2;

end;

run;

```

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

```
proc sort data=ths1;by ord; run;
```

```
data ths;
```

```
merge x(in=a ) ths1(in=b drop=style);
```

```
by ord;
```

```
if a;
```

```
run;
```

```
data ths_fin;
```

```
set ths oveall_ths1 ex;
```

```
by ord;
```

```
drop aebodsys aedecod aerel aeexpec;
```

```
run;
```

```
%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.));

%mend;

data ths;

set ths_fin;

%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 ;

run;

```

```

data sa;

set sa1;

%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);

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

if style= " " then call missing(sanoabs,sapreoabs,saabs,ev_sanoabs,ev_sapreoabs,ev_saabs);

run;
```

```
data mccc;

set mccc1;

%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;

run;
```

```
data ae_fin;

set
```

```
ths(in=a)

    mccc(in=b)

    sa(in=c);

if ord not in (0.02,0.03) and strip(style)="Expected" then style="    Expected";

if ord not in (0.02,0.03) and strip(style)="Not expected" then style="    Not expected";

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 ev_thscc="0" and ev_thsths="0" and ev_thsdual="0" and strip(style)^="Related to IP" then call
missing(ev_thscc,ev_thsths,ev_thsdual,thscc,thsths,thsdual);

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 " " and asper not in(2,3);


quit;

data ae_fin1;

set ae_fin;

if asper in (2,3) then call missing
(mccc,ev_mccc,sanoabs,ev_sanoabs,sapreoabs,ev_sapreoabs,saabs,ev_saabs,style);

if asper=2 then cat=15;

if asper=3 then cat=16;

if strip(style) in ("Expected","Not expected") and ord not in (0.02,0.03) and ev_thscc=" " and ev_thsths="
" and ev_thsdual=" " then delete;

run;


data ae_fin;

set ae_fin1;

```

```
if asper=1 then output;  
if asper=2 and ord=0 then output;  
if asper=3 and ord=0 then output;  
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 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 ae_fin 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;

proc sort data=ae6a;by asper cat ord;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 15.2.6.6 Summary of Adverse Events by Product Use Category, System
Organ Class, Preferred Term and Relationship to Study Product Exposure and Expectedness - 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" style

    ("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" style

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

%end;

```

```

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

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

    ("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=l} "";

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

    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=c cellwidth=1.0cm} style(header)={just=l} "";

    define ev_mccc    / 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 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 AFTER PAGE/STYLE={JUST=CENTER CELLWIDTH=5CM PROTECTSPECIALCHARS=OFF};

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

        LINE "No adverse events related to study product exposure and expectedness were reported ";

        LINE " ";

%END;

        ENDCOMP;

```

```

compute before _page_ / style={just=left protectspecialchars=off};

        line "\b\fs24\sa24&_FSRTITL." ; * \b = bold, \fs24 is font size 12pt, \sa24 is space after 12pt;

                line " ";

                line "&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 ;


%outrtf(blankn=36, halfblnk=N);

%m_logchk;

*=====;

* END OF PROGRAM CODE                ;

*=====;
```