

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

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

```
*Program Name       :t_ae_sum_produce.sas
```

```
*Purpose           : Summary of Adverse Events by Product Use categoryin Ambulatory
```

```
                        Safety Population
```

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

```
*Output Data       :
```

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

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

```
*Creation Date     : 15 May 2015
```

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

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

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

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

```
%M_PRINTTO;
```

```
/* 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_02;
```

```
/* 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(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: _THSc
```

```
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 &Nthscc &Nthsths &NTHSdual &Nmccc &Nsaabs &Nsanoabs &Nsapreoabs;
```

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

```
data ae1;
```

```
set adam.adae;
```

```
aeacnoth=propcase(aeacnoth);
```

```
run;
```

```
data ae;
```

```
set ae1;
```

```
where safaf1='Y' and anyae1='Y' and anl01f1='Y' and asper eq 3 and trtan=&trtan ;
```

```
output;
```

```
run;
```

```
/* over all adverse event*/
```

```
proc sql;
```

```
create table ae_n1 as select count(distinct usubjid) as ae_n,gpucat1n,"Adverse events(AE)" as col  
length=200,
```

```
0 as ord from ae group by gpucat1n,col,ord order by col, ord;
```

```
create table ae_ev1 as select count(usubjid) as ae_ev,gpucat1n,"Adverse events(AE)" as col length=200,
```

```
0 as ord from ae group by gpucat1n,col,ord order by col, 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=col ord , outds=ae_N,var=ae_n,prefix=n);

%trans(inds=ae_ev1,byvar=col ord , outds=ae_ev,var=ae_ev,prefix=ev);

%mrg(inds1=ae_n,inds2=ae_ev,outds=ae_any,byvar=col ord );


data a eser1;

set ae;

if a eser=" " then a eser="Missing";

if a erel=" " then a erel="Missing";

if a erelsp=" " then a erelsp="Missing";

if a esev=" " then a esev="Missing";

```

```

if aecontr=" " then aecontr="Missing";

if aeacnp1=" " then aeacnp1="Missing";

run;

/* n= count inds= inputdataset outds=outputdataset var=variable on which summary to be performed
   style=label value ord=order value ,value=value of varibale*/

%macro count (n=,inds=, outds=,var=,style=,ord=,val=);

proc sql;

create table &outds. as select

count(distinct(usubjid)) as &n. ,&style. as col length 200,gpucat1n,

&ord. as ord from aaser1 where upcase(&var.)="&val" group by gpucat1n,col,ord;

quit;


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

by col ord ;

var &n.;

id gpucat1n;

run;


%mend;


%macro events(n=,inds=, outds=,var=,style=,ord=,val=);

proc sql;

create table &outds. as select count(usubjid) as &n. ,gpucat1n,

&style. as col length 200,

&ord. as ord from aaser1 where upcase(&var.)="&val" group by gpucat1n,col,ord;

```



```
quit;
```

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

```
by col ord ;
```

```
var &n.;
```

```
id gpucat1n;
```

```
run;
```

```
%mend;
```

```
%macro set (inds_ev=,inds_n=,set_ev=,set_n=,outds=);
```

```
data &inds_ev.;
```

```
set &set_ev.;
```

```
run;
```

```
data &inds_n.;
```

```
set &set_n.;
```

```
run;
```

```
proc sort data=&inds_ev.;by col ord;run;
```

```
proc sort data=&inds_n.;by col ord;run;
```

```
data &outds.;
```

```
merge &inds_ev.(where=(col ne " ")) &inds_n.(where=(col ne " "));
```

```
by col ord;
```

```
if col ne " ";
```

```
run;
```

```
%mend;
```

```
/*AE SERIOUS*/
```

```
%events(n=ser_ev_n,inds=aeser1,outds=ser_ev_yes,var=aeser,style=' Yes("SAE")',ord=1.1,val=Y);
```

```
%events(n=ser_n,inds=aeser1,outds=ser_ev_no,var=aeser,style=' No("AE")',ord=1.2,val=N);
```

```
%events(n=ser_n,inds=aeser1,outds=ser_ev_mis,var=aeser,style=' Missing',ord=1.3,val=MISSING);
```

```
%count(n=ser_n,inds=aeser1,outds=ser_yes,var=aeser,style=' Yes("SAE")',ord=1.1,val=Y);
```

```
%count(n=ser_n,inds=aeser1,outds=ser_no,var=aeser,style=' No("AE")',ord=1.2,val=N);
```

```
%count(n=ser_n,inds=aeser1,outds=ser_mis,var=aeser,style=' Missing',ord=1.3,val=MISSING);
```

```
%set(inds_ev=ser_ev,inds_n=ser_n,set_ev=ser_ev_yes ser_ev_no ser_ev_mis,set_n=ser_yes ser_no  
ser_mis,outds=serious);
```

```
/*AE RELATED TO IP*/
```

```
%events(n=ser_ev_n,inds=aeser1,outds=rel_ev_yes,var=aerel,style=' Related',ord=2.3,val=RELATED);
```

```
%events(n=ser_n,inds=aeser1,outds=rel_ev_no,var=aerel,style=' Not related',ord=2.2,val=NOT  
RELATED);
```

```
%events(n=ser_n,inds=aeser1,outds=rel_ev_mis,var=aerel,style=' Missing',ord=2.1,val=MISSING);
```

```
%count(n=ser_n,inds=aeser1,outds=rel_yes,var=aerel,style=' Related',ord=2.3,val=RELATED);
```

```
%count(n=ser_n,inds=aeser1,outds=rel_no,var=aerel,style=' Not related',ord=2.2,val=NOT RELATED);
```

```
%count(n=ser_n,inds=aeser1,outds=rel_mis,var=aerel,style=' Missing',ord=2.1,val=MISSING);
```

```
%set(inds_ev=rel_ev,inds_n=rel_n,set_ev=rel_ev_yes rel_ev_no rel_ev_mis,set_n=rel_yes rel_no  
rel_mis,outds=related_ip1);
```

```
/* TO CALCULATE EXPECTED AND NOT EXEPECTED WHICH IS RELATED TO IP*/
```

```
data aaser2;
```

```
set aaser1;
```

```
where aere1="RELATED" ;
```

```
if AEEXPEC =" " then AEEXPEC="Missing";
```

```
run;
```

```
%macro count1 (n=,inds=, outds=,var=,style=,ord=,val=);
```

```
proc sql;
```

```
create table &outds. as select
```

```
count(distinct(usubjid)) as &n. ,&style. as col length 200,gpucat1n,
```

```
&ord. as ord from aaser2 where upcase(&var.)="&val" group by gpucat1n,col,ord;
```

```
quit;
```

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

```
by col ord ;
```

```
var &n.;
```

```
id gpucat1n;
```

```
run;
```

```
%mend;
```

```
%macro events1(n=,inds=, outds=,var=,style=,ord=,val=);
```

```

proc sql;

create table &outds. as select count(usubjid) as &n. ,gpucat1n,

&style. as col length 200,

&ord. as ord from aaser2 where upcase(&var.)="&val" group by gpucat1n,col,ord;

quit;


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

by col ord ;

var &n.;

id gpucat1n;

run;


%mend;


%events1(n=ser_ev_n,inds=aaser2,outds=ex_ev_yes,var=AEEXPEC,style=' Expected',ord=2.32,val=Y);

%events1(n=ser_n,inds=aaser2,outds=ex_ev_no,var=AEEXPEC,style=' Not expected',ord=2.33,val=N)

%events1(n=ser_n,inds=aaser2,outds=ex_ev_mis,var=AEEXPEC,style='
Missing',ord=2.31,val=MISSING);


%count1(n=ser_n,inds=aaser2,outds=ex_yes,var=AEEXPEC,style=' Expected',ord=2.32,val=Y);

%count1(n=ser_n,inds=aaser2,outds=ex_no,var=AEEXPEC,style=' Not expected',ord=2.33,val=N);

%count1(n=ser_n,inds=aaser2,outds=ex_mis,var=AEEXPEC,style=' Missing',ord=2.31,val=MISSING);

%set(inds_ev=ex_ev,inds_n=ex_n,set_ev=ex_ev_yes ex_ev_no ex_ev_mis,set_n=ex_yes ex_no
ex_mis,outds=related_ip2);


data related_ip;

```

```
set related_ip1 related_ip2;
```

```
run;
```

```
/*AE RELATED TO STUDY PROCEDURE*/
```

```
%events(n=ser_ev_n,inds=aeser1,outds=sp_ev_yes,var=aerelsp,style=' Related',ord=3.3,val=RELATED);
```

```
%events(n=ser_n,inds=aeser1,outds=sp_ev_no,var=aerelsp,style=' Not related',ord=3.2,val=NOT  
RELATED);
```

```
%events(n=ser_n,inds=aeser1,outds=sp_ev_mis,var=aerelsp,style=' Missing',ord=3.1,val=MISSING);
```

```
%count(n=ser_n,inds=aeser1,outds=sp_yes,var=aerelsp,style=' Related',ord=3.3,val=RELATED);
```

```
%count(n=ser_n,inds=aeser1,outds=sp_no,var=aerelsp,style=' Not related',ord=3.2,val=NOT RELATED);
```

```
%count(n=ser_n,inds=aeser1,outds=sp_mis,var=aerelsp,style=' Missing',ord=3.1,val=MISSING);
```

```
%set(inds_ev=sp_ev,inds_n=sp_n,set_ev=sp_ev_yes sp_ev_no sp_ev_mis,set_n=sp_yes sp_no  
sp_mis,outds=related_sp);
```

```
/*AE SEV*/
```

```
%events(n=ser_ev_n,inds=aeser1,outds=sev_ev_mild,var=aesev,style=' Mild',ord=4.2,val=MILD);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=sev_ev_yes,var=aesev,style='  
Moderate',ord=4.3,val=MODERATE);
```

```
%events(n=ser_n,inds=aeser1,outds=sev_ev_no,var=aesev,style=' Severe',ord=4.4,val=SEVERE);
```

```
%events(n=ser_n,inds=aeser1,outds=sev_ev_mis,var=aesev,style=' Missing',ord=4.1,val=MISSING);
```

```
%count(n=ser_n,inds=aeser1,outds=sev_mild,var=aesev,style=' Mild',ord=4.2,val=MILD);
```

```
%count(n=ser_n,inds=aeser1,outds=sev_yes,var=aesev,style=' Moderate',ord=4.3,val=MODERATE);
```

```
%count(n=ser_n,inds=aeser1,outds=sev_no,var=aesev,style=' Severe',ord=4.4,val=SEVERE);  
%count(n=ser_n,inds=aeser1,outds=sev_mis,var=aesev,style=' Missing',ord=4.1,val=MISSING);
```

```
%set(inds_ev=sev_ev,inds_n=sev_n,set_ev=sev_ev_yes sev_ev_no sev_ev_mis  
sev_ev_mild,set_n=sev_yes sev_no sev_mis sev_mild,outds=sev);
```

```
/* ACTION TAKEN DUE TO AE*/
```

```
%events(n=ser_n,inds=aeser1,outds=acn_ev_pint,var=aeacnp1,style=' Product use  
interrupted',ord=5.1,val=PRODUCT USE INTERRUPTED);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=acn_ev_pstop,var=aeacnp1,style=' Product use  
stopped',ord=5.2,val=PRODUCT USE STOPPED);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=acn_ev_pred,var=aeacnp1,style=' Product use  
reduced',ord=5.3,val=PRODUCT USE REDUCED);
```

```
%events(n=ser_n,inds=aeser1,outds=acn_ev_na,var=aeacnp1,style=' Not applicable',ord=5.4,val=NOT  
APPLICABLE);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=acn_ev_none,var=aeacnp1,style=' None',ord=5.5,val=NONE);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=acn_ev_mis,var=aeacnp1,style='  
Missing',ord=5.51,val=MISSING);
```

```
%count(n=ser_n,inds=aeser1,outds=acn_pint,var=aeacnp1,style=' Product use  
interrupted',ord=5.1,val=PRODUCT USE INTERRUPTED);
```

```
%count(n=ser_n,inds=aeser1,outds=acn_pstop,var=aeacnp1,style=' Product use  
stopped',ord=5.2,val=PRODUCT USE STOPPED);
```

```
%count(n=ser_n,inds=aeser1,outds=acn_pred,var=aeacnp1,style=' Product use  
reduced',ord=5.3,val=PRODUCT USE REDUCED);
```

```
%count(n=ser_n,inds=aeser1,outds=acn_na,var=aeacnp1,style=' Not applicable',ord=5.4,val=NOT APPLICABLE);
```

```
%count(n=ser_n,inds=aeser1,outds=acn_none,var=aeacnp1,style=' None',ord=5.5,val=NONE);
```

```
%count(n=ser_n,inds=aeser1,outds=acn_mis,var=aeacnp1,style=' Missing',ord=5.51,val=MISSING);
```

```
%set (inds_ev=acn_ev,inds_n=acn_n,set_ev=acn_ev_pint acn_ev_pstop acn_ev_pred acn_ev_na  
acn_ev_none acn_ev_mis,
```

```
set_n=acn_pint acn_pstop acn_pred acn_na acn_none acn_mis,outds=acn);
```

```
/*TREATMENT GIVEN*/
```

```
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_yes,var=aecontrt,style=' Yes',ord=5.7,val=Y);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_no,var=aecontrt,style=' No',ord=5.8,val=N);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_mis,var=aecontrt,style=' Missing',ord=5.9,val=M);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_yes,var=aecontrt,style=' Yes',ord=5.7,val=Y);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_no,var=aecontrt,style=' No',ord=5.8,val=N);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_mis,var=aecontrt,style=' Missing',ord=5.9,val=M);
```

```
%set(inds_ev=trt_ev,inds_n=trt_n,set_ev=trt_ev_yes trt_ev_no trt_ev_mis,
```

```
set_n=trt_yes trt_no trt_mis,outds=trt);
```

```
/*AEACNOTH*/
```

```

proc sql;

create table oth as select gpucat1n, count(distinct usubjid) as n_ae,aeacnoth,

" Other action taken" as col length 200,6.1 as ord

from ae where aeacnoth ne " " group by gpucat1n ,aeacnoth order by col, ord,aeacnoth ;

create table oth_eve as select gpucat1n,count(usubjid) as ae_event,aeacnoth,

" Other action taken" as col length 200,6.1 as ord

from ae where aeacnoth ne " " group by gpucat1n ,aeacnoth order by col, ord,aeacnoth ;

quit;

proc transpose data=oth out=oth_n1(drop=_name_) prefix=n;

by col ord aeacnoth ;

var n_ae;

id gpucat1n;

run;

proc transpose data=oth_eve out=oth_ev1(drop=_name_) prefix=ev;

by col ord aeacnoth;

var ae_event;

id gpucat1n;

run;

proc sort data=oth_n1;by col ord aeacnoth;run;

proc sort data=oth_ev1;by col ord aeacnoth;run;

data other;

merge oth_n1 oth_ev1;

by col ord aeacnoth;

if col ne " ";

```



```
run;
```

```
proc format;
```

```
value $oth
```

```
"Crushed Ice To Sooth Irritated Throat"=6.1
```

```
"Heating Pad"=6.2
```

```
"Prune Juice Given"=6.3
```

```
"Repeat Cbc In 1 Week Ordered"=6.4
```

```
"Repeat Labs Done"=6.5
```

```
"Repeated Lab"=6.6
```

```
"Vital Signs Taken"=6.7;
```

```
run;
```

```
data other;
```

```
set other;
```

```
ord=input(put(AEACNOTH,$oth.),best.);
```

```
run;
```

```
data other1;
```

```
length col $200.;
```

```
col="Other action taken";ord=6;output;
```

```
col=" Action taken with study product"; ord=5.01; output;
```

```
run;
```

```

proc sql;

create table noact_n as select gpucat1n, count(distinct usubjid) as n_ae,

"No action taken due to AE" as col length 200,7 as ord

from ae where aeacnoth eq " " and aeacnp1 eq "NONE" and aecontrt=" " group by gpucat1n order by
col, ord ;

create table noact_eve as select gpucat1n,count(usubjid) as ae_event,

"No action taken due to AE" as col length 200,7 as ord

from ae where aeacnoth eq " " and aeacnp1 eq "NONE" and aecontrt=" " group by gpucat1n order by
col, ord ;

quit;

```

```

proc transpose data=noact_n out=noact_n1(drop=_name_) prefix=n;

by col ord ;

var n_ae;

id gpucat1n;

run;

proc transpose data=noact_eve out=noact_ev1(drop=_name_) prefix=ev;

by col ord ;

var ae_event;

id gpucat1n;

run;

proc sort data=noact_n1;by col ord ;run;

proc sort data=noact_ev1;by col ord ;run;

data noact;

```

```

merge noact_n1 noact_ev1;

by col ord ;

if col eq " " then do; col="No action taken due to AE" ; ord=7;end;

run;


data final;

set ae_any serious related_ip related_sp sev acn trt other other1 noact;

if col=" Other action taken" then col=" " | aeacnoth;

run;


data dummy;

length style $200.;

style="Adverse events (AE)"; ord=0;cat=0; output;

style="AE Serious";ord=1;cat=1;output;

style=' Yes("SAE")';ord=1.1;cat=1; output;

style=' No("AE")';ord=1.2;cat=1;output;

style=' Missing';ord=1.3;cat=1;output;

style="AE related to IP";ord=2;cat=2;output;

style=' Related';ord=2.3;cat=2;output;

style=' Not related';ord=2.2;cat=2;output;

style=' Missing';ord=2.1;cat=2;output;

style=' Expected';ord=2.32;cat=2;output;

style=' Not expected';ord=2.33;cat=2;output;

style=' Missing';ord=2.31;cat=2;output;

style="AE related to study procedure";ord=3;cat=3;output;

```

style=' Related';ord=3.3;cat=3;output;

style=' Not related';ord=3.2;cat=3;output;

style=' Missing';ord=3.1;cat=3;output;

style="AE severity" ; ord=4;cat=4;output;

style=' Mild';ord=4.2; cat=4;output;

style=' Moderate';ord=4.3;cat=4;output;

style=' Severe';ord=4.4;cat=4;output;

style=' Missing';ord=4.1;cat=4;output;

style="Action taken due to AE";ord=5;cat=5;output;

style=" Action taken with study product"; ord=5.01;cat=5; output;

style=' Product use interrupted';ord=5.1;cat=5;output;

style=' Product use stopped';ord=5.2;cat=5;output;

style=' Product use reduced';ord=5.3;cat=5;output;

style=' Not applicable';ord=5.4;cat=5;output;

style=' None';ord=5.5;cat=5;output;

style=' Missing';ord=5.51;cat=5;output;

style=" Treatment given";ord=5.6;cat=5.1;output;

style=' Yes';ord=5.7;cat=5.1;output;

style=' No';ord=5.8;cat=5.1;output;

style=' Missing';ord=5.9;cat=5.1;output;

style=" Other action taken";ord=6;cat=6;output;

style=" Crushed Ice To Sooth Irritated Throat";ord=6.1;cat=6;output;

style=" Heating Pad";ord=6.2;cat=6;output;

style=" Prune Juice Given";ord=6.3;cat=6;output;

style=" Repeat Cbc In 1 Week Ordered";ord=6.4;cat=6;output;

```
style=" Repeat Labs Done";ord=6.5;cat=6;output;  
style=" Repeated Lab";ord=6.6;cat=6;output;  
style=" Vital Signs Taken";ord=6.7;cat=6;output;  
style="No action taken due to AE" ; ord=7;cat=7; output;  
run;
```

```
proc sort data=dummy;by ord cat;run;
```

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

```
data &outds.;
```

```
merge dummy(in=a rename=(style=col)) final(in=b drop=col);
```

```
by ord;
```

```
if a;
```

```
%if &trtan.=4 %then %do;
```

```
    if nmiss(n1,n2,n3,ev1,ev2,ev3) eq 6 and strip(col)='Missing' then delete ;
```

```
    if ord in (6.1,6.2,6.3,6.4,6.5,6.6,6.7) and nmiss(n1,n2,n3,ev1,ev2,ev3)=6 then delete;
```

```
%end;
```

```
run;
```

```

%mend;

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

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

%prod(trtan=5,outds=mcc1)

data ths1;

set ths1;

run;

data sa1;

set sa1;

run;

data mcc11;

set mcc1;

run;

%macro arm(var_n= ,pt=, var_ev= , nam=,ev= );

if(_n_=1) then do;

    if(lengthn(vnamex("&var_n."))< 1 ) then do;

        &var_n =.;

    end;

    if(lengthn(vnamex("&var_ev."))< 1 ) then do;

        &var_ev =.;

    end;

end;

end;

```

```

if &var_n ^= . and &var_ev ne . then do;

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

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

    end;

else if ord not in (1,2,3,4,5,5.01,5.6,6) then do;

    &nam='0';

    end;

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

    else if ord not in (1,2,3,4,5,5.01,5.6,6) then do;

        &ev='0';

        end;

%mend;

data ths;

set ths1;

%arm(var_n=n1,pt=&Nthsc.,var_ev=ev1,nam=n1a,ev=ev1a);

%arm(var_n=n2,pt=&Nthsths.,var_ev=ev2,nam=n2a,ev=ev2a);

%arm(var_n=n3,pt=&NTHSdual.,var_ev=ev3,nam=n3a,ev=ev3a);

keep col ord cat n1a n2a n3a ev1a ev2a ev3a ;

run;

data sa;

set sa1;

%arm(var_n=n4,pt=&Nsanoabs,var_ev=ev4,nam=n4a,ev=ev4a);

```

```
%arm(var_n=n5,pt=&Nsapreoabs,var_ev=ev5,nam=n5a,ev=ev5a);

%arm(var_n=n6,pt=&Nsaabs,var_ev=ev6,nam=n6a,ev=ev6a);

if n4a="0" and n5a="0" and n6a="0" and strip(col)="Missing" then delete;

if ord in (6.1,6.2,6.3,6.4,6.5,6.6,6.7) and n4a="0" and n5a="0" and n6a="0" then delete;

keep col ord cat n4a n5a n6a ev4a ev5a ev6a ;

run;
```

```
data mcc;

set mccc1;

%arm(var_n=n1,pt=&Nmccc,var_ev=ev1,nam=n1a,ev=ev1a);

keep col ord cat n1a ev1a ;

if n1a="0" and strip(col)="Missing" then delete;

if ord in (6.1,6.2,6.3,6.4,6.5,6.6,6.7) and n1a ="0" then delete;

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;

if ord=5.8 then delete;/*AECONTRT only captures Y or missing, please delete the 'Missing' row and
count all missing values under 'No' row*/

if ord =5.9 then do;

col="  No";

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 ae_fin;

    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;


if column="THS" then do;

    if n1a="0" then ev1a=" ";

    if n2a="0" then ev2a=" ";

    if n3a="0" then ev3a=" ";

end;


if column="CC" then do;

    if n1a="0" then ev1a=" ";

end;


if column="SA" then do;

    if n4a="0" then ev4a=" ";

    if n5a="0" then ev5a=" ";

    if n6a="0" then ev6a=" ";

end;

run;


/* Standard - leave this */

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=\~;

%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;

ods proclabel = ' ';


data comp;

    set paging end=eof;

        where page=&i;


    /* Amend title as needed */

        _firtitl="Table 15.2.6.2 Summary of Adverse Events by Product Use Category in
Ambulatory - 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" col
```

```
        ("THS 2.2 $(N=&nthsths) &linebot" (" n (%)    Events" n2a ev2a)) ("Dual$(N=&nthsdual)  
&linebot" (" n (%)    Events" n3a ev3a ))
```

```
        ("CC $(N=&nthsc) &linebot" (" n (%)    Events" n1a ev1a )))
```

```
%end;
```

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

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

```
        ("CC $(N=&nmc) &linebot" (" n (%)    Events" n1a ev1a)) )
```

```
%end;
```

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

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

```
        ("Abstinent $(N=&Nsaabs) &linebot" (" n (%)    Events" n6a ev6a))
```

```
        ("Predominantly $ Abstinent $(N=&Nsapreoabs) &linebot" (" n (%)    Events" n5a ev5a ))
```

```

("Not Abstinent $(N=&Nsanoabs) &linebot" (" n (%)    Events" n4a ev4a) ))

%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 col    / display style={just=left cellwidth=5cm asis = on}' ';

define n2a    / display style={just=c cellwidth=2.0cm} style(header)={just=left} "";

define ev2a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";

define n3a    / display style={just=c cellwidth=2.0cm} style(header)={just=left} "";

define ev3a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";

define n1a    / display style={just=c cellwidth=2.0cm} style(header)={just=left} "";

define ev1a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";

%end;

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

define col    / display style={just=left cellwidth=5cm asis = on}' ';

define n1a    / display style={just=c cellwidth=1.0cm} style(header)={just=right} "";

define ev1a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";

%end;

```

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

```
    define col    / display style={just=left cellwidth=5cm asis = on}' ';
```

```
    define n6a    / display style={just=c cellwidth=1.0cm} style(header)={just=right} "";
```

```
    define ev6a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";
```

```
    define n5a    / display style={just=c cellwidth=1.0cm} style(header)={just=right} "";
```

```
    define ev5a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";
```

```
    define n4a    / display style={just=c cellwidth=1.0cm} style(header)={just=right} "";
```

```
    define ev4a    / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";
```

```
%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.but were not enrolled';

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

line 'Note: IP=Investigational product(THSm2.2 or mCC)';

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 ;

```


*=====;