

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

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

```
*Program Name       : t_ae_sum.sas
```

```
*Purpose            : Summary of Adverse Events Safety Population
```

Table 15.2.6.1

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

```
*Output Data        :
```

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

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

```
*Creation Date       : 12 May 2015
```

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

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

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

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

```
%m_printto;
```

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

```
* START OF PROGRAM CODE                ;
```

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

```
/* 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_01;
```

```

/* 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 ;
*****

/* BIG N for PRE RANDOMIZATION PERIOD*/

data adsl;

set adam.adsl;

where safbfl="Y";

output;

    trt01an=99;

    trt01a='Overall Safety';

output;

run;

proc sql noprint;

    select count (distinct usubjid) into: _THS

```

```

        from adsl where trt01a='THSm2.2';

select count (distinct usubjid) into: _MCC

        from adsl where trt01a='mCC';

select count (distinct usubjid) into: _SA

        from adsl where trt01a='SA';

select count (distinct usubjid) into: _PT

        from adsl where trt01a='Product Test';

select count (distinct usubjid) into: _tot

        from adsl where trt01a= 'Overall Safety';

quit;

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

data N;

    length label $100.;

    label='Total';

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

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

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

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

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

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

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

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

    call symput('N96', strip(pt));

```

```

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

run;

/* BIG N POST RANDOMIZATION*/

data adslp;

set adam.adsl;

where safaf1="Y";

output;

        trt01an=99;

        trt01a='Overall Safety';

output;

run;

proc sql noprint;

        select count (distinct usubjid) into: _THSp

                from adslp where trt01a='THSm2.2';

        select count (distinct usubjid) into: _MCCp

                from adslp where trt01a='mCC';

        select count (distinct usubjid) into: _SAp

                from adslp where trt01a='SA';

        select count (distinct usubjid) into: _totp

                from adslp where trt01a= 'Overall Safety';

quit;

%put THS=&_thsp MCC=&_mccp SA=&_sap TOT=&_totp;

```

```

data N;

    length label $100.;

    label='Total';

    THSp=strip(put(&_thsp,best.));

    MCCp=strip(put(&_mccp,best.));

    SAp=strip(put(&_sap,best.));

    OVERALL_SFp=strip(put(&_totp,best.));

    call symput('N3p',strip(sap));

    call symput('N4p',strip(thsp));

    call symput('N5p',strip(mccp));

    call symput('N99p',strip(OVERALL_SFp));

run;

%put THS=&n3p MCC=&n4p SA=&n5p TOT=&n99p;

/* PRE RANDOMIZATION*/

data ae1;

set adam.adae;

aeacnoth=propcase(aeacnoth);

run;

data ae;

set /*adam.adae*/ae1;

    where safbfl='Y' and anyaefl='Y' and anl01fl='Y' and asper=1;

output;

trtan=99;

```

```

        trta='Overall Safety';

output;

run;

/* over all adverse event*/

proc sql;

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

0 as ord from ae group by trtan,col,ord order by col, ord;

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

0 as ord from ae group by trtan,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 trtan;

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 aaser1;

set ae;

if aaser=" " then aaser="Missing";

if aerel=" " then aerel="Missing";

if aerelsp=" " then aerelsp="Missing";

if aesev=" " then aesev="Missing";

if aecontrt=" " then aecontrt="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,trtan,

```

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

```
proc transpose data=&outds. out=&outds.(drop=_name_) prefix=n;  
by col ord ;  
var &n.;  
id trtan;  
run;
```

```
%mend;
```

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

```
proc sql;
```

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

```
&style. as col length 200,
```

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

```
proc transpose data=&outds. out=&outds.(drop=_name_) prefix=ev;  
by col ord ;  
var &n.;  
id trtan;  
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 aeser2;
```

```
set aeser1;
```

```
where aerel="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,trtan,

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

quit;
```

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

by col ord ;

var &n.;

id trtan;

run;
```

```
%mend;
```

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

```
proc sql;

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

&style. as col length 200,

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

quit;
```

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

by col ord ;

var &n.;

id trtan;
```

```
run;
```

```
%mend;
```

```
%events1(n=ser_ev_n,inds=aeser2,outds=ex_ev_yes,var=AEEXPEC,style=' Expected',ord=2.32,val=Y);
```

```
%events1(n=ser_ev_n,inds=aeser2,outds=ex_ev_no,var=AEEXPEC,style=' Not  
expected',ord=2.33,val=N)
```

```
%events1(n=ser_ev_n,inds=aeser2,outds=ex_ev_mis,var=AEEXPEC,style='  
Missing',ord=2.31,val=MISSING);
```

```
%count1(n=ser_n,inds=aeser2,outds=ex_yes,var=AEEXPEC,style=' Expected',ord=2.32,val=Y);
```

```
%count1(n=ser_n,inds=aeser2,outds=ex_no,var=AEEXPEC,style=' Not expected',ord=2.33,val=N);
```

```
%count1(n=ser_n,inds=aeser2,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=5.8,val=Y);
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_no,var=aecontrt,style='  No',ord=5.9,val=N);
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_mis,var=aecontrt,style='  Missing',ord=5.7,val=M);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_yes,var=aecontrt,style='  Yes',ord=5.8,val=Y);
%count(n=ser_n,inds=aeser1,outds=trt_no,var=aecontrt,style='  No',ord=5.9,val=N);
%count(n=ser_n,inds=aeser1,outds=trt_mis,var=aecontrt,style='  Missing',ord=5.7,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 trtan, 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 trtan ,aeacnoth order by col, ord,aeacnoth ;
create table oth_eve as select trtan,count(usubjid) as ae_event,aeacnoth,
" Other action taken" as col length 200,6.1 as ord
from ae where aeacnoth ne " " group by trtan ,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 trtan;
```

```

run;

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

by col ord aeacnoth;

var ae_event;

id trtan;

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

"Subject Discontinued From Study"=6.2

"Prune Juice Given"=6.3

"Subject Was Discontinued From Study"=6.4

"Repeat Labs Done"=6.5

"Repeated Lab"=6.6

"Vital Signs Taken"=6.7

```


"Treatment Given Was To Lay The Subject Down No Medication Given"=6.8

"Vital Signs, Blood Sugar And O2 Saturation Subject Discontinued From Study"=6.9;

run;

data other;

set other;

if aeacnoth ne " " then 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 trtan, 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 trtan ;

create table noact_eve as select trtan,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 trtan ;

quit;

```

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

by col ord ;

var n_ae;

id trtan;

run;

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

by col ord ;

var ae_event;

id trtan;

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=5.8;cat=5.1;output;
style=' No';ord=5.9;cat=5.1;output;
style=' Missing';ord=5.7;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=" Subject Discontinued From Study";ord=6.2;cat=6;output;
style=" Prune Juice Given";ord=6.3;cat=6;output;
style=" Subject Was Discontinued From Study";ord=6.4;cat=6;output;
style=" Repeat Labs Done";ord=6.5;cat=6;output;
style=" Vital Signs Taken";ord=6.7;cat=6;output;
style=" Repeated Lab";ord=6.6;cat=6;output;
style=" Treatment Given Was To Lay The Subject Down No Medication Given";ord=6.8;cat=6;output;
style=" Vital Signs, Blood Sugar And O2 Saturation Subject Discontinued From
Study";ord=6.9;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 final1;

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

by ord;

if a ;

if nmiss(n3,n4,n5,n96,n99,ev3,ev4,ev5,ev96,ev99) eq 10 and strip(col)='Missing' then delete ;

run;

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

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;

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 ae_pre;

set final1;

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

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

```

```
%arm(var_n=n3,pt=&_sa.,var_ev=ev3,nam=n3a,ev=ev3a);  
  
%arm(var_n=n96,pt=&_pt.,var_ev=ev96,nam=n96a,ev=ev96a);  
  
%arm(var_n=n99,pt=&_tot.,var_ev=ev99,nam=n99a,ev=ev99a);  
  
keep col ord cat n4a n5a n3a n96a n99a ev4a ev5a ev3a ev96a ev99a;
```

```
run;
```

```
/* POST RANDOMIZATION*/
```

```
%MACRO RAND(asper= ,final=);
```

```
data ae1;
```

```
set adam.adae;
```

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

```
run;
```

```
data ae;
```

```
set ae1;
```

```
where safaf1='Y' and anyae1='Y' and anl01fl='Y' and asper in (&asper.);
```

```
output;
```

```
trtan=99;
```

```
trta='Overall Safety';
```

```
output;
```

```
run;
```

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

```
proc sql;
```

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

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

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

```
0 as ord from ae group by trtan,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 trtan;
```

```
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 erel sp=" " then a erel sp="Missing";

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

if a econtrt=" " then a econtrt="Missing";

if a eacnp1=" " then a eacnp1="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,trtan,

&ord. as ord from a eser1 where upcase(&var.)="&val" group by trtan,col,ord;

quit;

```



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

```
by col ord ;
```

```
var &n.;
```

```
id trtan;
```

```
run;
```

```
%mend;
```

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

```
proc sql;
```

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

```
&style. as col length 200,
```

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

```
quit;
```

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

```
by col ord ;
```

```
var &n.;
```

```
id trtan;
```

```
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 aeser2;
```

```
set aeser1;
```

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

```
proc transpose data=&outds. out=&outds.(drop=_name_) prefix=n;  
by col ord ;  
var &n.;  
id trtan;  
run;
```

```
%mend;
```

```
%macro events1(n=,inds=, outds=,var=,style=,ord=,val=);  
proc sql;  
create table &outds. as select count(usubjid) as &n. ,trtan,  
&style. as col length 200,  
&ord. as ord from aaser2 where upcase(&var.)="&val" group by trtan,col,ord;  
quit;
```

```
proc transpose data=&outds. out=&outds.(drop=_name_) prefix=ev;  
by col ord ;  
var &n.;  
id trtan;  
run;
```

```
%mend;
```

```
%events1(n=ser_ev_n,inds=aeser2,outds=ex_ev_yes,var=AEEXPEC,style=' Expected',ord=2.32,val=Y);
```

```
%events1(n=ser_n,inds=aeser2,outds=ex_ev_no,var=AEEXPEC,style=' Not expected',ord=2.33,val=N)
```

```
%events1(n=ser_n,inds=aeser2,outds=ex_ev_mis,var=AEEXPEC,style='  
Missing',ord=2.31,val=MISSING);
```

```
%count1(n=ser_n,inds=aeser2,outds=ex_yes,var=AEEXPEC,style=' Expected',ord=2.32,val=Y);
```

```
%count1(n=ser_n,inds=aeser2,outds=ex_no,var=AEEXPEC,style=' Not expected',ord=2.33,val=N);
```

```
%count1(n=ser_n,inds=aeser2,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);
```

```
/*%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,*/
```

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

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

```
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_yes,var=aecontrt,style=' Yes',ord=5.8,val=Y);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_no,var=aecontrt,style=' No',ord=5.9,val=N);
```

```
%events(n=ser_ev_n,inds=aeser1,outds=trt_ev_mis,var=aecontrt,style=' Missing',ord=5.7,val=M);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_yes,var=aecontrt,style=' Yes',ord=5.8,val=Y);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_no,var=aecontrt,style=' No',ord=5.9,val=N);
```

```
%count(n=ser_n,inds=aeser1,outds=trt_mis,var=aecontrt,style=' Missing',ord=5.7,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 trtan, 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 trtan ,aeacnoth order by col, ord,aeacnoth ;
```

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

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

```
from ae where aeacnoth ne " " group by trtan ,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 trtan;

run;

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

by col ord aeacnoth;

var ae_event;

id trtan;

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

"Subject Discontinued From Study"=6.71

"Subject Was Discontinued From Study"=6.72

"Subject Withdrew Consent" =6.73

"Treatment Given Was To Lay The Subject Down No Medication Given"=6.8

"Vital Signs, Blood Sugar And O2 Saturation Subject Discontinued From Study"=6.9;

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 trtan, 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 trtan order by col,
ord ;

create table noact_eve as select trtan,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 trtan order by col,
ord ;

quit;

```

```

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

by col ord ;

var n_ae;

id trtan;

run;

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

by col ord ;

var ae_event;

id trtan;

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=5.8;cat=5.1;output;

style=' No';ord=5.9;cat=5.1;output;

style=' Missing';ord=5.7;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=" Subject Discontinued From Study";ord=6.71;cat=6;output;
style=" Subject Was Discontinued From Study";ord=6.72;cat=6;output;
style=" Subject Withdrew Consent" ;ord=6.73;cat=6;output;
style=" Treatment Given Was To Lay The Subject Down No Medication Given";ord=6.8;cat=6;output;
style=" Vital Signs, Blood Sugar And O2 Saturation Subject Discontinued From
Study";ord=6.9;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 final1;
merge dummy(in=a rename=(style=col)) final(in=b drop=col);
by ord;
if a;
if(_n_=1) then do;
    if(lengthn(vnamex("n3"))< 1 ) then do;
        n3 =.;
    end;
    if(lengthn(vnamex("ev3"))< 1 ) then do;

```

```

    ev3 =.;
end;
end;
if nmiss(n3,n4,n99,ev3,ev4,ev99) 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 n99 eq . then delete;
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 ^= . then do;
    pct= '('||strip(put((round(&var_n/&pt*100,0.01)),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 &final.;

set final1;

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

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

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

%arm(var_n=n99,pt=&_totp.,var_ev=ev99,nam=n99a,ev=ev99a);

keep col ord cat n4a n5a n3a n99a ev4a ev5a ev3a ev99a;

run;

%MEND;

%rand(asper=2 3 4,final=prand);

%rand(asper=2,final=confi );

%rand(asper=3,final=amb);

%rand(asper=4,final=sf);

data ae_fin;

set

```



```
ae_pre(in=e)
```

```
prand(in=a)
```

```
confi(in=b)
```

```
amb(in=c)
```

```
sf(in=d);
```

```
length column $200;
```

```
if e then do ;column="Pre-Randomization";asper=1; end;
```

```
if a then do ;column="Post-Randomization";asper=1.1; end;
```

```
if b then do;column="Confinement";asper=2; end;
```

```
if c then do;column="Ambulatory";asper=3; end;
```

```
if d then do;column="Safety Follow-Up";asper=4; end;
```

```
if ord=5.9 then delete;/*AECONTRT only captures Y or missing, please delete the 'Missing' row and  
count all missing values under 'No' row*/
```

```
if ord =5.7 then do;
```

```
col=" No";
```

```
ord=5.9;
```

```
end;
```

```
run;
```

```
data ae_fin;
```

```
set ae_fin;
```

```
if strip(col) in ("Crushed Ice To Sooth Irritated Throat","Subject Discontinued From Study","Prune Juice  
Given",
```

```
"Subject Was Discontinued From Study",
```

```
"Repeat Labs Done",
```

```
"Repeated Lab",
```

```
"Vital Signs Taken", "Subject Withdrew Consent",  
"Treatment Given Was To Lay The Subject Down No Medication Given",  
"Vital Signs, Blood Sugar And O2 Saturation Subject Discontinued From Study") and n99a="0" then  
delete;  
  
run;
```

```
data ae4(rename=(wrap=col));  
  
set ae_fin;  
  
attrib wrap length = $200;  
  
ord1=strip(put(ord,best.));  
  
wrap = col;
```

```
i=38; *This is the max length allowed on a single line - change as needed;  
  
if index(ord1,".")>0 then do;  
  
if length(wrap)>i then do;  
  
    nwraps = int(length(wrap)/i); *Calculate how many lines the text will wrap over;  
  
    do while(nwraps > 0);  
  
        fin=0;  
  
        j = i*nwraps; *Calculate starting point - loop will cycle backwards from this point looking for a space;  
  
        do while(fin=0 and j gt 1);  
  
            if substr(wrap,j,1)=' ' then do;  
  
                if asper ne 1 then do;  
  
                    wrap=substR(wrap,1,j-1) || "^n ^S={foreground=white}.^S={ } " || substr(wrap,j+1);  
  
                    end;  
  
                    else if asper eq 1 then do;  
  
                        wrap=substR(wrap,1,j-1) || "^n ^S={foreground=white}.^S={ } " || substr(wrap,j+1);
```

```
        end;

        fin=1;

        end;

        else j=j-1; *No space found - move back one character;

        end;

        nwraps=nwraps-1; *Once this wrap is handled, move up a line until all are handled (when nwraps = 0);

        end;

    end;

end;

drop col ord1 i nwraps fin j;

run;
```

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

```
proc sql noprint;
```

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

```
    select *
```

```
    from ae_fin;
```

```
quit;
```

```
proc sort data=ae4;by asper ord cat;run;
```

data paging;

set ae4;

by asper cat ord;

if first.asper or ln gt 7 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 n3a="0" then ev3a=" ";

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

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

if n96a="0" then ev96a=" ";

if n99a="0" then ev99a=" ";

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, halfbInk=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 15.2.6.1 Summary of Adverse Events - 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 spacing=1 style={cellspacing=4pt } split = '$' %if &i=1  
%then %do; contents=' ' %end; %else %do; contents=" %end;;;
```

```
column page cat ord /*col*/
```

```
("Adverse Events" (" " col))
```

```
("THSm2.2 $(N=&n4) &linebot" (" n (%) Events" n4a ev4a)) ("mCC$(N=&n5) &linebot" (" n (%)  
Events" n5a ev5a )) /* 1) JMH 10Jul2014 */
```

```
("SA $(N=&n3) &linebot" (" n (%) Events" n3a ev3a)) ("Product Test$(N=&n96) &linebot" (" n  
(%) Events" n96a ev96a))
```

```
%if &asper1.=1 %then %do;("Overall$Safety$(N=&n99) &linebot" (" n (%)  
Events" n99a ev99a)) %end;
```

```
%else %do;("Overall$Safety$(N=&n99p) &linebot" (" n (%) Events" n99a  
ev99a)) %end;
```

```
;
```

```
define page / order order = internal noprint;
```

```
define cat / order order = internal noprint;
```

```
define ord / order order = internal noprint;
```

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

```
define col / display style={just=left cellwidth=6.6cm asis = on}' ';
```

```
%end;
```

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

```
define col / display style={just=left cellwidth=6.3cm asis = on}' ';
```

```
%end;
```

```
define n4a / display style={just=c cellwidth=1.8cm} style(header)={just=left} "";
```

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

```

define n5a      / display style={just=c cellwidth=1.8cm} style(header)={just=right} "";
define ev5a     / display style={JUST=c cellwidth=1.1cm} style(header)={just=left} "";


define n3a      / display style={just=c cellwidth=1.8cm} style(header)={just=right} "";
define ev3a     / display style={JUST=c cellwidth=1.1cm} style(header)={just=left} "";


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

    define n96a  / display style={just=c cellwidth=1.8cm} style(header)={just=right} "";
    define ev96a / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";

%end;

%else %do;

    define n96a  /noprint "";
    define ev96a /noprint "";

%end;

    define n99a  / display style={just=c cellwidth=1.8cm} style(header)={just=right} "";
    define ev99a / display style={just=c cellwidth=1.1cm} style(header)={just=right} "";


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 "Safety Time Period: &perid";

line "&linebot";

endcomp;


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

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

LINE 'Note: "Product Test" refers to all subjects who tested the THS Product but were not
randomized.';

LINE 'Note: The Overall Safety refers to all subjects exposed to THSm2.2.';

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)";

%end;

%else %do;

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)";

    %end;

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                ;

*=====;

```