

```
proc datasets lib=work nolist memtype=data kill; quit;
```

```
/*=====
*Covance Study ID   : 000000106343
*Program Name       : t_analset.sas
*Purpose            : 15.2.1.3.2 Analysis Sets and Reasons for exclusion from Anlysis Sets

*Input Data         : adam.adsl,
*Output Data        :
*Macros Called       : m_printto m_logchk
*Programmed by      : cvn_sbikki
*Creation Date       : 28Apr2015
*== Modification History =====
*Date    Initials  No. Reason;
*=====*/;
```

```
options notes source source2 nofullstimer validvarname=upcase missing=' ';
```

```
%m_printto;
```

```
%let sup_1_ = %nrstr({\super [1]}); /* superscript 1 (iĉ½) */
```

```
%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;
```

```
data adsl;
```

```
set adam.adsl;
```

```
run;
```

```
data dm;
```

```
set adsl;
```

```
output;
```

```
trt01an =100;
```

```
trt01a = "total";
```

```
output;
```

```
run;
```

```
proc sql ;
```

```
select count (distinct usubjid) into: n1 from dm where trt01an = 4;
```

```
select count (distinct usubjid) into: n2 from dm where trt01an = 5;
```

```
select count (distinct usubjid) into: n3 from dm where trt01an = 3;

select count (distinct usubjid) into: n4 from dm where trt01an = 96;

select count (distinct usubjid) into: n5 from dm where trt01an = 99;

select count (distinct usubjid) into: ntot from dm where trt01an = 100;

quit;
```

```
%put @@ &n1 &n2 &n3 &n4 &n5 &ntot;
```

```
data adsl0;

set adam.adsl;

where trt01an not in (96 99);

run;
```

```
data dm_0;

set adsl0;

output;

trt01an =100;

trt01a = "total";

output;

run;
```

```
proc sql ;

select count (distinct usubjid) into: n6 from dm_0 where trt01an = 4;

select count (distinct usubjid) into: n7 from dm_0 where trt01an = 5;
```

```
select count (distinct usubjid) into: n8 from dm_0 where trt01an = 3;

select count (distinct usubjid) into: ntot1 from dm_0 where trt01an = 100;

quit;
```

```
%put @@ &n6 &n7 &n8 &ntot1;
```

```
proc sql noprint;

create table dm0 as

/*block1*/

select count (distinct usubjid) as n, trt01an, trt01a, 1 as ord, 1 as block ," Subjects screened" as term
length =200

from dm where SCRFFL ^= ' '

group by trt01an , trt01a

/*Block2*/

union select count (distinct usubjid) as n, trt01an, trt01a, 2 as ord, 2 as block ," Subjects included in
Safety Population" as term length =200

from dm where SAFBFL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 3 as ord, 2 as block, " Subjects excluded from
Safety Population" as term length =200

from dm where SAFBFL = 'N'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 4 as ord, 2 as block, " Not exposed to
THSm2.2" as term length=200
```

from dm where SAFBFL = 'N' and SAFBREA = "Not exposed to THS 2.2"

group by trt01an , trt01a

/**BLOCK3*/

union select count (distinct usubjid) as n, trt01an, trt01a, 5 as ord, 3 as block , " Total Subjects
Randomized" as term length =200

from dm_0 where RANDFL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 6 as ord, 3 as block , " Subjects included in
Safety Population" as term length =200

from dm_0 where SAFAFL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 7 as ord, 3 as block , " Subjects excluded from
Safety Population" as term length =200

from dm_0 where SAFAFL = 'N'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 8 as ord, 3 as block, " Not exposed to
THSm2.2" as term length=200

from dm_0 where SAFAFL = 'N' and SAFAREA = "Not exposed to THS 2.2"

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 9 as ord, 3 as block, " Subjects did not have
valid safety assessment post-randomization" as term length=200

from dm_0 where SAFAFL = 'N' and SAFAREA = "Subjects did not have valid safety assessment post-
randomization"

group by trt01an , trt01a

/*BLOCK 4*/

union select count (distinct usubjid) as n, trt01an, trt01a, 10 as ord, 4 as block , " Subjects included in FAS" as term length =200

from dm_0 where FASFL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 11 as ord, 4 as block , " Subjects excluded from FAS" as term length =200

from dm_0 where FASFL = 'N'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 12 as ord, 4 as block , " " as term length =200

from dm_0 where FASFL = 'N' and FASREAS = " "

group by trt01an , trt01a

/*BLOCK 5*/

union select count (distinct usubjid) as n, trt01an, trt01a, 14 as ord, 5 as block , " Period 1" as term length =200

from dm_0 where PPROT1FL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 15 as ord, 5 as block , " Period 2" as term length =200

from dm_0 where PPROT2FL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 16 as ord, 5 as block , " Period 3" as term length =200

from dm_0 where PPROT3FL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 17 as ord, 5 as block , " Period 4" as term length =200

from dm_0 where PPROT4FL = 'Y'

group by trt01an , trt01a

/*BLOCK 6*/

union select count (distinct usubjid) as n, trt01an, trt01a, 19 as ord, 6 as block , " Not in FAS" as term
length =200

from dm_0 where PPROT1FL = 'N' and PPREAS1 = "Not in FAS"

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 20 as ord, 6 as block , " Has major protocol
deviations not compliant" as term length =200

from dm_0 where PPROT1FL = 'N' and index(PPREAS1, "Has major protocol deviations not compliant")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 22 as ord, 6 as block , " Has other major
protocol deviations impacting evaluability" as term length =200

from dm_0 where PPROT1FL = 'N' and index(PPREAS1, "Has other major protocol deviations impacting
evaluability")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 24 as ord, 6 as block , " Discontinued in
previous period" as term length =200

from dm_0 where PPROT1FL = 'N' and PPREAS1 = "Discontinued in previous period"

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 21 as ord, 6 as block , " Access to medical
records were granted for SDV and data entry after withdrawal of PHI authorization" as term length =200

from dm_0 where PPROT1FL = 'N' and index(PPREAS1, "Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization")>0

group by trt01an , trt01a

/*BLOCK 7*/

union select count (distinct usubjid) as n, trt01an, trt01a, 27 as ord, 7 as block , " Has major protocol deviations not compliant" as term length =200

from dm_0 where PPROT2FL = 'N' and index(PPREAS2 , "Has major protocol deviations not compliant")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 30 as ord, 7 as block , " Has other major protocol deviations impacting evaluability" as term length =200

from dm_0 where PPROT2FL = 'N' and index(PPREAS2 , "Has other major protocol deviations impacting evaluability")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 31 as ord, 7 as block , " Discontinued in previous period" as term length =200

from dm_0 where PPROT2FL = 'N' and index(PPREAS2, "Discontinued in previous period")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 28 as ord, 7 as block , " Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization" as term length =200

from dm_0 where PPROT2FL = 'N' and index(PPREAS2 , "Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization")>0

group by trt01an , trt01a

/*BLOCK 8*/

union select count (distinct usubjid) as n, trt01an, trt01a, 34 as ord, 8 as block , " Has major protocol deviations not compliant" as term length =200

from dm_0 where PPROT3FL = 'N' and index(PPREAS3, "Has major protocol deviations not compliant")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 36 as ord, 8 as block , " Has other major protocol deviations impacting evaluability" as term length =200

from dm_0 where PPROT3FL = 'N' and index(PPREAS3 , "Has other major protocol deviations impacting evaluability")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 38 as ord, 8 as block , " Discontinued in previous period" as term length =200

from dm_0 where PPROT3FL = 'N' and index(PPREAS3 , "Discontinued in previous period")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 35 as ord, 8 as block , " Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization" as term length =200

from dm_0 where PPROT3FL = 'N' and index(PPREAS3,"Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization")>0

group by trt01an , trt01a

/*BLOCK 9*/

union select count (distinct usubjid) as n, trt01an, trt01a, 41 as ord, 9 as block , " Has major protocol deviations not compliant" as term length =200

from dm_0 where PPROT4FL = 'N' and index(PPREAS4 , "Has major protocol deviations not compliant")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 43 as ord, 9 as block , " Has other major protocol deviations impacting evaluability" as term length =200

from dm_0 where PPROT4FL = 'N' and index(PPREAS4 , "Has other major protocol deviations impacting evaluability")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 44 as ord, 9 as block , " Discontinued in previous period" as term length =200

from dm_0 where PPROT4FL = 'N' and index(PPREAS4 , "Discontinued in previous period")>0

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 42 as ord, 9 as block , " Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization"as term length =200

from dm_0 where PPROT4FL = 'N' and index(PPREAS4 , "Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization")>0

group by trt01an , trt01a

/*BLOCK 10*/

union select count (distinct usubjid) as n, trt01an, trt01a, 46 as ord, 10 as block , " Period 1" as term length =200

from dm_0 where COMPP1FL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 47 as ord, 10 as block , " Period 2" as term length =200

```

from dm_0 where COMPP2FL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 48 as ord, 10 as block , "   Period 3" as term
length =200

from dm_0 where COMPP3FL = 'Y'

group by trt01an , trt01a

union select count (distinct usubjid) as n, trt01an, trt01a, 49 as ord, 10 as block , "   Period 4" as term
length =200

from dm_0 where COMPP4FL = 'Y'

group by trt01an , trt01a


order by block,ord, trt01an , trt01a;

quit;

```

```

proc sort data=dm0;

by block ord term;

run;

```

```

proc transpose data=dm0 out=all_tra prefix=trt;

by block ord term ;

var n;

id trt01an;

run;

```

```
data dummy;  
do ord = 1 to 49;  
output;  
end;  
run;
```

```
data final;  
merge dummy(in=a) all_tra;  
by ord;  
if a;  
run;
```

```
data final1;  
set final;  
if ord ge 6 and ord not in (13 18 25 32 39 45) then do;  
if trt4 ne . then do;  
per1= strip(put(trt4/&n6*100,5.1));  
if per1 = "100.0" then per1 = "100";  
else per1 = per1;  
t1 = strip(put(trt4,best.))||' ('||compress(per1)||');  
end;  
else if trt4 = . then do;  
t1 = "0 (0.0)";  
end;
```

```
if trt5 ne . then do;  
  per1= strip(put(trt5/&n7*100,5.1));  
  if per1 = "100.0" then per1 ="100";  
  else per1 = per1;  
  t2 = strip(put(trt5,best.))||' ('||compress(per1)||')';  
  end;  
  else if trt5 = . then do;  
    t2 = "0 (0.0)";  
  end;
```

```
  if trt3 ne . then do;  
    per1= strip(put(trt3/&n8*100,5.1));  
    if per1 = "100.0" then per1 ="100";  
    else per1 = per1;  
    t3 = strip(put(trt3,best.))||' ('||compress(per1)||')';  
    end;  
    else if trt3 = . then do;  
      t3 = "0 (0.0)";  
    end;
```

```
  if trt100 ne . then do;  
    per1= strip(put(trt100/&ntot1*100,5.1));  
    if per1 = "100.0" then per1 ="100";
```

```

else per1 = per1;

t6 = strip(put(trt100,best.))||' ('||compress(per1)||');

end;

else if trt100 = . then do;

t6 = "0 (0.0)";

end;

end;

else do;

t1 = strip(put(trt4,best.));

t2 = strip(put(trt5,best.));

t3 = strip(put(trt3, best.));

t4 = strip(put(trt96,best.));

t5= strip(put(trt99,best.));

t6 = strip(put(trt100,best.));

end;

drop trt3 trt4 trt5 trt96 trt99 trt100;

run;

```

```

data final2;

set final1;

if ord = 7 then do;

block = 3;

term = " Subjects excluded from Safety Population";

end;

```

if ord = 13 then do;

block= 5;

term = " Subjects included in PP Set";

end;

if ord = 18 then do;

block= 6;

term = " Subjects excluded from PP Set for Period 1";

end;

if ord = 24 then do;

block = 6;

term =" Discontinued in previous period";

end;

if ord = 25 then do;

block= 7;

term = " Subjects excluded from PP Set for Period 2";

end;

if ord = 32 then do;

block= 8;

term = " Subjects excluded from PP Set for Period 3";

end;

```
if ord = 39 then do;  
  
block= 9;  
  
term = " Subjects excluded from PP Set for Period 4";  
  
end;
```

```
if ord =45 then do;  
  
block= 10;  
  
term = " Subjects included in Compliant Population";  
  
end;
```

```
drop _name_;  
  
if ord = 8 or ord = 9 then delete;
```

```
if block = 2 then do;  
  
if t1 = " " then t1 = "0";  
  
if t2 = " " then t2 = "0";  
  
if t3 = " " then t3 = "0";  
  
if t4 = " " then t4 = "0";  
  
if t5 = " " then t5 = "0";  
  
end;
```

```
if ord = 5 then do;  
  
t4 = "NA";  
  
t5 = "NA";  
  
end;
```

```
if ord = 2 then do;  
  
t5 = "0";  
  
end;
```



```
run;
```

```
data final3;
```

```
set final2;
```

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

```
term = '\b ' || trim(term) || '\b0';
```

```
t1 = '\b ' || trim(t1) || '\b0';
```

```
t2 = '\b ' || trim(t2) || '\b0';
```

```
t3 = '\b ' || trim(t3) || '\b0';
```

```
t4 = '\b ' || trim(t4) || '\b0';
```

```
t5 = '\b ' || trim(t5) || '\b0';
```

```
t6 = '\b ' || trim(t6) || '\b0';
```

```
end;
```

```
if ord in (1 2 5 6 10 13 45) then do;
```

```
term = '\b ' || trim(term) || '\b0';
```

```
end;
```

```
run;
```

```
proc sort data= final3;
```

```
by ord block term;
```

```
run;
```

```
data page1;
```

```
set final3;
```

```
by ord block term;

if ord le 9 then page = 1;

else if 9< ord<= 17 then page = 2;

else if 17< ord<= 24 then page = 3;

else if 24< ord<= 30 then page = 4;

else if 30< ord<= 38 then page = 5;

else page=6;

run;
```

```
proc sql;

create table final_page as

select distinct a.*, b.page

from final3 as a

left join page1 as b

on a.block = b.block and a.ord = b.ord

order by ord, block;

quit;
```

```
data final_page;

set final_page end=last;

by ord block term;

if last then call symputx("page", page);

if term ne " ";

run;

%let tflno = %str(T_15_02_01_03_02);
```

```
data tflds.&tflno;
```

```
set final2;
```

```
where term ne " ";
```

```
run;
```

```
%put &page;
```

```
data final_page(rename=(wrap=term));
```

```
set final_page;
```

```
attrib wrap length = $300;
```

```
wrap = term;
```

```
i=47; *This is the max length allowed on a single line - change as needed;
```

```
if index(term,"\")= 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;
```

```
        wrap=substR(wrap,1,j-1) || "^n ^S={foreground=white}.^S={} " || substr(wrap,j+1);
```

```
        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 term i nwraps fin j;

*keep ev_: wrap ord cat ths mcc sa pt tot;

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, halfblnk=N);

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

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

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 final_page end=eof;

        where page=&i;

        /* Amend title as needed */

            _firtitl="Table 15.2.1.3.2 Analysis Sets and Reasons for Exclusions from Analyses";

            _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('_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 = '$' style = [outputwidth = 100%]  
style(header)=[asis = on just = center protectspecialchars = off]
```

```
%if &i=1 %then %do; contents=' ' %end; %else %do; contents="" %end;;;
```

```
column page block ord term t1 t2 t3 t4 t5 t6;
```

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

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

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

```
define term /"Population Sets" display style={just=left cellwidth=6.4cm  
asis=on}' ' /*style(header)={just=left}*/ ;
```

```
define t1 /"THSm2.2$n (%)" display style={just=c cellwidth=1.4cm}  
style(header)={just=center};
```

```
define t2 /"mCC$n (%)" display style={just=c cellwidth=1.4cm}  
style(header)={just=center};
```

```
define t3 / "SA$n (%)" display style={JUST=c cellwidth=1.4cm}  
style(header)={just=center};
```

```
define t4      /"Product Test$n (%)" display style={just=c cellwidth=1.4cm}  
style(header)={just=center};
```

```
define t5      /"Screen Failure$n (%)" display style={JUST=c  
cellwidth=1.4cm} style(header)={just=center};
```

```
define t6      /"Overall$n (%)" display style={just=c cellwidth=1.4cm}  
style(header)={just=center};
```

```
break after page / page;
```

```
compute after block;
```

```
line " ";
```

```
endcomp;
```

```
compute before page / style={protectspecialchars=off};;
```

```
line "&linetop";
```

```
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 "&linebot";
```

```
endcomp;
```

```

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

line 'Note: NA = Not applicable; mCC = Menthol conventional cigarettes; SA = Smoking
abstinence; THSm2.2 = Tobacco Heating System 2.2 Menthol.';

line 'Note: Percentages appearing after randomization are based on the number of
randomized subjects in each column.';

line %str('Note: "Product Test" refers to all subjects who tested the THS product but
were not randomized.');
```

line %str('Note: Periods defined as Period 1 ([Day 1 - Day 6 confinement]), Period 2 ([Day 6 ambulatory - Day 30 Visit]), Period 3 ([Day 30 Visit - Day 60 Visit]) and Period 4 ([Day 60 Visit - Day 90 Visit]).');

```

line ' ';

line 'Appendix 15.3.1.8 and 15.3.2.3';

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

endcomp;

run;

%end;

ods rtf close;

ods results on;

ods path sashelp.tmplmst (read);

%mend ;

%outtrtf(blankn=36, halfblank=N);

ods listing;

%m_logchk2;
```


